Submitter : Mr. Tyler Wilson **Date:** 09/25/2006

Organization : American Association for Homecare

Category : Device Association

Issue Areas/Comments

GENERAL

GENERAL

See attachments (3)

CMS-1304-P-65-Attach-1.DOC

CMS-1304-P-65-Attach-2.DOC

CMS-1304-P-65-Attach-3.DOC

ATTACHMENT 1 TO #65

AMERICAN ASSOCIATION FOR HOMECARE

Via Hand Delivery and Electronic Submission

September 25, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201
http://www.cms.hhs.gov/eRulemaking

Re: 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[2]

Dear Dr. McClellan:

The American Association for Homecare (AAHomecare) submits the following comments in response to the Centers for Medicare and Medicaid Services' (CMS') request for comments on the above captioned proposed rule. AAHomecare is the only national association representing every line of service within the homecare community. AAHomecare members include providers of oxygen equipment and therapy, providers and manufacturers of durable medical equipment (DME), prosthetics, orthotics, and supplies (collectively "DMEPOS") including rehab and assistive technologies, home health agencies, and pharmacies that provide home infusion and inhalation drug therapies to patients in their homes. Our membership reflects a cross-section of the homecare community, including national, regional, and local providers and suppliers. With approximately 800 member companies at 3,000 locations nationwide, AAHomecare and its members are committed to advancing the value of quality health care services at home.

Section 5101 of the Deficit Reduction Act of 2005 (DRA) amends the provisions of the Social Security Act (Act) governing Medicare payment for home oxygen therapy and capped rental DME. Beneficiaries who use home oxygen or rent DME now bear a

[1] Pub. L. 109 -171 (2006).
[2] 71 Fed. Reg. 44082 (August 3, 2006).

greater burden to manage their care and coordinate service and maintenance for their medical equipment. These comments primarily address CMS' implementation of the DRA's transfer of ownership requirement for oxygen equipment.[3] The proposed rule would establish new payment amounts for different classes of oxygen equipment and specify new billing and other requirements that would apply to suppliers furnishing oxygen or capped rental equipment.

We understand the need to examine the current payment methodology for oxygen. The fee schedules result in one payment amount (plus an add-on for portable equipment) for all oxygen equipment regardless of the beneficiary's clinical needs. We remain concerned, however, that the approach in the NPRM compounds the flawed policy codified under the DRA which does not recognize the full array of professional and administrative costs of furnishing oxygen to Medicare beneficiaries. Importantly, our analysis indicates that CMS' proposal to revise payment for oxygen is not budget neutral, contrary to the controlling statute. CMS' goals in implementing the DRA should be to preserve beneficiary choice of oxygen equipment and modality, promote high quality care, and support the continuing development of new oxygen technologies. The proposal in the NPRM does not promote these goals.

We recommend that CMS refine payments for oxygen in a manner that supports increased mobility for patients and continuing innovation in product development. We look forward to working with CMS and other oxygen stakeholders to ensure that these refinements are based on accurate data that reflects the current product and service costs of furnishing oxygen to Medicare beneficiaries. We also strongly urge CMS to "grandfather" beneficiaries currently on oxygen from the implementation of the new policies. This will promote a smooth transition to the new policies for all stakeholders. We address these issues and our concerns about operational impact of the new policy in greater detail below.

I. BACKGROUND

1. Chronic Obstructive Pulmonary Disease is a Chronic, Progressive and Debilitating Disease

Home oxygen is critical to approximately one million Medicare beneficiaries who suffer from respiratory illnesses such as chronic obstructive pulmonary disease (COPD). These beneficiaries require oxygen therapy for their long-term survival and well-being. COPD includes chronic bronchitis and emphysema and has been defined as the physiologic finding of nonreversible impairment of pulmonary function.[4] COPD is the fourth leading cause of death in the world and the only leading cause of death for which both prevalence

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[3] Although the main focus of these comments is on the implementation of the new payment policies for home oxygen, we have a number of concerns about the application of the proposed rule to capped rental DME. We discuss these issues in later sections of these comments.

[4] Centers for Disease Control and Prevention – MMWR Surveillance Summaries, August 2, 2002/Vol. 51/ no. SS-6

and mortality are rising.[5] The clinical course of COPD is characterized by chronic disability with intermittent acute exacerbations that occur more often during the winter months. The World Health Organization has projected that COPD will rank fifth in 2020 as a global burden of disease.[6]

Approximately 15 million Americans have been diagnosed with COPD, and an estimated 15 million more have undiagnosed COPD. COPD costs the U.S. economy over $18 billion a year in direct medical costs and an estimated $11 billion in indirect costs.[7] Although oxygen represents a substantial expenditure for Medicare under the DME benefit, beneficiaries on home oxygen also incur significant expenses for other health care services. COPD is responsible for a significant part of all physician office visits and emergency room (ER) visits and ranks number three (3) in acute hospital admissions among Medicare aged persons. Based on 2001 data from Medicare, over 397,000 patients were discharged from acute care hospitals with a diagnosis of COPD. The average length of stay for a COPD admission is 5.1 days at the rate of $4,000 per day. Medicare payments to hospitals for routine COPD admissions alone exceed $1.5 billion.

The profile of the patient who uses oxygen suggests that these individuals comprise what has been called the "frail elderly." AAHomecare members who serve oxygen patients report that these beneficiaries are likely to live alone and are highly circumscribed in their activities of daily living (ADLs). Recent clinical studies have examined the correlation between the ADLs and patients with severe COPD who are on long-term oxygen therapy. A study last year in *Chest* examined the impact on the ADLs for individuals suffering from one of three long-term chronic conditions, including COPD. [8] The study concluded that, for all the patients in the sample, COPD was associated with a distinctive pattern of disability expressed by loss of selected ADLs. Other studies have shown that of individuals with COPD, those who required long-term oxygen therapy, were less independent in their ADLs than those who did not require oxygen therapy. [9] Earlier studies also confirm that individuals with COPD decline in their cognitive function as their disease progresses. These studies find that: "cognitive decline is faster in the presence of severe bronchial obstruction and parallels the worsening of the affective status in COPD patients on oxygen therapy."[10 11]

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[5] Global Initiative for Chronic Obstructive Lung Disease (GOLD) of the U.S. National Heart, Lung, and Blood Institute and the World Health Organization, Am J Respir Crit Care Med Vol 163. pp 1256- 1276, 2001.

[6] Murray CJ, Lopez AD. Evidence-Based Health Policy—Lessons from the Global Burden of Disease Study. Science. 1 996; 274: 740-743.

[7] Data derived from Moran & Associates estimates from the 2001 MEPS full year consolidated file.

[8] Incalzi RA, et al. Construct Validity of Activities of Daily Living Scale: A Clue to Distinguish the Disabling Effects of COPD and Congestive Heart Failure. *Chest* 2005; 127:830-838

[9] Okubadejo AA, et al. Home assessment of activities of daily living in patients with severe chronic obstructive pulmonary disease on long-term oxygen therapy. *Eur Respir J* 1997;10:1572-1595

[10] Incalzi RA, et al. Predicting cognitive decline in patients with hypoxemic chronic obstructive pulmonary disease. *Respir Med* 198; 92:527-533.

[11] Incalzi RA, et al. Verbal memory impairment in COPD: Its mechanisms and clinical relevance. *Chest* 1997; 112:1506-1513.

Clearly, Medicare payment policies for oxygen will impact a large number of very vulnerable patients. Consequently, we urge CMS to proceed cautiously in establishing new payment methodologies for oxygen. Payment for oxygen must be adequate to support on an ongoing basis the array of professional and administrative services that are necessary to safely furnish oxygen to beneficiaries in their homes. Payment policies also need to preserve beneficiary and physician access to their choice of oxygen modality and technology both before and after title to the oxygen equipment transfers to the beneficiary. Moreover, while spending for home oxygen may be a sizeable portion of overall Medicare spending for DMEPOS, spending for oxygen should not be viewed in isolation. CMS must consider the other health care services and resources that beneficiaries on oxygen consume. Maintaining these patients at home on oxygen is by far more cost effective for the Medicare program than institutional care.

2. Medicare Reimbursement for Home Oxygen Has Declined Sharply Since 1997

Prior to February 8, 2006, Medicare reimbursed for oxygen and oxygen equipment on the basis of a continuous rental. In other words, Medicare would pay for home oxygen therapy as long as a beneficiary met Medicare's coverage criteria. Medicare reimburses home oxygen under fee schedules established by Congress in 1989. The first fee schedule payments were based on supplier charges from 1986. The fee schedules bundled the payment for the oxygen and stationary oxygen equipment and included and add-on fee for portable equipment only (because contents payments were bundled into the payment for the stationary equipment). Consequently, the monthly rental payment for oxygen is a "modality neutral" bundled payment that covers ongoing service and maintenance for the equipment. Fee schedule updates were based on the Consumer Price Index (CPI).

Payment rates for oxygen have been subject to numerous freezes and reductions since the inception of the fee schedules. The largest reduction occurred under the Balanced Budget Act of 1997 (BBA). The BBA cut Medicare reimbursement for oxygen by 25% in 1998 and an additional 5% for 1999. The BBA also permanently froze all CPI updates for home oxygen. With the exception of modest, temporary updates that occurred in 2000 and 2001, the BBA statutory provisions for oxygen preclude any further CPI updates to oxygen payments unless Congress expressly approves them. Congress applied further reductions to oxygen payments under the Medicare Modernization Act of 2003 (MMA). The MMA reduced oxygen payment by an amount equal to the percentage difference in the median reimbursement for oxygen between the Federal Employee Health Benefit (FEHB) program plans and Medicare. The FEHB reductions, which averaged 10% across each durable medical equipment regional carrier (DMERC) region, were effective in 2005.

Congress did not change the fee schedule methodology or explicitly reduce payment for oxygen under the DRA. Instead, §5101 of the DRA limits rental payments for oxygen equipment to a 36 month period of "continuous use," after which ownership of the equipment transfers to the beneficiary. After the conclusion of the period of continuous use, Medicare will pay only for "oxygen" and service and maintenance of oxygen equipment that the Secretary deems "reasonable and necessary." This payment

methodology became effective January 1, 2006 for all Medicare beneficiaries on home oxygen as of December 31, 2005.

Under the NPRM, CMS proposes to establish separate classes and payment for oxygen equipment based on its authority under §1834 (a) (9)(D) which permits the Secretary to depart from the modality neutral methodology so long as the result is "budget neutral."[12] The proposed rule would create separate classes and monthly payment amounts for oxygen generating technologies and separate classes and monthly payment amounts for stationary gaseous and liquid systems that require refills of oxygen contents. To obtain budget neutrality, CMS would offset payment increases for these classes with a reduction in the monthly payment for concentrators.

II. COMMENTS

A. CMS Has Not Established Budget Neutrality for the Proposal in the NPRM or Met Minimum Requirements for Notice and Comment Under the Administrative Procedure Act (APA)

1. The Proposed Policy is Not Budget Neutral

As CMS acknowledges, the proposal to tie the monthly payment for oxygen to the equipment technology must be budget neutral.[13] While we understand the need to revisit the current methodology, we are concerned by the lack of data to establish that this proposal is budget neutral. 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.[14] Without this data, stakeholders cannot fully evaluate a proposed rule and assess its impact. CMS has not satisfied the notice and comment requirement under the APA.[15] The lack of adequate data to support CMS' analysis also falls short of the agency's commitment to ensure the quality, utility, objectivity, and integrity of the information it disseminates contrary to the requirements of the Data Quality Act (DQA).[16]

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[12] 42 U.S.C. §1395m (a)(9)(D)(ii), (2006).

[13] 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 result 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.

[14] Motor Vehicle Mfrs. Ass'n. v. State Farm Mutual Insurance Co. 463 U. S. 29 (1983).

[15] Association of Data Processing Serv. Orgs. V. Board of Governors, 745 F.2d 677 (D. C. Cir. 1984); Air Transp. Assn. of Am. V. FAA, 169 F. 3d. 1 (D. C. Cir. 1999).

[16] CMS has an obligation under the DQA to ensure the quality, utility, objectivity, and integrity of the information it disseminates. Under CMS' guidelines, the DQA standards apply to the information in the

Our own shows analysis that the reimbursement methodology announced in the policy is not budget neutral. The Lewin Group examined the proposal on behalf of AAHomecare using different assumptions about the migration of beneficiaries to portable concentrators and transfilling systems. For 2007 alone, Lewin concluded that the policy would result in a ten percent (10%) reduction in payments for oxygen with additional reductions in later years. According to Lewin, if no migration is assumed, the CMS proposal includes an additional $257 million payment reduction over what would otherwise be necessary to achieve budget neutrality. When Lewin assumed a 5% migration, the difference between the CMS proposal and what would be necessary for budget neutrality was approximately $239 million.[17] Lewin concluded that CMS would have to assume that approximately 73 percent of patients would switch to portable concentrators and transfilling systems to achieve budget neutrality.

Clearly, CMS cannot implement the new policy unless it demonstrates that the policy is budget neutral. We encourage CMS to review Lewin's analysis and reevaluate its assumptions to assure that the proposed policy is in fact budget neutral as required under the statute. We believe that Lewin correctly concludes that the CMS proposal includes $239 million more than what would otherwise be necessary to establish budget neutrality. We also request that CMS articulate the factual basis for its conclusions and allow all stakeholders an opportunity to comment on the data.

2. Medicare Payment for Home Oxygen Must Support Beneficiary Access to Portable Oxygen Contents and the Development of New Technologies

Once CMS has revised the new policy to make it budget neutral, we recommend that CMS reallocate the monthly payment amounts for oxygen equipment using the $239 million identified by Lewin. This reallocation should occur in a manner that supports portable oxygen contents as well as the continuing development of new oxygen technologies. AAHomecare has worked collaboratively with the physician and respiratory practitioner community over the past several years. We understand their concerns that patients on oxygen be assured access to the portable equipment of their choice. Promoting increased mobility for oxygen patients is an important clinical objective because active COPD patients have better overall health status and greater ability to participate in ADLs. Beneficiaries and their physicians have numerous choices for portable oxygen equipment today, and Medicare payment policy should preserve those choices.

Current reimbursement is inadequate to support these goals, especially after ownership of the equipment transfers to the beneficiary. The new payment policy is likewise inadequate. The inaccurate reimbursement occurs because CMS has not acknowledged that providers will continue to incur professional and administrative costs after title to the

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proposed rule. We believe that the analysis in the NPRM fails to meet DQA standards. *See* Treasury and General Government Appropriations Act of 2001, Pub. L. No. 106-544, 114 Stat. 2763A-150, 153-154).

[17] Letter from Joan E. DaVanzo, Ph.D, The Lewin Group, to Mr. Tyler Wilson, President and CEO, American Association for Homecare, September 22, 2006 (Lewin study), attached.

equipment transfers. Moreover, CMS lacks the data to evaluate those costs in light of the proposed payment policies. In fact, until CMS has accurate data, all attempts to establish payment policies based on the relative cost of one type of equipment over another will be arbitrary. As we discuss below, the study by Morrison Informatics published by AAHomecare earlier this year, is the only source of current data on the equipment and service costs of furnishing oxygen to Medicare beneficiaries.[18] We encourage CMS to consider the Morrison study when it reconsiders the policy in the NPRM.

3. Equipment Acquisition Costs Constitute less than One-Third of the Total Cost of Furnishing Oxygen to Medicare Beneficiaries

We understand that the DRA dictates the transfer of ownership of oxygen equipment and that CMS' role is to implement the DRA requirements. Nonetheless, we want to emphasize that the policies underlying the DRA are fundamentally flawed and based on a misapprehension of the full range of administrative and support services that are necessary to ensure that Medicare beneficiaries receive safe and effective oxygen therapy in their homes. This misunderstanding is evident in the CMS longstanding position that the oxygen benefit is an equipment benefit only. As a result of this "equipment only" stance, Medicare has never fully acknowledged the array of professional and administrative services, including delivery, education, oversight, and monitoring that are necessary to ensure that that oxygen therapy is administered safely and effectively in the home. Moreover, oxygen is a prescription drug that is regulated by multiple Federal and State agencies, including the Food and Drug Administration (FDA), other Federal agencies such as the Department of Transportation (DOT), and State pharmacy boards. A payment policy that fails to explicitly recognize the professional and administrative costs inherent in furnishing home oxygen results in inaccurate reimbursement and can seriously erode the quality of care that beneficiaries receive.

At least one rationale underlying the DRA is that Medicare rental payments for oxygen equipment are many times over homecare providers' acquisition costs. This reasoning incorrectly assumes that equipment acquisition cost is the only cost inherent in serving these beneficiaries. Morrison Informatics recently completed the most comprehensive analysis to date of the services and costs of furnishing home oxygen to Medicare beneficiaries. Morrison examined the costs of 74 providers who collectively serve more than 600,000 beneficiaries who use oxygen. Morrison concluded that equipment acquisition costs represent only 28% of the total cost of servicing Medicare beneficiaries using home oxygen. Other administrative and support functions necessary to safely deliver oxygen to beneficiaries in their home account for the remaining 72% of providers' costs. These administrative and support costs include obtaining patient information and related documentation, labor related to the initial preparation of the equipment, equipment delivery and set-up, scheduled and unscheduled maintenance and repair, ongoing patient support, delivery costs, and ongoing patient assessment, training, education, and compliance monitoring as well as other necessary operating and overhead

[18] *A Comprehensive Cost Analysis of Medicare Home Oxygen Therapy*, Morrison Informatics, Inc, prepared for the American Association for Homecare, June 27, 2006.

costs.[19] On average, the direct costs of furnishing home oxygen to Medicare beneficiaries breakdown as follows:

Cost Component	Average Cost Per-Patient Per-Month
1. SYSTEM ACQUISITION[20]	$55.81
2. INTAKE AND CUSTOMER SERVICE[21]	$12.66
3. PREPARATION, RETURN, DISPOSABLES, AND SCHEDULED MAINTENANCE[22]	$25.24
4. UNSCHEDULED REPAIRS AND MAINTENANCE[23]	$6.10
5. PATIENT ASSESSMENT, TRAINING, EDUCATION AND MONITORING[24]	$17.54
6. DELIVERY ASSOCIATED WITH PREPARATION, RETURN, DISPOSABLES, AND SCHEDULED MAINTENANCE[25]	$42.26
7. OTHER MONTHLY OPERATING AND OVERHEAD[26]	$41.59
8. TOTAL DIRECT COST BEFORE TAXES	$201.20

In the past there may have been concerns that the cost categories identified by Morrison were not representative of costs incurred by all suppliers serving Medicare beneficiaries. In other words, CMS may have been reluctant to acknowledge the non-equipment professional and administrative services furnished to oxygen beneficiaries out of a concern that not all suppliers adhered to the same standards. This issue was resolved

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[19] Overhead and operating costs accounted for 21% of supplier's total costs. This data were reported to Morrison in the aggregate, so data on specific cost components for this category are not available.

[20] The amount includes acquisition costs for stationary, portable and backup units, conserving devices, ancillary equipment and accessories, and oxygen system contents (liquid and gaseous oxygen).

[21] The amount includes labor associated with patient intake functions, ongoing customer service (patient inquiries, scheduling of deliveries/maintenance/clinical visits, accommodating patient travel plans), and initial and renewal prescription processing.

[22] The amount includes labor associated with equipment preparation (testing, cleaning, and repair), equipment set-up and maintenance upon return, initial patient instruction, cost of disposable and maintenance supplies, and labor costs associated with scheduled preventive equipment maintenance.

[23] The amount includes labor and vehicle costs associated with unscheduled equipment repair and maintenance.

[24] The amount includes labor and travel costs associated with clinical visits by respiratory care practitioner, in-home patient assessments (including home environment safety assessment and oxygen therapy plan of care), training, education and compliance monitoring.

[25] The amount includes delivery costs associated with oxygen fills (liquid and gaseous oxygen), preparation, return, disposables and scheduled maintenance.

[26] The amount includes rent and other facility costs, administration, insurance, legal, regulatory compliance, MIS systems/controls, communications systems, employee training, accreditation, supplies, billing and compliance functions.

when CMS published quality standards for DME providers this year.[27] In addition to business standards that apply to all DMEPOS providers, the new standards contain detailed requirements for patient intake and assessment, equipment selection and maintenance, delivery, patient education, monitoring and follow-up that apply specifically to oxygen suppliers.

Providers who furnish oxygen to Medicare beneficiaries will be required to demonstrate that they comply with these standards in order to bill the Medicare program. For the first time all providers of home oxygen to Medicare beneficiaries will be required to meet the same standards and receive accreditation to document their compliance with the standards. Importantly, the new quality standards confirm that the cost categories reported in the Morrison study are legitimate costs that should be recognized in the Medicare payment for home oxygen. The Medicare program recognizes the cost of complying with quality standards and accreditation for providers and suppliers in other settings. Failing to acknowledge these costs for providers who furnish oxygen would be a disservice to Medicare beneficiaries who rely on this important therapy.

4. CMS Should Delay Implementation of the Payment and Policy Changes Proposed in the NPRM

CMS states that the policies announced in the NPRM will not be effective prior to January 1, 2007. This statement is ambiguous because the DRA period of "continuous use" is already in effect. The proposal in the NPRM should apply prospectively only. The proposed policy should not apply to patients on oxygen in 2006. By "grandfathering" these beneficiaries, CMS would promote a smooth transition to the new payment policies, avoid disruptions in the care of beneficiaries currently on oxygen, and minimize the impact on providers of a pronounced change from current reimbursement levels. This transition would also permit CMS to work with stakeholders to refine the new methodology in a way that accomplishes the goals we identified above. The DRA requires only that title to oxygen equipment transfer to the beneficiary after 36 months of continuous use. It does not require CMS to make any changes to reimbursement for home oxygen. Consequently, it unnecessary for CMS to rush to implement this policy by January 1, 2007. Given the interests that are at stake, all stakeholders would be well served by a delay the payment changes until CMS has current data to adjust the policy.

B. CMS Cannot Require Suppliers to Enter Into Private Supplier Agreements

CMS proposes to require suppliers to notify beneficiaries of their "intentions" regarding whether they will accept assignment for all monthly rental claims for the duration of the rental period before furnishing oxygen or capped rental equipment to the beneficiary. For oxygen e quipment, this provision would require the supplier to notify the beneficiary whether it will accept assignment for all rental claims for the entire 36-month period of continuous use. The proposed regulation would permit suppliers to express their intentions in a written agreement between the supplier and the beneficiary.

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[27] Quality Standards for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, available at: http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/04_new_quality_standards.asp

Medicare contractors are authorized to pay certain Part B claims on the basis of an itemized bill or on an assignment related basis.[28] This requirement is widely understood to permit physicians and suppliers to accept assignment on a claim by claim basis. This understanding of the statute is longstanding and not open to further interpretation. Indeed, CMS acknowledges in the preamble that suppliers may determine whether to accept assignment on a claim by claim basis. There is an exception to this rule for participating physicians and suppliers who determine *on annual basis* whether they will accept assignment of all Medicare claims. Although the participating provider program includes a number of incentives to promote participation, the decision to become a participating provider is voluntary. However, once a supplier agrees to be a participating supplier, the supplier *must* accept assignment of all Medicare claims for that calendar year. Nonparticipating physicians and suppliers may continue to make the assignment decision on a claim by claim basis.

Although CMS has great latitude in implementing regulations to administer the program, those regulations must be consistent with the statutory framework established by Congress.[29] CMS clearly cannot require suppliers to accept assignment of all monthly rental claims throughout the period of continuous use. Such a requirement would contradict the provision of the Act that directs contractors to pay claims on the basis of an itemized bill or on an assignment-related basis. CMS also cannot require suppliers to enter into private assignment agreements such as the ones contemplated by the regulation. The law requires participating supplier agreements to be effective for one year, after which the supplier can elect not to participate. Because the statute permits suppliers to decide *annually* whether they will accept assignment of all Medicare claims, CMS could not require suppliers to make that decision effective for the entire rental period of 13 or 36 months. Otherwise, CMS would effectively change the terms of the participating supplier program established by Congress. CMS has no authority under the Act to require suppliers to enter into agreements that conflict with the statutory framework for the participating provider program. Consequently, we recommend that CMS withdraw this proposal.

C. CMS Must Work with the FDA to Address Compliance Issues for Patient-Owned Equipment

CMS proposes that beneficiaries receive title to both the oxygen cylinder or vessel currently in use by the beneficiary as well as the one being refilled by the supplier. This proposal is unworkable. As a practical matter, the provider cannot keep track of the cylinders or vessels in the manner that the NPRM contemplates so that the beneficiary retains ownership to the same set of cylinders/vessels. Many suppliers do not own the cylinders. As we describe below, they lease them from a commercial gas company that is responsible for filling them. Additionally, some suppliers may process a large volume of containers themselves while others rely on a contractor to perform this function. In either case, tracking the containers by serial number would be unmanageable from an

[28] 42 U.S.C. §1395u(b)(B)(i)(ii) (2006).
[29] 42 U. S. C. §1395hh (2006).

operations perspective. Suppliers also must comply with specific labeling requirements for oxygen containers under FDA and DOT rules. Under the current regulatory framework for oxygen as a medical gas, suppliers are not permitted to label this equipment with the beneficiary's name.

Importantly, the containers and their components are an integral part of the drug delivery system under FDA regulations and guidance.[30] As such, they are subject to detailed cleaning, maintenance and calibration requirements, a number of pre-fill and post-fill inspections and testing, and specific transportation and labeling requirements. These activities must be carried out by qualified individuals and documented in comprehensive records. As a highly regulated medical gas, oxygen has a unique status among drugs, because its container is re-usable.

FDA guidance defines the custody, control, and management of filling liquid containers to be in compliance when the filling company owns the liquid containers and the containers are filled at the company's location or curbside at the patient's home. When the patient owns the liquid containers after 36 months, the company would no longer be able to fill the container without extensive testing prior to filling because the containers would be considered by FDA to be out of the filler's control. In addition, the filling company would no longer be assured the container was maintained in accordance with the manufacturer's specification. Under these circumstances, the medical oxygen provider would be reluctant to assume responsibility for a cylinder or liquid oxygen container that is not under its control.[31]

Similarly, in accordance with DOT regulations,[32] a cylinder filled with a hazardous material may not be offered for transportation unless it was filled by the owner of the cylinder or with the owner's consent. This requires the manufacturer of the medical oxygen, *i.e.*, the company that fills the oxygen container under FDA regulations, to have the equipment owner's permission prior to refilling the container. After the patient owns the oxygen equipment, compliance with this regulation will be very difficult for the provider of medical oxygen in the home, especially if the transfilling is done by a third-party.

Medical oxygen cylinders must also be inspected for the hydrostatic test date as part of the pre-fill inspection requirements. If the cylinder test date has expired, the cylinder can not be filled. The "out-of-test" cylinder must be sent to a company that is certified by the

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[30] See 42 CFR § 210 Subpart E, Control of Components and Drug Product Closures and Containers; Specifically, the FDA defines the container and its components, including the closure, as follows:

> A *container closure system* refers to the sum of packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection to the drug product. A *packaging system* is equivalent to a container closure system.

[31] See Fresh Air 2000 testing and filling requirements for cryogenic home units.

[32] 49 CFR Part 107 173.301 (e), "*Ownership of cylinder.*"

equipment must be repaired or serviced at the provider's facility. Because repairs can take upwards of 30 days, the proposed rule would build in added costs of administration and delivery if the original piece of equipment must be delivered to the patient.

CMS believes this new requirement is necessary to prevent unscrupulous providers from replacing newer equipment with older used equipment before the end of the rental period. CMS can address this issue simply by requiring that the beneficiary receive title to equipment that is of comparable quality to the equipment delivered at the beginning of the period of continuous use. Moreover, with respect to oxygen equipment, the preamble acknowledges that the vast majority of beneficiaries will not require oxygen for the full 36-month period of continuous use. Consequently, for oxygen beneficiaries, there is less concern that providers will use the "bait and switch" practices CMS describes.

b) Replacement of Beneficiary-Owned Equipment

The proposed rule would require providers to replace, at no cost to the patient or the Medicare program, patient-owned equipment if the cumulative total repairs during the useful life of the equipment exceed 60% of the equipment's value and the manufacturer's warranty has expired. Given the five-year useful life of the equipment, the circumstances that would require equipment to be replaced may be so far removed from the date that title transferred that there would be no plausible connection between the provider's actions and a conclusion that the provider delivered substandard equipment. Moreover, the provider will have no control over patient-owned equipment. For example, there will be no record of routine, ongoing service and maintenance, placing the provider in the untenable position of having to replace equipment that may not have been properly maintained. We recommend that responsibility for the equipment shift to the patient once he receives the title.

We also question the rationale underlying this proposal. CMS states that the policy is necessary to prevent providers from offsetting lost revenue from rentals with revenue for repairs. Our members report that reimbursement for repairs is inadequate and requires extensive documentation. Guidelines for processing repair claims also inconsistent. Consequently, we doubt that the providers will adopt a business strategy to offset lost rental income with increased revenue from repairs. We do agree with CMS, however, that there is likely to be an up-tick in the volume of Medicare claims for repairs. As we describe more fully below, CMS can expect the increased volume because most beneficiaries chose to continue renting their equipment in the past.

It is also unclear from the regulatory language, or the preamble, how CMS would determine that the cumulative costs of repairs are 60% of the value of the equipment. We request that CMS explain the methodology it will use to make this determination.

c) Billing for Equipment Repairs

CMS must require the DME Medicare Administrative Contractors (MACs) to issue specific and comprehensive guidance for submitting claims for repairs. Specifically, we

request guidance on the type of documentation that CMS expects providers to obtain to support repair claims. As we discussed above, there is not a high volume of claims for repairs because most beneficiaries have chosen to continue to rent capped rental equipment. For oxygen, equipment repairs have been covered under the monthly fee schedule. As a result, it is reasonable to expect an increase in the volume of claims for repairs for patient owned equipment; however, the increase in volume for repair claims will be the logical consequence of the new policy, not evidence of program abuse. The MAC jurisdictions and CMS must have clear policies outlining when Medicare will pay for repairs and the documentation it will require to support those claims.

Additionally, 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. For example, the following chart includes a partial list of parts that are not identified by HCPCS codes:

Hospital Beds	**Nebulizers**	**Patients Lifts**	**Concentrator**	**Liquid Oxygen Reservoirs**
Pendant control	Tubing adapter	Hydraulic cylinder	Filter, inlet	Regulator
Motor assembly	Case	Seal kit	Filter, cabinet	Primary relief valve
Drive shaft	Power cord	Hydraulic fluid	Filter, bacterial	Secondary relief valve
Junction box		Base spreader kit	Outlet nipple	Condensing coils
Frame with spring, head and foot sections		Caster wheels	Sieve bed	Flow control valve
Power cord			Regulator	Contents indicator
			Flow meter	Cryogenic vessel
			Compressor	Vent valve
			Valve , 4 way	Economizer valve
			Control board	Cover Assembly
			Product tank	
			Power cord	

d) Payment for Routine and Non-Routine Maintenance

CMS is proposing to pay for maintenance and service for beneficiary-owned capped rental DME and oxygen equipment. 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."

CMS should not assume that all beneficiaries will be able to perform routine maintenance and service on their equipment. There are beneficiaries, especially the frail elderly, who will be unable to perform these tasks. As a result, CMS must ensure that beneficiary-owned can be maintained in good working order. We recommend that CMS establish codes to 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 that fee schedules are established that appropriately account for all parts and services incurred in providing the maintenance and service for patient owned capped rental and oxygen equipment.

e) Payment for Ongoing Services

It is very important for CMS to include an ongoing service and maintenance fee to cover emergency services, respiratory practitioner evaluations, on-call availability, and after hours troubleshooting for patient-owned oxygen equipment. Providers currently furnish these services under the monthly payment amount for oxygen. These services were documented in the Morrison study and are a critical component of safely furnishing oxygen in the home. When the monthly rental payments end, there will be no additional payment for these important support services.

We urge CMS to not take the position that these are noncovered services therefore placing the burden of paying for them on beneficiaries. Some, if not most, beneficiaries will elect not to pay for the services, placing these beneficiaries at risk and creating a two tiered system of care. Moreover, to the extent that the new supplier standards recognize that these services should be the standard of care for Medicare beneficiaries, Medicare payment policies should recognize them for patient owned equipment as well.

2. CMS Must Clarify How It will Determine the Period of Continuous Use

a) Application of Break-In-Service Rules

Consistent with the requirements of the DRA, the NPRM designates a 36-month period of continuous use for oxygen equipment and a 13-month period for capped rental equipment. We have numerous concerns with respect to how CMS would determine the period of continuous use for oxygen equipment. These concerns relate to the application of the break-in-service rules, replacement of equipment that is lost stolen or irreparably damaged, and the impact of these new rules on beneficiaries who move or travel. Specifically, with respect to the break-in-service rules, the proposed rule is silent on how a break-in-service affects the calculation of the period of continuous use.

There are a number of situations where a beneficiary may have a short term need for oxygen. CMS coverage policy identifies these patients as falling within the Group II coverage criteria. These patients may not be sufficiently hypoxemic to require ongoing oxygen therapy, although eventually they will need oxygen on a continuous basis. Their short-term oxygen use should not be included in the 36-month rental period when they subsequently resume oxygen therapy. Similarly, there are other breaks-in-service that

should not count towards the period of continuous use. These include skilled nursing facility (SNF) stays or acute care admissions any longer than a month. Because suppliers do not have access to the common working file (CWF), they do not know in advance of these admissions. Often, providers learn of these admissions a year or more after the fact when the DME MAC identifies an overpayment. Current Medicare program rules identify that a break-in-service of 60 days or more supported by appropriate documentation, will not count toward the capped-rental period. We believe that there is no basis for CMS to apply different break-in-service rules to oxygen. We recommend that CMS explicitly clarify this issue in the final rule.

These scenarios also underscore important related issues. The first is that CMS must move towards an audit process that is reasonably contemporaneous with the period of continuous use so that suppliers are not subject to overpayments long after title to the equipment transferred. The second is that suppliers should have access to the CWF in order to effectively administer their obligations under the DRA.

b) Equipment that is Lost, Stolen, or Irreparably Damaged

Under the proposed regulations, a new period of continuous use would begin when beneficiary-owned equipment is lost, stolen, or irreparably damaged. While we agree that this provision is necessary to ensure that beneficiaries have access to medically needed equipment, we question CMS' decision to apply this exception only to beneficiary-owned equipment. When equipment is lost, stolen, or irreparably damaged during the period of continuous use and a provider furnishes replacement equipment, a new period of continuous should begin. Otherwise, the regulation would impose a patently unfair result when rented equipment is lost or damaged through no fault of the supplier.

For example, if an expensive item like a portable concentrator is lost or stolen in the 30th rental month and the provider replaces it, the provider would in effect have to transfer title to two devices, but receive payment only for one. Under the former continuous-rental methodology for oxygen equipment, providers typically replaced lost, stolen, or irreparably damaged equipment because the provider retained title to the asset which could be used for future rentals. There is no similar rationale that would support requiring the provider to provide a beneficiary with replacement equipment during the rental period under circumstances where the provider is not responsible for the events that precipitated the need to replace the equipment.

CMS may have limited this provision to beneficiary-owned equipment out of a misplaced concern that providers would submit claims for lost, stolen, or irreparably damaged equipment simply to circumvent the DRA requirements. If this is the case, CMS should at least allow the DME MACs to make the determination whether to initiate a new period of continuous use on a case-by-case basis. This would ensure a more balanced application of the requirement to transfer equipment ownership to beneficiaries.

c) Beneficiaries Who Travel or Move Outside the Provider's Service Area

We also have questions on how the transfer of title provisions would apply to oxygen patients who travel for extended periods and beneficiaries who move out of the provider's area during the period of continuous use. The proposed regulations state that a new period of continuous use does not begin when the beneficiary changes providers. The impact of this provision will be to limit access for beneficiaries who relocate during the rental period. We recommend that CMS address this issue by permitting a new period of continuous use to begin.

Similarly, CMS should clarify which provider's equipment transfers to the beneficiary if the beneficiary has two residences with a local provider in each area. Beneficiaries who are "snow birds," or who may move or relocate during the period of continuous need will face hurdles in maintaining access to equipment, unless a new period of continuous begins when they change suppliers. Extended travel outside of the provider's service area should not be counted toward the period of continuous use to the extent the provider is not paid for oxygen during that period.

3. Backup Oxygen Equipment

The NPRM does not address backup oxygen equipment. Many beneficiaries have backup equipment solely for use in an emergency such as a power outage. AAHomecare believes that title to backup equipment does not transfer under the coverage rules established by the oxygen LCD. The LCD states that backup equipment is noncovered because it is provided solely for the convenience of the beneficiary. To the extent that CMS has not made any rental payments for the backup equipment, title to the equipment should not transfer to the beneficiary. We request that the final rule explicitly clarify this issue.

4. Title to Equipment Should not Transfer Unless all Beneficiary Copays and Deductibles have Been Paid

The DRA requires that title to oxygen and capped rental equipment transfer to the beneficiary at the conclusion of the period of continuous use. Title to equipment should not transfer to the beneficiary unless all outstanding copay and deductible amounts have been paid. Under the framework established by Congress, Medicare beneficiaries share in the cost of their care under Part B. The Medicare program pays for 80% of the fee schedule amount for oxygen and capped rental equipment and the beneficiary pays the remaining 20% co-payment plus a deductible.[34] The application of the DRA transfer of title provisions to this statutory reimbursement framework suggest that the beneficiary must pay any outstanding copay and deductible amounts before receiving title to equipment. Any other conclusion would clearly be contrary to common sense and the payment scheme devised by Congress. Moreover, transferring title of equipment to beneficiaries before they have met their financial obligations under Medicare program

[34] 42 U.S.C. §1395m(a)(1) (2006).

rules amounts to a de facto waiver of copays and deductibles in violation of the beneficiary inducement statute.[35] Once a beneficiary receives title to equipment, he will have little incentive to pay any outstanding balance. Consequently, we request that the final rule state that the beneficiary must have paid all outstanding copay and deductible amounts before receiving title to equipment.

III. CONCLUSION

We very much appreciate the opportunity to submit these comments. As we stated above, CMS must address the lack of budget neutrality in its methodology and publish all the data and assumptions it uses in this analysis. We strongly recommend that CMS apply any additional monies available after it has accounted for budget neutrality to increase monthly payment amounts for portable oxygen contents and support the continuing development of new technologies. CMS should delay the implementation of the new payment policies by grandfathering beneficiaries already receiving oxygen. This allows a smooth transition to the new policies as we described above. We also request that CMS clarify the operational issues in the manner we recommended above.

AAHomecare remains available to meet with you to discuss our recommendations in further detail. Please feel free to contact me if you have questions or if I can be of assistance in any way.

Sincerely,

Tyler J. Wilson
President and CEO

CC: Herb Kuhn
Joel Kaiser
Laurence Wilson

Enclosures: 1. Morrison Informatics study
2. Lewin letter

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[35] 42 U. S. C. §1320a -7b (2006). ___.

ATTACHMENT 2 TO #6

Morrison Informatics, Inc.

STRATEGIC DIRECTION THROUGH INFORMATION MANAGEMENT

A Comprehensive Cost Analysis of Medicare Home Oxygen Therapy

A Study for the American Association for Homecare

June 27, 2006

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A Comprehensive Cost Analysis of Medicare Home Oxygen Therapy
A Study for the American Association for Homecare

Executive Summary

A national study of the costs and resources required for providing home oxygen therapy for Medicare beneficiaries was conducted for the American Association for Homecare. Seventy-four (74) oxygen services providers delivering services to more than 1.7 million Medicare beneficiaries and more than 600,000 beneficiaries receiving medical oxygen at home, completed a detailed survey, which identified the costs and resources used in providing oxygen services. Survey findings demonstrated that oxygen systems (equipment) alone represent only 28 percent of the cost of providing medically necessary oxygen to Medicare beneficiaries. Oxygen therapy in the home also requires preparing and delivering equipment, delivering supplies and maintenance of oxygen equipment, assessing, training and educating patients, obtaining required medical documentation and providing customer service for beneficiaries, other related services, and operating and overhead costs, which taken together represent 72 percent of the cost of home oxygen therapy for Medicare beneficiaries. These services are essential components of providing oxygen therapy to the more than 1 million Medicare beneficiaries who rely on this treatment.

Introduction

The total costs of services for providing medical oxygen therapy in the home have not been well documented; however, it is known that multiple items contribute to these costs. In addition to the cost of equipment, the cost of providing oxygen therapy to homecare patients includes costs such as patient intake, preparation and delivery, scheduled and unscheduled maintenance, patient

assessment, training and education, ongoing patient support, including costs associated with oxygen fills, disposable supply items and delivery, related services and compliance with Federal and State regulations, including Food and Drug Administration (FDA) and Department of Transportation (DOT) requirements. Limited documentation of these components and their costs has led to misunderstanding by policymakers about the resources required to provide home oxygen equipment and services for Medicare beneficiaries.

A clear understanding of the costs for home oxygen therapy is particularly important because of policy changes made by the Deficit Reduction Act of 2005 (DRA), which changed the method of reimbursement for home oxygen under the Medicare program. The DRA requires that patients take ownership of home oxygen equipment after 36 months of rental. The changes assume that the ongoing costs of services required for home oxygen therapy are low and can be essentially disregarded in determining Medicare reimbursement. The DRA changes also assume that the overseeing of key services required for home oxygen therapy can in some manner become the responsibility of home oxygen patients, who require oxygen therapy for such illnesses as chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), respiratory failure, ALS and other serious diseases.

In order to more completely document the costs for providing home oxygen to Medicare beneficiaries, the American Association for Homecare (AAHomecare) commissioned a study by Morrison Informatics, Inc. (MII), to determine the costs of providing oxygen to Medicare homecare patients. MII conducted a national survey of provider members of AAHomecare to collect comprehensive financial and resource use data associated with providing home oxygen to Medicare beneficiaries. The survey captured detailed activity-based cost data from providers

representing more than 600,000 Medicare home oxygen beneficiaries, or approximately 60% of the estimated 1 million total Medicare population receiving such services.

Methods

The *Homecare Oxygen Service Provision Survey* was developed and sent in March 2006 to members of AAHomecare, an organization that includes homecare providers of all sizes operating in all 50 states. The survey contains detailed questions on the costs and resources for providing oxygen to Medicare homecare patients for the most current year-to-date time period available (Appendix A). Major cost categories contained in the survey include: total oxygen system cost; patient intake, obtaining required medical documentation and providing customer service for beneficiaries; preparation and return processing of equipment; equipment delivery, set-up and instructions for the patient; scheduled and unscheduled delivery and equipment maintenance; maintenance supplies and disposables; patient assessment and compliance monitoring; and other operating and overhead costs. The survey collected data on the average time, materials and cost for each survey item within a category for providing home oxygen and oxygen equipment to home oxygen patients for each homecare provider. Detailed explanations of each survey question are contained in the survey (Appendix A).

Home Oxygen Provision Survey Results

1. Survey Participants

A total of 78 provider organizations completed the survey; 74 usable surveys were obtained (four surveys were not usable because of missing data). The 74 completed surveys represent results from providers serving 1.7 million Medicare beneficiaries, of whom 600,000 receive oxygen equipment. This represents a substantial proportion of all Medicare beneficiaries receiving home

oxygen equipment. Providers responding to the survey provide services to an average of 24,000 Medicare beneficiaries per year and an average of 8,000 oxygen equipment Medicare beneficiaries per year (Table 1).

Table 1: Organizations Responding to the Oxygen Service Provision Survey

Total number of provider organizations responding to survey	74
Total number of Medicare beneficiaries YTD serviced by providers	1,750,723
Total number of oxygen equipment Medicare beneficiaries YTD by providers	607,484
Average number of Medicare beneficiaries YTD per company	23,982
Average number of oxygen equipment Medicare beneficiaries YTD per company	8,209

2. Survey Results

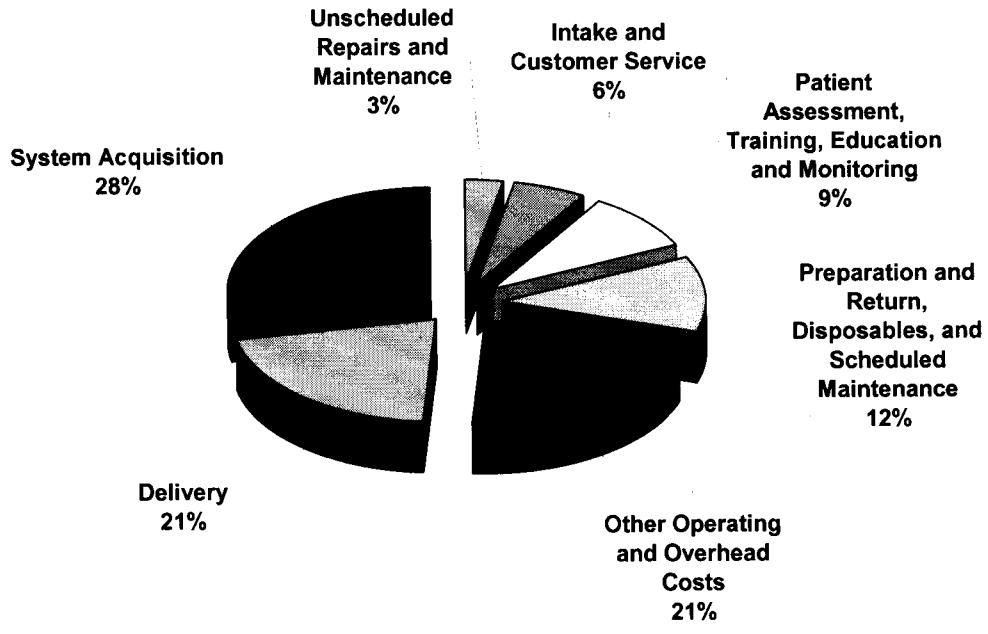
The overall average per-patient, per-month cost and resource use data from each survey item can be found in Appendix B. In addition to total oxygen equipment costs, including stationary, portable and backup unit costs, the major cost components of providing oxygen to patients at home include: the cost of obtaining patient information and related medical documentation necessary for patient intake; labor related to initial preparation of equipment; equipment delivery and set-up time; costs associated with scheduled and unscheduled maintenance and repair; ongoing patient support, including costs associated with oxygen fills, disposable supply items and delivery; vehicle costs associated with deliveries, maintenance and other in-home patient support services; costs of ongoing patient assessment, training, education and compliance monitoring; and other necessary operating and overhead costs. The average provider cost of each major cost component is shown in Table 2 and the relative proportional contribution of each major cost component to the total direct cost is shown in Figure 1.

Table 2: Overall per-Patient per-Month Costs for Major Cost Components of Home Oxygen Provision

Cost Component	Average Cost Per-Patient Per-Month
1. SYSTEM ACQUISITION[1]	$55.81
2. INTAKE AND CUSTOMER SERVICE[2]	$12.66
3. PREPARATION, RETURN, DISPOSABLES, AND SCHEDULED MAINTENANCE[3]	$25.24
4. UNSCHEDULED REPAIRS AND MAINTENANCE[4]	$6.10
5. PATIENT ASSESSMENT, TRAINING, EDUCATION AND MONITORING[5]	$17.54
6. DELIVERY ASSOCIATED WITH PREPARATION, RETURN, DISPOSABLES, AND SCHEDULED MAINTENANCE[6]	$42.26
7. OTHER MONTHLY OPERATING AND OVERHEAD[7]	$41.59
8. TOTAL DIRECT COST BEFORE TAXES	$201.20

[1] The amount includes acquisition costs for stationary, portable and backup units, conserving devices, ancillary equipment and accessories, and oxygen system contents (liquid and gaseous oxygen).
[2] The amount includes labor associated with patient intake functions, ongoing customer service (patient inquiries, scheduling of deliveries/maintenance/clinical visits, accommodating patient travel plans), and initial and renewal prescription processing.
[3] The amount includes labor associated with equipment preparation (testing, cleaning, and repair), equipment set-up and maintenance upon return, initial patient instruction, cost of disposable and maintenance supplies, and labor costs associated with scheduled preventive equipment maintenance.
[4] The amount includes labor and vehicle costs associated with unscheduled equipment repair and maintenance.
[5] The amount includes labor and travel costs associated with clinical visits by respiratory care practitioner, in-home patient assessments (including home environment safety assessment and oxygen therapy plan of care), training, education and compliance monitoring.
[6] The amount includes delivery costs associated with oxygen fills (liquid and gaseous oxygen), preparation, return, disposables and scheduled maintenance.
[7] The amount includes rent and other facility costs, administration, insurance, legal, regulatory compliance, MIS systems/controls, communications systems, employee training, accreditation, supplies, billing and compliance functions.

Figure 1: Home Oxygen Services Cost Component Proportions



3. Discussion

The purpose of this study was to determine, for homecare providers, the relative cost of the components of providing home oxygen to Medicare beneficiaries. The *Homecare Oxygen Service Provision Survey* did not collect data on specific components of *other operating and overhead* costs, which contributed a large proportion (21%) of the total cost of providing home oxygen. The components of *other operating and overhead* costs include costs associated with rent and other facility costs, administration, insurance, legal, regulatory compliance, MIS systems/controls, communications systems, employee training, accreditation, supplies, and billing and compliance functions. Because the values for other operating and overhead costs reported by the survey respondents were collected on an aggregate basis, further study of these

components will be necessary to better understand the nature of these expenses. The reported provider average total cost of providing oxygen, oxygen equipment and services, per patient is $201.20 per month.

The costs of providing oxygen and oxygen equipment for Medicare beneficiaries consist of multiple components, including ***total oxygen equipment costs, patient intake and obtaining required medical documentation and providing customer service for beneficiaries, preparation and return processing of equipment, equipment delivery, set-up and instruction of the patient, scheduled and unscheduled delivery and equipment maintenance, maintenance supplies, disposables and deliveries, patient assessment and compliance monitoring, and other operating and overhead costs***. The cost of oxygen equipment represents only 28 percent of the total cost of providing oxygen to Medicare beneficiaries. Many, if not most, of the other costs of providing home oxygen have not been carefully documented and recognized by policymakers, and have been assumed to be low and easily obtained when providing home oxygen services. Data from the *Homecare Oxygen Service Provision Survey* demonstrate that providing homecare oxygen requires multiple interdependent tasks which are essential to assure continuous and consistent oxygen services for Medicare beneficiaries. These required tasks are performed by providers to assure adequate oxygen services for Medicare beneficiaries. It is not clear how these services would be performed for beneficiaries if Medicare coverage of the required services were not provided.

Conclusions

A national study of the costs and resources required for providing home oxygen therapy for Medicare beneficiaries was conducted for the American Association for Homecare. Seventy-

four (74) oxygen services providers delivering services to more than 1.7 million Medicare beneficiaries and more than 600,000 beneficiaries receiving medical oxygen at home, completed a detailed survey, which identified the costs and resources used in providing oxygen services. Survey findings demonstrated that oxygen systems (equipment) alone represented only 28 percent of the cost of providing medically necessary oxygen to Medicare beneficiaries. Oxygen therapy in the home also requires preparing and delivering equipment, delivering supplies and maintenance of oxygen equipment, assessing, training and educating patients, obtaining required medical documentation and providing customer service for beneficiaries, other related services, and operating and overhead costs, which taken together represent 72 percent of the cost of home oxygen therapy for Medicare beneficiaries. These services are essential components of providing oxygen therapy to the more than 1 million Medicare beneficiaries who rely on this treatment. Further reductions in Medicare reimbursement for home oxygen as a result of the 36-month cap, the CPI freeze and the effects of competitive bidding will be problematic for home care providers and may jeopardize the quality of home care oxygen services given to Medicare beneficiaries.

Appendix A: Oxygen Service Provision Survey Items

1. The total number of Medicare beneficiaries served during the most recent one-year period
2. The total number of Medicare oxygen equipment beneficiaries during the most recent one-year period

A. EQUIPMENT ACQUISITION (Stationary, Back-up and Portable Equipment)

1. Stationary system average acquisition cost
2. Home back-up unit average cost (cylinder, stand, regulator, flow meter)
3. Portable system average acquisition cost, including conserving devices
4. Equipment salvage / trade-in average value for stationary and portable
5. Total equipment average acquisition cost
   ***** A1 + A2 + A3 - A4 *****
6. Average useful equipment life in months
7. Average monthly equipment acquisition cost
   ***** A5 / A6 *****
8. Total oxygen contents average cost per month, all systems
9. Average cost of debt %
10. Average monthly financing charge - equipment acquisition
    ***** (A1+A2+A3-A4) x A9 / 12 *****
11. Average monthly acquisition cost of system
    ***** A7 + A8 + A10 *****
12. Average number of stationary systems required in stock
    to support every 10 units in the field
13. *TOTAL SYSTEM AVERAGE COST PER MONTH*
    ***** *A11+ (A7 + A10) x (A12 / 10)* *****

B. CUSTOMER SERVICE AND PATIENT INTAKE

1. Estimated annual intake time per patient, in minutes (Complete ***Patient Intake Worksheet***)
2. Ongoing customer service time, in minutes, per patient per month
   (patient inquiries, scheduling of deliveries/maintenance/
   clinical visits, accommodating patient travel plans, etc.)
3. Annual prescription renewal preparation and processing time, in minutes per patient
4. Labor cost per hour - Customer Service Representative
   a. Average hourly wage rate
   b. Fringe benefits as a % of wage rate
   c. *Labor cost per hour*
   ***** B4a x (1+ B4b) *****
5. *AVERAGE TOTAL MONTHLY COST OF INTAKE AND CUSTOMER SERVICE PER PATIENT*
   ***** ((B2 + (B1 + B3)/12) / 60) x B4c *****

C. PREPARATION BEFORE DELIVERY

1. Average labor amount per unit (teardown, testing, cleaning, reassembly, bagging, boxing, loading), in minutes
2. Repair labor necessary as a result of problems encountered during pre-delivery preparation:
   a. Percentage of units requiring repair
   b. Average labor amount per unit (diagnosis and repair), in minutes
   c. Average repeat preparation labor amount per unit (testing, cleaning, etc,), in minutes
   d. Total weighted average repair labor per unit, in minutes

   ***** (C2b + C2c) x C2a *****
3. *Total weighted average preparation and repair labor per unit, in minutes*

   ***** C1 + C2d *****
4. Labor cost per hour - Equipment Technician
   a. Average wage rate
   b. Fringe benefits as a % of wage rate
   c. *Average labor cost per hour*

   ***** C4a x (1+ C4b) *****
5. *AVERAGE TOTAL COST OF PREPARATION PER UNIT*

   ***** (C4c / 60) x C3 *****

D. VEHICLE COST PER MILE

1. Acquisition and repair cost:
   a. Average vehicle acquisition cost per month (fully outfitted) - lease
   b. Average maintenance & repair cost per vehicle per year
   c. Average insurance & registration cost per vehicle per year
   d. Average odometer miles per vehicle per year
   e. Average vehicle acquisition, maintenance & repair cost per mile

   ***** ((D1a x 12) + (D1b + D1c)) / D1d *****
2. Gasoline cost per mile:
   a. Average miles per gallon
   b. Average gasoline cost per gallon
   c. Average gasoline cost per mile

   ***** D2b / D2a *****
3. *TOTAL VEHICLE COST PER MILE*

   ***** D1f + D2c *****

E. DELIVERY / SETUP / PICKUP COST

1. Average round trip travel time, in minutes
2. Average in-home setup time, in minutes
3. Average in-home client instruction time (Complete Patient Education Worksheet)
4. Average in-home pickup time, in minutes
5. a. Average service technician wage rate per hour
   b. Fringe benefits as a % of wage rate
6. Labor cost - delivery, setup, pickup

   ***** (E1 x 2 + E2 + E3 + E4) x (E5a x (1+E5b)) / 60
7. Average round trip miles
8. Average vehicle cost - delivery, setup, pickup

   ***** E7 x D3 *****
9. TOTAL AVERAGE DELIVERY / SETUP / PICKUP COST PER PATIENT

   ***** E6 + E8 *****

F. EQUIPMENT MAINTENANCE UPON RETURN

1. Average labor amount (preparation plus filter change), in minutes
2. Repair labor necessary as a result of problems encountered during pre-delivery preparation:
   a. Percentage of units requiring repair upon return
   b. Average labor amount per unit (diagnosis, repair), in minutes
   c. Average repeat preparation labor amount per unit (testing, cleaning, etc,), in minutes
   d. Total weighted average repair labor per unit, in minutes

   ***** (F2b + F2c) x F2a *****
   e. Total weighted average preparation and repair labor per unit, in minutes

   ***** F1 + F2d *****
3. Average wage rate, including fringe benefits
4. AVERAGE TOTAL COST OF MAINTENANCE PER UNIT UPON RETURN

   ***** F3 / 60 x F2e *****

G. AVERAGE MONTHLY COST TO PREPARE, DELIVER AND RETURN

1. Average total cost for delivery and return

   ***** C5 + E9 + F4 *****
2. Average number of months in service, per patient
3. AVERAGE MONTHLY COST TO PREPARE, DELIVER AND RETURN

   ***** G1 / G2 *****

H. ROUTINE, IN-HOME DELIVERY, DISPOSABLE AND SCHEDULED MAINTENANCE COSTS

1. Maintenance Supplies:
   - a. Gross particle filters
     - Quantity used per year
     - Price, each
   - b. Pre-felt filters
     - Quantity used per year
     - Price, each
   - c. Hepa filters
     - Quantity used per year
     - Price, each
   - d. Intake filters
     - Quantity used per year
     - Price, each
   - e. *Average monthly maintenance supplies cost*

     ***** (Sum 1a thru 1d) / 12 *****
2. Disposable Supplies:
   - a. Humidifier bottles
     - Quantity used per month
     - Price, each
   - b. Tubing
     - Quantity used per month
     - Price, each
   - c. Tubing Connectors
     - Quantity used per month
     - Price, each
   - d. Nasal Cannulas
     - Quantity used per month
     - Price, each
   - e. *Average monthly disposable supplies cost*

     ***** (Sum 1a thru 1d Totals) *****
3. Routine, in-home delivery and scheduled maintenance labor and vehicle costs:
   - a. Average vehicle cost per mile ***** D3 *****
   - b. Average round trip miles ***** E7 *****
   - c. Average round trip travel time, in minutes ***** E1 *****
   - d. Average time to perform scheduled/preventive equipment maintenance, in minutes ***** C2c *****

     {including filter cleaning/replacement, oxygen purity testing, alarm battery testing, PSI check on back-up unit, liter flow compliance with Rx, and in-home repair of unit}
   - e. Average time to perform gaseous and/or liquid fills, in minutes ***** C2c *****
   - f. Service Technician wage rate per hour plus fringes ***** E5a x (1+E5b) *****
   - g. Number of scheduled/preventive equipment maintenance visits per year
   - h. Number of oxygen contents delivery visits per year (including gaseous and/or liquid fills)
   - *i.* *Average monthly routine maintenance labor and vehicle cost*

     ** (H3a x H3b + (H3c/60 x H3f) x ((H3g + H3h) - H3g) / 12 + ((H3d / 60) x H3f x H3g) / 12 + ((H3e / 60) x H3f x H3h) / 12 **

     Note: Formula assumes that preventive maintenance visit occurs simultaneously with a delivery of oxygen fills
4. *AVERAGE TOTAL MONTHLY ROUTINE DISP AND SCHEDULED MAINT COSTS PER PATIENT*

   ***** H1 + H2 + H3 *****

I. COST OF UNSCHEDULED MAINTENANCE

1. Average vehicle cost, round trip ***** D3 x E6 *****
2. Service Technician labor cost per hour ***** E1 x H3e *****
3. Repair / Maintenance labor cost ***** F2b x F4 / 60 *****
4. Average # of calls per month per 10 units in service
5. Vehicle and delivery cost per unit per month
   ***** (I1 + I2 + I3) x (I4 /10) *****

J. COST OF PATIENT ASSESSMENT

1. Average number of clinical visits per year by RCP
2. Average round trip travel time, in minutes
3. Average in-home patient assessment time per visit, in minutes
   - Include time for home environment safety assessment - storage and maintenance
   - Include time for home environment safety assessment - administration
   - Include time for development of oxygen and equipment in-home care plan
4. Average in-home follow up and compliance monitoring time per visit, in minutes
   - Include weekly calls to patients to determine requirement for portable oxygen
   - Include compliance monitoring conducted in the home at least once per month
   - Include time for contacting physician whenever there is a question about the oxygen order or a change in patient status or care plan
5. a. Average RCP wage rate per hour, excluding benefits
   b. Fringe benefits as a % of wage rate
6. Average vehicle reimbursement per visit for RCP (at federal rate per mile of $0.445)
7. AVERAGE TOTAL COST OF PATIENT ASSESSMENT PER PATIENT PER MONTH
   ***** ((J2 + J3 + J4) x ((J5a x (1 + J5b)) / 60) +J6) x (J1 / 12) *****

K. TOTAL MONTHLY DIRECT COST BEFORE OVERHEAD AND PROFIT

***** A13 + B5 + G3 + H5 + I5 + J7 *****

L. OVERHEAD COSTS

1. Overhead Factor - Overhead costs as a % of Direct Costs
   {Rent, Facility, Administration, Insurance, Legal, MIS Systems/Controls, Regulatory Compliance, Communications Systems, Training, Accreditation, Supplies, Billing and Reimbursement Functions}
2. Estimated average monthly overhead cost per patient

M. TOTAL MONTHLY COST

***** K + L2 *****

N. PROFIT SUMMARY

1 Average Medicare Reimbursement per patient - Stationary and Portable Oxygen
2. Less: Write-offs, Hardships, etc. (%)
3. Net Reimbursement per patient per month **** N1 + N2 ****
4. Less: Average Total Costs to Supplier Per Patient
5. Average Net Profit Per Patient Before Taxes **** N3 + N4 ****

O. Net Profit Margin Before Taxes

***** N5 / N1 *****

PATIENT INTAKE (Minutes per-patient per year)

A. Verification of beneficiary eligibility, claims management, and claims submission

B. Collect and record physician information

C. Receive, document and process order for oxygen and oxygen equipment

D. Verification of the following:

1 Patient demographic information

2. Patient possession of a valid Medicare number

3. Patient emergency contact information

4. Caregiver and/or conservator information

5. Secondary insurance information

6. Qualifying diagnosis

7. Estimated total time for verification per year per patient

**** D1 + D2 + D3 + D4 + D5 + D6 ****

E. Input patient data in computer at service center

F. Schedule delivery

G. Contact physician to verify order, demographic information and license number

H. Verify physician UPIN with independent database

I. Coordinate or verify the existence of independent blood oxygen saturation study or ABG test

J. Obtain physician-signed certificate of medical necessity (CMN)

K. *Average estimated annual total intake time per patient*

**** *A + B + C + D7 + E + F + G + H + I + J + K* ****

PATIENT EDUCATION (Minutes per-patient per episode)

A. Supplier required training of patient and caregiver

B. Contracted interpreter services, if applicable

C. Patient and/or caregiver instruction in assembly and operation of oxygen and equipment

D. Oxygen safety training

E. Patient and/or caregiver training on "troubleshooting" possible equipment problems

F. Patient and/or caregiver instruction on proper infection control in the home

G. Patient and/or caregiver instruction on safe handling and storage of medications

H. *Average total intake time per patient*

**** *A + B + C + D + E + F + G* ****

Appendix B: Overall per Patient per Month Costs for Home Oxygen Providers

Survey Item	Average
A1.Stationary system average acquisition cost	$706.23
A2.Home back-up unit average cost (cylinder, stand, regulator, flow meter)	$152.32
A3.Portable system average acquisition cost, including conserving devices	$471.09
A4.Equipment salvage / trade-in average value for stationary and portable	$40.11
A5.Total equipment average acquisition cost	$1,288.63
A6.Average useful equipment life in months	60.44
A7.Average monthly equipment acquisition cost	$23.23
A8.Total oxygen contents average cost per month, all systems	$17.77
A9.Average cost of debt %	0.07
A10.Average monthly financing charge - equipment acquisition	$7.76
A11.Average monthly acquisition cost of system	$48.76
A12.Average number of stationary systems required in stock to support every 10 units in the field	2.53
A13.TOTAL SYSTEM AVERAGE COST PER MONTH	$55.81
B1. Estimated annual intake time per patient, in minutes (From the Patient Intake Worksheet)	166.36
B2. Ongoing customer service time, in minutes, per patient per month (patient inquiries, scheduling of deliveries/maintenance/ clinical visits, accommodating patient travel plans, etc.)	28.73
B3. Annual prescription renewal preparation and processing time, in minutes	43.07
B4a. Labor cost per hour - Customer Service Representative Average wage rate	$13.52
B4a. Labor cost per hour - Customer Service Representative Fringe benefits as a % of wage rate	0.22
B4a. Labor cost per hour - Customer Service Representative Labor cost per hour	$16.55
B5. AVERAGE TOTAL MONTHLY COST OF INTAKE AND CUSTOMER SERVICE PER PATIENT	$12.66
C1. Average labor amount per unit (teardown, testing, cleaning, reassembly, bagging, boxing, loading), in minutes	36.70
C2a. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Percentage of units requiring repair	0.10
C2b. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Average labor amount per unit (diagnosis and repair), in minutes	37.09
C2c. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Average repeat preparation labor amount per unit (testing, cleaning, etc,), in minutes	30.54
C2d. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Total weighted average repair labor per unit, in minutes	6.70

C3. Total weighted average preparation and repair labor per unit, in minutes	43.40
C4a. Labor cost per hour - Equipment Technician Average wage rate	$13.82
C4b. Labor cost per hour - Equipment Technician Fringe benefits as a % of wage rate	0.22
C4c. Labor cost per hour - Equipment Technician Average labor cost per hour	$16.92
C5. AVERAGE TOTAL COST OF PREPARATION PER UNIT	$11.93
D1a. VEHICLE COST PER MILE Acquisition and repair cost: Average vehicle acquisition cost per month (fully outfitted) – lease	$599.19
D1b. VEHICLE COST PER MILE Acquisition and repair cost: Average maintenance & repair cost per vehicle per year	$1,844.74
D1c. VEHICLE COST PER MILE Acquisition and repair cost: Average insurance & registration cost per vehicle per year	$1,427.62
D1d. VEHICLE COST PER MILE Acquisition and repair cost: Average odometer miles per vehicle per year	28,764
D1e. VEHICLE COST PER MILE Acquisition and repair cost: Average vehicle acquisition, maintenance & repair cost per mile	$0.40
D2a. Gasoline cost per mile: Average miles per gallon	13.45
D2b. Gasoline cost per mile: Average gasoline cost per gallon	$2.46
D2c. Gasoline cost per mile: Average gasoline cost per mile	$0.19
D3. TOTAL VEHICLE COST PER MILE	$0.60
E1. Average round trip travel time, in minutes	46.22
E2. Average in-home setup time, in minutes	33.35
E3. Average in-home client instruction time, in minutes	60.22
E4. Average in-home pickup time, in minutes	18.36
E5a. Average service technician wage rate per hour	14.01
E5b. Fringe benefits as a % of wage rate	0.22
E6. Labor cost - delivery, setup, pickup	$59.33
E7. Average round trip miles	23.43
E8. Average vehicle cost - delivery, setup, pickup	$13.73
E9. TOTAL AVERAGE DELIVERY / SETUP / PICKUP COST PER PATIENT	$73.06
F1. Average labor amount (preparation plus filter change), in minutes	35.81
F2a. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Percentage of units requiring repair upon return	0.21
F2b. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Average labor amount per unit (diagnosis, repair), in minutes	37.64
F2c. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Average repeat preparation labor amount per unit (testing, cleaning, etc,), in minutes	30.95

F2d. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Total weighted average repair labor per unit, in minutes	13.17
F2e. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Total weighted average preparation and repair labor per unit, in minutes	48.98
F3. Average wage rate, including fringe benefits	$16.92
F4. AVERAGE TOTAL COST OF MAINTENANCE PER UNIT UPON RETURN	$13.65
G1. Average total cost for delivery and return	$98.63
G2. Average number of months in service, per patient	22.13
G3. AVERAGE MONTHLY COST TO PREPARE, DELIVER AND RETURN	$5.34
H1a. Maintenance Supplies: Gross particle filters quantity used per year	2.32
H1a. Maintenance Supplies: Gross particle filters Price each	$2.98
H1b. Maintenance Supplies: Pre-felt filters, quantity used per year	1.77
H1b. Maintenance Supplies: Pre-felt filters, price each	$2.01
H1c. Maintenance Supplies: Hepa filters quantity used per year	1.54
H1c. Maintenance Supplies: Hepa filters Price each	$7.00
H1d. Maintenance Supplies: Intake filters Quantity used per year	3.19
H1d. Maintenance Supplies: Intake filters Price each	$3.89
H1e. Maintenance Supplies: Average monthly maintenance supplies cost	$2.34
H2a. Disposable Supplies: Humidifier bottles Quantity used per month	1.38
H2a. Disposable Supplies: Humidifier bottles Price each	$1.46
H2b. Disposable Supplies: Tubing Quantity used per month	1.73
H2b. Disposable Supplies: Tubing Price each	$1.83
H2c. Disposable Supplies: Tubing Connectors Quantity used per month	1.43
H2c. Disposable Supplies: Tubing Connectors Price each	$0.84
H2d. Disposable Supplies: Nasal Cannula Quantity used per month	3.19
H2d. Disposable Supplies: Nasal Cannula Price each	$0.69
H2e. Disposable Supplies: Average monthly disposable supplies cost	$7.53
H3a. Average vehicle cost per mile	$0.59
H3b. Average round trip miles	23.43

H3c. Average round trip travel time, in minutes	46.26
H3d. Average time to perform scheduled/preventive equipment maintenance, in minutes {including filter cleaning/replacement, oxygen purity testing, alarm battery testing, PSI check on back-up unit, liter flow compliance with Rx, and in-home	26.69
H3e. Average time to perform gaseous and/or liquid fills, in minutes	20.16
H3f. Service Technician wage rate per hour plus fringes	$17.09
H3g. Number of scheduled/preventive equipment maintenance visits per year	4.90
H3h. Number of oxygen contents delivery visits per year (including gaseous and/or liquid fills)	19.01
H3i. Average monthly routine maintenance labor and vehicle cost	$53.40
H4. AVERAGE TOTAL MONTHLY ROUTINE DISP AND SCHEDULED MAINT COSTS PER PATIENT	$62.16
I1. COST OF UNSCHEDULED MAINTENANCE Average vehicle cost, round trip	$13.54
I2. COST OF UNSCHEDULED MAINTENANCE Service Technician labor cost per hour	$13.20
I3. COST OF UNSCHEDULED MAINTENANCE Repair / Maintenance labor cost	$10.31
I4. COST OF UNSCHEDULED MAINTENANCE Average # of calls per month per 10 units in service	$1.60
I5. COST OF UNSCHEDULED MAINTENANCE Vehicle and delivery cost per unit per month	$6.10
J1. COST OF PATIENT ASSESSMENT Average number of clinical visits per year by RCP	10.82
J2. COST OF PATIENT ASSESSMENT Average round trip travel time, in minutes	46.02
J3. COST OF PATIENT ASSESSMENT Average in-home patient assessment time per visit, in minutes; Include time for home environment safety assessment - storage and maintenance; Include time for home environment safety assessment - administration; Include time	45.72
J4. COST OF PATIENT ASSESSMENT Average in-home follow up and compliance monitoring time per visit, in minutes; Include weekly calls to patients to determine requirement for portable oxygen; Include compliance monitoring conducted in the home at least once	45.89
J5a. COST OF PATIENT ASSESSMENT Average RCP wage rate per hour, excluding benefits	$21.74
J5b. COST OF PATIENT ASSESSMENT Fringe benefits as a % of wage rate	0.22
J6. COST OF PATIENT ASSESSMENT Average vehicle reimbursement per visit for RCP (at a federal rate per mile of $0.445)	$10.13
J7. COST OF PATIENT ASSESSMENT AVERAGE TOTAL COST OF PATIENT ASSESSMENT PER PATIENT PER MONTH	$17.54
K. TOTAL MONTHLY DIRECT COST BEFORE OVERHEAD AND PROFIT	$159.61
L2. OVERHEAD COSTS Estimated average monthly overhead cost per patient {Rent, Facility, Administration, Insurance, Legal, MIS Systems/Controls, Regulatory Compliance, Communications Systems, Training, Accreditation, Supplies, Billing and Reimbursement}	$41.59
M. TOTAL MONTHLY COST PER PATIENT	$201.20

PATIENT INTAKE	Average Minutes
A. Verification of beneficiary eligibility, claims management, and claims submission	43
B. Collect and record physician information	8
C. Receive, document and process order for oxygen and oxygen equipment	12
D1. Verification of Patient demographic information	4
D2. Verification of Patient possession of a valid Medicare number	3
D3. Verification of Patient emergency contact information	3
D4. Verification of Caregiver and/or conservator information	2
D5. Verification of Secondary insurance information	4
D6. Verification of Qualifying diagnosis	5
D7. Estimated total time for verification per year per patient	21
E. Input patient data in computer at service center	7
F. Schedule delivery	7
G. Contact physician to verify order, demographic information and license number	7
H. Verify physician UPIN with independent database	3
I. Coordinate or verify the existence of independent blood oxygen saturation study or ABG test	11
J. Obtain physician-signed certificate of medical necessity (CMN)	38
K. Total intake time per patient	157
PATIENT EDUCATION	Average Minutes
A. Supplier required training of patient and caregiver	16
B. Contracted interpreter services, if applicable	5
C. Patient and/or caregiver instruction in assembly and operation of oxygen and equipment	14
D. Oxygen safety training	7
E. Patient and/or caregiver training on "troubleshooting" possible equipment problems	7
F. Patient and/or caregiver instruction on proper infection control in the home	6
G. Patient and/or caregiver instruction on safe handling and storage of medications	4
H. Average total intake time per patient	60

ATTACHMENT 3 TO #65

The LEWIN GROUP

The Lewin Group
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Falls Church, VA 22042
703.269.5500/Fax 703.269.5501
www.lewin.com

September 22, 2006

Tyler J. Wilson
President & CEO
American Association for Homecare
625 Slaters Lane, Suite 200
Alexandria, VA 22314

Dear Mr. Wilson:

The Lewin Group is pleased to provide you and the association with an independent assessment of: 1) the likely impact of the Notice for Proposed Rulemaking (NPRM) on Medicare payment for home oxygen therapy and oxygen equipment; and, 2) the extent to which the proposed rule meets the budget neutrality requirement.

After careful assessment of the proposed rule and a financial analysis using CMS' utilization figures, The Lewin Group has concluded that the proposed payments are not budget neutral for oxygen and oxygen equipment in 2007. The proposed regulations would result in a reduction of approximately 10 percent ($257M) in the amount paid for oxygen and equipment in 2007 alone, with additional payment reductions from the capped rental provision in the Deficit Reduction Act that requires providers to transfer title of oxygen equipment to the beneficiary after 36 months of rental. Table 1 summarizes our findings.

Table 1: Impact of NPRM on Medicare Payment for Oxygen and Oxygen Equipment in 2007

	In Millions
Total Calculated Payment – Current	$2,607
Proposed Payment – NPRM	$2,349
Calculated Loss to Industry	$ 257

Source: Lewin Group analysis.

Under the proposed rule, CMS changes the oxygen classification system, dividing stationary and portable oxygen contents into two separate payment classes. The proposal also calls for a third payment class for new technologies, such as portable concentrators and home transfilling systems, that eliminate the need for refilling and delivery of oxygen contents.

According to the NPRM, payment for portable oxygen contents would increase to $55 compared to the current average payments of $21, but the monthly payment amounts for stationary oxygen equipment and contents would drop from an average of $199 to $177.

The proposed payment rates take effect January 1, 2007 and are as follows:

- Stationary payment: $177
- Portable add-on: $32
- Oxygen-generating portable equipment add-on (portable concentrators or transfilling systems): $64
- Stationary contents delivery: $101
- Portable contents delivery: $55

Lewin Group Analysis

Our analysis involved several steps, beginning with identifying utilization and payment data supplied by CMS in the NPRM, as outlined below. We first calculated the current payment for oxygen and oxygen equipment provided to 975,561 Medicare beneficiaries per month (11,706,733 per year using 2004 claims). We then calculated payment using the proposed rates, assuming no migration into portable concentrators or transfilling equipment. See Table 2, where the rule results in a reduction in payment of $257,548,126.

Utilization data provided in the proposed rule were based on Medicare beneficiary claims for 2004. Unfortunately, these claims do not provide specific utilization rates for portable concentrators or transfilling systems, since separate HCPC codes did not exist for these services at that time. In order to determine the potential impact of the multiple changes in payments across modalities, The Lewin Group estimated a migration in modality use from stationary concentrators to the portable concentrators or transfilling systems of five percent, consistent with industry estimates. See Table 3, where the rule results in a reduction in payment of $238, 817,353.

Table 2: Impact of NPRM on Oxygen and Oxygen Equipment for 2007 – Assumes No Migration into O2 Generating

Payment Analysis- Impact of NPRM	***Current Per Month Payment***	***Proposed Payment***	***Proportion Users***	***Number of Users- Annual***	***Number of Users - Per Month***	***Total Current Annual Payment***	***Total Annual Proposed Payment***	***Proposed Difference in Annual Payment***
Stationary Concentrator	$199	$177	24%	2,809,616	234,135	$559,113,568	$497,302,018	-$61,811,550
Stationary Liquid/Gas System	$199	$177	2%	234,135	19,511	$46,592,797	$41,441,835	-$5,150,963
Stationary Concentrator + Portable System	$231	$209	69%	8,077,646	673,137	$1,865,936,173	$1,688,227,966	-$177,708,207
Stationary Concentrator + O2 Generating Portable	$231	$241	0%	0	0	$0	$0	$0
Stationary Liquid Gas System + Portable	$231	$209	5%	585,337	48,778	$135,212,766	$122,335,360	-$12,877,406
Stationary L/G + O2 Generating Portable	$231	$241	0%	0	0	$0	$0	$0
Beneficiaries on O2				11,706,733	975,561	$2,606,855,304	$2,349,307,178	-$257,548,126

Table 3: Impact of NPRM on Oxygen and Oxygen Equipment for 2007 – Assumes 5% Migration into O2 Generating

Equipment Modality	*Current Per Month Payment*	*Proposed Payment*	*Proportion Users*	*Number of Users- Annual*	*Number of Users - Per Month*	*Total Current Annual Payment*	*Total Annual Proposed Payment*	*Proposed Difference in Annual Payment*
Stationary O2 Concentrator	$199	$177	24%	2,809,616	234,135	$559,113,568	$497,302,018	-$61,811,550
Stationary Liquid/Gas System	$199	$177	2%	234,135	19,511	$46,592,797	$41,441,835	-$5,150,963
Stationary O2 Concentrator + Portable System	$231	$209	64%	7,492,309	624,359	$1,730,723,407	$1,565,892,606	-$164,830,801
Stationary O2 Concentrator + O2 Generating Portable	$231	$241	5%	585,337	48,778	$135,212,766	$141,066,133	$5,853,367
Stationary Liquid Gas System + Portable	$231	$209	5%	585,337	48,778	$135,212,766	$122,335,360	-$12,877,406
Stationary Liquid/Gas System + O2 Generating Portable	$231	$241	0%	0	0	$0	$0	$0
Beneficiaries on O2				11,706,733	975,561	$2,606,855,304	$2,368,037,951	-$238,817,353

In addition to the straightforward analysis described in the preceding table, we simulated several different potential scenarios to determine what it would take to result in the proposed payment rates being budget neutral in the first year of implementation. The proposed payment for oxygen and oxygen equipment based on the newly proposed rates (2004 utilization) vary depending on the assumptions related to migration from stationary concentrators to portable equipment. With a two percent migration in 2007, the payment would be $2,415,840,000, with a loss to industry of $256,320,000. The negative impact on the industry decreases as migration assumptions increase. With a 20 percent migration, the loss to industry would be $162,120,000. In order for the proposed payments to be budget neutral, one would have to assume a 73% migration from stationary to O2 generating portable equipment in the first year. It is our understanding that this kind of shift in the first year of the new payment rates is not possible.

In the event that we can be of further help in your work, please do not hesitate to call.

Sincerely,

Joan E. DaVanzo, PhD
Vice President

Submitter : Mr. Peter Kelly **Date:** 09/25/2006

Organization : Council For Quality Respiratory Care

Category : Device Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1304-P-66-Attach-1.PDF

CMS-1304-P-66-Attach-2.PDF

CMS-1304-P-66-Attach-3.PDF

ATTACHMENT 1 TO #66

CQRC | COUNCIL FOR QUALITY RESPIRATORY CARE

September 25, 2006

Dr. Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1304-P
7500 Security Blvd.
Baltimore, MD

Re: Comments to 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,

On behalf of the Council for Quality Respiratory Care (Council), I am writing to comment on the Proposed Rule on the Deficit Reduction Act (DRA) of 2005 Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment (71 Fed. Reg. 44082). The Council is a coalition of the nation's eleven leading home oxygen therapy provider and manufacturing companies, representing a majority of the more than one million Medicare patients who rely upon home oxygen therapy to maintain their independence and enhance their quality of life. We appreciate the opportunity to comment on these provisions implementing the home oxygen payment changes enacted by the DRA, as well as the proposed reimbursement policy changes. We look forward to working closely with the Centers for Medicare and Medicaid Services (CMS) to develop a payment system that will ensure access to these vital services for Medicare beneficiaries.

Specifically, the Council is concerned about certain aspects of the proposal.

- First, the proposed policy does not meet the statutory requirement of being budget neutral. In fact, based upon an analysis prepared by The Lewin Group, which is attached to this letter, the proposed policy takes hundreds of millions of dollars out of the system in direct contradiction to the congressional mandate.

- Second, based upon The Lewin Group analysis, $239 million has been removed from the system annually and must be reallocated among the proposed classes of oxygen and oxygen equipment. We strongly believe these dollars should be

reallocated by directing a vast majority of the funding to the provision of portable gaseous and liquid systems.

- Third, the Agency should adopt a transition period for its proposed reimbursement policy changes, which significantly modify the reimbursement of home oxygen therapy. In other health care sectors, CMS has recognized that major shifts in reimbursement policy can destabilize a sector and threaten beneficiary access. In these cases, CMS has provided for a transition period that allows the community to adjust to the new policy so that it remains economically viable. CMS should follow a similar approach with home oxygen therapy.

- Fourth, we recommend that CMS evaluate its proposed system in light of the current reimbursement policy and safety requirements. An important benefit of the current policy is that it is "modality neutral," which means that physicians can provide their patients with the equipment that best meets the patients' needs. While we understand the existing policy may be changed, we encourage CMS to examine the clinical and operational needs of the home oxygen community and adjust its policy so that physicians may continue to prescribe the most appropriate equipment to their patients.

- Finally, to ensure appropriate implementation and uninterrupted access for patients, CMS should also clarify several provisions of the Proposed Rule.

I. The Proposed Policy Does Not Meet the Statutory Budget Neutrality Requirements.

There is no disagreement that the proposed policy must be budget neutral. As CMS notes in the Preamble, Congress mandated that any changes in payment rates for home oxygen equipment must "not result in expenditures for any year to be more or less than the expenditures which would have been made if such actions had not been taken." 42 U.S.C. § 1395m(9)(D)(ii). The Preamble states that the proposed increases and decreases are "roughly equal over the next two or three years."

Although the Proposed Rule acknowledges that the proposed policy must be budget neutral, it does not provide the data or methodology CMS used to reach this conclusion. In addition, there has been no pilot or study to evaluate the impact on patients, providers, or other members of the home oxygen community. Given the sweeping nature of the proposed changes, CMS should provide the home oxygen community with sufficient information to evaluate its work.[1] As a threshold matter, the Council urges CMS to provide greater transparency regarding the calculations used to develop the new policy, as well as the data supporting the specific proposed rates. In particular, CMS should provide the data and methodology used to establish its conclusion about budget neutrality.

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[1] *See generally*, 67 Fed. Reg. 8452, 8458 (Feb. 22, 2002); *Guidelines for Ensuring the Quality of Information Disseminated to the Public* Centers for Medicare and Medicaid Services, *available at* http://aspe.hhs.gov/infoquality/Guidelines/CMS-9-20.html.

Even without this information, however, it appears clear that the proposed changes do not meet the statutory budget neutrality requirement. In its analysis, The Lewin Group[2] estimated the migration in modality use from stationary concentrators to the portable concentrators or transfilling systems of five percent. (See Attachment 1) This percentage is consistent with the estimates of the home oxygen community, as well as the estimate CMS described in a meeting with members of the Council. When this estimate is used, however, it is clear that the proposed changes are not budget neutral. As the table below demonstrates, it results in approximately $239 million per year being pulled out of the system in 2007 alone.

Table 3: Impact of NPRM on Oxygen and Oxygen Equipment for 2007 – Assumes 5% Migration into O2 Generating

Equipment Modality	Current Per Month Payment	Proposed Payment	Proportion Users	Number of Users - Annual	Number of Users - Per Month	Total Current Annual Payment	Total Annual Proposed Payment	Proposed Difference in Annual Payment
Stationary O2 Concentrator	$199	$177	24%	2,809,616	234,135	$559,113,568	$497,302,018	-$61,811,550
Stationary Liquid/Gas System	$199	$177	2%	234,135	19,511	$46,592,797	$41,441,835	-$5,150,963
Stationary O2 Concentrator + Portable System	$231	$209	64%	7,492,309	624,359	$1,730,723,407	$1,565,892,606	-$164,830,801
Stationary O2 Concentrator + O2 Generating Portable	$231	$241	5%	585,337	48,778	$135,212,766	$141,066,133	$5,853,367
Stationary Liquid Gas System + Portable	$231	$209	5%	585,337	48,778	$135,212,766	$122,335,360	-$12,877,406
Stationary Liquid/Gas System + O2 Generating Portable	$231	$241	0%	0	0	$0	$0	$0
Beneficiaries on O2				11,706,733	975,561	$2,606,855,304	$2,368,037,951	-$238,817,353

The Lewin Group also simulated several different potential scenarios to determine what assumptions the Agency would have had to make to meet the statutory budget neutrality requirement. If there were only a two percent increase, the loss to the system would be approximately $239 million in 2007. With a 20 percent increase to self-generating portable systems, the one-year loss would be $162 million. To get close to a budget neutral system using sound methodology, the assumption would have to be that approximately 73 percent of patients would switch to such oxygen self-generating portable systems during the first year. Based upon our understanding of the market, as well as CMS's own assumptions, it is indeed more likely that the first year would see a much more modest increase.

Additionally, the Proposed Rule indicates that CMS must offset increased payments for portable oxygen contents and oxygen generating portable equipment. The preamble indicates the Agency obtains the offset by reducing the current stationary payment by $22. Assuming the calculations are correct, the offset should be $16 million. However, based upon the work of The

[2]A letter from The Lewin Group describing its analysis and findings is attached to this letter.

Lewin Group, the actual offset is approximately $223 million for one year alone, assuming a five percent assumption for new technology.

The Agency should review the attached data analysis from The Lewin Group and re-evaluate its assumptions to assure that the proposed policy is in fact budget neutral, as required by law. Once the changes are budget neutral, the Council believes The Lewin Group analysis correctly predicts that $239 million has been removed from the system inappropriately. As discussed in detail below, at a minimum, the Council urges CMS to reallocate the $223 million (the $239 million minus the $16 million for the change in payments) within the system.

II. CMS Should Reallocate the Remaining Dollars So that the Final Rule Is Budget Neutral.

After CMS has complied with the budget neutrality requirement, the Agency should reallocate the $223 million by directing the funding to portable equipment and the delivery of contents, including lightweight liquid and gaseous equipment and contents and self-generating portable equipment (collectively, portable equipment and contents). These classes remain underfunded when compared to the cost of providing them. The problem would be greater after ownership transfers and the reimbursement is capped at 36 months. CMS states that one of its goals is to ensure that patients have ongoing access to portable devices. Thus, the Agency should pay particular attention to the reimbursement rate it sets for them.

Increasing payment for portable equipment and contents would meet an important clinical and policy goal as well. One of the major goals of caring for oxygen-dependent patients is encouraging them to be more active and mobile. Limited mobility can lead to an exacerbation of the patient's clinical condition and has the potential to result in hospitalization or institutional care. In the early decades of the Part B home oxygen benefit, patients were limited in their ability to be more active and mobile because of the cumbersome nature of large tanks and home concentrator systems. In recent years, however, manufacturers have responded to the clinical goal of increasing a patient's ambulatory abilities and freedom by developing smaller, more portable oxygen tanks and systems that can serve as both stationary and portable systems. The days of patients being forced to stay close to their homes have ended.

The Council is pleased that CMS recognizes the importance of providing patients with greater freedom of movement. However, the Council is concerned that the proposed rates for portable equipment and contents are not sufficient to offset the cost of providing these systems to beneficiaries. As described below, we encourage CMS to work with the home oxygen community to develop the data necessary to establish appropriate reimbursement rates. In the meantime, however, we encourage CMS to direct the majority of the "extra" money that results from the appropriate calculation of the budget neutrality requirement to portable devices. This shift will not only assist in maintaining beneficiary access to these devices, but also provide patients with an improved quality of life and improved health, as numerous clinical studies demonstrate.

III. CMS Should Provide for an Appropriate Transition Period to Minimize the Negative Impact the Revisions Will Have on the Home Oxygen Community and To Allow for the Collection of Data that Will Support the Development of Accurate Reimbursement Rates.

A. Consistent with Its Implementation of Other Major Reimbursement Policy Changes, CMS Should Implement the Proposed Reimbursement Policy Over a Three-Year Transition Period.

In addition to the significant changes in the proposed reimbursement rates for individual modalities, the Proposed Rule implements the transfer of ownership requirements and a 36-month cap established by Congress. These changes, if implemented, together could destabilize the home oxygen community. Another important change will be the implementation of the competitive bidding program scheduled to begin in late 2007. The Proposed Rule states that it would implement the revisions to the payment system for oxygen and other capped rental equipment on January 1, 2007. If the implementation date were adopted, the home oxygen community would have only one or two months to make the adjustments necessary under these policies. Because the DRA does not mandate that the reimbursement policy changes occur by this date, we strongly urge CMS to adopt a blended rate[3] during a three-year transition policy.

In the past, when CMS has proposed significant reimbursement changes, it has provided a transition period. For example, both the payment policy changes for ambulatory surgical centers included in the Proposed Rule on the Changes to the FY 2007 Hospital Outpatient Prospective Payment System (71 Fed. Reg. 49506) and the changes to the diagnosis-related groups (DRG) rates contained in the Final Rule on Changes to the FY 2007 Hospital Inpatient Prospective Payment System (71 Fed. Reg. 47870) include transition periods in an effort to manage the economic stability of the affected providers. Similarly, CMS provided transition periods before implementing new prospective payments systems for both skilled nursing facilities (SNF) and long term care hospitals (LTCH).

At the very least, CMS should establish a "blended" payment rate to phase-in the proposed rate changes over a three-year period. Not only would this transition period allow affected parties to prepare for the forthcoming changes, but it would also provide the industry and CMS with the necessary time to develop the cost data needed to develop accurate payment rates. The Council looks forward to collaborating with CMS in this data collection process and believes it is an important step towards CMS's goal of creating an effective payment system that reimburses providers appropriately for the quality oxygen services furnished to Medicare beneficiaries.

Alternatively, CMS could establish a grandfather policy that would allow Medicare patients currently receiving oxygen services to remain under the current oxygen reimbursement system. This would eliminate the significant disruption that would otherwise occur for patients and providers. These patients have become accustomed to operating under the current oxygen delivery service, and a new reimbursement system may impede the ability of suppliers to maintain that system in the fashion to which those patients have become accustomed. Under this transition model, CMS would allow patients receiving service prior to January 1, 2007, to remain subject to the current reimbursement system, whereas new patients who begin using services after that date will be reimbursed under the new reimbursement system.

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[3]Traditionally, CMS has established blended rates by taking 75 percent of the original rate and 25 percent of the new rate during Year One; 50 percent and 50 percent in Year Two; and 25 percent and 75 percent in Year Three.

Another alternative would be for CMS to establish a "grace period" during which providers could transfer patients with their consent to other modalities. Because the Rule, as proposed, would restrict these activities (unless modified as suggested below), allowing a grace period would provide patients with a smoother transition between payment methodologies. Given the change in the flexibility of a supplier to make such transfers, it may be necessary to adjust modalities in order to best serve the patient's long-term needs. As such, CMS should consider allowing suppliers an adequate grace period in which they can assess patient needs and make adjustments where appropriate before the more restrictive policy takes effect.

B. A Transition Period Will Provide CMS with Time to Collect Appropriate Data To Ensure It Establishes Appropriate Reimbursement Rates for the Classes.

A transition is even more important to the home oxygen community because there is very little data about the total cost of providing services to beneficiaries. Implementing a phased-in reimbursement policy will provide the Agency and the community with the time needed to determine what data it needs and how to collect it. It will also allow sufficient time to develop the appropriate methodology to set reimbursement rates based upon the data it collects.

Allowing CMS time to develop the necessary information upon which it should base its payment policies is critical to achieving an appropriate payment structure and is a required component in the Agency's compliance with its responsibilities under the Information Quality Act.[4] Under the Information Quality Act, CMS must use accurate, objective data in the formulation of the policies it disseminates to the public through the Federal Register publication. Given the lack of data available to establish the payment rates, we encourage CMS to provide a transition period during which it can work with the community to ensure that the rates it believes are appropriate in fact are.

Home oxygen therapy provides beneficiaries with the freedom to remain with their families while they receive this life-saving treatment. CMS should ensure that the reimbursement rates it sets for these products and services cover the cost of providing them. If they do not, beneficiaries will suffer. Without the appropriate data, it is difficult to determine the true cost of these products and services. CMS should examine how the proposed rates relate to the cost of integrating new technology into the home oxygen therapy benefit. It may determine that higher payments are needed to encourage its adoption. The community has recently undertaken significant efforts to gather and validate industry-wide data on the costs of providing oxygen services to beneficiaries, such as the cost analysis of Medicare home oxygen therapy published by Morrison Informatics, Inc. in June 2006 (Morrison Study) (See attachment 2). The Morrison Study provides essential information on the costs of all aspects of providing oxygen to patients, beyond the costs of equipment alone, and data such as this is critical to developing a reimbursement system that pays appropriately based upon the actual costs of suppliers. For example, this study supports the Council's position that the rates proposed for providing portable oxygen are too low. Therefore, the Council encourages CMS to work with the community during the transition period to identify the appropriate data and develop the methodology necessary to establish reimbursement rates for home oxygen that are based on solid evidence.

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[4] 44 U.S.C. §3516 (2002); *see supra* note 1 for CMS guidelines implementing the Act.

The Council appreciates the difficulty in collecting appropriate data to set reimbursement rates. CMS should set an appropriate timetable to work with the community to ensure that the appropriate data is collected. The Proposed Rule, however, appears to rush the process by relying on anecdotal evidence. For example, the Proposed Rule cites an example from the Department of Veterans Affairs (VA) to justify the proposed payment system changes. The conclusion drawn from this comparison is a *non sequitur* and should not be used as the basis to form CMS policies or rates. First, according to the contract provider, American Medical Equipment, the Tampa VA contract referred to in the Proposed Rule is an unbundled contract that reimburses separately for each portable cylinder and pound of liquid oxygen provided to a beneficiary. That means if viewed in the aggregate, this VA contract may pay more than the Medicare rate. Thus, it is inappropriate for CMS to use the unbundled rates to set Medicare bundled rates. In addition to the bundling difference noted above, there are a number of other differences between the VA and Medicare that are worth noting:

- The VA currently uses competitive bidding in procurement of its oxygen service contracts, while Medicare renders payment to all qualifying providers. Thus, VA contractors may be able to provide a lower rate because they are guaranteed a specified volume of business and exclusivity, whereas Medicare providers have no such guarantee.

- Medicare providers spend a significant amount of time and resources ensuring their compliance with Medicare requirements and the associated administrative paperwork and processes related to patient intake, billing, and collections. In contrast, the VA process is relatively simple and streamlined. It requires significantly fewer resources for compliance and billing, which significantly lowers the cost of providing services.

- The VA has no patient co-payment requirements. In contrast, a Medicare provider must pursue individual patients and secondary payers to reimburse portions of the service, with additional administrative and documentation costs. These obligations are often left unfulfilled, resulting in expensive bad debt write-offs for Medicare providers.

- The VA contract referenced in the Proposed Rule also includes additional rate protections and service fees that Medicare does not provide. Among other things, VA contractors receive separate service fees for equipment maintenance, refills of oxygen, therapy visits, and supplies. VA contracts also include built-in escalation provisions to account for providers' increasing costs over time.

This example demonstrates that there is a need to engage in a more rigorous review of data regarding home oxygen therapy pricing and costs. A transition period would allow CMS to undertake this important activity.

C. The Transition Period Will Also Provide CMS with the Necessary Time To Work with the Home Oxygen Community to Develop a Fee Schedule for Equipment and Maintenance Services Provided after the Transfer of Title.

The Proposed Rule indicates that Medicare will make maintenance and service payments for capped rental oxygen equipment after title has transferred to the beneficiary using the existing policy

that covers only certain routine maintenance or periodic servicing. Because not all maintenance and services will be reimbursed, CMS should establish a specific, standardized fee schedule that all DME MACs reference and that clearly describes the specific maintenance and services that Medicare would cover. The Council looks forward to working with CMS as it develops this fee schedule. Because this will take time to establish the codes and appropriate reimbursement rates, the need to develop this fee schedule also supports the need to allow for a transition of the new reimbursement policy.

D. A Transition Period Will Allow CMS Time to Address Providing Emergency and On-Call Services to Patients after the Transfer of Ownership.

Under the current reimbursement policy, providers provide emergency and on-call services to patients as part of the rental arrangement. However, the Proposed Rule does not address the need for after-hours or emergency services for patients following the transfer of title for either their capped rental or oxygen equipment. Without such a policy and reimbursement rates that acknowledge the need for such services, patients may be at serious risk for increased levels of hospitalization, emergency room visits, or physician visits.[4] The Council would be pleased to work with CMS to develop a rational, reasonable methodology to provide for emergency services for patient-owned equipment to ensure that beneficiaries continue to have access to life sustaining services during power outages or other emergency situations.

E. A Transition Period Will Allow CMS Time to Address the Implementation of Competitive Bidding and the Impact the Proposed DRA Policy and Payment Changes Will Have on that Program and Participating Providers.

The Proposed Rule contains sweeping changes to the reimbursement policies for home oxygen equipment. The Council is concerned that these changes, along with the ownership changes mandated by Congress and the upcoming competitive bidding rules will destabilize the community and place patients at risk and may threaten their ability to access these life-saving technologies. The competitive bidding program will also introduce new supplier quality standards, restrictive contracting requirements, and market-driven pricing for the first time in the history of the home oxygen therapy benefit. The introduction of these changes significantly increases the complexity of the landscape. Yet, there has been little examination of the interaction of these new policies. Without a transition period, basic questions about implementation that may arise will not be answered until it may be too late to address them. Given the reframing of the entire home oxygen benefit, the Council strongly urges CMS to provide a transition period during which the community can resolve problems that may arise at the intersection of these different policies.

IV. Any New Reimbursement Methodology Should Ensure that Physicians May Continue to Prescribe the Equipment that Most Appropriately Meets Patients' Needs and Ensures High Quality Care.

Although we understand the Agency's goals in revising the reimbursement policy, it is important that patients continue to receive the equipment and services that most appropriately meets their needs and ensures high quality care and quality of life for patients. In general, the

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[4] *See* Michael J. O'Grady, "White Paper on Medicare's Payment Policy for Oxygen" (Sept. 12, 2006) (Attachment 3).

Council recommends that CMS evaluate its proposed system in light of the current reimbursement policy. An important benefit of the current policy is that it is "modality neutral," which means that physicians can prescribe the equipment that best meets the patients' needs. We encourage CMS to examine the clinical and operational needs of the home oxygen community and adjust its policy so that physicians may continue to prescribe the most appropriate equipment to their patients and that patient compliance and safety remain a top priority.

A. CMS Should Work with the Home Oxygen Community to Develop Safety Standards to Ensure that Patients and Their Caregivers Understand the Responsibilities Associated with Owning Home Oxygen Equipment.

The Council understands that Congress requires the transfer of the title of ownership for home oxygen equipment after 36 months. Because the Council remains extremely concerned about this requirement, it encourages CMS to work with it and other members of the home oxygen community to develop safety standards that can be applied to patient-owned equipment to reduce the risk of oxygen-related accidents or improper use. The patients who receive home oxygen therapy through Medicare are often elderly and/or have disabilities. These vulnerable patients rely upon caregivers to assist them. In many cases, these caregivers are also elderly spouses. It may be extremely difficult for the patients and their caregivers to perform simple troubleshooting of their equipment despite written instructions or professional guidance via phone.

The recently-published OIG report entitled "Medicare Home Oxygen Equipment: Cost and Servicing," issued on September 14, 2006, supports the Council's concerns that many patients will not be able to perform routine maintenance once they own their equipment. "When suppliers visit beneficiaries, they often perform services that a beneficiary has been instructed to do. The data suggests that 50 percent of the visits conducted by homecare providers included what has been described as 'routine maintenance' by CMS."[5] Under the current reimbursement policy, providers do not receive additional payments for providing routine maintenance. Therefore, it is reasonable to conclude that providers perform this routine maintenance on behalf of patients because the patients and caregivers cannot do so.

In the experience of the Council members, patients rely on the 24-hour, seven-day-a-week on-call service provided by their homecare company to answer questions related to their equipment. They call providers frequently, namely whenever there is a major or minor issue or concern. For example, one large national provider that provides services and equipment outside of the home oxygen community indicates that the number one and two product categories for which patients access its after-hours service are oxygen and home medical equipment, respectively. A large percentage of these calls result in an in-home visit after hours and on weekends.

Once the title transfers, the patient will be responsible for performing certain services that would have otherwise been covered in a monthly bundled rental and service fee (in the case of oxygen) or a semi-annual service and maintenance fee (in the case of other capped rental medical equipment). The Council is concerned that under the proposed system, ongoing beneficiary education and monitoring regarding oxygen usage and safety will no longer be tracked or performed,

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[5]Office of Inspector General Report: "Medicare Home Oxygen Equipment: Cost and Servicing," September 2006. Page 11-12.

creating the potential for unsafe use of oxygen and oxygen equipment. Oxygen cylinders must be stored properly in order to be safe and must be periodically tested hydrostatically to assure they will safely 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 stations are deemed manufacturing plants and are highly regulated by the Food and Drug Administration (FDA). These stations may be reluctant to fill beneficiary-owned equipment in those cases in which the beneficiary does not label the transferred cylinder properly or its fill history is unknown. This would create a 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. Additionally, oxygen requires compliance with specific regulations developed by the respective state boards of pharmacy, Department of Transportation (DOT), FDA, as well as guidelines from the Compressed Gas Association (CGA). Refilling cylinders requires medical quality oxygen content to avoid life-threatening contamination problems. Patients may not be aware of, or comply with, these guidelines thus putting them and others at risk. We strongly urge CMS to work with the Council and other interested groups to develop safety standards that can be applied to patient-owned equipment in an effort to reduce the risk of oxygen-related accidents or improper use.

In particular, the Council remains extremely concerned about the transfer of ownership title as it relates to the ownership of cylinders, regulators, and oxygen vessels although it appreciates that CMS may have little authority to change this congressional mandate. Specifically, the transfer of title of ownership of cylinders means that patients will be more likely to try to move cylinders on their own. This can be extremely dangerous, as demonstrated by the tragic bus fire that occurred during the evacuation of nursing home residents during Hurricane Katrina. A single spark that resulted from the bus having a flat tire led to the volatile oxygen accelerating the resulting fire and killing the evacuees. If ownership remained with the provider, the provider would be responsible for moving this dangerous equipment and be able to provide trained personnel to ensure its safe transport.

The Council is also concerned about the effect of the transfer of title on the current practice of exchanging cylinders. Today, when a cylinder empties, the provider is responsible for picking it up and providing the patient with a full cylinder. The provider retains ownership of the cylinder, while the beneficiary rents it. This allows for the provider to use different cylinders with the same patient. The current process is efficient. The Proposed Rule implies that patients would own two or more cylinders. This would be unnecessarily costly and inefficient because providers would have to develop tracking systems that would ensure that each patient's cylinder could be identified. In addition, cylinders must be disposed of safely. The more efficient and safer approach is for the provider to retain ownership of all cylinders and for the current rental process to continue. This is also the practice in other countries and other non-medical industries.

B. CMS Should Work with the Food and Drug Administration (FDA) and the Home Oxygen Community To Ensure the Safety of Used Home Oxygen Equipment Sold by Patients or Their Families.

With the title of ownership transferring to beneficiaries, it is likely that more home oxygen equipment will become part of the marketplace for used goods. Therefore, the Council strongly urges CMS to coordinate with the FDA to develop national guidelines that apply specifically to the public resale of used medical devices.

Even before the transfer of title, used medical devices (either discarded inappropriately, stolen, or in limited circumstances patient-owned) are already finding their way into flea markets and classified ads, as well as on-line marketplaces for sale. The sellers advertise oxygen cylinders "as-is" without evidence or guarantees that the devices are functioning properly. Some online marketplaces require a seller to check a box that the seller is licensed to distribute the equipment. However, there is no check to confirm the truth of the assertion. There is virtually no safeguard for the average patient or interested party to know whether or not the medical device purchased, such as an oxygen concentrator, is appropriate for their condition, 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. Transmission of respiratory pathogens is highly likely if the device is not properly disinfected in between patient uses as it is by accredited providers who comply with the infection control requirements of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or other accreditors.[6] These "new" patients would lack the necessary training and knowledge for safe use and operation of these devices, creating potentially dangerous situations.

In addition to providing equipment with questionable quality, sellers are transporting used oxygen cylinders through United Parcel Service (UPS), FedEx, and other air carriers without providing sufficient information to Transportation Safety Administration (TSA), Homeland Security Department, or the Federal Aviation Administration (FAA). With the legal transfer of ownership to patients, these practices are likely to increase.

Because the Safe Medical Device Act (SMDA) never technically contemplated the concept of broad-based medical device ownership among the American public, we strongly believe CMS should confer with the FDA to review the impact of the changes in the ownership requirement. For example, the transfer of ownership will mean that current FDA requirements that mandate that providers trace equipment so that they can provide notices of recalls will be next to impossible to meet if a patient sells his/her equipment. In addition, CMS and the FDA should discuss the ability for medical oxygen fillers to comply with 21 C.F.R. §§ 210 and 211 once the patients own their own devices and equipment. If necessary, the Federal Trade Commission (FTC) should be consulted to stop 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.

We would welcome the opportunity to work through these important safety issues with CMS and FDA.

V. CMS Should Clarify Several Provisions in the Final Rule to Ensure the Appropriate Implementation of the New Reimbursement Methodology and Transfer of Ownership Requirements.

[6]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.

In addition to addressing the budget neutrality concerns and providing for a transition period, CMS should also clarify several provisions of the Proposed Rule. These clarifications will ensure the appropriate implementation of the changes and ensure that patients continue to receive high quality care.

A. In the Final Rule, CMS Should Clarify Reimbursement for Exchanges or Changes of Equipment.

The Proposed Rule, while appearing to address the issue of changing clinical needs of patients, does not adequately account for the expense associated with servicing this vulnerable population. For example, a subset of oxygen patients will progress to the point of requiring higher flow rates. An informal survey of six large home oxygen providers indicated that one-to-two percent of oxygen patients require a liter flow of four liters per minute (LPM) or greater, inferring that the patients are in the later stages of their illnesses and perhaps even approaching the terminal stage.[7] While there is an increase in payment for flow rates greater than four liters per minute, the higher reimbursement does not offset the increased cost of changing the equipment (*i.e.*, to a ten LPM concentrator) or the modality (*i.e.*, to liquid oxygen, which can accommodate higher liter flow requirements). This disparity in payment versus equipment cost increases throughout the first 36 months of rental; however, it becomes even more critical after 36 months. The need for higher flow rates typically comes late in the progression of their disease and is most likely to occur after the 36-month transfer of title and cessation of payments to the provider.

The Council suggests that CMS develop a mechanism to increase payments to providers who, for medically necessary reasons, are required to provide additional equipment to support the patient as he/she progresses through his/her illness. This would include a mechanism to increase payments when a change to a more expensive modality is required during the time period in which they are providing services to a patient.

B. CMS Should Clarify Its Restrictions on Equipment Exchange or Change Options.

The Council appreciates the Agency's attempt to ensure that providers do not substitute substandard equipment to patients just before the required transfer of title. However, we are concerned that as drafted the Proposed Rule is too restrictive. Therefore, we encourage CMS to clarify that in certain circumstances it is appropriate to exchange or change equipment as long as the exchange or change is sufficiently documented and the provider certifies that the equipment is not a lesser-quality device.

In some cases, it may be appropriate for a provider to exchange or change a patient's home oxygen equipment. For example, if a patient who refuses to stop smoking in the home, the provider should be allowed to adjust the equipment to lessen the danger associated with this non-compliant behavior. Providers should also be permitted to exchange or change equipment when a more appropriate item is available. Additionally, patients may learn about new equipment through friends, their doctors, or their support groups, such as The American Lung Association's Better Breathers

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[7]Survey of CQRC members Air Products Homecare, American HomePatient, Apria Healthcare, Lincare, Pacific Pulmonary Services and Praxair Healthcare Services.

Clubs. Traditionally, providers have accommodated these requests when appropriate. However, home oxygen providers would be placed in a difficult situation if a patient who has had one type of equipment for 33 months were to learn about a new device and were to request it. The provider would have to tell the patient that Medicare would not permit the change. As drafted, the Proposed Rule would restrict the ability of providers to provide patients with new equipment that represents important technological advances or has demonstrated improved clinical outcomes of patients.

The most important reason to exchange or change patient equipment is because of a change in the patient's clinical needs. The Propose Rule acknowledges that equipment may be exchanged or changed if the patient's medical condition changes, but limits the exception to situations when the equipment is no longer appropriate or medically necessary. An exchange or change may also be appropriate if the equipment is still appropriate and/or medically necessary, but a different piece of equipment would better meet the patient's changing needs. For example, a different piece of equipment may allow a patient to perform more activities of daily living. When the equipment is first provided, a patient's movement may be limited as she recovers from a recent hospitalization. Yet, once the patient's strength increases, she may be able to engage in more daily life activities. A different piece of equipment could help speed her recovery and her independence. The Proposed Rule would not permit an exchange of equipment that would clearly benefit the patient.

The proposed carrier determination exception is not sufficient to address this concern because it does not outline the process for the carrier to make these determinations. To be effective, an exception must provide clear guidance to the community. Without such guidance, providers are unlikely to make exchanges or changes in equipment that are warranted, which will only hurt patients. Therefore, we recommend that CMS allow providers to judiciously exchange or change a patient's equipment during the period of medical need provided that this exchange or change is sufficiently documented and that the provider certifies that the new equipment is not a lesser-quality device. CMS should also develop medical necessity requirements for modality changes that take into account the medical benefit that a change in equipment might provide in terms of ambulatory ability and participating in activities of daily living.

C. CMS Should Clarify the Responsibility of Providers To Repair or Replace Equipment After Patients Receive the Title of Ownership.

The Council is concerned that the Proposed Rule would require providers to replace equipment for which ownership has already transferred to the patient if the repair cost is greater than 60 percent of the replacement cost. The proposed requirement is inconsistent with the intent of Congress to make patients more responsible for their home oxygen equipment. It also inappropriately holds providers responsible for equipment over which they no longer have control or ownership. CMS should specify that once ownership shifts to the patient, it becomes the patient's responsibility to maintain and repair the equipment. The patient is also protected from any concerns about substandard equipment through the restrictions on the exchange or change of equipment requirements.

The Rule proposes that, if equipment replacement is not covered by a manufacturer's or provider's warranty, the provider must still replace patient-owned oxygen equipment or patient-owned capped rental items at no cost to the patient or to the Medicare program if (1) the total accumulated costs to repair the equipment are greater than 60 percent of the replacement cost and (2) the item has been in continuous use for less than its reasonable useful lifetime. First, the 60

percent repair versus replacement comparison does not equitably apply to a capped rental item. For capped rental home medical equipment or devices, the item will convert to sale at 13 months, or at 21.7 percent of the item's "useful life" (currently defined as 5 years by CMS). For example, if a wheelchair that converts to sale to a beneficiary at 13 months breaks down in the 14th month, the Proposed Rule would require the provider to be responsible for replacing this wheelchair if the total accumulated cost to repair the wheelchair was greater than 60 percent of the replacement cost. This places an unreasonable economic burden on providers because it shifts the responsibility for the equipment in years four and five from the manufacturers to the providers. This is clearly not an economically equitable proposal because providers will have no control over the maintenance and servicing of the equipment by the patient, but will still be responsible for the equipment.

Second, for oxygen equipment, the beneficiary would own the equipment after 36 months. However, the provider would be responsible for replacing the currently owned equipment if the repair cost is greater than 60 percent of the replacement cost. Again, CMS is proposing that the provider continue to be responsible for equipment for which it has no control over how it is maintained.

We recommend that CMS specify that once equipment converts to sale, the responsibility for repairing or replacing the equipment should become the responsibility of the beneficiary. Although the proposed exchange and change of equipment restrictions should address any concerns about substandard equipment, CMS could establish a separate toll free number could be established for Medicare beneficiary complaints to determine if the problem really exists. CMS could also establish a provider responsibility period of 30 days that would require replacement if the repair costs were 60 percent of the replacement cost if the equipment failed during the first 30 days after the transfer of title. This would allow a patient to examine the equipment to ensure they have received the equipment in good working order, similar to a "free look" period or "lemon law" provided to consumers by some states now. Additionally, the 60 percent rule should be viewed as a one-time repair cost and not be viewed cumulatively.

The Council is also concerned that the Proposed Rule does not define the term "replacement cost" for purposes of calculating the 60 percent threshold. The Council assumes that the replacement cost would equal the total of the monthly payments or purchase price. However, because these payments differ on a state-by-state basis, CMS should clarify how the replacement cost would be established. CMS should also clarify and provide additional guidance about how it expects providers to account for the replacement cost or to track accumulated repair costs per beneficiary.

Finally, as noted earlier in this letter we encourage CMS to work with the home oxygen community to develop the appropriate data to support the provisions. For example, there is only anecdotal data that supports that 60 months is the useful life of equipment. In the experience of members of the Council, however, we have found that many lightweight portable systems break before 36 months. Most of their warranties are only 36 months as well. Therefore, CMS should work with the community to address the data issues before implementing policies that are not evidence based.

D. CMS Should Clarify the Requirements for In-Home Clinical Patient Assessments after the Transfer of Ownership/36 month cap.

CMS should clarify whether or not in-home clinical assessments will be part of patient care after they have received home oxygen therapy for 36 months. In-home clinical patient assessments are extremely important to ensuring high quality care for patients. 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 compliance to the physician's prescribed regimen, and document other findings in a summary to be provided to the physician. In fact, he/she may write an order for a homecare provider to conduct such a visit every three or six months depending on the patient's individual needs. In addition, certain oxygen modalities have built-in oxygen conserving devices (OCDs), such as the transfilling systems and portable oxygen concentrators (POCs). A patient must be tested and titrated on an OCD before he/she can use that oxygen modality. Most state respiratory therapist licensing laws require these therapists to perform that testing and titration. In the case in which a patient exceeds the 36th month and an equipment exchange is warranted, the Council is concerned that there would be no requirement for the in-home testing/titration to be provided.

The Council strongly encourages CMS to allow patients to continue to receive these assessments pursuant to physician orders. However, this activity is sustainable only if CMS establishes a new code and an appropriate reimbursement rate. The rate should take into account the value of the therapists' time, mileage reimbursement expense, and related costs. Patient assessment, training, education and monitoring currently comprise nine percent of providers' total costs of caring for patients.[8] Providers cannot provide these assessments without fair reimbursement rates because they could constitute an illegal inducement and raise other fraud and abuse concerns. The Council welcomes the opportunity to work with CMS to provide accurate, fully-loaded cost data that would facilitate the Agency's ability to establish not only a fair reimbursement rate, but also a process that would inhibit any potential for fraud or abuse.

E. CMS Should Clarify the Definitions of Routine and Non-Routine Maintenance.

The Council encourages CMS to clarify the definitions of "routine maintenance" and "non-routine maintenance" so providers have a better understanding of what services would be covered. The Proposed Rule contains conflicting guidance as to what services would be reimbursed once the title transfers to the patient. For example, the Proposed Rule suggests that patients should perform routine maintenance, while also indicating that if special tools were required to perform such maintenance (tools which patients would not typically own, such as an oxygen analyzer), Medicare would reimburse providers for the services.

The Council encourages the Agency to establish definitions of routine and non-routine maintenance to take into account the differing needs of patients. Many of the tasks required in performing ongoing medical equipment and oxygen concentrator maintenance require hand-to-eye coordination, strength, depth perception, and tactile ability. Although some patients or their caregivers may possess the necessary physical skills, others may not. Many patients who require

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[8] "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.

home oxygen therapy are vulnerable, elderly individuals who have difficulties performing certain basic activities of daily living and simply may not be able to perform repair or maintenance tasks.[9]

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. The changing of the internal filters requires the ability to loosen the tubing attached to both ends of the in-line regulator filter and then to reattach the tubing to the new filter. This requires hand strength and dexterity, both of which are compromised in most COPD patients, as well as those with arthritis. While these may seem like simple tasks to most individuals, experience shows that they are complex for many elderly patients. The Council encourages the Agency to take a second look at the definition of routine maintenance so that it avoids the problems encountered when CMS required beneficiaries to change their own power wheelchair batteries. This policy was ultimately changed when it became apparent that beneficiaries often reversed polarity on the batteries and ruined the electronics on the chair.

To provide more clarity on this issue, we suggest that CMS develop specific definitions as to what should be considered routine or non-routine equipment maintenance for both oxygen and capped rental home medical equipment. Based upon surveys of oxygen equipment manufacturers and oxygen equipment technicians who repair and service the same, we suggest the following tasks should be considered "routine" oxygen concentrator maintenance:

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

Of course, there should also be an exception to permit providers to engage in reimbursable maintenance when patients do not have the physical ability to undertake such activities. We also recommend the following tasks be considered "non-routine" maintenance 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 mail flow and regulator flow bacteria filters;
3. Using any specialized device to test oxygen purity output of equipment;
4. Cleaning of internal heat dissipation coils; and
5. Any maintenance that requires breaking of internal seals such as sieve bed repair, compressor rebuilds electric motor repair, etc.

We look forward to working with CMS to help develop the appropriate definitions for all product and service categories subject to this Rule.

F. CMS Should Clarify the Definition of Modality.

The Council encourages CMS to establish a definition of "modality" so that there is no confusion between the clinical meaning of this term and the regulatory use of it. Clinicians have

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[9] *See* O'Grady, "White Paper on Medicare's Payment Policy for Oxygen."

established three oxygen modality categories: (1) liquid oxygen; (2) compressed gas; and (3) oxygen extraction from room air (*i.e.*, concentrator). These categories are then divided into subcategories based upon the level of ambulation afforded to patients: (1) stationary (which might include stationary concentrators, large compressed gas cylinders, and liquid reservoirs); (2) portable; and (3) ambulatory (which include high-tech "lightweight" portable systems that dispense oxygen in various ways depending on the patient's breathing strength and rate). The Proposed Rule appears to use a different definition of "modality."

The Council believes it is important to provide a clear definition of modality to ensure that when it is appropriate to switch a patient, there is no confusion as to what constitutes medical necessity. 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 from a transfilling unit since there is no change in modality (both are compressed gas). However, that would not be the case under the Proposed Rule's use of the term.

CMS should clarify its definition and interpretation of the term "modality" in the Final Rule. If CMS does not adopt the clinical community's definition, the Agency should also define the specific circumstances when patients may be changed from one type of equipment to another. For example, if CMS seeks to encourage home oxygen providers to adopt newer, more operationally efficient equipment, the Final Rule should also set out: (1) the medical policy that clearly defines the criteria allowing patients to switch from one category to another (*i.e.*, gaseous or liquid cylinders that are delivered to the home vs. cylinders that are self-filled in the home); and (2) a payment policy that allows for full reimbursement when the patient changes from one equipment type to another, even if the change occurs during the first 36 months of rental. The Council encourages CMS to work with the home oxygen community to develop these policies.

G. CMS Should Clarify the Transfer of Ownership Provisions.

The Council is concerned that the Proposed Rule does not provide sufficient guidance about how the transfer of ownership requirement will be implemented. Although we have serious concerns about the appropriateness of the transfer of title to patients, we appreciate that CMS is bound by the DRA mandate. However, we urge CMS to provide additional guidance about the actual implementation of this requirement.

The Proposed Rule states that the title for oxygen equipment will transfer to a Medicare beneficiary after 36 months of continuous rental and after payments have been made for these months, consistent with the DRA requirement. For capped rental home medical equipment products and services, the title will transfer after 13 months. However, the Proposed Rule does not address how this timeframe would be affected by a break-in-service or whether the title of the equipment will transfer to the beneficiary if their rental period includes such a break. For example, a patient who receives eight tanks of oxygen per month, but is then hospitalized during flu season, may require 14 tanks per month upon discharge. Let us assume that the patient is in the 20th rental month of service. Because the patient's volume requirement for oxygen has increased, there is clearly a change in medical necessity. The Proposed Rule is not clear how those additional six tanks per month would be reimbursed and whether the "36-month" clock starts over on the new equipment that the home oxygen provider must place in the home.

The DRA specifically states that the transfer must occur "after the 36th continuous month during which payment is made." 42 U.S.C. § 1395m(a)(5)(F)(ii)(I). If there is a break or change in service, there is not continuous payment. Therefore, CMS should clarify in the Final Rule that if there is a break in service or rental period, the clock is reset.

Additionally, the Proposed Rule does not address how the beneficiary copayments or secondary payer payments are accounted for in the determination of the 36th continuous month calculation. Because the DRA uses the generic term "payment," CMS should clarify that payments must include not only Medicare payments, but also beneficiary copayments and secondary copayments. If these payments have not been made continuously during the 36th months, the title should not transfer.

To address these potential problems, we recommend that CMS: (1) establish a mechanism to indicate a "non-transfer of title to the beneficiary" so that CMS can distinguish an ongoing rental decision related to a pre-existing capped rental beneficiary from the above-described situation; (2) allow providers to have access to the Common Working File to verify break-in-service or previous equipment from another provider; and (3) address the impact of a break-in-service on the calculation of the 13 or 36 month period for purposes of capped rental home medical equipment and oxygen equipment ownership, respectively; and (4) implement a policy that specifies that title to capped rental home medical equipment and oxygen equipment will not transfer to a beneficiary if there remains any unpaid portion of the Medicare allowable charge, whether the unpaid portion is from Medicare, a secondary payer or the beneficiary themselves.

H. CMS should clarify its notice requirements about Medicare Assignment

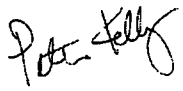
The Propose Rule requires all providers to "disclose to the beneficiary [their] intention regarding whether [they] will accept assignment of all monthly rental claims for the duration of the rental period." 71 Fed. Reg. at 44107. The rental period may be as long as three years. Participating providers must accept assignment on all claims for a period of a single calendar year. The decision to become a participating provider is voluntary.

The Council urges CMS to clarify this language to ensure that it is consistent with the general rule that participating providers are bound to accept assignment on an annual basis and can modify their status as a participating provider annually as well. If this clarification is not made, beneficiaries could be confused and make incorrect assumptions about their financial liability, which is inconsistent with CMS's intent in establishing the notice requirement. We recommend that the Agency clarify that providers disclose to beneficiaries their intent to accept assignment on all claims for the duration of the rental period (as defined in the disclosure). In addition, the provider should be able to clarify under what circumstances assignment would no longer be appropriate, such as if the beneficiary is no longer eligible for coverage. The Council agrees that beneficiaries must understand their financial obligations and strongly encourages CMS to clarify that providers have the flexibility to provide clear explanations of these obligations.

VI. Conclusion

The Council members sincerely appreciate your review of our concerns and look forward to working with the Agency on these issues. Please do not hesitate to contact Peter Kelly at 800-572-7522 ext. 206 if you have questions regarding these comments.

Sincerely,



Peter Kelly
Chief Executive Officer of Pacific Pulmonary Services and
Chairman of the Council for Quality Respiratory Care

Council Members

American HomePatient

Pacific Pulmonary Services

Apria Healthcare

Respironics Inc.

AirSep Corporation

Rotech Healthcare Inc.

Invacare Corporation

Air Products Global Healthcare

Lincare Holdings Inc.

Praxair Healthcare Services, Inc.

Sunrise Medical

ATTACHMENT 2 TO #66

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September 22, 2006

Tyler J. Wilson
President & CEO
American Association for Homecare
625 Slaters Lane, Suite 200
Alexandria, VA 22314

Dear Mr. Wilson:

The Lewin Group is pleased to provide you and the association with an independent assessment of: 1) the likely impact of the Notice for Proposed Rulemaking (NPRM) on Medicare payment for home oxygen therapy and oxygen equipment; and, 2) the extent to which the proposed rule meets the budget neutrality requirement.

After careful assessment of the proposed rule and a financial analysis using CMS' utilization figures, The Lewin Group has concluded that the proposed payments are not budget neutral for oxygen and oxygen equipment in 2007. The proposed regulations would result in a reduction of approximately 10 percent ($257M) in the amount paid for oxygen and equipment in 2007 alone, with additional payment reductions from the capped rental provision in the Deficit Reduction Act that requires providers to transfer title of oxygen equipment to the beneficiary after 36 months of rental. Table 1 summarizes our findings.

Table 1: Impact of NPRM on Medicare Payment for Oxygen and Oxygen Equipment in 2007

	In Millions
Total Calculated Payment - Current	$2,607
Proposed Payment - NPRM	$2,349
Calculated Loss to Industry	$ 257

Source: Lewin Group analysis.

Under the proposed rule, CMS changes the oxygen classification system, dividing stationary and portable oxygen contents into two separate payment classes. The proposal also calls for a third payment class for new technologies, such as portable concentrators and home transfilling systems, that eliminate the need for refilling and delivery of oxygen contents.

According to the NPRM, payment for portable oxygen contents would increase to $55 compared to the current average payments of $21, but the monthly payment amounts for stationary oxygen equipment and contents would drop from an average of $199 to $177.

The proposed payment rates take effect January 1, 2007 and are as follows:

- Stationary payment: $177
- Portable add-on: $32
- Oxygen-generating portable equipment add-on (portable concentrators or transfilling systems): $64
- Stationary contents delivery: $101
- Portable contents delivery: $55

Lewin Group Analysis

Our analysis involved several steps, beginning with identifying utilization and payment data supplied by CMS in the NPRM, as outlined below. We first calculated the current payment for oxygen and oxygen equipment provided to 975,561 Medicare beneficiaries per month (11,706,733 per year using 2004 claims). We then calculated payment using the proposed rates, assuming no migration into portable concentrators or transfilling equipment. See Table 2, where the rule results in a reduction in payment of $257,548,126.

Utilization data provided in the proposed rule were based on Medicare beneficiary claims for 2004. Unfortunately, these claims do not provide specific utilization rates for portable concentrators or transfilling systems, since separate HCPC codes did not exist for these services at that time. In order to determine the potential impact of the multiple changes in payments across modalities, The Lewin Group estimated a migration in modality use from stationary concentrators to the portable concentrators or transfilling systems of five percent, consistent with industry estimates. See Table 3, where the rule results in a reduction in payment of $238, 817,353.

Table 2: Impact of NPRM on Oxygen and Oxygen Equipment for 2007 – Assumes No Migration into O2 Generating

Payment Analysis- Impact of NPRM	Current Per Month Payment	Proposed Payment	Proportion Users	Number of Users- Annual	Number of Users - Per Month	Total Current Annual Payment	Total Annual Proposed Payment	Proposed Difference in Annual Payment
Stationary Concentrator	$199	$177	24%	2,809,616	234,135	$559,113,568	$497,302,018	-$61,811,550
Stationary Liquid/Gas System	$199	$177	2%	234,135	19,511	$46,592,797	$41,441,835	-$5,150,963
Stationary Concentrator + Portable System	$231	$209	69%	8,077,646	673,137	$1,865,936,173	$1,688,227,966	-$177,708,207
Stationary Concentrator + O2 Generating Portable	$231	$241	0%	0	0	$0	$0	$0
Stationary Liquid Gas System + Portable	$231	$209	5%	585,337	48,778	$135,212,766	$122,335,360	-$12,877,406
Stationary L/G + O2 Generating Portable	$231	$241	0%	0	0	$0	$0	$0
Beneficiaries on O2				11,706,733	975,561	$2,606,855,304	$2,349,307,178	-$257,548,126

Table 3: Impact of NPRM on Oxygen and Oxygen Equipment for 2007 – Assumes 5% Migration into O2 Generating

Equipment Modality	Current Per Month Payment	Proposed Payment	Proportion Users	Number of Users- Annual	Number of Users - Per Month	Total Current Annual Payment	Total Annual Proposed Payment	Proposed Difference in Annual Payment
Stationary O2 Concentrator	$199	$177	24%	2,809,616	234,135	$559,113,568	$497,302,018	-$61,811,550
Stationary Liquid/Gas System	$199	$177	2%	234,135	19,511	$46,592,797	$41,441,835	-$5,150,963
Stationary O2 Concentrator + Portable System	$231	$209	64%	7,492,309	624,359	$1,730,723,407	$1,565,892,606	-$164,830,801
Stationary O2 Concentrator + O2 Generating Portable	$231	$241	5%	585,337	48,778	$135,212,766	$141,066,133	$5,853,367
Stationary Liquid Gas System + Portable	$231	$209	5%	585,337	48,778	$135,212,766	$122,335,360	-$12,877,406
Stationary Liquid/Gas System + O2 Generating Portable	$231	$241	0%	0	0	$0	$0	$0
Beneficiaries on O2				11,706,733	975,561	$2,606,855,304	$2,368,037,951	-$238,817,353

In addition to the straightforward analysis described in the preceding table, we simulated several different potential scenarios to determine what it would take to result in the proposed payment rates being budget neutral in the first year of implementation. The proposed payment for oxygen and oxygen equipment based on the newly proposed rates (2004 utilization) vary depending on the assumptions related to migration from stationary concentrators to portable equipment. With a two percent migration in 2007, the payment would be $2,415,840,000, with a loss to industry of $256,320,000. The negative impact on the industry decreases as migration assumptions increase. With a 20 percent migration, the loss to industry would be $162,120,000. In order for the proposed payments to be budget neutral, one would have to assume a 73% migration from stationary to O2 generating portable equipment in the first year. It is our understanding that this kind of shift in the first year of the new payment rates is not possible.

In the event that we can be of further help in your work, please do not hesitate to call.

Sincerely,

Joan E. DaVanzo, PhD
Vice President

Morrison Informatics, Inc.

STRATEGIC DIRECTION THROUGH INFORMATION MANAGEMENT

A Comprehensive Cost Analysis of Medicare Home Oxygen Therapy

A Study for the American Association for Homecare

June 27, 2006

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A Comprehensive Cost Analysis of Medicare Home Oxygen Therapy
A Study for the American Association for Homecare

Executive Summary

A national study of the costs and resources required for providing home oxygen therapy for Medicare beneficiaries was conducted for the American Association for Homecare. Seventy-four (74) oxygen services providers delivering services to more than 1.7 million Medicare beneficiaries and more than 600,000 beneficiaries receiving medical oxygen at home, completed a detailed survey, which identified the costs and resources used in providing oxygen services. Survey findings demonstrated that oxygen systems (equipment) alone represent only 28 percent of the cost of providing medically necessary oxygen to Medicare beneficiaries. Oxygen therapy in the home also requires preparing and delivering equipment, delivering supplies and maintenance of oxygen equipment, assessing, training and educating patients, obtaining required medical documentation and providing customer service for beneficiaries, other related services, and operating and overhead costs, which taken together represent 72 percent of the cost of home oxygen therapy for Medicare beneficiaries. These services are essential components of providing oxygen therapy to the more than 1 million Medicare beneficiaries who rely on this treatment.

Introduction

The total costs of services for providing medical oxygen therapy in the home have not been well documented; however, it is known that multiple items contribute to these costs. In addition to the cost of equipment, the cost of providing oxygen therapy to homecare patients includes costs such as patient intake, preparation and delivery, scheduled and unscheduled maintenance, patient

assessment, training and education, ongoing patient support, including costs associated with oxygen fills, disposable supply items and delivery, related services and compliance with Federal and State regulations, including Food and Drug Administration (FDA) and Department of Transportation (DOT) requirements. Limited documentation of these components and their costs has led to misunderstanding by policymakers about the resources required to provide home oxygen equipment and services for Medicare beneficiaries.

A clear understanding of the costs for home oxygen therapy is particularly important because of policy changes made by the Deficit Reduction Act of 2005 (DRA), which changed the method of reimbursement for home oxygen under the Medicare program. The DRA requires that patients take ownership of home oxygen equipment after 36 months of rental. The changes assume that the ongoing costs of services required for home oxygen therapy are low and can be essentially disregarded in determining Medicare reimbursement. The DRA changes also assume that the overseeing of key services required for home oxygen therapy can in some manner become the responsibility of home oxygen patients, who require oxygen therapy for such illnesses as chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), respiratory failure, ALS and other serious diseases.

In order to more completely document the costs for providing home oxygen to Medicare beneficiaries, the American Association for Homecare (AAHomecare) commissioned a study by Morrison Informatics, Inc. (MII), to determine the costs of providing oxygen to Medicare homecare patients. MII conducted a national survey of provider members of AAHomecare to collect comprehensive financial and resource use data associated with providing home oxygen to Medicare beneficiaries. The survey captured detailed activity-based cost data from providers

representing more than 600,000 Medicare home oxygen beneficiaries, or approximately 60% of the estimated 1 million total Medicare population receiving such services.

Methods

The *Homecare Oxygen Service Provision Survey* was developed and sent in March 2006 to members of AAHomecare, an organization that includes homecare providers of all sizes operating in all 50 states. The survey contains detailed questions on the costs and resources for providing oxygen to Medicare homecare patients for the most current year-to-date time period available (Appendix A). Major cost categories contained in the survey include: total oxygen system cost; patient intake, obtaining required medical documentation and providing customer service for beneficiaries; preparation and return processing of equipment; equipment delivery, set-up and instructions for the patient; scheduled and unscheduled delivery and equipment maintenance; maintenance supplies and disposables; patient assessment and compliance monitoring; and other operating and overhead costs. The survey collected data on the average time, materials and cost for each survey item within a category for providing home oxygen and oxygen equipment to home oxygen patients for each homecare provider. Detailed explanations of each survey question are contained in the survey (Appendix A).

Home Oxygen Provision Survey Results

1. Survey Participants

A total of 78 provider organizations completed the survey; 74 usable surveys were obtained (four surveys were not usable because of missing data). The 74 completed surveys represent results from providers serving 1.7 million Medicare beneficiaries, of whom 600,000 receive oxygen equipment. This represents a substantial proportion of all Medicare beneficiaries receiving home

oxygen equipment. Providers responding to the survey provide services to an average of 24,000 Medicare beneficiaries per year and an average of 8,000 oxygen equipment Medicare beneficiaries per year (Table 1).

Table 1: Organizations Responding to the Oxygen Service Provision Survey

Total number of provider organizations responding to survey	74
Total number of Medicare beneficiaries YTD serviced by providers	1,750,723
Total number of oxygen equipment Medicare beneficiaries YTD by providers	607,484
Average number of Medicare beneficiaries YTD per company	23,982
Average number of oxygen equipment Medicare beneficiaries YTD per company	8,209

2. Survey Results

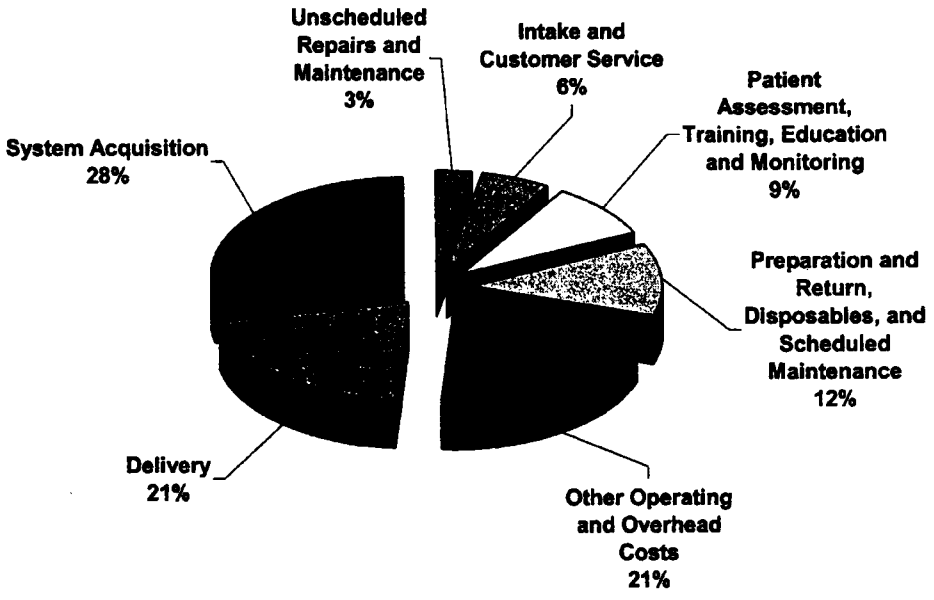
The overall average per-patient, per-month cost and resource use data from each survey item can be found in Appendix B. In addition to total oxygen equipment costs, including stationary, portable and backup unit costs, the major cost components of providing oxygen to patients at home include: the cost of obtaining patient information and related medical documentation necessary for patient intake; labor related to initial preparation of equipment; equipment delivery and set-up time; costs associated with scheduled and unscheduled maintenance and repair; ongoing patient support, including costs associated with oxygen fills, disposable supply items and delivery; vehicle costs associated with deliveries, maintenance and other in-home patient support services; costs of ongoing patient assessment, training, education and compliance monitoring; and other necessary operating and overhead costs. The average provider cost of each major cost component is shown in Table 2 and the relative proportional contribution of each major cost component to the total direct cost is shown in Figure 1.

Table 2: Overall per-Patient per-Month Costs for Major Cost Components of Home Oxygen Provision

Cost Component	Average Cost Per-Patient Per-Month
1. SYSTEM ACQUISITION[1]	$55.81
2. INTAKE AND CUSTOMER SERVICE[2]	$12.66
3. PREPARATION, RETURN, DISPOSABLES, AND SCHEDULED MAINTENANCE[3]	$25.24
4. UNSCHEDULED REPAIRS AND MAINTENANCE[4]	$6.10
5. PATIENT ASSESSMENT, TRAINING, EDUCATION AND MONITORING[5]	$17.54
6. DELIVERY ASSOCIATED WITH PREPARATION, RETURN, DISPOSABLES, AND SCHEDULED MAINTENANCE[6]	$42.26
7. OTHER MONTHLY OPERATING AND OVERHEAD[7]	$41.59
8. TOTAL DIRECT COST BEFORE TAXES	$201.20

[1] The amount includes acquisition costs for stationary, portable and backup units, conserving devices, ancillary equipment and accessories, and oxygen system contents (liquid and gaseous oxygen).
[2] The amount includes labor associated with patient intake functions, ongoing customer service (patient inquiries, scheduling of deliveries/maintenance/clinical visits, accommodating patient travel plans), and initial and renewal prescription processing.
[3] The amount includes labor associated with equipment preparation (testing, cleaning, and repair), equipment set-up and maintenance upon return, initial patient instruction, cost of disposable and maintenance supplies, and labor costs associated with scheduled preventive equipment maintenance.
[4] The amount includes labor and vehicle costs associated with unscheduled equipment repair and maintenance.
[5] The amount includes labor and travel costs associated with clinical visits by respiratory care practitioner, in-home patient assessments (including home environment safety assessment and oxygen therapy plan of care), training, education and compliance monitoring.
[6] The amount includes delivery costs associated with oxygen fills (liquid and gaseous oxygen), preparation, return, disposables and scheduled maintenance.
[7] The amount includes rent and other facility costs, administration, insurance, legal, regulatory compliance, MIS systems/controls, communications systems, employee training, accreditation, supplies, billing and compliance functions.

Figure 1: Home Oxygen Services Cost Component Proportions



3. Discussion

The purpose of this study was to determine, for homecare providers, the relative cost of the components of providing home oxygen to Medicare beneficiaries. The *Homecare Oxygen Service Provision Survey* did not collect data on specific components of *other operating and overhead* costs, which contributed a large proportion (21%) of the total cost of providing home oxygen. The components of *other operating and overhead* costs include costs associated with rent and other facility costs, administration, insurance, legal, regulatory compliance, MIS systems/controls, communications systems, employee training, accreditation, supplies, and billing and compliance functions. Because the values for other operating and overhead costs reported by the survey respondents were collected on an aggregate basis, further study of these

components will be necessary to better understand the nature of these expenses. The reported provider average total cost of providing oxygen, oxygen equipment and services, per patient is $201.20 per month.

The costs of providing oxygen and oxygen equipment for Medicare beneficiaries consist of multiple components, including ***total oxygen equipment costs, patient intake and obtaining required medical documentation and providing customer service for beneficiaries, preparation and return processing of equipment, equipment delivery, set-up and instruction of the patient, scheduled and unscheduled delivery and equipment maintenance, maintenance supplies, disposables and deliveries, patient assessment and compliance monitoring, and other operating and overhead costs***. The cost of oxygen equipment represents only 28 percent of the total cost of providing oxygen to Medicare beneficiaries. Many, if not most, of the other costs of providing home oxygen have not been carefully documented and recognized by policymakers, and have been assumed to be low and easily obtained when providing home oxygen services. Data from the *Homecare Oxygen Service Provision Survey* demonstrate that providing homecare oxygen requires multiple interdependent tasks which are essential to assure continuous and consistent oxygen services for Medicare beneficiaries. These required tasks are performed by providers to assure adequate oxygen services for Medicare beneficiaries. It is not clear how these services would be performed for beneficiaries if Medicare coverage of the required services were not provided.

Conclusions

A national study of the costs and resources required for providing home oxygen therapy for Medicare beneficiaries was conducted for the American Association for Homecare. Seventy-

four (74) oxygen services providers delivering services to more than 1.7 million Medicare beneficiaries and more than 600,000 beneficiaries receiving medical oxygen at home, completed a detailed survey, which identified the costs and resources used in providing oxygen services. Survey findings demonstrated that oxygen systems (equipment) alone represented only 28 percent of the cost of providing medically necessary oxygen to Medicare beneficiaries. Oxygen therapy in the home also requires preparing and delivering equipment, delivering supplies and maintenance of oxygen equipment, assessing, training and educating patients, obtaining required medical documentation and providing customer service for beneficiaries, other related services, and operating and overhead costs, which taken together represent 72 percent of the cost of home oxygen therapy for Medicare beneficiaries. These services are essential components of providing oxygen therapy to the more than 1 million Medicare beneficiaries who rely on this treatment. Further reductions in Medicare reimbursement for home oxygen as a result of the 36-month cap, the CPI freeze and the effects of competitive bidding will be problematic for home care providers and may jeopardize the quality of home care oxygen services given to Medicare beneficiaries.

Appendix A: Oxygen Service Provision Survey Items

1. The total number of Medicare beneficiaries served during the most recent one-year period
2. The total number of Medicare oxygen equipment beneficiaries during the most recent one-year period

A. EQUIPMENT ACQUISITION (Stationary, Back-up and Portable Equipment)

1. Stationary system average acquisition cost
2. Home back-up unit average cost (cylinder, stand, regulator, flow meter)
3. Portable system average acquisition cost, including conserving devices
4. Equipment salvage / trade-in average value for stationary and portable
5. Total equipment average acquisition cost
   ***** A1 + A2 + A3 - A4 *****
6. Average useful equipment life in months
7. Average monthly equipment acquisition cost
   ***** A5 / A6 *****
8. Total oxygen contents average cost per month, all systems
9. Average cost of debt %
10. Average monthly financing charge - equipment acquisition
    ***** (A1+A2+A3-A4) x A9 / 12 *****
11. Average monthly acquisition cost of system
    ***** A7 + A8 + A10 *****
12. Average number of stationary systems required in stock
    to support every 10 units in the field
13. *TOTAL SYSTEM AVERAGE COST PER MONTH*
    ***** *A11+ (A7 + A10) x (A12 / 10)* *****

B. CUSTOMER SERVICE AND PATIENT INTAKE

1. Estimated annual intake time per patient, in minutes (Complete ***Patient Intake Worksheet***)
2. Ongoing customer service time, in minutes, per patient per month
   (patient inquiries, scheduling of deliveries/maintenance/
   clinical visits, accommodating patient travel plans, etc.)
3. Annual prescription renewal preparation and processing time, in minutes per patient
4. Labor cost per hour - Customer Service Representative
   a. Average hourly wage rate
   b. Fringe benefits as a % of wage rate
   c. *Labor cost per hour*
   ***** B4a x (1+ B4b) *****
5. *AVERAGE TOTAL MONTHLY COST OF INTAKE AND CUSTOMER SERVICE PER PATIENT*
   ***** ((B2 + (B1 + B3)/12) / 60) x B4c *****

C. **PREPARATION BEFORE DELIVERY**

1. Average labor amount per unit (teardown, testing, cleaning, reassembly, bagging, boxing, loading), in minutes

2. Repair labor necessary as a result of problems encountered during pre-delivery preparation:

   a. Percentage of units requiring repair

   b. Average labor amount per unit (diagnosis and repair), in minutes

   c. Average repeat preparation labor amount per unit (testing, cleaning, etc,), in minutes

   d. Total weighted average repair labor per unit, in minutes

   ***** (C2b + C2c) x C2a *****

3. *Total weighted average preparation and repair labor per unit, in minutes*

   ***** C1 + C2d *****

4. Labor cost per hour - Equipment Technician

   a. Average wage rate

   b. Fringe benefits as a % of wage rate

   c. *Average labor cost per hour*

   ***** C4a x (1+ C4b) *****

5. *AVERAGE TOTAL COST OF PREPARATION PER UNIT*

   ***** (C4c / 60) x C3 *****

D. **VEHICLE COST PER MILE**

1. Acquisition and repair cost:

   a. Average vehicle acquisition cost per month (fully outfitted) - lease

   b. Average maintenance & repair cost per vehicle per year

   c. Average insurance & registration cost per vehicle per year

   d. Average odometer miles per vehicle per year

   e. Average vehicle acquisition, maintenance & repair cost per mile

   ***** ((D1a x 12) + (D1b + D1c)) / D1d *****

2. Gasoline cost per mile:

   a. Average miles per gallon

   b. Average gasoline cost per gallon

   c. Average gasoline cost per mile

   ***** D2b / D2a *****

3. *TOTAL VEHICLE COST PER MILE*

   ***** D1f + D2c *****

E. DELIVERY / SETUP / PICKUP COST

1. Average round trip travel time, in minutes
2. Average in-home setup time, in minutes
3. Average in-home client instruction time (Complete Patient Education Worksheet)
4. Average in-home pickup time, in minutes
5. a. Average service technician wage rate per hour
   b. Fringe benefits as a % of wage rate
6. Labor cost - delivery, setup, pickup
   ***** (E1 x 2 + E2 + E3 + E4) x (E5a x (1+E5b)) / 60
7. Average round trip miles
8. Average vehicle cost - delivery, setup, pickup
   ***** E7 x D3 *****
9. TOTAL AVERAGE DELIVERY / SETUP / PICKUP COST PER PATIENT
   ***** E6 + E8 *****

F. EQUIPMENT MAINTENANCE UPON RETURN

1. Average labor amount (preparation plus filter change), in minutes
2. Repair labor necessary as a result of problems encountered during pre-delivery preparation:
   a. Percentage of units requiring repair upon return
   b. Average labor amount per unit (diagnosis, repair), in minutes
   c. Average repeat preparation labor amount per unit (testing, cleaning, etc,), in minutes
   d. Total weighted average repair labor per unit, in minutes
   ***** (F2b + F2c) x F2a *****
   e. Total weighted average preparation and repair labor per unit, in minutes
   ***** F1 + F2d *****
3. Average wage rate, including fringe benefits
4. AVERAGE TOTAL COST OF MAINTENANCE PER UNIT UPON RETURN
   ***** F3 / 60 x F2e *****

G. AVERAGE MONTHLY COST TO PREPARE, DELIVER AND RETURN

1. Average total cost for delivery and return
   ***** C5 + E9 + F4 *****
2. Average number of months in service, per patient
3. AVERAGE MONTHLY COST TO PREPARE, DELIVER AND RETURN
   ***** G1 / G2 *****

H. ROUTINE, IN-HOME DELIVERY, DISPOSABLE AND SCHEDULED MAINTENANCE COSTS

1. Maintenance Supplies:
   - a. Gross particle filters
     - Quantity used per year
     - Price, each
   - b. Pre-felt filters
     - Quantity used per year
     - Price, each
   - c. Hepa filters
     - Quantity used per year
     - Price, each
   - d. Intake filters
     - Quantity used per year
     - Price, each
   - *e. Average monthly maintenance supplies cost*
     ***** (Sum 1a thru 1d) / 12 *****
2. Disposable Supplies:
   - a. Humidifier bottles
     - Quantity used per month
     - Price, each
   - b. Tubing
     - Quantity used per month
     - Price, each
   - c. Tubing Connectors
     - Quantity used per month
     - Price, each
   - d. Nasal Cannulas
     - Quantity used per month
     - Price, each
   - *e. Average monthly disposable supplies cost*
     ***** (Sum 1a thru 1d Totals) *****
3. Routine, in-home delivery and scheduled maintenance labor and vehicle costs:
   - a. Average vehicle cost per mile ***** D3 *****
   - b. Average round trip miles ***** E7 *****
   - c. Average round trip travel time, in minutes ***** E1 *****
   - d. Average time to perform scheduled/preventive equipment maintenance, in minutes ***** C2c *****
     {including filter cleaning/replacement, oxygen purity testing, alarm battery testing, PSI check on back-up unit, liter flow compliance with Rx, and in-home repair of unit}
   - e. Average time to perform gaseous and/or liquid fills, in minutes ***** C2c *****
   - f. Service Technician wage rate per hour plus fringes ***** E5a x (1+E5b) *****
   - g. Number of scheduled/preventive equipment maintenance visits per year
   - h. Number of oxygen contents delivery visits per year (including gaseous and/or liquid fills)
   - *i. Average monthly routine maintenance labor and vehicle cost*
     ** (H3a x H3b + (H3c/60 x H3f) x ((H3g + H3h) - H3g) / 12 + ((H3d / 60) x H3f x H3g) / 12 + ((H3e / 60) x H3f x H3h) / 12 **
     Note: Formula assumes that preventive maintenance visit occurs simultaneously with a delivery of oxygen fills
4. *AVERAGE TOTAL MONTHLY ROUTINE DISP AND SCHEDULED MAINT COSTS PER PATIENT*
   ***** H1 + H2 + H3 *****

I. COST OF UNSCHEDULED MAINTENANCE

1. Average vehicle cost, round trip ***** D3 x E6 *****
2. Service Technician labor cost per hour ***** E1 x H3e *****
3. Repair / Maintenance labor cost ***** F2b x F4 / 60 *****
4. Average # of calls per month per 10 units in service
5. Vehicle and delivery cost per unit per month
   ***** (I1 + I2 + I3) x (I4 /10) *****

J. COST OF PATIENT ASSESSMENT

1. Average number of clinical visits per year by RCP
2. Average round trip travel time, in minutes
3. Average in-home patient assessment time per visit, in minutes
   - Include time for home environment safety assessment - storage and maintenance
   - Include time for home environment safety assessment - administration
   - Include time for development of oxygen and equipment in-home care plan
4. Average in-home follow up and compliance monitoring time per visit, in minutes
   - Include weekly calls to patients to determine requirement for portable oxygen
   - Include compliance monitoring conducted in the home at least once per month
   - Include time for contacting physician whenever there is a question about the oxygen order or a change in patient status or care plan
5. a. Average RCP wage rate per hour, excluding benefits
   b. Fringe benefits as a % of wage rate
6. Average vehicle reimbursement per visit for RCP (at federal rate per mile of $0.445)
7. AVERAGE TOTAL COST OF PATIENT ASSESSMENT PER PATIENT PER MONTH
   ***** ((J2 + J3 + J4) x ((J5a x (1 + J5b)) / 60) +J6) x (J1 / 12) *****

K. TOTAL MONTHLY DIRECT COST BEFORE OVERHEAD AND PROFIT

***** A13 + B5 + G3 + H5 + I5 + J7 *****

L. OVERHEAD COSTS

1. Overhead Factor - Overhead costs as a % of Direct Costs
   {Rent, Facility, Administration, Insurance, Legal, MIS Systems/Controls, Regulatory Compliance, Communications Systems, Training, Accreditation, Supplies, Billing and Reimbursement Functions}
2. Estimated average monthly overhead cost per patient

M. TOTAL MONTHLY COST

***** K + L2 *****

N. PROFIT SUMMARY

1. Average Medicare Reimbursement per patient - Stationary and Portable Oxygen
2. Less: Write-offs, Hardships, etc. (%)
3. Net Reimbursement per patient per month **** N1 + N2 ****
4. Less: Average Total Costs to Supplier Per Patient
5. Average Net Profit Per Patient Before Taxes **** N3 + N4 ****

O. Net Profit Margin Before Taxes

***** N5 / N1 *****

PATIENT INTAKE (Minutes per-patient per year)

A.	Verification of beneficiary eligibility, claims management, and claims submission
B.	Collect and record physician information
C.	Receive, document and process order for oxygen and oxygen equipment
D.	Verification of the following:
1	Patient demographic information
2.	Patient possession of a valid Medicare number
3.	Patient emergency contact information
4.	Caregiver and/or conservator information
5.	Secondary insurance information
6.	Qualifying diagnosis
7.	Estimated total time for verification per year per patient
	**** D1 + D2 + D3 + D4 + D5 + D6 ****
E.	Input patient data in computer at service center
F.	Schedule delivery
G.	Contact physician to verify order, demographic information and license number
H.	Verify physician UPIN with independent database
I.	Coordinate or verify the existence of independent blood oxygen saturation study or ABG test
J.	Obtain physician-signed certificate of medical necessity (CMN)
K.	*Average estimated annual total intake time per patient*
	**** *A + B + C + D7 + E + F + G + H + I + J + K* ****

PATIENT EDUCATION (Minutes per-patient per episode)

A.	Supplier required training of patient and caregiver
B.	Contracted interpreter services, if applicable
C.	Patient and/or caregiver instruction in assembly and operation of oxygen and equipment
D.	Oxygen safety training
E.	Patient and/or caregiver training on "troubleshooting" possible equipment problems
F.	Patient and/or caregiver instruction on proper infection control in the home
G.	Patient and/or caregiver instruction on safe handling and storage of medications
H.	*Average total intake time per patient*
	**** *A + B + C + D + E + F + G* ****

Appendix B: Overall per Patient per Month Costs for Home Oxygen Providers

Survey Item	Average
A1.Stationary system average acquisition cost	$706.23
A2.Home back-up unit average cost (cylinder, stand, regulator, flow meter)	$152.32
A3.Portable system average acquisition cost, including conserving devices	$471.09
A4.Equipment salvage / trade-in average value for stationary and portable	$40.11
A5.Total equipment average acquisition cost	$1,288.63
A6.Average useful equipment life in months	60.44
A7.Average monthly equipment acquisition cost	$23.23
A8.Total oxygen contents average cost per month, all systems	$17.77
A9.Average cost of debt %	0.07
A10.Average monthly financing charge - equipment acquisition	$7.76
A11.Average monthly acquisition cost of system	$48.76
A12.Average number of stationary systems required in stock to support every 10 units in the field	2.53
A13.TOTAL SYSTEM AVERAGE COST PER MONTH	$55.81
B1. Estimated annual intake time per patient, in minutes (From the Patient Intake Worksheet)	166.36
B2. Ongoing customer service time, in minutes, per patient per month (patient inquiries, scheduling of deliveries/maintenance/ clinical visits, accommodating patient travel plans, etc.)	28.73
B3. Annual prescription renewal preparation and processing time, in minutes	43.07
B4a. Labor cost per hour - Customer Service Representative Average wage rate	$13.52
B4a. Labor cost per hour - Customer Service Representative Fringe benefits as a % of wage rate	0.22
B4a. Labor cost per hour - Customer Service Representative Labor cost per hour	$16.55
B5. AVERAGE TOTAL MONTHLY COST OF INTAKE AND CUSTOMER SERVICE PER PATIENT	$12.66
C1. Average labor amount per unit (teardown, testing, cleaning, reassembly, bagging, boxing, loading), in minutes	36.70
C2a. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Percentage of units requiring repair	0.10
C2b. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Average labor amount per unit (diagnosis and repair), in minutes	37.09
C2c. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Average repeat preparation labor amount per unit (testing, cleaning, etc,), in minutes	30.54
C2d. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Total weighted average repair labor per unit, in minutes	6.70

C3. Total weighted average preparation and repair labor per unit, in minutes	43.40
C4a. Labor cost per hour - Equipment Technician Average wage rate	$13.82
C4b. Labor cost per hour - Equipment Technician Fringe benefits as a % of wage rate	0.22
C4c. Labor cost per hour - Equipment Technician Average labor cost per hour	$16.92
C5. AVERAGE TOTAL COST OF PREPARATION PER UNIT	$11.93
D1a. VEHICLE COST PER MILE Acquisition and repair cost: Average vehicle acquisition cost per month (fully outfitted) – lease	$599.19
D1b. VEHICLE COST PER MILE Acquisition and repair cost: Average maintenance & repair cost per vehicle per year	$1,844.74
D1c. VEHICLE COST PER MILE Acquisition and repair cost: Average insurance & registration cost per vehicle per year	$1,427.62
D1d. VEHICLE COST PER MILE Acquisition and repair cost: Average odometer miles per vehicle per year	28,764
D1e. VEHICLE COST PER MILE Acquisition and repair cost: Average vehicle acquisition, maintenance & repair cost per mile	$0.40
D2a. Gasoline cost per mile: Average miles per gallon	13.45
D2b. Gasoline cost per mile: Average gasoline cost per gallon	$2.46
D2c. Gasoline cost per mile: Average gasoline cost per mile	$0.19
D3. TOTAL VEHICLE COST PER MILE	$0.60
E1. Average round trip travel time, in minutes	46.22
E2. Average in-home setup time, in minutes	33.35
E3. Average in-home client instruction time, in minutes	60.22
E4. Average in-home pickup time, in minutes	18.36
E5a. Average service technician wage rate per hour	14.01
E5b. Fringe benefits as a % of wage rate	0.22
E6. Labor cost - delivery, setup, pickup	$59.33
E7. Average round trip miles	23.43
E8. Average vehicle cost - delivery, setup, pickup	$13.73
E9. TOTAL AVERAGE DELIVERY / SETUP / PICKUP COST PER PATIENT	$73.06
F1. Average labor amount (preparation plus filter change), in minutes	35.81
F2a. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Percentage of units requiring repair upon return	0.21
F2b. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Average labor amount per unit (diagnosis, repair), in minutes	37.64
F2c. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Average repeat preparation labor amount per unit (testing, cleaning, etc,), in minutes	30.95

F2d. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Total weighted average repair labor per unit, in minutes	13.17
F2e. Repair labor necessary as a result of problems encountered during pre-delivery preparation: Total weighted average preparation and repair labor per unit, in minutes	48.98
F3. Average wage rate, including fringe benefits	$16.92
F4. AVERAGE TOTAL COST OF MAINTENANCE PER UNIT UPON RETURN	$13.65
G1. Average total cost for delivery and return	$98.63
G2. Average number of months in service, per patient	22.13
G3. AVERAGE MONTHLY COST TO PREPARE, DELIVER AND RETURN	$5.34
H1a. Maintenance Supplies: Gross particle filters quantity used per year	2.32
H1a. Maintenance Supplies: Gross particle filters Price each	$2.98
H1b. Maintenance Supplies: Pre-felt filters, quantity used per year	1.77
H1b. Maintenance Supplies: Pre-felt filters, price each	$2.01
H1c. Maintenance Supplies: Hepa filters quantity used per year	1.54
H1c. Maintenance Supplies: Hepa filters Price each	$7.00
H1d. Maintenance Supplies: Intake filters Quantity used per year	3.19
H1d. Maintenance Supplies: Intake filters Price each	$3.89
H1e. Maintenance Supplies: Average monthly maintenance supplies cost	$2.34
H2a. Disposable Supplies: Humidifier bottles Quantity used per month	1.38
H2a. Disposable Supplies: Humidifier bottles Price each	$1.46
H2b. Disposable Supplies: Tubing Quantity used per month	1.73
H2b. Disposable Supplies: Tubing Price each	$1.83
H2c. Disposable Supplies: Tubing Connectors Quantity used per month	1.43
H2c. Disposable Supplies: Tubing Connectors Price each	$0.84
H2d. Disposable Supplies: Nasal Cannula Quantity used per month	3.19
H2d. Disposable Supplies: Nasal Cannula Price each	$0.69
H2e. Disposable Supplies: Average monthly disposable supplies cost	$7.53
H3a. Average vehicle cost per mile	$0.59
H3b. Average round trip miles	23.43

H3c. Average round trip travel time, in minutes	46.26
H3d. Average time to perform scheduled/preventive equipment maintenance, in minutes {including filter cleaning/replacement, oxygen purity testing, alarm battery testing, PSI check on back-up unit, liter flow compliance with Rx, and in-home	26.69
H3e. Average time to perform gaseous and/or liquid fills, in minutes	20.16
H3f. Service Technician wage rate per hour plus fringes	$17.09
H3g. Number of scheduled/preventive equipment maintenance visits per year	4.90
H3h. Number of oxygen contents delivery visits per year (including gaseous and/or liquid fills)	19.01
H3i. Average monthly routine maintenance labor and vehicle cost	$53.40
H4. AVERAGE TOTAL MONTHLY ROUTINE DISP AND SCHEDULED MAINT COSTS PER PATIENT	$62.16
I1. COST OF UNSCHEDULED MAINTENANCE Average vehicle cost, round trip	$13.54
I2. COST OF UNSCHEDULED MAINTENANCE Service Technician labor cost per hour	$13.20
I3. COST OF UNSCHEDULED MAINTENANCE Repair / Maintenance labor cost	$10.31
I4. COST OF UNSCHEDULED MAINTENANCE Average # of calls per month per 10 units in service	$1.60
I5. COST OF UNSCHEDULED MAINTENANCE Vehicle and delivery cost per unit per month	$6.10
J1. COST OF PATIENT ASSESSMENT Average number of clinical visits per year by RCP	10.82
J2. COST OF PATIENT ASSESSMENT Average round trip travel time, in minutes	46.02
J3. COST OF PATIENT ASSESSMENT Average in-home patient assessment time per visit, in minutes; Include time for home environment safety assessment - storage and maintenance; Include time for home environment safety assessment - administration; Include time	45.72
J4. COST OF PATIENT ASSESSMENT Average in-home follow up and compliance monitoring time per visit, in minutes; Include weekly calls to patients to determine requirement for portable oxygen; Include compliance monitoring conducted in the home at least once	45.89
J5a. COST OF PATIENT ASSESSMENT Average RCP wage rate per hour, excluding benefits	$21.74
J5b. COST OF PATIENT ASSESSMENT Fringe benefits as a % of wage rate	0.22
J6. COST OF PATIENT ASSESSMENT Average vehicle reimbursement per visit for RCP (at a federal rate per mile of $0.445)	$10.13
J7. COST OF PATIENT ASSESSMENT AVERAGE TOTAL COST OF PATIENT ASSESSMENT PER PATIENT PER MONTH	$17.54
K. TOTAL MONTHLY DIRECT COST BEFORE OVERHEAD AND PROFIT	$159.61
L2. OVERHEAD COSTS Estimated average monthly overhead cost per patient {Rent, Facility, Administration, Insurance, Legal, MIS Systems/Controls, Regulatory Compliance, Communications Systems, Training, Accreditation, Supplies, Billing and Reimbursement}	$41.59
M. TOTAL MONTHLY COST PER PATIENT	$201.20

PATIENT INTAKE	Average Minutes
A. Verification of beneficiary eligibility, claims management, and claims submission	43
B. Collect and record physician information	8
C. Receive, document and process order for oxygen and oxygen equipment	12
D1. Verification of Patient demographic information	4
D2. Verification of Patient possession of a valid Medicare number	3
D3. Verification of Patient emergency contact information	3
D4. Verification of Caregiver and/or conservator information	2
D5. Verification of Secondary insurance information	4
D6. Verification of Qualifying diagnosis	5
D7. Estimated total time for verification per year per patient	21
E. Input patient data in computer at service center	7
F. Schedule delivery	7
G. Contact physician to verify order, demographic information and license number	7
H. Verify physician UPIN with independent database	3
I. Coordinate or verify the existence of independent blood oxygen saturation study or ABG test	11
J. Obtain physician-signed certificate of medical necessity (CMN)	38
K. Total intake time per patient	157
PATIENT EDUCATION	Average Minutes
A. Supplier required training of patient and caregiver	16
B. Contracted interpreter services, if applicable	5
C. Patient and/or caregiver instruction in assembly and operation of oxygen and equipment	14
D. Oxygen safety training	7
E. Patient and/or caregiver training on "troubleshooting" possible equipment problems	7
F. Patient and/or caregiver instruction on proper infection control in the home	6
G. Patient and/or caregiver instruction on safe handling and storage of medications	4
H. Average total intake time per patient	60

monitored carriers' performance in carrying out these steps, it did not evaluate the appropriateness of the new payment levels established.[8]

In 1987, the Congress and HCFA began moving the Medicare program from paying based on individual providers' charges to fee schedules for medical equipment and supplies.[9] State-level fees were determined based on average supplier Medicare charges in the state during 1986 and 1987.

Prior to 1998, these fees were adjusted each year using formulas correlated with the Consumer Price Index (CPI). No update was provided from 1998 through 2000 or in 2002, although updates were provided in 2001. The 2002 payment amounts later were revised downward by Section 302 of the MMA to median state level 2002 FEHBP rates.

The net effect of all these changes was a disconnect between the costs that providers faced and the fees they were paid. Using the CPI to index payments for a range of goods and services is a crude instrument even under the best of circumstances. In the past, The Medicare Payment Advisory Commission (MedPAC) has warned the Congress about the negative effects of using more general indices such as the CPI to adjust payments for specific medical goods and services.[10]

In a field as significantly affected by technological advancements as oxygen therapy, correlating payments to the CPI for a decade is virtually guaranteed to overpay for some items and underpay for others. Indexing for one decade by the CPI and then making incremental adjustments without rebasing for another decade means the last serious attempt to rigorously determine a "fair" price for individual components of equipment, supplies and services was undertaken in the 1980's – 20 years ago.

The result was a de facto global payment. As long as overpayments balanced underpayments, the system worked. While payments for equipment were sufficient to also cover underpayments for services and supplies, significant problems either with access or quality were avoided. However, the history of Medicare payment policy has shown that this type of situation cannot continue forever. This became clear in other areas of Medicare payment policy, most notably oncology drugs paid under Part B. The government, through either the Inspector General's Office or the Government Accountability Office (GAO), began to focus on the items that were overpaid without considering those areas in which underpayments were made. Not surprisingly, neither the HHS Inspector General nor the GAO focuses on identifying areas in which the taxpayer should be paying more.

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[8] Testimony Before the Subcommittee on Labor, Health and Human Services, Education and Related Agencies, Committee on Appropriations, U.S. Senate United States General Accounting Office GAO Wednesday, June 12, 2002 "MEDICARE Challenges Remain in Setting Payments for Medical Equipment and Supplies and Covered Drugs," Statement of Leslie G. Aronovitz , GAO-02-833T page 5.

[9] Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, § 4062, 101 Stat. 1330, 1330-101 (codified at 42 U.S.C. § 1395m (1988)).

[10] Report to the Congress, "Blood Safety in Hospitals and Medicare Inpatient Payment," Medicare Payment Advisory Commission, December 21, 2001.

Further complicating matters, a provision of the Deficit Reduction Act of 2005 shifted ownership of the oxygen equipment from the provider to the Medicare beneficiary after 36 months. We estimate that 26.4 percent of Medicare oxygen patients use oxygen for more than 36-months (see Chart 6 below).[11, 12] The full implications of this transfer of ownership are not yet apparent. The CMS Proposed Rule would have suppliers still responsible for maintenance services after the 36-month cap has been reached.[13] However, this may be difficult given questions surrounding the legal liability of suppliers for equipment they no longer own, and the possible voiding of manufacturer warrantees by the transfer of title. Another complication involves the advanced stage of the beneficiary's illness at the time of transfer. There is a high probability that the beneficiary may be close to the end of life. With the transfer of title, presumably the beneficiary's heirs would take possession of the oxygen equipment after the beneficiary's death. The specter of taxpayer-purchased oxygen equipment being sold on e-Bay by the heirs seems far from Congress' policy intention of a more efficient, effective Medicare oxygen payment policy.

At a minimum, a movement away from a de facto global payment covering all equipment, supplies and services requires a re-estimation of appropriate payment levels for each of the components rather than a selective review of only those items the government feels may be overpaid. CMS realized as much in its latest work in this area, the new proposed rule for oxygen payments. It stated: "The current fee schedule amounts for oxygen contents are based on calendar year data from 1986 for the combined average Medicare monthly payment for both stationary and portable contents divided by number of rental months for stationary liquid and gaseous oxygen equipment."[14] While this represents an effort by CMS to offer a more reasonable and rational approach, they are still left having to rely on 20-year-old data.

What is the likelihood that a rigorous re-estimation of component payments will actually occur? The results of the CMS competitive bidding demonstration projects from 1999-2003 for durable medical equipment, including oxygen showed that prices were lower and that quality of services were essentially unchanged".[15] As a result, Congress included competitive bidding as a major change in oxygen payment policy in the MMA in 2003. The Section 302 of the (MMA) requires competitive bidding to begin in 10 of the largest MSAs in 2007; in 80 of the largest MSAs in 2009; and in additional

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[11] An analysis of the combined 2002, 2003 and 2004 5 percent Medicare claims files shows 26.4% of December 2004 users had at least 36 months of oxygen. Providers with a growing market share may tend to have a smaller percentage over 36 months, while providers with a stable or shrinking market share tend to have more over the 36-month threshold.

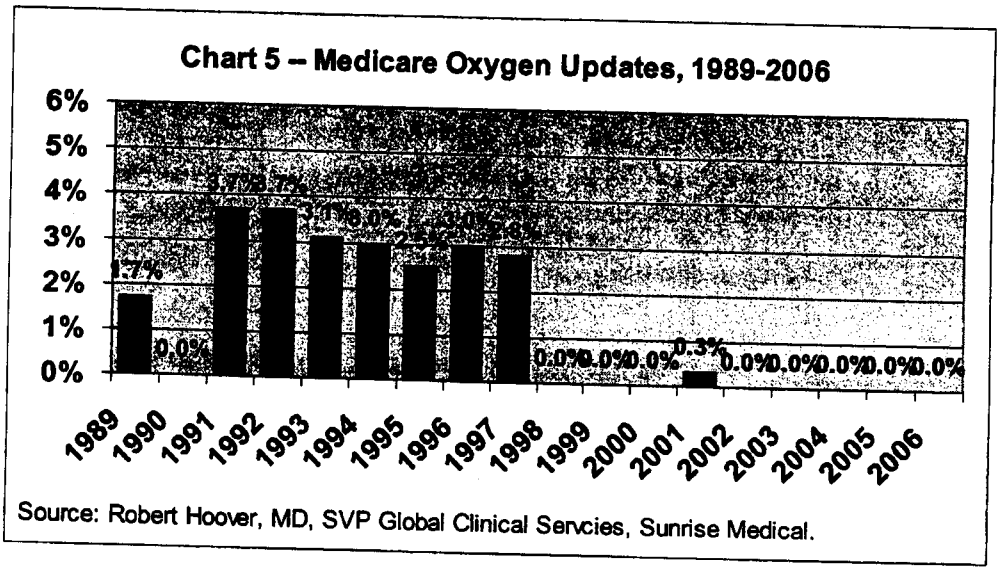
[12] CMS published results estimating the 36 percent of beneficiaries will exceed the 36 month cap. CMS Proposed Rule, "Home Health Prospective Payment System Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment; Proposed Rule" p.73. Attempts to resolve the difference are ongoing. http://www.cms.hhs.gov/HomeHealthPPS/downloads/CMS1304Pdisplay.pdf.

[13] Ibid.

[14] Ibid.

[15] http://www3.cms.hhs.gov/DemoProjectsEvalRpts/downloads/CMS_rtc.pdf. page two, Final Report to Congress: Evaluation of Medicare's Competitive Bidding Demonstration For Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Tommy G. Thompson, Secretary of Health and Human Services 2004.

areas after 2009. Given this timetable, CMS may ultimately choose not to spend scarce resources to refine a payment methodology that they intend to phase-out. Chart 5 below displays a summary of the changes over the last few years.



Effects of Recent Payment Policy Changes

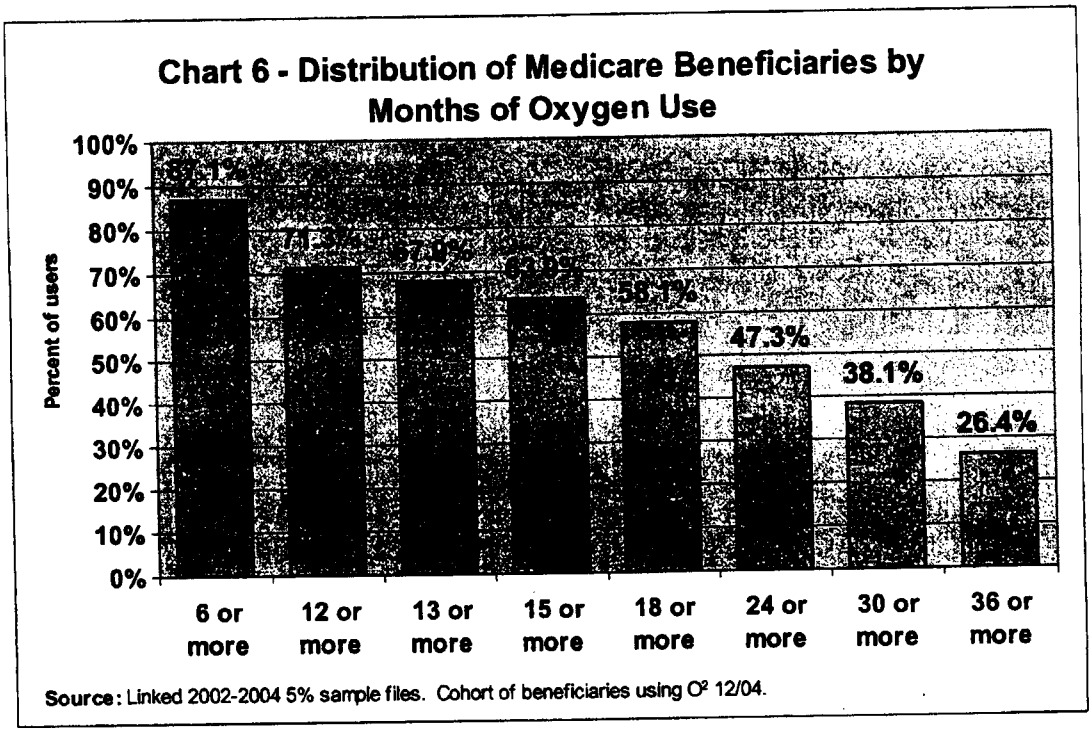
This section examines the effect of the 36-month cap on three key populations – beneficiaries, taxpayers and providers.

Effects of policy changes on patients:

Chart 6 shows the distribution of oxygen patients by the number of months they used oxygen in 2004. The vast majority use oxygen for more than six months, 87.1 percent, with 26.4 percent using oxygen for 36 months or more.

The subpopulation with more than 36 months of oxygen use does not appear significantly different from other oxygen patients across a range of measures, e.g., average age, percent dually eligible for Medicare and Medicaid, or percent disabled.[16] As stated earlier, Medicare patients requiring oxygen therapy tend to be older, more likely to also be on Medicaid and closer to end-of-life, than other Medicare patients. The 36-month subpopulation may not look much different for the rest of oxygen users, but we know that oxygen users are significantly more at risk than the Medicare population in general.

[16] Medicare Oxygen Users 2002-2004, Persons with any Oxygen Concentrator Use in December 2004. Mean age all oxygen users 73.4. Mean age 36-month oxygen users 72.7. Percent dually eligible all oxygen users 29%. Percent dually eligible 36-month oxygen users 28%. Percent disabled (non-aged) all oxygen users 14%. Percent disabled (non-aged) 36-month oxygen users 16%.



Source: Linked 2002-2004 5% sample files. Cohort of beneficiaries using O^2 12/04.

It is this subpopulation that will be affected by a 36-month cap, and it is this subpopulation that probably is in a weak position to effectively navigate this new market. As so starkly demonstrated by the implementation of the new Medicare drug benefit, the older and sicker the beneficiary, the greater the level of difficulty associated with choosing among different plans, balancing benefits and premiums, and making the other decisions needed in a more open market. Moreover, the greater the difficulty in navigating this new system, the more likely that significant problems will occur, both with access and quality of services and supplies.

Compounding this problem is the lack of an accurate rebasing of the component payment rates for the last 20 years. Without this rebasing, it is unclear why there would be an effective market for supplies and support services. Inaccurate payments at or above market rates should be available, as long as significant issues like legal liability can be resolved. However, if the inaccurate payments are lower than market rates, and certainly if they are lower than cost, other provisions of Medicare payment policy make it almost impossible for the market to work. Given Medicare provisions barring balanced billing beyond Medicare cost-sharing provisions, providers are unable to offer the supplies or services without losing money. In the private sector if an insurer pays less than market rates and the patient still wants the goods or services, the patient pays the difference and still has access to the desired goods and services. In Medicare that is illegal.

Medicare has seen this pattern in the past. The most significant example in recent Medicare history is withdrawal of Medicare+Choice HMOs during the late 1990s and early 2000s. The Medicare+Choice HMOs withdrew from markets where the Medicare contribution no longer covered the cost of providing benefits. Between 1999 and 2003 enrollments in these plans dropped almost a third – from 6.4 million to 4.6 million, as plans withdrew from market after market.[17] Undoubtedly plans were overpaid in 1997 when the payments methodology was changed, but the overpayments of the 1990 were more than compensated for by capping payments to no more than two percent a year during a time period when underlying costs were growing by at least five or six percent. As a result, the program underwent a near death experience.

The same negative potential exists for the oxygen program and the vulnerable beneficiaries it serves. Oxygen providers may follow the same pattern with geographic variation being the key determinant of access problems. However, given the methodology for updating oxygen payments over the years, it may be that the key determinant of access and quality problems is the particular supply or service. For example, underpaying for portable oxygen could leave beneficiaries stranded in their homes and is in direct contradiction to the President's "New Freedom Initiative" to assist the disabled in rejoining the community.

There is the potential for significant access and quality problems. The combined effect of a number of factors leads to these serious concerns:

- A particularly vulnerable population in a poor position to navigate a new system for oxygen supplies and services.
- A payment methodology for specific supplies and services that has not gone through a serious recalculation since the 1980s.
- The small likelihood that CMS will be able or willing to invest significant scarce resources into developing a workable payment methodology so close to the transition to competitive bidding,
- Medicare's balance billing prohibitions that would block any ability to offset underpayment.
- A new generation of legal questions involving liability for equipment no longer owned by the provider.

All these factors point to the likelihood that 26 percent of vulnerable oxygen patients will face significant problems of access and possibly lesser quality of the services and supplies they need most.

[17] "A Data Book: Healthcare Spending and the Medicare Program" (MedPAC June 2006), http://www.medpac.gov/publications/congressional_reports/Jun06DataBookSec10.pdf

Effects of policy changes on taxpayers

As stewards of the taxpayers' dollars, the government has a responsibility to spend the taxpayers' dollars prudently. This is a key objective for changing Medicare payment policy and so the question is whether or not savings will materialize in light of the changes.

To estimate Medicare savings or costs from a change in one part of the program requires also estimating the possible savings or costs in other parts of the Medicare program. For years the HMO industry justified the additional spending on prevention and education as cost effective because of the resulting reduced hospitalizations. A similar dynamic occurs with oxygen therapy.

The best empirical estimate is that about 26 percent of beneficiaries will exceed the 36-month cap (see footnote 12 for a more complete discussion). Spending for these beneficiaries will shift from equipment to supplies and services. However, other Medicare spending may result.

The Agency for Healthcare Quality and Research (AHRQ), the Department of Health and Human Service in-house experts on patient quality, access and evidence-based medicine, released a comprehensive study in 2004 of the effect of Long-Term Oxygen Therapy (LTOT) on patients' health and related health care utilizations. "In a retrospective cohort study of 246 patients that focused on the effect of LTOT on hospitalization, Ringbaek et al. (2002) reported that the average number of hospital admissions per patient per year decreased from 2.1 to 1.6 and the average number of days hospitalized decreased from 23.7 to 13.4 after LTOT."[18]

Results like these indicate that any change in payment policy that restricts access to LTOT may actually cost taxpayers more than it saves them. The cost of an average day in the hospital is above $1,600[19] and those Medicare beneficiaries requiring oxygen therapy are likely to have higher than average hospital stays. Therefore, restricting access to needed oxygen therapy may well turn estimated taxpayer savings into added taxpayer expenditures with the additional risk of significant negative health outcomes for this already very vulnerable population.

A second major concern is the interaction between taxpayer savings that have been scored or associated with the introduction of the new competitive bidding program and savings associated with the 36-month cap. In scoring the Deficit Reduction Act of 2005 (DRA), the Congressional Budget Office (CBO) estimated savings associated with the durable medical equipment (DME) provisions included in the bill. "CBO estimates those changes to Medicare's payment rules for oxygen and other durable medical equipment would reduce Medicare spending by $0.7 billion over the 2006-2010 period

[18] AHRQ op. cit., footnote #1, page 23. .
[19] CMS Office of the Actuary, Medicare Cost Reports for Hospitals – updated with cost reports submitted as of March 31, 2006.

and by $1.9 billion over the 2006-2015 period." [20] Since this estimate included all the DME provisions, these estimates should not be interpreted as savings associated with the 36-month cap.

However, Section 302 of the MMA requires competitive bidding to be implemented in ten of the largest MSAs in 2007, in 80 of the largest MSAs in 2009, and in additional areas after 2009. In 2003, CBO estimated Section 302 savings of $9.2 billion over ten years.[21] As with the earlier estimate, other DME costs were also included in these calculations. Therefore, care would need to be taken to ensure that any potential savings were not already accounted for in CBO's earlier estimates. Counting them again as generating savings for the 36-month cap or lower month cap would result in double-counting.

Effects of policy changes on providers

The goals of the Medicare program have no provision to protect providers from financial hardship. However, an active market with multiple providers, especially under competitive systems, results in more choices for beneficiaries and more competitive pricing for the government. Precipitous or dramatic changes to market fundamentals can prompt economic chaos and market disruptions as a result of overregulation or overplaying a government's monopsonistic[22] powers. The California state employees' health insurance program, CalPERS, is one such example. During the peak of the HMO era, CalPERS enjoyed negative premium growth for three straight years, 1995-1997, but premiums grew by 25 percent a few years later. By contrast, the designers of the federal employees' health insurance program, FEHBP, the other major multi-plan employer-based system, made a conscious decision to keep more plans in the market rather than to push for deeper short-term premium discounts.[23]

Overly aggressive government regulation and price controls also have been shown to have a chilling effect on innovation and eventually on the industry itself.[24] This was the outcome in the European pharmaceutical industry, which has seen its strength wane significantly due to government controls.

Significant new policy changes to an industry attempting a smooth transition to the new competitive bidding system presents yet another concern. Major changes now may risk the success of competitive bidding. It may drive players out of the market that

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[20] Congressional Budget Office Cost Estimate, January 27, 2006, S. 1932, Deficit Reduction Act of 2005. Page 30.

[21] Congressional Budget Office Cost Estimate July 22, 2003, H.R. 1, Medicare Prescription Drug and Modernization Act of 2003 - As passed by the House of Representatives on June 27, 2003 and S. 1, Prescription Drug and Medicare Improvement Act of 2003 - As passed by the Senate on June 27, 2003, with a modification requested by Senate conferees. Table 13.

[22] Monopsony is a market similar to a monopoly except that a large buyer not seller controls a large proportion of the market and drives the prices down. Sometimes referred to as the buyer's monopoly.

[23] *Health Insurance Spending Growth – How Does Medicare Compare?* Joint Economic Committee June 10, 2003 and personal discussions with the Chief Actuary FEHBP

[24] *"What price competitiveness in the drugs industry?,"* THE LANCET • Vol 362 • July 26, 2003.

might not be efficient in the current fixed-priced system, but that would be very efficient in a competitive bidding system.

Towards a better designed oxygen payment policy

A well-designed oxygen payment policy is one that allows for a successful transition to a new competitive bidding process. Major changes in payment policy now may well prove highly disruptive to the implementation of competitive bidding already under way.

However, in the event that a new payment methodology must be implemented in the interim to replace the current methodology, certain steps can be taken to minimize the disruption. For example, ensuring the proper incentives; balancing price, quality and access; and collecting the best data available (not data from 1987).

The Medicare Payment Advisory Commission (MedPAC, chartered and appointed by Congress) defined the essential characteristics of an effective/efficient payment methodology for a well designed Medicare payment. [25] Each of these characteristics will be listed and then examined.

Is the product or service that Medicare is buying well defined and does HCFA have sufficient ability to monitor product attributes so that fixed-price contracting is desirable?

In considering the current payment policy with the 36-month cap, the answer is no. The mix of equipment, services and supplies has not been effectively monitored during the last twenty years. In addition, the CMS competitive bidding demonstrations have already shown that a more effective means of purchasing is available and indeed is being implemented.

If so, does the overall design—unit of payment, product or service classification system, and so forth— establish an appropriate basis for fixed-price contracting?

By not keeping up with changes occurring in the field and by allowing payments to be indexed by the general inflation rate in the economy rather than one of the range of indices better designed to measure technological change, the match between costs and reimbursements is almost guaranteed to diverge. In fact, this is the type of concern that attracted support for competitive bidding as an alternative to a formula-based price set by the government. An effective formula-based pricing methodology requires better data, better evaluation of the effects of technological change, better measures of input prices and geographic variation.

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[25] "Chapter 1: Evaluating Medicare's Payment Policies," MedPAC Report to the Congress: Medicare Payment Policy | March 2001 page 7.

Is the distribution of payments consistent with expected variation in efficient providers' costs resulting from differences in product mix or market conditions beyond providers' control?

As discussed above, the current payment methodology is conveniently based on equipment cost (which is relatively easy to determine); with very little consideration given to more difficult to measure cost elements such as service levels and supplies. The 36-month cap is an attempt to move payments away from equipment. The DRA[26] provides for increased payments for services and supplies. Although the recently released HHS proposed rule adjusted upward payments for oxygen supplies, two independent teams of Wall Street analysts concluded that CMS had not raised supply reimbursements enough to meet budget neutrality.[27] In the proposed rule, payment levels for oxygen services were delegated to CMS contractors (DMERCs) to determine at a later date.

Is the current level of the payment rates consistent with the costs efficient providers (or health care organizations) would incur in furnishing covered services to beneficiaries?

The current methodology, with the addition of the 36-month cap, is a blunt instrument to adjust payments over time. The decade of indexing to general inflation in the economy, the Consumer Price Index, rather than a measure that captured the changes actually relevant to oxygen created an extremely weak empirical base for making payments. CMS' recent efforts to rationalize payments are a real step in the right direction, yet they are still based on a foundation of questionable relevance.

How are providers' costs expected to change in the forthcoming year as a result of anticipated changes in legitimate factors, such as market input prices or the introduction of new technologies?

To properly address MedPAC's questions, the options are either a rigorous data collection effort to establish a sound empirical base for a formula-based payment or to allow the market to do what it does best and reflect the actual changes in the cost of doing business in a variety of different markets around the country. This concern/consideration feeds directly into the sixth criteria: what data is needed to ensure accurate payments are being made? The answer is the same – either use the market to adjust prices for oxygen, as is done with the vast majority of all other prices in the economy, or make the substantial investment in data collection and analysis to construct a formula-based payment system that works without risking reduced access, reduced quality or both.

What payment tools and data may need improvement and how might improvements be accomplished?

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[26] The Deficit Reduction Act of 2005, Section 5101(b)(1)(B).

[27] "AHG, LNCR: Proposed Rule Looks Bad," Wachovia Securities, Wachovia Capital Markets, Llc Equity Research Department, July 17, 2006. "Lincare Holdings Inc. CMS Proposed Rule Leads Us to Downgrade to Neutral, Lower Target," Bank of America, Equity Research, July 28, 2006.

This sixth criteria for an effective payment policy focuses on the site of care. Do the payment rates established for a particular setting create financial incentives for inappropriate shifts of services to or from potential substitute settings? In the case of oxygen the concern is more between modalities rather than sites of care. A serious miscalculation in payments for certain modalities, e.g., portable oxygen, can do significant damage to important policy achievements, such as the President's New Freedom Initiative and leave oxygen patients effectively trapped in their homes.

Conclusions

Medicare's oxygen payment policy has a long history, not all of it prime examples of a well-designed payment methodologies. For beneficiaries, we look for a payment policy that protects quality, access and innovation. For taxpayers, we look for a payment policy that shows careful stewardship of the taxpayers' money. For providers, we look for a payment methodology that accurately pays for providing the best quality at the most competitive price.

The good news is that oxygen payment policy is an example of the right way for policy to evolve over time. CMS experimented with competitive bidding in selected sites; learned from that experience and developed a more adaptable, efficient, accurate design for payments in the future. CMS demonstrations are not always heralded as prime examples of efficient, evidence-based policy development, but the competitive bidding demonstration is generally recognized as a good effort. Congress concurred and the system was made law.

This analysis has explored who these oxygen beneficiaries are; what equipment, supplies and services they receive; the market dynamics of the provider and payers involved; and what the essential characteristics of a well designed payment policy are. Given the vulnerability of the population involved and the imminent implementation of a new, very different payment methodology, it is hard to see the wisdom of additional short-term shocks to the system that would be triggered by policy changes designed to lower the 36-month cap to any duration.

Methodological note for the overall analysis:

The analysis of Medicare use and cost was based on 2002 to 2004 claims and enrollment information for a 5 percent sample of Medicare beneficiaries, using Medicare standard analytic file (SAF) and denominator file data. These files allow all services and payment information for a single beneficiary to be linked across all claims files and all years, using a CMS-supplied encrypted identifier.

Oxygen services were identified by the Healthcare Common Procedure Coding System (HCPCS) codes on CMS carrier claims. All HCPCS in the oxygen category in CMS's Berenson-Eggers type of service (BETOS) system were flagged as oxygen services. This included both monthly rental of oxygen concentrators and other associated items and services (portable oxygen, supplies, refills).

Throughout the analysis, measures of cost and spending are based on total allowed charges and total payments. These figures include both Medicare program outlays and beneficiary-paid coinsurance and deductible amounts. When determining prevalence of disease, the Agency for Healthcare Research and Quality Clinical Classification System (CCS) categories were used to combine diagnoses reported on claims into disease categories. Quantitative analysis of Medicare claims performed by Christopher Hogan, PhD, Direct Research LLC.

Submitter : Ms. MARYANN LARGEN **Date:** 09/25/2006

Organization : MED EMPORIUM

Category : Individual

Issue Areas/Comments

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

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

Adoption of policy of not covering certain routine maintenance or periodic servicing of purchase equipment assumes a level of competency of beneficiary that is inconsistent with the reality of the cognitive ability of the average respiratory patient. Whether due to advanced age or frailty of disease, the typical beneficiary is not likely to have dexterity or cognitive status to accomplish preventative maintenance of any machinery, especially that which delivers life sustaining drug. The average HME supplier performs regular preventative maintenance at 3 or 6-month intervals to assure delivery of medically appropriate purity of oxygen. Failure to perform the preventative maintenance schedule can compromise the success of therapy. Should the preventative maintenance not be done, making the supplier responsible for repairing equipment that has not been properly maintained is unfairly cost shifting. There should be an assumption of liability by the payer when payment rules impede therapeutic intent.

Payment rates for labor based on 15-minute increments that are established by the carriers are outdated. No increase for inflation has been made in many years. Most suppliers bill those charges as non-assigned, shifting the responsibility of the lack of updating to the beneficiary.

The assumption of the existence of a full manufacturers warranty for all parts and labor on oxygen concentrators is not realistic. Warranties are nullified with an exchange of title. Therefore, the assumption the beneficiary should incur little expense for repair is overly optimistic in months 37 through 60, when manufacturer warranties have been nullified.

Submitter : Mr. Mario LaCute **Date:** 09/25/2006

Organization : Seeley Medical

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1304-P-68-Attach-1.DOC

#68

Via Electronic Transmission

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)[1] Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment; Proposed Rule [CMS-1304-P] RIN 0938-AN76[2]

Dear Dr. McClellan:

On behalf of Seeley Medical, I am pleased to submit comments on CMS' Notice of Proposed Rulemaking (NPRM) for Competitive Acquisition for Certain DMEPOS. I have been a DMEPOS provider for more than 28 years and believe that our services are cost effective, medically efficacious and most importantly consumer preferred.

The following pages summarize the key issues as they affect Medicare beneficiaries and our ability to provide services related to CMS' Notice of Proposed Rulemaking published May 1, 2006 in the Federal Register.

Seelev Medical's Background

Seeley Medical is a regional respiratory and home medical equipment company founded in 1960. Currently, Seeley Medical has locations, Patient Management Centers ("PMCs"), in Andover, Cleveland, Akron, Sandusky and Poland. Each PMC serves several surrounding counties, including some counties in Western Pennsylvania.

Management

Seeley Enterprises, and its subsidiaries, (Seeley Medical, Andover, Seeley Medical, Mansfield and Seeley Medical, Cleveland) was purchased by Mario and Ann LaCute in 1989. Both had been involved in the company since 1977. Mario LaCute, BA in Business from Hiram College, Hiram, Ohio and a MBA from The Ohio State University, Columbus, Ohio. Ann LaCute, BS in Business Administration from Thiel College, Greenville, PA. Other key members on the

[1] Pub. L. 109 -171 (2006).
[2] 71 Fed. Reg. 44082 (August 3, 2006).

management team include: Joe Petrolla, President, BA, Youngstown State University; Ron Adamov, Controller, CPA, MBA, University of Akron, Linda Fee, Finance Operations Manager, BS in Business Administration, University of Toledo, Toledo, Ohio; Lisa Fleming, PMC Operations Manager; and Todd Arganti, RRT, Sales Manager, BS, Malone College, Canton, Ohio, Mike Sass, SPHR, Manager, Human Resources and Organizational Effectiveness, B.S. Kent State, Anthony LaCute, J.D./M.B.A, Cleveland-Marshall College of Law, Cleveland, Ohio, Director of Legislative and Regulatory Affairs; and Jim Moyer, Compliance

Operations Manager. This group has over 125 years collectively in home medical services.

Operations

The company utilizes a combined centralized and decentralized approach. Our Administration, Patient Accounting Center, Management of Information Systems and the Medical Products Division are centralized in the Andover Corporate Office to take advantage of economics of scale. Seeley Medical's order intake through billing process is seamless and is facilitated through its own Management Information System. Seeley Medical has over 11,000 active patient accounts. All locations are completely networked to the system, with a combined staff of 104 employees.

Each PMC is staffed with a Center Manager, Respiratory Therapists, Customer Service Representatives, Sales Representatives, Service Technicians (all of which are Emergency Medical Technicians), Document Control Data Entry Specialist ("DCDES"). This team is closest to the patient and is responsible for implementing programs and services. All decisions relating to patient service and care are made at the PMC.

Services

Seeley Medical is a full-service home medical equipment company that focuses its efforts on the following primary areas of expertise:

Respiratory services which include:

- Long-term oxygen therapy equipment (concentrators, liquid, light weight portable cylinders, oxygen conserving devices)
- Compressor driven nebulizers ("CDN5") for aerosolized therapy. A closed door pharmacy that provides mainly respiratory medications like Albuterol, lpratropium Bromide, etc.)
- CPAP and BiPAP therapy for obstructive sleep apnea.
- Ventilators for stable adult and pediatric patients.

Home medical equipment and supplies include:

- Disposable supplies (incontinent undergarments, dressings, enteral nutrition, etc.)
- Medical equipment (hospital beds, wheelchairs, commodes, etc.)

Commitment to Excellence

Seeley Medical places a strong emphasis on service, including professional education, quality

assurance and technical maintenance. We recently completed our CHAP Accreditation, after many years being JCAHO Accredited. Another part of this commitment is reflected by its membership in the American Association for Homecare (Mario LaCute is a former Chair and is currently an Executive Board Member), the Ohio Association of Medical Equipment Services, (Mario LaCute is former President and current ex officio Board Member) and its Accreditation. Additionally, members of our staff serve on various Boards of major service organizations such as the American Cancer Society, Health Planning Committees and Community Health Agencies. Members of our professional staff such as our Registered Respiratory Therapists, Licensed Practical Nurses and Emergency Medical Technicians are active in their respective professional organizations to maintain current standards of practice.

Section 5101 of the Deficit Reduction Act of 2005 (DRA) amends the provisions of the Social Security Act (Act) governing Medicare payment for home oxygen therapy and capped rental DME. Beneficiaries who use home oxygen or rent DME now bear a greater burden to manage their care and coordinate service and maintenance for their medical equipment. These comments primarily address CMS' implementation of the DRA's transfer of ownership requirement for oxygen equipment. The proposed rule would establish new payment amounts for different classes of oxygen equipment and specify new billing and other requirements that would apply to suppliers furnishing oxygen or capped rental equipment.

We agree that it is worthwhile to examine the current fee schedule methodology. The current methodology results one payment amount (plus an add-on for portable equipment) for all oxygen equipment regardless of the beneficiary's clinical needs. We remain concerned, however, that the approach in the NPRM compounds the flawed policy codified under the DRA. Importantly, our analysis indicates that CMS' proposal to revise payment for oxygen is not budget neutral, contrary to the controlling statute. CMS' goals in implementing the DRA should be to preserve beneficiary choice of oxygen equipment and modality, promote high quality care, and support innovation in the development of new oxygen technologies. The proposal in the NPRM does not promote these goals.

We recommend that CMS refine payments for oxygen in a manner that supports portability for patients and innovation in product development. We are willing to work with CMS and other oxygen stakeholders to ensure that these refinements are based on accurate data that reflects the current product and service costs of furnishing oxygen to Medicare beneficiaries. We also strongly urge CMS to delay implementation of the new policies. Inasmuch as the DRA ownership provisions are not effective until 2009, a delay will permit a smooth transition to the new policies for all stakeholders. A Delay will also allow CMS to work with stakeholders to collect data to revise the policy as we suggest. We address these issues and our concerns about operational impact of the new policy in greater detail below.

I. BACKGROUND

1. Chronic Obstructive Pulmonary Disease is a Chronic, Progressive and Debilitating Disease

Home oxygen is critical to approximately one million Medicare beneficiaries who suffer from

respiratory illnesses such as chronic obstructive pulmonary disease (COPD). These beneficiaries require oxygen therapy for their long-term survival and well-being. COPD includes chronic bronchitis and emphysema and has been defined as the physiologic finding of nonreversible impairment of pulmonary function.[3] COPD is the fourth leading cause of death in the world and the only leading cause of death for which both prevalence and mortality are rising.[4] The clinical course of COPD is characterized by chronic disability with intermittent acute exacerbations that occur more often during the winter months. The World Health Organization has projected that COPD will rank fifth in 2020 as a global burden of disease.[5]

Approximately 15 million Americans have been diagnosed with COPD; and an estimated 15 million more have undiagnosed COPD. COPD costs the U.S. economy over $18 billion a year in direct medical costs and an estimated $11 billion in indirect costs.[6] Although oxygen represents a substantial expenditure for Medicare under the DME benefit, beneficiaries on home oxygen also incur significant expenses for other health care services. COPD is responsible for a significant part of all physician office visits and emergency room (ER) visits and ranks number three (3) in acute hospital admissions among Medicare aged persons. Based on 2001 data from Medicare, over 397,000 patients were discharged from acute care hospitals with a diagnosis of COPD. The average length of stay for a COPD admission is 5.1 days at the rate of $4,000 per day. Medicare payments to hospitals for routine COPD admissions alone exceed $1.5 billion.

The profile of the patient who uses oxygen suggests that these individuals comprise what has been called the "frail elderly." Our members report that the beneficiaries they serve may live alone and are highly circumscribed in their activities of daily living (ADLs). Recent clinical studies have examined the correlation between the ADLs and patients with severe COPD who are on long-term oxygen therapy. A study last year in *Chest* examined the impact on the ADLs for individuals suffering from one of 3 long-term chronic conditions, including COPD.[7] The study concluded that, for all the patients in the sample, COPD was associated with a distinctive pattern of disability expressed by loss of selected ADLs. Other studies have shown that of individuals with COPD, those who required long-term oxygen therapy, were less independent in their ADLs than those who did not require oxygen therapy.[8] Earlier studies also confirm that individuals with COPD decline in their cognitive function as their disease progresses. These studies find that: "cognitive decline is faster in the presence of severe bronchial obstruction and parallels the worsening of the affective status in COPD patients on oxygen therapy."[9] [10]

Clearly, Medicare payment policies for oxygen will impact a large number of very vulnerable

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[3] Centers for Disease Control and Prevention – MMWR Surveillance Summaries, August 2, 2002/Vol. 51/ no. SS-6

[4] Global Initiative for Chronic Obstructive Lung Disease (GOLD) of the U.S. National Heart, Lung, and Blood Institute and the World Health Organization, Am J Respir Crit Care Med Vol 163. pp 1256- 1276, 2001.

[5] Murray CJ, Lopez AD. Evidence-Based Health Policy—Lessons from the Global Burden of Disease Study. Science. 1 996; 274: 740-743.

[6] Data derived from Moran & Associates estimates from the 2001 MEPS full year consolidated file.

[7] Incalzi RA, et al. Construct Validity of Activities of Daily Living Scale: A Clue to Distinguish the Disabling Effects of COPD and Congestive Heart Failure. *Chest* 2005; 127:830-838

[8] Okubadejo AA, et al. Home assessment of activities of daily living in patients with severe chronic obstructive pulmonary disease on long-term oxygen therapy. *Eur Respir J* 1997;10:1572-1595

[9] Incalzi RA, et al. Predicting cognitive decline in patients with hypoxemic chronic obstructive pulmonary disease. *Respir Med* 198; 92:527-533.

[10] Incalzi RA, et al. Verbal memory impairment in COPD: Its mechanisms and clinical relevance. *Chest* 1997; 112:1506-1513.

patients. Consequently, we urge CMS to proceed cautiously in establishing new payment methodologies for oxygen. Payment for oxygen must be adequate to support on an ongoing basis the array of professional and administrative services that are necessary to safely furnish oxygen to beneficiaries in their homes. Payment policies also need to preserve beneficiary and physician access to their choice of oxygen modality and technology both before and after equipment transfers title. Moreover, while spending for home oxygen may be a sizeable portion of overall Medicare spending for DMEPOS, spending for oxygen should not be viewed in isolation. CMS must consider the other health care services and resources that beneficiaries on oxygen consume. Maintaining these patients at home on oxygen is by far more cost effective for the Medicare program than institutional care.

2. Medicare Reimbursement for Home Oxygen Has Declined Sharply Since 1997

Prior to February 8, 2006, Medicare reimbursed oxygen and oxygen equipment on the basis of a continuous rental. In other words, Medicare would pay for home oxygen therapy as long as a beneficiary met Medicare's coverage criteria. Medicare reimburses home oxygen under fee schedules established by Congress in 1989. The first fee schedule payments were based on supplier charges from 1986. The fee schedules bundled the payment for the oxygen and stationary oxygen equipment an included and add-on fee for portable equipment only (because contents payments were bundled into the payment for the stationary equipment). Consequently, the monthly rental payment for oxygen is a "modality neutral" bundled payment that covers ongoing service and maintenance for the equipment. Fee schedule updates were based on the Consumer Price Index (CPI).

Payment rates for oxygen have been subject to numerous freezes and reductions since the inception of the fee schedules. The largest reduction occurred under the Balanced Budget Act of 1997 (BBA). The BBA cut Medicare reimbursement for oxygen by 25% in 1998 and an addition 5% for 1999. The BBA also permanently froze all CPI updates for home oxygen. With the exception of modest, temporary updates that occurred in 2000 and 2001, the BBA statutory provisions for oxygen preclude any further CPI updates to oxygen payments unless Congress expressly approves them. Congress applied further reductions to oxygen payments under the Medicare Modernization Act of 2003 (MMA). The MMA reduced oxygen payment by an amount equal to the percentage difference in the median reimbursement for oxygen between the Federal Employee Health Benefit (FEHB) program plans and Medicare. The FEHB reductions, which averaged 10% across each durable medical equipment regional carrier (DMERC) region, were effective in 2005.

Congress did not change the fee schedule methodology or explicitly reduce payment for oxygen under the DRA. Instead, §5101 of the DRA limits rental payments for oxygen equipment to a 36 month period of "continuous use," after which title to the equipment transfers to the beneficiary. After the conclusion of the period of continuous use, Medicare will pay only for "oxygen" and service and maintenance of oxygen equipment that the Secretary deems "reasonable and necessary." This payment methodology became effective January 1, 2006 for all Medicare beneficiaries on home oxygen as of December 31, 2005.

Under the NPRM, CMS proposes to establish separate classes and payment for oxygen

equipment based on its authority under §1834 (a) (9)(D) which permits the Secretary to depart from the modality neutral methodology so long as the result is "budget neutral."[11] The proposed rule would create separate classes and monthly payment amounts for oxygen generating technologies and separate classes and monthly payment amounts for stationary gaseous and liquid systems that require refills of oxygen contents. To obtain budget neutrality, CMS would offset payment increases for these classes with a reduction in the monthly payment for concentrators.

II. COMMENTS

A. The Proposed Rule Exacerbates the Flawed Policy Underlying the DRA Forced Ownership Provisions

1. Equipment Acquisition Costs Constitute less than One Third of the Total Cost of Furnishing Oxygen to Medicare Beneficiaries

We understand that the DRA dictates the transfer of ownership of oxygen equipment and that CMS' role is to implement the DRA requirements.[12] Nonetheless, we want to emphasize that the policies underlying the DRA are fundamentally flawed and based on a misappreciation of the full range of administrative and support services that are necessary to ensure that Medicare beneficiaries receive safe and effective oxygen therapy in their homes. This misunderstanding is evident in CMS' longstanding position that the oxygen benefit is an equipment benefit only. As a result of this "equipment only" stance, Medicare has never fully acknowledged the array of professional and administrative services, including delivery, education, oversight, and monitoring that are necessary to ensure that that oxygen therapy is administered safely and effectively in the home. Moreover, oxygen is a prescription drug that is highly regulated by the Food and Drug Administration (FDA), other Federal agencies such as the Department of Transportation (DOT), and State pharmacy boards. A payment policy that fails to explicitly recognize the professional and administrative costs inherent in furnishing home oxygen results in inaccurate payment and can seriously erode the quality of care that beneficiaries receive.

The DRA is based on the premise that Medicare rental payments for oxygen equipment are many times over suppliers' acquisition costs. This reasoning incorrectly assumes that equipment acquisition cost is the only cost inherent in serving these beneficiaries. Morrison Informatics recently completed the most comprehensive analysis to date of the services and costs of furnishing home oxygen to Medicare beneficiaries.[13] Morrison examined the costs of 74 providers who collectively serve more than 600, 000 beneficiaries who use oxygen. Morrison concluded that equipment acquisition costs represent only 28% of the total cost of servicing Medicare beneficiaries using home oxygen. Other administrative and support functions necessary to safely deliver oxygen to beneficiaries in their home account for the remaining 72%

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[11] 42 U.S.C. §1395m (a)(9)(D)(ii), (2006).

15. As we noted above, the DRA transfer of ownership provisions apply to both oxygen and capped rental DME. Although the main focus of these comments is on the implementation of these policies for home oxygen, we likewise believed that forced ownership of capped rental DME places unnecessary burdens on beneficiaries and creates unmanageable operational issues for suppliers. We discuss these operational issues in later sections of these comments.

[13] Morrison study.

of supplier's costs. These administrative and support costs include: obtaining patient information and related documentation, labor related to the initial preparation of the equipment, equipment delivery and set-up, scheduled and unscheduled maintenance and repair, ongoing patient support, delivery costs, and ongoing patient assessment, training, education, and compliance monitoring as well as other necessary operating and overhead costs.[14] On average, the direct costs of furnishing home oxygen to Medicare beneficiaries breakdown as follows:

Cost Component	Average Cost Per-Patient Per-Month
1. SYSTEM ACQUISITION[15]	$55.81
2. INTAKE AND CUSTOMER SERVICE[16]	$12.66
3. PREPARATION, RETURN, DISPOSABLES, AND SCHEDULED MAINTENANCE[17]	$25.24
4. UNSCHEDULED REPAIRS AND MAINTENANCE[18]	$6.10
5. PATIENT ASSESSMENT, TRAINING, EDUCATION AND MONITORING[19]	$17.54
6. DELIVERY ASSOCIATED WITH PREPARATION, RETURN, DISPOSABLES, AND SCHEDULED MAINTENANCE[20]	$42.26
7. OTHER MONTHLY OPERATING AND OVERHEAD[21]	$41.59
8. TOTAL DIRECT COST BEFORE TAXES	$201.20

In the past there may have been concerns that the cost categories identified by Morrison were not representative of costs incurred by all suppliers serving Medicare beneficiaries. In other words,

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[14] Overhead and operating costs accounted for 21% of supplier's total costs. This data were reported to Morrison in the aggregate, so data on specific cost components for this category are not available.

[15] The amount includes acquisition costs for stationary, portable and backup units, conserving devices, ancillary equipment and accessories, and oxygen system contents (liquid and gaseous oxygen).

[16] The amount includes labor associated with patient intake functions, ongoing customer service (patient inquiries, scheduling of deliveries/maintenance/clinical visits, accommodating patient travel plans), and initial and renewal prescription processing.

[17] The amount includes labor associated with equipment preparation (testing, cleaning, and repair), equipment set-up and maintenance upon return, initial patient instruction, cost of disposable and maintenance supplies, and labor costs associated with scheduled preventive equipment maintenance.

[18] The amount includes labor and vehicle costs associated with unscheduled equipment repair and maintenance.

[19] The amount includes labor and travel costs associated with clinical visits by respiratory care practitioner, in-home patient assessments (including home environment safety assessment and oxygen therapy plan of care), training, education and compliance monitoring.

[20] The amount includes delivery costs associated with oxygen fills (liquid and gaseous oxygen), preparation, return, disposables and scheduled maintenance.

[21] The amount includes rent and other facility costs, administration, insurance, legal, regulatory compliance, MIS systems/controls, communications systems, employee training, accreditation, supplies, billing and compliance functions.

CMS may have been reluctant to acknowledge the non-equipment professional and administrative services furnished to oxygen beneficiaries out of a concern that not all suppliers adhered to the same standards. This issue was resolved when CMS published quality standards for DME suppliers this year. In addition to business standards that apply to all DMEPOS suppliers, the new standards contain detailed requirements for patient intake and assessment, equipment selection and maintenance, delivery, patient education, monitoring and follow-up that apply specifically to oxygen suppliers.

Suppliers who furnish oxygen to Medicare beneficiaries will be required to demonstrate that they comply with these standards in order to bill the Medicare program.[22] For the first time all suppliers of home oxygen to Medicare beneficiaries will be required to meet the same standards and receive accreditation to document their compliance with the standards. Importantly, the new quality standards confirm that the cost categories reported in the Morrison study are legitimate costs that should be recognized in the Medicare payment for home oxygen. The Medicare program recognizes the cost of complying with quality standards and accreditation for providers and suppliers in other settings. Failing to acknowledge these costs for suppliers who furnish oxygen would be a disservice to Medicare beneficiaries who rely on this important therapy.

1. The Proposed Policy is Not Budget Neutral

As CMS acknowledges, the proposal to tie the monthly payment for oxygen to the equipment technology must be budget neutral.[23] While we support the effort to revisit the current methodology, we are concerned by the lack of data 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.[24] Without this data, Seeley Medical cannot fully evaluate this proposal and assess its impact on our members. As a consequence, CMS has not satisfied the notice and comment requirement under the Administrative Procedure Act.[25] The lack of adequate data to support CMS' analysis also falls short of the agency's commitment to ensure the quality, utility, objectivity, and integrity of the information it disseminates.[26]

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[22] DMEPOS Quality Standards published at CMS website

[23] 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.

[24] Motor Vehicle Mfrs. Ass'n. v. State Farm Mutual Insurance Co. 463 U. S. 29 (1983).

[25] Association of Data Processing Serv. Orgs. V. Board of Governors, 745 F.2d 677 (D. C. Cir. 1984); Air Transp. Ass'n of Am. V. FAA, 169 F. 3d. 1 (D. C. Cir. 1999).

[26] CMS has an obligation under the Data Quality Act (DQA), [cite], to ensure the quality, utility, objectivity, and integrity of the information it disseminates. Under CMS' guidelines, the DQA standards apply to the information in the proposed rule. We believe that the analysis in the NPRM fails to meet DQA standards.

Our own analysis of the new policy shows that the methodology is not budget neutral. The Lewin Group examined the proposal on behalf of AAHomecare and concluded that its impact would not be budget neutral. After reviewing the information in the NPRM and speaking to staff at CMS, Lewin concluded that the policy would result in a ten percent (10%) reduction in payments for oxygen for 2007. Specifically, Lewin 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[27]

CMS has indicated that it assumed only 5% of patients currently on oxygen would shift to portable equipment in 2007. However, Lewin 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. Lewin 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 Lewin's analysis, CMS must adjust its proposal to make it budget neutral. CMS must also articulate the factual basis for its conclusions and allow all stakeholders an opportunity to comment on the data and CMS' conclusions.

3. Medicare Payment for Home Oxygen Must Support Beneficiary Access to Portable Oxygen and the Development of New Technologies

Once CMS has revised the new policy to make it is budget neutral, we recommend that CMS reallocate the monthly payment amounts for oxygen equipment using the $256 million identified by Lewin. This reallocation should occur in a manner that supports portable oxygen contents, especially for beneficiary owned equipment as well as the continuing development of new oxygen technologies. Seeley Medical has worked collaboratively with the physician and respiratory practitioner community over the past several years. We understand their concerns that patient on oxygen be assured access to the portable equipment of their choice. Promoting increased mobility for oxygen patients is an important clinical objective because active COPD patients have better overall health status and the ability to participate in ADLs. Beneficiaries and their physicians have numerous choices for portable oxygen equipment today, and Medicare payment policy should seek to preserve those choices.

Current reimbursement is inadequate to support these goals, especially after title to the equipment transfers. The new payment policy is likewise inadequate. These inaccurate payments occur because CMS has not acknowledged that suppliers will continue to incur professional and administrative costs after title to the equipment transfers. Moreover, CMS lacks the data to evaluate those costs in light of the proposed payment policies. In fact, until CMS has accurate data, any attempts to establish payment policies based on the relative cost of one type of

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[27] Lewin.

equipment over another will be arbitrary. Seeley Medical is committed to working with CMS and all other oxygen stakeholders to collect the data necessary to accomplish these goals. That is why we strongly recommend that CMS delay implementation of the new policy.

4. CMS Should Delay Implementation of the Payment and Policy Changes Proposed in the NPRM

CMS states that the policies announced in the NPRM will not be effective prior to January 1, 2007. This statement is ambiguous because the DRA period of "continuous use" is already in effect. The proposal in the NPRM should apply prospectively only. Further, we recommend that CMS delay implementation of the payment and policy changes proposed in the NPRM. A delay would promote a smooth transition to the new payment policies, avoid disruptions in the care of beneficiaries currently on oxygen, and minimize the impact on suppliers of a pronounced change from current reimbursement levels. This transition would also permit CMS to work with stakeholders to refine the new methodology based on current data as we discussed above. Importantly, the DRA does not require CMS to make any changes to reimbursement for home oxygen. The law requires only that title to oxygen equipment transfer to the beneficiary after 36 months of continuous use. CMS has no need to rush implementation by January 1, 2007. Given the interests that are at stake, all stakeholders would be well served by a delay the payment changes until CMS has current data to adjust the policy.

B. CMS Cannot Require Suppliers to Enter Into Private Supplier Agreements for the Duration of the Period of Continuous Use

CMS proposes to require suppliers to notify beneficiaries of their "intentions" regarding whether they will accept assignment for all monthly rental claims for the duration of the rental period before furnishing oxygen or capped rental equipment to the beneficiary. For oxygen equipment, this provision would require the supplier to notify the beneficiary whether it will accept assignment for all rental claims for the entire 36 month period of continuous use. The proposed regulation would permit suppliers to express their intentions in a written agreement between the supplier and the beneficiary.

Medicare contractors are authorized to pay certain Part B claims on the basis of an itemized bill or on an assignment related basis.[28] This requirement is widely understood to permit physicians and suppliers to accept assignment on a claim by claim basis. This understanding of the statute is longstanding and not open to further interpretation. Indeed, CMS acknowledges in the preamble that suppliers may determine whether to accept assignment on a claim by claim basis. There is an exception to this rule for participating physicians and suppliers who determine *on annual basis* whether they will accept assignment of all Medicare claims. Although the participating provider program includes a number of incentives to promote participation, the decision to become a participating provider is voluntary. However, once a supplier agrees to be a participating supplier, the supplier *must* accept assignment of all Medicare claims for that calendar year. Nonparticipating physicians and suppliers may continue to make the assignment decision on a

[28] 42 U.S.C. §1395u(b)(B)(i)(ii).

claim by claim basis.

Although CMS has great latitude in implementing regulations to administer the program, those regulations must be consistent with the statutory framework established by Congress.[29] CMS clearly cannot require suppliers to accept assignment of all monthly rental claims throughout the period of continuous use. Such a requirement would contradict the provision of the Act that directs contractors to pay claims on the basis of an itemized bill or on an assignment related basis. CMS also cannot require suppliers to enter into private assignment agreements such as the ones contemplated by the regulation. The law requires participating supplier agreements to be effective for one year, after which the supplier can elect not to participate. Because the statute permits suppliers to decide *annually* whether they will accept assignment of all Medicare claims, CMS could not requires suppliers to make that decision effective for the entire rental period of 13 or 36 months. Otherwise, CMS would effectively change the terms of the participating supplier program established by Congress. CMS has no authority under the Act to require suppliers to enter into agreements that conflict with the statutory framework for the participating provider program. Consequently, we recommend that CMS withdraw this proposal.

C. CMS Must Work with the FDA to Address Compliance Issues for Patient Owned Equipment

CMS proposes that beneficiaries receive title to both the oxygen cylinder or vessel currently in use by the beneficiary as well as the one being refilled by the supplier. This proposal is unworkable. As a practical matter, the provider cannot keep track of the cylinders or vessels in the manner that the NPRM contemplates so that the beneficiary retains ownership to the same set of cylinders/vessels. Many suppliers do not own the cylinders. As we describe below, they lease them from a commercial gas company that is responsible for filling them. Additionally, some suppliers may process a large volume of containers themselves while others rely on a contractor to perform this function. In either case, tracking the containers by serial number would be unmanageable from an operations perspective. Suppliers also must comply with specific labeling requirements for oxygen containers under FDA and DOT rules. Under the current regulatory framework for oxygen as a medical gas, suppliers are not permitted to label this equipment with the beneficiary's name.

Importantly, the containers and their components are an integral part of the drug delivery system under FDA regulations and guidance.[30] As such, they are subject to detailed cleaning, maintenance and calibration requirements, a number of pre-fill and post-fill inspections and testing, and specific transportation and labeling requirements. These activities must be carried

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[29] APA

[30] See 42 CFR § 210 Subpart E, Control of Components and Drug Product Closures and Containers; Specifically, the FDA defines the container and its components, including the closure, as follows:

> A *container closure system* refers to the sum of packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection to the drug product. A *packaging system* is equivalent to a container closure system.

out by qualified individuals and documented in comprehensive records. As a highly regulated medical gas, oxygen has a unique status among drugs, because its container is re-usable.

FDA guidance defines the custody, control, and management of filling liquid containers to be in compliance when the filling company owns the liquid containers and the containers are filled at the company's location or curbside at the patient's home. When the patient owns the liquid containers after 36 months, the company would no longer be able to fill the container without extensive testing prior to filling because the containers would be considered by FDA to be out of the filler's control. In addition, the filling company would no longer be assured the container was maintained in accordance with the manufacturer's specification. Under these circumstances, the medical oxygen provider would be reluctant to assume responsibility for a cylinder or liquid oxygen container that is not under its control.[31]

Similarly, in accordance with DOT regulations, [32]a cylinder filled with a hazardous material may not be offered for transportation unless it was filled by the owner of the cylinder or with the owner's consent. This requires the manufacturer of the medical oxygen, *i.e.*, the company that fills the oxygen container under FDA regulations, to have the equipment owner's permission prior to refilling the container. After the patient owns the oxygen equipment, compliance with this regulation will be very difficult for the provider of medical oxygen in the home, especially if the transfilling is done by a third-party.

Medical oxygen cylinders must also be inspected for the hydrostatic test date as part of the pre-fill inspection requirements. If the cylinder test date has expired, the cylinder can not be filled. The "out-of-test" cylinder must be sent to a company that is certified by the DOT and be retested. Currently, the company filling the cylinder would quarantine the cylinder and the cylinder would be sent out for retest/requalification.[33]

DOT also provides very specific regulations for the proper handling and disposal of compressed cylinders that all companies that fill and transport cylinders must follow. The filler of liquid oxygen containers must also have access to service and maintenance records in order to determine which inspections and tests to perform and at what frequency. In this context, establishing the chain of custody for the equipment is an important step in determining what testing or servicing the equipment requires before it is filled and distributed to patients. If this information is not available to the filler, then the FDA mandates additional testing. These additional tests require more sophisticated testing equipment than the typical provider of home medical oxygen has available.

CMS' proposal to transfer title to both the cylinder/vessel that is being filled and the one in the beneficiary's home is unworkable given its impact on supplier's operations and regulatory framework for oxygen as a medical gas. Earlier this year we urged CMS to confer with the FDA about the application of FDA regulations to patient owned cylinders/vessels and we renew that request now.

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[31] See Fresh Air 2000 testing and filling requirements for cryogenic home units.

[32] 49 CFR Part 107 173.301 (e), "*Ownership of cylinder.*"

[33] See Department of Transportation 49 CFR Part 107 § 180.205 General requirements for requalification of cylinders thru §180.213 Requalification markings.

D. The Proposed Rule Creates Significant Operational Hurdles for Suppliers

1. CMS Must Clarify the Equipment Repair and Replacement Policies Outlined in the Proposed Rule

a) Prohibition on Replacing Equipment During the Period of Continuous Use

The proposed rule specifies that a supplier may not replace oxygen equipment prior to the expiration of the 13 or 36 month rental period unless one of the exceptions enumerated in the rule applies. CMS interprets the DRA to literally require that the beneficiary receive title to the same equipment that the supplier delivered to him on the first day of the rental period. To comply with this new regulation, providers would have to track equipment by serial number in order to make sure the beneficiary receives title to the equipment that the supplier furnished originally. This will be very difficult for providers to accomplish if the concentrator or other equipment is brought into the facility for repairs. Larger providers may have regional or even national distribution centers to stock and service equipment. Other providers may use contractors to service equipment. For both large and small providers, a requirement to track equipment in this manner would be unmanageable.

Currently providers simply replace equipment in need of service or repair with equipment of the same type that is in good working order. We suggest that during the period of continuous use, providers be permitted to continue this practice. This will allow providers to streamline their operations and serve beneficiaries more efficiently in the event equipment must be repaired or serviced at the provider's facility. Because repairs can take upwards of 30 days, the proposed rule would build in added costs of administration and delivery if the original piece of equipment must be delivered to the patient.

CMS believes this new requirement is necessary to prevent unscrupulous providers from replacing newer equipment with older used equipment before the end of the rental period. CMS can address this issue simply by requiring that the beneficiary receive title to equipment that is of comparable quality to the equipment delivered at the beginning of the period of continuous use. Moreover, with respect to oxygen equipment, the preamble acknowledges that the vast majority of beneficiaries will not require oxygen for the full 36 month period of continuous use. Consequently, for oxygen beneficiaries, there is less concern that suppliers will use the "bait and switch" practices CMS describes.

b) Replacement of Beneficiary Owned Equipment

The proposed rule would require suppliers to replace, at no cost to the patient or the Medicare program, patient owned equipment if the cumulative total repairs during the useful life of the equipment exceed 60% of the equipment's value and the manufacturer's warranty has expired. Given the five year useful life of the equipment, the circumstances that would require equipment to be replaced may be so far removed from the date that title transferred that there would be no plausible connection between the supplier's actions and a conclusion that the supplier delivered substandard equipment. Moreover, the supplier will have no control over patient owned equipment. For example, there will be no record of routine, ongoing service and maintenance,

placing the supplier in the untenable position of having to replace equipment that may not have been properly maintained. We recommend that responsibility for the equipment shift to the patient once he receives the title.

We also question the rationale underlying this proposal. CMS states that the policy is necessary to prevent suppliers from offsetting lost revenue from rentals with revenue for repairs. Our members report that reimbursement for repairs is inadequate and requires extensive documentation. Consequently, we doubt that the suppliers will adopt a business strategy to offset lost rental income with increased revenue from repairs. We do agree with CMS, however, that there is likely to be an up-tick in the volume of Medicare claims for repairs. As we describe more fully below, CMS can expect the increased volume because most beneficiaries chose to continue renting their equipment in the past.

It is also unclear from the regulatory language, or the preamble, how CMS would determine that the cumulative costs of repairs are 60% of the value of the equipment. We request that CMS explain the methodology it will use to make this determination.

c) Billing for Equipment Repairs

CMS must require the DME Medicare administrative contractors (MACs) to issue specific and comprehensive guidance for submitting claims for repairs. Specifically, we request guidance on the type of documentation that CMS expects suppliers to obtain to support repair claims. As we discussed above, there is not a high volume of claims for repairs because most beneficiaries have chosen to continue to rent capped rental equipment. For oxygen, equipment repairs have been covered under the monthly fee schedule. As a result, it is reasonable to expect an increase in the volume of claims for repairs for patient owned equipment; however, the increase in volume for repair claims will be the logical consequence of the new policy, not evidence of program abuse. The MAC jurisdictions and CMS must have clear policies outlining when Medicare will pay for repairs and the documentation it will require to support those claims.

Additionally, 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. For example, the following chart includes a partial list of parts that are not identified by HCPCS codes:

Hospital Beds	Nebulizers	Patients Lifts	Concentrator	Liquid Oxygen Reservoirs
Pendant control	Tubing adapter	Hydraulic cylinder	Filter, inlet	Regulator
Motor assembly	Case	Seal kit	Filter, cabinet	Primary relief valve
Drive shaft	Power cord	Hydraulic fluid	Filter, bacterial	Secondary relief valve
Junction box		Base spreader kit	Outlet nipple	Condensing coils
Frame with spring, head and foot sections		Caster wheels	Sieve bed	Flow control valve
Power cord			Regulator	Contents indicator
			Flow meter	Cryogenic vessel
			Compressor	Vent valve
			Valve , 4 way	Economizer valve
			Control board	Cover Assembly
			Product tank	
			Power cord	

d) Payment for Routine and Non-Routine Maintenance

CMS is proposing to pay for maintenance and service for beneficiary owned capped rental DME and oxygen equipment. 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."

CMS should not assume that all beneficiaries will be able to perform routine maintenance and service on their equipment. There are beneficiaries, especially the frail elderly, who will be unable to perform these tasks. As a result, CMS must ensure that these beneficiaries own their equipment it can be maintained in good working order. We recommend that CMS establish codes to 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 that fee schedules are established that appropriately account for all parts and services incurred in providing the maintenance and service for patient owned capped rental and oxygen equipment.

e) Payment for Ongoing Services

It is very important for CMS to include an ongoing service and maintenance fee to cover emergency services, respiratory practitioner evaluations, on call availability, and after hours troubleshooting for patient owned oxygen equipment. Suppliers currently furnish these services under the monthly payment amount for oxygen. These services were documented in the Morrison study and are a critical component of safely furnishing oxygen in the home. When the monthly rental payments end, there will be no additional payment for these important support

services.

We urge CMS to not take the position that these are noncovered services therefore placing the burden of paying for them on beneficiaries. Some, if not most, beneficiaries will elect not to pay for the services, placing these beneficiaries at risk and creating a two tiered system of care. Moreover, to the extent that the new supplier standards recognize that these services should be the standard of care for Medicare beneficiaries, Medicare payment policies should recognize them for patient owned equipment as well.

2. CMS Must Clarify How It will Determine the Period of Continuous Use

a) Application of Break-In-Service Rules

Consistent with the requirements of the DRA, the NPRM designates a 36 month period of continuous use for oxygen equipment and a 13 month period for capped rental equipment. We have numerous concerns with respect to how CMS would determine the period of continuous use for oxygen equipment. These concerns relate to the application of the break-in-service rules, replacement of equipment that is lost stolen or irreparably damaged, and the impact of these new rules on beneficiaries who move or travel. Specifically, with respect to the break-in-service rules, the proposed rule is silent on how a break-in-service affects the calculation of the period of continuous use.

There are a number of situations where a beneficiary may have a short term need for oxygen. CMS coverage policy identifies these patients as falling within the Group II coverage criteria. These patients may not be sufficiently hypoxemic to require ongoing oxygen therapy, although eventually they will need oxygen on a continuous basis. Their short-term oxygen use should not be included in the 36 month rental period when they subsequently resume oxygen therapy. Similarly, there are other breaks-in-service that should not count towards the period of continuous use. These include skilled nursing facility (SNF) stays or acute care admissions any longer than a month. Because suppliers do not have access to the common working file (CWF), they do not know in advance of these admissions. Often, suppliers learn of these admissions a year or more after the fact when the DME MAC identifies an overpayment. Current Medicare program rules identify that a break-in-service of 60 days or more supported by appropriate documentation, will not count towards the capped rental period. We believe that there is no basis for CMS to apply different break-in service rules to oxygen. We recommend that CMS explicitly clarify this issue in the final rule.

These scenarios also underscore important related issues. The first is that CMS must move towards an audit process that is reasonably contemporaneous with the period of continuous use so that suppliers are not subject to overpayments long after title to the equipment transferred. The second is that suppliers should have access to the CWF in order to effectively administer their obligations under the DRA.

b) Equipment that is Lost, Stolen, or Irreparably Damaged

Under the proposed regulations, a new period of continuous use would begin when beneficiary

owned equipment is lost, stolen, or irreparably damaged. While we agree that this provision is necessary to ensure that beneficiaries have access to medically needed equipment, we question CMS' decision to apply this exception only to beneficiary owned equipment. When equipment is lost, stolen, or irreparably damaged during the period of continuous use and a supplier furnishes replacement equipment, a new period of continuous should begin. Otherwise, the regulation would impose a patently unfair result when rented equipment is lost or damaged through no fault of the supplier.

For example, if an expensive item like a portable concentrator is lost or stolen in the 30th rental month and the supplier replaces it, the supplier would in effect have to transfer title to two devices, but receive payment only for one. Under the former continuous rental methodology for oxygen equipment, suppliers typically replaced lost, stolen, or irreparably damaged equipment because the supplier retained title to the asset which could be used for future rentals. There is no similar rationale that would support requiring the supplier to provide a beneficiary with replacement equipment during the rental period under circumstances where the supplier is not responsible for the events that precipitated the need to replace the equipment.

CMS may have limited this provision to beneficiary owned equipment out of a misplaced concern that suppliers would submit claims for lost, stolen, or irreparably damaged equipment simply to circumvent the DRA requirements. If this is the case, CMS should at least allow the DME MACs to make the determination whether to initiate a new period of continuous use on a case-by-case basis. This would ensure a more balanced application of the requirement to transfer equipment ownership to beneficiaries.

c) Beneficiaries Who Travel or Move Outside the Supplier's Service Area

We also have questions on how the transfer of title provisions would apply to oxygen patients who travel for extended periods and beneficiaries who move out of the supplier's area during the period of continuous use. The proposed regulations state that a new period of continuous use does not begin when the beneficiary changes providers. The impact of this provision will be to limit access for beneficiaries who relocate during the rental period. We recommend that CMS address this issue by permitting a new period of continuous use to begin.

Similarly, CMS should clarify which provider's equipment transfers to the beneficiary if the beneficiary has two residences with a local provider in each area. Beneficiaries who are "snow birds," or who may move or relocate during the period of continuous need will face hurdles in maintaining access to equipment, unless a new period of continuous begins when they change suppliers. Extended travel outside of the supplier's service area should not be counted towards the period of continuous use to the extent the supplier is not paid for oxygen during that period.

3. Backup Oxygen Equipment

The NPRM does not address backup oxygen equipment. Many beneficiaries have backup equipment solely for use in an emergency such as a power outage. Seeley Medical believes that title to backup equipment does not transfer under the coverage rules established by the oxygen LCD. The LCD states that backup equipment is noncovered because it is provided solely for the

convenience of the beneficiary. To the extent that CMS has not made any rental payments for the backup equipment, title to the equipment should not transfer to the beneficiary. We request that the final rule explicitly clarify this issue.

4. Title to Equipment Should not Transfer Unless all Beneficiary Copays and Deductibles have Been Paid

The DRA requires that title to oxygen and capped rental equipment transfer to the beneficiary at the conclusion of the period of continuous use. Title to equipment should not transfer to the beneficiary unless all outstanding copay and deductible amounts have been paid. Under the framework established by Congress, Medicare beneficiaries share in the cost of their care under Part B. The Medicare program pays for 80% of the fee schedule amount for oxygen and capped rental equipment and the beneficiary pays the remaining 20% co-payment plus a deductible.[34] The application of the DRA transfer of title provisions to this statutory reimbursement framework suggest that the beneficiary must pay any outstanding copay and deductible amounts before receiving title to equipment. Any other conclusion would clearly be contrary to common sense and the payment scheme devised by Congress. Moreover, transferring title of equipment to beneficiaries before they have met their financial obligations under Medicare program rules amounts to a de facto waiver of copays and deductibles in violation of the beneficiary inducement statute.[35] Once a beneficiary receives title to equipment, she will have little incentive to pay any outstanding balance. Consequently, we request that the final rule state that the beneficiary must have paid all outstanding copay and deductible amounts before receiving title to equipment.

III. CONCLUSION

We very much appreciate the opportunity to submit these comments. As we stated above, CMS must address the lack of budget neutrality in its methodology and publish all the data and assumptions it uses in this analysis. We strongly recommend that CMS apply any additional monies available after it has accounted for budget neutrality to increase monthly payment amounts for portable oxygen and support the development of new technologies. CMS should delay the implementation of the new payment policies by grandfathering beneficiaries already receiving oxygen. This will permit a transition during which CMS and stakeholders can collect the data necessary to make long-term refinements to the payment methodology. We also request that CMS clarify the operational issues in the manner we recommended above.

On behalf of Seeley Medical and our 104 employees, I appreciate the opportunity to submit these comments. Please feel free to contact me for any further clarifications, 440-812-0004 or mlacute@seelevmedical.com.

Sincerely,

Mario LaCute
CEO

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[34] 42 U.S.C. §1395m(a)(1), 2006.
[35] §1128b ___.

Submitter : Mr. francisco velazquez **Date:** 09/25/2006

Organization : Aspin Health Systems, Inc.

Category : Individual

Issue Areas/Comments

Background

Background

Surely unintended and unintentinal, but there's some irony in the exclusion of respiratory therapists or home medical equipment dealers/owners in your identifying categories. It is with a profound sense of indignation that I view the OIG's attempt to restructure the method for reimbursement of home medical 02. In 1981, when I first entered the home med equipment business, 02 therapy was paid at $315 (circa) and liquid 02 was paid by the pound as well as for the rental of the equipment. I've seen first hand the changes from that fee schedule to a global one and had no alternative but to abandon the liquid 02 systems. I've seen first hand what happens to patient's who are unable to access liquid systems and the effect on their healthcare. Your 02 patient is atypical; demanding more of us at a time when our costs are increasing. The 02 patient is totally dependent on the relationship that's established with the service company. I serviced a 19 year old patient on 02 at 8 lpm from April 1982 until September 2002; twenty years on high pressure and then liquid 02 on a 24/7 basis. Cap that one and pray tell how! The 02 patient is the most labor intensive patient in the home medical equipment industry. The 02 patient doesn't regularly perform even the slightest of preventive maintenance and most sadly, those that continue to smoke or have relatives that do, very often turn our machines into disrepair. In 25 years, i' ve been through all the cycles and know first hand the massive confusion this ill-conceived deficit reduction effort will cause those beneficiaries with medically fragile conditions. If you think the donut hole is a disaster under Part D, wait till the 13th month caps start shifting responsibilty to 02 dependent beneficiaires. How ill-conceived the matter of capping therapies.

Submitter : Mr. David Petsch

Organization : Petsch Respiratory

Category : Individual

Date: 09/25/2006

Issue Areas/Comments

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

The proposal as published will have several negative and elimination of services to the Medicare Beneficiaries. First, the patients access to the current service providers will be eliminated. 24 hour emergency services will be reduced simply because their will be no incentive for the provider to be available, much as you see at a physicians office after hours. The answering service simply informs the patient that if it is an emergency call 911. This will now occur for DME and all free emergency services that were provided by a DME company will now become an ambulance call, transport, ER visit and probably a hospital admit. CMS will end up paying more for that one incident (that they now get free) than what they have paid for an entire years worth of oxygen services. Second, the new patients that require oxygen services will become confined to their home because no provider will have an incentive to issue the ambulatory oxygen they now provide for free. Why give something away any longer when there is no incentive to get or keep that patient. Third, the medicare beneficiary is being forced into a limited provider network much like an HMO and they have no choices. This in turn forces them to stay home, not travel, will get no assistance if they relocate and will not find providers willing to do so for free. This again eliminates a service they were getting for free, created competition among providers, and allowed the patient a choice when relocating. They will loose all of those benefits from day one. Fourth, access to better technology will be lost. No provider is going to be able or willing to provide the newest, better technology unless they are getting a fair price. We are really creating two levels of healthcare here. Those that can afford to pay for quality products and technology and those under Medicare that get the lowest priced, cheapest equipment, with no services. Mail order equipment has proven to be an idea, but in the long run, would you want mail order equipment and services for your parents or for yourself. Who would you call for after our services then. Fifth, Since 1988 the six point plan created and placed different DME equipment into categories according to the experts opinion as to what amount of service and maintenance these products required. Since 1988 we have not moved any because no one felt there were any in incorrect categories. Yet this year due to the DRA, now several pieces of equipment need to be moved due to financial incentives for the Budget and against. Does that sound like the decision is made due to clinical and quality care or are we just cutting the budget in a different way. If we were just cutting the budget we should do it the same way we have been doing it for 18 years and let the industry find the median professional way to provide the outcomes. IN SUMMARY, this proposal is doing nothing to help the beneficary. It is a 22% cut to providers, it will cost shift any possible savings to DME into the institutional side and increase the actual costs to the program by 150 to 200% more than what is being done on the home care side. It will take away several of the benefits beneficiaries depend up to live at home or independently. It will force them into institutions and/or die. Their (meaning the medicare patients) life expectancy will be shorten for many. David Petsch 332 Patton Ct. Martinez, Ga. 30907 706-863-6252

Submitter : Ms. Carol Napierski **Date:** 09/25/2006

Organization : nymep

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1304-P-71-Attach-1.DOC

CMS-1304-P-71-Attach-2.DOC

ATTACHMENT 1 TO #71

NYMEP NY Medical Equipment Providers Association

27 Elk Street
Albany, New York 12207
Phone: 518-436-9637
Fax: 518-436-9667

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

Dr. Mark McClellan
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-11304-P
P.O. Box 8014
Baltimore, MS 21244-8014

Dear Dr. McClellan,

New York Medical Equipment Providers Association (NYMEP) appreciates the opportunity to provide comments on the Proposed Rule Making entitled Medicare Program: 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; published in the Federal Registrar on 8/3/06

NYMEP is a state association comprised primarily of 140 durable medical equipment providers (DME) and manufactures employing over 5,000. NYMEP, on behalf of our membership, is submitting comments related to the documentation and procedural issues as they relate to the implementation of the proposed rule making for the Capped Rental of Durable Medical Equipment.

NYMEP is a member of American Association for Homecare (AAH) and of the MAC Jurisdiction A Advisory Council. NYMEP has reviewed and concurs with the comments submitted by both AAH and the Advisory Council. NYMEP's immediate concerns with the implementation of the Proposed Rule and the desired outcomes of the Final Rule are in the areas of:

- Assurance that patients continue to receive necessary access to providers and the needed services.
- Defining realistic operational requirements for all providers.
- Accessing to the Common Working File in order to avoid denial for duplicate payments

Assurance that patients continue to receive necessary access to providers and needed services:

Respiratory Services:

CMS stated in its response to the American Association for Homecare's questions on the implementation of the forced sale provisions of the DRA that after title to oxygen equipment transfers to the beneficiary, beneficiaries would be responsible to pay for clinical services such as those of a respiratory therapist that are not otherwise covered by Medicare. As a result, the beneficiary will be required to pay out of pocket for these services. In addition they may lose access to after hour's services such as trouble shooting equipment problems or access to a respiratory therapist once title to oxygen equipment transfers to the beneficiary.

Exchange of Equipment during Rental Period:

Currently as defined in the proposed rule; oxygen equipment furnished may not be replaced by the supplier prior to the expiration of the 36 month rental period unless:

1. The equipment is lost, stolen, or irreparably damaged
2. The furnishing of loaner equipment is necessary while the equipment is being repaired
3. The equipment is no longer medically necessary
4. The carrier determines the change in equipment is warranted

This provision that does not allow providers to change equipment from what was initially delivered unless one of the four above noted criteria was met would potential restrict the patient's choice and limit the providers ability to change equipment based upon patient need. CMS should not impede the service delivery by restricting replacement of equipment during the capped rental period.

1. This equipment requirement would limit the ability of the patient to try new or different equipment / enhanced technology.
2. Patient's living arrangements may change during this period and the original system may no longer be appropriate for the environment
3. DME providers should not be prohibited from removing equipment from a patients' residence because of non compliance or safety issues.

Backup Oxygen Equipment:

Many beneficiaries have backup equipment solely for use in emergence situations. The LCD states that a backup system is not covered because it is provided solely for the convenience of the beneficiary. Medicare will not pay for backup oxygen equipment because the equipment is not medically necessary. To the extent that CMS has not made any rental payment provisions for the back up equipment and because the equipment is

not medically necessary, title to the equipment should not be transferred to the beneficiary under the DRA.

Defining realistic operational requirements for all providers:

Ownership:

1. Title to medical equipment cannot transfer until the beneficiary has paid all outstanding co-payments and deductibles.
2. Beneficiaries may have more than one home location or relocate during the period of continuous use which will potentially create an issue of maintaining access to equipment. The proposed rule states that a change in supplier would not begin a new period of continuous need therefore, Medicare beneficiaries who move after the conclusion of the 36 month rental period may have a difficult time transferring to a new provider.
3. Break in service provisions have not been clearly communicated to the provider community. How will this rule be changed to address the situation where a patient requires a stay in a skilled nursing facility?

Payment:

CMS has recognized that the current modality neural payment system for stationary systems was based upon reimbursement to the provider for rental of stationary equipment and oxygen contents for both portable and stationary systems. The fee recommendations by CMS are not budget neutral. In fact it appears that they may result in approximately a 10% reduction. CMS has identified a 65% stationary and 35% portable split and increased reimbursement for some new technology. We question the rational for this allocation of dollars.

Repairs and Maintenance and Service:

Providers and beneficiaries need to have clear guidance on the specific coverage requirements. Billing for repairs needs to be addressed through the issuance of new codes. Billing for repairs will require specific guidance on the type of documentation

that CMS will require on these claims. Currently there is not a high volume of repairs because oxygen equipment has been a continuous rental and repairs were covered. CMS and the DME MAC will need to prepare for the increased number of repair claims being submitted and develop policies that address repair claim submission.

Accessing the Common Working File in order to avoid denial for duplicate payments:

DME providers should have access to the Common Working File to avoid denials for duplicate payments. If this is not possible, prior to the implementing the DRA then CMS must establish criteria for using ABNs to notify the beneficiaries of their financial responsibility if there is "same or similar" medical equipment.

Conclusion

NYMEP appreciates the opportunity to submit these comments and remain available to discuss them with you in greater detail.

For further information contact:

Carol Napierski
New York Medical Equipment Providers Association
27 Elk Street
Albany, New York 12207
Telephone: 518-436-9637
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Respectfully Submitted,

Carol Napierski

Executive Director

ATTACHMENT 2 TO #71

NYMEP NY Medical Equipment Providers Association

27 Elk Street
Albany, New York 12207
Phone: 518-436-9637
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Via Electronic Mail:
http://www.cms.hhs.gov/eRulemaking

Dr. Mark McClellan
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-11304-P
P.O. Box 8014
Baltimore, MS 21244-8014

Dear Dr. McClellan,

New York Medical Equipment Providers Association (NYMEP) appreciates the opportunity to provide comments on the Proposed Rule Making entitled Medicare Program: 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; published in the Federal Registrar on 8/3/06

NYMEP is a state association comprised primarily of 140 durable medical equipment providers (DME) and manufactures employing over 5,000. NYMEP, on behalf of our membership, is submitting comments related to the documentation and procedural issues as they relate to the implementation of the proposed rule making for the Capped Rental of Durable Medical Equipment.

NYMEP is a member of American Association for Homecare (AAH) and of the MAC Jurisdiction A Advisory Council. NYMEP has reviewed and concurs with the comments submitted by both AAH and the Advisory Council. NYMEP's immediate concerns with the implementation of the Proposed Rule and the desired outcomes of the Final Rule are in the areas of:

- Assurance that patients continue to receive necessary access to providers and the needed services.
- Defining realistic operational requirements for all providers.
- Accessing to the Common Working File in order to avoid denial for duplicate payments

Assurance that patients continue to receive necessary access to providers and needed services:

Respiratory Services:

CMS stated in its response to the American Association for Homecare's questions on the implementation of the forced sale provisions of the DRA that after title to oxygen equipment transfers to the beneficiary, beneficiaries would be responsible to pay for clinical services such as those of a respiratory therapist that are not otherwise covered by Medicare. As a result, the beneficiary will be required to pay out of pocket for these services. In addition they may lose access to after hour's services such as trouble shooting equipment problems or access to a respiratory therapist once title to oxygen equipment transfers to the beneficiary.

Exchange of Equipment during Rental Period:

Currently as defined in the proposed rule; oxygen equipment furnished may not be replaced by the supplier prior to the expiration of the 36 month rental period unless:

1. The equipment is lost, stolen, or irreparably damaged
2. The furnishing of loaner equipment is necessary while the equipment is being repaired
3. The equipment is no longer medically necessary
4. The carrier determines the change in equipment is warranted

This provision that does not allow providers to change equipment from what was initially delivered unless one of the four above noted criteria was met would potential restrict the patient's choice and limit the providers ability to change equipment based upon patient need. CMS should not impede the service delivery by restricting replacement of equipment during the capped rental period.

1. This equipment requirement would limit the ability of the patient to try new or different equipment / enhanced technology.
2. Patient's living arrangements may change during this period and the original system may no longer be appropriate for the environment
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Defining realistic operational requirements for all providers:

Ownership:

1. Title to medical equipment cannot transfer until the beneficiary has paid all outstanding co-payments and deductibles.
2. Beneficiaries may have more than one home location or relocate during the period of continuous use which will potentially create an issue of maintaining access to equipment. The proposed rule states that a change in supplier would not begin a new period of continuous need therefore, Medicare beneficiaries who move after the conclusion of the 36 month rental period may have a difficult time transferring to a new provider.
3. Break in service provisions have not been clearly communicated to the provider community. How will this rule be changed to address the situation where a patient requires a stay in a skilled nursing facility?

Payment:

CMS has recognized that the current modality neural payment system for stationary systems was based upon reimbursement to the provider for rental of stationary equipment and oxygen contents for both portable and stationary systems. The fee recommendations by CMS are not budget neutral. In fact it appears that they may result in approximately a 10% reduction. CMS has identified a 65% stationary and 35% portable split and increased reimbursement for some new technology. We question the rational for this allocation of dollars.

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Providers and beneficiaries need to have clear guidance on the specific coverage requirements. Billing for repairs needs to be addressed through the issuance of new codes. Billing for repairs will require specific guidance on the type of documentation

that CMS will require on these claims. Currently there is not a high volume of repairs because oxygen equipment has been a continuous rental and repairs were covered. CMS and the DME MAC will need to prepare for the increased number of repair claims being submitted and develop policies that address repair claim submission.

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DME providers should have access to the Common Working File to avoid denials for duplicate payments. If this is not possible, prior to the implementing the DRA then CMS must establish criteria for using ABNs to notify the beneficiaries of their financial responsibility if there is "same or similar" medical equipment.

Conclusion

NYMEP appreciates the opportunity to submit these comments and remain available to discuss them with you in greater detail.

For further information contact:

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Respectfully Submitted,

Carol Napierski

Executive Director

Submitter : Ms. Ashley Wolfe

Organization : Lambert's Health Care

Category : Other Health Care Professional

Date: 09/25/2006

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1304-P-72-Attach-1.DOC

#72

September 25, 2006

Comments on NPRM for DRA Oxygen Provisions

Submitted by: Ashley Wolfe; Knoxville, TN. *Both my grandmother, grandfather, and my aunt benefit from oxygen therapy, and I think it is crucial for Medicare and CMS to review some of the policies outlined in their legislation of the DRA in order for my family to continue to receive quality care.*

General Comments:

1. **Under the proposed S. 1932 Legislation, Medicare would now only allow patients to rent oxygen concentrators and related oxygen equipment provided with it for up to 36 months.** Earlier versions of the bill limited the rental to as little as 18 months. Placing any monthly cap limit on this benefit is a drastic and dangerous change to the oxygen benefit currently in place that now puts no limit on the coverage of oxygen rented to the patient. Current Medicare benefit guidelines as well as those for all major national insurance companies, state Medicaid programs, workman's comp benefit programs, and all home care industry accreditation organizations have always classified oxygen equipment as *"high maintenance equipment needing frequent maintenance service which is not recommended or advisable for patients to own"*.

2. **Under this new pending rule, Medicare will stop paying for the rental, and the provider will no longer be involved the patient's care or management of his/her oxygen concentrator after 36 months.** According to congressional reports, the average patient rents such equipment for 30 months. By capping the units at 36 months, congress will be cutting off rental benefits to as many as 15 to 20 percent of all Medicare patients on oxygen. Patients will no longer receive free 24-hour service on the equipment, and they will no longer receive any free service. They will have to be financially responsible for each service provided. This includes preventative maintenance and routine inspections of the equipment. Repair and necessary service to the machine will now be billable to the patient and assignment will only be accepted by the oxygen provider on a case-by-case basis. There is also concern that oxygen providers may not accept assignment on the historically low Medicare fees for repair of medical equipment for patients they no longer provide rental services for since some of Medicare's fees do not even cover the provider's wholesale cost.

3. **Some industry experts are concerned for the patients who live far away from the oxygen provider's offices. These patients in particular may find it very difficult to find a provider who will service their owned, used equipment once the equipment has been transferred to the patient.** Medicare does not pay for delivery and pick-up charges for such services. This will make it even more difficult for providers to accept assignment on any repairs that would be done in the home. Under the proposed plan once the rental caps, title and all responsibility for the used equipment will simply be transferred to the patient. At that time, the oxygen provider will no longer be responsible for any of its upkeep. If there were any warranty remaining, it would be managed and controlled through the manufacturer of the product. Any warranty claims made would now bypass the provider and ultimately be processed by the manufacturer. As with all factory warranties on sold equipment, this will now have to be processed through the procedures required by the manufacturer. This will likely cause delays in processing repair work for patients or force patients to accept financial responsibility for repairs until warranty authorizations are approved by the factory.

4. **When patient owned non-working equipment is being repaired or reviewed by the factory for a warranty determination, the patient will be financially responsible for the rental of a temporary replacement unit. There is no factory warranty that covers this.** Most warranties on oxygen concentrators are only for 3 years from the date the supplier purchases the machine. The net effect will be that after 36 months of rental, the patient will be 100% responsible for

managing and caring for the non-warranted item. A three year old oxygen concentrator can have as many as 26,000 hours of use on it at the time it is transferred to the patient. Based on the average life of an oxygen concentrator, this is equivalent to owning a typical American automobile out of warranty with over 100,000 miles on the odometer.

5. **Once the patient owns the equipment, the supplier will have no obligation to provide free 24-hour service on the equipment**. This is a service that is provided at no additional charge for rental equipment owned by the supplier. Free emergency backup tanks for power outages and equipment failure will be picked up or billed to the patient privately as this is also a service pertaining to the rental equipment owned by the oxygen provider. Duplicate equipment, such as the backup tank, has never been a covered service billable to Medicare. Patients wanting a backup tank as well as patients wanting to be covered by a 24-hour service contract will have to pay privately for them. Patients who are unable or unwilling to make financial arrangements for 24-hours service capability will be advised to keep several family members aware of their dependence on oxygen and their need for assistance should there be inclement weather or other events that may cause an interruption in electrical power to their home.

6. **Patients who are unable to move freely throughout their home without assistance, who are vision impaired, who have periods of confusion related to their condition, or who live alone will be most affected by this new change.** These patients will be in the most risk of being unable to care for their equipment or to know when it needs service or how to manage the new financial arrangements for the service each time it is needed. Such patients are advised to find other family resources or community services to assist them in the managing and monitoring of their equipment needs.

7. **Patient-owned equipment will not be managed for billing of services the way rental equipment is managed. Each time an oxygen provider is called out to check on the equipment, regardless of there being anything wrong with it or not, a separate charge will be billed to the patient.** Patients or family members who need re-education and retraining on the use of the equipment will also no longer receive these services free. Service calls after-hours, if available, will be billed at a higher rate than service calls during working hours. Service calls will no longer be free of charge. Equipment that cannot be repaired at the patient's home will have to be retuned to the provider's office for repairs or sent to the factory. All repair parts and labor will be billed separately. Additional charges will also be billed for substitute equipment left with the patient while repairs are done elsewhere. Equipment that cannot be repaired will result in the patient having to be responsible for the purchase of replacement equipment should Medicare not cover the cost of its replacement. Medicare does not provide for the replacement of medical equipment (i.e. wheelchairs, walkers, and hospital beds) that has been owned by the patient unless it has been damaged beyond repair by fire or accident or unless it has been purchased for over five years and then becomes inoperable and unrepairable. As with all other Medicare-covered equipment purchased by Medicare, should the patient want a different brand, model, or type of concentrator once title is transferred for the one they have been renting, they will not be eligible to exchange it for one until their existing unit is no longer repairable. Medicare currently does not recognize the difference in the different types of oxygen concentrators currently available to patients. As new technology arrives in the marketplace, patients will not be able to swap their old units in and receive any reimbursement from Medicare for the upgraded newer unit.

8. **Under the new rules, once the used concentrator is owned by the patient, all supply tubing, humidifiers, nasal canulas, water traps, and any other disposable oxygen supply circuits and attachments will be separately billed to the patient.** Again, as with repair charges, the acceptance of assignment by suppliers for each item sold will be on a case-by-case basis by each oxygen provider. A provider's decision to accept assignment will be based on the reasonableness of the fee allowed by Medicare for each item. Currently the fees for these items are extremely low and in some cases do not cover the providers' cost.

9. **Under the new rules, patients who move or travel will have to either take their own equipment with them or pay privately for another company to rent them replacement equipment where they will be staying.** Under previous rules for oxygen coverage, patients wishing to travel to areas outside their provider's coverage area could do so at no charge to the patient. Their home oxygen provider would continue to bill for monthly rental and make separate arrangements for another company to provide the same equipment and service to the patient in the area the patient is staying (even if out of state). The home company, as required by Medicare, would pay the out of state company for its use on behalf of the patient when the patient stay was to be temporary. This service has been widely used for patients who stay with family one part of the year and with others during other parts of the year. This also has been used for patients visiting other parts of the country for extensive outpatient medical treatments requiring them to stay for weeks or months at a time. Under the old plan, if the patient needed to travel for a longer period of time or move to another area, the patient would simply change suppliers and receive their oxygen equipment and necessary services from a different rental company in the new location. This will no longer be available for patients who own their own equipment. Medicare will no longer pay for the rental of the equipment once the patient owns his or her own equipment.

10. **Requirements necessary for Federal Drug Administration (FDA) tracking would now have to be maintained by the patient or their caregiver should a recall occur for the particular medical device (concentrator) owned by the patient**. Providers are required to notify individuals who have purchased medical equipment subject to a recall under the FDA Medical Device Act. Such contact must be made by certified mail and by phone. Unless the provider is given all future address changes for patients, the patient would not receive such a recall notice. Special attention would need to be given to patients and their families who would now be personally responsible for receiving and acknowledging such recall notices. If the patient cannot keep up with such records, he/she would have to appoint a family member or other dependable party to be responsible for such communications.

Comments on Costs Pertaining to Home Oxygen Therapy

1. **Equipment cost only accounts for 28% of the total Home Oxygen Therapy costs.** The Morrison study finds that other services account for the significant majority of costs associated with Home Oxygen Therapy. These include: preparing and delivering the equipment; delivering supplies and maintenance of oxygen equipment; assessing, training and educating patients; obtaining required medical documentation and providing customer service for beneficiaries; related services and compliance with Federal & State Regulations (included FDA and DOT requirements); other related services; and operating and overhead costs.

2. **Medicare oxygen patients are provided home oxygen therapy for about $7.50/day ($2,784/year), with their co-pay amounting to less than $1.50/day. The annual costs to beneficiaries without supplemental insurance is approximately $574/year.** In 2002, there were 673,000 hospitalizations for patients with Chronic Obstructive Pulmonary Disease, the fourth leading cause of death among Americans each year. When COPD patients were hospitalized, the average length of stay was 5.2 days. It is vital for patients using Home Oxygen Therapy to have the services needed to keep them in the home and out of the hospital from a financial standpoint. At a cost of $7.50/day for the home oxygen, it is vitally important that CMS insures that this change in policy does not result in any increases in hospital stays, which costs an average of $3,606/day. One hospitalization of an average length of stay would wipe out all of the financial benefits to Medicare of five people's *annual* capped rental costs.

3. **70% of problems that technicians are called to the home to check on are not services that Medicare would cover.** This leaves the beneficiary paying out-of-pocket for services that were previously covered under the oxygen rental program once the beneficiary owns his/her

equipment. As previously mentioned above, these services include: Free 24-hour service on equipment; Free back-up tank, stand, regulator, or supply tubing; Free replacement equipment during extensive repairs of rented equipment; Local warranty services; Free access to Respiratory Therapists; the Ability for the provider to arrange for free 24-hour service when the beneficiary travels to another city; Free deliveries and pick-ups for services or parts.

4. **Suppliers cannot be held responsible for replacing patient owned equipment within 5 years of the date the item is sold to the patient if the repair cost exceeds 60% of the cost of the item.** These items are not delivered new. They are rented as used items. However even it the item was delivered as new, it is totally unreasonable and unprecedented for Medicare to expect any supplier to replace the unless the unit is in fact covered by a manufacturers warranty. Medicare has used this 5-year period in the past to determine if the benefit plan will actually replace an item of equipment or continue to repair it. For DME items that no longer work or are damaged beyond repair, Medicare does not require the supplier to replace the unit if the repair cost exceeds 60% of the replacement cost. Even Medicare will not do that. Medicare continues to pay all the way up to 100% of the items replacement cost to avoid replacing it. There also is no 60% factor involved in the decision to repair the unit. It is apparent that this an attempt to avoid what Medicare already knows will be an extensive cost to the program. These items require frequent service and maintenance. This service and maintenance is "the responsibility of the beneficiary". Providers will NOT be paid by Medicare to maintain the equipment. Providers will be paid ONLY to repair it after the fact. Since providers are not receiving any money to keep the equipment up and since it is the patient who is 100% responsible for taking care of the equipment and performing the frequent and routine maintenance and service on the machine (everything other than major repairs), it should therefore be the responsibility of the beneficiary to replace the unit if the cost to repair it exceeds 60% if in fact Medicare wants to limit the repair cost to that. Unless suppliers are paid to maintain the item over the 5-year period they cannot be expected to be at risk for the equipment's failure. This is not fair or reasonable.

Comments on Beneficiaries that Receive Home Oxygen Therapy

1. **COPD, the fourth leading cause of death each year in the United States, affects approximately 15 million Americans, with an estimated additional 15 million that have gone undiagnosed.** By 2020, the World Health Organization estimates that COPD will rank fifth as a global burden of disease. Oxygen Therapy is the only current treatment or drug scientifically proven to extend the life of patients with chronic lung disease. Other people who benefit from oxygen therapy include those with congestive heart failure, respiratory failure, ALS, and other serious diseases.

2. **The average COPD person is considered to be in the "frail/elderly" category, have numerous activities of daily living that are impaired, and may live alone.** Since this disease is a debilitative, progressive, non-curable one, it is important that these people are able to receive their oxygen therapy—even once they are incapable of performing the "routine or periodic servicing" that Medicare outlines for them. Under previous Home Oxygen Rental programs, these services would be provided free of charge to the beneficiary. As previously stated, one slip-up on the beneficiary's side of caring for his/her equipment could result in expensive, extended stays in the hospital.

Comments Concerning Issues Not Addressed in Legislation

1. **Which Provider's equipment transfers to the beneficiary if the beneficiary has two residences with a local provider in each residence?**

2. **With patient-owned equipment, there is no record of routine ongoing service and maintenance that is supposed to be performed by the beneficiary or caregiver.** CMS states,

> "We would, however, also propose to apply our existing policy of not covering certain routine 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 policy for beneficiary-owned capped rental equipment."

   a) If the beneficiary neglects the equipment, the equipment could malfunction. Is this the responsibility of the provider to repair the equipment when the root of the problem was improper care by the beneficiary?
   b) What if this repair adds to the overall repair cost of greater than 60% of the cost of replacement equipment? What safeguards are in place for the supplier to ensure that the beneficiary will take care of the equipment to reduce repairs and replacements?
   c) In the event that the beneficiary lives in an assisted living facility (therefore being unable to have the services provided by a caregiver), if the beneficiary reaches the point where he/she is unable to perform some of the "routine or periodic servicing" that is required by him/herself, will that force the beneficiary into a nursing home, thus increasing costs to Medicare?

3. **How is the supplier supposed to have accurate liter-flow information about the beneficiary from the physician if the patient is no longer in their system under the oxygen rental program?** If the supplier is called out for an "after hours" house-call, unless proper documentation is available to the supplier technicians, no action may be taken. This will result in an ambulance coming to the beneficiary's home and taking him/her to the hospital. This will undoubtedly cost Medicare more.

Comments from the Homecare Industry Regarding Consequences of Implementation

1. **Beneficiary access to ambulatory oxygen will be limited.** Providers cannot utilize liquid oxygen as a modality for their beneficiaries, further limiting access to beneficiaries due to a lack of reimbursement during the initial 36 months and the succeeding periods after ownership has been transferred to the beneficiary.

2. **Beneficiary access to innovation and new technology will be limited.** CMS states,

> "Payments for oxygen contents for beneficiary-owned portable equipment would exceed what is currently paid for these items to ensure access to portable oxygen regardless of the type of equipment used. These increased payments would be offset by a reduction in the stationary payment."

The difference in reimbursement between the traditional equipment would be $32/month. Most of the types of products that fall within this category is anywhere from $1,200 to $2,500 difference to the purchase price of the traditional oxygen equipment. The $32/month additional is $1,152 in additional reimbursement payments. This hardly covers the cost to acquire the newer technology. Providers will be reluctant in providing this equipment at a loss; therefore the proposed rule limits access to newer technology by not providing adequate reimbursement to cover the cost of the equipment.

3. **Beneficiary's ability to relocate on a permanent or temporary basis prior to transfer of title of ownership is limited.** The supplier in the new area will not have the full 36 months to collect reimbursement. ((In addition to the question of which provider gives the equipment to the beneficiary, does the new provider have to transfer ownership without having collected the full amount to justify the cost of the concentrator and the services?)) This limits the

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.

Comments Regarding Oxygen Concentrator Rentals

Medicare currently pays a flat fee for the rental of an oxygen concentrator. This single flat fee is described as a "bundled" rental fee under Medicare guidelines that includes the patient's concentrator machine as well the provision of all the related supplies and services associated with the machine. This fee is expected to cover all costs the oxygen provider incurs that are associated with the provision of the rental unit. Among those includes the cost for all necessary internal and external replacement filters, all preventive maintenance service calls, and all repairs needed on the machine while rented. Should the machine become inoperable and unrepairable, this rental fee is to cover the oxygen provider's cost for replacing the machine with another one. A recent oxygen supplier survey in Tennessee taken by the Tennessee Association for Home Care [TAHC] revealed that of the suppliers surveyed between 18% and 40% of the oxygen concentrators on rent are exchanged and replaced each year with different units. These exchanges are made by the providers due to equipment repair, service, and maintenance needs that cannot be reasonably performed in the home. As a rental item, these exchanges are done in the patient's home with no significant inconvenience to the patient. In general, the rental fee covers everything associated with the providing an uninterrupted supply of oxygen to the patient as well all costs for providing the patient with his/her monthly respiratory supplies to be used with the machine. The supplies covered includes oxygen supply tubing, humidifiers, nasal canulas or face masks, water traps, and any other disposable oxygen supply circuits and attachments ordered by the patient's physician that are needed for the delivery of oxygen to the patient. As with all other rented equipment, this bundled fee covers the initial and ongoing training of the patient and/or the family for proper use and care of the equipment. Lastly, this fee is also to cover the oxygen provider's cost for the required ongoing monitoring of the patient's use of the equipment to insure that the equipment is being properly utilized according to the physician's written orders.

The oxygen concentrator is a highly sophisticated, complicated, and sensitive item of equipment. It operates by compressing room air into and through a group of pneumatically sealed containers filled with sieve material that filters the nitrogen out of the room air, leaving a highly enriched oxygen concentration of air that is approximately 93% to 95% pure oxygen. This process is achieved by directing the air through a series of pneumatic pressurized chambers under timed cycles controlled by pressure sensors and gages. At no time can there be any pressure leaks or significant variances in the synchronization of the air exchanges in the system. When variances occur over time, the oxygen concentration will begin to drop. If they persist, the concentration levels can drop as low as 30% to 40% and even as low as normal room air. When the levels drop to substandard oxygen concentration levels over a period of time, the machine can also start to experience other problems including the contamination of the machine's sieve beds. Sieve beds are small granular beads inside the sealed metal chambers or canisters that filter the nitrogen from the air, leaving only highly enriched oxygenated air delivered to the patient. Leaks to the sieve bed chambers can result in an extensive repair cost to the machine but more importantly can cause damage to the patient, as the patient also will not receive adequate oxygen intake once the sieve beds are compromised. If the machine's pre-filters and internal filters are not cleaned and changed according to factory guidelines, the machine will also overheat and begin to destroy the soft pliable hoses within the unit. Once these hoses lose their ability to seal around internal gaskets, the machine will also begin to lose concentration and complete the downward cycle of equipment failure.

Although there are mechanisms and built-in alarms in some models of the machines that can indicate a corruption in the airflow seals and detect significant drops in pressure, they are by no means fool proof. Many of these self-detecting sensors only alarm when the concentration has fallen well below the concentration necessary to provide the patient with his/her prescribed needs. Some machines can appear to be working properly and not show any outward sign of problems until an oxygen analyzer is put on the machine's output to test its concentration levels. The oxygen analyzer is a small calibration device that measures the oxygen concentration output of the machine. This again is one of the routine services oxygen providers perform on all rented concentrators before and during the rental episodes. Preventative

maintenance is a service provided at no extra charge by providers and is performed on the rental machines at the patient's home during the rental episode. It is done to prevent future equipment failure and minimize future repair needs. It is also done to further insure that the equipment is producing the prescribed level of oxygen that the physician has ordered. Although preventative maintenance is performed as part of the rental program, it is not in itself a separate Medicare covered charge for equipment owned by patients. Medicare, as well as most health care insurance programs, does not routinely provide benefits for preventative health care services or for preventative equipment that can potentially prevent an illnesses or injury. Examples of items not covered as for preventative value are bathtub benches or grab bars around the bathroom. In keeping with this philosophy, Medicare also does not provide preventative inspection and equipment analysis to patient-owned medical equipment regardless of how beneficial such inspections and preventative care may end up being. This would be a dangerous problem for patients whose oxygen equipment has not shown signs of equipment failure yet is not producing adequate levels of oxygen.

Oxygen concentrators run on electricity. They attach to any well-grounded, home utility electrical circuit. During any time of equipment malfunction or equipment failure, continuous use can likely further damage the machine. The machine should be turned off any time the machine alarm sounds or when it appears to be running louder than normal or feeling hot to touch. Under the rental program, patients and families are advised to call their oxygen provider when the machine does not run properly. Although many of the problems with oxygen concentrators are due to improper attachment of tubing or humidifiers to the machine itself, most patients are unable to determine what is wrong without assistance of a medical equipment technician. All rentals of oxygen equipment include, at no extra cost, 24-hour emergency service. Most service calls that require adjustments, repairs, or exchanges will be done within two to four hours of the call. During such equipment failure, patients are advised to change over to their free back-up oxygen gas filled tank until the technician arrives at their house. This back up gas tank is provided by the rental company as a free service as part of its 24 hour-service to patients renting oxygen equipment so that the patient will not have to call 911 for assistance between the time that the equipment first fails and the technician arrives at the patients home.

Oxygen concentrator machines can be damaged over a period of time when placed too close to a wall or piece of furniture which occludes the air intake opening. They can also be damaged by the excessive use of baby powder or other dry particle agents used in a patient room for incontinence. Use of such airborne powders can cause clogging of the pre-filters if not replaced or cleaned frequently in such environments. Restriction of air intake to a concentrator causes the machine to overwork to compensate for the reduced air flow into the machine and eventually will result in overheating and damage to the machine. Patients and caregivers should pay special attention to always ensure that the air intake remains open and unobstructed. When patients plan to travel and take their machine from one residence to another, it is recommended that they always contact their equipment supplier first to make sure it is advisable for the equipment to be moved by their caregivers or through special arrangements made by the oxygen provider. Special attention should always be given to care for the machine when in transit. Certain manufacturers' service and maintenance guidelines state that the machines should never be turned on their side in order to prevent breaking of seals in the airway connectors.

As with all medical devices covered under the Federal Drug Administration (FDA) Medical Device Tracking Act, the concentrator must be monitored and cared for properly in order to insure continual safe use. As a FDA device, the machine is eligible for recall and patient health and safety tracking log reporting of injury or death occurrences caused by its design or other mitigating causes of its manufacturer. As required by law, the supplier maintains compliance with the FDA tracking requirements while the supplier owns the unit. This is another service covered and provided for by law as long as the oxygen provider owns the equipment.

Submitter : Mrs. GEORGETTA BLACKBURN **Date:** 09/25/2006

Organization : PA ASSOCIATION OF MEDICAL SUPPLIERS

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-1304-P-73-Attach-1.DOC

CMS-1304-P-73-Attach-2.DOC

ATTACHMENT 1 TO #73

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)[1] Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment; Proposed Rule [CMS-1304-P] RIN 0938-AN76[2]

Dear Dr. McClellan:

The PA Association of Medical Suppliers (PAMS) appreciates the opportunity to submit comments relative to the proposed changes to the Medicare payment rate for oxygen equipment and capped rental durable medical equipment.

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Our providers must have realistic operational requirements within the proposed rule just as we must insure ongoing quality of care and continuity of care for our patients. The following comments and concerns are submitted on behalf of our membership:

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Caption: Provision of Proposed Regulation

Exchange of equipment during the rental period

Continuous use regulations are being changed to identify that a new period of need does not begin when the beneficiary receives new equipment. The rational is that the payment system is modality neutral. That would lead one to believe that the system was originally designed to allow for the changes in patients' clinical needs and physical abilities. Since oxygen therapy is covered for patients in a chronic stable state, the therapy is normally long term in nature and the normal progression of the disease may require changes in technology to meet those needs. Currently as written the rule would not allow the provider to change equipment from what was delivered unless one of four criteria are met:

1. The equipment is lost, stolen, or irreparably damaged
2. The equipment is being repaired while loaner equipment is in use
3. There is a change in medical condition such that the equipment initially furnished is no longer appropriate or medically necessary
4. The carrier determines the change in equipment is warranted

Our concern with this guidance is that it restricts patients' choice and limits the providers' ability to keep technology available for patients if their needs change or there is new technology. Also, it severely disrupts the providers' normal operation during the rental period. CMS should not restrict the ability of a provider to change out equipment during the rental period. The following are scenarios that CMS has not considered. We would like to reference CMS's numbers that 64% of the patients will not be using oxygen more than 36 months.

For efficiency and timely response to the patients' needs, providers' normally exchange equipment when patients call and indicate the equipment is not working properly or needs adjustments. Requiring that provider's pick-up the equipment, provide a loaner, assess the equipment for repairs and return it to the patient is inefficient and costly. Each time a provider delivers equipment to a patient, that patient has the opportunity to accept or reject the product if it is not operating properly or does not meet their needs. Since a large percentage of patients may never reach the 13-month (capped rental) or 36 month (oxygen) force purchased, CMS should not dictate the terms of the rental

This requirement would limit the ability of the patient to try new or different technology. During the course of therapy the patients' needs may change several times. Providers and physicians evaluate the patients' needs on an ongoing basis

Example:

A patient that is using a concentrator and portable oxygen cylinders could not change to a home fill system because there has not been a change in medical condition. This also restricts patients' choice to evaluate other technologies that may be easier or simpler for them to use. Many times when a patient first starts using oxygen, they have no reference or expectation of how or in what situations they will need to use their oxygen

- Patients living arrangements may change and one type of oxygen system may be preferred over another for safety reasons
- Providers should not be prohibited from removing equipment from a patient's residence because of non compliance or safety reasons

Ownership

Break in service rules have not been clearly communicated to providers. The rule states that after 13 months of continuous rental for capped rental items and 36 months of rental for oxygen items, title of the equipment transfers to the beneficiary.

How will the rules be changed to address the situation where a patient requires a stay in a skilled facility? During that time, payment may or may not be suspended. Currently what occurs is that if a patient is in a skilled facility for any period of time and their stay includes the rental anniversary date, the claim may be denied initially. But more often what occurs is that the DME MAC notifies providers several months or even years later identifying that the patient was in a skilled facility over their rental anniversary date. At that time the DME MAC's request a refund. What this means in the new forced ownership model is that the provider refunds the month or months of rental that the patient is in the skilled facility. The impact to the provider is that they will not receive their full reimbursement and title has already transferred to the patient

Recommendations:

- If a patient is home during any portion of a rental month pay the claim regardless of in skilled stay on the rental anniversary date
- Do not do recoupments if the patient continued to use the equipment for more that the 36 months plus the months in a facility
- Any recoupment should come from the beneficiary since ownership of the equipment has transferred to the beneficiary
- Allow providers' access to the CWF (Common Working File) or claims rental file history. If providers had access, this would help avoid duplicate denials. If access to the CWF or claims rental history file is not feasible within the time frame for implementing the DRA, then CMS must establish protocols that allows for limited liability for the provider by identifying these situations as a "patient responsibility denial"

Similarly, CMS did not respond to AAHomecare's question regarding equipment transfers to the beneficiary if the beneficiary has two residences with a local provider in each area. Beneficiaries who are "snow birds," or who may move or relocate during the period of continuous need will face hurdles in maintaining access to equipment. Because the proposed rule states that a change in supplier would not begin a new period of continuous use, Medicare beneficiaries who move after the conclusion of the 36 month rental period for oxygen will have a very difficult time transferring to a new provider.

Considerations:

- If a patient moves out of the provider's service area before the title transfers, begin a new rental period
- In the case of the snowbird, pay the primary provider the full payment 13 months (capped rental), 36 months (oxygen)
- Title to medical equipment cannot transfer unless the beneficiary has paid all outstanding co-pays and deductibles.
- The proposal by CMS that the patient owns 2 sets of cylinders is not appropriate or realistic. An example would be that many providers do not own oxygen cylinders. They lease them from a commercial gas company that is responsible for filling them and following all FDA guidelines.

Recommendations:

- Do not transfer title of the oxygen cylinders to the patient for the following reasons.
  - There are several concerns with maintaining compliance with FDA guidelines. Not transferring ownership would negate these concerns
  - There does not seem to be a legal basis for CMS to require two sets of cylinders. The rental payments are for the stand, cart, regulator and flow meter. We are unaware of any other government or private programs that operate this way
  - Consider the use of the container as part of the contents fee. This would help protect consumers from inappropriate disposal of the tanks
  - If the patient moves, it allows them to obtain tanks from any provider
- The requirement that providers notify beneficiaries of their "intent" with respect to accepting assignment is unworkable and conflicts with longstanding Medicare program rules that allow suppliers to accept assignment on a claim by claim basis. This is further compounded by the fact that providers do not have access to the CWF or claims rental history file so they do not know at the time of rental if the patient had previously rented equipment. This knowledge is part of the provider's decision-making process regarding accepting assignment or not.
- Providers should not be subject to overpayments and recoupment actions after title to equipment has transferred to the beneficiary. The DME MACs and PSCs need to bring their audit activity current so the audit activity occurs within the period of continuous use absent evidence of fraud or other wrongful conduct on the part of the provider.

Payment

CMS has recognized that the current modality neutral payment system for stationary systems was based on reimbursement to the provider for rental of stationary equipment and oxygen contents for both portable and stationary systems. In considering appropriate fees for the stationary and portable system, CMS needs to look at the historical data in developing a budget neutral payment methodology. Consideration must also be given to the cost of delivering the product and ongoing services to the patient. A recent industry study revealed that only 28% of the providers cost is product cost.

The fee recommendations by CMS are not budget neutral. In fact it appears that they may result in approximately a 10% reduction. CMS has identified a 65% stationary and 35% portable split and increased reimbursement for some new technology. We question the rational for this arbitrary allocation of dollars.

Recommendations:

- Reconsider the calculations for equipment and validate a budget neutral calculation
- Work with the stakeholders to develop a methodology that is going to achieve the appropriate goals
- Develop a payment methodology that assures that ongoing services will be available to the beneficiary after the title of the equipment has transferred
- Identify cost saving processes

Documentation

The current oxygen reimbursement system requires that a DME MAC CMN (484.03) be to be completed by the physician. However, CMS has removed the need for CMN's for several product lines such as wheelchairs, hospital beds and Enteral nutrition.

Recommendations:

- Consideration should be given to streamlining the documentation for these services
- A physicians order and documented laboratory results could suffice as required documentation and reduce physician/provider cost

Replacement

The proposed rule would require suppliers to replace, at no, cost patient owned equipment if the cumulative total repairs during the useful life of the equipment exceed 60% of the equipment's value. We question the guidance and authority to require replacement of equipment under the circumstances described in the proposal rule. Once title has transferred to the patient, the provider has no control over the maintenance or use of the equipment. The provider would have to replace a nonfunctioning unit, incur cost of a new unit, and repair of a unit that may not have been maintained properly. The provider would not have access to any manufacturers warranty since most warranties do not transfer to the end user. In addition, the provider would not have any manufacturers warrantee since in most cases the manufacturers warranty does not extend to the end user.

The provider cannot guarantee that the equipment will function as it should if it is not properly maintained. Similarly, the provider that furnished the equipment would have no control over the repairs that may be performed by another provider. Again, the original provider would be placed in the situation of having to guarantee the work of another provider who may have lacked the appropriate credentials to repair the specific equipment involved. This is not merely a hypothetical concern. Under the proposed rules for the DMEPOS competitive bidding program CMS would require that only winning bidders within an MSA perform repairs.

We are unclear on how CMS or the DME MAC would determine the 60% threshold that would trigger the supplier's obligation to replace equipment. The example CMS uses in the preamble is for capped rental equipment where CMS pays the purchase price of the equipment after 13 months and the purchase price "constitutes the equipment "value" for purposes of this provision. It appears that the 60% represents allowed/fee schedule amounts. Currently there are many repair parts that would need to be coded and priced. Providers would have no way of knowing the allowed amount without specific detailed HCPCS with fees. Also it is unclear if the 60% figure included the labor. While there may be some reference for the formula for capped rental items, we question its application to oxygen equipment.

Recommendations:

- Eliminate the 60% provision since it may be impossible to track and manage. When patients receive their equipment they have the right at that time to inspect the equipment and request other equipment if they are not satisfied. They also have 13 months for capped rental items and 36 months for oxygen equipment to evaluate if the equipment is meeting their needs. Again this supports the rationale for allowing exchange of equipment during the rental period

- Pay a reasonable fee for maintenance and service of patient owned equipment, not just a fee for repairs. Do not expect the patients who are sick, may lack manual dexterity or have vision or memory issues to perform routine maintenance and understand if the units are functioning properly

Repairs and Maintenance and Service

Repair policies need to be further defined. Providers, patients and the Medicare contractors need to have clear guidance on the specific coverage requirements. One of the most difficult claims that a provider submits is for repairs. The reimbursement is inconsistent, lacks specific coding for repair parts and requires extensive documentation. Providers are paid a one-month loaner fee if they need to provide a loaner while the patient's product is being repaired. The repair parts and labor fee does not take into consideration any travel time or time to evaluate the equipment. In some cases the equipment can be repaired on site. With the increase of equipment purchases rather than continuation of service from continual rental there will be an increase in repair claims.

Recommendations:

- CMS needs to provide clear guidelines on repair policies and develop HCPCS codes to allow for efficient processing of claims
- The DME MACs must standardize claims processing for repairs
- CMS and the DME MAC must work with interested parties to establish repair parts codes

The following chart identifies some of the products and respective parts that may be required.

Hospital Beds	Nebulizers	Patients Lifts	Concentrator	Liquid Oxygen Reservoirs
Pendant control	Tubing adapter	Hydraulic cylinder	Filter, inlet	Regulator
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Maintenance and Service

We believe it is very important for CMS to include an ongoing service and maintenance fee to cover emergency services, back-up equipment, respiratory practitioner evaluations, on call availability, and after hours troubleshooting for oxygen equipment after 36 months. Suppliers currently furnish these services under the monthly payment amount for oxygen.

These services were documented in the Morrison study and are a critical component of safely furnishing oxygen in the home. When the monthly rental payments end, there will be no payment for these support services.

Recommendations:

- We urge CMS to not take the position that these are no covered services therefore placing the burden of paying for them on beneficiaries. Some, if not most, beneficiaries will elect not to pay for the services, placing these beneficiaries at risk and creating a two-tiered system of care. Moreover, to the extent that the new supplier standards recognize that these services should be the standard of care for Medicare beneficiaries, Medicare payment policies should recognize them as well

- If CMS does not cover routine maintenance and service, back-up units, on call, or therapist clinical evaluations, there needs to be clear guidance that defines the contracted relationships that may be developed between providers and patients

SUMMARY

The PA Association of Medical Suppliers (PAMS) has very serious concerns regarding the proposed purchase of Oxygen by Medicare beneficiaries. Our respiratory patients represent a high percentage of our most compromised and chronically ill. To impose the responsibility of maintenance and care of their equipment upon them does not equate with improved care.

While Beds, Wheelchairs and other products may be considered a commodity and logically be considered for purchase after a specific time period, Oxygen is a legend drug and should not be included within the list of equipment that may be purchased. If CMS determines Oxygen will indeed be purchased, on behalf of the PA Association of Medical Suppliers, we urge that our operational concerns be considered the basis for revisions of the original proposal.

The Deficit Reduction Act of 2005 has sweeping impact on the industry and more importantly, on the patients we serve. The action plan must be logical and implemented in a manner that is successful.

We sincerely appreciate the opportunity to submit our comments and look forward to your consideration of our comments, concerns and recommendations and would appreciate the opportunity to further discuss the issues presented.

Respectfully submitted,

David Fiorini
Executive Director, PAMS

Georgetta Blackburn
President, PAMS

The Pennsylvania Association of Medical Suppliers
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ATTACHMENT 2 TO #73

PAMS

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

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Caption: Provision of Proposed Regulation

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These services were documented in the Morrison study and are a critical component of safely furnishing oxygen in the home. When the monthly rental payments end, there will be no payment for these support services.

Recommendations:

- We urge CMS to not take the position that these are no covered services therefore placing the burden of paying for them on beneficiaries. Some, if not most, beneficiaries will elect not to pay for the services, placing these beneficiaries at risk and creating a two-tiered system of care. Moreover, to the extent that the new supplier standards recognize that these services should be the standard of care for Medicare beneficiaries, Medicare payment policies should recognize them as well

- If CMS does not cover routine maintenance and service, back-up units, on call, or therapist clinical evaluations, there needs to be clear guidance that defines the contracted relationships that may be developed between providers and patients

SUMMARY

The PA Association of Medical Suppliers (PAMS) has very serious concerns regarding the proposed purchase of Oxygen by Medicare beneficiaries. Our respiratory patients represent a high percentage of our most compromised and chronically ill. To impose the responsibility of maintenance and care of their equipment upon them does not equate with improved care.

While Beds, Wheelchairs and other products may be considered a commodity and logically be considered for purchase after a specific time period, Oxygen is a legend drug and should not be included within the list of equipment that may be purchased. If CMS determines Oxygen will indeed be purchased, on behalf of the PA Association of Medical Suppliers, we urge that our operational concerns be considered the basis for revisions of the original proposal.

The Deficit Reduction Act of 2005 has sweeping impact on the industry and more importantly, on the patients we serve. The action plan must be logical and implemented in a manner that is successful.

We sincerely appreciate the opportunity to submit our comments and look forward to your consideration of our comments, concerns and recommendations and would appreciate the opportunity to further discuss the issues presented.

Respectfully submitted,

David Fiorini
Executive Director, PAMS

Georgetta Blackburn
President, PAMS

The Pennsylvania Association of Medical Suppliers
1000 Bent Creek Boulevard, Ste. 10 · Mechanicsburg, PA 17050
(717) 795-9684 · Fax (717) 795-9685
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Submitter : Mr. John Sganga **Date: 09/25/2006**

Organization : Innovatix, LLC

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1304-P-74-Attach-1.PDF

#74

Innovatix

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September 25, 2006

Administrator Mark McClellan
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1304-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Proposed Rule on 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

Dear Administrator McClellan:

Innovatix, LLC is pleased to offer comments on the proposed rule on Home Health Prospective Payment System Rate Updates and the Deficit Reduction Act of 2005 Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment. Innovatix provides high quality group purchasing and consultative services to a national membership base of alternate care and non acute care institutional providers. Innovatix members provide services to patients in: Home Infusion, Extended Care, Long Term Care (dispensing pharmacy), Retail and Mail Order Pharmacy, and select medical oncologist segments.

Innovatix and its members are directly impacted by this proposed regulation. We have a number of concerns and comments regarding the proposed rule, and specifically on the oxygen and capped rental portion of the proposal. Our specific comments and concerns are provided below.

I. General Comments

The proposed rule clarifies Medicare payment for oxygen equipment and capped rental Durable Medical Equipment (DME) regarding number of rental months, maintenance and servicing, oxygen contents, replacements and oxygen supplies and accessories. In addition, CMS is proposing additional supplier requirements to safeguard beneficiaries, and modifying payment for oxygen classes to reflect new technology and compensation for delivery and refilling of portable contents. CMS proposes to implement the new home oxygen payment methodology January 2007.

Innovatix is concerned about the implementation schedule of this proposed regulation. There has been a recent influx of regulations impacting the DMEPOS industry, particularly oxygen, and we feel that suppliers will need time to understand and adapt to these changes, including the new quality standards, mandatory accreditation, and competitive bidding. Adding a new payment system and stricter requirements to the mix could make many suppliers leave the market, thus reducing patient access to this life-saving therapy.

Innovatix recommends that the implementation of the proposed rule be delayed until CMS assesses the impact of the competitive bidding and accreditation processes on suppliers and beneficiaries. In addition, we also strongly urge CMS to "grandfather" beneficiaries already on home oxygen under Medicare on December 31, 2006 from the provisions of this proposed rule. We discuss these issues and our concerns about the operational impact of the proposed rule in greater detail below.

In addition, we would recommend CMS to consult with the oxygen industry and professional associations and work together to address patient safety concerns, prior to releasing the final rule. The impact of this proposal on beneficiaries should be fully assessed. The overhaul of the payment system for home oxygen therapy may have a negative impact on providers' ability to assure access to the level of care and services beneficiaries expect and deserve.

Home oxygen therapy is the delivery of a life-sustaining prescription drug to people with chronic, often debilitating medical conditions. Under this proposed rule, beneficiaries will become responsible for the management of their oxygen equipment and therapy. This places an unrealistic burden on the patient that most beneficiaries do not want or are not ready to manage. These frail, elderly patients should not have to be concerned with maintenance and servicing of their oxygen equipment to ensure the appropriate functioning of an increasingly sophisticated technology. Oxygen suppliers already have the technical knowledge and capability to safely and effectively service and maintain this equipment. We believe that transferring the burden of maintenance and repair of oxygen technologies to the patient presents a serious risk to patient safety and care.

II. Provisions of the Proposed Rule (specifically, the Oxygen Provisions)

Concern for Patients

The home oxygen patients that our members serve have multiple and changing therapy needs. Many patients become increasingly ill over time, and high-quality home oxygen therapy keeps many of these patients stable and living independently in the home setting. As such, we are concerned that some of the provisions included in the proposed rule will adversely impact beneficiaries' access to oxygen, jeopardize the health and safety of these patients, and create additional costs to the Medicare program through an increase in the number of hospitalizations and urgent care visits.

First, with respect to access, we fear that the new payment system coupled with the anticipated competitive acquisition for durable medical equipment will change the way oxygen services are delivered to beneficiaries. Providers will not be able to offer the same quality services that beneficiaries have come to expect and rely upon, because their cost exceeds Medicare reimbursement. Some providers will be forced to leave the market and the beneficiary's access will be impacted.

Second, many of the patients receiving home oxygen are elderly and ill. Their hand eye coordination is not what it used to be and therefore they will not be able to use, change or service the equipment as well and as safely as a trained technician. Not to mention that most will not understand the workings of a concentrator's regulator or filter to know whether it is producing the correct flow. Limiting the payment for maintenance and servicing to those situations when an "authorized technician's" services are required assumes that frail seniors on home oxygen and/or

their caregivers will be able to handle routine maintenance. We believe that, for safety reasons, the burden for these operations should not be on the beneficiary.

Furthermore, from time to time, the FDA has issued recalls on certain items of oxygen equipment, or has issued advisories. Beneficiaries are not aware of these recalls or advisories as they are not tracking them (nor should they be required to). Providers however are tracking FDA recalls and advisories to ensure beneficiary safety. When the FDA issues a recall, providers will and do make necessary adjustments as to not interrupt the patient's service.

Thus, we recommend **that routine maintenance and servicing should be reimbursed by Medicare – including testing, cleaning, regulating, changing filters, and general inspection of beneficiary-owned DME – and not just when an authorized technician's services are required.**

Grandfathering of beneficiaries

CMS states that the payment and other policies announced in the NPRM will not be effective prior to January 1, 2007. With respect to patients receiving oxygen therapy under Medicare in 2006, this statement is ambiguous because the period of "continuous use" mandated under the DRA is in effect for any patient receiving home oxygen under Medicare on or after December 31, 2005. **The new payment policies and additional supplier requirements announced in the NPRM should not apply to any beneficiary currently under a period of "continuous use" to which the DRA transfer of ownership provisions apply. Consequently, the policies announced in the NPRM should not apply to any beneficiary receiving Medicare covered oxygen on December 31, 2006, although the DRA transfer of ownership will apply to these beneficiaries.**

Operational Issues for Providers of Oxygen

Ownership Issues for Oxygen and DME

The NPRM prohibits changing the equipment that is provided to a beneficiary on the first day of continuous use unless an exception applies. There are a number of significant operational issues that arise under this proposal:

a) Providers would have to track equipment by serial number in order to make sure that the beneficiary receives title to the equipment that was delivered on the first day of continuous use. This will be very difficult for providers to track internally if the concentrator or another type of equipment is brought into the facility for repairs. Importantly, larger providers may have regional or even national distribution centers which stock and service equipment. Other providers may use contractors to service equipment.
b) It is not clear how the "break in service" rules will apply to oxygen equipment. Will CMS simply apply the existing break in service rules to oxygen? There are a number of situations in which a beneficiary may have a short term need for oxygen that should not be included in the period of continuous use.
c) We have questions regarding which provider's equipment transfers to the beneficiary if the beneficiary has two residences with a local provider in each area. Beneficiaries who are "snow birds," or who may move or relocate during the period of continuous need will face hurdles in maintaining access to equipment. Because the propose rule states that a change in supplier would not begin a new period of continuous use, Medicare beneficiaries who move

after the conclusion of the 36 month rental period for oxygen, will have a very difficult time transferring to a new provider.

d) Title to medical equipment cannot transfer unless the beneficiary has paid all outstanding copays and deductibles.

e) The requirement that providers notify beneficiaries of their "intent" with respect to accepting assignment is unworkable and conflicts with longstanding Medicare program rules that allow suppliers to accept assignment on a claim by claim basis.

Reimbursement

The proposed rule revamps the oxygen classification system by splitting stationary and portable oxygen contents into two separate payment classes and calls for a third payment class for new technologies, such as portable concentrators and home transfilling systems. However, a majority of providers provide traditional oxygen technology and thus this new system will mainly result in reducing reimbursement to most providers. We are concerned that a further reduction in payment will cause access problems for beneficiaries.

In addition, we believe that the proposed payment structure should move beyond payment for the equipment itself and incorporate all necessary services that suppliers of oxygen and oxygen equipment provide.

For example, oxygen providers now work to:

- Make sure that beneficiaries manage their oxygen therapy in natural disasters or emergency, including 24-hour emergency support of all home oxygen patients.
- Check the purity and the 'flow' (dose) of the oxygen delivered and administered to the patient; verification is conducted periodically by specially trained technicians or therapists using calibrated oxygen analyzing technologies. This verification is key to ensuring the oxygen therapy the beneficiary receives is safe and effective.
- Check the alarm functions of the oxygen concentrator to ensure the beneficiary or caregiver has sufficient time to switch to back-up systems.
- Periodic verification and replacement of filter systems. Currently, the clean-up or replacement of filters is performed by respiratory therapists or trained technicians in accordance with the manufacturer's specifications, often a requirement to retain the equipment warranty. While beneficiaries and caregivers could be trained to conduct some of these checks and maintenance operations, many do not feel they could safely rely on their own ability to do so.

Without proper payment for these services, providers may not be able to continue to provide these much needed – sometimes life-saving services. **Our recommendation is to develop a payment structure that accurately and adequately captures all necessary services supplied by oxygen provider.**

Supplier Requirements

The proposed rule includes additional supplier requirements to safeguard beneficiaries. While Innovatix and its members do applaud CMS for trying to safeguard beneficiaries, we are concerned that these additional requirements are imposed at the same time with reduced reimbursement, which will threaten the viability of many oxygen providers, thus affecting patient access.

The additional supplier requirements include requiring a supplier who furnishes rented oxygen equipment or a capped rental item in the first month to continue furnishing the same item

throughout the entire rental period, not allowing suppliers to switch out equipment except under specified circumstances, and requiring a supplier to disclose its intentions regarding assignment for the entire rental period.

We recommend that the implementation of these additional supplier requirements should [redacted] the potential impact on beneficiary is assessed, in consultation with the industry.

III. Conclusion

Home oxygen therapy is the delivery of a life-sustaining prescription therapy to people with chronic, often debilitating medical conditions. We understand the need to control cost and safeguard beneficiaries, and applaud CMS for trying to do so. However, we are very concerned that transferring the burden of managing maintenance and repair of sophisticated oxygen technologies to the patient presents a serious risk to patient safety and care. Moreover, the reduced reimbursement coupled with additional requirements and the multitude of regulatory changes affecting the oxygen industry could lead to many oxygen providers leaving the market or drastically reducing the range of services offered, thus impacting patient access to this life-saving therapy.

Innovatix appreciates the opportunity to provide our comments on this proposed regulation. We look forward to working with CMS on this issue and would be happy to provide additional information.

Sincerely,

John P. Sganga
President and Chief Executive Officer

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

Organization : Michael DeLozier

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I have several relatives and friends that rely on oxygen therapy, and I think that these new policies, if enacted, will greatly reduce their ability to receive quality care related to that therapy. I hope that these policies do not come into effect, as I believe these changes are dangerous to those who rely on oxygen therapy.

Submitter : Mr. Tim Zipp

Organization : The SCOOTER Store

Category : Health Care Provider/Association

Date: 09/25/2006

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1304-P-76-Attach-1.DOC

CMS-1304-P-76-Attach-2.DOC

ATTACHMENT 1 TO #76

September 25, 2006

The Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1304-P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare; 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 Equipment; Proposed Rule (CMS-1304-P)

To Whom It May Concern:

On behalf of The SCOOTER Store, a nationwide supplier of motorized wheelchairs and power operated vehicles (POVs), we submit these comments in response to the August 3, 2006 Federal Register notice entitled "Medicare; 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 Equipment; Proposed Rule."[1]

The Proposal That the Supplier Replace Beneficiary-Owned Capped Rental Items at No Cost to the Beneficiary or to the Medicare Program if Accumulated Costs to Repair Exceed 60 Percent

Per 42 C.F.R. § 414.210(e)(3) of the proposed rule, a supplier must furnish equipment to a beneficiary at no cost if the total repair costs "exceed 60 percent of the cost to replace the equipment and the equipment has been in use for less than its reasonable useful lifetime."

We agree that the proposed 60 percent rule does not, and should not, apply to equipment for which the beneficiary has opted for a lump-sum purchase. We also urge CMS to remove this proposal for equipment furnished in accordance with 414.229 (f) (2) in which title has been transferred to the beneficiary at the end of the 13 month rental term. The cost to replace Power Mobility Devices is subject to change with new coding and pricing set to take effect in November 2006 and CMS is piloting Competitive Bidding in 70 MSA's in the next several years for Durable Medical Equipment. With all of this change, suppliers who are asked to serve Medicare beneficiaries will not know the future acquisition costs of the products which they sell today. Secondly, the proposal implies a five year warranty on

[1] 71 Fed. Reg. 44081-44180.

all rented equipment. Most manufacturers currently provide warranties for one year. To achieve a 5 year warranty, a manufacturer would be required to engineer and build more expensive products. This will only drive the costs of providing these devices higher at a time when Medicare and this Act are seeking to reduce costs. Further, many accessories have a shorter useful life than 5 years. Batteries are one example of an accessory which must be replaced throughout the useful life of a power mobility device and should not be included in the 60% calculation.

In the preamble to the proposed rule, CMS informs the public that it is "*proposing this provision to safeguard the beneficiary from receiving, and the Medicare program from paying for, substandard equipment, and to avoid creating an incentive for suppliers to increase the number of claims submitted for repairs in an effort to recover revenue lost as a result of DRA section 5101. We believe that this requirement is not unreasonable since suppliers should be furnishing items in good working order and are otherwise bound by regulations at Sec. 424.57(c)(15) to accept returns from beneficiaries of substandard items.*" 71 Fed. Reg. 44100. The vast majority of suppliers in this sector are honest and committed to providing top quality equipment and services to Medicare beneficiaries. CMS supplier standards and other laws/regulations establish sufficient protection for beneficiaries and the Medicare program. The answer is not to levy mass punishment on the entire industry but rather to punish those suppliers who consistently provide substandard equipment.

We most strongly urge removing the "60 percent" proposal from the final rule.

Very truly yours,

Tim Zipp
SVP, Corporate Compliance
The SCOOTER Store

ATTACHMENT 2 TO #76

September 25, 2006

The Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1304-P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare; 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 Equipment; Proposed Rule (CMS-1304-P)

To Whom It May Concern:

On behalf of The SCOOTER Store, a nationwide supplier of motorized wheelchairs and power operated vehicles (POVs), we submit these comments in response to the August 3, 2006 Federal Register notice entitled "Medicare; 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 Equipment; Proposed Rule."[1]

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[1] 71 Fed. Reg. 44081-44180.

all rented equipment. Most manufacturers currently provide warranties for one year. To achieve a 5 year warranty, a manufacturer would be required to engineer and build more expensive products. This will only drive the costs of providing these devices higher at a time when Medicare and this Act are seeking to reduce costs. Further, many accessories have a shorter useful life than 5 years. Batteries are one example of an accessory which must be replaced throughout the useful life of a power mobility device and should not be included in the 60% calculation.

In the preamble to the proposed rule, CMS informs the public that it is "*proposing this provision to safeguard the beneficiary from receiving, and the Medicare program from paying for, substandard equipment, and to avoid creating an incentive for suppliers to increase the number of claims submitted for repairs in an effort to recover revenue lost as a result of DRA section 5101. We believe that this requirement is not unreasonable since suppliers should be furnishing items in good working order and are otherwise bound by regulations at Sec. 424.57(c)(15) to accept returns from beneficiaries of substandard items.*" 71 Fed. Reg. 44100. The vast majority of suppliers in this sector are honest and committed to providing top quality equipment and services to Medicare beneficiaries. CMS supplier standards and other laws/regulations establish sufficient protection for beneficiaries and the Medicare program. The answer is not to levy mass punishment on the entire industry but rather to punish those suppliers who consistently provide substandard equipment.

We most strongly urge removing the "60 percent" proposal from the final rule.

Very truly yours,

Tim Zipp
SVP, Corporate Compliance
The SCOOTER Store

Submitter : Mrs. Laura Steelquist **Date:** 09/25/2006

Organization : Hawaiian Islands Medical Corp

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

As a small durable medical equipment supplier, accredited, who strives to provide excellent service to our beneficiaries, I have several strong concerns with the proposed rule. First, the requirement that the supplier replace equipment for a period of five years for which the accumulated repair costs exceed 60% of the replacement cost. The tracking on this seems onerous and the fact that we're assuming a five-year liability for a one-year payment seems unfair. Second, the requirement that suppliers keep the same piece of equipment with the patient for the entire rental period. If a patient has a problem with a piece of equipment currently, we will switch it out with a similar piece of equipment and bring the first one back for repairs, thereby reducing the inconvenience to our customer. Your rule will require us to send a technician to repair the equipment, which will result in delays for the patient and additional labor costs for our small business which is already being squeezed unmercifully. The third area of concern is the proposal that one supplier must furnish equipment for the entire thirteen month period. We live in Hawaii. We have many beneficiaries who come here and leave again. Are they taking our hospital bed with them to the mainland? What if it needs repairs? Your statement "in cases where a beneficiary moves outside a supplier's service area, another supplier may be arranged to provide the equipment either temporarily or permanently" doesn't say how this will happen. Is CMS arranging this?

I think you're doing your beneficiaries a disservice by including hospital beds in this ruling. Right now, when a beneficiary passes away, the family calls for us to pick up the hospital bed (which may be in the middle of the living room) and we'll be there the same day to remove it (at no charge, because it's rental equipment.) Under your new scheme, they will have to call a removal company - and will have to pay for the service. Did you factor that into the "savings" calculations? It seems that you're trying to legislate against unscrupulous suppliers by adding all these rules. Why don't you try to eliminate the unscrupulous suppliers on the front end so the rest of us who are working very hard to provide a necessary service to our beneficiaries can get on with it?

And, in closing, I highly recommend that before you add all the repair claims from every piece of equipment becoming "patient-owned" you figure out how to pay the ones we're submitting now. Your abysmal record on repair claims payment have forced us to stop accepting assignment for these claims - and now you're going to have so many, many more of them. Sad for the beneficiaries you say you want to help.

Thank you for allowing these comments. Aloha, Laura

Submitter : **Mr. Randy Wolfe** **Date: 09/25/2006**

Organization : **Wolfe Medical, Inc.**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1304-P-78-Attach-1.DOC

#78

September 25, 2006

Comments on NPRM for DRA Oxygen Provisions

Submitted by: Ashley Wolfe; Knoxville, TN. *Both my grandmother, grandfather, and my aunt benefit from oxygen therapy, and I think it is crucial for Medicare and CMS to review some of the policies outlined in their legislation of the DRA in order for my family to continue to receive quality care.*

General Comments:

1. **Under the proposed S. 1932 Legislation, Medicare would now only allow patients to rent oxygen concentrators and related oxygen equipment provided with it for up to 36 months.** Earlier versions of the bill limited the rental to as little as 18 months. Placing any monthly cap limit on this benefit is a drastic and dangerous change to the oxygen benefit currently in place that now puts no limit on the coverage of oxygen rented to the patient. Current Medicare benefit guidelines as well as those for all major national insurance companies, state Medicaid programs, workman's comp benefit programs, and all home care industry accreditation organizations have always classified oxygen equipment as *"high maintenance equipment needing frequent maintenance service which is not recommended or advisable for patients to own"*.

2. **Under this new pending rule, Medicare will stop paying for the rental, and the provider will no longer be involved the patient's care or management of his/her oxygen concentrator after 36 months.** According to congressional reports, the average patient rents such equipment for 30 months. By capping the units at 36 months, congress will be cutting off rental benefits to as many as 15 to 20 percent of all Medicare patients on oxygen. Patients will no longer receive free 24-hour service on the equipment, and they will no longer receive any free service. They will have to be financially responsible for each service provided. This includes preventative maintenance and routine inspections of the equipment. Repair and necessary service to the machine will now be billable to the patient and assignment will only be accepted by the oxygen provider on a case-by-case basis. There is also concern that oxygen providers may not accept assignment on the historically low Medicare fees for repair of medical equipment for patients they no longer provide rental services for since some of Medicare's fees do not even cover the provider's wholesale cost.

3. **Some industry experts are concerned for the patients who live far away from the oxygen provider's offices. These patients in particular may find it very difficult to find a provider who will service their owned, used equipment once the equipment has been transferred to the patient**. Medicare does not pay for delivery and pick-up charges for such services. This will make it even more difficult for providers to accept assignment on any repairs that would be done in the home. Under the proposed plan once the rental caps, title and all responsibility for the used equipment will simply be transferred to the patient. At that time, the oxygen provider will no longer be responsible for any of its upkeep. If there were any warranty remaining, it would be managed and controlled through the manufacturer of the product. Any warranty claims made would now bypass the provider and ultimately be processed by the manufacturer. As with all factory warranties on sold equipment, this will now have to be processed through the procedures required by the manufacturer. This will likely cause delays in processing repair work for patients or force patients to accept financial responsibility for repairs until warranty authorizations are approved by the factory.

4. **When patient owned non-working equipment is being repaired or reviewed by the factory for a warranty determination, the patient will be financially responsible for the rental of a temporary replacement unit. There is no factory warranty that covers this.** Most warranties on oxygen concentrators are only for 3 years from the date the supplier purchases the machine. The net effect will be that after 36 months of rental, the patient will be 100% responsible for

managing and caring for the non-warranted item. A three year old oxygen concentrator can have as many as 26,000 hours of use on it at the time it is transferred to the patient. Based on the average life of an oxygen concentrator, this is equivalent to owning a typical American automobile out of warranty with over 100,000 miles on the odometer.

5. **Once the patient owns the equipment, the supplier will have no obligation to provide free 24-hour service on the equipment**. This is a service that is provided at no additional charge for rental equipment owned by the supplier. Free emergency backup tanks for power outages and equipment failure will be picked up or billed to the patient privately as this is also a service pertaining to the rental equipment owned by the oxygen provider. Duplicate equipment, such as the backup tank, has never been a covered service billable to Medicare. Patients wanting a backup tank as well as patients wanting to be covered by a 24-hour service contract will have to pay privately for them. Patients who are unable or unwilling to make financial arrangements for 24-hours service capability will be advised to keep several family members aware of their dependence on oxygen and their need for assistance should there be inclement weather or other events that may cause an interruption in electrical power to their home.

6. **Patients who are unable to move freely throughout their home without assistance, who are vision impaired, who have periods of confusion related to their condition, or who live alone will be most affected by this new change.** These patients will be in the most risk of being unable to care for their equipment or to know when it needs service or how to manage the new financial arrangements for the service each time it is needed. Such patients are advised to find other family resources or community services to assist them in the managing and monitoring of their equipment needs.

7. **Patient-owned equipment will not be managed for billing of services the way rental equipment is managed. Each time an oxygen provider is called out to check on the equipment, regardless of there being anything wrong with it or not, a separate charge will be billed to the patient.** Patients or family members who need re-education and retraining on the use of the equipment will also no longer receive these services free. Service calls after-hours, if available, will be billed at a higher rate than service calls during working hours. Service calls will no longer be free of charge. Equipment that cannot be repaired at the patient's home will have to be retuned to the provider's office for repairs or sent to the factory. All repair parts and labor will be billed separately. Additional charges will also be billed for substitute equipment left with the patient while repairs are done elsewhere. Equipment that cannot be repaired will result in the patient having to be responsible for the purchase of replacement equipment should Medicare not cover the cost of its replacement. Medicare does not provide for the replacement of medical equipment (i.e. wheelchairs, walkers, and hospital beds) that has been owned by the patient unless it has been damaged beyond repair by fire or accident or unless it has been purchased for over five years and then becomes inoperable and unrepairable. As with all other Medicare-covered equipment purchased by Medicare, should the patient want a different brand, model, or type of concentrator once title is transferred for the one they have been renting, they will not be eligible to exchange it for one until their existing unit is no longer repairable. Medicare currently does not recognize the difference in the different types of oxygen concentrators currently available to patients. As new technology arrives in the marketplace, patients will not be able to swap their old units in and receive any reimbursement from Medicare for the upgraded newer unit.

8. **Under the new rules, once the used concentrator is owned by the patient, all supply tubing, humidifiers, nasal canulas, water traps, and any other disposable oxygen supply circuits and attachments will be separately billed to the patient.** Again, as with repair charges, the acceptance of assignment by suppliers for each item sold will be on a case-by-case basis by each oxygen provider. A provider's decision to accept assignment will be based on the reasonableness of the fee allowed by Medicare for each item. Currently the fees for these items are extremely low and in some cases do not cover the providers' cost.

9. **Under the new rules, patients who move or travel will have to either take their own equipment with them or pay privately for another company to rent them replacement equipment where they will be staying.** Under previous rules for oxygen coverage, patients wishing to travel to areas outside their provider's coverage area could do so at no charge to the patient. Their home oxygen provider would continue to bill for monthly rental and make separate arrangements for another company to provide the same equipment and service to the patient in the area the patient is staying (even if out of state). The home company, as required by Medicare, would pay the out of state company for its use on behalf of the patient when the patient stay was to be temporary. This service has been widely used for patients who stay with family one part of the year and with others during other parts of the year. This also has been used for patients visiting other parts of the country for extensive outpatient medical treatments requiring them to stay for weeks or months at a time. Under the old plan, if the patient needed to travel for a longer period of time or move to another area, the patient would simply change suppliers and receive their oxygen equipment and necessary services from a different rental company in the new location. This will no longer be available for patients who own their own equipment. Medicare will no longer pay for the rental of the equipment once the patient owns his or her own equipment.

10. **Requirements necessary for Federal Drug Administration (FDA) tracking would now have to be maintained by the patient or their caregiver should a recall occur for the particular medical device (concentrator) owned by the patient**. Providers are required to notify individuals who have purchased medical equipment subject to a recall under the FDA Medical Device Act. Such contact must be made by certified mail and by phone. Unless the provider is given all future address changes for patients, the patient would not receive such a recall notice. Special attention would need to be given to patients and their families who would now be personally responsible for receiving and acknowledging such recall notices. If the patient cannot keep up with such records, he/she would have to appoint a family member or other dependable party to be responsible for such communications.

Comments on Costs Pertaining to Home Oxygen Therapy

1. **Equipment cost only accounts for 28% of the total Home Oxygen Therapy costs.** The Morrison study finds that other services account for the significant majority of costs associated with Home Oxygen Therapy. These include: preparing and delivering the equipment; delivering supplies and maintenance of oxygen equipment; assessing, training and educating patients; obtaining required medical documentation and providing customer service for beneficiaries; related services and compliance with Federal & State Regulations (included FDA and DOT requirements); other related services; and operating and overhead costs.

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3. **70% of problems that technicians are called to the home to check on are not services that Medicare would cover.** This leaves the beneficiary paying out-of-pocket for services that were previously covered under the oxygen rental program once the beneficiary owns his/her

equipment. As previously mentioned above, these services include: Free 24-hour service on equipment; Free back-up tank, stand, regulator, or supply tubing; Free replacement equipment during extensive repairs of rented equipment; Local warranty services; Free access to Respiratory Therapists; the Ability for the provider to arrange for free 24-hour service when the beneficiary travels to another city; Free deliveries and pick-ups for services or parts.

4. **Suppliers cannot be held responsible for replacing patient owned equipment within 5 years of the date the item is sold to the patient if the repair cost exceeds 60% of the cost of the item.** These items are not delivered new. They are rented as used items. However even it the item was delivered as new, it is totally unreasonable and unprecedented for Medicare to expect any supplier to replace the unless the unit is in fact covered by a manufacturers warranty. Medicare has used this 5-year period in the past to determine if the benefit plan will actually replace an item of equipment or continue to repair it. For DME items that no longer work or are damaged beyond repair, Medicare does not require the supplier to replace the unit if the repair cost exceeds 60% of the replacement cost. Even Medicare will not do that. Medicare continues to pay all the way up to 100% of the items replacement cost to avoid replacing it. There also is no 60% factor involved in the decision to repair the unit. It is apparent that this an attempt to avoid what Medicare already knows will be an extensive cost to the program. These items require frequent service and maintenance. This service and maintenance is "the responsibility of the beneficiary". Providers will NOT be paid by Medicare to maintain the equipment. Providers will be paid ONLY to repair it after the fact. Since providers are not receiving any money to keep the equipment up and since it is the patient who is 100% responsible for taking care of the equipment and performing the frequent and routine maintenance and service on the machine (everything other than major repairs), it should therefore be the responsibility of the beneficiary to replace the unit if the cost to repair it exceeds 60% if in fact Medicare wants to limit the repair cost to that. Unless suppliers are paid to maintain the item over the 5-year period they cannot be expected to be at risk for the equipment's failure. This is not fair or reasonable.

Comments on Beneficiaries that Receive Home Oxygen Therapy

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> "We would, however, also propose to apply our existing policy of not covering certain routine 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 policy for beneficiary-owned capped rental equipment."

   a) If the beneficiary neglects the equipment, the equipment could malfunction. Is this the responsibility of the provider to repair the equipment when the root of the problem was improper care by the beneficiary?
   b) What if this repair adds to the overall repair cost of greater than 60% of the cost of replacement equipment? What safeguards are in place for the supplier to ensure that the beneficiary will take care of the equipment to reduce repairs and replacements?
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3. **How is the supplier supposed to have accurate liter-flow information about the beneficiary from the physician if the patient is no longer in their system under the oxygen rental program?** If the supplier is called out for an "after hours" house-call, unless proper documentation is available to the supplier technicians, no action may be taken. This will result in an ambulance coming to the beneficiary's home and taking him/her to the hospital. This will undoubtedly cost Medicare more.

Comments from the Homecare Industry Regarding Consequences of Implementation

1. **Beneficiary access to ambulatory oxygen will be limited.** Providers cannot utilize liquid oxygen as a modality for their beneficiaries, further limiting access to beneficiaries due to a lack of reimbursement during the initial 36 months and the succeeding periods after ownership has been transferred to the beneficiary.

2. **Beneficiary access to innovation and new technology will be limited.** CMS states,

> "Payments for oxygen contents for beneficiary-owned portable equipment would exceed what is currently paid for these items to ensure access to portable oxygen regardless of the type of equipment used. These increased payments would be offset by a reduction in the stationary payment."

The difference in reimbursement between the traditional equipment would be $32/month. Most of the types of products that fall within this category is anywhere from $1,200 to $2,500 difference to the purchase price of the traditional oxygen equipment. The $32/month additional is $1,152 in additional reimbursement payments. This hardly covers the cost to acquire the newer technology. Providers will be reluctant in providing this equipment at a loss; therefore the proposed rule limits access to newer technology by not providing adequate reimbursement to cover the cost of the equipment.

3. **Beneficiary's ability to relocate on a permanent or temporary basis prior to transfer of title of ownership is limited.** The supplier in the new area will not have the full 36 months to collect reimbursement. ((In addition to the question of which provider gives the equipment to the beneficiary, does the new provider have to transfer ownership without having collected the full amount to justify the cost of the concentrator and the services?)) This limits the

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.

Comments Regarding Oxygen Concentrator Rentals

Medicare currently pays a flat fee for the rental of an oxygen concentrator. This single flat fee is described as a "bundled" rental fee under Medicare guidelines that includes the patient's concentrator machine as well the provision of all the related supplies and services associated with the machine. This fee is expected to cover all costs the oxygen provider incurs that are associated with the provision of the rental unit. Among those includes the cost for all necessary internal and external replacement filters, all preventive maintenance service calls, and all repairs needed on the machine while rented. Should the machine become inoperable and unrepairable, this rental fee is to cover the oxygen provider's cost for replacing the machine with another one. A recent oxygen supplier survey in Tennessee taken by the Tennessee Association for Home Care [TAHC] revealed that of the suppliers surveyed between 18% and 40% of the oxygen concentrators on rent are exchanged and replaced each year with different units. These exchanges are made by the providers due to equipment repair, service, and maintenance needs that cannot be reasonably performed in the home. As a rental item, these exchanges are done in the patient's home with no significant inconvenience to the patient. In general, the rental fee covers everything associated with the providing an uninterrupted supply of oxygen to the patient as well all costs for providing the patient with his/her monthly respiratory supplies to be used with the machine. The supplies covered includes oxygen supply tubing, humidifiers, nasal canulas or face masks, water traps, and any other disposable oxygen supply circuits and attachments ordered by the patient's physician that are needed for the delivery of oxygen to the patient. As with all other rented equipment, this bundled fee covers the initial and ongoing training of the patient and/or the family for proper use and care of the equipment. Lastly, this fee is also to cover the oxygen provider's cost for the required ongoing monitoring of the patient's use of the equipment to insure that the equipment is being properly utilized according to the physician's written orders.

The oxygen concentrator is a highly sophisticated, complicated, and sensitive item of equipment. It operates by compressing room air into and through a group of pneumatically sealed containers filled with sieve material that filters the nitrogen out of the room air, leaving a highly enriched oxygen concentration of air that is approximately 93% to 95% pure oxygen. This process is achieved by directing the air through a series of pneumatic pressurized chambers under timed cycles controlled by pressure sensors and gages. At no time can there be any pressure leaks or significant variances in the synchronization of the air exchanges in the system. When variances occur over time, the oxygen concentration will begin to drop. If they persist, the concentration levels can drop as low as 30% to 40% and even as low as normal room air. When the levels drop to substandard oxygen concentration levels over a period of time, the machine can also start to experience other problems including the contamination of the machine's sieve beds. Sieve beds are small granular beads inside the sealed metal chambers or canisters that filter the nitrogen from the air, leaving only highly enriched oxygenated air delivered to the patient. Leaks to the sieve bed chambers can result in an extensive repair cost to the machine but more importantly can cause damage to the patient, as the patient also will not receive adequate oxygen intake once the sieve beds are compromised. If the machine's pre-filters and internal filters are not cleaned and changed according to factory guidelines, the machine will also overheat and begin to destroy the soft pliable hoses within the unit. Once these hoses lose their ability to seal around internal gaskets, the machine will also begin to lose concentration and complete the downward cycle of equipment failure.

Although there are mechanisms and built-in alarms in some models of the machines that can indicate a corruption in the airflow seals and detect significant drops in pressure, they are by no means fool proof. Many of these self-detecting sensors only alarm when the concentration has fallen well below the concentration necessary to provide the patient with his/her prescribed needs. Some machines can appear to be working properly and not show any outward sign of problems until an oxygen analyzer is put on the machine's output to test its concentration levels. The oxygen analyzer is a small calibration device that measures the oxygen concentration output of the machine. This again is one of the routine services oxygen providers perform on all rented concentrators before and during the rental episodes. Preventative

maintenance is a service provided at no extra charge by providers and is performed on the rental machines at the patient's home during the rental episode. It is done to prevent future equipment failure and minimize future repair needs. It is also done to further insure that the equipment is producing the prescribed level of oxygen that the physician has ordered. Although preventative maintenance is performed as part of the rental program, it is not in itself a separate Medicare covered charge for equipment owned by patients. Medicare, as well as most health care insurance programs, does not routinely provide benefits for preventative health care services or for preventative equipment that can potentially prevent an illnesses or injury. Examples of items not covered as for preventative value are bathtub benches or grab bars around the bathroom. In keeping with this philosophy, Medicare also does not provide preventative inspection and equipment analysis to patient-owned medical equipment regardless of how beneficial such inspections and preventative care may end up being. This would be a dangerous problem for patients whose oxygen equipment has not shown signs of equipment failure yet is not producing adequate levels of oxygen.

Oxygen concentrators run on electricity. They attach to any well-grounded, home utility electrical circuit. During any time of equipment malfunction or equipment failure, continuous use can likely further damage the machine. The machine should be turned off any time the machine alarm sounds or when it appears to be running louder than normal or feeling hot to touch. Under the rental program, patients and families are advised to call their oxygen provider when the machine does not run properly. Although many of the problems with oxygen concentrators are due to improper attachment of tubing or humidifiers to the machine itself, most patients are unable to determine what is wrong without assistance of a medical equipment technician. All rentals of oxygen equipment include, at no extra cost, 24-hour emergency service. Most service calls that require adjustments, repairs, or exchanges will be done within two to four hours of the call. During such equipment failure, patients are advised to change over to their free back-up oxygen gas filled tank until the technician arrives at their house. This back up gas tank is provided by the rental company as a free service as part of its 24 hour-service to patients renting oxygen equipment so that the patient will not have to call 911 for assistance between the time that the equipment first fails and the technician arrives at the patients home.

Oxygen concentrator machines can be damaged over a period of time when placed too close to a wall or piece of furniture which occludes the air intake opening. They can also be damaged by the excessive use of baby powder or other dry particle agents used in a patient room for incontinence. Use of such airborne powders can cause clogging of the pre-filters if not replaced or cleaned frequently in such environments. Restriction of air intake to a concentrator causes the machine to overwork to compensate for the reduced air flow into the machine and eventually will result in overheating and damage to the machine. Patients and caregivers should pay special attention to always ensure that the air intake remains open and unobstructed. When patients plan to travel and take their machine from one residence to another, it is recommended that they always contact their equipment supplier first to make sure it is advisable for the equipment to be moved by their caregivers or through special arrangements made by the oxygen provider. Special attention should always be given to care for the machine when in transit. Certain manufacturers' service and maintenance guidelines state that the machines should never be turned on their side in order to prevent breaking of seals in the airway connectors.

As with all medical devices covered under the Federal Drug Administration (FDA) Medical Device Tracking Act, the concentrator must be monitored and cared for properly in order to insure continual safe use. As a FDA device, the machine is eligible for recall and patient health and safety tracking log reporting of injury or death occurrences caused by its design or other mitigating causes of its manufacturer. As required by law, the supplier maintains compliance with the FDA tracking requirements while the supplier owns the unit. This is another service covered and provided for by law as long as the oxygen provider owns the equipment.

Submitter : Mrs. yvonne coffey **Date:** 09/25/2006

Organization : Lambert's Health Care

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

see attatchment

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

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

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

Submitter : Mrs. SHERI PARKINSON **Date:** 09/25/2006

Organization : SOUTHEASTERN MEDEQUIP, INC

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

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CMS PROPOSAL 1304-P WOULD PREVENT HME DEALERS FROM PROVIDING OXYGEN SERVICES TO BENEFICIARIES DUE TO PROPOSED FEE SCHEDULE CUT BACKS. IT WOULD ALSO HINDER A BENEFICIARY'S ABILITY TO OBTAIN OXYGEN FOR AMBULATION. THE LARGEST CONCERN IS THAT THE BENEFICIARY WOULD BE UNABLE TO CHANGE OXYGEN SUPPLIERS OR TO MOVE TO ANOTHER CITY PRIOR TO THE 36 MONTH CAPPED RENTAL PERIOD. THE TRANSFER OF OWNERSHIP WOULD ALSO LIMIT THE BENEFICARY'S ROUND THE CLOCK SERVICE AND MAINTENANCE OF THEIR OXYGEN EQUIPMENT. IF OWNERSHIP TRANSFERS TO THE BENEFICIARY AFTER 36 MONTHS AND NEW TECHNOLOGY IS AVAILABLE, THE BENEFICARY MAY NOT HAVE ACCESS TO THE NEW TECHNOLOGY. IN CONCLUSION, PROPOSED RULE 1304-P NOT BE A FAVORABLE ONE TO THE BENEFICIARY.

Submitter : Mrs. Mary Erslon **Date:** 09/25/2006

Organization : Nellcor Puritan Bennett, Inc.

Category : Device Industry

Issue Areas/Comments

Provisions of the Proposed Regulations

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Thank you for your consideration of our concerns and comments. Please do not hesitate to contact me if we can be of assistance. I can be reached at (314) 654-3309. We look forward to working with CMS to obtain the best clinical and economic solutions for oxygen delivery systems in 2007 and beyond.

Submitter : Ms. Cassandra Russell **Date:** 09/25/2006

Organization : Lambert's Health Care

Category : Home Health Facility

Issue Areas/Comments

GENERAL

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see attachment

CMS-1304-P-82-Attach-1.DOC

#82

September 25, 2006

Comments on NPRM for DRA Oxygen Provisions

Submitted by: Casey Russell- Knoxville, TN

General Comments:

1. **Under the proposed S. 1932 Legislation, Medicare would now only allow patients to rent oxygen concentrators and related oxygen equipment provided with it for up to 36 months.** Earlier versions of the bill limited the rental to as little as 18 months. Placing any monthly cap limit on this benefit is a drastic and dangerous change to the oxygen benefit currently in place that now puts no limit on the coverage of oxygen rented to the patient. Current Medicare benefit guidelines as well as those for all major national insurance companies, state Medicaid programs, workman's comp benefit programs, and all home care industry accreditation organizations have always classified oxygen equipment as *"high maintenance equipment needing frequent maintenance service which is not recommended or advisable for patients to own"*.

2. **Under this new pending rule, Medicare will stop paying for the rental, and the provider will no longer be involved the patient's care or management of his/her oxygen concentrator after 36 months.** According to congressional reports, the average patient rents such equipment for 30 months. By capping the units at 36 months, congress will be cutting off rental benefits to as many as 15 to 20 percent of all Medicare patients on oxygen. Patients will no longer receive free 24-hour service on the equipment, and they will no longer receive any free service. They will have to be financially responsible for each service provided. This includes preventative maintenance and routine inspections of the equipment. Repair and necessary service to the machine will now be billable to the patient and assignment will only be accepted by the oxygen provider on a case-by-case basis. There is also concern that oxygen providers may not accept assignment on the historically low Medicare fees for repair of medical equipment for patients they no longer provide rental services for since some of Medicare's fees do not even cover the provider's wholesale cost.

3. **Some industry experts are concerned for the patients who live far away from the oxygen provider's offices. These patients in particular may find it very difficult to find a provider who will service their owned, used equipment once the equipment has been transferred to the patient**. Medicare does not pay for delivery and pick-up charges for such services. This will make it even more difficult for providers to accept assignment on any repairs that would be done in the home. Under the proposed plan once the rental caps, title and all responsibility for the used equipment will simply be transferred to the patient. At that time, the oxygen provider will no longer be responsible for any of its upkeep. If there were any warranty remaining, it would be managed and controlled through the manufacturer of the product. Any warranty claims made would now bypass the provider and ultimately be processed by the manufacturer. As with all factory warranties on sold equipment, this will now have to be processed through the procedures required by the manufacturer. This will likely cause delays in processing repair work for patients or force patients to accept financial responsibility for repairs until warranty authorizations are approved by the factory.

4. **When patient owned non-working equipment is being repaired or reviewed by the factory for a warranty determination, the patient will be financially responsible for the rental of a temporary replacement unit. There is no factory warranty that covers this.** Most warranties on oxygen concentrators are only for 3 years from the date the supplier purchases the machine. The net effect will be that after 36 months of rental, the patient will be 100% responsible for managing and caring for the non-warranted item. A three year old oxygen concentrator can have as many as 26,000 hours of use on it at the time it is transferred to the patient. Based on the

average life of an oxygen concentrator, this is equivalent to owning a typical American automobile out of warranty with over 100,000 miles on the odometer.

5. **Once the patient owns the equipment, the supplier will have no obligation to provide free 24-hour service on the equipment**. This is a service that is provided at no additional charge for rental equipment owned by the supplier. Free emergency backup tanks for power outages and equipment failure will be picked up or billed to the patient privately as this is also a service pertaining to the rental equipment owned by the oxygen provider. Duplicate equipment, such as the backup tank, has never been a covered service billable to Medicare. Patients wanting a backup tank as well as patients wanting to be covered by a 24-hour service contract will have to pay privately for them. Patients who are unable or unwilling to make financial arrangements for 24-hours service capability will be advised to keep several family members aware of their dependence on oxygen and their need for assistance should there be inclement weather or other events that may cause an interruption in electrical power to their home.

6. **Patients who are unable to move freely throughout their home without assistance, who are vision impaired, who have periods of confusion related to their condition, or who live alone will be most affected by this new change.** These patients will be in the most risk of being unable to care for their equipment or to know when it needs service or how to manage the new financial arrangements for the service each time it is needed. Such patients are advised to find other family resources or community services to assist them in the managing and monitoring of their equipment needs.

7. **Patient-owned equipment will not be managed for billing of services the way rental equipment is managed. Each time an oxygen provider is called out to check on the equipment, regardless of there being anything wrong with it or not, a separate charge will be billed to the patient.** Patients or family members who need re-education and retraining on the use of the equipment will also no longer receive these services free. Service calls after-hours, if available, will be billed at a higher rate than service calls during working hours. Service calls will no longer be free of charge. Equipment that cannot be repaired at the patient's home will have to be retuned to the provider's office for repairs or sent to the factory. All repair parts and labor will be billed separately. Additional charges will also be billed for substitute equipment left with the patient while repairs are done elsewhere. Equipment that cannot be repaired will result in the patient having to be responsible for the purchase of replacement equipment should Medicare not cover the cost of its replacement. Medicare does not provide for the replacement of medical equipment (i.e. wheelchairs, walkers, and hospital beds) that has been owned by the patient unless it has been damaged beyond repair by fire or accident or unless it has been purchased for over five years and then becomes inoperable and unrepairable. As with all other Medicare-covered equipment purchased by Medicare, should the patient want a different brand, model, or type of concentrator once title is transferred for the one they have been renting, they will not be eligible to exchange it for one until their existing unit is no longer repairable. Medicare currently does not recognize the difference in the different types of oxygen concentrators currently available to patients. As new technology arrives in the marketplace, patients will not be able to swap their old units in and receive any reimbursement from Medicare for the upgraded newer unit.

8. **Under the new rules, once the used concentrator is owned by the patient, all supply tubing, humidifiers, nasal canulas, water traps, and any other disposable oxygen supply circuits and attachments will be separately billed to the patient.** Again, as with repair charges, the acceptance of assignment by suppliers for each item sold will be on a case-by-case basis by each oxygen provider. A provider's decision to accept assignment will be based on the reasonableness of the fee allowed by Medicare for each item. Currently the fees for these items are extremely low and in some cases do not cover the providers' cost.

9. **Under t he ne w r ules, p atients w ho m ove o r t ravel w ill h ave t o e ither t ake t heir o wn equipment with them or pay privately for another company to rent them replacement**

equipment where they will be staying. Under previous rules for oxygen coverage, patients wishing to travel to areas outside their provider's coverage area could do so at no charge to the patient. Their home oxygen provider would continue to bill for monthly rental and make separate arrangements for another company to provide the same equipment and service to the patient in the area the patient is staying (even if out of state). The home company, as required by Medicare, would pay the out of state company for its use on behalf of the patient when the patient stay was to be temporary. This service has been widely used for patients who stay with family one part of the year and with others during other parts of the year. This also has been used for patients visiting other parts of the country for extensive outpatient medical treatments requiring them to stay for weeks or months at a time. Under the old plan, if the patient needed to travel for a longer period of time or move to another area, the patient would simply change suppliers and receive their oxygen equipment and necessary services from a different rental company in the new location. This will no longer be available for patients who own their own equipment. Medicare will no longer pay for the rental of the equipment once the patient owns his or her own equipment.

10. **Requirements necessary for Federal Drug Administration (FDA) tracking would now have to be maintained by the patient or their caregiver should a recall occur for the particular medical device (concentrator) owned by the patient.** Providers are required to notify individuals who have purchased medical equipment subject to a recall under the FDA Medical Device Act. Such contact must be made by certified mail and by phone. Unless the provider is given all future address changes for patients, the patient would not receive such a recall notice. Special attention would need to be given to patients and their families who would now be personally responsible for receiving and acknowledging such recall notices. If the patient cannot keep up with such records, he/she would have to appoint a family member or other dependable party to be responsible for such communications.

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The difference in reimbursement between the traditional equipment would be $32/month. Most of the types of products that fall within this category is anywhere from $1,200 to $2,500 difference to the purchase price of the traditional oxygen equipment. The $32/month additional is $1,152 in additional reimbursement payments. This hardly covers the cost to acquire the newer technology. Providers will be reluctant in providing this equipment at a loss; therefore the proposed rule limits access to newer technology by not providing adequate reimbursement to cover the cost of the equipment.

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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.

Comments Regarding Oxygen Concentrator Rentals

Medicare currently pays a flat fee for the rental of an oxygen concentrator. This single flat fee is described as a "bundled" rental fee under Medicare guidelines that includes the patient's concentrator machine as well the provision of all the related supplies and services associated with the machine. This fee is expected to cover all costs the oxygen provider incurs that are associated with the provision of the rental unit. Among those includes the cost for all necessary internal and external replacement filters, all preventive maintenance service calls, and all repairs needed on the machine while rented. Should the machine become inoperable and unrepairable, this rental fee is to cover the oxygen provider's cost for replacing the machine with another one. A recent oxygen supplier survey in Tennessee taken by the Tennessee Association for Home Care [TAHC] revealed that of the suppliers surveyed between 18% and 40% of the oxygen concentrators on rent are exchanged and replaced each year with different units. These exchanges are made by the providers due to equipment repair, service, and maintenance needs that cannot be reasonably performed in the home. As a rental item, these exchanges are done in the patient's home with no significant inconvenience to the patient. In general, the rental fee covers everything associated with the providing an uninterrupted supply of oxygen to the patient as well all costs for providing the patient with his/her monthly respiratory supplies to be used with the machine. The supplies covered includes oxygen supply tubing, humidifiers, nasal canulas or face masks, water traps, and any other disposable oxygen supply circuits and attachments ordered by the patient's physician that are needed for the delivery of oxygen to the patient. As with all other rented equipment, this bundled fee covers the initial and ongoing training of the patient and/or the family for proper use and care of the equipment. Lastly, this fee is also to cover the oxygen provider's cost for the required ongoing monitoring of the patient's use of the equipment to insure that the equipment is being properly utilized according to the physician's written orders.

The oxygen concentrator is a highly sophisticated, complicated, and sensitive item of equipment. It operates by compressing room air into and through a group of pneumatically sealed containers filled with sieve material that filters the nitrogen out of the room air, leaving a highly enriched oxygen concentration of air that is approximately 93% to 95% pure oxygen. This process is achieved by directing the air through a series of pneumatic pressurized chambers under timed cycles controlled by pressure sensors and gages. At no time can there be any pressure leaks or significant variances in the synchronization of the air exchanges in the system. When variances occur over time, the oxygen concentration will begin to drop. If they persist, the concentration levels can drop as low as 30% to 40% and even as low as normal room air. When the levels drop to substandard oxygen concentration levels over a period of time, the machine can also start to experience other problems including the contamination of the machine's sieve beds. Sieve beds are small granular beads inside the sealed metal chambers or canisters that filter the nitrogen from the air, leaving only highly enriched oxygenated air delivered to the patient. Leaks to the sieve bed chambers can result in an extensive repair cost to the machine but more importantly can cause damage to the patient, as the patient also will not receive adequate oxygen intake once the sieve beds are compromised. If the machine's pre-filters and internal filters are not cleaned and changed according to factory guidelines, the machine will also overheat and begin to destroy the soft pliable hoses within the unit. Once these hoses lose their ability to seal around internal gaskets, the machine will also begin to lose concentration and complete the downward cycle of equipment failure.

Although there are mechanisms and built-in alarms in some models of the machines that can indicate a corruption in the airflow seals and detect significant drops in pressure, they are by no means fool proof. Many o f t hese s elf-detecting s ensors o nly alarm w hen t he c oncentration has f allen well below the concentration necessary to provide the patient with his/her prescribed needs. Some machines can appear to be working properly and not show any outward sign of problems until an oxygen analyzer is put on the machine's output to test its concentration levels. The oxygen analyzer is a small calibration device that measures the oxygen concentration output of the machine. This again is one of the routine services oxygen providers perform on all rented concentrators before and during the rental episodes. Preventative

maintenance is a service provided at no extra charge by providers and is performed on the rental machines at the patient's home during the rental episode. It is done to prevent future equipment failure and minimize future repair needs. It is also done to further insure that the equipment is producing the prescribed level of oxygen that the physician has ordered. Although preventative maintenance is performed as part of the rental program, it is not in itself a separate Medicare covered charge for equipment owned by patients. Medicare, as well as most health care insurance programs, does not routinely provide benefits for preventative health care services or for preventative equipment that can potentially prevent an illnesses or injury. Examples of items not covered as for preventative value are bathtub benches or grab bars around the bathroom. In keeping with this philosophy, Medicare also does not provide preventative inspection and equipment analysis to patient-owned medical equipment regardless of how beneficial such inspections and preventative care may end up being. This would be a dangerous problem for patients whose oxygen equipment has not shown signs of equipment failure yet is not producing adequate levels of oxygen.

Oxygen concentrators run on electricity. They attach to any well-grounded, home utility electrical circuit. During any time of equipment malfunction or equipment failure, continuous use can likely further damage the machine. The machine should be turned off any time the machine alarm sounds or when it appears to be running louder than normal or feeling hot to touch. Under the rental program, patients and families are advised to call their oxygen provider when the machine does not run properly. Although many of the problems with oxygen concentrators are due to improper attachment of tubing or humidifiers to the machine itself, most patients are unable to determine what is wrong without assistance of a medical equipment technician. All rentals of oxygen equipment include, at no extra cost, 24-hour emergency service. Most service calls that require adjustments, repairs, or exchanges will be done within two to four hours of the call. During such equipment failure, patients are advised to change over to their free back-up oxygen gas filled tank until the technician arrives at their house. This back up gas tank is provided by the rental company as a free service as part of its 24 hour-service to patients renting oxygen equipment so that the patient will not have to call 911 for assistance between the time that the equipment first fails and the technician arrives at the patients home.

Oxygen concentrator machines can be damaged over a period of time when placed too close to a wall or piece of furniture which occludes the air intake opening. They can also be damaged by the excessive use of baby powder or other dry particle agents used in a patient room for incontinence. Use of such airborne powders can cause clogging of the pre-filters if not replaced or cleaned frequently in such environments. Restriction of air intake to a concentrator causes the machine to overwork to compensate for the reduced air flow into the machine and eventually will result in overheating and damage to the machine. Patients and caregivers should pay special attention to always ensure that the air intake remains open and unobstructed. When patients plan to travel and take their machine from one residence to another, it is recommended that they always contact their equipment supplier first to make sure it is advisable for the equipment to be moved by their caregivers or through special arrangements made by the oxygen provider. Special attention should always be given to care for the machine when in transit. Certain manufacturers' service and maintenance guidelines state that the machines should never be turned on their side in order to prevent breaking of seals in the airway connectors.

As with all medical devices covered under the Federal Drug Administration (FDA) Medical Device Tracking Act, the concentrator must be monitored and cared for properly in order to insure continual safe use. As a FDA device, the machine is eligible for recall and patient health and safety tracking log reporting of injury or death occurrences caused by its design or other mitigating causes of its manufacturer. As required by law, the supplier maintains compliance with the FDA tracking requirements while the supplier owns the unit. This is another service covered and provided for by law as long as the oxygen provider owns the equipment.

Submitter : Mr. Tim Good

Organization : GoodCare by CPCI

Date: 09/25/2006

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

The proposal to continue to decrease oxygen reimbursement for stationary oxygen is not balanced by the proposed allowable for portable oxygen. Patients who require significant amounts of portable oxygen will be unable to receive appropriate portable oxygen equipment with these allowables. This is particularly important with the scenario of transferring ownership of stationary oxygen systems to the patient after 36 months of use; the allowable remaing for reimbursement for provision of portable oxygen will be insufficient to allow the provider to stay in business - unless the patient is charged additional charges.

Submitter : **Ms. Gail Fiedorowicz** **Date: 09/25/2006**

Organization : **Lamberts Health Care**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1304-P-84-Attach-1.DOC

#84

September 25, 2006

Comments on NPRM for DRA Oxygen Provisions

Submitted by: Gail Fiedorowicz; Crab Orchard, TN

General Comments:

1. **Under the proposed S. 1932 Legislation, Medicare would now only allow patients to rent oxygen concentrators and related oxygen equipment provided with it for up to 36 months.** Earlier versions of the bill limited the rental to as little as 18 months. Placing any monthly cap limit on this benefit is a drastic and dangerous change to the oxygen benefit currently in place that now puts no limit on the coverage of oxygen rented to the patient. Current Medicare benefit guidelines as well as those for all major national insurance companies, state Medicaid programs, workman's comp benefit programs, and all home care industry accreditation organizations have always classified oxygen equipment as *"high maintenance equipment needing frequent maintenance service which is not recommended or advisable for patients to own"*.

2. **Under this new pending rule, Medicare will stop paying for the rental, and the provider will no longer be involved the patient's care or management of his/her oxygen concentrator after 36 months.** According to congressional reports, the average patient rents such equipment for 30 months. By capping the units at 36 months, congress will be cutting off rental benefits to as many as 15 to 20 percent of all Medicare patients on oxygen. Patients will no longer receive free 24-hour service on the equipment, and they will no longer receive any free service. They will have to be financially responsible for each service provided. This includes preventative maintenance and routine inspections of the equipment. Repair and necessary service to the machine will now be billable to the patient and assignment will only be accepted by the oxygen provider on a case-by-case basis. There is also concern that oxygen providers may not accept assignment on the historically low Medicare fees for repair of medical equipment for patients they no longer provide rental services for since some of Medicare's fees do not even cover the provider's wholesale cost.

3. **Some industry experts are concerned for the patients who live far away from the oxygen provider's offices. These patients in particular may find it very difficult to find a provider who will service their owned, used equipment once the equipment has been transferred to the patient**. Medicare does not pay for delivery and pick-up charges for such services. This will make it even more difficult for providers to accept assignment on any repairs that would be done in the home. Under the proposed plan once the rental caps, title and all responsibility for the used equipment will simply be transferred to the patient. At that time, the oxygen provider will no longer be responsible for any of its upkeep. If there were any warranty remaining, it would be managed and controlled through the manufacturer of the product. Any warranty claims made would now bypass the provider and ultimately be processed by the manufacturer. As with all factory warranties on sold equipment, this will now have to be processed through the procedures required by the manufacturer. This will likely cause delays in processing repair work for patients or force patients to accept financial responsibility for repairs until warranty authorizations are approved by the factory.

4. **When patient owned non-working equipment is being repaired or reviewed by the factory for a warranty determination, the patient will be financially responsible for the rental of a temporary replacement unit. There is no factory warranty that covers this.** Most warranties on oxygen concentrators are only for 3 years from the date the supplier purchases the machine. The net effect will be that after 36 months of rental, the patient will be 100% responsible for managing and caring for the non-warranted item. A three year old oxygen concentrator can have as many as 26,000 hours of use on it at the time it is transferred to the patient. Based on the

average life of an oxygen concentrator, this is equivalent to owning a typical American automobile out of warranty with over 100,000 miles on the odometer.

5. **Once the patient owns the equipment, the supplier will have no obligation to provide free 24-hour service on the equipment**. This is a service that is provided at no additional charge for rental equipment owned by the supplier. Free emergency backup tanks for power outages and equipment failure will be picked up or billed to the patient privately as this is also a service pertaining to the rental equipment owned by the oxygen provider. Duplicate equipment, such as the backup tank, has never been a covered service billable to Medicare. Patients wanting a backup tank as well as patients wanting to be covered by a 24-hour service contract will have to pay privately for them. Patients who are unable or unwilling to make financial arrangements for 24-hours service capability will be advised to keep several family members aware of their dependence on oxygen and their need for assistance should there be inclement weather or other events that may cause an interruption in electrical power to their home.

6. **Patients who are unable to move freely throughout their home without assistance, who are vision impaired, who have periods of confusion related to their condition, or who live alone will be most affected by this new change.** These patients will be in the most risk of being unable to care for their equipment or to know when it needs service or how to manage the new financial arrangements for the service each time it is needed. Such patients are advised to find other family resources or community services to assist them in the managing and monitoring of their equipment needs.

7. **Patient-owned equipment will not be managed for billing of services the way rental equipment is managed. Each time an oxygen provider is called out to check on the equipment, regardless of there being anything wrong with it or not, a separate charge will be billed to the patient.** Patients or family members who need re-education and retraining on the use of the equipment will also no longer receive these services free. Service calls after-hours, if available, will be billed at a higher rate than service calls during working hours. Service calls will no longer be free of charge. Equipment that cannot be repaired at the patient's home will have to be retuned to the provider's office for repairs or sent to the factory. All repair parts and labor will be billed separately. Additional charges will also be billed for substitute equipment left with the patient while repairs are done elsewhere. Equipment that cannot be repaired will result in the patient having to be responsible for the purchase of replacement equipment should Medicare not cover the cost of its replacement. Medicare does not provide for the replacement of medical equipment (i.e. wheelchairs, walkers, and hospital beds) that has been owned by the patient unless it has been damaged beyond repair by fire or accident or unless it has been purchased for over five years and then becomes inoperable and unrepairable. As with all other Medicare-covered equipment purchased by Medicare, should the patient want a different brand, model, or type of concentrator once title is transferred for the one they have been renting, they will not be eligible to exchange it for one until their existing unit is no longer repairable. Medicare currently does not recognize the difference in the different types of oxygen concentrators currently available to patients. As new technology arrives in the marketplace, patients will not be able to swap their old units in and receive any reimbursement from Medicare for the upgraded newer unit.

8. **Under the new rules, once the used concentrator is owned by the patient, all supply tubing, humidifiers, nasal canulas, water traps, and any other disposable oxygen supply circuits and attachments will be separately billed to the patient.** Again, as with repair charges, the acceptance of assignment by suppliers for each item sold will be on a case-by-case basis by each oxygen provider. A provider's decision to accept assignment will be based on the reasonableness of the fee allowed by Medicare for each item. Currently the fees for these items are extremely low and in some cases do not cover the providers' cost.

9. **Under t he ne w r ules, p atients w ho m ove o r t ravel w ill h ave t o e ither t ake t heir o wn equipment with them or pay privately for another company to rent them replacement**

equipment where they will be staying. Under previous rules for oxygen coverage, patients wishing to travel to areas outside their provider's coverage area could do so at no charge to the patient. Their home oxygen provider would continue to bill for monthly rental and make separate arrangements for another company to provide the same equipment and service to the patient in the area the patient is staying (even if out of state). The home company, as required by Medicare, would pay the out of state company for its use on behalf of the patient when the patient stay was to be temporary. This service has been widely used for patients who stay with family one part of the year and with others during other parts of the year. This also has been used for patients visiting other parts of the country for extensive outpatient medical treatments requiring them to stay for weeks or months at a time. Under the old plan, if the patient needed to travel for a longer period of time or move to another area, the patient would simply change suppliers and receive their oxygen equipment and necessary services from a different rental company in the new location. This will no longer be available for patients who own their own equipment. Medicare will no longer pay for the rental of the equipment once the patient owns his or her own equipment.

10. **Requirements necessary for Federal Drug Administration (FDA) tracking would now have to be maintained by the patient or their caregiver should a recall occur for the particular medical device (concentrator) owned by the patient.** Providers are required to notify individuals who have purchased medical equipment subject to a recall under the FDA Medical Device Act. Such contact must be made by certified mail and by phone. Unless the provider is given all future address changes for patients, the patient would not receive such a recall notice. Special attention would need to be given to patients and their families who would now be personally responsible for receiving and acknowledging such recall notices. If the patient cannot keep up with such records, he/she would have to appoint a family member or other dependable party to be responsible for such communications.

Comments on Costs Pertaining to Home Oxygen Therapy

1. **Equipment cost only accounts for 28% of the total Home Oxygen Therapy costs.** The Morrison study finds that other services account for the significant majority of costs associated with Home Oxygen Therapy. These include: preparing and delivering the equipment; delivering supplies and maintenance of oxygen equipment; assessing, training and educating patients; obtaining required medical documentation and providing customer service for beneficiaries; related services and compliance with Federal & State Regulations (included FDA and DOT requirements); other related services; and operating and overhead costs.

2. **Medicare oxygen patients are provided home oxygen therapy for about $7.50/day ($2,784/year), with their co-pay amounting to less than $1.50/day. The annual costs to beneficiaries without supplemental insurance is approximately $574/year.** In 2002, there were 673,000 hospitalizations for patients with Chronic Obstructive Pulmonary Disease, the fourth leading cause of death among Americans each year. When COPD patients were hospitalized, the average length of stay was 5.2 days. It is vital for patients using Home Oxygen Therapy to have the services needed to keep them in the home and out of the hospital from a financial standpoint. At a cost of $7.50/day for the home oxygen, it is vitally important that CMS insures that this change in policy does not result in any increases in hospital stays, which costs an average of $3,606/day. One hospitalization of an average length of stay would wipe out all of the financial benefits to Medicare of five people's *annual* capped rental costs.

3. **70% of problems that technicians are called to the home to check on are not services that Medicare would cover.** This leaves the beneficiary paying out-of-pocket for services that were previously covered under the oxygen rental program once the beneficiary owns his/her equipment. As previously mentioned above, these services include: Free 24-hour service on equipment; Free back-up tank, stand, regulator, or supply tubing; Free replacement equipment

during extensive repairs of rented equipment; Local warranty services; Free access to Respiratory Therapists; the Ability for the provider to arrange for free 24-hour service when the beneficiary travels to another city; Free deliveries and pick-ups for services or parts.

4. **Suppliers cannot be held responsible for replacing patient owned equipment within 5 years of the date the item is sold to the patient if the repair cost exceeds 60% of the cost of the item.** These items are not delivered new. They are rented as used items. However even it the item was delivered as new, it is totally unreasonable and unprecedented for Medicare to expect any supplier to replace the unless the unit is in fact covered by a manufacturers warranty. Medicare has used this 5-year period in the past to determine if the benefit plan will actually replace an item of equipment or continue to repair it. For DME items that no longer work or are damaged beyond repair, Medicare does not require the supplier to replace the unit if the repair cost exceeds 60% of the replacement cost. Even Medicare will not do that. Medicare continues to pay all the way up to 100% of the items replacement cost to avoid replacing it. There also is no 60% factor involved in the decision to repair the unit. It is apparent that this an attempt to avoid what Medicare already knows will be an extensive cost to the program. These items require frequent service and maintenance. This service and maintenance is "the responsibility of the beneficiary". Providers will NOT be paid by Medicare to maintain the equipment. Providers will be paid ONLY to repair it after the fact. Since providers are not receiving any money to keep the equipment up and since it is the patient who is 100% responsible for taking care of the equipment and performing the frequent and routine maintenance and service on the machine (everything other than major repairs), it should therefore be the responsibility of the beneficiary to replace the unit if the cost to repair it exceeds 60% if in fact Medicare wants to limit the repair cost to that. Unless suppliers are paid to maintain the item over the 5-year period they cannot be expected to be at risk for the equipment's failure. This is not fair or reasonable.

Comments on Beneficiaries that Receive Home Oxygen Therapy

1. **COPD, the fourth leading cause of death each year in the United States, affects approximately 15 million Americans, with an estimated additional 15 million that have gone undiagnosed.** By 2020, the World Health Organization estimates that COPD will rank fifth as a global burden of disease. Oxygen Therapy is the only current treatment or drug scientifically proven to extend the life of patients with chronic lung disease. Other people who benefit from oxygen therapy include those with congestive heart failure, respiratory failure, ALS, and other serious diseases.

2. **The average COPD person is considered to be in the "frail/elderly" category, have numerous activities of daily living that are impaired, and may live alone.** Since this disease is a debilitative, progressive, non-curable one, it is important that these people are able to receive their oxygen therapy—even once they are incapable of performing the "routine or periodic servicing" that Medicare outlines for them. Under previous Home Oxygen Rental programs, these services would be provided free of charge to the beneficiary. As previously stated, one slip-up on the beneficiary's side of caring for his/her equipment could result in expensive, extended stays in the hospital.

Comments Concerning Issues Not Addressed in Legislation

1. **Which Provider's equipment transfers to the beneficiary if the beneficiary has two residences with a local provider in each residence?**

2. **With patient-owned equipment, there is no record of routine ongoing service and maintenance that is supposed to be performed by the beneficiary or caregiver.** CMS states,

> "We would, however, also propose to apply our existing policy of not covering certain routine 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 policy for beneficiary-owned capped rental equipment."

   a) If the beneficiary neglects the equipment, the equipment could malfunction. Is this the responsibility of the provider to repair the equipment when the root of the problem was improper care by the beneficiary?
   b) What if this repair adds to the overall repair cost of greater than 60% of the cost of replacement equipment? What safeguards are in place for the supplier to ensure that the beneficiary will take care of the equipment to reduce repairs and replacements?
   c) In the event that the beneficiary lives in an assisted living facility (therefore being unable to have the services provided by a caregiver), if the beneficiary reaches the point where he/she is unable to perform some of the "routine or periodic servicing" that is required by him/herself, will that force the beneficiary into a nursing home, thus increasing costs to Medicare?

3. **How is the supplier supposed to have accurate liter-flow information about the beneficiary from the physician if the patient is no longer in their system under the oxygen rental program?** If the supplier is called out for an "after hours" house-call, unless proper documentation is available to the supplier technicians, no action may be taken. This will result in an ambulance coming to the beneficiary's home and taking him/her to the hospital. This will undoubtedly cost Medicare more.

Comments from the Homecare Industry Regarding Consequences of Implementation

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2. **Beneficiary access to innovation and new technology will be limited.** CMS states,

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Although there are mechanisms and built-in alarms in some models of the machines that can indicate a corruption in the airflow seals and detect significant drops in pressure, they are by no means fool proof. Many of these self-detecting sensors only alarm when the concentration has fallen well below the concentration necessary to provide the patient with his/her prescribed needs. Some machines can appear to be working properly and not show any outward sign of problems until an oxygen analyzer is put on the machine's output to test its concentration levels. The oxygen analyzer is a small calibration device that measures the oxygen concentration output of the machine. This again is one of the routine services oxygen providers perform on all rented concentrators before and during the rental episodes. Preventative

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Oxygen concentrators run on electricity. They attach to any well-grounded, home utility electrical circuit. During any time of equipment malfunction or equipment failure, continuous use can likely further damage the machine. The machine should be turned off any time the machine alarm sounds or when it appears to be running louder than normal or feeling hot to touch. Under the rental program, patients and families are advised to call their oxygen provider when the machine does not run properly. Although many of the problems with oxygen concentrators are due to improper attachment of tubing or humidifiers to the machine itself, most patients are unable to determine what is wrong without assistance of a medical equipment technician. All rentals of oxygen equipment include, at no extra cost, 24-hour emergency service. Most service calls that require adjustments, repairs, or exchanges will be done within two to four hours of the call. During such equipment failure, patients are advised to change over to their free back-up oxygen gas filled tank until the technician arrives at their house. This back up gas tank is provided by the rental company as a free service as part of its 24 hour-service to patients renting oxygen equipment so that the patient will not have to call 911 for assistance between the time that the equipment first fails and the technician arrives at the patients home.

Oxygen concentrator machines can be damaged over a period of time when placed too close to a wall or piece of furniture which occludes the air intake opening. They can also be damaged by the excessive use of baby powder or other dry particle agents used in a patient room for incontinence. Use of such airborne powders can cause clogging of the pre-filters if not replaced or cleaned frequently in such environments. Restriction of air intake to a concentrator causes the machine to overwork to compensate for the reduced air flow into the machine and eventually will result in overheating and damage to the machine. Patients and caregivers should pay special attention to always ensure that the air intake remains open and unobstructed. When patients plan to travel and take their machine from one residence to another, it is recommended that they always contact their equipment supplier first to make sure it is advisable for the equipment to be moved by their caregivers or through special arrangements made by the oxygen provider. Special attention should always be given to care for the machine when in transit. Certain manufacturers' service and maintenance guidelines state that the machines should never be turned on their side in order to prevent breaking of seals in the airway connectors.

As with all medical devices covered under the Federal Drug Administration (FDA) Medical Device Tracking Act, the concentrator must be monitored and cared for properly in order to insure continual safe use. As a FDA device, the machine is eligible for recall and patient health and safety tracking log reporting of injury or death occurrences caused by its design or other mitigating causes of its manufacturer. As required by law, the supplier maintains compliance with the FDA tracking requirements while the supplier owns the unit. This is another service covered and provided for by law as long as the oxygen provider owns the equipment.

Submitter : SHARON THOMPSON

Organization : GULF MEDICAL SERVICES

Category : Other Health Care Provider

Date: 09/25/2006

Issue Areas/Comments

GENERAL

GENERAL

HAVING BEEN IN HOME MEDICAL EQUIPMENT FIELD FOR 11 YEARS, TO CAP OXYGEN WOULD BE LIKE CUTTING OFF THE LIFE LINE TO MANY OF OUR ELDERLY. THE TYPE OF MEDICAL EQUIPMENT AND MAINTENANCE REQUIRED ON SUCH ITEMS WOULD COST THE US GOVERNMENT TONS OVER WHAT IS BEING PAID NOW. OVER THE YEARS THAT I'VE BEEN AWARE OF HOME OXYGEN, THE TIMES THAT TECHNICIANS AND RESPIRATORY THERAPISTS HAVE GONE OUT AT NO CHARGE IS AMAZING. TO BILL THE GOVERNMENT FOR THESE SERVICES WOULD BE CAUSE FOR AN OUT CRY FROM THE PUBLIC.

Submitter : Mr. randy wolfe

Organization : Wolfe Medical, Inc.

Category : Other Health Care Provider

Date: 09/25/2006

Issue Areas/Comments

GENERAL

GENERAL

see attachment

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

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

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

Submitter : Mrs. Laura Vick

Date: 09/25/2006

Organization : Lambert's Health Care

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1304-P-87-Attach-1.DOC

#89

September 25, 2006

Comments on NPRM for DRA Oxygen Provisions

Submitted by: Laura Vick; Strawberry Plains, TN. *Both my grandmother,and great-grandfather benefit from oxygen therapy, and I think it is crucial for Medicare and CMS to review some of the policies outlined in their legislation of the DRA in order for my family to continue to receive quality care.*

General Comments:

1. **Under the proposed S. 1932 Legislation, Medicare would now only allow patients to rent oxygen concentrators and related oxygen equipment provided with it for up to 36 months**. Earlier versions of the bill limited the rental to as little as 18 months. Placing any monthly cap limit on this benefit is a drastic and dangerous change to the oxygen benefit currently in place that now puts no limit on the coverage of oxygen rented to the patient. Current Medicare benefit guidelines as well as those for all major national insurance companies, state Medicaid programs, workman's comp benefit programs, and all home care industry accreditation organizations have always classified oxygen equipment as *"high maintenance equipment needing frequent maintenance service which is not recommended or advisable for patients to own"*.

2. **Under this new pending rule, Medicare will stop paying for the rental, and the provider will no longer be involved the patient's care or management of his/her oxygen concentrator after 36 months.** According to congressional reports, the average patient rents such equipment for 30 months. By capping the units at 36 months, congress will be cutting off rental benefits to as many as 15 to 20 percent of all Medicare patients on oxygen. Patients will no longer receive free 24-hour service on the equipment, and they will no longer receive any free service. They will have to be financially responsible for each service provided. This includes preventative maintenance and routine inspections of the equipment. Repair and necessary service to the machine will now be billable to the patient and assignment will only be accepted by the oxygen provider on a case-by-case basis. There is also concern that oxygen providers may not accept assignment on the historically low Medicare fees for repair of medical equipment for patients they no longer provide rental services for since some of Medicare's fees do not even cover the provider's wholesale cost.

3. **Some industry experts are concerned for the patients who live far away from the oxygen provider's offices. These patients in particular may find it very difficult to find a provider who will service their owned, used equipment once the equipment has been transferred to the patient**. Medicare does not pay for delivery and pick-up charges for such services. This will make it even more difficult for providers to accept assignment on any repairs that would be done in the home. Under the proposed plan once the rental caps, title and all responsibility for the used equipment will simply be transferred to the patient. At that time, the oxygen provider will no longer be responsible for any of its upkeep. If there were any warranty remaining, it would be managed and controlled through the manufacturer of the product. Any warranty claims made would now bypass the provider and ultimately be processed by the manufacturer. As with all factory warranties on sold equipment, this will now have to be processed through the procedures required by the manufacturer. This will likely cause delays in processing repair work for patients or force patients to accept financial responsibility for repairs until warranty authorizations are approved by the factory.

4. **When patient owned non-working equipment is being repaired or reviewed by the factory for a warranty determination, the patient will be financially responsible for the rental of a temporary replacement unit. There is no factory warranty that covers this.** Most warranties on oxygen concentrators are only for 3 years from the date the supplier purchases the machine. The net effect will be that after 36 months of rental, the patient will be 100% responsible for

managing and caring for the non-warranted item. A three year old oxygen concentrator can have as many as 26,000 hours of use on it at the time it is transferred to the patient. Based on the average life of an oxygen concentrator, this is equivalent to owning a typical American automobile out of warranty with over 100,000 miles on the odometer.

5. **Once the patient owns the equipment, the supplier will have no obligation to provide free 24-hour service on the equipment**. This is a service that is provided at no additional charge for rental equipment owned by the supplier. Free emergency backup tanks for power outages and equipment failure will be picked up or billed to the patient privately as this is also a service pertaining to the rental equipment owned by the oxygen provider. Duplicate equipment, such as the backup tank, has never been a covered service billable to Medicare. Patients wanting a backup tank as well as patients wanting to be covered by a 24-hour service contract will have to pay privately for them. Patients who are unable or unwilling to make financial arrangements for 24-hours service capability will be advised to keep several family members aware of their dependence on oxygen and their need for assistance should there be inclement weather or other events that may cause an interruption in electrical power to their home.

6. **Patients who are unable to move freely throughout their home without assistance, who are vision impaired, who have periods of confusion related to their condition, or who live alone will be most affected by this new change.** These patients will be in the most risk of being unable to care for their equipment or to know when it needs service or how to manage the new financial arrangements for the service each time it is needed. Such patients are advised to find other family resources or community services to assist them in the managing and monitoring of their equipment needs.

7. **Patient-owned equipment will not be managed for billing of services the way rental equipment is managed. Each time an oxygen provider is called out to check on the equipment, regardless of there being anything wrong with it or not, a separate charge will be billed to the patient.** Patients or family members who need re-education and retraining on the use of the equipment will also no longer receive these services free. Service calls after-hours, if available, will be billed at a higher rate than service calls during working hours. Service calls will no longer be free of charge. Equipment that cannot be repaired at the patient's home will have to be retuned to the provider's office for repairs or sent to the factory. All repair parts and labor will be billed separately. Additional charges will also be billed for substitute equipment left with the patient while repairs are done elsewhere. Equipment that cannot be repaired will result in the patient having to be responsible for the purchase of replacement equipment should Medicare not cover the cost of its replacement. Medicare does not provide for the replacement of medical equipment (i.e. wheelchairs, walkers, and hospital beds) that has been owned by the patient unless it has been damaged beyond repair by fire or accident or unless it has been purchased for over five years and then becomes inoperable and unrepairable. As with all other Medicare-covered equipment purchased by Medicare, should the patient want a different brand, model, or type of concentrator once title is transferred for the one they have been renting, they will not be eligible to exchange it for one until their existing unit is no longer repairable. Medicare currently does not recognize the difference in the different types of oxygen concentrators currently available to patients. As new technology arrives in the marketplace, patients will not be able to swap their old units in and receive any reimbursement from Medicare for the upgraded newer unit.

8. **Under the new rules, once the used concentrator is owned by the patient, all supply tubing, humidifiers, nasal canulas, water traps, and any other disposable oxygen supply circuits and attachments will be separately billed to the patient.** Again, as with repair charges, the acceptance of assignment by suppliers for each item sold will be on a case-by-case basis by each oxygen provider. A provider's decision to accept assignment will be based on the reasonableness of the fee allowed by Medicare for each item. Currently the fees for these items are extremely low and in some cases do not cover the providers' cost.

9. **Under the new rules, patients who move or travel will have to either take their own equipment with them or pay privately for another company to rent them replacement equipment where they will be staying.** Under previous rules for oxygen coverage, patients wishing to travel to areas outside their provider's coverage area could do so at no charge to the patient. Their home oxygen provider would continue to bill for monthly rental and make separate arrangements for another company to provide the same equipment and service to the patient in the area the patient is staying (even if out of state). The home company, as required by Medicare, would pay the out of state company for its use on behalf of the patient when the patient stay was to be temporary. This service has been widely used for patients who stay with family one part of the year and with others during other parts of the year. This also has been used for patients visiting other parts of the country for extensive outpatient medical treatments requiring them to stay for weeks or months at a time. Under the old plan, if the patient needed to travel for a longer period of time or move to another area, the patient would simply change suppliers and receive their oxygen equipment and necessary services from a different rental company in the new location. This will no longer be available for patients who own their own equipment. Medicare will no longer pay for the rental of the equipment once the patient owns his or her own equipment.

10. **Requirements necessary for Federal Drug Administration (FDA) tracking would now have to be maintained by the patient or their caregiver should a recall occur for the particular medical device (concentrator) owned by the patient**. Providers are required to notify individuals who have purchased medical equipment subject to a recall under the FDA Medical Device Act. Such contact must be made by certified mail and by phone. Unless the provider is given all future address changes for patients, the patient would not receive such a recall notice. Special attention would need to be given to patients and their families who would now be personally responsible for receiving and acknowledging such recall notices. If the patient cannot keep up with such records, he/she would have to appoint a family member or other dependable party to be responsible for such communications.

Comments on Costs Pertaining to Home Oxygen Therapy

1. **Equipment cost only accounts for 28% of the total Home Oxygen Therapy costs.** The Morrison study finds that other services account for the significant majority of costs associated with Home Oxygen Therapy. These include: preparing and delivering the equipment; delivering supplies and maintenance of oxygen equipment; assessing, training and educating patients; obtaining required medical documentation and providing customer service for beneficiaries; related services and compliance with Federal & State Regulations (included FDA and DOT requirements); other related services; and operating and overhead costs.

2. **Medicare oxygen patients are provided home oxygen therapy for about $7.50/day ($2,784/year), with their co-pay amounting to less than $1.50/day. The annual costs to beneficiaries without supplemental insurance is approximately $574/year.** In 2002, there were 673,000 hospitalizations for patients with Chronic Obstructive Pulmonary Disease, the fourth leading cause of death among Americans each year. When COPD patients were hospitalized, the average length of stay was 5.2 days. It is vital for patients using Home Oxygen Therapy to have the services needed to keep them in the home and out of the hospital from a financial standpoint. At a cost of $7.50/day for the home oxygen, it is vitally important that CMS insures that this change in policy does not result in any increases in hospital stays, which costs an average of $3,606/day. One hospitalization of an average length of stay would wipe out all of the financial benefits to Medicare of five people's *annual* capped rental costs.

3. **70% of problems that technicians are called to the home to check on are not services that Medicare would cover.** This leaves the beneficiary paying out-of-pocket for services that were previously covered under the oxygen rental program once the beneficiary owns his/her

equipment. As previously mentioned above, these services include: Free 24-hour service on equipment; Free back-up tank, stand, regulator, or supply tubing; Free replacement equipment during extensive repairs of rented equipment; Local warranty services; Free access to Respiratory Therapists; the Ability for the provider to arrange for free 24-hour service when the beneficiary travels to another city; Free deliveries and pick-ups for services or parts.

4. **Suppliers cannot be held responsible for replacing patient owned equipment within 5 years of the date the item is sold to the patient if the repair cost exceeds 60% of the cost of the item.** These items are not delivered new. They are rented as used items. However even it the item was delivered as new, it is totally unreasonable and unprecedented for Medicare to expect any supplier to replace the unless the unit is in fact covered by a manufacturers warranty. Medicare has used this 5-year period in the past to determine if the benefit plan will actually replace an item of equipment or continue to repair it. For DME items that no longer work or are damaged beyond repair, Medicare does not require the supplier to replace the unit if the repair cost exceeds 60% of the replacement cost. Even Medicare will not do that. Medicare continues to pay all the way up to 100% of the items replacement cost to avoid replacing it. There also is no 60% factor involved in the decision to repair the unit. It is apparent that this an attempt to avoid what Medicare already knows will be an extensive cost to the program. These items require frequent service and maintenance. This service and maintenance is "the responsibility of the beneficiary". Providers will NOT be paid by Medicare to maintain the equipment. Providers will be paid ONLY to repair it after the fact. Since providers are not receiving any money to keep the equipment up and since it is the patient who is 100% responsible for taking care of the equipment and performing the frequent and routine maintenance and service on the machine (everything other than major repairs), it should therefore be the responsibility of the beneficiary to replace the unit if the cost to repair it exceeds 60% if in fact Medicare wants to limit the repair cost to that. Unless suppliers are paid to maintain the item over the 5-year period they cannot be expected to be at risk for the equipment's failure. This is not fair or reasonable.

Comments on Beneficiaries that Receive Home Oxygen Therapy

1. **COPD, the fourth leading cause of death each year in the United States, affects approximately 15 million Americans, with an estimated additional 15 million that have gone undiagnosed.** By 2020, the World Health Organization estimates that COPD will rank fifth as a global burden of disease. Oxygen Therapy is the only current treatment or drug scientifically proven to extend the life of patients with chronic lung disease. Other people who benefit from oxygen therapy include those with congestive heart failure, respiratory failure, ALS, and other serious diseases.

2. **The average COPD person is considered to be in the "frail/elderly" category, have numerous activities of daily living that are impaired, and may live alone.** Since this disease is a debilitative, progressive, non-curable one, it is important that these people are able to receive their oxygen therapy—even once they are incapable of performing the "routine or periodic servicing" that Medicare outlines for them. Under previous Home Oxygen Rental programs, these services would be provided free of charge to the beneficiary. As previously stated, one slip-up on the beneficiary's side of caring for his/her equipment could result in expensive, extended stays in the hospital.

Comments Concerning Issues Not Addressed in Legislation

1. **Which Provider's equipment transfers to the beneficiary if the beneficiary has two residences with a local provider in each residence?**

2. **With patient-owned equipment, there is no record of routine ongoing service and maintenance that is supposed to be performed by the beneficiary or caregiver.** CMS states,

> "We would, however, also propose to apply our existing policy of not covering certain routine 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 policy for beneficiary-owned capped rental equipment."

   a) If the beneficiary neglects the equipment, the equipment could malfunction. Is this the responsibility of the provider to repair the equipment when the root of the problem was improper care by the beneficiary?
   b) What if this repair adds to the overall repair cost of greater than 60% of the cost of replacement equipment? What safeguards are in place for the supplier to ensure that the beneficiary will take care of the equipment to reduce repairs and replacements?
   c) In the event that the beneficiary lives in an assisted living facility (therefore being unable to have the services provided by a caregiver), if the beneficiary reaches the point where he/she is unable to perform some of the "routine or periodic servicing" that is required by him/herself, will that force the beneficiary into a nursing home, thus increasing costs to Medicare?

3. **How is the supplier supposed to have accurate liter-flow information about the beneficiary from the physician if the patient is no longer in their system under the oxygen rental program?** If the supplier is called out for an "after hours" house-call, unless proper documentation is available to the supplier technicians, no action may be taken. This will result in an ambulance coming to the beneficiary's home and taking him/her to the hospital. This will undoubtedly cost Medicare more.

Comments from the Homecare Industry Regarding Consequences of Implementation

1. **Beneficiary access to ambulatory oxygen will be limited.** Providers cannot utilize liquid oxygen as a modality for their beneficiaries, further limiting access to beneficiaries due to a lack of reimbursement during the initial 36 months and the succeeding periods after ownership has been transferred to the beneficiary.

2. **Beneficiary access to innovation and new technology will be limited.** CMS states,

> "Payments for oxygen contents for beneficiary-owned portable equipment would exceed what is currently paid for these items to ensure access to portable oxygen regardless of the type of equipment used. These increased payments would be offset by a reduction in the stationary payment."

The difference in reimbursement between the traditional equipment would be $32/month. Most of the types of products that fall within this category is anywhere from $1,200 to $2,500 difference to the purchase price of the traditional oxygen equipment. The $32/month additional is $1,152 in additional reimbursement payments. This hardly covers the cost to acquire the newer technology. Providers will be reluctant in providing this equipment at a loss; therefore the proposed rule limits access to newer technology by not providing adequate reimbursement to cover the cost of the equipment.

3. **Beneficiary's ability to relocate on a permanent or temporary basis prior to transfer of title of ownership is limited.** The supplier in the new area will not have the full 36 months to collect reimbursement. ((In addition to the question of which provider gives the equipment to the beneficiary, does the new provider have to transfer ownership without having collected the full amount to justify the cost of the concentrator and the services?)) This limits the

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.

Comments Regarding Oxygen Concentrator Rentals

Medicare currently pays a flat fee for the rental of an oxygen concentrator. This single flat fee is described as a "bundled" rental fee under Medicare guidelines that includes the patient's concentrator machine as well the provision of all the related supplies and services associated with the machine. This fee is expected to cover all costs the oxygen provider incurs that are associated with the provision of the rental unit. Among those includes the cost for all necessary internal and external replacement filters, all preventive maintenance service calls, and all repairs needed on the machine while rented. Should the machine become inoperable and unrepairable, this rental fee is to cover the oxygen provider's cost for replacing the machine with another one. A recent oxygen supplier survey in Tennessee taken by the Tennessee Association for Home Care [TAHC] revealed that of the suppliers surveyed between 18% and 40% of the oxygen concentrators on rent are exchanged and replaced each year with different units. These exchanges are made by the providers due to equipment repair, service, and maintenance needs that cannot be reasonably performed in the home. As a rental item, these exchanges are done in the patient's home with no significant inconvenience to the patient. In general, the rental fee covers everything associated with the providing an uninterrupted supply of oxygen to the patient as well all costs for providing the patient with his/her monthly respiratory supplies to be used with the machine. The supplies covered includes oxygen supply tubing, humidifiers, nasal canulas or face masks, water traps, and any other disposable oxygen supply circuits and attachments ordered by the patient's physician that are needed for the delivery of oxygen to the patient. As with all other rented equipment, this bundled fee covers the initial and ongoing training of the patient and/or the family for proper use and care of the equipment. Lastly, this fee is also to cover the oxygen provider's cost for the required ongoing monitoring of the patient's use of the equipment to insure that the equipment is being properly utilized according to the physician's written orders.

The oxygen concentrator is a highly sophisticated, complicated, and sensitive item of equipment. It operates by compressing room air into and through a group of pneumatically sealed containers filled with sieve material that filters the nitrogen out of the room air, leaving a highly enriched oxygen concentration of air that is approximately 93% to 95% pure oxygen. This process is achieved by directing the air through a series of pneumatic pressurized chambers under timed cycles controlled by pressure sensors and gages. At no time can there be any pressure leaks or significant variances in the synchronization of the air exchanges in the system. When variances occur over time, the oxygen concentration will begin to drop. If they persist, the concentration levels can drop as low as 30% to 40% and even as low as normal room air. When the levels drop to substandard oxygen concentration levels over a period of time, the machine can also start to experience other problems including the contamination of the machine's sieve beds. Sieve beds are small granular beads inside the sealed metal chambers or canisters that filter the nitrogen from the air, leaving only highly enriched oxygenated air delivered to the patient. Leaks to the sieve bed chambers can result in an extensive repair cost to the machine but more importantly can cause damage to the patient, as the patient also will not receive adequate oxygen intake once the sieve beds are compromised. If the machine's pre-filters and internal filters are not cleaned and changed according to factory guidelines, the machine will also overheat and begin to destroy the soft pliable hoses within the unit. Once these hoses lose their ability to seal around internal gaskets, the machine will also begin to lose concentration and complete the downward cycle of equipment failure.

Although there are mechanisms and built-in alarms in some models of the machines that can indicate a corruption in the airflow seals and detect significant drops in pressure, they are by no means fool proof. Many of these self-detecting sensors only alarm when the concentration has fallen well below the concentration necessary to provide the patient with his/her prescribed needs. Some machines can appear to be working properly and not show any outward sign of problems until an oxygen analyzer is put on the machine's output to test its concentration levels. The oxygen analyzer is a small calibration device that measures the oxygen concentration output of the machine. This again is one of the routine services oxygen providers perform on all rented concentrators before and during the rental episodes. Preventative

maintenance is a service provided at no extra charge by providers and is performed on the rental machines at the patient's home during the rental episode. It is done to prevent future equipment failure and minimize future repair needs. It is also done to further insure that the equipment is producing the prescribed level of oxygen that the physician has ordered. Although preventative maintenance is performed as part of the rental program, it is not in itself a separate Medicare covered charge for equipment owned by patients. Medicare, as well as most health care insurance programs, does not routinely provide benefits for preventative health care services or for preventative equipment that can potentially prevent an illnesses or injury. Examples of items not covered as for preventative value are bathtub benches or grab bars around the bathroom. In keeping with this philosophy, Medicare also does not provide preventative inspection and equipment analysis to patient-owned medical equipment regardless of how beneficial such inspections and preventative care may end up being. This would be a dangerous problem for patients whose oxygen equipment has not shown signs of equipment failure yet is not producing adequate levels of oxygen.

Oxygen concentrators run on electricity. They attach to any well-grounded, home utility electrical circuit. During any time of equipment malfunction or equipment failure, continuous use can likely further damage the machine. The machine should be turned off any time the machine alarm sounds or when it appears to be running louder than normal or feeling hot to touch. Under the rental program, patients and families are advised to call their oxygen provider when the machine does not run properly. Although many of the problems with oxygen concentrators are due to improper attachment of tubing or humidifiers to the machine itself, most patients are unable to determine what is wrong without assistance of a medical equipment technician. All rentals of oxygen equipment include, at no extra cost, 24-hour emergency service. Most service calls that require adjustments, repairs, or exchanges will be done within two to four hours of the call. During such equipment failure, patients are advised to change over to their free back-up oxygen gas filled tank until the technician arrives at their house. This back up gas tank is provided by the rental company as a free service as part of its 24 hour-service to patients renting oxygen equipment so that the patient will not have to call 911 for assistance between the time that the equipment first fails and the technician arrives at the patients home.

Oxygen concentrator machines can be damaged over a period of time when placed too close to a wall or piece of furniture which occludes the air intake opening. They can also be damaged by the excessive use of baby powder or other dry particle agents used in a patient room for incontinence. Use of such airborne powders can cause clogging of the pre-filters if not replaced or cleaned frequently in such environments. Restriction of air intake to a concentrator causes the machine to overwork to compensate for the reduced air flow into the machine and eventually will result in overheating and damage to the machine. Patients and caregivers should pay special attention to always ensure that the air intake remains open and unobstructed. When patients plan to travel and take their machine from one residence to another, it is recommended that they always contact their equipment supplier first to make sure it is advisable for the equipment to be moved by their caregivers or through special arrangements made by the oxygen provider. Special attention should always be given to care for the machine when in transit. Certain manufacturers' service and maintenance guidelines state that the machines should never be turned on their side in order to prevent breaking of seals in the airway connectors.

As with all medical devices covered under the Federal Drug Administration (FDA) Medical Device Tracking Act, the concentrator must be monitored and cared for properly in order to insure continual safe use. As a FDA device, the machine is eligible for recall and patient health and safety tracking log reporting of injury or death occurrences caused by its design or other mitigating causes of its manufacturer. As required by law, the supplier maintains compliance with the FDA tracking requirements while the supplier owns the unit. This is another service covered and provided for by law as long as the oxygen provider owns the equipment.

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

Organization : Oxygen Stakeholder Summit Organizing Committee

Category : Device Association

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1304-P-88-Attach-1.PDF

#88

Via Hand Delivery and Electronic Submission

September 25, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1304-P
Room 445-G
Hubert M. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: File Code CMS-1304-P - Comments Related to Proposed Rule re: 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 (July 28, 2006)

Dear Dr. McClellan:

Thank you for the opportunity to provide written comments in response to the Notice of Proposed Rule Making (NPRM or Proposed Rule) related to the planned implementation of the Deficit Reduction Act of 2005 (DRA). The Proposed Rule relates to the Centers for Medicare & Medicaid Services' (CMS) plans to implement the statutory directives associated with certain home medical equipment and services, home oxygen therapy and related services.

These comments are being submitted on behalf of the Oxygen Stakeholders Summit, a non-profit conference that involved a wide range of stakeholder groups and was held in June 2006. Attendees at the Summit were a diverse and representative team of stakeholders that included manufacturers of oxygen technology and accessories, homecare providers (representing large, small, public and private entities), patient advocacy organizations, clinical advocacy organizations and physician organizations dedicated to the advancement of pulmonary medicine in the United States. Approximately 75 attendees were present at the meeting, which was structured via a formal consensus-building method.

The purpose of the Summit was to bring the various stakeholders together to discuss the challenges presented by the Deficit Reduction Act of 2005 (DRA) and the possibility of developing a new philosophical and reimbursement approach to home oxygen therapy as covered under Medicare Part B. While the final consensus statement is still a work in progress, we were encouraged by the significant amount of consensus around the shared goals of:

- Ensuring Medicare beneficiary access to home oxygen therapy and the right to choose a qualified home oxygen provider;

- Preserving prescribing physicians' right to choose a quality home oxygen provider for their patients and the oxygen modalities most appropriate for their patients' individual needs;

- Increasing patient and physician access to those oxygen modalities that offer patients portability and the ability to perform activities of daily living (ADLs) both inside and outside the home, as well as encouraging manufacturers to continue investing in the development of newer oxygen technologies;

- Recognizing that providers deliver more than just oxygen equipment to patients, but actually provide or perform a wide range of patient support services, administrative services, 24/7 on-call and emergency response services and clinical consultation to physicians and patients.

- Ensuring that home oxygen providers adhere to quality, financial and compliance standards;

- Ensuring that Medicare fee schedules are appropriate and adequate in terms of providing a suitable amount of reimbursement necessary to cover providers' costs of caring for Medicare beneficiaries; and

- Discussing other methods – outside of ongoing payment reductions for oxygen therapy – that CMS might realize savings related to the care of patients with Chronic Obstructive Pulmonary Disease (COPD), the fourth leading cause of death in the United States.

Shared Concerns Regarding the Proposed Rule on the DRA

Although the Oxygen Stakeholder Summit attendees represent diverse segments of the health care industry, all share a number of concerns that are associated with the Proposed Rule. Since individual industry stakeholders will be affected more than others by various aspects of the Proposed Rule, we expect that those individual providers, advocacy groups and trade associations will submit their concerns directly to CMS.

The purpose of this letter is to outline seven (7) primary concerns that are shared by all industry stakeholders represented by the Summit. We outline each of the seven areas below.

1. **Existing choice of oxygen modalities will be restricted, especially from months 37-60 after a significant percentage of beneficiaries take ownership of their equipment.**

Our understanding from the Proposed Rule is that patients will only be able to obtain different equipment or modalities if a limited number of exceptions apply. Under the current system, if a patient electively chooses to try another oxygen modality, or if his/her physician prescribes a different system for him/her purely due to a change in activity, lifestyle, equipment weight or other needs, the alternate oxygen modality is provided by a home oxygen provider. A change in medical condition does not have to apply.

In the Proposed Rule, it appears that a patient will not have the right to change equipment for the reasons described above. A "change in medical condition" will have to apply, and that has not been defined in the Proposed Rule or statute. In addition, those patients who assume ownership of equipment at month 36 may be particularly restricted if they are not able to switch equipment for at least 23 months.

We urge CMS to provide for a method that allows patients some reasonable choice to change equipment when desired, without penalizing the home oxygen provider financially for doing so. In addition, CMS must give the DME MACs very clear guidance about how to process exceptions, since it is giving the DME MACs authority to do so for the very first time. If these exceptions are not managed correctly, such a restriction will increase patient dissatisfaction and

be inconsistent with CMS' stated goals of making new technologies and/or portable oxygen more available to patients in the future.

2. **Physician choice of prescribed oxygen modalities and selection of homecare providers may be restricted, especially for patients who reach the 36th month and beyond.**

The same four exceptions described in section (1) above could limit physicians' choice of oxygen modalities for their patients. If a patient does not meet the exception criteria associated with a "change in medical condition", he/she will not qualify for a different oxygen modality even if the physician chooses to prescribe it for him/her. The homecare provider cannot be expected to provide alternate modalities that might cost significantly more to acquire and provide if there is not going to be a corresponding different level of payment. With more flexibility in this area, CMS will also benefit from those situations where a patient moves from a higher cost modality to a lower cost one, as in the example where a patient reaches the terminal phase of COPD they may no longer require portability for ambulation. COPD is a progressive disease that can require changes in oxygen therapy and technology, a practice discouraged by the Proposed Rule.

The 36-month cap and the Proposed Rule's policies also make it difficult for a physician to select a different homecare provider for his/her patient in the event of the patient's or the physician's dissatisfaction with a particular homecare provider. If the patient has already reached the 32nd month of continuous rental and desires to change providers, other homecare providers are not likely to accept the patient on to service if the patient only has four more rental months left. The receiving provider would be required to supply all-new oxygen equipment, accessories and services to the transferring patient and would not be able to cover those costs if only four months' rental were left. This situation will also apply to patients who simply choose to move from one area of the country to another, unless they are with a national provider with multiple locations. Even then, that provider will incur costs associated with the transfer from one location to another.

3. **The Proposed Rule is not budget neutral.**

Summit attendees support the general direction that CMS has taken in developing the Proposed Rule's differential payment levels regarding oxygen modalities. Attendees might have categorized the oxygen modalities a bit differently than CMS' approach, but in general, we understand CMS' goals of increasing access to certain agreed upon oxygen classes.

However, various attendees of the Summit have evaluated the proposed rates found in the Proposed Rule and, using CMS' own data published in this Proposed Rule as well as the one related to Competitive Bidding for DMEPOS, determined that the proposal is not budget-neutral as mandated by statute. The proposed rates appear to result in an actual reimbursement rate reduction of 10% starting in January 2007, which translates to approximately $260 million that CMS could reallocate within the oxygen benefit. More detailed analyses of the lack of budget neutrality will likely be submitted by other stakeholders, so we will not provide that analysis in this document.

However, we do recommend that CMS reallocate any necessary adjustment to the proposed payment rates primarily into the area of portable and ambulatory oxygen classes. By reallocating funds to portable and ambulatory oxygen classes, particularly in the post-36 month scenario, CMS would meet its goal of encouraging patient mobility while also appropriately paying providers for the service.

4. Increased legal liability associated with patient-owned equipment.

As a group, Summit attendees are very concerned about laypersons being responsible for servicing, maintaining and disposing of their FDA-approved medical equipment. Physician members of the Summit advised that the patients impacted are typically frail, elderly, live alone and may not be able to perform even the most "routine" maintenance on their medical equipment.

Physicians already face time and financial challenges when caring for Medicare beneficiaries and cannot be expected to advise on the equipment's performance and routine maintenance either before or after the transfer of ownership. This is a service that homecare providers have always provided in a rental situation. Now that ownership transfers to the patients, we are unclear as to what services homecare providers will be expected to provide, especially those patients who will soon own their hospital beds, wheelchairs and patient lifts, since the service and maintenance fee that was paid to providers semi-annually to help cover the costs of 24/7 on-call and other services has been eliminated.

Summit attendees are also very concerned about the possibility for increased used, unsanitary, improperly maintained medical equipment to be resold or distributed to unsuspecting future patients. eBay and other Internet vehicles are already causing problems in this area, with the unregulated sale of used oxygen cylinders (presumably stolen from providers since they are rarely sold) and other devices. CMS must confer with the FDA to obtain clear rules and regulations on the resale of medical equipment.

5. Repair and maintenance policies are not clear, and there are no standardized payment schedules for repair parts, labor or service.

In the Proposed Rule, CMS states that in the past, patients who own equipment have not had any problems accessing service for repairs and maintenance. Yet, most providers will advise that a very small percentage of capped rental HME patients ever took ownership of their medical equipment, and since oxygen was not subject to such a provision, oxygen-dependent beneficiaries rarely needed to access such services. Providers simply exchanged the equipment in the patients' homes, and returned the malfunctioning equipment to the providers' warehouse for internal repairs (without any claim billed to Medicare). CMS could see a substantial increase in access issues once a large number of patients assume equipment ownership.

Additionally, the DME MACs and DMERC have confirmed that there is no single, standardized reimbursement schedule for DMEPOS repair parts, labor or other service. If CMS expects providers to repair patient-owned equipment as soon as February 2007 when the first patients who assume ownership of their capped rental HME are impacted, CMS must establish a standardized, fair and equitable fee schedule with industry input. We will assist the agency in any way possible.

As described in the oxygen example earlier in this document, patients often desire a different model or modality of a medical device, and a change in medical condition may not apply. For example, patients who require a CPAP device to treat Obstructive Sleep Apnea (OSA), may request a device with different features, noise level, size or other attributes. Patients who rely on a nebulizer may request one that is hand-held, portable or has other features.

We are also concerned about the CMS plan to provide the DME MACs with the authority to approve an exception. The DME MACs have never been in such a role before, and will require a significant amount of training and preparation in order to do so. Also, the Proposed Rule did not

specify the clinical background, role or title of the person or persons at the DME MAC who would be authorized to approve such an exception. We request that only a licensed clinician or physician with experience in pulmonary or respiratory care be authorized to approve exceptions related to Part B respiratory equipment and services. Only a licensed clinician or physician should be able to approve exceptions for other home medical equipment exchanges, although the pulmonary/respiratory specialty need not apply to such devices as hospital beds, patient lifts, wheelchairs and other HME capped rental products/services.

In order to avoid a great deal of confusion and patient dissatisfaction upon the implementation of the final rule, we urge CMS to consult with pulmonologists from Washington, DC-based advocacy groups, home respiratory therapists and other clinical experts to develop standardized definitions of "change in medical condition." Members of our Summit stand ready to assist CMS and the DME MAC physicians in developing such criteria.

6. Transition Period Needed to Ensure Ongoing Access While Changes Are Underway

Again, we understand CMS' goals in developing certain content of the Proposed Rule that was not explicitly stated in the DRA, such as the decision to propose oxygen modality-specific reimbursement rates. However, given the nearness of the new calendar year, and the fact that the final rule will not be published until at least November, we recommend that CMS institute a transition process. Such a process would allow patients, providers, manufacturers and physicians enough time to communicate the changes with other stakeholders and make changes in their medical practice, operations, manufacturing facilities, engineering plans, branch and billing operations. If a transition period is not allowed, we are concerned that the dramatic changes to the home oxygen therapy benefit -- brought about by the confluence of the 36-month cap, competitive bidding in 2007 and any payment changes CMS elects to implement – will have a disruptive effect on the entire industry and therefore not serve either patients or CMS well.

Thank you for the opportunity to submit these comments. If you have any questions, please feel free to contact the Oxygen Stakeholder Summit Organizing Committee through the American Association for Homecare's Alexandria, Virginia, office, at (703) 836-6263.

Respectfully Submitted,

American Association for Homecare
Apria Healthcare
Inogen Incorporated
The MED Group
National Emphysema/COPD Association
National Association for Medical Direction of Respiratory Care
National Home Oxygen Patients Association

Submitter : Ms. Mary Hirsch-Erslon

Organization : Nellcor Puritan Bennett Inc.

Date: 09/25/2006

Category : Device Industry

Issue Areas/Comments

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See Attachment

CMS-1304-P-89-Attach-1.PDF

#89

WWW. cms.hhs. gov /eRulemaking
"Submit electronic comments"

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

RE: Proposed Changes to Medicare Payment for Oxygen Equipment, Oxygen Contents and Capped Rental Durable Medical Equipment

I am writing on behalf of Nellcor Puritan Bennett, Inc., a manufacturer of stationary and portable liquid oxygen delivery systems. We appreciate the opportunity to comment on the proposed changes to Medicare payment for oxygen equipment, oxygen contents, and capped rental durable medical equipment as published in Federal Register Volume 42, Parts 414 and 484 on Thursday, August 3, 2006. We support the intent of the Centers for Medicare & Medicaid Services (CMS) to revise current oxygen payment policies in an effort to reduce Medicare expenditures while still ensuring appropriate beneficiary access to oxygen therapy. However, three provisions in this proposed rule may unintentionally negatively impact appropriate beneficiary access to ambulatory modalities of oxygen therapy and should be carefully considered:

1. Price-driven proposed payment classifications;
2. Title transfer to oxygen vessels that are refilled at the supplier's place of business;
3. Payment for oxygen for beneficiaries who relocate.

Comments re: Provisions of the Proposed Regulations

1. Proposed Payment Classifications

Recommendation

We suggest that the payment classes and accompanying payment rates should be revised to reflect objective clinical criteria supportive of beneficiaries' lifestyle needs, particularly their clinical need for lightweight and long duration ambulatory oxygen systems. We defer to the clinical expertise of the pulmonary physician community to assist with the creation of more clinically-driven payment classes.

Issue

We are concerned that the proposed payment classes do not accurately reflect objective clinical criteria; rather, that the proposed payment classes are based on price and therefore that some oxygen providers may be motivated to select devices that are profitable regardless of clinical appropriateness.

Commentary

In Section *I., Classes of Oxygen and Oxygen Equipment*, it is noted that historical Medicare payment methodologies for oxygen have provided a financial incentive for suppliers to furnish low cost concentrator systems instead of gaseous or liquid systems. The proposed rule clearly states that by establishing class-specific

payment rates, CMS' intent is that the Medicare payment methodology should result in payments for oxygen and oxygen equipment that are accurate, do not impede beneficiary access to innovations in technology, and do not create inappropriate incentives for suppliers. With the classes and payment rates proposed, we believe that CMS has inadvertently proposed a price-driven oxygen product selection process that may motivate some oxygen providers to select devices that are profitable regardless of clinical appropriateness.

Conceptually, the proposed creation of payment classes reflects many of the recommendations of oxygen stakeholders (oxygen beneficiaries, pulmonary physicians, oxygen providers and oxygen manufacturers) at the 2006 Oxygen Summit. Summit participants agreed that appropriate Medicare payment for oxygen should be class-specific based upon objective clinical criteria and the judgment of the prescribing physician. For patients who are ambulatory, the most appropriate technology should be the lightest weight, longest duration oxygen system needed to support the beneficiary's clinical and lifestyle needs according to the judgment of the prescribing physician. While such ambulatory oxygen technologies may not have the lowest "upfront" costs, technologies that enable the oxygen beneficiary to be as ambulatory as possible may decrease the longer-term costs associated with a sedentary lifestyle, such as the costs of hospitalization, Emergency Room visits and medications. We are concerned that the proposed payment classes do not accurately reflect objective clinical criteria; rather, that the proposed payment classifications are based solely on price and therefore that some oxygen providers may be motivated to select devices that are simply profitable, regardless of clinical appropriateness. We suggest that the payment classes and accompanying payment rates should be revised to reflect objective clinical criteria supportive of beneficiaries' lifestyle needs, particularly their need for lightweight and long duration ambulatory systems. We defer to the clinical expertise of the pulmonary physician community to assist with the creation of more clinically-driven payment classes.

2. Title Transfer to Refilling Vessels

Recommendation

We suggest that the oxygen provider be responsible for transferring equipment title for the total number of liquid oxygen vessels or oxygen cylinders that would be present in the patient's home at any one time.

Issue

It is in the oxygen provider's best interest to provide the highest quality liquid and compressed gas oxygen vessels in order to maximize product efficiencies and minimize deliveries to beneficiaries; therefore, it is unnecessary to require oxygen providers to transfer title to *all oxygen equipment in circulation* for the beneficiary, such as vessels awaiting refill at the provider's place of business.

Commentary

We understand that CMS is required to comply with the DRA mandate that an oxygen supplier must transfer title to the stationary and/or portable oxygen equipment after a capped rental period of 36 months. However, we are concerned about CMS' proposal that "suppliers must transfer title for all equipment that will meet the beneficiary's continued medical need, including those oxygen cylinders or vessels that are refilled at the supplier's place of business." We believe CMS' intent is to ensure that beneficiaries are provided with high-quality, high-performing equipment, and we agree. In the instances of liquid and compressed gas oxygen systems, however, we don't believe it is necessary to enforce quality standards on suppliers by requiring them to transfer title to "circulating" equipment, since it is already in the supplier's best interest to provide the highest quality liquid and compressed gas oxygen vessels in order to maximize product efficiencies and minimize deliveries to beneficiaries. For example, if an oxygen provider supplied a poor quality "leaky" liquid oxygen vessel, the supplier would be required to make more frequent purchases of liquid oxygen contents and more frequent deliveries to the beneficiary's home in order to ensure an adequate supply of liquid oxygen. Because providing a high quality, high integrity liquid oxygen vessel is in the best interest of the oxygen provider's business, we believe it is an unnecessary mandate to require oxygen suppliers to transfer title to *two* liquid oxygen vessels, for instance. Similarly, if an oxygen provider does not provide enough compressed gas cylinders to allow the oxygen beneficiary to ambulate as much as he or she is able, the provider will be forced to make additional trips to the beneficiary's home in order to provide additional cylinders, assuming delivery expenses which reduce the provider's profitability. As stated, normal business practices and economic efficiencies will dictate that oxygen providers must provide high quality liquid and compressed gas oxygen systems to patients in order to maximize their business profitability. Requiring oxygen suppliers to transfer title to all equipment in circulation for a given patient creates an unnecessary financial burden for the oxygen provider and an unnecessary equipment burden for the family of the oxygen beneficiary when there is no longer a medical need for home oxygen. We recommend that the oxygen provider be responsible for transferring equipment title for the total number of liquid oxygen vessels or oxygen cylinders that would be present in the patient's home at any one time.

3. Beneficiary Relocation

Issue

The provision requiring the original oxygen provider or the beneficiary to "arrange for another supplier in the new area to furnish the item" should the beneficiary relocate may be burdensome for the original oxygen supplier, the new oxygen supplier, and most importantly, the beneficiary.

Commentary

We applaud CMS' intent to ensure that oxygen beneficiaries have access to medically necessary oxygen equipment during their entire episode of medical

need as stated in Section *G., Payment for Oxygen, Oxygen Equipment and Capped Rental DME Items*. We agree that beneficiaries should not be forced to change equipment or suppliers during the period of medical need unless he or she wants to. However, when a beneficiary *must relocate* during their period of medical need, we believe that the provision requiring the original oxygen provider or the beneficiary to "arrange for another supplier in the new area to furnish the item" will become problematic for the original oxygen supplier, the new oxygen supplier, and most importantly, the beneficiary. Under the proposed provision, if an original supplier arranges for a supplier in another area to furnish oxygen equipment and services to a patient who has relocated, neither the original nor the new supplier will receive Medicare's full allowable amount for the equipment and neither may be adequately compensated for transferring ownership of the equipment to the beneficiary after what may be just a short period of rental. Because the oxygen provider may not be fully compensated for transferring ownership of equipment to the beneficiary, once again this may cause some oxygen providers to select devices that are profitable under this narrow payment window at the expense of clinical appropriateness.. While we do not have a satisfactory solution to offer CMS at this time, we offer our services and expertise to work together with the CMS, provider and beneficiary communities to devise a satisfactory solution.

Thank you for your consideration of our concerns and comments. Please do not hesitate to contact me if we can be of assistance. I can be reached at (314) 654-3309. We look forward to working with CMS to obtain the best clinical and economic solutions for oxygen delivery systems in 2007 and beyond.

Regards,

Mary Erslon, RN, MSN, MBA
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Submitter : Ms. Linda Leone

Date: 09/25/2006

Organization : Illinois HomeCare Council

Category : Home Health Facility

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1304-P-93-Attach-1.DOC

#93

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

Dear Sir or Madame:

Thank you for this opportunity to comment on the proposed regulation entitled "Medicare Program; 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 Medicare Equipment" published in the Federal Register on August 3, 2006 (Vol. 71, No 149, page 44081). The Illinois HomeCare Council (IHCC) is a trade association representing approximately 200 home health providers and suppliers serving Illinois' most vulnerable citizens. These comments were developed by IHCC's Regulatory and Reimbursement Committee.

II. PROVISIONS OF THE PROPOSED REGULATIONS

C. Rural Add-On

While IHCC members recognize that Congressional action would be required to extend the 5% add-on for rural providers, IHCC would like to go on record supporting its retention. Staffing shortages in the home health industry have not improved since the home health prospective payment system was introduced. In fact, they have worsened, spreading beyond rural areas in to more heavily populated areas. Chicago metro-area provider organizations are struggling to find therapists to work in home care, and finding clinicians of any kind who are experienced and knowledgeable about home care is difficult statewide.

Needless to say, staffing shortages are much worse in rural areas, and gasoline prices have placed considerable pressure on rural home health provider organizations whose employees must often drive 100 miles or more round trip to

meet the needs of an individual patient. This is not a good time to discontinue the extra boost that the rural add-on has given rural providers and their patients.

D. OASIS and Pay for Reporting

CMS is proposing to implement Section 5201(c)(2) of the Deficit Reduction Act of 2005 (DRA) by examining OASIS data submission records during the time period from July 1, 2005 to July 1, 2006. Page 44088 or the preamble to the proposed regulation states that "HHAs that meet the reporting requirement would be eligible for the full home health market basket percentage increase" available for the 2007 calendar year.

IHCC members are concerned about the vague nature of the above statement. Will CMS expect that providers will have submitted every OASIS data set they are required to submit within the established time frame in order to avoid the two percentage point penalty being applied to the market basket increase? Will failure to submit a single required data set invoke the penalty? CMS' preamble is unclear on the manner in which the performance of agencies will be evaluated.

IHCC members believe that any agency making a clear, good faith effort to submit the required data should be able to avoid the penalty, and that CMS' final rule should make this policy clear.

IHCC has a number of suggestions for CMS to consider as they work in the next several years to modify the current OASIS tool and to develop process measures to evaluate agency quality.

First, IHCC strongly advocates the elimination of M0280 which asks for a prognosis of life expectancy. This item is quite subjective and adds nothing to the assessment of the home health patient that is not addressed by other OASIS items. There is no evidence-based method for estimating life expectancy that is appropriate for the use of the professionals who are completing comprehensive assessments of home health patients.

In addition, this item is used to generate a quite inappropriate and potentially inflammatory adverse event outcome referred to as "Unexpected Death." The unwarranted public relations nightmare that could arise if this score should become available to consumers and their families is of grave concern to IHCC members. CMS should eliminate both this item and the adverse event outcome measure generated from it as soon as possible. It has no potential to help home health agencies or their patients, and every potential to harm them.

IHCC also recommends reworking the OASIS items related to integumentary status, particularly the manner in which improvement is evaluated. First, M0440 provides virtually no meaningful information given how broadly the CMS instructions define a lesion. It is clear from the subsequent questions that CMS

is only interested in detailed information about three types of lesions: pressure ulcers, stasis ulcers and surgical wounds. Given that OASIS alone is not a comprehensive assessment, including M0440 without linking it to payment is meaningless. IHCC recommends eliminating this item and revising the skip patterns throughout the subsequent integumentary status items.

Consideration of the integumentary status items and the manner in which improvement and stabilization are evaluated reveals that CMS is only evaluating one aspect of improvement in wounds and their care—wound healing. Though we have seen great strides in wound care technology during recent years that have improved healing rates significantly, some wounds still do not heal. Also, the inclusion of data from managed care patients potentially skews improvement rates when only wound healing is being measured. Healing is often not the goal of a home health intervention paid for by a managed care company participating in Medicare—teaching the patient or his caregiver to be independent in wound care is frequently the goal of these time-limited interventions.

IHCC recommends that CMS re-examine and revise the manner in which they measure improvement and stabilization in wounds, and incorporate measures more like those used in the medication and equipment management items (M0780-M0820). These items reflect the acquisition of knowledge and independence in managing the patient's condition, not just improvement in the patient's health status. In this manner, the measurement of improvement and stabilization of wounds would be more fully evaluated.

IHCC members believe that M0550 should be revised to include urinary ostomies which require service delivery that is as costly and demanding as care for ostomies for bowel elimination.

While IHCC recognizes and supports the purpose of the development of patient-level process measures, members have considerable concerns about how this will be done. IHCC members believe that any process measures that CMS develops to evaluate home health agencies or for use in a performance-based system of payment adjustments must be: 1) evidence-based, objective and measurable; 2) risk adjusted to decrease subjectivity; and, 3) present no additional data submission burden to providers without adequate compensation for these activities. Process measures must also take into account the patient's ability to refuse services and to refuse to comply with the care plan.

IHCC also has concerns about the use of patient satisfaction measures in efforts to evaluate home heath agencies or to adjust their payments. IHCC believes that measuring patients' perception(s) of the care they are receiving is worthwhile, but experience shows that it is a very subjective and imprecise process. Few scientifically-developed, standardized tools are available for agencies to use. And, even when a good tool is used, it is very difficult to insure that patient's responses truly reflect the experiences about which they are being questioned.

IHCC member agencies using these tools find that they are often completed by caregivers, rather than patients, that respondents are confused about which staff members were nurses and which were home health aides, and that they often respond to the questions taking the entire constellation of service delivery personnel with whom they come into contact—the Medicare agency staff, the homemaker who provides them with services under a Medicaid-funded community support program, the folks who deliver their meals, etc. As a result, the information collected is not a reliable reflection of the patient's experience with the home health agency alone.

Finally, the few patient satisfaction tools available that are statistically tested are very expensive. The cost limits their implementation in the industry.

F. Hospital Wage Index—Revised OMB Definition for Geographical Statistical Areas

IHCC members remain concerned about the impact of implementation of the Core-Based Statistical Areas (CBSA) for wage area designation. Adoption of CBSAs alone will have a significant negative impact on several areas in Illinois, including Lake County, the northernmost part of the Chicago metropolitan area. Implementation of the CBSAs will include Lake County in the wage index area with Racine, WI, rather than with Chicago. This is an inaccurate representation of reality, and should be corrected.

In fact, Lake County draws from the same employment pool as does the Chicago metro area. Few of the professionals working in home health agencies maintain licensure in more than one state, and dual licensure would be needed in order for agencies in Lake County, Illinois to hire nurses from the Racine, Wisconsin area. This single change will cost one of IHCC's larger member agencies $70,000 in the coming year.

Sections G – L Regarding Payment for and Transfer of Ownership of Oxygen Equipment

While IHCC recognizes that CMS is faced with DRA requirements imposed by Congress, our members find it impossible to support CMS' proposed regulations related to the transfer of ownership of oxygen equipment and payment for the equipment and its contents. IHCC members believe that Congressional action and these proposals arise from an inaccurate and potentially dangerous view of oxygen and the equipment required to make it available to the Medicare beneficiaries who need it, many of whom are frail and unable to survive without this critical medication.

As has been noted by the American Association for Homecare (AA Homecare) and numerous others writing and speaking on this topic, neither Congress nor CMS seems to recognize that oxygen is a life-preserving medication. As long as

Congress and CMS continue to consider the provision of home and portable oxygen supplies and equipment to be just supplies and equipment, proposals such as this will continue to come forward, Instead, Congress and CMS should recognize that safe and effective provision of oxygen to those living in the community is a service that includes the delivery of equipment and supplies, insuring that the equipment is properly maintained and operating safely, and that the users of this medication are receiving the maximum available benefit from the medication.

It seems that CMS and Congress believe that suppliers of oxygen and related equipment are making too much money from Medicare. Even if this were the case, these proposals will hurt consumers much more than they will benefit Medicare. Unfortunately, it seems that the manner in which CMS has historically viewed the oxygen benefit contributes to this view. Because suppliers have been paid for equipment and supplies, instead of for providing an oxygen service that includes equipment, supplies, equipment maintenance, and evaluation of the patient's ability to gain the available benefits, suppliers have had to find ways to support these activities from the amounts paid for the equipment. If CMS were to update its view, a more rational payment system could be developed that would safeguard against over-paying for the equipment while at the same time providing support for the service delivery aspects of the provision of oxygen in the home. IHCC recommends a comprehensive re-thinking and revision of the oxygen benefit under Medicare.

IHCC wishes to go on record supporting the comments made by AA Homecare in their letter on this proposed regulation. Many of the proposals are unworkable and show a real lack of understanding of how the provision of oxygen services works in the real world. Similarly, CMS' expectations of the role frail, elderly Medicare beneficiaries will be able to play in the maintenance of oxygen equipment are unrealistic. Not only will many of these individuals be physically unable to perform the tasks required, many will also fail to understand why they are important. Finally, CMS suggestion that Medicare beneficiaries will be able to rely on the internet to secure needed maintenance manuals and other technical documentation is unrealistic for many of the patients IHCC members serve, particularly in rural areas where the closest computer with internet capability may be miles and miles away.

Health Care Information Transparency and Health Information Technology

While IHCC recognizes the critical role that the Certification Commission for Health Information Technology (CCHIT) potentially plays in advancing the adoption and usefulness of computerized information, our members are concerned about the potential impact of these proposals on agency costs. In the preamble, CMS quotes the 2007 Budget as stating that "the Administration supports the adoption of health information technology (IT) as a normal cost of doing business...." IHCC members recognize that IT is a critical piece of both

patient care and agency operations, but do not feel that CMS has sufficiently supported the significant investments agencies have had to make in the past several years to establish and maintain capabilities.

IHCC supports proposals that will facilitate the development and adoption of software that will communicate with other software, and is aware of CCHIT's role in this movement. IHCC's reservation about the proposal focuses on the potential financial impact on providers who have invested significantly in IT. IHCC wants CMS to pay its fair share of IT costs. IHCC also wants to be sure that CMS will not take actions that will negate the investments of agencies to date by suddenly rendering their software obsolete. Information technology transitions must be made in a measured and realistic manner, not overnight via the adoption of a new regulation.

Sincerely,

Linda Leone
IHCC President

Submitter : Mrs. Stacey Smiddy **Date:** 09/25/2006

Organization : Lambert's Health Care

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

see attachment