Submitter : **Ms. Cara Bachenheimer** **Date: 09/25/2006**

Organization : **Invacare Corporation**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1304-P-47-Attach-1.DOC

CMS-1304-P-47-Attach-2.DOC

Attachment 1 to #47

SUBMITTED ELECTRONICALLY

September 25, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicare Program; Home Health prospective Payment Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 (DRA)[1] Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment; Proposed Rule [CMS-1304-P] RIN 0938-AN76

Dear Dr. McClellan,

Invacare Corporation (Invacare) appreciates the opportunity to submit comments to CMS on the Notice of Proposed Rulemaking, Medicare Program; Home Health prospective Payment Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 Changes to Medicare Payments for Oxygen Equipment, and Capped Rental Durable Medical Equipment (CMS-1304-P). Based in Elyria, Ohio, Invacare is the largest manufacturer of home respiratory devices in the United States, including oxygen concentrators, portable oxygen tanks, and oxygen generating portable equipment.

Overall Comments

Invacare Corporation commends CMS for its recognition of the many benefits that oxygen generating portable equipment can provide. It provides patients with the mobility and convenience they desire, it provides physicians with the understanding that their patients always have access to ambulatory oxygen, and it provides costs savings to the health care system. While CMS' proposed rule appropriately provides some financial incentives for providers to provide oxygen generating portable equipment, CMS should ensure that its policies create no obstacles to beneficiaries with medical need for portable home oxygen therapy from receiving oxygen generating portable equipment.

For example, patients should be able to transfer to these systems at any time; without any financial disincentives for providers. If a patient wishes to transfer to oxygen generating portable equipment at a point when he/she is well towards the 36 month rental cap, there are financial barriers due to the significantly larger capital investment required for these

[1] Pub. L. 109 -171 (2006).

systems and the requirement that ownership transfer to the patient. CMS should, therefore, begin again the 36-month count or provide a higher reimbursement in these later rental months to guard against any short term financial barriers. The more beneficiaries that transfer to these systems, the faster the respective benefits will accrue to all. Any short term increased costs will be more than offset by the longer term savings that would result from a higher percentage of patients utilizing the oxygen generating portable systems.

Invacare estimates that less than ten percent of the current ambulatory patient population is using oxygen generating portable equipment. As a result, there are a significant number of beneficiaries that could benefit by transitioning to these new oxygen systems. CMS must ensure that its policies do not erect artificial barriers to beneficiary access to these systems.

Finally, given frail condition of most beneficiaries on home oxygen therapy, the serious safety issues discussed in detail below, CMS should ensure that its home oxygen payment policies provide a solid foundation to ensure that the beneficiary always has access to a home oxygen provider. If the policies do not provide this foundation, beneficiaries will end up in hospitals. CMS should bear in mind that oxygen can be provided to a chronic obstructive pulmonary disease (COPD) patient who lives at home for one year at less than the average Medicare cost for one day in the hospital, which is $4,603.[2]

Summary of Comments

Our detailed recommendations follow. In summary, Invacare recommends the following:

1. Medicare payment structure and levels need to be sufficient to encourage the use and development of new and better technology.
2. CMS should increase the payment rate for new technology to further encourage the transition to and use of new portable oxygen systems.
3. CMS should publicly release the data and assumptions upon which CMS proposes that this proposed rule is budget neutral.
4. CMS should modify the general prohibition of exchange of equipment during the rental period to allow beneficiary access to new technology (proposed 42 CFR 414.226(a)(2)).
5. CMS should modify the "useful life" definition to be consistent with manufacturer warranties.
6. CMS should establish payment for maintenance and servicing of oxygen and oxygen equipment and capped rental items, regardless of the technology provided.
7. CMS should establish an ongoing service fee to support beneficiary access to necessary clinical, support, emergency and other services.
8. CMS should develop specific safety standards.

---

[2] (Annual Statistical Supplement, 2005, Social Security Bulletin). Direct medical costs for COPD in the U.S. total $18 billion per year, nearly 9% of Medicare expenditures. (Dunne PJ. "The demographics and economics of long-term oxygen therapy." *Respiratory Care*. 45:223-228, 2000.)

9. CMS must address the safety issues associated with the likely proliferation of eBay/Internet and black market sales of used medical equipment.
10. Routine vs. non-routine maintenance must be better defined by CMS.
11. The proposed rule is not budget neutral; therefore the proposed payment rates should be increased.

1. Medicare Payment Structure and Levels Needs to be Sufficient to Encourage the Use and Development of New and Better Technology

While there may be advantages to a technology specific payment methodology, there are currently limitations. First, how does a new technology get recognized and paid? If a manufacturer develops a new technology, do beneficiaries have to wait until CMS incorporates the new technology into a revised version of the regulation? Will there be alternate and faster ways for beneficiaries to be able to access new technologies? We encourage CMS to re-examine this payment methodology and provide a concrete opportunity for new technologies to be incorporated into the payment methodology.

One significant advantage of modality neutral payment method over a technology-specific method is that it creates market incentives for manufacturers and providers to provide the most cost effective and patient friendly technology.

In the absence of a modality neutral payment methodology, CMS needs to create the appropriate incentives to ensure that beneficiaries have access to new technologies. Within the constraints of a 36-month cap and forced beneficiary ownership, CMS should increase payment rates for new technology during months one through thirty-six to enable providers to afford the higher capital investment associated with new technologies. A significant limitation of the 36 month cap and CMS' proposal is the lack of any payment stream to providers for patients receiving new technology after 36 months. As we discuss below, there is a need for an ongoing financial foundation for the provider for the entire period of medical need, regardless of technology provided, to cover costs related to emergency and other support services. With the 36 month cap, and the financial constraints this imposes, CMS should increase further the payment rates for new technology to ensure that financial barriers do not create beneficiary access to new technology problems.

In an ideal market environment, CMS' policies would stimulate ongoing advances in oxygen technology that would enable patients to be as active as possible and allow providers to reduce their overall cost structure. Better oxygen technologies will be developed if appropriate financial incentives are in place for manufacturers to pursue the research. For that reason, we urge CMS to increase payment levels for newer technology, and work with manufacturers to ensure that over time there are sufficient resources to support research and development that fosters the creation of better and more cost effective technologies. CMS should use its annual rulemaking process with notice and comment to ensure that its oxygen policies are current and appropriate.

2. CMS Should Increase the Payment Rate for New Technology to Further Encourage the Transition to and Use of New Portable Oxygen Systems

The proposed monthly payment rates for this new class of oxygen system may be insufficient to fully support the cost of innovation and as a result, may limit adoption and use of such oxygen technologies. While CMS acknowledges the concern that the current Medicare payment for oxygen (approximately $231 per month) may not be sufficient to facilitate the use of this technology and proposes a higher monthly payment amount for these systems to allow for the increased up front cost associated with the provision of these innovative technologies. The newly proposed fee schedule ($241 per month) amounts to an increase of approximately $10 per month (maximum of $360) over the current Medicare combined stationary and portable oxygen payment. Many of the new oxygen generating portable oxygen devices cost suppliers four to five times the cost of an older and more traditional stationary and portable oxygen combination. We believe these data must be considered and incorporated into any new fee schedule to ensure adequate payment for this important class of oxygen technology. Further, if CMS increases the payment rate for new technology, CMS will increase the conversion rate to newer more cost effective technology.

Recommendation:
We agree that Home Oxygen Generating Portable Equipment can save on contents fees and deliveries to beneficiaries' homes. We question the basis, however, for the proposed add-on fee which is designed to compensate the supplier for the additional acquisition cost of these pieces of equipment. We do not believe that the proposed rate provide adequate compensation for providers to invest in newer technologies, and recommend that this amount be increased. In addition, CMS needs to provide assurances that payment levels will not decrease (except in the event of competitive bidding) and that each year the fees will get a CPI update.

3. CMS Should Publicly Release the Data and Assumptions Upon which CMS Proposes that this Proposal is Budget Neutral

We strongly urge CMS to release the detailed data and assumptions it used to conclude that the regulation is budget neutral. The proposed regulation relies entirely on a detailed historical and projects utilization of various oxygen technologies. This data and assumption set must be released to enable a fuller understanding of the proposed rule, and to allow public comment on the data and assumptions and methodologies CMS used to develop the conclusions in the rule.

4. CMS should modify the General Prohibition of Exchange of Equipment during the Rental Period (Proposed 42 CFR 414.226(a)(2))

CMS has proposed that the supplier cannot exchange the beneficiary's equipment during the period of medical need in which payments are made except in very limited situations. Specifically CMS has proposed these exceptions:

- Cases where the item becomes subject to a competitive acquisition program implemented in accordance with section 1847(a) of the Act;
- Cases where a beneficiary relocates on either a temporary or permanent basis to an area that is outside the normal service are of the initial supplier
- Cases where the beneficiary chooses to obtain equipment from a different supplier
- Other cases where CMS or the carrier determine that an exception is warranted

This requirement will prevent beneficiaries from having access to more technologically advanced equipment from their supplier. Under CMS' proposed rule, a beneficiary who begins a rental period with a concentrator and a gaseous portable tank could not receive, even upon physician authorization, a Home Oxygen Generating Portable unit from his or her supplier. In this example, the only way a beneficiary could obtain this more technologically advanced equipment would be to change suppliers. We do not believe it was CMS' intention to restrict beneficiary access to new, patient friendly more cost effective oxygen technology.

CMS has stated this prohibition was included to prevent suppliers from substituting substandard equipment prior to the beneficiary taking ownership of these items. This can be addressed by CMS' proposal "that the replacement item must be equipment that is, at minimum, in the same condition as the equipment being replaced." This provision will prevent unscrupulous suppliers from replacing equipment with poor or substandard equipment.

If access to newer, lighter, more portable oxygen systems is restricted through reimbursement constraints or lack of clearly-defined medical necessity criteria and documentation requirements, oxygen therapy patients will suffer serious medical consequences. Patient choice and an elective process to change equipment must be incorporated into the exceptions for changing equipment. As the Medicare beneficiary and an educated consumer of the health care products prescribed for their use, the beneficiary should be afforded freedom to make a conscious decision to change equipment based on his or her individual lifestyle needs. Beneficiary choice of prescribed and medically appropriate oxygen technologies and the ability to change their oxygen equipment should be incorporated into the exceptions in the rule. This freedom of patient choice will impose additional free-market forces that we believe will encourage improved patient access to new and innovative oxygen therapy technologies

Recommendation:
Suppliers should be allowed to exchange and/or change a beneficiary's equipment during the period of medical need provided this exchange /change is documented, including the reason. This event could be tracked and recorded/reported to CMS via a new modifier to document the reason for the exchange. CMS and its carriers should not be a part of the process to determine that a change in condition be warranted, this will be administratively burdensome.

5. CMS should modify the "useful life" definition to be consistent with manufacturer warranties.

CMS' current definition of "useful life" exceeds the warranty that manufacturers typically provide on most of the current oxygen technologies on the market. Forcing a provider to be financially responsible for a device beyond the manufacturer's warranty period imposes significant financial burdens on providers. CMS needs to establish "useful life" definitions specific to the oxygen technology. CMS should review current manufacturer warranties and use these as a guide in establishing the "useful life" of specific oxygen technologies.

Manufacturers determine warranty period for devices based upon a variety of reasons. In general, newer technology will have shorter warranty periods than technology that is more mature and has been tested over a significant period of time.

Recommendation:
CMS should modify its definition of "useful life" and should develop technology or equipment-specific definitions. CMS should use current manufacturer warranty information as a guide to develop these definitions.

6. Payment for Maintenance and Servicing of Oxygen and Oxygen Equipment and Capped Rental Items, Regardless of the Technology Provided

CMS is proposing that "maintenance and service" payments are permitted for capped rental DME and oxygen equipment after title has transferred to the beneficiary; however, CMS has also proposed to "apply our existing policy of not covering certain routine maintenance or periodic servicing of purchased equipment, such as testing, cleaning, regulating, changing filters, and general inspection of beneficiary-owned oxygen equipment and to continue that policy for beneficiary-owned capped rental equipment." Invacare is happy to provide CMS with a list of the most commonly used items that are used as replacement parts; we are providing this list under separate cover.

Invacare is concerned that CMS assumes that beneficiaries are more capable than their frail conditions typically allow. The average age of a beneficiary on oxygen after 36 months is 73 years old, and has multiple diagnoses that include both physical and mental limitations. Additionally, 16% are disabled. The oxygen that these prescription devices produce is a prescription drug.

Despite these facts, CMS maintains that beneficiaries will be responsible for the routine maintenance of their equipment. We believe this is an oversimplified assumption by CMS that all beneficiaries will be able to perform routine maintenance and service on their equipment to keep it in good working order. We urge CMS to understand there are beneficiaries who may not be able to perform this routine maintenance and service. As a result, CMS must provide a process to ensure that these beneficiaries will continue to have good functioning equipment.

Recommendation:
CMS will need to establish codes to adequately describe the parts and repair services that will be covered and reimbursed for beneficiary-owned oxygen equipment. We encourage CMS to work with manufacturers and providers to ensure fee schedules are established that appropriately account for all parts and services incurred in providing the maintenance and service for capped rental and oxygen equipment after title has transferred to the beneficiary. We are providing under separate cover a list of the most commonly purchased repair/replacement parts for oxygen devices and capped rental items (hospital beds, manual wheelchair parts, and power wheelchair parts. – none of which currently have a HCPCS code (they are currently billed as E1399 – Miscellaneous)).

7. CMS Should Establish an Ongoing Service Fee to Support Beneficiary Access to Necessary Clinical, Support, Emergency and Other Services

The proposed rule makes no provision to provide after-hours or emergency services for beneficiaries post title transfer of either their capped rental or oxygen equipment. We are concerned that there is no provision for these emergency services to be provided by suppliers and that this would place beneficiaries in unsafe conditions. Conditions that could have been prevented had such provisions been considered and provided for. Examples include power outages or other natural disasters, all of which will require the beneficiary to be able to speedily obtain access to back up tanks to ensure no gap in his or her access to home oxygen therapy. This will be required regardless of the technology the beneficiary is using.

CMS needs to establish a regular and ongoing payment after ownership transfers to ensure beneficiary-owned equipment is appropriately maintained, e.g., a payment every 6 months. This needs to occur even with new technology such as oxygen generating portable equipment.

It is not reasonable to expect a frail senior who has a medical need for oxygen to be responsible for performing filter checks and cleanings; checking purity levels, etc. – to even be responsible for routine maintenance. More importantly, Medicare needs to anticipate emergency situations and provide financial foundations for those. Otherwise, beneficiaries will go to hospital emergency rooms, incurring significant Medicare expenditures.

Without a financial foundation to sustain the provider-patient relationship, patients will likely be left "stranded", using equipment that may not be operating correctly – this can be life threatening for patients.

In a 1994 report, the OIG stressed the need and importance of regular, frequent servicing of oxygen patients (Oxygen Concentrator Services, OEI 03-91-01710, November 1994). At that point, the OIG was examining the need for services standards for suppliers of home oxygen therapy. We are unclear why the government would completely reverse its position, not recognizing the need for the many critical support services that home oxygen suppliers provide to patients. Specifically, the OIG found: "The importance of

support services, such as equipment and patient monitoring, for oxygen concentrator patients is critical for the proper functioning of the equipment as well as the effectiveness of the therapy it provides."

We are concerned that home oxygen beneficiaries may be in jeopardy if there is no financial foundation to support an ongoing relationship between the provider and the patient. Emergency situations such as power outages require the beneficiary to have access to portable tanks, regardless of the technology the patient uses. For example, a beneficiary on oxygen for 40 months experiencing electrical failure will need to obtain a supply of portable tanks. Otherwise, that patient will be forced to go to a hospital emergency room, incurring significant and unnecessary costs.

Recommendation:
CMS should establish an ongoing service fee to support beneficiary access to necessary clinical, support, and other services. We recommend CMS develop a rational, reasonable methodology to provide for emergency services for beneficiary owned equipment. This will ensure beneficiaries continue to have access to life sustaining services during power outages or other emergency situations.

8. CMS Should Develop Specific Safety Standards

The patient population represented by Medicare consists of the elderly and disabled. Home oxygen beneficiaries are dependent upon healthcare delivery to their homes. Many live alone, are unable to drive, have poor eyesight, hearing, and arthritis. Caregivers are frequently aged spouses with similar physical and mental issues. Few are able to perform simple troubleshooting of their equipment despite professional guidance via phone and require home visits to assure the equipment is functioning properly. Ongoing beneficiary education and monitoring regarding oxygen usage and safety will no longer be performed, creating the potential for unsafe use of oxygen (e.g., smoking while using oxygen).

Oxygen cylinders must be periodically tested hydrostatically to assure they will safety hold contents under high pressures. Liquid oxygen vessels are regularly inspected for leaks to assure the cryogenic contents are safety contained. There is also a requirement that equipment repair and maintenance be documented to provide a history for each item. Filling beneficiary-owned equipment without knowing the cylinder's history is a potentially dangerous situation. Cylinder concerns include the need for hydrostatic cylinder testing, product traceability, drug product labeling with potential for misbranding, chain of custody and control issues.

Oxygen requires compliance with specific guidelines developed by the Department of Transportation (DOT), Food & Drug Administration (FDA) and the Compressed Gas Association (CGA). Beneficiaries may not be aware of, or comply with, these guidelines thus putting them and others at risk.

The DRA provision forcing beneficiaries to assume ownership of complex medical equipment such as various oxygen technologies is troubling, particularly given the fact that beneficiaries on home oxygen therapy are typically very frail and have a series of serious health issues. As a result, CMS should develop and implement policies to safeguard against possible safety issues.

For example, the following situations create increased potential for safety issues to arise under the forced beneficiary ownership policy. FDA-approved medical devices must be subjected to preventive maintenance regularly according to manufacturers' recommended schedules; oxygen cylinders are heavily regulated by the FDA, DOT, FAA and hazardous materials regulators, FDA product recalls on equipment that is patient-owned and therefore the responsibility of the patient/caregiver to comply with the direction of the FDA recall notice.

Once ownership has converted to the beneficiary and the beneficiary expires, relatives may decide to dispose of cylinders containing liquid or gaseous oxygen in the trash leading to potentially unsafe conditions for the general public. These cylinders may also be used by inexperienced, untrained, and unqualified individuals in ways that are inappropriate and dangerous.

Recommendation:
We recommend CMS develop safety standards that can be applied to beneficiary owned equipment.

9. CMS Must Address the Safety Issues Associated with the Likely Proliferation of eBay/Internet and Black Market Sales of Used Medical Equipment

The proliferation of a pool of patient-owned equipment and medical devices could adversely affect the health and safety of oxygen patients. Used medical devices (either discarded inappropriately, stolen or in limited circumstances patient-owned (such as managed care patients whose payor has bought them a nebulizer or CPAP) is currently finding its way into flea markets, garage sales, classified ads, on to the Internet and eBay-type, on-line marketplaces for sale. The sale of these medical devices is not monitored or controlled to ensure the condition of the device being sold, patient safety and clinical effectiveness. Oxygen devices, for example, must produce a certain level of purity in order to meet the expectations of a physician's prescription. Yet, eBay and other on-line marketplaces have begun to sell oxygen cylinders "as-is," even marketing their features and benefits by describing the name of homecare company from which the cylinders were technically stolen. EBay Sellers have begun transporting used oxygen cylinders through United Parcel Service (UPS), FedEx and other air carriers without the Transportation Safety Administration's (TSA) or the Federal Aviation Administration's (FAA) knowledge.

A proliferation of beneficiary-owned medical devices caused by the DRA will force the patients' families to accept responsibility for its disposal or resale. (Up until now, the family simply called the homecare provider to retrieve the equipment or devices that

were no longer needed or being used and the provider picked it up.) These families will not realize that these are highly regulated medical devices.

Under these scenarios, there is virtually no safeguard for the average patient to know whether one's medical device purchase, such as an oxygen concentrator, is appropriate for his or her application, if that device is in proper working order providing therapeutic oxygen levels, needs preventive maintenance, minor or major repairs or other service and maintenance. In addition, the potential for the spread of infection is highly likely. The general public does not have the knowledge or expertise to properly disinfect this equipment prior to selling to other members of the public. These "new" patients would lack the necessary training and knowledge for safe use and operation of these devices, creating potentially dangerous situations. These devices are shipped around the country, without the needed safeguards on the receiving end to make sure equipment is performing properly, further taking these devices outside the reach of HME providers who are responsible for the necessary checks to ensure performance. Lastly, HME providers are responsible for the traceability of these devices into specific patient homes in the event of medical product updates or recalls. Once the patient takes ownership and the title transfers, many of these devices will no longer be able to be tracked for this recall purposes.

Oxygen, and medical devices responsible for the generation of oxygen, is heavily regulated by the FDA. Therefore, any oxygen-related equipment or device requires special consideration and safety guidelines to prevent catastrophic results to the general public. Patient-owned medical devices will provide significantly less control over potentially explosive technologies.

Recommendation

We urge CMS to work with the FDA to develop standardized guidelines that apply specifically to the public's resale of used medical devices as a result of the forced ownership provision of the DRA. Because the Safe Medical Device Act (SMDA) never technically contemplated the concept of broad-based medical device ownership among the American public, CMS should confer with the FDA to review the impact of this specific law and proposed rule. In addition, CMS and the FDA should discuss the ability for medical oxygen fillers to comply with 21 CFR 210 and 211 once the patients own their own devices and equipment, including the portable oxygen cylinders that are operationally fungible for most home oxygen providers. If necessary, the Federal Trade Commission (FTC) must be consulted as well in order to stop eBay and other on-line marketplaces from selling medical equipment that may only be sold or dispensed to a specific patient based on a licensed physician's prescription.

In addition, CMS must outline its process for reimbursing homecare providers for any in-home services it expects providers to perform in conjunction with a FDA recall after the patient takes title to the device. Unless a separate fee schedule is established for such a service, few homecare providers, if any, will be able to afford to conduct the necessary in-home switchout or repair mandated by the manufacturer as long as there is no payment to perform the same.

10. Routine versus Non-Routine Maintenance Must Be Better Defined by CMS

CMS issued conflicting guidelines as they relate to what will be reimbursed by the program once the title transfers to the patient. In one section, CMS implied that patients would be able to perform routine maintenance. In another, CMS indicates that if special tools are required to perform that maintenance – tools which patients would not typically own, such as an oxygen analyzer – then payment would be provided by Medicare to the provider.

Some of the tasks required in performing ongoing medical equipment and oxygen concentrator maintenance require hand-to-eye coordination, strength, depth perception and tactile ability. These are skills that not all patients may possess or, if so, are compromised enough to prevent them from performing certain activities of daily living, let alone repair or maintenance tasks.

For example, the simple removal of the cover of an oxygen concentrator requires the proper use of a screwdriver and adequate strength to loosen and remove the screws, then lift the cover off the unit; the reverse is required once the maintenance has been performed. While it is possible for a beneficiary to open the concentrator, the manufacturer does not recommend this. The changing of the internal filters requires the ability to loosen the tubing attached to both ends of the in-line filter, then reattach the tubing to the new filter. This requires hand strength and dexterity, all things compromised in most COPD patients who probably also have arthritis. In addition, some of the tasks require knowledge of the location of certain filters and tubing inside of the concentrator. If the patients do not know where these items are located they certainly cannot change them. Further, if a patient were to begin randomly probing inside the concentrator, with the cover removed without first unplugging the unit, a very real electrocution hazard exists as concentrators contain many 110 volt electrical components.

While these may seem like simple tasks to the able individual, experience shows that they are complex for many Medicare beneficiaries.

The following should be considered "non-routine" maintenance, should be performed by trained professionals and reimbursed via a fair and equitable payment structure by CMS:

1. Inspection of internal components for dust, debris, evidence of wear
2. Changing of internal air and bacteria filters
3. Cleaning of internal heat dissipation coils
4. Any maintenance that requires breaking of internal seals such as sieve bed repair, compressor rebuilds electric motor repair, etc.

Importantly, the HCPCS codes must be revised to include codes for equipment parts. Because we anticipate that the number of repair claims will increase, it is important that the billing process be efficient. This will not be possible if there are a large number of uncoded products. We are providing under separate cover a list of the most purchased

replacement parts for oxygen concentrators, hospital beds, manual wheelchair parts, and power wheelchair parts. This list can be used to establish HCPCS codes for the most frequently used repair/replacement parts.

Recommendation
CMS should establish a separate HCPCS code for the most frequently used repair/replacement parts for capped rental items and oxygen devices. We are happy to work with CMS to facilitate the agency's ability to establish not only a fair payment rate, but also a process that would inhibit any potential for fraud or abuse.

11. The Proposal is Not Budget Neutral

As CMS acknowledges, the proposal to tie the monthly payment for oxygen to the equipment technology must be budget neutral.[3] We are concerned by the lack of data CMS has released to establish budget neutrality for this proposal. The preamble vaguely asserts that the proposed payments result in increases and offsets that are "roughly equal," but there is no data or analysis to support that conclusion. The lack of verifiable data on this threshold issue falls short of the requirement that CMS give stakeholders reasonable notice of a proposed action. CMS has an obligation to publish the factual basis for its determination in sufficient detail so that all stakeholders can confirm its analysis. Without this data, we cannot fully evaluate this proposal and assess its impact.

A Lewin Group analysis of the new policy shows that the methodology is not budget neutral. The Lewin Group examined the proposal on behalf of the American Association for Homecare and concluded that its impact would not be budget neutral. After reviewing the information in the NPRM and speaking to staff at CMS, the Lewin analysis concluded that the policy would result in a ten percent (10%) reduction in payments for oxygen for 2007. Specifically, the Lewin analysis found that:

- The proposed payments are not budget neutral for oxygen and oxygen equipment in 2007
- Proposed regulations would result in at least a ten percent reduction ($256M) in the amount paid for oxygen and equipment in 2007
- Payment reduction will be greater following transfer of ownership for equipment beyond 36 months

---

[3] The statute limits the Secretary's authority as follows:

> [T]he secretary may take actions under clause (i) only to the extent such actions do not results in expenditures *for any year* to be more or less than the expenditures which would have been made if such action had not been taken.

42 U.S.C. §1395m (a) (9)(D)(ii) (emphasis added).

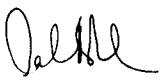
The statutory requirement for budget neutrality is not satisfied if payments in any year are more of less than would have otherwise been made.

CMS has indicated that it assumed only 5% of patients currently on oxygen would shift to portable equipment in 2007. However, the Lewin analysis determined that, to achieve budget neutrality under the proposal, CMS would need to assume a more pronounced shift in the patient population using portable oxygen. The Lewin analysis concluded that CMS' proposal includes an additional $256 million payment reduction over what would otherwise be necessary for budget neutrality. Clearly, CMS cannot implement the new unless it demonstrates that the policy is budget neutral. Given the Lewin analysis, CMS must adjust its proposal to make it budget neutral and increase payment rates accordingly. CMS must also articulate the factual basis for its conclusions and allow all stakeholders an opportunity to comment on the data and CMS' conclusions.

Conclusion

Invacare appreciates the opportunity to provide comments to CMS on this proposed rule. We would be happy to discuss any of these in more detail. Please contact me at 440-329-6226.

Sincerely,



Cara C. Bachenheimer
Vice President, Government Relations

Provided under Separate cover – List of 25 most commonly used repair/replacement parts for oxygen concentrators, hospital beds, manual wheelchair parts, and power wheelchair parts.

ATTACHMENT 2 TO #4

SUBMITTED ELECTRONICALLY

September 25, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicare Program; Home Health prospective Payment Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 (DRA)[1] Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment; Proposed Rule [CMS-1304-P] RIN 0938-AN76

Dear Dr. McClellan,

Invacare Corporation (Invacare) appreciates the opportunity to submit comments to CMS on the Notice of Proposed Rulemaking, Medicare Program; Home Health prospective Payment Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 Changes to Medicare Payments for Oxygen Equipment, and Capped Rental Durable Medical Equipment (CMS-1304-P). Based in Elyria, Ohio, Invacare is the largest manufacturer of home respiratory devices in the United States, including oxygen concentrators, portable oxygen tanks, and oxygen generating portable equipment.

Overall Comments

Invacare Corporation commends CMS for its recognition of the many benefits that oxygen generating portable equipment can provide. It provides patients with the mobility and convenience they desire, it provides physicians with the understanding that their patients always have access to ambulatory oxygen, and it provides costs savings to the health care system. While CMS' proposed rule appropriately provides some financial incentives for providers to provide oxygen generating portable equipment, CMS should ensure that its policies create no obstacles to beneficiaries with medical need for portable home oxygen therapy from receiving oxygen generating portable equipment.

For example, patients should be able to transfer to these systems at any time; without any financial disincentives for providers. If a patient wishes to transfer to oxygen generating portable equipment at a point when he/she is well towards the 36 month rental cap, there are financial barriers due to the significantly larger capital investment required for these

[1] Pub. L. 109 -171 (2006).

systems and the requirement that ownership transfer to the patient. CMS should, therefore, begin again the 36-month count or provide a higher reimbursement in these later rental months to guard against any short term financial barriers. The more beneficiaries that transfer to these systems, the faster the respective benefits will accrue to all. Any short term increased costs will be more than offset by the longer term savings that would result from a higher percentage of patients utilizing the oxygen generating portable systems.

Invacare estimates that less than ten percent of the current ambulatory patient population is using oxygen generating portable equipment. As a result, there are a significant number of beneficiaries that could benefit by transitioning to these new oxygen systems. CMS must ensure that its policies do not erect artificial barriers to beneficiary access to these systems.

Finally, given frail condition of most beneficiaries on home oxygen therapy, the serious safety issues discussed in detail below, CMS should ensure that its home oxygen payment policies provide a solid foundation to ensure that the beneficiary always has access to a home oxygen provider. If the policies do not provide this foundation, beneficiaries will end up in hospitals. CMS should bear in mind that oxygen can be provided to a chronic obstructive pulmonary disease (COPD) patient who lives at home for one year at less than the average Medicare cost for one day in the hospital, which is $4,603.[2]

Summary of Comments

Our detailed recommendations follow. In summary, Invacare recommends the following:

1. Medicare payment structure and levels need to be sufficient to encourage the use and development of new and better technology.
2. CMS should increase the payment rate for new technology to further encourage the transition to and use of new portable oxygen systems.
3. CMS should publicly release the data and assumptions upon which CMS proposes that this proposed rule is budget neutral.
4. CMS should modify the general prohibition of exchange of equipment during the rental period to allow beneficiary access to new technology (proposed 42 CFR 414.226(a)(2)).
5. CMS should modify the "useful life" definition to be consistent with manufacturer warranties.
6. CMS should establish payment for maintenance and servicing of oxygen and oxygen equipment and capped rental items, regardless of the technology provided.
7. CMS should establish an ongoing service fee to support beneficiary access to necessary clinical, support, emergency and other services.
8. CMS should develop specific safety standards.

---

[2] (Annual Statistical Supplement, 2005, Social Security Bulletin). Direct medical costs for COPD in the U.S. total $18 billion per year, nearly 9% of Medicare expenditures. (Dunne PJ. "The demographics and economics of long-term oxygen therapy." *Respiratory Care.* 45:223-228, 2000.)

9. CMS must address the safety issues associated w ith the likely proliferation of eBay/Internet and black market sales of used medical equipment.
10. Routine vs. non-routine maintenance must be better defined by CMS.
11. The proposed rule is not budget neutral; therefore the proposed payment rates should be increased.

1. M edicare Payment Structure and Levels Needs to be Sufficient to Encourage the Use and Development of New and Better Technology

While there may be advantages to a technology specific payment methodology, there are currently limitations. First, how does a new technology get recognized and paid? If a manufacturer develops a new technology, do beneficiaries have to wait until CMS incorporates the new technology into a revised version of the regulation? Will there be alternate and faster ways for beneficiaries to be able to access new technologies? We encourage CMS to re-examine this payment methodology and provide a concrete opportunity for new technologies to be incorporated into the payment methodology.

One significant advantage of modality neutral payment method over a technology-specific method is that it creates market incentives for manufacturers and providers to provide the most cost effective and patient friendly technology.

In the absence of a modality neutral payment methodology, CMS needs to create the appropriate incentives to ensure that beneficiaries have access to new technologies. Within the constraints of a 36-month cap and forced beneficiary ownership, CMS should increase payment rates for new technology during months one through thirty-six to enable providers to afford the higher capital investment associated with new technologies. A significant limitation of the 36 month cap and CMS' proposal is the lack of any payment stream to providers for patients receiving new technology after 36 months. As we discuss below, there is a need for an ongoing financial foundation for the provider for the entire period of medical need, regardless of technology provided, to cover costs related to emergency and other support services. With the 36 month cap, and the financial constraints this imposes, CMS should increase further the payment rates for new technology to ensure that financial barriers do not create beneficiary access to new technology problems.

In an ideal market environment, CMS' policies would stimulate ongoing a dvances in oxygen technology that would enable patients to be as active as possible and allow providers to reduce their overall cost structure. Better oxygen technologies will be developed if appropriate financial incentives are in place for manufacturers to pursue the research. For that reason, we urge CMS to increase payment levels for newer technology, and work with manufacturers to ensure that over time there are sufficient resources to support research and development that fosters the creation of better and more cost effective technologies. CMS should use its annual rulemaking process with notice and comment to ensure that its oxygen policies are current and appropriate.

2. **CMS Should Increase the Payment Rate for New Technology to Further Encourage the Transition to and Use of New Portable Oxygen Systems**

The proposed monthly payment rates for this new class of oxygen system may be insufficient to fully support the cost of innovation and as a result, may limit adoption and use of such oxygen technologies. While CMS acknowledges the concern that the current Medicare payment for oxygen (approximately $231 per month) may not be sufficient to facilitate the use of this technology and proposes a higher monthly payment amount for these systems to allow for the increased up front cost associated with the provision of these innovative technologies. The newly proposed fee schedule ($241 per month) amounts to an increase of approximately $10 per month (maximum of $360) over the current Medicare combined stationary and portable oxygen payment. Many of the new oxygen generating portable oxygen devices cost suppliers four to five times the cost of an older and more traditional stationary and portable oxygen combination. We believe these data must be considered and incorporated into any new fee schedule to ensure adequate payment for this important class of oxygen technology. Further, if CMS increases the payment rate for new technology, CMS will increase the conversion rate to newer more cost effective technology.

Recommendation:
We agree that Home Oxygen Generating Portable Equipment can save on contents fees and deliveries to beneficiaries' homes. We question the basis, however, for the proposed add-on fee which is designed to compensate the supplier for the additional acquisition cost of these pieces of equipment. We do not believe that the proposed rate provide adequate compensation for providers to invest in newer technologies, and recommend that this amount be increased. In addition, CMS needs to provide assurances that payment levels will not decrease (except in the event of competitive bidding) and that each year the fees will get a CPI update.

3. **CMS Should Publicly Release the Data and Assumptions Upon which CMS Proposes that this Proposal is Budget Neutral**

We strongly urge CMS to release the detailed data and assumptions it used to conclude that the regulation is budget neutral. The proposed regulation relies entirely on a detailed historical and projects utilization of various oxygen technologies. This data and assumption set must be released to enable a fuller understanding of the proposed rule, and to allow public comment on the data and assumptions and methodologies CMS used to develop the conclusions in the rule.

4. **CMS should modify the General Prohibition of Exchange of Equipment during the Rental Period (Proposed 42 CFR 414.226(a)(2))**

CMS has proposed that the supplier cannot exchange the beneficiary's equipment during the period of medical need in which payments are made except in very limited situations. Specifically CMS has proposed these exceptions:

- Cases where the item becomes subject to a competitive acquisition program implemented in accordance with section 1847(a) of the Act;
- Cases where a beneficiary relocates on either a temporary or permanent basis to an area that is outside the normal service are of the initial supplier
- Cases where the beneficiary chooses to obtain equipment from a different supplier
- Other cases where CMS or the carrier determine that an exception is warranted

This requirement will prevent beneficiaries from having access to more technologically advanced equipment from their supplier. Under CMS' proposed rule, a beneficiary who begins a rental period with a concentrator and a gaseous portable tank could not receive, even upon physician authorization, a Home Oxygen Generating Portable unit from his or her supplier. In this example, the only way a beneficiary could obtain this more technologically advanced equipment would be to change suppliers. We do not believe it was CMS' intention to restrict beneficiary access to new, patient friendly more cost effective oxygen technology.

CMS has stated this prohibition was included to prevent suppliers from substituting substandard equipment prior to the beneficiary taking ownership of these items. This can be addressed by CMS' proposal "that the replacement item must be equipment that is, at minimum, in the same condition as the equipment being replaced." This provision will prevent unscrupulous suppliers from replacing equipment with poor or substandard equipment.

If access to newer, lighter, more portable oxygen systems is restricted through reimbursement constraints or lack of clearly-defined medical necessity criteria and documentation requirements, oxygen therapy patients will suffer serious medical consequences. Patient choice and an elective process to change equipment must be incorporated into the exceptions for changing equipment. As the Medicare beneficiary and an educated consumer of the health care products prescribed for their use, the beneficiary should be afforded freedom to make a conscious decision to change equipment based on his or her individual lifestyle needs. Beneficiary choice of prescribed and medically appropriate oxygen technologies and the ability to change their oxygen equipment should be incorporated into the exceptions in the rule. This freedom of patient choice will impose additional free-market forces that we believe will encourage improved patient access to new and innovative oxygen therapy technologies

Recommendation:
Suppliers should be allowed to exchange and/or change a beneficiary's equipment during the period of medical need provided this exchange /change is documented, including the reason. This event could be tracked and recorded/reported to CMS via a new modifier to document the reason for the exchange. CMS and its carriers should not be a part of the process to determine that a change in condition be warranted, this will be administratively burdensome.

5. CMS should modify the "useful life" definition to be consistent with manufacturer warranties.

CMS' current definition of "useful life" exceeds the warranty that manufacturers typically provide on most of the current oxygen technologies on the market. Forcing a provider to be financially responsible for a device beyond the manufacturer's warranty period imposes significant financial burdens on providers. CMS needs to establish "useful life" definitions specific to the oxygen technology. CMS should review current manufacturer warranties and use these as a guide in establishing the "useful life" of specific oxygen technologies.

Manufacturers determine warranty period for devices based upon a variety of reasons. In general, newer technology will have shorter warranty periods than technology that is more mature and has been tested over a significant period of time.

Recommendation:
CMS should modify its definition of "useful life" and should develop technology or equipment-specific definitions. CMS should use current manufacturer warranty information as a guide to develop these definitions.

6. Payment for Maintenance and Servicing of Oxygen and Oxygen Equipment and Capped Rental Items, Regardless of the Technology Provided

CMS is proposing that "maintenance and service" payments are permitted for capped rental DME and oxygen equipment after title has transferred to the beneficiary; however, CMS has also proposed to "apply our existing policy of not covering certain routine maintenance or periodic servicing of purchased equipment, such as testing, cleaning, regulating, changing filters, and general inspection of beneficiary-owned oxygen equipment and to continue that policy for beneficiary-owned capped rental equipment." Invacare is happy to provide CMS with a list of the most commonly used items that are used as replacement parts; we are providing this list under separate cover.

Invacare is concerned that CMS assumes that beneficiaries are more capable than their frail conditions typically allow. The average age of a beneficiary on oxygen after 36 months is 73 years old, and has multiple diagnoses that include both physical and mental limitations. Additionally, 16% are disabled. The oxygen that these prescription devices produce is a prescription drug.

Despite these facts, CMS maintains that beneficiaries will be responsible for the routine maintenance of their equipment. We believe this is an oversimplified assumption by CMS that all beneficiaries will be able to perform routine maintenance and service on their equipment to keep it in good working order. We urge CMS to understand there are beneficiaries who may not be able to perform this routine maintenance and service. As a result, CMS must provide a process to ensure that these beneficiaries will continue to have good functioning equipment.

Recommendation:
CMS will need to establish codes to adequately describe the parts and repair services that will be covered and reimbursed for beneficiary-owned oxygen equipment. We encourage CMS to work with manufacturers and providers to ensure fee schedules are established that appropriately account for all parts and services incurred in providing the maintenance and service for capped rental and oxygen equipment after title has transferred to the beneficiary. We are providing under separate cover a list of the most commonly purchased repair/replacement parts for oxygen devices and capped rental items (hospital beds, manual wheelchair parts, and power wheelchair parts. – none of which currently have a HCPCS code (they are currently billed as E1399 – Miscellaneous)).

7. CMS Should Establish an Ongoing Service Fee to Support Beneficiary Access to Necessary Clinical, Support, Emergency and Other Services

The proposed rule makes no provision to provide after-hours or emergency services for beneficiaries post title transfer of either their capped rental or oxygen equipment. We are concerned that there is no provision for these emergency services to be provided by suppliers and that this would place beneficiaries in unsafe conditions. Conditions that could have been prevented had such provisions been considered and provided for. Examples include power outages or other natural disasters, all of which will require the beneficiary to be able to speedily obtain access to back up tanks to ensure no gap in his or her access to home oxygen therapy. This will be required regardless of the technology the beneficiary is using.

CMS needs to establish a regular and ongoing payment after ownership transfers to ensure beneficiary-owned equipment is appropriately maintained, e.g., a payment every 6 months. This needs to occur even with new technology such as oxygen generating portable equipment.

It is not reasonable to expect a frail senior who has a medical need for oxygen to be responsible for performing filter checks and cleanings; checking purity levels, etc. – to even be responsible for routine maintenance. More importantly, Medicare needs to anticipate emergency situations and provide financial foundations for those. Otherwise, beneficiaries will go to hospital emergency rooms, incurring significant Medicare expenditures.

Without a financial foundation to sustain the provider-patient relationship, patients will likely be left "stranded", using equipment that may not be operating correctly – this can be life threatening for patients.

In a 1994 report, the OIG stressed the need and importance of regular, frequent servicing of oxygen patients (Oxygen Concentrator Services, OEI 03-91-01710, November 1994). At that point, the OIG was examining the need for services standards for suppliers of home oxygen therapy. We are unclear why the government would completely reverse its position, not recognizing the need for the many critical support services that home oxygen suppliers provide to patients. Specifically, the OIG found: "The importance of

support services, such as equipment and patient monitoring, for oxygen concentrator patients is critical for the proper functioning of the equipment as well as the effectiveness of the therapy it provides."

We are concerned that home oxygen beneficiaries may be in jeopardy if there is no financial foundation to support an ongoing relationship between the provider and the patient. Emergency situations such as power outages require the beneficiary to have access to portable tanks, regardless of the technology the patient uses. For example, a beneficiary on oxygen for 40 months experiencing electrical failure will need to obtain a supply of portable tanks. Otherwise, that patient will be forced to go to a hospital emergency room, incurring significant and unnecessary costs.

Recommendation:
CMS should establish an ongoing service fee to support beneficiary access to necessary clinical, support, and other services. We recommend CMS develop a rational, reasonable methodology to provide for emergency services for beneficiary owned equipment. This will ensure beneficiaries continue to have access to life sustaining services during power outages or other emergency situations.

8. CMS Should Develop Specific Safety Standards

The patient population represented by Medicare consists of the elderly and disabled. Home oxygen beneficiaries are dependent upon healthcare delivery to their homes. Many live alone, are unable to drive, have poor eyesight, hearing, and arthritis. Caregivers are frequently aged spouses with similar physical and mental issues. Few are able to perform simple troubleshooting of their equipment despite professional guidance via phone and require home visits to assure the equipment is functioning properly. Ongoing beneficiary education and monitoring regarding oxygen usage and safety will no longer be performed, creating the potential for unsafe use of oxygen (e.g., smoking while using oxygen).

Oxygen cylinders must be periodically tested hydrostatically to assure they will safety hold contents under high pressures. Liquid oxygen vessels are regularly inspected for leaks to assure the cryogenic contents are safety contained. There is also a requirement that equipment repair and maintenance be documented to provide a history for each item. Filling beneficiary-owned equipment without knowing the cylinder's history is a potentially dangerous situation. Cylinder concerns include the need for hydrostatic cylinder testing, product traceability, drug product labeling with potential for misbranding, chain of custody and control issues.

Oxygen requires compliance with specific guidelines developed by the Department of Transportation (DOT), Food & Drug Administration (FDA) and the Compressed Gas Association (CGA). Beneficiaries may not be aware of, or comply with, these guidelines thus putting them and others at risk.

The DRA provision forcing beneficiaries to assume ownership of complex medical equipment such as various oxygen technologies is troubling, particularly given the fact that beneficiaries on home oxygen therapy are typically very frail and have a series of serious health issues. As a result, CMS should develop and implement policies to safeguard against possible safety issues.

For example, the following situations create increased potential for safety issues to arise under the forced beneficiary ownership policy. FDA-approved medical devices must be subjected to preventive maintenance regularly according to manufacturers' recommended schedules; oxygen cylinders are heavily regulated by the FDA, DOT, FAA and hazardous materials regulators, FDA product recalls on equipment that is patient-owned and therefore the responsibility of the patient/caregiver to comply with the direction of the FDA recall notice.

Once ownership has converted to the beneficiary and the beneficiary expires, relatives may decide to dispose of cylinders containing liquid or gaseous oxygen in the trash leading to potentially unsafe conditions for the general public. These cylinders may also be used by inexperienced, untrained, and unqualified individuals in ways that are inappropriate and dangerous.

Recommendation:
We recommend CMS develop safety standards that can be applied to beneficiary owned equipment.

9. CMS Must Address the Safety Issues Associated with the Likely Proliferation of eBay/Internet and Black Market Sales of Used Medical Equipment

The proliferation of a pool of patient-owned equipment and medical devices could adversely affect the health and safety of oxygen patients. Used medical devices (either discarded inappropriately, stolen or in limited circumstances patient-owned (such as managed care patients whose payor has bought them a nebulizer or CPAP) is currently finding its way into flea markets, garage sales, classified ads, on to the Internet and eBay-type, on-line marketplaces for sale. The sale of these medical devices is not monitored or controlled to ensure the condition of the device being sold, patient safety and clinical effectiveness. Oxygen devices, for example, must produce a certain level of purity in order to meet the expectations of a physician's prescription. Yet, eBay and other on-line marketplaces have begun to sell oxygen cylinders "as-is," even marketing their features and benefits by describing the name of homecare company from which the cylinders were technically stolen. EBay Sellers have begun transporting used oxygen cylinders through United Parcel Service (UPS), FedEx and other air carriers without the Transportation Safety Administration's (TSA) or the Federal Aviation Administration's (FAA) knowledge.

A proliferation of beneficiary-owned medical devices caused by the DRA will force the patients' families to accept responsibility for its disposal or resale. (Up until now, the family simply called the homecare provider to retrieve the equipment or devices that

were no longer needed or being used and the provider picked it up.) These families will not realize that these are highly regulated medical devices.

Under these scenarios, there is virtually no safeguard for the average patient to know whether one's medical device purchase, such as an oxygen concentrator, is appropriate for his or her application, if that device is in proper working order providing therapeutic oxygen levels, needs preventive maintenance, minor or major repairs or other service and maintenance. In addition, the potential for the spread of infection is highly likely. The general public does not have the knowledge or expertise to properly disinfect this equipment prior to selling to other members of the public. These "new" patients would lack the necessary training and knowledge for safe use and operation of these devices, creating potentially dangerous situations. These devices are shipped around the country, without the needed safeguards on the receiving end to make sure equipment is performing properly, further taking these devices outside the reach of HME providers who are responsible for the necessary checks to ensure performance. Lastly, HME providers are responsible for the traceability of these devices into specific patient homes in the event of medical product updates or recalls. Once the patient takes ownership and the title transfers, many of these devices will no longer be able to be tracked for this recall purposes.

Oxygen, and medical devices responsible for the generation of oxygen, is heavily regulated by the FDA. Therefore, any oxygen-related equipment or device requires special consideration and safety guidelines to prevent catastrophic results to the general public. Patient-owned medical devices will provide significantly less control over potentially explosive technologies.

Recommendation

We urge CMS to work with the FDA to develop standardized guidelines that apply specifically to the public's resale of used medical devices as a result of the forced ownership provision of the DRA. Because the Safe Medical Device Act (SMDA) never technically contemplated the concept of broad-based medical device ownership among the American public, CMS should confer with the FDA to review the impact of this specific law and proposed rule. In addition, CMS and the FDA should discuss the ability for medical oxygen fillers to comply with 21 CFR 210 and 211 once the patients own their own devices and equipment, including the portable oxygen cylinders that are operationally fungible for most home oxygen providers. If necessary, the Federal Trade Commission (FTC) must be consulted as well in order to stop eBay and other on-line marketplaces from selling medical equipment that may only be sold or dispensed to a specific patient based on a licensed physician's prescription.

In addition, CMS must outline its process for reimbursing homecare providers for any in-home services it expects providers to perform in conjunction with a FDA recall after the patient takes title to the device. Unless a separate fee schedule is established for such a service, few homecare providers, if any, will be able to afford to conduct the necessary in-home switchout or repair mandated by the manufacturer as long as there is no payment to perform the same.

10. Routine versus Non-Routine Maintenance Must Be Better Defined by CMS

CMS issued conflicting guidelines as they relate to what will be reimbursed by the program once the title transfers to the patient. In one section, CMS implied that patients would be able to perform routine maintenance. In another, CMS indicates that if special tools are required to perform that maintenance – tools which patients would not typically own, such as an oxygen analyzer – then payment would be provided by Medicare to the provider.

Some of the tasks required in performing ongoing medical equipment and oxygen concentrator maintenance require hand-to-eye coordination, strength, depth perception and tactile ability. These are skills that not all patients may possess or, if so, are compromised enough to prevent them from performing certain activities of daily living, let alone repair or maintenance tasks.

For example, the simple removal of the cover of an oxygen concentrator requires the proper use of a screwdriver and adequate strength to loosen and remove the screws, then lift the cover off the unit; the reverse is required once the maintenance has been performed. While it is possible for a beneficiary to open the concentrator, the manufacturer does not recommend this. The changing of the internal filters requires the ability to loosen the tubing attached to both ends of the in-line filter, then reattach the tubing to the new filter. This requires hand strength and dexterity, all things compromised in most COPD patients who probably also have arthritis. In addition, some of the tasks require knowledge of the location of certain filters and tubing inside of the concentrator. If the patients do not know where these items are located they certainly cannot change them. Further, if a patient were to begin randomly probing inside the concentrator, with the cover removed without first unplugging the unit, a very real electrocution hazard exists as concentrators contain many 110 volt electrical components.

While these may seem like simple tasks to the able individual, experience shows that they are complex for many Medicare beneficiaries.

The following should be considered "non-routine" maintenance, should be performed by trained professionals and reimbursed via a fair and equitable payment structure by CMS:

1. Inspection of internal components for dust, debris, evidence of wear
2. Changing of internal air and bacteria filters
3. Cleaning of internal heat dissipation coils
4. Any maintenance that requires breaking of internal seals such as sieve bed repair, compressor rebuilds electric motor repair, etc.

Importantly, the HCPCS codes must be revised to include codes for equipment parts. Because we anticipate that the number of repair claims will increase, it is important that the billing process be efficient. This will not be possible if there are a large number of uncoded products. We are providing under separate cover a list of the most purchased

replacement parts for oxygen concentrators, hospital beds, manual wheelchair parts, and power wheelchair parts. This list can be used to establish HCPCS codes for the most frequently used repair/replacement parts.

Recommendation
CMS should establish a separate HCPCS code for the most frequently used repair/replacement parts for capped rental items and oxygen devices. We are happy to work with CMS to facilitate the agency's ability to establish not only a fair payment rate, but also a process that would inhibit any potential for fraud or abuse.

11. The Proposal is Not Budget Neutral

As CMS acknowledges, the proposal to tie the monthly payment for oxygen to the equipment technology must be budget neutral.[3] We are concerned by the lack of data CMS has released to establish budget neutrality for this proposal. The preamble vaguely asserts that the proposed payments result in increases and offsets that are "roughly equal," but there is no data or analysis to support that conclusion. The lack of verifiable data on this threshold issue falls short of the requirement that CMS give stakeholders reasonable notice of a proposed action. CMS has an obligation to publish the factual basis for its determination in sufficient detail so that all stakeholders can confirm its analysis. Without this data, we cannot fully evaluate this proposal and assess its impact.

A Lewin Group analysis of the new policy shows that the methodology is not budget neutral. The Lewin Group examined the proposal on behalf of the American Association for Homecare and concluded that its impact would not be budget neutral. After reviewing the information in the NPRM and speaking to staff at CMS, the Lewin analysis concluded that the policy would result in a ten percent (10%) reduction in payments for oxygen for 2007. Specifically, the Lewin analysis found that:

- The proposed payments are not budget neutral for oxygen and oxygen equipment in 2007
- Proposed regulations would result in at least a ten percent reduction ($256M) in the amount paid for oxygen and equipment in 2007
- Payment reduction will be greater following transfer of ownership for equipment beyond 36 months

---

[3] The statute limits the Secretary's authority as follows:

> [T]he secretary may take actions under clause (i) only to the extent such actions do not results in expenditures *for any year* to be more or less than the expenditures which would have been made if such action had not been taken.

42 U.S.C. §1395m (a) (9)(D)(ii) (emphasis added).

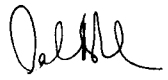
The statutory requirement for budget neutrality is not satisfied if payments in any year are more of less than would have otherwise been made.

CMS has indicated that it assumed only 5% of patients currently on oxygen would shift to portable equipment in 2007. However, the Lewin analysis determined that, to achieve budget neutrality under the proposal, CMS would need to assume a more pronounced shift in the patient population using portable oxygen. The Lewin analysis concluded that CMS' proposal includes an additional $256 million payment reduction over what would otherwise be necessary for budget neutrality. Clearly, CMS cannot implement the new unless it demonstrates that the policy is budget neutral. Given the Lewin analysis, CMS must adjust its proposal to make it budget neutral and increase payment rates accordingly. CMS must also articulate the factual basis for its conclusions and allow all stakeholders an opportunity to comment on the data and CMS' conclusions.

Conclusion

Invacare appreciates the opportunity to provide comments to CMS on this proposed rule. We would be happy to discuss any of these in more detail. Please contact me at 440-329-6226.

Sincerely,



Cara C. Bachenheimer
Vice President, Government Relations

Provided under Separate cover – List of 25 most commonly used repair/replacement parts for oxygen concentrators, hospital beds, manual wheelchair parts, and power wheelchair parts.

Submitter : Ms. Kathleen Sanchez
Organization : AirSep Corporation
Category : Device Industry
Date: 09/25/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1304-P-48-Attach-1.DOC

#48

Industrial & Medical Air Separation Equipment

September 25, 2006

Via Electronic Mail
http://www.cms.hhs.gov/eRulemaking.

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1304-P
7500 Security Blvd.
Baltimore, MD

Re: Comments on CMS-1304-P, Deficit Reduction Act (DRA) of 2005 Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment Proposed Rule

Dear Dr. McClellan,

AirSep Corporation is a manufacturer of medical equipment, including oxygen concentrators. We pioneered the first Portable Oxygen Concentrator (POC) over 4 years ago. We are the largest supplier of oxygen concentrators in the world. Our comments on CMS-1304-P are as follows:

1) In the proposed rule, CMS states that beneficiaries will have the right to change providers. We agree that a beneficiary needs this right to ensure quality service and equipment. We fail to see how this will be possible unless a new 36 month period begins with the new provider. To take the most extreme case, the beneficiary becomes dissatisfied with the current provider near the 36th month and desires to change. A new provider would have no incentive to accept this patient (financially the new provider could not afford to provide the beneficiary with new equipment with only a few months of payment remaining). The current provider would have no incentive or requirement to sell/transfer/rent the current equipment to the new provider. The new provider might not have experience or training (or be authorized by the manufacturer) on the current provider's equipment. How then does the beneficiary accomplish the transition to a new provider?

2) In the proposed rule, CMS does not address how beneficiaries manage warranty options or equipment age. Equipment could be brand new, or used when put out on a patient. As a result, one patient might receive equipment with 5 years of warranty remaining, while another patient receives equipment with no warranty remaining. Different concentrators carry different warranty lengths (1 to 5 years) and have different exclusions in the warranty. Or one patient might receive new cylinders, while another patient receives cylinders that need hydrostatic testing right after title transfers. How does the new rule address these issues?

3) Under the proposed rule, by requiring the beneficiary to keep the same equipment throughout their use puts added costs into the system at a time CMS is trying to reduce costs. This requires extra inventory and administrative costs to the provider. Having the provider required to keep "like" equipment in the beneficiary's home, as opposed to "exact," will significantly reduce costs. This is consistent with the current mode of operation by providers and is far more efficient.

4) We believe most people feel that the modality neutral methodology has provided the most cost effective mode of oxygen equipment, while meeting the beneficiary's needs. The proposed rules of modality specific go back to a more complicated system which can encourage "gaming" to try to maximize reimbursement. If instead, a flat monthly stationary equipment fee, a flat monthly ambulatory equipment fee, and an ongoing contents/repair/support fee after ownership transfers in month 36 for stationary equipment and one for ambulatory equipment, would address so many of the problems with the proposed new rules.

We appreciate this opportunity to comment on the proposed rules. We would welcome the opportunity to discuss any of the issues with the Agency. You can reach us by contacting Kathleen Sanchez at ksanchez@airsep.com, or 716-691-0202, ext. 328.

Sincerely,

AirSep Corporation

Submitter : **Tom Daulton** **Date: 09/25/2006**

Organization : **Denver Biomedical, Inc.**

Category : **Device Industry**

Issue Areas/Comments

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See attached PDF file.

CMS-1304-P-49-Attach-1.PDF

#49

Denver®
BIOMEDICAL

14998 W. 6th Ave., Bldg E-700
Golden, CO 80401

September 25, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1304-P
P.O. Box 8014
Baltimore, MD 21244-8014

RE: CMS-1304-P

Dear Sir or Madam:

We are Denver Biomedical, Inc. (DBI). We are a Colorado corporation and currently employ about 43 workers. We manufacture clinically-proven, patented Pleurx Pleural Catheters, Drainage Kits, and Vacuum Drainage Bottles used for the drainage of symptomatic, recurrent, pleural effusions and malignant ascites. For your review, we have attached a copy of a Benefit Category Determination Memorandum by the Centers for Medicare and Medicaid Services (CMS) dated March 14, 2002, classifying our products as implanted prosthetic devices and accessories to implanted prosthetic devices. We respectfully submit our comments to the proposed rule regarding the Home Health Prospective Payment System Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment (CMS-1304-P), which was published on August 3, 2006 (71 Fed. Reg. 44082).

Specifically, we respectfully request that CMS exclude from Home Health PPS our Vacuum Drainage Bottle, which is denoted by HCPCS code A7043 (vacuum drainage bottle and tubing for use with implanted catheter). These sterile bottles are accessories to the implanted catheter/prosthesis denoted by HCPCS code A7042 (implanted pleural catheter). For your consideration, we set forth two (2) reasons for unbundling the payment for this bottle from the Home Health PPS rates.

First, the regulations authorize CMS to exclude from Home Health PPS prosthetic devices and items related to prosthetic devices that are covered under Medicare Part B. 42 C.F.R. §409.49(f). Furthermore, although "[c]atheters, catheter supplies, ostomy bags, and supplies relating to ostomy care" are not subject to this exclusion from Home Health coverage, the Pleurx Pleural Catheter and Vacuum Drainage Bottle squarely meet the definition of a prosthetic device set forth in §410.36(a)(2) because they replace the malfunctioning pleura (an internal body organ) by artificially draining the pleura. Consequently, the Pleurx Pleural Catheter and

Tel: (303) 279-7500 Toll Free: (800) 824-8454 Fax: (303) 279-7575 www.denverbiomedical.com

Vacuum Drainage Bottle are covered under Part B as a prosthetic device as set forth in the attached Benefit Category Determination Memorandum.

Second, the current and proposed Home Health PPS rates do not adequately compensate home health agencies when they care for beneficiaries requiring the Pleurx Pleural Catheter and Vacuum Drainage Bottle because the cost of these bottles was not included in the cost data base used by CMS to compute the Home Health PPS rates. In addition, prior to 2003, the Vacuum Drainage Bottle was billed using a miscellaneous HCPCS code. Consequently, the specific cost of these bottles was not considered during the development of the home health prospective payment system. Furthermore, CMS has not refined the case-mix weights used to calculate payment rates since the inception of the Home Health PPS. Thus, cost data specific to these bottles has not been included in the case-mix weights used to determine the Home Health PPS rates.

Overall, Medicare beneficiaries typically use one Vacuum Drainage Bottle per day, but some cancer patients require more than one bottle per day. Home health agencies pay approximately $34.50 per bottle. Plus, along with other medically necessary items (e.g., latex gloves, gauze), home health agencies need a catheter cap to replace each bottle, which costs $5.75. This means that, over a 60-day episode, the cost to a typical home health agency just to replace these bottles in cancer patients exceeds $2,412. Accordingly, we respectfully request that CMS unbundle the payment for the Vacuum Drainage Bottle (HCPCS Code A7043) from the Home Health PPS and permit them to bill Part B separately or otherwise adjust Medicare payments to home health agencies caring for such cancer patients so that home health agencies can continue to furnish this non-routine care.

* * * * *

On behalf of over 40 hard-working families of DBI, we thank you for the opportunity to comment on the proposed rule. We hope that CMS will consider our comments.

Sincerely,

Tom Daulton
Vice President and General Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop N2-13-16
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicare Management/Chronic Care Policy Group

DATE: MAR 14 2002

FROM: Director
Chronic Care Policy Group
Center for Medicare Management

SUBJECT: Revised Benefit Category Determination for the Pleurx Pleural Catheter and the Pleurx Pleural Drainage Kit

TO: Ms. Stephanie Gammon
Region Six - Dallas Regional Office
Centers for Medicare & Medicaid Services

Dr. Paul Metzger
Medical Director
Region C DMERC

Stephanie Gammon of the Dallas Regional Office submitted a benefit category determination request regarding the Pleurx Pleural Drainage Kit on April 4, 2000. The patient or caregiver uses the Pleurx Pleural Drainage Kit (Drainage Kit) at home to periodically drain fluid from the Pleurx Pleural Catheter (a catheter implanted in the pleural lining of the patient's lung).

Our original benefit category determination found that the Pleurx Pleural Drainage Kit may be considered as "incident to" a physician's service, and when used under a home health plan of care, is a covered supply under the home health benefit. We have further researched the "incident to" benefit category and found that the Pleurx Pleural Drainage Kit is not "incident to" a physician's service according to section 1861(s)(2)(A) of the Social Security Act (the Act). However, the Drainage Kit would continue to be covered under the home health benefit as a covered supply as long as the patient was under a home health plan of care.

Section 1861(s)(2)(A) defines medical and other health services as including "services and supplies.... furnished as an incident to a physicians professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills;". MCM 2050.1 further states "Incident to a physicians professional service means that the services or supplies are furnished as an integral, although incidental, part of the physicians personal professional services..." Therefore, this provision is intended to cover incidental supplies used by the physician in providing a professional service, but not intended for ongoing use by the patient or caregiver at home.

Based on the above findings, we have reconsidered the benefit category determination for the Pleurx Pleural Catheter and Pleurx Drainage Kit. The Pleurx Pleural Catheter falls under the prosthetic device benefit category and specific components of the Pleurx Drainage Kit would then be categorized as accessories to the prosthetic device.

We have made this determination on the basis of the following findings:

- The Pleurx Pleural Catheter and drainage kit are indicated for intermittent, long term drainage of symptomatic, recurrent, pleural effusion and other recurrent effusions that do not respond to medical management of the underlying disease. The pleural and other effusions result from the malfunction of the pleura and its inability to maintain a sealed lining around the lung and prevent fluid build-up. These items are used for 1) the palliation of dyspnea due to pleural effusion and 2) for providing pleurodesis (resolution of the pleural effusion). The Pleurx Pleural Catheter is for single use only and inserted in the patient in a hospital operating room or hospital procedure room. Once the catheter is in place, fluid is evacuated from the pleural space. A sterile dressing is applied after the fluid has been evacuated and the patient can then be discharged from the hospital when the physician determines that the patient is stable. Once the patient is at home, components of the Pleurx Drainage Kit are used to collect the pleural fluid and is obtained directly from a supplier, but only when prescribed by a physician.

- Section 1861 (s)(8) of the Social Security Act defines a prosthetic as a device that replaces all or part of an internal body organ. The Medicare Carriers Manual at section 2130 further extends this definition by stating that, "Prosthetic Devices which replace all or part of an internal body organ, or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ are covered when furnished on a physician's order." Because the Pleurx Pleural Catheter replaces the malfunctioning pleura (an internal body organ) by artificially draining the pleura, it meets the definition of a prosthetic device.

- The vacuum drainage bottle and tubing, gauze, gloves and the wound clamp and cup would be considered as accessories to the prosthetic device (Pleurx Pleural Catheter). In addition, those components of the Drainage Kit may be covered as nonroutine medical supplies under the home health benefit. Under section 206.4 of the Home Health Agency Manual, non-routine medical supplies are covered to treat a patient's specific illness or injury in accordance with the physician's plan of care. The physician must specifically order non-routine supplies or the physician's order for services must require the use of the specific supplies to be effectively furnished. If the patient is in a Skilled Nursing Facility (SNF), then these supplies would be included as supplies provided by the SNF.

If you have any questions concerning the revised benefit category determination, please contact Lynn Riley at (410) 786-1286.

Thomas E. Hoyer

cc: Dr. Paul Hughes, Tricenturion
Dr. Adrian Oleck, DMERC Region B
Dr. Robert Hoover, DMERC Region D
Dr. Mike Nelson, SADMERC

Submitter : Paula Koenig **Date:** 09/25/2006

Organization : Hamilton's Health Aid Services

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1304-P-50-Attach-1.DOC

#50

Comments on proposed rule CMS-1304-P
Deficit Reduction Act of 2005 Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment

Many other providers are submitting comments on the oxygen provisions of the proposed rule. I am concerned about provisions that apply to capped rental items as well as to oxygen equipment.

I have worked in home medical businesses for 27 years. I have experienced a lot of changes, and know that change is inevitable. However, I am very concerned about some of the implications of the proposed rule as it affects the use of capped rental durable medical equipment, and the relationships between providers, beneficiaries and Medicare.

I can accept the change from 'capped rental' to a rent-to purchase program, as the DRA creates with 13 months rent automatically converting to purchase. I would request that CMS reconsider the assignment of certain products to this category, especially those that sell for under $250.00 or rent for under $25.00 per month. This would included compressor/nebulizers (code E0570), and drop-arm commodes (E0165); the expense of submitting and processing claims for 13 months for these inexpensive items exceeds any savings from short-term rentals; it would be more economical for CMS/Medicare to purchase these items on initial need.

The greater concerns are the following:

1) Inability of providers to switch equipment during a capped rental period. This sounds innocuous, and is designed to protect the beneficiary from suppliers exchanging better quality equipment to lesser quality equipment just before it converts to purchase. First, I believe that this would rarely happen. But there are fairly common circumstances where a provider must exchange equipment in order to best serve the beneficiary. For example, if a motor on a semi-electric hospital bed fails, the best practice for the patient is for the supplier to come to the patient's home and exchange the broken bed with a different, working, bed. If the provider cannot exchange equipment, they may have to perform a complex repair in the patient's home, disrupting patient care, or pick up the bed to take it to their office for repair, leaving the patient without a bed for a period of time; or pick up the broken bed, temporarily replace it with a loaner, repair the broken bed, then return to the patient's home and pick up the loaner bed, re-delivering the now repaired bed; causing stress and disruption to the patient and caregivers. Another example is a situation where a provider may not have immediate availability of the exact item prescribed by the physician for a beneficiary; they may provide a piece of equipment that meets but exceeds the patient's needs in order to provide equipment on a timely basis. The provider would then replace the initial item with the prescribed item as soon as possible. An example may be as simple as a standard wheelchair rental; if a standard wheelchair is ordered for an immediate need, the provider may deliver a lightweight wheelchair if a standard weight chair is not available; then replace the lightweight wheelchair with the prescribed standard weight chair a few days later. The provider should not be placed in

the situation where they have to choose between not being able to provide service to the beneficiary at the time of need versus providing a higher level of equipment and taking a financial loss over the next 13 months if they are unable to switch to the prescribed level of equipment. Please preserve the provider's ability to assess a situation, and replace equipment instead of repair when that is more efficient and better serves the beneficiary. The rule could be modified to clarify that it is acceptable for a provider to exchange equipment if (a) the exchange is for same or similar equipment; or (b) the exchange is to equipment that better matches the physician order.

2) The proposed rule states that the supplier who provides a piece of equipment at the time of initial order must continue to provide the equipment for the full 13 months (assuming continued medical necessity). Again, the intent seems to be protection of the beneficiary from 'unscrupulous' providers that may 'dump' the bene just prior to the equipment converting to purchase. The rule goes on to say that exceptions may be made in case of bene choice, or if the bene moves out of the initial supplier's service area. However, there is no explanation of how 'bene choice' would be communicated to Medicare; there is no process currently in place to do this. And there are already significant issues with the process of changing providers when a bene moves out of a service area; there are no incentives, and there are substantial financial drawbacks for a supplier in the new location to accept the bene as a new customer, provide equipment, then be paid for a very limited number of months before they must convert the rental to purchase. CMS needs to re-assess this policy in light of the ever increasing number of geographically mobile seniors. The vague suggestion that the initial provider make an 'arrangement' with the new provider simply does not work in many situations. The initial provider cannot be responsible for repairs once the bene leaves their normal service area; it is not practical or efficient or reasonable. The 'new' provider cannot reasonably be expected to accept the bene and provide equipment for which they may be minimally reimbursed. There can also be complications and changes in providers when a bene enters a facility (hospital, nursing home) for a period of time in the middle of a capped rental period; the equipment is returned to the initial provider on admission, on discharge a new provider may be contacted. The initial provider may not be aware of the discharge date or change.

3) There is an ever-growing complication with how these provisions (switching equipment, continued provision of equipment, and consistent assignment choice for the 13 month period) apply now that more and more Medicare beneficiaries are enrolling – and dis-enrolling – in Medicare HMOs. This is a growing issue as a result of the Medicare Part D program; part D coverage is often offered as a package with a Medicare HMO; the bene may or may not realize exactly what they are signing up for when they enroll. They rarely consider the effect on their continued access to oxygen and capped rental DME from their current providers. Many HMOs have closed contracts with DME/O2 providers; enrollment in those HMOs requires that the bene switch suppliers to maintain coverage. The initial provider may not be contracted with the HMO. So, how are these situations reconciled with the proposed provisions? How can the initial supplier continue to provide the equipment? A single bene may be in traditional Medicare, enroll in one HMO, dis-enroll and go back on traditional Medicare, then enroll in a different HMO all in one 13 month period. How can these scenarios possibly be addressed in a reasonable manner under the proposed rule?

4) Repairs and replacement under the proposed rule. Medicare policy allows for needed repairs to owned DME and O2 equipment, if the equipment is not under warranty. Equipment warranty length varies significantly by product and by manufacturer. Equipment warranty is one consideration in choosing the appropriate equipment choice for a bene, but it is not the only factor. CMS appears to be trying to balance appropriate coverage for needed non-warranty repairs with bene protection from receiving poor quality equipment via the proposed rule that covers repairs until they accumulate to 60% of the replacement cost; the rule then states that the provider must replace the equipment at no charge if the next repair would put the accumulated repair expense over the 60% mark. This proposal raises many red flags. (a) Some equipment such as semi-electric hospital beds and especially power wheelchairs, have component parts (mostly motors and electronics) that can be quite expensive to repair/replace; the costs in these repairs could quite easily exceed the 60% trigger but still be in the equipment's useful lifetime. (b) Repair of this equipment is often a function of active use; it is not due to poor quality or defective equipment. (relate this to a car – one driven more miles a year will need more repairs than a car driven fewer miles, while still under same warranties and not related to abuse or defects); passing full replacement responsibility to the provider is absurd, when the equipment is no longer under their control after it has been purchased. (c) There is routine maintenance that must be performed by the user; the provider has no means to assure when or if this is done, or done correctly (and would not be allowed to charge or be reimbursed for doing this maintenance themselves). (d) Many repairs are due to use/abuse; it is extremely difficult to distinguish between the two. The proposed rule offers an exception for 'abuse', however there is no detail on how this would be documented or processed by the DME MACs; there are no procedures currently in place to review this type of situation in advance of a claim being submitted, denied, then reviewed (a process that is financially too uncertain for the provider and the bene). (e) There may be multiple providers involved in performing repairs; especially for 'snow-bird' benes; how will a provider know if other repairs have been done and paid? How will they know how much (in dollars) has accumulated? (f) Is the 60% value based on current allowables/ allowables at the time the item was provided/allowables for the state the bene is in now or was in at the time of initial delivery? (g) If there are more than one provider involved in providing the equipment, for example, if the bene moves, which one is responsible for providing the 'free' replacement' equipment? (h) There is an emphasis in the proposed rule on 'equipment useful life" which is stated as 5 years. There seems to be an assumption that equipment that is needed for more than 5 years can easily be replaced and new payment obtained after the 5 year mark. The reality is that DME MACs do <u>not</u> have consistent procedures in place to pay for new equipment after 5 years. While there is some variation between jurisdictions, it is generally very difficult to receive payment for new (replacement) equipment when the equipment initially provided is no longer functional for a beneficiary. Claims are rarely if ever paid on initial submission; providers have to send the claim through several levels of appeal with a quite detailed level of documentation in order to be paid. This seems to be primarily an issue with the way that certificates of medical necessity and lengths of need are set up in the common working file; system edits prevent claims from being paid without manual overrides of these edits. If the intent of this proposed rule is to enable new equipment to be provided after 5 years of use, new processes need to put in place at the Carriers for this

to function as intended. (i) The proposed rule states that exceptions may be made in cases of bene-owned equipment when it is "lost, stolen, or irreparably damaged"; again, the concern is that there is no process in place with the DME MACs to review these situations in advance of the provider replacing the equipment and submitting a claim. CMS needs to require that DME MACs create a process of 'approving' these situations to provide assurance to both the bene and the provider of reasonable compensation; needs to provide information on previous use of equipment, previous repair expenses; perhaps access to the CWF?, in order for any of these provisions to applied in a practical and reasonable way.

Please accept and review these comments when considering the practical implications and implementation of the DRA rule regarding changes to capped rental and oxygen equipment. The final rule should honor the intent of the DRA at the same time that it offers clear guidance and protection to both beneficiaries and providers. Thank you.

Paula Koenig
Hamilton's Health Aid Services, Inc.
8132 Woodland Dr
Indianapolis, IN 46278
317-428-7505
Paula.Koenig@HamiltonsHAS.com

Submitter : Mr. Carey Britton **Date:** 09/25/2006

Organization : South Florida Mobility, Inc.

Category : Other Health Care Professional

Issue Areas/Comments

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

My concern about the capped rental of DME, creates an issue of quality and durability. After attending the latest med-trade show, I noticed that basic equipment has become more basic, a K1 is not the same K1 chair that Medicare was paying for only a month ago. Mfgs are now making the chairs with out of the box options, not modifications, or substitutions, which makes these chairs not as functional as they were. Also the warranties now coorespond to the capped period and are non-transferrable to the bene. This means that the marginal money being saved, is for a lesser chair, w/ a lessor warranty, and a lessor anticipated life span.

For Medicare, this could be repeat purchases for items that could have been maintained or under warranty, which may now cause the chair's repair costs to superceed the purchase price, or require more routinely purchased chairs.

Submitter : **Date: 09/25/2006**

Organization :

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1304-P-52-Attach-1.DOC

#52

RITA S. HOSTAK
Vice President
Government Relations

Sunrise Medical HHG, Inc.
7477 East Dry Creek Parkway
Longmont, CO 80503
Tel: 704-846-4096
Fax: 704.846.4098
rita.hostak@sunmed.com

Via Electronic Mail
http://www.cms.hhs.gov/erulemaking

September 25, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Home Health prospective Payment Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 (DRA) Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment; Proposed Rule [CMS-1304-P]

Dear Dr. McClellan,

The following comments are submitted on behalf of Sunrise Medical, a global healthcare provider and manufacturer of home medical equipment. Through DeVilbiss, our respiratory division, we manufacturer oxygen therapy equipment including stationary concentrators, portable oxygen concentrators (iGo®) and transfilling units (iFill®). The format of our comments will follow the sections delineated in the proposed rule with page numbers referenced from the .PDF document distributed by the Centers for Medicare & Medicaid Services.

Introduction

Oxygen therapy is a treatment utilized in myriad clinical conditions; however, it is estimated that approximately 66% of Medicare beneficiaries receive oxygen treatment as a result of chronic obstructive pulmonary disease (COPD).[1] COPD is a progressive disease that often compounds and adversely impacts several other disease processes including diabetes, congestive heart failure, sleep apnea and coronary artery disease. Long-term oxygen therapy is the *only* treatment proven to treat the pulmonary destruction caused by COPD.[2]

In 2004, there were an estimated 1.4 million Medicare beneficiaries receiving oxygen therapy resulting in expenditures of over $2 billion dollars. With a growing COPD population, it is even more critical that CMS and Congress recognize that homecare is the "least costly medically appropriate alternative"

[1] 2004 claims for All Oxygen Codes, most common line diagnoses, 5% sample file
[2] Heaton RK, Grant I, McSweeny AJ, Adams KM, Petty TL. Psychological effects of continuous and nocturnal oxygen therapy in hypoxemic chronic obstructive pulmonary disease. *Arch Intern Med* 1983;143(4):1941-1947

to care for Medicare beneficiaries. Oxygen can be provided for *one year* to a COPD patient who lives at home for less than the cost of *one day* in the hospital.[3]

The proposed changes as a result of the Deficit Reduction Act – title transfer for capped rental equipment at 13 months and oxygen equipment at 36 months and the changes to long-standing maintenance and service policy – have the potential to adversely impact Medicare beneficiaries and the home medical equipment providers that service this population. Oxygen therapy is drug therapy as defined by the Food and Drug Administration (FDA) and similarly should be considered as such by Congress and agencies such as the Centers for Medicare & Medicaid Services (CMS) rather than just a commodity. Sunrise is concerned that the rules being contemplated will restrict access to new technologies, create safety issues, impose a financial burden on providers of respiratory services and ultimately, will result in clinical consequences that shift the burden of healthcare to more expensive venues such as acute care facilities.

G. PAYMENT FOR OXYGEN , OXYGEN EQUIPMENT AND CAPPED RENTAL DME ITEMS

1. Implementation Date (p. 61)
   The proposed regulation states that the effective date of January 1, 2007 will be for all claims for oxygen and capped rental items. Although this may be acceptable for certain capped rental items, the timeframe for the oxygen equipment provisions is inadequate. One of the stated goals of the regulation is to create new product classes that promote the use of new technologies such as portable concentrators and transfilling systems. We agree with this objective; however, there are significant decisions that must be made by beneficiaries and medical equipment providers that simply cannot be accomplished in the two months prior to a January 1, 2007 effective date. This is a crucial point, given the restrictions outlined in later sections that limit the circumstances in which a provider may change equipment once a patient has been accepted for services. In effect, the provider must analyze their patient mix, determine the appropriate patients for the new technologies, secure funding for the capital investment in the new equipment and deploy that equipment all before January 1, 2007. Those tasks simply cannot be accomplished in two months.

   Recommendation:
   We recommend that CMS allow a grace period for implementation of the section outlining when providers may change equipment. Permit providers, with beneficiary consent, to change equipment without proof of medical necessity for claims with dates of service prior to at least June 30, 2007. This recommendation would provide for implementation of the new payment rates and product classes but not penalize beneficiaries and providers who have to make complex oxygen equipment decisions on the currently proposed short timeframe.

2. Furnishing Services for Entire Period of Medical Need (p. 62)
   We agree that beneficiaries need the security of knowing that once they begin service with a particular medical equipment provider, that provider will provide services for the entire period of medical need. Furthermore, we agree that there should be exceptions such as in cases where an item becomes subject to competitive bidding or unique situations where the Medicare contractor has discretionary authority. However, the other stated exceptions – temporary or permanent relocation and beneficiary choice of a new provider – create financial and logistical issues not present under the current payment scheme.

[3] Dunne, PJ. The demographics and economics of long-term oxygen therapy. *Respiratory Care* 2000; 45:223-228.

In the case of exception #2 (temporary or permanent relocation) the proposed regulation states that this is consistent with what currently happens when a beneficiary moves outside of a provider's service area. While correct that a beneficiary may choose a new provider when they relocate either on a temporary or permanent basis, even the current payment model is problematic for capped rental items. Providers must engage in 3-way phone conferences with their Medicare contractor to determine at what point the beneficiary is in their 15 month capped rental cycle in order to bill the remaining months properly. Moreover, unless there is a break in service or medical necessity reason for a change in equipment, the new provider must accept payment for the remaining months of the capped rental cycle. By example, although not ideal to begin servicing a new beneficiary in the 10th month of a 15 month rental cycle, the provider often accepts the patient knowing that 1) there is no loss of their capital asset through title transfer; and 2) there are 5 remaining rental payments and a residual maintenance and service payment every 6 months once the cap is reached. For oxygen, the current system continues to make payments for the entire period of medical need with no time limitation.

Under the proposed regulation and using the above example, the provider is being asked to take on a new patient with three months of payments remaining and will be required to transfer title to the equipment at the end of that period. In the case of oxygen, there is a larger capital investment for oxygen equipment, especially newer technologies like portable concentrators and transfilling units. The cost of equipment and title transfer will necessitate providers' refusal of new beneficiaries that are beyond a determined point in their rental period.

We recognize that CMS is saddled with the statutory limitations on payment caps and title transfer imposed by the DRA; however, we feel compelled to comment that there can be no comparison between the circumstances of today with respect to beneficiary relocation or provider change and the new system required by the DRA provisions. Moreover, we sympathize with CMS' attempt to craft a regulation that attempts to protect beneficiary choice. Unfortunately, payment caps and title transfer create a situation that disadvantages both the beneficiary and the provider with each passing month in a rental arrangement.

Recommendation:
CMS should develop a reimbursement mechanism that allows for payments to a new provider when a beneficiary chooses to relocate or elects to have services delivered by a new provider. The new provider should not be penalized financially for accepting a new patient at any point in the rental period. By creating this disincentive for accepting new patients, it negates the intended goal of the exception and serves as an impediment to beneficiary relocation or changing their initial provider.

3. Replacing Equipment Once the Rental Agreement has Commenced (p. 64)
We commend CMS for their beneficiary-centric approach to protecting against substitution of older equipment prior to title transfer. Clearly CMS recognizes the significant capital investment providers have in equipment, especially new technologies like tranfilling systems and portable concentrators. Similar to the previous comment, we agree with certain of the exceptions enumerated in the proposed regulation – lost, stolen or damaged equipment; repair situations where a loaner is needed; and contractor discretion. However, requiring demonstration of a change in medical necessity is an exception that requires further clarification on several points.

First, CMS must further clarify their mean of "modality." The proposed rule appears to misuse the well-established clinical definition of "modality" in favor of a generic use of the term tied to specific categories of equipment. When clinicians consider oxygen modalities, there are traditionally three categories:

1. Liquid oxygen
2. Compressed gas
3. Oxygen extraction from room air (i.e., concentrator)

In the proposed regulation, rather than consider oxygen modalities the way that clinicians define them, CMS will create new payment categories and redistribute reimbursement among certain "new" and existing categories of oxygen equipment. For example, the regulation discusses new payment categories for transfilling units and portable oxygen concentrators and equates these to payments for "new" modalities. From a clinical viewpoint, these are not new modalities but rather new technologies. For example, compressed gas is often used for portable oxygen needs and is provided in cylinders that that traditionally have been filled at the medical equipment provider's place of business. New technologies are now available for patients to fill their cylinders at home, still a compressed gas modality, using a transfilling system. CMS recognizes the evolution of technology with this proposed regulation by creating a category for transfilling technology; however, both the traditional cylinder method and the transfilling systems are commonly considered "compressed gas" modalities by the clinical community.

While the distinction regarding the definition of "modality" may seem like an argument about semantics, it raises serious issues related to changing between "modalities" and the medical necessity statements in the proposed rule (discussed below). For example, if the clinical viewpoint is taken, there would be no medical necessity justification necessary to change a patient from compressed gas cylinders delivered to the patient's home versus providing them with a transfilling unit since there is no change in modality (i.e., both are compressed gas). Moreover, based on statements made in the proposed rule, it appears that CMS is hopeful that medical equipment providers will adopt these new "operationally efficient equipment models" to avoid the residual payments after 36 months for delivery of contents. The proposed regulations, by putting restrictions on when medical equipment providers can change "modalities," would seem to be at odds with the stated intent of CMS to encourage adoption of the new technologies.

Recommendation:
CMS must clarify their interpretation of "modality" in the final rule. Assuming it is the clinical community's definition, CMS must define the specific circumstances when patients may be changed from one modality to another. Furthermore, if it is the intent of CMS to encourage home oxygen providers to adopt newer, more operationally efficient equipment types, there must be:

a. Medical policy that clearly defines the criteria allowing patients to switch from one modality to another (e.g., liquid oxygen to compressed gas)
b. Clarification that providers, with beneficiary consent, may change within a modality (e.g., delivered cylinders vs. cylinders self-filled in the home) without proof of medical necessity; and,
c. Payment policy that allows for full reimbursement when the patient changes from one equipment type to another within a modality, even if that change occurs during the first 36 months of rental. For providers and beneficiaries that switch to newer technologies such as transfill and portable oxygen concentrators, CMS will benefit by reduced cost in years four and five from the elimination of content payments.

4. Medical Necessity Exception for Equipment Changes (p. 64)
We recognize that CMS delegates the authority for determining medical necessity criteria to the Durable Medical Equipment Program Safeguard Contractors (DME PSC). The proposed rule delineates an exception for medically necessary changes; however, it is the local coverage determination (LCD) that will provide the details of this provision. We are very concerned that the

LCD will not be published in time to allow clinicians, beneficiaries and providers an adequate public comment and notice period.

Medicare contractors typically make medical necessity determinations and delineate the coverage and documentation requirements for such in their LCDs. In developing medical necessity requirements for modality changes, CMS should take into consideration the medical benefit that a change in equipment type may provide in terms of ambulatory ability and participation in activities of daily living. One common reason for patients to choose lighter, more portable oxygen delivery systems is for the increase in mobility these systems afford. In the case of oxygen patients, this is not simply a "lifestyle" choice. Medical literature has thoroughly documented the benefit to pulmonary patients of increased activity levels. Moreover, CMS confirms the medical necessity of increasing activity levels in pulmonary patients by reimbursement for pulmonary rehabilitation programs (see among others - Riverbend Government Benefit Administrators LCD at http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=1605&lcd_version=25&show=all).

As further support of our position, several of the Medicare contractor policies state that the goal of pulmonary rehabilitation is not to reach maximal exercise tolerance during the pulmonary rehabilitation sessions but rather to provide the patient with education and training so that a patient can extend his/her endurance through continued self-care in the home and community environment. In other words, pulmonary rehabilitation is designed to provide the patient with tools that they can use throughout their daily lives to improve their function once discharged from the rehab program. If access to newer, lighter, more portable oxygen systems is restricted through reimbursement constraints or lack of clearly-defined medical necessity criteria and documentation requirements, oxygen therapy patients will suffer serious medical consequences. More importantly, those that have participated in pulmonary rehabilitation programs will see their money (and that of the Medicare program) wasted for failure to provide access to the equipment necessary to complete the pulmonary rehab goals.

Recommendation:
We recommend that CMS instruct its DME PSC contractor medical directors to incorporate specific medical necessity coverage and documentation requirements in the revised Oxygen and Oxygen Equipment LCD prior to the proposed January 1, 2007 implementation date of this regulation. Specifically, the LCD should address:

- Under what circumstances or diagnoses it is medically necessary to change from one oxygen modality or equipment type (see comments above "CMS Must Clarify Definition of Modality) to another;
- How providers will be reimbursed for changing equipment;
- Specific documentation requirements for both the provider and the physician to ensure that the contractors can make appropriate coverage determinations.

It is critical that CMS define what diagnoses or conditions constitute a change in medical condition and enumerate those reasons through the LCD development process. However, given the 45 day comment period and subsequent 45 day notice period required once the LCD is finalized[4], it appears impossible that the DME PSCs will be able to meet a January 1, 2007 implementation date. Allowing providers until June 30, 2007 or later to make changes in equipment without regard to medical necessity, as recommended above, will provide time for the DME PSCs to publish a revised LCD.

[4] CMS Internet Only Manual Pub. 100-8, *Medicare Program Integrity Manual*, Ch. 13, Section 13.7.4

H. PAYMENT FOR OXYGEN CONTENTS FOR BENEFICIARY-OWNED EQUIPMENT

1. Title Transfer of Oxygen Equipment (p. 69)
We disagree with the requirement that providers must transfer both the cylinders at use in the beneficiary's home and an equivalent number of cylinders used for exchange. There is a commonly used model in place today that exemplifies the proper approach to cylinder ownership and transfer – propane cylinder exchange. Propane cylinders are used for gas grills, portable outdoor heating and other applications. At initial issuance, you pay for both the cylinder vessel and contents. Once the propane contents are exhausted, you return the cylinder and exchange it for a full cylinder. At this point, payment is made only for the propane contents and while you do not receive the same vessel in return, the consumer is "made whole" because they receive an equivalent cylinder vessel in exchange.

Requiring title transfer of two sets of cylinders – those used in the home and those maintained at the provider's business – is a considerable depletion of assets and a significant financial burden for the provider. One national provider of home oxygen equipment estimates they have over 1 million cylinders currently in use. Moreover, the logistical issues of assigning specific cylinders to specific beneficiaries will require tracking systems that are not currently utilized and will result in further financial expenditures to implement.

Recommendation:
CMS should not require transfer of title for both sets of cylinder vessels but rather only those that are in use in the home and not the ones that the provider refills in its business location.

2. Safety Issues Associated with Beneficiary-Owned Equipment (p. 70)
Contrary to CMS' assertions in the proposed regulation, there are significant safety concerns once title to oxygen equipment transfers to the beneficiary. With provider ownership of equipment, particularly compressed gas cylinders, the integrity of the vessel was assured through periodic testing and inspection as required by state and federal regulations. Individual cylinders were tracked and records maintained regarding the required service and testing. With title transfer and beneficiary ownership, the periodic testing is no longer assured since once title transfers, the beneficiary is free to choose whomever they wish to supply contents. For other non-capped items, beneficiaries frequently switch between providers and it is anticipated that the same will occur with oxygen services after the 36 month cap.

This situation creates a serious dilemma for the potential new provider of contents. The new provider has no knowledge of how the compressed gas cylinders have been stored and maintained and how or when federally-mandated hydrostatic testing has been performed. This is a tenuous position for the new provider who most likely will decline to service the "unknown" cylinders for fear of employee injury and subsequent liability.

A related safety concern is the disposal of oxygen equipment once it is no longer needed by the beneficiary. Even today, oxygen equipment is bought and sold on the internet, at garage sales and flea markets – a situation very concerning to the home oxygen equipment industry. The sale of these medical devices is rarely monitored or controlled to ensure the condition of the device being sold, patient safety and clinical effectiveness. Oxygen devices, for example, must produce a certain level of purity in order to meet the expectations of a physician's prescription. Yet, eBay and other on-line marketplaces have begun to sell oxygen cylinders "as-is," even marketing their features and benefits by describing the name of homecare company from which the cylinders were technically stolen.

Prior to the DRA, a legal mechanism existed to pursue sellers who technically did not have title to oxygen equipment (i.e., prior to DRA title transfer, the home equipment provider held title). Often manufacturers and providers confronted sellers where ownership was unclear. When confronted by the homecare providers' Legal or Compliance departments, the seller usually stated that he/she bought left over equipment at an elderly neighbor's garage sale, or they retracted the sale of an item for which they could not produce a valid receipt. EBay sellers have begun transporting used oxygen cylinders through United Parcel Service (UPS), FedEx and other air carriers without the Transportation Safety Administration's (TSA) or the Federal Aviation Administration's (FAA) knowledge.

A proliferation of beneficiary-owned medical devices caused by the DRA will force the patients' families to accept responsibility for its disposal or resale. (Up until now, the family simply called the homecare provider to retrieve the equipment or devices that were no longer needed or being used and the provider picked it up). We are concerned that families will not realize that these are highly regulated medical devices.

Under these scenarios, there is virtually no safeguard for the average patient or interested party to know whether or not one's medical device purchase, such as an oxygen concentrator, is appropriate for their application, if that device is in proper working order providing therapeutic oxygen levels, needs preventive maintenance, minor or major repairs or other service and maintenance. In addition, the potential for the spread of infection is greatly increased. The general public does not have the knowledge or expertise to properly disinfect this equipment prior to selling to other members of the public. Transmission of respiratory pathogens is highly likely if the device is not properly disinfected in between patient uses, a requirement for accredited providers who must comply with the infection control requirements of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or other accrediting organizations.[5] These "new" patients would lack the necessary training and knowledge for safe use and operation of these devices, creating potentially dangerous situations. These devices are shipped around the country, without the needed safeguards on the receiving end to make sure equipment is functioning properly, further taking these devices outside the reach of medical equipment providers who are responsible for the necessary checks to ensure performance.

Lastly, providers are responsible for the traceability of these devices into specific patient homes in the event of medical product updates or recalls. Once the patient takes ownership and the title transfers, many of these devices will no longer be able to be tracked for recall purposes.

Recommendation:
While we recognize that CMS cannot reverse the decision to transfer title required under the DRA, there are several actions that can be taken to help ensure patient and home medical equipment employee safety and access:

a. Minimize the number of patient-owned cylinders by adopting the recommendation outlined in #1 above.
b. CMS must coordinate with the FDA the development of standardized guidelines that apply specifically to the public's resale of used medical devices as a result of the title transfer provision of the DRA. Because the Safe Medical Device Act (SMDA) never technically contemplated the concept of broad-based medical device ownership among the American public, we strongly encourage CMS to confer with the FDA to review the impact of this specific law and proposed rule.

[5] Joint Commission on Accreditation of Healthcare Organizations Standards Manual for Home Medical Equipment Providers, 2006. Sections on Infection Control, Quarantine of Clean/Dirty Equipment and Patient Safety Goals.

c. CMS and the FDA should discuss the ability for medical oxygen fillers to comply with 21 CFR 210 and 211 once the patients own their own devices and equipment, including the portable oxygen cylinders that are operationally fungible for most home oxygen providers.
d. The Federal Trade Commission (FTC) must be consulted and encouraged by CMS to stop eBay and other on-line marketplaces from selling medical equipment that may only be sold or dispensed to a specific patient based on a licensed physician's prescription.
e. CMS must outline its process for expectations of actions to be taken in conjunction with a FDA recall after the patient takes title to the device.

I. Classes of Oxygen and Oxygen Equipment

1. Appropriateness of Payment Structure (p. 73)

CMS outlines a payment structure for new classes of oxygen equipment and asserts that "[W]e want to ensure that the Medicare payment methodology results in payments for oxygen that are accurate, do not impede beneficiary access to innovations in technology, and do not create inappropriate incentives for providers." In our opinion, CMS has failed to accomplish these goals with the proposed payment structure.

New technologies require considerable resources to develop in terms of engineering resources, manpower and financing. Under existing reimbursement amounts, manufacturers have been able to make advances in technology that create opportunities for beneficiaries to lead active, productive lives. For example, portable oxygen concentrators have afforded the option of air travel that, prior to their introduction, was logistically difficult with compressed gas cylinder use. Transfilling technologies have freed the beneficiary from waiting for a home medical equipment provider to deliver cylinders. The medical benefits of a more active lifestyle cannot be underestimated in this population of patients and is well-documented in the medical literature.

While these technological advances have resulted in smaller, lighter, more portable equipment, there is still more that needs to be and can be accomplished. New types of batteries are needed to provide longer running times. Existing concentrator technology depends on molecular sieve technology. Because sieve-based oxygen extraction requires a certain mass of material and a compressor system, there are physical limitations on the amount of size reduction that can be achieved. Adequate funding will allow manufacturers to pursue alternative technologies that will result in even smaller, highly portable and more energy efficient equipment.

CMS has indicated in this proposed rule that the additional $10 per month reimbursement for Home Oxygen Generating Portable Equipment was calculated by "estimating potential savings that the Medicare program would realize as a result of not having to pay for delivery of oxygen contents for beneficiary-owned portable oxygen systems in the fourth and fifth years of use." (p. 83). Although CMS describes in great detail the derivation for the proposed $10 per month additional fee, there is no basis for this fee. The only basis referred to by CMS is "projected savings in the fourth and fifth years." While we agree that devices such as portable oxygen concentrators and transfilling units can result in significant savings to the beneficiary and CMS, especially in residual costs of content payment after the 36 month rental period and fewer home visits, we believe the proposed add-on fee of $10 per month or a total of $360 for the life of the asset is inadequate. On average, transfilling units cost $2,500 - $3,000 and portable oxygen concentrators are similarly priced, averaging approximately $2,500 - $3,500.

Recommendation:
Given the high acquisition cost of this equipment, CMS should reconsider the proposed fee schedule for these new technologies and increase reimbursement to accurately reflect the cost of the equipment and provide reasonable incentives for continued development of these types of technology. As a manufacturer, Sunrise/DeVilbiss offers to work with CMS to help determine the appropriate reimbursement in order to maintain budget neutrality.

2. Title Transfer for Transfilling Equipment (p. 75)
CMS states that "[I]n accordance with the DRA, after 36 months of continuous use, title for the transfilling equipment and accompanying portable oxygen tanks would transfer to the beneficiary who would then own a portable equipment system that self-generates oxygen in their home." We disagree with the CMS interpretation that the DRA language requires title transfer for transfilling equipment. Section 5101 states "[I]n general, payment for oxygen equipment (including portable oxygen equipment) under this paragraph may not extend over a period of continuous use (as determined by the Secretary) of longer than 36 months." It is only in the language of the proposed regulation that transfilling technology is redefined as "portable oxygen generating equipment."

The definition of portable oxygen equipment is well-establish and includes 3 major equipment categories:

a. Compressed gas cylinders;
b. Liquid oxygen systems;
c. Portable concentrators

All three types of equipment provide oxygen directly to the patient. Furthermore, one could also include two of the three transfilling units on the market today in that definition since they are products that combine a stationary concentrator and transfill capability into one device. As such, these products also deliver oxygen directly to the patient. There is only one transfill product that serves solely as an oxygen transfilling device - Sunrise Medical/DeVilbiss' iFill®. The iFill® system is unique in that it operates independently from a stationary concentrator. In other words, a beneficiary can have a stationary concentrator in their living room and fill oxygen cylinders with an iFill® unit located in a spare bedroom. It does not provide oxygen directly to the patient like other "dual use" units in the marketplace today.

The DeVilbiss iFill® unit functions *exactly* like the equipment owned by the provider that is filling oxygen cylinders at their place of business. It is not "portable oxygen equipment" as described in the DRA. We believe this interpretation that a transfill unit is not portable oxygen equipment is consistent with the plain, unambiguous language of the DRA and unique to the DeVilbiss iFill® product. Consequently, title to this piece of expensive, capital investment should not transfer at the conclusion of the 36 months of rental payments.

Recommendation:

a. CMS has the authority to interpret statutory language in the manner described above and should do so in order to be consistent with long-standing definitions of oxygen equipment.
b. Restrict products included in HCPCS code K0738 to those products that meet the definition of the code - a home compressor that is used solely to fill oxygen cylinders and not "dual use" devices (i.e., devices that combine a stationary concentrator and transfilling capability into one unit).
c. For those products that serve solely as a transfilling device (e.g., the DeVilbiss iFill®), title should not transfer at the end of the 36 month rental period. Because these units represent a considerable capital investment, allowing continued provider ownership of the equipment past 36 months will afford providers the opportunity to reissue transfilling units to another

beneficiary when the unit is no longer medical necessary. We believe the provider community would support the loss in revenue resulting from leaving the unit in the beneficiary's residence, without compensation past 36 months until medical need ends, in exchange for retaining ownership of the unit.

d. A new HCPCS code should be created to describe "dual use" devices. Creation of a new HCPCS code to describe devices that combine stationary concentrator and transfill technology into one unit will allow CMS and its contractors to distinguish which devices will not undergo title transfer. We recommend Kxxx1 with the following descriptor:

   Kxxx1 – Stationary gaseous oxygen system, rental, dual use, includes stationary concentrator component and capability to fill portable oxygen cylinders, includes portable containers, regulator, flow meter, humidifier, cannula or mask and tubing.

3. Separate Payment Classes for Differing Equipment Types (p. 76)
We appreciate CMS' attempt to define the different equipment and technologies used in the marketplace today and create new classes of payment that reflect the advances in technology such as portable oxygen concentrators and transfilling systems. Unfortunately, the new payment distribution does not adequately compensate the medical equipment provider for the capital expenditure necessary to acquire these new technologies.

   As noted above, the cost of new technologies that allow providers to further CMS' stated goal of eliminating residual costs past 36 months is considerable. Without equitable payments to encourage providers and physicians to move towards this goal, CMS will not realize the long-term goal of expenditure reduction in years four and five of the rental period.

   Recommendation:

   a. As noted above, CMS should re-evaluate the distribution of payments among the various classes of equipment and support the transition to newer technologies such as portable oxygen concentrators and transfilling systems through higher reimbursement in those product categories.
   b. CMS should develop a long-term reimbursement strategy for gaseous and liquid content payments that furthers the goal of encouraging transition to newer technologies. This must be a long-term goal since providers currently have patients utilizing older technologies and require increased payment support to continue servicing those patients until physician education can be accomplished.
   c. Since the type of oxygen therapy utilized by the beneficiary is often driven by the physician, CMS should work to educate physicians about the benefits of newer technologies and encourage the movement of oxygen therapy away from older, more expensive equipment models.

J. Payment for Maintenance and Servicing of Oxygen and Oxygen Equipment and Capped Rental Items

1. Access to Providers Willing to Provide Maintenance and Service (p. 90)
CMS asserts that "[W]e are not aware of instances where beneficiaries have encountered problems in finding providers to provide maintenance and service of beneficiary-owned DME." This statement is followed by CMS' stated belief that under the new payment system, beneficiaries will continue to encounter no problems when seeking maintenance and service. We believe this assumption is erroneous.

Beneficiary-owned DME is unusual since most beneficiaries elect to continue renting equipment once the 15 month cap is reached. Similarly, beneficiary-owned oxygen equipment is rare under the current payment system since Medicare has required rental of oxygen equipment for over 17 years. Only if the beneficiary owned equipment prior to 1989 does Medicare pay for maintenance and service. Consequently, it *is* unlikely that CMS would be aware of any issues related to maintenance and service of equipment because of the extremely small number of beneficiaries that either own DME or oxygen equipment. Conversely, under the DRA and title transfer, millions of beneficiaries will own DME and oxygen equipment beginning in February 2007 (13 months) or January 2009 (36 months).

CMS should be aware of the importance of proper maintenance and service. In November 1994 the OIG issued a report entitled *Oxygen Concentrator Services* (OEI 03-91-01710) that stressed the need and importance of regular, frequent servicing of oxygen patients. At that point, the OIG was examining the need for services standards for providers of home oxygen therapy. We are unclear why the government would completely reverse its position, not recognizing the need for the many critical support services that home oxygen providers provide to patients. Specifically, the OIG found: "The importance of support services, such as equipment and patient monitoring, for oxygen concentrator patients is critical for the proper functioning of the equipment as well as the effectiveness of the therapy it provides."

As noted elsewhere in these comments, providers will not know when or if maintenance has been performed. Furthermore, providers will not know from what source the equipment was acquired once beneficiaries or their families start disposing of unneeded equipment.

Recommendation:

a. CMS must carefully consider the reimbursement amount for maintenance and service to avoid compounding the issue of restricted access to qualified service providers. The amount must be adequate to cover the cost of parts and labor plus the overhead costs associated with repair technician salaries, required specialized training and equipment, travel expense to pick up and deliver repaired equipment (e.g., vehicle cost, insurance, fuel).
b. CMS should monitor the access to qualified technicians once payment amounts are established to ensure that beneficiaries are not endangered by faulty, poorly maintained equipment.

2. Failure to Account for Value of Clinical Services (p. 90)

While there is discussion in the proposed rule regarding payment for maintenance and service, there is no provision for reimbursement of after-hour, emergency or clinical services after the 36th month rental payment. The value of the home care provider to the physician community in these situations should not be underestimated. It is not uncommon for a physician to ask a home oxygen provider to conduct an in-home clinical patient assessment on a long-term oxygen patient so that the licensed homecare clinician can listen to breath sounds, discuss the patient's level of adherence to the physician's prescribed regimen, and document other findings in a summary to be provided to the physician. These in-home clinical assessments are extremely important to ensuring high quality care for patients. However, this activity is sustainable only if CMS establishes a new code and an appropriate reimbursement rate. Patient assessment, training, education and monitoring currently comprise nine percent of providers' total costs of caring for patients.[6] Providers cannot provide these assessments without fair reimbursement rates because they would constitute an illegal inducement and raise other fraud and abuse concerns.

[6] "A Comprehensive Cost Analysis of Medicare Home Oxygen Therapy - A Study for the American Association for Homecare," June 27, 2006, Morrison Informatics, Inc. The report collected data from 74 home oxygen providers nationwide who collectively serve over 600,000, or approximately 60 percent, of the total Medicare oxygen-dependent beneficiaries in the United States.

Recommendation

CMS should establish a payment mechanism for the emergency and clinical services rendered by the medical equipment provider including after-hours care, in-home assessments, patient education and adherence monitoring. The rate should take into account the value of the therapists' time, mileage reimbursement expense, and related costs.

3. Definition of Maintenance and Service (p. 90)

CMS issued conflicting guidelines as to what will be reimbursed by the program once the title for oxygen equipment transfers to the patient. In one section, CMS stated that beneficiaries or their caregiver would be able to perform routine maintenance (p. 91) and includes "testing...regulating." Shortly after (p. 92), CMS indicates that if special tools are required to perform that maintenance – tools which patients would not typically own, such as an oxygen analyzer – then reimbursement would be provided by Medicare to the provider (p. 92). These two statements appear to be in conflict since testing and regulating oxygen equipment both require specialized tools.

Even "routine" tasks are often complicated for many seniors, especially those with COPD and other co-morbidities such as diabetes, congestive heart failure and coronary artery disease. The average age of a Medicare beneficiary receiving oxygen after 36 months is 73 years old. Most of the tasks required to perform ongoing medical equipment and oxygen concentrator maintenance require hand-to-eye coordination, strength, depth perception and tactile ability. A recent OIG report was critical with respect to home oxygen equipment providers and the frequency of home visits to perform "routine" maintenance, stating that visits occurred approximately every 4 months.[7] According to the OIG report "[W]hen providers visit beneficiaries, they often perform services that a beneficiary has been instructed to do. For example, based on our sample, 50% of the visits to service the concentrators included cleaning the external filter, which the beneficiary is trained to maintain." Rather than take the OIG view that these visits are unnecessary, one could realistically argue that they are vital *because the beneficiary cannot or does not perform simple maintenance.*

While the simple task of cleaning an external filter may seem easy to the able individual, experience shows that they are complex for many Medicare-age beneficiaries. In fact, as reported by many of our dealer-customers, few are able to perform simple troubleshooting of their equipment despite professional guidance via phone and require home visits to assure the equipment is functioning properly. CMS only needs to recall the decision "requiring" beneficiaries to change their own power wheelchair batteries. That decision by the Durable Medical Equipment Regional Carriers (DMERCs) was reversed after learning from medical equipment providers that, despite what seems like a simple task, beneficiaries often reversed polarity on the batteries and ruined the electronics on the chair.

Recommendation:

From surveys of oxygen equipment manufacturers and home medical equipment technicians, the following tasks should be considered "routine" concentrator maintenance that theoretically could be performed by a patient or caregiver. However, we reiterate again that dexterity or cognitive challenges could make even the following list of seemingly "routine" tasks difficult:

1. Wiping down external surfaces

[7] Office of Inspector General Report entitled *Medicare Home Oxygen Equipment: Cost and Servicing*, September 2006 (OEI 09-04-00420), p. 11

2. Removing, cleaning and replacing the external cabinet filter
3. Changing oxygen tubing
4. Cleaning, disinfecting and replacing O_2 humidifiers if used

The following should be considered "non-routine" maintenance, should be performed by trained professionals and reimbursed via a fair and equitable payment structure by CMS:

1. Inspection of internal components for dust, debris, evidence of wear
2. Changing of internal filters
3. Cleaning of internal heat dissipation coils
4. Any maintenance that requires breaking of internal seals such as sieve bed repair, compressor rebuilds, electric motor repair, etc.

4. Warranty Repair (p. 93)
The proposed regulation states that some manufacturers of commonly used oxygen concentrators offer full warranties that cover all parts and labor for 5 years. CMS should be aware that warranties from most manufacturers, including Sunrise Medical, extend only to the first owner of the equipment, the medical equipment provider. They do not transfer to subsequent owners (i.e., the beneficiary). This has significant consequences with respect to the replacement proposal outlined in Section K of the regulation.

Recommendation:
Sunrise Medical will work with CMS to provide further information about our product's warranties and their limitations. CMS should obtain warranty information from other manufacturers in order to craft maintenance and service and replacement policies that benefit both the beneficiary and the provider and ensure that critical services are available.

K. PAYMENT FOR REPLACEMENT OF BENEFICIARY-OWNED OXYGEN EQUIPMENT, CAPPED RENTAL ITEMS AND ASSOCIATE SUPPLIES AND ACCESSORIES

1. Replacement at No Cost After Warranty but Prior to Five Years (p. 96)
There is no precedent under current Medicare regulations for requiring a provider to replace, at no cost to the beneficiary, items that have accumulated repair costs that exceed 60% of replacement prior to reaching their reasonable useful lifetime limit. CMS cites the statutory reference Section 1834 (h)(1)(G) of the Act in support of this new proposal and implies that the proposal is consistent with the rules applied to artificial limbs by stating:

> *"[W]e believe this threshold should apply to oxygen equipment and capped rental items as well, because artificial limbs, like these items, are built to withstand repeated use."*

To the contrary, the proposed regulation has several major differences with respect to the rules applied to prosthetic limbs. The 60% replacement rule for prosthetic limbs was enacted through The Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA 2000), Section 428 entitled "Replacement of Prosthetic Devices and Parts." That section reads, in part:

> *(i) In General: Payment shall be made for replacement of prosthetic devices which are artificial limbs, or for the replacement of any part of such devices, without regard to continuous use or useful lifetime restrictions if an ordering physician determines that the provision of a replacement device or a replacement part of such a device, is necessary because of any of the following:* [Subsection III is pertinent]

III. The condition of the device, or the part of the device, requires repairs and the cost of those repairs would be more than 60% of the cost of a replacement device, or, as the case may be, of the part being replaced.

From the plain and unambiguous BIPA 2000 language, it is clear that Congress intended CMS to *pay* for replacement of an item when the cost of repairs exceeded 60% of the replacement value. Moreover, payment was to be made for replacement under these circumstances without regard to continuous use or reasonable useful lifetime.

The proposed regulation for oxygen equipment and capped rental items, while stating that these items are equivalent to prosthetic limbs and should therefore have the same replacement rules apply, significantly deviates from the 60% replacement rule for prosthetics in three respects:

a. For oxygen equipment and capped rental, the provider is expected to pay for a replacement item; and,
b. Continuous use requirements apply; and,
c. Reasonable useful lifetime restrictions apply.

CMS further justifies this 60% rule for oxygen equipment and capped rental on a belief that "the item in this case did not last for the entire reasonable useful lifetime."

Clearly the proposed regulation and statements justifying the new replacement rules are inconsistent. CMS states that these items are similar to artificial limbs; therefore, it is reasonable to apply the same rules used to determine artificial limb replacement. However, CMS fails to apply the rules in place for artificial limbs by failing to payment for replacement or replacement part and disregarding the statutory mandate to apply the rules without regard to continuous use or reasonable useful lifetime.

Recommendation:
We strongly recommend CMS remove the 60% rule for replacement of oxygen therapy equipment and capped rental items. Medicare should reimburse providers for all necessary repairs for the health and safety of beneficiaries requiring oxygen equipment and other life-sustaining capped rental items. The argument in the proposed regulation that providers will make unnecessary repairs in order to recover lost revenue is fallacious. CMS presents no evidence that unnecessary repairs occur today. Moreover, given the historic inadequacies of Medicare's fee schedule for parts and labor, there is no basis for the belief that this will occur under the new rules imposed by the DRA.

3. Calculation of 60% Replacement Rule (p. 96)
Notwithstanding the position stated above with respect to the proposed 60% replacement rule, the regulation does not provide information regarding how the 60% amount will be calculated. CMS states that the provider should be responsible for replacing the item when the cost of repairs exceeds 60% of the cost to replace the item. CMS does not state the basis for the cost calculation. Is this 60% of the providers' equipment acquisition cost, manufacturer's suggested retail price, or Medicare fee schedule amount?

Recommendation:
CMS must clarify the cost upon which the 60% threshold is established. While we disagree with the entire proposal to establish a 60% replacement rule and have stated those reasons in other sections of this response, should CMS decide to include this rule in the final regulation, there must be further guidance upon which replacement "cost" is determined.

L. PERIODS OF CONTINUOUS USE

1. Continuous Use for New or Additional Equipment Redefined (p. 98)
   As noted in previous comments above, there are situations where there is medical necessity to change from one equipment type to another. In the proposed rule, CMS proposes to change the regulations on continuous use found in §414.230(f) such that even if a new piece of equipment is prescribed by a physician and found to be medically necessary, a new period of continuous use would not apply. This proposal is inconsistent with all other regulations governing medical necessity and changes in equipment.

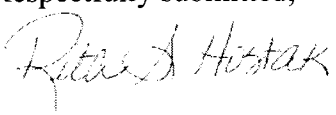
   We assume CMS will direct the DME PSCs to determine through the required notice and comment period the medically necessary situations where oxygen equipment can be changed. For example, a beneficiary may be using a 5 L stationary concentrator at the time of their admission to an acute care facility. Following discharge, their oxygen requirements are such that they now require a 10 L stationary concentrator to meet their medically necessary flow rate needs. The new stationary concentrator is more expensive and despite the incre
   ase in payments for flow rates greater than 4 liters per minute, the provider will be placed at a financial disadvantage to provide this new piece of equipment. Moreover, without the start of a new rental period for the new, medically necessary piece of equipment, the financial inequity will increase with each month of that beneficiary's 36 month rental cycle.

   Recommendation:
   CMS should continue to apply the existing continuous use regulations for DME found in §414.230. If it is medically necessary to substitute equipment, based on a physician's prescription, a new period of continuous use should apply. Without this provision, medical equipment providers will be unable to shoulder the financial burden of making medically necessary changes in equipment.

Conclusion

Sunrise Medical appreciates the opportunity to comment on the proposed regulations for oxygen equipment and capped rental items of DME. Sunrise Medical is committed to protecting the welfare – both health and financial – of the beneficiaries we serve. We believe our analysis of the proposed regulation and the recommendations made are well-reasoned and consistent with a beneficiary-centric mission. Where recommendations offer the support and assistance of our Sunrise Medical expertise, one that extends over 125 years of providing respiratory services, we hope that CMS will exercise that opportunity. Should you have further questions, please do not hesitate to contact me at 704.846.4096 or via e-mail at rita.hostak@sunmed.com.

Respectfully submitted,



Rita Hostak
Vice-President, Government Relations

Submitter : **Mr. Brad Lipham** **Date: 09/25/2006**

Organization : **Durable Medical Equipment, Inc.**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

The proposed changes in oxygen reimbursement will place the beneficiary in harm because most are elderly and the equipment is to complicated for them and they don't understand the medical consequence(if I feel good at 2liters/minute I should feel great at 4 liters/ minute. WRONG
The payment methodology does not make sense. New technology can,t be financed with only $64/month fee.
Portable contents can't be financed for $55/ month. You can,t cover the cost of tank delivery ($75/trip) or the cost of the cylinder refill ($12-$15 per tank) for only $55.
The 36 month cap will limit beneficiary access to portable oxygen,to innovation and new technology, limit freedom to relocate on a perment or temporary basis(Who will take a new oxygen patient with only 15 months before title of equipment changes which also limits suppliers) and limit patient access to 24/7 service, and maintenance support(impossible to provide at the submitted fees).
If this goes into effect CMS better get ready to pay hugh amounts for emergency room visits.

Submitter : **Mr. Jeff Meischen** **Date: 09/25/2006**

Organization : **Mr. Jeff Meischen**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1304-P-54-Attach-1.DOC

#54

July 7 proposed rule 1307-P Which revamps the oxygen classification system.
The rule proposes to split the oxygen into two payment classes, portable oxygen and stationary oxygen.

I support the move to recognize differences in various types of delivery systems and methods. However, the provision to make this change and maintain budget neutrality in the manner suggested simply makes this proposal ludicrous. In the following paragraphs some real world examples which should justify why I believe that an additional class should be added to oxygen: a service component reimbursement category.

A portable oxygen concentrator wholesales for over $3600. Under the proposed rule, only $64 per month would be paid. What dealer in their right mind would place a piece of equipment on a patient and finance it out 0% interest over 36 months for a total of only $2304. ($64 x 36 months). This same math is evident when considering oxygen transfilling systems which wholesale for about $2500. Additionally, there is nothing to take into account delivery and maintenance costs associated with servicing the patient.
This is not to mention that at the end of the rental cap, when the equipment fails, as most equipment does at least annually, there is no payment methodology for paying a technician to make a 3 am call to repair or replace this equipment. Instead the patient is going to be told to call 911 and be taken to the hospital by ambulance, and then be admitted until such time as the equipment can be repaired or replaced; in other words there will be a tremendous cost shift to in-patient hospital, ER, long-term care, ambulance and other ancillary services. Additionally, what happens during a natural disaster, the DME dealer certainly is not going to maintain a disaster plan to include oxygen patients for which they receive no reimbursement? There needs to be a reasonable monthly reimbursement fee for maintaining 24-hour emergency services or a per incident fee at a rate which realistically takes into account the costs associated to the dealer for providing this service component.

Portable contents monthly delivery charge of $55 is woefully inadequate. Especially when taking into account increase fuel charges, rising labor costs, added expense burdens such as mandatory accreditation, licensing, liability insurance and documentation burdens. Example: you have a patient that uses cylinders weekly and lives 30 miles from the nearest DME. Average

cost of transportation alone given $.50 per mile is $30 x 4 weeks per month = $120. $55 will simply not cut it, dealers will simply begin to refuse or limit service to these beneficiaries, particularly those in rural areas. There needs to be a rural add on component to adequately reimburse patients in outlying areas.

A portable add on of $32 certainly does not take into account real life situations. On a 36-month cap this equals only $1152. An average oxygen patient will have a portable E-cylinder with cart and regulator for back up in case of emergencies such as equipment failure or power outage. Additionally, they will have 2-3 extra e-cylinder tanks depending on the liter flow. For portability the patient will have a small shoulder carry bag with a M6 cylinder and anywhere from 3 to as many as 20 portable tanks for rural patients. Additionally almost all patients now use an expensive conserving device to assist in keeping the patient mobile. Keep in mind that while under the cap the $32 includes the cost of refills. Transfilling systems and portable concentrators are simply clinically inappropriate for many patients due to oxygen desaturation while utilizing those systems. Patients whom have been prescribed oxygen with a mask cannot use low flow oxygen devices and must have high flow equipment. High utilization and high liter flow patients will be turned down for service from most if not all DME providers, thus forcing them into long-term care facilities. The portable add on should be much higher for high liter flow patients, rural patients, or patients whose medical records indicated that the patient cannot use certain types of devices due to oxygen desaturation.

If you ask most dealers they would like to be paid for the service component they provide. Just like a salesman on commission, DME dealers will take service very seriously indeed if they can be reimbursed for the services provided. There should be a category added which will reimburse for call outs to the home and after hours calls. Your plumber charges you quite handsomely when he has to come out to unstop your toilet on a Saturday night. Why should a DME company providing life sustaining oxygen services receive nothing for his after-hours service?

Supplies require frequent changes, typically at least monthly for oxygen patients. Very little has been said about what if anything will be reimbursed for a DME company to provide ongoing supplies. There are many factors to consider here: the cost of the supplies, the frequency of use by individual patients, documentation burdens, and patient compliance with physician

orders. If the reimbursement for supplies is to low and delivery and the other above mentioned items are not factored into the costs, then dealers will either refuse to continue to provide the supplies or will only file non-assigned for them, forcing the financial burden to the patient. Either way the patients will be largely take on the responsible for determining when the supplies should be changed out. If it will cost them out of pocket money to do this (assuming they are even competent to make that decision) they simply will not change the supplies when clinically appropriate and thus often will set themselves up for respiratory infections, increased hospital stays and a larger overall healthcare budget.

Each time a DME Respiratory Therapist makes a trip out to check on the status of the homecare patient, they should be reimbursed. If a technician replaces oxygen tubing, washes filters, provides training & instruction to a patient, his time should be worth something. That service might be the difference between an upper respiratory infection followed by a lengthy exacerbation and hospital stay with pneumonia and a normal trip in to the doctor for a checkup. This concept is called preventative medicine and is practiced far to seldom in homecare due to reimbursement constraints. By having reimbursed homecare services for critically ill patients overall healthcare spending will drop, not increase. Is this not the purposed of the proposed rule, to reduce overall healthcare dollars? The DME business in not about just delivering equipment, dropping it on the front porch like UPS would do. When a HME technician does a home safety evaluation he is potentially keeping that patient from a trip to the hospital. Hospital and physician care is very expensive. Homecare by comparison is very economical. Reimburse a fair price and make the DME submit signed notes just like a physician or physical therapist would have to do. It is only fair to pay equipment dealers a realistic rate for services actually rendered.

Submitter : Jackie Bolt **Date:** 09/25/2006

Organization : Carolina Homecare Medical Equipment Center

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

The NPRM prohibits changing the equipment that is provided to a beneficiary on the first day of continuous use unless an exception applies. Issues with this provision are: 1) title of the equipment should not be transferred to the beneficiary unless all coinsurance or patient portion has been paid. 2) Providers would have to track equipment by serial number to make sure that the beneficiary receives title to equipment that was delivered on first day of continuous use. This will be very difficult, especially when equipment is exchanged due to servicing, repairs, etc. This will be an additional expense to incur for the provider, however this change in policy is reducing reimbursement to the providers. 3) We have not received clarification on how the "break in service" rules will apply to oxygen equipment. There are a number of situations in which a patient may have a short term need for oxygen that should not apply to continuous use. 4) Also, if a beneficiary has two residences, i.e lives up north in the summer and in the south in the winter, which provider must convert the equipment to purchase for the patient. I live in South Carolina and also serve as President of our state association and providers in the coastal area of our state are already saying that they will not be providing service to "snowbirds" in the future due to this change in regulations. Medicare beneficiaries are not going to be able to continue to travel and find providers that will provider them rental equipment as in the past due to this change in policy. 5) The requirement that providers notify beneficiaries of their intent with respect to accepting assignment is unworkable and conflicts with Medicare program rules that allow suppliers to accept assignment on a claim by claim basis.

The requirement to replace equipment - With patient owned equipment, there will be no record of routine ongoing service and maintenance. The supplier cannot guarantee that the equipment will function as it should if it is not properly maintained. Suppliers will not be able to monitor servicing and repairs done by other companies, so therefore they should not be held to have to replace the equipment. There is a concern expressed by CMS that suppliers will try to offset lost revenues from rentals with repair revenues. This is highly unlikely in that with existing reimbursement for repairs, equipment repairs is not even a break even business. As a company, we discontinued repairing any equipment unless it was originally purchased from us because we could not even cover our costs in repair. However, I think that there will be a significant increase in requests from beneficiaries for repairs once everything converts to purchase with a high liklihood that the bene will have trouble getting these repairs taken care of.

CMS needs to address their repair codes and they need to add additional codes for the repair of more complicated equipment like oxygen concentrators, etc. CMS will also need to publish guidelines on billing for repairs - outlining exactly what documentation will be required to be paid for repairs.

The NPRM does not address back up oxygen equipment. It is my belief that title to back-up equipment does not transfer under the coverage rules for oxygen. Under LCD guidelines, Medicare does not pay for back-up equipment because it is not medically necessary. Once the oxygen concentrator is purchased, providers will be forced to remove this back-up tank from the home since there is no reimbursement. Patients will be placed at risk in the event of a power outage, due to Medicare policy. Also, many providers do not own their tanks and so you can't transfer title to equipment that you don't own. Many providers also have 5 year leases on oxygen equipment. CMS needs to recognize that this will be a problem with a 36 month cap because many providers don't even own their oxygen equipment until they have had it for 5 years.

Submitter : **Anthony Ellis** **Date: 09/25/2006**

Organization : **Ellis Home Oxygen and Medical Equipment**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

I beleive that the medhodology that CMS has arrived at the proposed rule 1340-P is flawed. Is all CMS is doing is cost shifting from one delivery system to another. CMS is lowering the price on the concentrator and portable system and giving more on the new portable battery operated or transfilling system. On page 69 of the propose changes tranferring title of gaseous epuipment to the beneficiary is an undo burden on both parties. By requiring the supplier to transfer ownership of the full and empty cylinders creates additonal cost to the supplier and additonal cost to warehouse all those cylinders. According to CMS they are going to pay for 1 stationary system and 1 portable system not give a patient all they want. Also each cyclinder has to be retested every 5 years according to the manufacture. Who is going to be responsible if the patient does not pay to have the test performed and the tank explose? According to the CMS they are going to pay $32 for portables we can not do this now and you expect us to take less. On page 62 of the proposed rule, CMS: "Therefore, we are proposing that unless an exception applies, the supplier that furnishes oxygen equipment or a capped rental item for the first month of the statutorily prescribed rental period must continue to furnish the oxygen equipment or the capped rental item for as long as the equipment remains medically necessary, up to and includingthe last month for which a rental payment is made by Medicare." Exceptions noted on pg 63. Comment: A provider in the new area will not have a total 36-month time period to collect reimbursement. However, based on the proposal, at 36-months ownership of the oxygen equipment needs to transfer to the beneficiary. If you have two different companies that have provided service for 36-months, whose equipment gets transferrd? As stated abpve. "This proposed exception is consistent with what currently happended when beneficiaries move outside a supplier's service area on either a temporary or permanent basis." This is a true statement, however, a suplier today knows that they will receive reimbursement on an ongoing basis for the use of the equipment and for providing the services required. This limits beneficiary's ability to relocate because they may not be able to find a provider in their new desired locale to provide the necessary equipment. The proposed rule further limits the number of suppliers a beneficiary may choose from. Purposed rule: On pages 90-91 CMS proposes: "We would, however also propose to apply our existing policy of not coverning certain routine maintenance or periodic servicing of purchased equipment, such as testing, cleaning, regulating, changing filters, and general inspection of beneficiary-owned DME that can be done by the beneficiary or caregiver, to beneficiary-owned oxygen equipment and to continue that polciy for beneficiary-owned capped rental equipment. As specified in current program instructions at section 110.2.B of chapter 15 of the Medicare Benefit Policy Manual (Pub 100-02), "the owner [of the equipment] is expected to perform such routine maintenance rather than a retailer of some other person who chrges the beneficiary."Comment: Currently when a beneficiary has a problem with their equipment they call the supplier to come and check the equipment. Once the ownership of the equipment has transfered to the beneficiary, the benficiary will be responsible to pay for any service call that would be related to routine maintenance. You don't call Sears service department to come to your house without paying. It is going to be the same with calling the provider. We can not make a service call for free. To sum up what has been stated here, I will not work for free. Eighteen years ago I recieved $350.00/month to service just the stationary system now you want me to do it for under $200.00 and you are trying to drive the price down. "See Attachment"

CMS-1304-P-56-Attach-1.DOC

#56

Have you ever been called in the middle of the night when a patient with Chronic Obstructive Pulmonary Disease calls because they are having trouble breathing? When you get to the house the humidifier bottle was not on correctly. How about a patient with Asthma calls because they can not get their nebulizer circuit back together due to their arthritis. I have many times. Evidently no one at CMS cares. I ask you to visit some of these patients. See what we see almost daily. Is your memory that short that you do not remember what happened with Home Nursing in the mid 1990's? You just about killed that industry off and that is what you are trying to do with us. Remember without us hospitalizations go up. Without us ER visits will rise and so does Medicare spending. We have been the solution to rising healthcare cost and will continue to be the solution not the problem. If you want the Wal-Mart approach to homecare we can give it. Just remember be careful what you wish for it may come true.

Sincerely,
Anthony Ellis
President of Ellis Home Oxygen and Medical Equipment

Submitter : Mr. Michael Graham **Date:** 09/25/2006

Organization : Gulf Medical Services, Inc.

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

In reference to the 36 month cap on Oxygen Equipment, I feel you are hurting the beneficiary by limiting which provider(s) they may use. Most providers will not accept a new Oxygen patient if they were already using a competitor and are close the the 36 month point. Medical oxygen is a prescribed drug and I feel it is inapproapriate to transfer title of this equipment to a patient. It is well known that high concentrations of oxygen can be damaging to those who do not need it. By transferring title of the equipment to the patient you are in essence giving them the source of a controlled substance. What is to stop the family members from taking the equipment and using the medical Oxygen when the patient passes away? I truely believe the proposed rule is detrimental to the beneficiary. While I agree that the defecit needs to be reduced substantially, the cuts do not need to be made in the area of elderly patient care. These people spent their lives paying taxes and as repayment the government wants the quality of service they receive in their twilight years to be diminished. CMS does not seem to understand the amount of service that goes into Oxygen therapy from a DME provider.

Submitter : **Mr. John Kirkwood** **Date: 09/25/2006**

Organization : **American Lung Association**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-1304-P-58-Attach-1.DOC