Submitter : Mr. Case Horton

Date: 06/21/2006

Organization : Tanglewood Medical Supplies

Category : Home Health Facility

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

This program is unfair to small businesses if allowed only to the few Medicare has the ability to dictate pricing so why not just set it at the lowest available price and then allow for providers to choose to participate or not in the program.

Submitter : Dr. Eric Tarr **Date:** 06/21/2006

Organization : Generations R.C., Inc.

Category : Physical Therapist

Issue Areas/Comments

GENERAL

GENERAL

GENERATIONS
PHYSICAL THERAPY OF BARBOURSVILLE
3552 US Route 60 East, Barboursville, WV 25504-1639
Phone: 304-733-9560 Fax: 304-733-1141

To Whom It May Concern:

I am Dr. Eric Tarr, PT, OCS, a physical therapist with 12 years experience. I practice in private practice in rural West Virginia. I am board certified as an Orthopedic Specialist. The Centers for Medicare and Medicaid Services (CMS) issued a proposed rule May 1 to implement a competitive bidding (also known as competitive acquisition) program for suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) in the Medicare program. This rule could significantly impact the ability of physical therapists to furnish off-the shelf orthotics, wheelchairs, ambulatory assistive devices, and other items to their patients.

The provision of orthotics, braces, and splints is necessary for assessment of and facilitation of function within the rehabilitation process. This is an absolutely integral part of our plan of care. Commercial suppliers do not have the training to assess the appropriateness or effect of the orthotics, braces, and splints used in delivering orthopedic physical therapy.

Also, at times, braces and splints must be immediately available to a patient in order to proceed with functional activities. For instance, last week a female patient presented with acute, disabling pain at the knee associated with arthritis and bursitis that prevented her from squatting. Being able to instantly provide bracing allowed her to initiate proper exercises to address the arthritis while relieving pain from the bursitis. We had to modify the brace as it was applied due to the combination of pathologies. It is very likely that had she gone to a commercial supplier, she would have had to wait over the weekend to obtain the brace. Once obtained, the brace would have been inappropriate since the commercial supplier would not be trained to decide to make or implement necessary modifications that were necessary with application of the brace. Since implementing the brace, we have had to modify/adjust it three times. As a PT I routinely perform adjustments to orthotics, braces and splints as part of practicing physical therapy. If CMS is to allow efficient and effective delivery of physical therapy they must recognize that physical therapists perform adjustments to orthotics, braces, and splints.

Being able to specify brands is also extremely important in the delivery of physical therapy when using orthotics, braces, and splints in order to prevent adverse medical outcomes. Many DME products are patented. Mandatory substitution of a different brand can mean having to choose a brand that is not proven by research or not readily modifiable. In the previous example of a knee brace, had I not been able to choose a Donjoy knee sleeve with removable medial and lateral metal stays, this lady would not have tolerated an off the shelf brace. Rather we would have had to either order a much more expensive custom knee brace or go through three knee braces and possibly forgo any brace, causing loss of time from work and functional exercise for restoration of knee function.

For the sake of the patients in my care, I strongly urge CMS to revise the proposed regulations and establish a process that will enable physical therapists to continue to furnish orthotics, braces, and splints that are critical to the care of their patients.

Sincerely,

Eric Tarr, PT, DPT, OCS
Doctor of Physical Therapy
Board Certified Orthopedic Specialist

CMS-1270-P-273-Attach-1.DOC

GENERATIONS
PHYSICAL THERAPY OF BARBOURSVILLE
3552 US Route 60 East, Barboursville, WV 25504-1639
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Eric Tarr, PT, DPT, OCS
Doctor of Physical Therapy
Board Certified Orthopedic Specialist

Submitter : Mrs. Veniece Fagerlin

Organization : Mrs. Veniece Fagerlin

Category : Individual

Date: 06/21/2006

Issue Areas/Comments

Low Vision Aid Exclusion

Low Vision Aid Exclusion

My mother and brother are only receiving SS & SSI for income due to their low vision due to their diagnosis of Optic Nerve Atrpohy caused by a genetic factor. They struggle enough and need Medicare/Medicaid help. These are the people Medicare was put in place for in the first place.

Submitter : Mr. Scott Moore **Date:** 06/21/2006

Organization : Criticare Home Health Services, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

See Attachment

GENERAL

GENERAL

See Attachment

CMS-1270-P-275-Attach-1.DOC

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

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

Re: Written Comments file code CMS-1270-P

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SUMMARY:

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

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

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

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

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

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

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

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

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

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

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

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

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

Submitter : Mr. Scott Moore

Organization : Professional

Category : Other Practitioner

Date: 06/21/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-276-Attach-1.DOC

From: Scott D. Moore, RCP
320 Bowstring Drive
Lawrence, KS 66049

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

Re: Written Comments file code CMS-1270-P

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

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- Blind patients – Many equipment types are not able to be utilized by these patients and with a "standardized", low cost piece of equipment, they will be underserved and/or un-served.
- Arthritic patients – many patients are unable to perform daily living activities without assistance, and the current DMEPOS provider often provides additional services which are not addressed by the competitive bidding model, such as equipment cleaning, maintenance, humidifier changes, etc. which will be unavailable.
- Patients without caregivers/family helpers – DMEPOS providers often assist patients in the home without reimbursement simply because the service interval has been increased for at risk patients. The low bid scenario will eliminate such assistance and these patients will utilize the ambulance, emergency room and hospital services at a much higher cost to the Medicare Trust Fund.
- Deaf patients – special patient populations require added time and instruction, even specialized equipment services. These un-reimbursed "services" will not be available under the competitive bidding model.
- Disabled patients (wheelchair bound) – these patients are often unable to perform routine daily maintenance of equipment due to their disability. Such services are un-recognized by the competitive bidding model and will be unavailable or at an increased cost to the beneficiary.
- Ventilator patients – this high risk patient population must not be forgotten. Numerous factors regarding mobility, emergency services and patient/caregiver instruction will be unavailable in the competitively bid "product". A lack of professional services will place this patient at great risk of injury or death.
- Medicated patients – many patients suffer from confusion and/or medication effect(s), causing them to be unable to perform simple tasks such as filter and humidifier changes, etc. Who will provide these

services using the competitive bidding model? These patients are often confused and unable to understand instructions, much less perform complex maintenance on medical equipment.

- Hospice transfers to Medicare – patients who revoke hospice services to enter the Medicare program will not have access to services and/or will be required to change suppliers. Such continuity changes are distressing and often dangerous to this special population of patients. A contract supplier will be required to provide equipment, but will they be able to provide the "service" that these critically ill patients require?
- No transportation patients (no drivers license or vehicle) – public transportation is not everywhere, these patients will likely over-utilize emergency services when their equipment fails as they are likely unable to afford the service charges that will be required of a contract supplier.
- No telephone patients – this patient population will not even be able to "call" a contract supplier for emergency and/or after hour services, even if they are able to identify such a supplier. Who will care for them when a disaster strikes? Who will know that they even need assistance?

SUMMARY:

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

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

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

Access to new technology will be stifled – travel will be limited to what the beneficiary can afford to pay for privately – and no out of MSA competitive bidding area provider will be willing or able to provide services for the new reimbursement amount, whatever it may be. The intake process alone, considering paperwork burden, compliance with standards of care, etc. will cost the provider more than reimbursement (which, by the way, is the current situation as well, except they can attempt to at least break even if they provide a concentrator at the current low level of reimbursement).

The lack of providers (over half are expected to close their doors with competitive bidding), standardization and homogenization of equipment (no "new" technologies will be provided – after all, we are just "selling" a

product, not services) will occur in order for the few, surviving, large companies to provide the lowest level of equipment services they can. Large companies may well be able to "lowball" the bidding and control the process through size and financial reserves that are unavailable to the average small business owner. It will be only a few years before the surviving companies raise the prices to a sustainable level – it is inevitable that once the monopoly has been established, it will become "apparent" that service is something that both the Medicare program and the beneficiary require.

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

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

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

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

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

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

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

Submitter : **Dr. Maeva Pennucci** **Date: 06/22/2006**

Organization : **White Memorial Medical Center**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am a physical therapist working in a hospital setting who regularly provides orthotics to my patients to help them to walker more normally and to walk longer distances. This new regulation limits my ability to provide orthotics and adjust orthotics for my patients. I make adjustments as a regular part of my therapy session so I can immediately evaluate the benefits and fit for the patient. Please revise the regulation to recognize that physical therapists provide adjustments to orthotics including trimming, molding and assembly.

DME providers should be required to carry multiple brands of a product. Frequently a specific brand of walker, for instance, does not have the necessary options to be safe for a patient. It would be helpful if the physical therapist could specify the brand of walker so the patient could safely ambulate without risk of falling.

Sincerely,
Maeva Pennucci, PT, DPT

Submitter : Herman Henkes **Date:** 06/22/2006

Organization : Army Nurse

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

As I understand, this proposal would place negative pressure wound therapy (NPWT) up for competitive bidding. I am an active duty Army nurse currently working in the intensive care unit. We routinely use wound vacs for treatment of burns and other trauma wounds to include retired military members and dependents.

I daily witness wound vac therapy speeding the healing of wounds and protecting them from infection. I believe this type of treatment can be easily missrepresented to those who are not familiar with the wounds we use this equipment on. Please be very careful not to pass a one-size-for-all ruling just to get a cheap bidder. I use wound vacs on ulcers as small as a quarter and on wounds that literally circle the chest and abdomen of a patient's body. One size doesn't fit all.

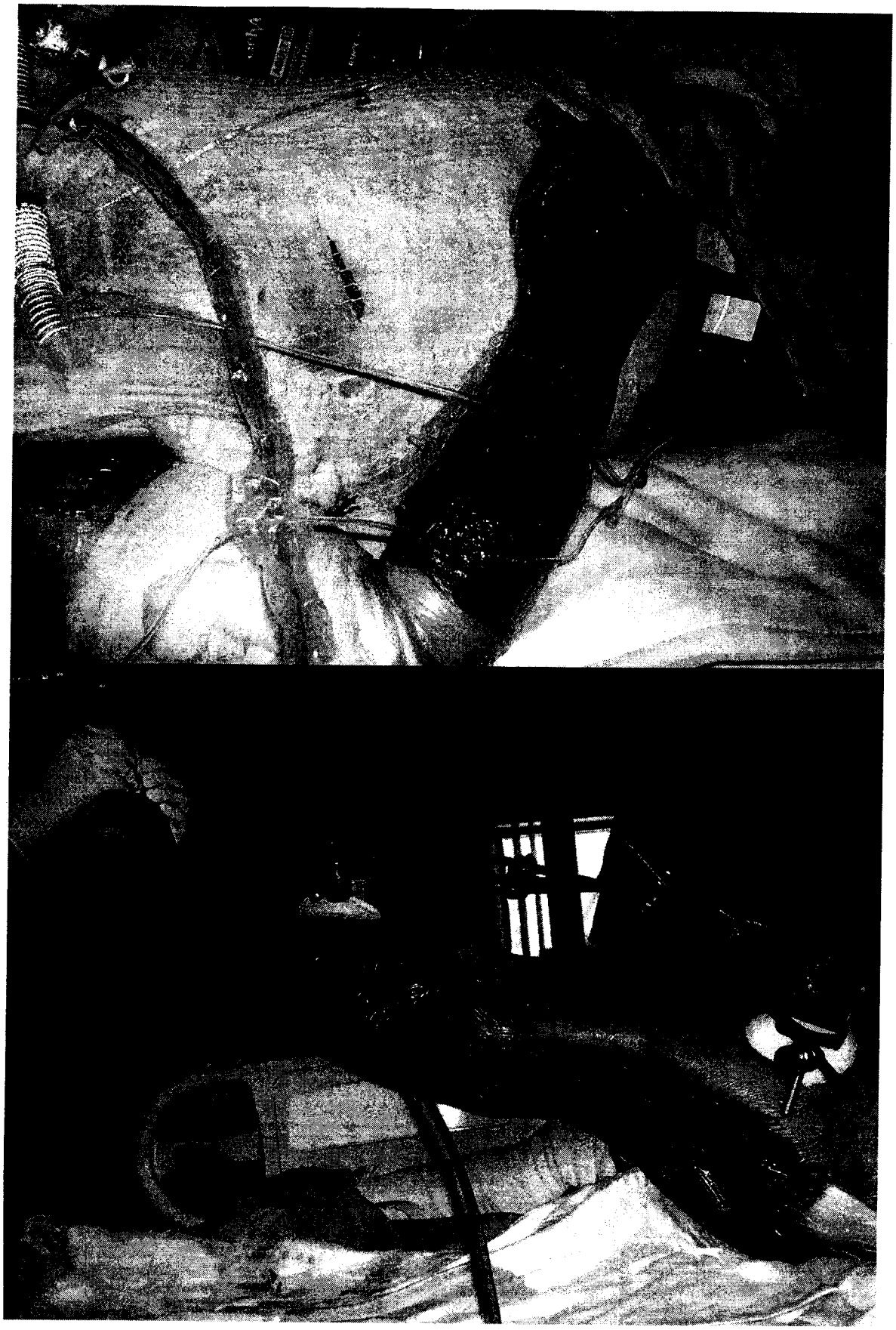
The KCI vac system is what the military uses. This product has literally set the standard for NPWT. If patient healing and hospital time/expense is the primary concern, no government agency will allow an inferior product to replace it. The result will be additional costs in greater-than-normal equipment needed for larger wounds and increased risk of infection and hospital stays.

I am attempting to include photographs of woundvac therapy in use. The pictures show successful KCI wound vac treatment covering entire hands and forearms, chests, entire trunks, etc. I have never had an infection under a KCI wound vac treatment of a patient and I have never seen a KCI wound vac fail to accomplish the job for which the surgeon placed it, to include skin grafts and healing of traumatic injuries. Do not allow a ruling to bring the unintended consequence of losing this quality product for these patients.

CMS-1270-P-278-Attach-1.DOC

CMS-1270-P-278-Attach-2.DOC

#278



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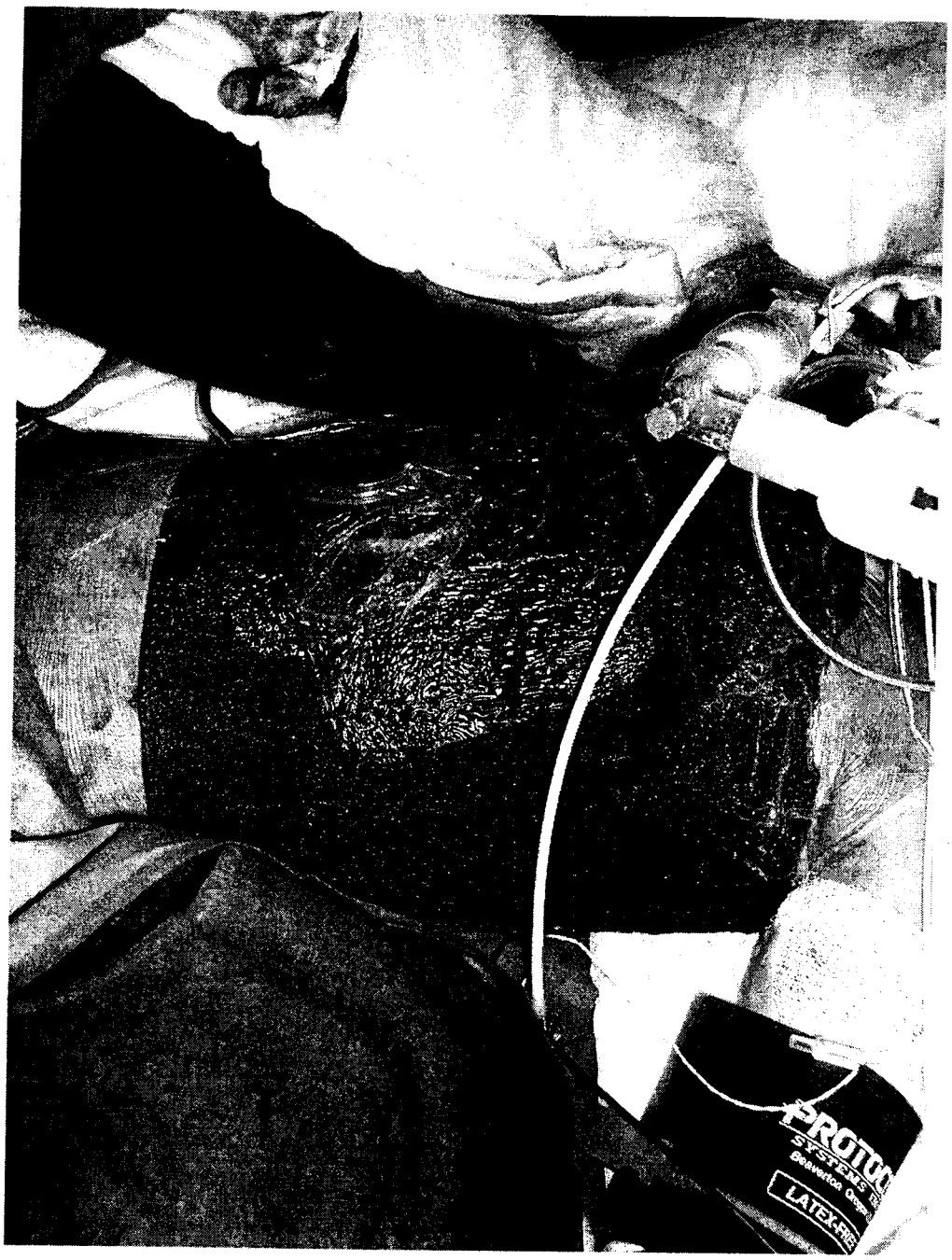

Submitter : **Mr. Craig Rowitz** **Date: 06/22/2006**

Organization : **Care Medical**

Category : **Physical Therapist**

Issue Areas/Comments

GENERAL

GENERAL

I am the owner of a smaller (4 million annually) medical equipment company in Cincinnati, Ohio. My comments are divided into a few headings below.

SUBCONTRACTING

I can see a large number of companies bidding on product categories that they currently do not provide and/or in areas that they currently do not serve. Those winning providers will then subcontract for performance of services. This will create an entire class of "middle men" companies with the sole intention of skimming a small amount off the top of the payments from Medicare with no intention or care for the actual provision of services. There must be mechanisms in place to prevent the awarding of bids to companies that do not provide at least some percentage of the services themselves. There is clearly a need to allow for some subcontracting but if winning bidders are allowed to subcontract the entire or a large portion of the product class, quality will be lost. The beneficiary will be receiving lower quality services at the expense of the profit skimmed by the winning bidder that does not actually provide a good/service.

POWER WHEELCHAIRS:

As a clinician and equipment dealer, I am very concerned about the impact users of Rehab equipment will experience with the movement to competitive bidding. The product category of power wheelchairs is undergoing a very positive change with the addition of 60+ codes. I strongly urge that competitive bidding on power wheelchair be delayed in two ways. 1) Allow manufacturers and SADMERC to have newly coded products enter the marketplace first. This will greatly decrease the over profitability of the K0011 chair in the "Sit and Drive" or non-rehab market. 2) Once the marketplace is selling newly coded products, competitively bid only those products in the consumer or "Sit and Drive" area. Rehab consumers must not be included in the competitive bidding process. The high level of complexity and customization of rehab equipment would not be served under the format of competitive bidding. I doubt that there could be a demonstrated significant cost savings.

REBATES:

As a small provider, I feel that the proposal to allow winning bidders to provide a rebate to consumers if the bid price is below the established payment is dangerous. This appears to be a Kickback and would provide a negative incentive in the market for consumers to use one provider over another or worse, request a kickback from a provider who does not provide a "Rebate".

What happens if a provider provides a rebate to some customers and not others? It truly is a reward or Kickback that can cause the appearance of fraud.

QUALITY STANDARDS:

My company is accredited by ACHC. We have worked hard to meet the high standards of our accrediting organization. I am very aware of the fixed costs associated with providing products and meeting high standards. In order to prepare an accurate bid for this process, I would need to know what quality standards my company would have to meet. At this time, I am not aware of the actual standards that must be met. Bidding should not begin until the final standards are released. The cost of providing a good or service can drastically change if additional staffing must added, service area is changed, service times are changed, etc.

LOW BALL BIDS:

I am concerned that there is no process to exclude "lowball" bids from the process. Without controls, the quality of services delivered will be lowered by bidders who hope to be reimbursed at a higher rate following a lowball bid.

Thank you for your attention to my comments,

Sincerely

Craig Rowitz, MPT, ATP
Care Medical, Inc.
8340 Reading Rd.
Cincinnati, OH 45237
800-305-8122 x 17

Submitter : Mrs. Danica Lofton

Date: 06/22/2006

Organization : Crtiticare Home Health Services, Inc.

Category : Other Practitioner

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-280-Attach-1.DOC

#280

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

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

Re: Written Comments file code CMS-1270-P

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- Transtracheal Oxygen patients – these patients require specialized instruction, care and supplies. A contract supplier must be able to provide such services or should not be allowed to accept such patients. A Respiratory Therapist is usually specially trained to address specific patient issues such as catheter care, cleaning and instruction.
- Tracheostomy patients – again, such patients require specialized instruction, care instruction and supplies, usually by a Respiratory Therapist.
- High Oxygen Liter Flow patients – such patients require special attention to their oxygen needs – a "standardized" approach to their care will prove both dangerous and inadequate.
- Blind patients – Many equipment types are not able to be utilized by these patients and with a "standardized", low cost piece of equipment, they will be underserved and/or un-served.
- Arthritic patients – many patients are unable to perform daily living activities without assistance, and the current DMEPOS provider often provides additional services which are not addressed by the competitive bidding model, such as equipment cleaning, maintenance, humidifier changes, etc. which will be unavailable.
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Submitter : Mr. EDWIN HOLLAND **Date:** 06/22/2006

Organization : GAYLE ENTERPRISES

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

MEDICARE HOULD ADOPT THE "ANY WILLING SUPPLIER" CONCEPT. SETTING STANDARDS AND REIMBURSEMENT LEVELS ANF LEAVE TO THE PROVIDER TO PARTICIPATE.

Submitter : Criticare Home Health Services **Date:** 06/22/2006

Organization : Criticare Home Health Services, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-282-Attach-1.DOC

#282

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

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

Re: Written Comments file code CMS-1270-P

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SUMMARY:

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

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

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

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

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

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

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

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

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

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

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

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

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

Submitter : Mr. Ronald Drees **Date:** 06/22/2006

Organization : St. Rita's Medical Center

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. William Wragge **Date:** 06/22/2006

Organization : Multi Plex Healthcare Services, Inc.

Category : Health Care Professional or Association

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Competitive Bidding in all sectors and locations will have a negative effect on avalible services. This is especially true in the rual area. This will do away with the a vast majority of the indepentent provider. The indepentent provider is the sucess link to health care safty in the home. With Competive Acquisition patients will experiance increased hospitizations, which will increase cost. Is this a smart move?

Submitter : Mr. Mark Lotz **Date:** 06/22/2006

Organization : Denman Medical Equipment Inc.

Category : Other Practitioner

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Your comparison of fees charged by V.A. contractors is flawed. The V.A. providers do not provide the same level of service you demand of Medicare approved providers. If competative bidding proceeds, there will be a significant reduction in the level of service providers will be able to provide. Oxygen and Respiratory equipment is proned to improper use by elderly patients. Medicare will end up paying more in the long run due to increased hospital bills and doctor bills and medications for Respiratory patients who are being ineffectively treated by poorly maintained and misused equipment.

Submitter : Mr. Stan Powell **Date:** 06/22/2006

Organization : Pitzing Pharmaceuticals

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

The new Medicare rules requiring accreditation will have a negative financial impact on smaller businesses and also prove to worsen the service aspect of this industry. I have worked for a company that went through accreditation and the extra time it took to perform accreditation-related tasks was taken away from providing service for our patients. As a result, new business was given priority and service related tasks were put off until a later time. The competitive bidding process will have a negative impact on the small provider also. Many providers will be driven from the business because they fail to submit a winning bid. The process should be handled differently. If competitive bidding must happen all providers should be invited to participate with the determination of pricing handled in the way it is laid out. Please be aware that providers will not be able to provide the same level of service for these deeply discounted prices. Unfortunately, our legislators have seen fit to model a program after the VA program. This process currently provides a disgraceful level of service to our veterans, but our government saves money. Someone should talk with VA patients to see how they perceive the services they receive. I do not believe that Medicare patients will stand for this. They already expect a higher level of service than humanly possible many times. I believe the cost savings represented by competitive bidding will fail to be realized. I believe that due to the complexity and cost providers, that the companies forced to leave the industry will push service to such a low level, that competitive bidding will actually cause a cost increase due to a higher utilization of hospital facilities. Home care SAVES Medicare money. I hope our legislators figure that out someday.

Submitter : **Date: 06/22/2006**

Organization : **American Diabetes Association**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-287-Attach-1.DOC

THE AMERICAN DIABETES ASSOCIATION'S COMMENTS ON PROPOSED RULE CMS-1270-P: COMPETITIVE ACQUISITION FOR CERTAIN DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES (DMEPOS)

Submitted by the American Diabetes Association
June 22, 2006

The American Diabetes Association submits the following comments on the Proposed Rule issued on May 1, 2006 regarding Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). The Association is both a patient advocacy organization and a medical professional organization committed to improving the lives of people with diabetes. Our work to ensure that people with diabetes have access to quality care is a key part of this commitment.

Successful management of diabetes requires that patients have access to appropriate and high-quality health care. Additionally, because diabetes treatment and management strategies will vary widely from one patient to another, it is critically important that people with diabetes have access to a wide variety of products in order to successfully manage their blood glucose level. Furthermore, these products must meet quality standards to ensure that they are safe and effective, and that patients are adequately educated on their use and maintenance.

The Association remains concerned that the Proposed Rule as currently written does not properly address some access and quality issues which may have a negative impact on the quality of care for people with diabetes. The Association submits the following comments highlighting these issues.

I. General Comments

ADA Position on Competitive Bidding - Guiding Principles

The development of the Medicare competitive bidding program should be guided by the following principles:

1. *Access to High-Quality Products*: The program must provide coverage for an appropriate range of products such that the medical needs of all beneficiaries with diabetes are adequately addressed. Furthermore, coverage must be limited only to products that have been approved by the Food and Drug Administration (FDA) for testing blood glucose in people with diabetes.
2. *Appropriate Exemption and Appeals Process:* There must be a fair, expedient, and appropriate appeals and exemption process which allows beneficiaries to utilize products with specific modifications and/or features based on medical necessity. Such a process should be initiated by any members of diabetes care teams, including physicians, beneficiaries, other health care professionals, as well as other care givers (including family of beneficiaries). In all appeals, appropriate medical documentation should be required. Finally, the burden of proof should not be on the health care provider or the patient to demonstrate that inadequate access to proper equipment will lead to 'adverse medical reactions.'
3. *Full Time Access to Supplies:* In order to properly protect beneficiaries in the event of emergency situations, beneficiaries must be able to access all components of blood glucose monitoring systems –including, but not necessarily limited to, a meter, testing strips, testing lancets, and a lancet-delivery device– at all times. The program must include proper safeguards such that any beneficiary will be able to access such equipment at any time without excessive burden –financial or otherwise– on the beneficiary.

4. *Inclusion of Diabetes Management Experts in Decision-Making Bodies and Processes:* Diabetes management experts –physicians, Certified Diabetes Educators, other health professionals, and layperson with diabetes– must be included in policy determination and implementation processes associated with the competitive bidding program. Similarly, diabetes management experts must be included as part of the appeals and exemption processes for beneficiaries with diabetes.
5. *Technology Review Procedures:* The program should include periodic technology and contract reviews to ensure that beneficiaries have access to appropriate supplies. Such reviews should lead to alterations in contracts and/or monitor availability when evidence demonstrates that technological upgrades lead to improved diabetes care. Furthermore, in order to ensure that new technologies are fully considered, contracts should not be awarded for an overly extensive period of time.
6. *Evaluation Systems:* CMS should endeavor to collect and analyze data to study the health outcomes of beneficiaries with diabetes to ensure that all have proper access to blood glucose monitoring systems and supplies. Because no competitive bidding pilot program was conducted for blood glucose monitoring systems, the analysis should focus on the effects of the competitive bidding program itself to ensure that it is not causing undue harm to people with diabetes.

After careful review and analysis of the Proposed Rule, the Association finds that the provisions contained therein are not founded on these six guiding principles and therefore do not adequately address the needs of Medicare beneficiaries with diabetes.

II. Comments on Specific Sections of the Proposed Rule

A. Payment Basis - Requirement to Obtain Competitively Bid Items From Contract Supplier (proposed § 414.408(f))

Because the Association believes that full-time access to supplies is crucial for people with diabetes, we have concerns about the proposed provision that all competitively bid items be supplied by a contract supplier for that program. By requiring beneficiaries to purchase only from contract suppliers, the Proposed Rule by definition limits the number of places where people with diabetes can purchase the supplies they need to effectively manage their disease. Such limitations could potentially be quite disruptive to older Americans with diabetes, who typically purchase their supplies –along with their medications– at their local neighborhood pharmacy. Beneficiaries who find that they can no longer purchase their supplies according to their regular method may be greatly inconvenienced, thus resulting in poorer diabetes management. CMS should anticipate that at least some Medicare beneficiaries with diabetes will experience a difficult and tumultuous transition into the competitive bidding program and plan accordingly. An aggressive education and outreach program should be implemented to ensure that patients continue to have access to their supplies and remain compliant with their diabetes self-management regimens.

The Association foresees another more serious problem with the Proposed Rule. As it is currently written, there is no provision specifying the geographic distribution of suppliers within a competitive bidding area. It thus remains possible –and perhaps even likely– that a significant portion of beneficiaries will be "stranded" miles away from the nearest contract supplier. Thus, the Association strongly urges CMS to consider geographic proximity rules similar to those under Medicare Part D, which ensure that there will be at least one contract supplier within a finite and limited radius of all beneficiaries located within a competitive bidding area.

Also, many Medicare beneficiaries temporarily change their residence during the course of a year, and thus may find themselves outside of a specified competitive bidding area for several months at a time. Thus, the Association urges CMS to establish a system to ensure that all beneficiaries will continue to have access to their supplies even while residing outside of their permanent domicile. This plan should require that suppliers aggressively educate beneficiaries on the proper procedures for obtaining their supplies while away from home, and should allow beneficiaries to purchase extra supplies for extended vacations or temporary changes of residence. Furthermore, this plan should allow beneficiaries to purchase their supplies from non-contract suppliers in the event of an emergency.

B. Competitive Bidding Areas

1. Proposed Methodology for MSA selection for 2007 and 2009 competitive bidding programs (proposed § 414.410)

The Association sees the potential for geographic barriers to arise *within* an MSA, thereby creating local access problems. Beneficiaries might be physically located miles away from the nearest contract supplier, thus creating logistical problems for people with limited mobility. Such problems will discourage compliance with diabetes self-management regimens and will lead to poorer health outcomes for the individual as well as high Medicare costs with the onset of diabetic complications. The Association recommends adding a provision requiring that there be at least one contract supplier within a finite and limited radius of all beneficiaries located within a competitive bidding area.

2. *Nationwide or Regional Mail Order Competitive Bidding Program (Proposed § 414.410(d)(2)*

The Association has grave concerns about this section of the Proposed Rule, which would allow CMS to establish a competitive bidding area to be served solely by a mail order supplier. Mail order of diabetes supplies raises a number of access and quality issues which should be addressed in its own separate section of the Proposed Rule.

First, mail order would eliminate the face-to-face counseling and assistance ordinarily available to beneficiaries when they purchase their diabetes supplies from their local pharmacy. It is crucial that people with diabetes continue to have access to individualized and inter-personal instruction in order to ensure accuracy of blood glucose monitoring and compliance with self-care regimens. Currently, local pharmacies assume much of the responsibility for this type of education by instructing beneficiaries on the features, proper use, and maintenance of their supplies. They also troubleshoot problems to help ensure that patients do not stop self-monitoring when they encounter difficulties

in using their supplies and equipment However, if the local pharmacy is not a contract supplier, it has little or no incentive to continue providing this crucial education and assistance.

If CMS intends to develop a mail order program for competitively bid items, the Association recommends that CMS also include safeguards to ensure that beneficiaries with diabetes continue to have access to face-to-face counseling and assistance with their supplies. For example, CMS could include a provision to specify reimbursement for face-to-face counseling sessions with a Certified Diabetes Educator for beneficiaries with diabetes who are forced to obtain their supplies through mail order. This would afford beneficiaries the opportunity to learn more about the devices they must use to manage their blood glucose levels, and to ask the Certified Diabetes Educator any questions they might have about the product and their self-management strategy.

C. Criteria for Item Selection

The Balanced Budget Act of 1997 authorized CMS to conduct up to 5 competitive bidding demonstration projects which would provide Medicare with the data to determine whether competitive bidding would provide substantial savings to the program while still offering beneficiaries sufficient access to quality products. Only two such demonstration projects were conducted, and only a limited range of supplies were tested by the competitive bidding process. Even with this limited data, the demonstrations were deemed a success, as each site experienced a 20% overall savings and statistical and qualitative data showed that beneficiary access to quality products were unchanged. However, the Association believes it is critically important to note that neither

demonstration included diabetes supplies within the products which were subject to competitive bidding.

Given the lack of knowledge about and experience with subjecting diabetes supplies to competitive bidding, the Association is concerned about CMS's proposal to include them in the first round of competitive bidding, which is to take place in 10 of the largest MSA's in the country in 2007. This type of competitive bidding for diabetes supplies is likely to raise access and quality issues not relevant to products and supplies that were part of the 2 previously conducted demonstrations.

Diabetes supplies are significantly dissimilar from oxygen equipment, hospital beds, enteral nutrition formulas and equipment, urological supplies, and surgical dressings, all of which were tested in the two demonstration projects. Unlike these items, diabetes supplies are typically purchased by beneficiaries at local pharmacies. As such, limiting the number of suppliers within a geographical area will necessarily affect patient access and quality of diabetes care. However, it is unknown what the exact effect will be.

It is certainly foreseeable that the competitive acquisition of diabetes supplies could cause great disruption in patient access, leading to non-compliance and increased health care costs, but we do not know with certainty how patients with diabetes will fare under the competitive bidding program. Therefore, we strongly urge CMS to consider implementing very strong safeguards for beneficiaries with diabetes to ensure that the competitive bidding program does not lead to poorer health outcomes by impinging upon access to or quality of diabetes equipment and supplies.

Furthermore, the section of the Proposed Rule governing selection of items includes no guarantees of periodic technology and contract reviews to ensure that

beneficiaries have access to supplies with technological upgrades proven to improve diabetes care. The Proposed Rule only requires that suppliers who submit bid for items within a particular HCPCS code make those particular items available to consumers. CMS must add a periodic and regular technology review procedure to their Final Rule in order to ensure that beneficiaries with diabetes have access to highest-quality evidence-based care.

D. Conditions for Awarding Contracts - Quality Standards and Accreditation (Proposed §414.414(c)

Under the Proposed Rule, a winning contract supplier must meet certain quality standards and be accredited by a CMS-approved accreditation organization. However, the applicable quality standards remain unspecified at this time, and therefore, CMS and its designated accreditation organizations cannot possibly know whether a particular supplier meets quality standards which do not yet exist.

The Association believes that the quality standards –and the related accreditation processes– must be complete before competitive bidding is implemented. Poor performance by a contract supplier could have an immediate impact on millions of Medicare beneficiaries with diabetes. A delay in the implementation of the competitive bidding is absolutely necessary if it prevents a decline in the quality of care received by beneficiaries with diabetes. It is imperative that appropriate quality standards be established and enforced through the proposed accreditation process *before* competitive bidding begins.

Furthermore, the Association unequivocally urges and requests that CMS include diabetes management experts in the development of DMEPOS quality standards and the accreditation of suppliers. This is particularly important as diabetes supplies comprise such a high volume of Medicare-covered DMEPOS items. Physicians, Certified Diabetes Educators, other health professionals, and laypersons with diabetes are uniquely positioned to understand the needs of beneficiaries of diabetes and can provide helpful guidance on the standards which suppliers should meet, as well as the ways in which diabetes supplies differ from other types of DMEPOS items.

E. Physician Authorization/Treating Practitioner and Consideration of Clinical Efficiency and Value of Items in Determining Categories for Bids (Proposed § 414.420)

This section of the Proposed Rule attempts to address situations in which beneficiaries with special needs require products with specific features or require alternate modes of delivery. The Association believes that it is crucial for the competitive bidding program to allow health care providers to prescribe specific items with special features when medical necessary. While most beneficiaries with diabetes will not need access to special systems in order to effectively manage their diabetes, there are likely to be cases where such an exemption will be medically necessary.

The Proposed Rule does not adequately ensure that beneficiaries with diabetes will have access to the products which their health professionals feel are most appropriate and medically necessary for their individualized needs. Under the Proposed Rule, if a patient requires a specific item that is not pre-approved under the competitive bid, health

care providers must spend valuable time contacting and negotiating with contract suppliers to determine if they are able to supply the prescribed product, or if a substitution must be made. This process is not only labor- and time-intensive, it may also lead to damaging health outcomes if it precludes beneficiaries from accessing life-sustaining equipment.

Furthermore, it is inappropriate to require health care providers to provide documentation that lack of medically-necessary equipment will lead to an adverse outcome. CMS must exhibit trust in the medical teams that care for beneficiaries with diabetes. Although it is appropriate to request documentation explaining why a specific product is medically necessary, it is not appropriate for a health care provider to demonstrate an adverse outcome in the absence of such equipment.

The above concerns are largely due to the fact that, under the Proposed Rule, suppliers have no incentive to provide products which are appropriate to specific medical needs. Indeed, because they will not receive additional reimbursement for providing such items, the Association remains concerned that suppliers will limit products to a narrow range that do not account for a wide spectrum of diabetes-related medical needs.

The Association recommends that CMS modify this section to allow for an adequate variety of diabetes supplies to suit a range of individualized needs of beneficiaries with diabetes. Additionally, CMS must create a less burdensome process to ensure that these supplies are rapidly available upon documentation of medical need. It is possible that adjusting the payment rate for these special items upward will encourage suppliers to provide them in cases where an exemption is warranted.

Submitter : Mr. Steven Curry **Date:** 06/22/2006

Organization : Criticare home health service

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

My name is Steven R Curry lpn and I have been a nurse since 1984 and have worked several diffrent areas from hospitals to home health to now a nurse clinical specailist at Criticare Home heath (DME). I'm very worried about having the the oxygen being the pt responsibility. The #1 sign of low oxygen is confusion so..... we are Now ....going to place the responsibility of oxygen that is a drug and flamable in the hands of alot of patients that are impared due to their medical condition. We do so much teaching and re-education with our patients. .Alot of our patients we have to change out their supplies or it doesn't get done. We have patients that use humidifiers with their oxygen...if they are put on wrong they get cross-threaded and it restricts their oxygen flow(this is a #1 problem that we face when we take call). When we set up our oxygen patients we check their machine every 90 days to make sure its working like it should(that its putting out enough oxygen...most machines if used 24/7 will need to be rebuilt every year) and we also give them new tubing or nasal cannulas.(we recomend changing out tubing and cannula every month) We also call the doctor office if we notice any changes in our patients or call back and some one from the office will call. I just feel like you are going to be putting a heavy burden on all oxygen patients by the changes you want and it will be costing the taxpayers more in the end. Please think this over carefully Thank you .....Steve Curry

CMS-1270-P-288-Attach-1.DOC

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

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

Re: Written Comments file code CMS-1270-P

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SUMMARY:

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

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

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

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

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

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

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

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

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

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

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

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

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

Submitter : Ms. Wanda Austin **Date:** 06/22/2006

Organization : Criticare Home Health Services, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-289-Attach-1.DOC

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

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

Re: Written Comments file code CMS-1270-P

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

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

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

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

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

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

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

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

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

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

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

Submitter : Mrs. **Date:** 06/22/2006

Organization : Mrs.

Category : Nurse

Issue Areas/Comments

Submission of Bids Under the Competitive Bidding Program

Submission of Bids Under the Competitive Bidding Program

If the goverment contract with DME's that simply offer the lowest price of a product with out investigating the quality, then the entire country loses. Inaccurate blood glucose readings from cheap and low quality meters, is a HUGE patient safety concern. Patients could potentially die from this very careless decision. Please reconsider and continue to allow Medicare patients a CHOICE of meters, and not dictate to them their meter. Also having a choice ensures the patient has the best meter for their personal use, as each meter is very different.

Submitter : Ms. Michelle Barnett **Date:** 06/22/2006

Organization : University of Michigan Health System

Category : Critical Access Hospital

Issue Areas/Comments

GENERAL

GENERAL

Submitter : Brent Mattox **Date:** 06/22/2006

Organization : Reimbursement Services Inc.

Category : Individual

Issue Areas/Comments

Conditions for Awarding Contracts

Conditions for Awarding Contracts

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 and publish that criteria. CMS should grandfather all providers accredited by organizations that meet the criteria that CMS identifies. CMS should allow additional time for providers to analyze the quality standards in conjunction with the NPRM. The quality standards will have a significant impact on the cost of servicing our beneficiaries. Until these quality standards have been released and providers can implement them, as well as see the costs of becoming accredited (both internal costs and the actual cost of the accreditation process), then it is impossible to prepare bid pricing. Companies that have not gone through the accreditation process can submit unrealistic bid prices due to the fact that they have not completed the process nor obtained accreditation. These low bids can significantly impact final pricing. And if these companies choose not to get accredited and drop out of the contract supplier group, they have lowered pricing for these products.

CMS should require accreditation of all locations of a company. It is not appropriate to think that if one branch of a business such as Wal-Mart is accredited, that all branches of the business provide the same level of service. This would also give the national companies an unfair advantage over the single location companies, because they could accredit one branch and spread that accreditation cost over many locations, while the single location small provider will have to absorb the large cost of accreditation and factor that into their bid price.

It is also important to note that the timelines that CMS are considering for implementation of competitive bidding are unrealistic based on accreditation requirements. For the majority of companies in this industry, they have not prepared for nor gone through the accreditation process. This is a time-consuming process and one that many companies do not want to prepare for until they have all the answers. Providers want to see final quality standards and then a list of the accrediting bodies recognized by CMS before they begin the lengthy, expensive process of accreditation. It requires a minimum of 6 months to prepare for your initial survey plus the majority of accreditation bodies require that companies be in compliance with quality standards for a minimum of 4 months prior to survey. So, realistically, providers going through accreditation for the first time will need 10-12 months to complete that process. Add on to that timeframe another 4-8 weeks after the survey before the accreditation body notifies the provider of the official results of their survey. So, it is important to realize that on average, CMS should expect it to take a minimum of one year to complete the accreditation process and become officially accredited. This doesn t even take into consideration the tremendous backlog that all accrediting bodies are going to face once quality standards are finalized and accreditation organizations are selected. It is unrealistic to think that this won t add additional time to the already lengthy process.

The final rule needs to contain more detailed information regarding financial standards that are going to be utilized during the bid process and how they are going to be utilized. CMS needs to define what financial ratios that they will be requiring, what the ratios should be, etc. so that providers know going in if they are considered viable candidates before submitting their bids. CMS also needs to decide how they are going to define a small business. Is it the business as a whole or is it each individual branch location? CMS should look at the business as a whole, not by supplier number.

Submitter : Mrs. Lori Sears **Date:** 06/22/2006

Organization : Active Home Medical Supply

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-293-Attach-1.DOC

June 22, 2006

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

Re: Comments on CMS-1270-P

To Whom It May Concern:

I own a small medical supply and equipment company. We have been providing service to Medicare beneficiaries for over 17 years. In reviewing this proposed rule I would like you to consider the following points. I apologize if this isn't in the proper format but I really hope to get my opinions to you prior to the deadline.

I believe that the entire competitive bidding rule should be thrown out because in no way does it recognize the value of the service component. Even products as seemingly simple as diabetic supplies and ostomy products can require extensive service and patient guidance especially when they are new or when problems and complications arise. Physicians and nurses apparently don't have the time to properly help patients and they often come to us scared and confused. It is not uncommon at all to spend an hour or more with a patient requiring these products for the first time sometimes with significant follow up as well. Patients need this service and should have a choice in finding the supplier most willing and able to give them the time and help that they need. Without us they would end up back at the doctors office or hospital and CMS would be actually paying for the time spent so is there really a cost savings there? What about after hours? How much will CMS pay when the patient seeks help in the Urgent Care or ER because they either got bad service during business hours or they couldn't get any service at night? We provide 24-hour service for almost every product we sell. After competitive bidding how many providers will do that? Will the winning bidder be able to afford that level of service? What about delivery of products? Will the lowest bidders still absorb the increasing fuel and other costs or will they require their patients to pick up their products? How many patients or caregivers can actually do that and what other programs will be affected with increased costs?

If this plan must be implemented then I would at least urge you to do it in a way that minimizes the negative effects on the beneficiary and affords an opportunity for small companies with long track records like mine to continue to service these patients. I therefore offer the following comments:

Delay Implementation Time Line Pending Release of Supplier Standards and Mandatory Accreditation Guidelines

CMS should finalize the supplier standards and choose accreditation agencies prior to moving forward with Competitive Bidding. You should also finalize and publish what help if any will be available to small businesses as directed by Congress. This will be a huge, costly and time-consuming endeavor for us. Many providers like myself are anxious to get started but absolutely cannot afford to work in the wrong direction. We also need to know our costs before we are able to bid. How can you expect accurate bids when the cost of doing business is unknown?

Products Selection

Off the shelf orthotics should not be included. Patients need local choice due to the nature of so many products within this category. They need to be properly fitted and offered choices in style and material and they need this right away. They are typically not in a position to drive across town for these products.

Wheelchairs and accessories (both power and manual) should also be excluded. Many have suggested that standard (K0001) chairs be included but I strongly disagree. I would fear that if only some bases were included and others were not many beneficiaries that should be properly fitted for a higher end chair or with non-standard options would end up in an inappropriate chair. The cost of an ill-fitting chair is enormous. Not just from the beneficiaries' standpoint but also financially to CMS with wound care, back pain and shoulder problems just to name of few. The time and skills required to properly fit a patient for the right mobility devise should simply not be subject to competitive bidding and artificial price restraints. Mobility products are not commodities and to treat them as such will have a terrible impact on the patients and cost CMS so much more than the savings anticipated in this category. Do I have figures to back this up? No, again I am a small provider but I am one that has seen the wounds caused by an incorrect seat depth and I've spoken to patients that are groggy and on pain medication when all they needed is a simple change in axle position or seat to floor height. We spend probably 5% of our gross revenue within this category in continuing education for our employees that fit patients for mobility devises because it matters so much. Subjecting this to competitive bidding says it doesn't. One final point is that you cannot rely on doctors and other healthcare professionals (OTs and PTs) to properly recommend chairs. While there are some that are very well educated and informed on the latest products and innovations there are many more that have no idea. They may be well versed in the problems and conditions of the body but have no idea the best products to resolve these and as they are further constrained by their fee screens and budgets they will have even less time to stay current. They rely on us for that.

Rebates from low bidders:
Isn't this a kick back or a financial inducement that is currently illegal?

Pricing:
I believe that beneficiaries will be better served if the lowest bids are eliminated and that the final fee will be an average or a median. There are so many variables in the quality of products within each code and in the service provided with the selection and delivery of each product. The cost to service a cheap product can easily exceed the initial investment and with the end of a continued rental option CMS will end up paying more to keep the equipment functioning in the long run. With ostomy products we have already seen the effects of low Medicaid fees. The generic products that can fit within that fee have caused severe skin irritation on 50% of the patients that tried them. How much savings has that reduced fee really generated with the additional cost of the skin care?

Method to calculate savings:

I'm not an accountant but it doesn't take a degree in finance to see that there is an unseen cost of using the wrong product and often times the cheapest product. Look away from our industry for a moment at some of the products you use in your own life. Do you pay more for your car simply because it has nice cushy leather seats? No, you do it because you want it to be both safe and reliable. Did you buy your lawn mower directly from the manufacturer in China? Of course not, you know you need a safe reliable product and service that you can count on when you need it. The examples could go on but the point will be the same. On everyday household products you choose the best product at the best dealer or store based on quality, reliability, service and convenience. Why should medical equipment and supplies be any different? Our products and our services are so much more important to our patients than most any household item could be. We keep beneficiaries productive. We help them grow stronger and more active. We sometimes keep them working and caring for their own families. We certainly keep them in their homes as long as possible. The products and services that combine to do this are a significant, critical part of the lives of those that need them and they should have a right to choose the best service and products possible.

Thank you for taking the time to consider these and all of the other comments you'll receive. Please keep them in mind as you make the decisions that will affect so many of the weakest people in our country.

Sincerely,

Lori M. Sears
Active Home Medical Supply, Inc.

Submitter : **Dr. Scott Koppel** **Date: 06/22/2006**

Organization : **Dr. Scott Koppel**

Category : **Physician**

Issue Areas/Comments

Quality Standards and Accreditation for Supplies of DMEPOS

Quality Standards and Accreditation for Supplies of DMEPOS

June 22, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1270-P
Electronic Comments

Dear Dr. McClellan:

I hav been in practice for more than 11 years, and I am concerned with the recent proposal from the Centers for Medicare & Medicaid Services (CMS) that would require physicians to participate in the new competitive acquisition program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). I am especially concerned that CMS is using the narrow definition of physicians as 1861 (r) (1) instead of 1861 (r) which included podiatric physicians in this definition of physicians. I support excluding all physicians, including podiatric physicians, from the new program.

I currently am a DMEPOS supplier. I simply cannot provide quality care wihout providing durable goods from my office. I use a many DMEPOS items, including pneumatic boots for fractures, ankle braces, dressings for wound care. If, as a result of the new program, my patients will be required to obtain these items from another supplier away from my office, additional injury and treatment delay will result.
If CMS cares at all about patient care and improved outcomes as well as cost containment, you will reconsider your proposal and exclude all physicians, including podiatric physicians, from the new competitive acquisition program for certain DMEPOS. Instead, allow me as a qualified supplier to continue to directly supply items to Medicare beneficiaries.

Sincerely,

Scott Koppel, DPM, FACFAS

Submitter : Mac Bray **Date:** 06/23/2006

Organization : Capital Pharmacy and Medical Equipment

Category : Pharmacist

Issue Areas/Comments

Opportunity for Participation by Small Suppliers

Opportunity for Participation by Small Suppliers

We are a swmall independent pharmacy and medical equipment supplier in Ky. For us to be able to participate in competitive biding will be so expensive with the new programs we bill probably be locked out of providing for medicare patinets. Another barrier of complication and expence is being placed in front of the small supplier. Accreditation will be expensive 5-20 thousand dollars to even play to even get to participate in the bidding with little hope of getting a bid or evening knowing. lower rembursement pay every rising cost to meet all then complex rules and regulations. There will be very few small bussiness able to provide. Another example of the government spending a dollar to save a dime.

Submitter : Dr. Nancy Kaplan **Date:** 06/23/2006

Organization : Dr. Nancy Kaplan

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1270-P-296-Attach-1.DOC

#296

Nancy A.Kaplan, DPM,FACFAS
420 Morris Ave
Springfield, NJ 07081
KA538902

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).

- 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. To treat my small practice as a major DME supplier and force me to compete against NYC and New Jersey behemoths will negatively impact my patients.

- 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. I will not be able to have my patients obtain supplies in a timely and closely supervised fashion which is ESSENTIAL for diabetic foot care and prevention of complications. I do not want to supply DME items to patients that are not my patients

- 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. 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 want to be able to continue to provide medically necessary and appropriate care to the patients I serve. It makes no sense to treat Podiatric physicians differently that MD/DO physicians. Our practices are often smaller than MD/DO practices. It would make more sense to differentiate this definition by the size of the practice. This definition could include the number of employees or physicians.

- 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.

Sincerely

Nancy A.Kaplan,DPM,FACFAS

Submitter : Dr. Scott Hughes

Date: 06/23/2006

Organization : Foot & Ankle Specialists, PC

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:

A new CMS rule regarding DMEPOS 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 DMEPOS only to my patients. I meet all the same requirements as MD and DO providers. As a physician in the Medicare program I should have the same right to dispense DME. There is no logical reason to discriminate against DPM's.

In office dispensing of DME improves patient compliance, allows physician supervision, is more convenient for the patient and leads to better outcomes.

Please reconsider the CMS definition of physician and change it to 1861(r), which will allow DPM s to supply DMEPOS to their patients

Sincerely,

Scott E. Hughes, DPM, FACFAS

Submitter : **Dr. Brenna Steinberg** **Date: 06/23/2006**

Organization : **Frederick Foot & Ankle Specialists, PC**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan,

I am writing to ask that you please exclude Podiatrists from this competative bidding program. Our Medicare patients who require DME will be greatly inconvienced as well as receive sub-standard products if we are forced to outsource.

For example, a 90 year old blind and neuropathic diabetic with an ulcer on the bottom of her foot needs an aircast diabetic walking system to offload it. Her daugher who has 3 children has already had to take off of work to bring her to the office. Under the competative bidding program, we may have to send them packing down the street to have a potentially non-physician supplier fit her for it. Will they take off the sterile bandage? Do they cut out the hole in the bottom to accomadate the ulcer? Or must she come back to our office tomarrow? What if she can not get a ride? The choice is forcing her daugher to take off more work and her family suffering. Or the patient going home, potentially having been fitted wrong, developing an infection, losing her foot, limb or life? NOW, WHAT IF THIS LADY WAS YOUR MOTHER???!!!PLEASE don;t tell me that we can ask for special consideration for some cases because everyday we are buried under more and more paperwork. If we are not excluded from this program, I foresee problems like this occurring everyday in an insurance climate and litiginous world that is becoming increasingly harder to practice in. Thank you for your time and understanding. If you have any further questions, it would be my pleasure to speak with you.

Brenna Steinberg, DPM, FACFAS

Submitter : Mrs. Sue McClanahan

Organization : Valley Home Care LLC

Category : Home Health Facility

Date: 06/23/2006

Issue Areas/Comments

Competitive Bidding Areas

Competitive Bidding Areas

Competitive Bidding will be a diaster for the small DME companies, they will not be able to get the discounts offered to big companies that offer rebates and rate decreases if you order a big quantity. Which will give the big companies an advantage to give a lower bid on equipment and service.

If this goes into effect you can kiss the small companies goodbye and once again the rich and powerful wins out against the little people.

This country was started on the backs of the little man without them big companies would not have gotten a start. It seems to me that our country is now trying to destroy all the mom and pop people so they can back all the big companies that can line their pockets for them. Just in our community I have seen so many mom and pop shops close because they were unable to compete with the larger companies in price, even through they can give that individual attention to their patients and their families and not make them just a number in the system it seems as if you do not care about the quality of care and equipment they are receiveing as long as it's cheap.

I ask that you take another look at this competitive bidding and think about how the patients should be treated when they are in need of medical equipment and care. Please do not make them just another number on paper let them be treated as an individual by someone who cares how they feel and if they are getting the best service that can be given to them when they need it, not just cheap and get it done.

Thank You for letting us vent our opinion on this matter and we hope that you come to the same conclusion that we have about patient care and quality.

Valley Home Care LLC
7880 Foundation Drive
Florence, Kentucky 41042

Submitter : Mr. Charlie Trapani

Organization : Tycon Medical

Category : Health Care Provider/Association

Date: 06/23/2006

Issue Areas/Comments

GENERAL

GENERAL

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