Via Hand Delivery and Electronic Submission

September 25, 2006

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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

[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 analysis shows 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

[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 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.

[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.*"

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.

D. The Proposed Rule Creates Significant Operational Hurdles for Providers

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 provider 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 provider 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 provider 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

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

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). ___.