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

Organization : American Lung Association

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

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

#58

NATIONAL HEADQUARTERS

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AMERICAN LUNG ASSOCIATION®

September 25, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201

RE: CMS-1304-P

To Whom It May Concern:

The American Lung Association is one of the nation's oldest voluntary health organizations. Founded in 1904 to combat tuberculosis, our mission continues to prevent lung disease and promote lung health. Through research, advocacy and education, the American Lung Association works to fight all lung diseases. Chronic Obstructive Pulmonary Disease is a great concern to the Lung Association. COPD is the fourth leading cause of death in America, claiming the lives of 122,283 Americans in 2003. In 2004, 11.4 million U.S. adults (aged 18 and over) were estimated to have COPD but close to 24 million U.S. adults have evidence of impaired lung function, indicating an under-diagnosis of COPD.

On behalf of millions of Americans with lung disease and especially those Medicare patients who require oxygen, the American Lung Association is pleased to submit these comments. Home and portable oxygen systems enable many patients to lead active lives. However, some patients are quite infirm and the smallest tasks of daily life are a struggle.
We appreciate that Centers for Medicare and Medicaid Services (CMS) has attempted to address many questions that patients are asking regarding oxygen systems by clarifying how the 36-month capped rental system will operate, ensuring the CMS will continue to pay for supplies and accessories and replace oxygen equipment after the expiration of the equipment's useful lifetime.

Patient health must be the foremost consideration and CMS must ensure that any change to the provision of oxygen to Medicare patients protects the patient's health.

Quality of Care
Patients need the most appropriate oxygen system based on their specific health needs. For patients that are able, an oxygen system that ensures the

patient the maximum mobility and independence is preferred. The Lung Association appreciates that CMS has recognized that different oxygen systems have different costs by proposing six classes of equipment that reflect different costs. We do not have independent data or analysis to determine if the payment rates are appropriate, although we are concerned that CMS noted the budget neutrality seemed to be a primary factor in determining the payment amounts. We request that CMS monitor the impact of the new payment categories on patients to ensure that the new payment system does not create unintended consequences such as disincentives for providing patients the most medically appropriate equipment that best meets their health needs. This is critically important during both the 36-month rental period and during the ownership period. As a patient's medical needs change or if new technology that can improve the patient's health or quality of life becomes available, the appropriate oxygen equipment must be made available to the patient.

Continuity of Care

A number of questions arise from the proposed regulations concerning continuity of patient care. Under the current rental system, patients have the opportunity to switch providers if the patient is dissatisfied for any reason. In many communities, this provides the patient important leverage to ensure good service and support. Under the 36-month capped rental system, will a patient have the flexibility to switch to a new provider? At what point in the 36-month rental period will a new provider be unwilling to accept a new patient? After title transfer, will a patient be locked in with their previous provider? Without the leverage to switch, will patient support suffer – i.e., will individual patients at some point be a captive market for a provider? What happens to a patient if their provider goes out of business or exits the market? Who will support those patients during the rental period or the patient ownership period? Will patients be in essence orphans without a provider for support or access to maintenance? If an equipment manufacturer goes out of business and therefore the warranty ceases, who will provide the patient with warranty coverage, or will CMS replace the equipment?

Many patients travel and spend part of the year in another part of the country. Currently, these patients arrange with their supplier to provide equipment at their destination. After the 36-month rental period and ownership is transferred, will the patient need to rent or purchase additional equipment at their own expense or ship their own equipment, which again raises cost concerns? CMS must clarify the rules to ensure that patients continue to receive the equipment and servicing required.

Protecting Patient's Health

Medicare needs to clearly define and delineate what is routine maintenance and what is non-routine for each type of oxygen system in language that is easily understood by patients and their caregivers. The proposal indicates that patients or their caregivers will be responsible for the "routine maintenance and servicing."

The proposed rule is not clear about what testing will be considered routine. CMS indicates that patient responsibility for routine maintenance is a reiteration of existing regulation.

Anecdotally, we are aware of suppliers providing ongoing "routine" maintenance for their patients. Properly functioning and well-maintained equipment is in the best interest of the patient as improperly functioning equipment could lead to adverse and severe health outcomes, including hospitalization. Further, patients with compromised lung function may not be physically able to perform such routine maintenance tasks that require bending over to remove a filter. Moreover, exposure to dirty and dusty filters is problematic to patients with such compromised lung function. The proposal clearly creates incentives for suppliers to ensure the equipment does not fail by holding the supplier and/or manufacturer liable for replacing failing equipment. Is this an adequate incentive to protect patient's health?

If equipment is not operating properly or if a patient believes that the equipment is not functioning properly, how is the patient to determine if the needed servicing or maintenance is routine or non-routine? We understand that there are many situations when a patient is having a problem with their equipment and patients place a service call with their supplier and the repair or service to resolve the problem turns out to be minor or routine. But patients should be able to call on their supplier to check equipment and perform maintenance to protect their health. Further, suppliers should be fairly compensated for providing this support. CMS proposes that this is the responsibility of the patient or the caregiver, yet there is no clear affirmative responsibility to ensure that the patient and/or caregiver are properly trained and that they can demonstrate the knowledge and ability to perform the routine maintenance. The proposal suggests "*We expect that the supplier, when transferring title to the equipment to the beneficiary, would also provide to the beneficiary any operating manuals published by the manufacturer which describe the servicing an owner may perform to properly maintain the equipment. We also believe that these owner manuals are commonly available at the various manufacturer Web sites. In addition, the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) supplier standards at § 424.57(c)(12) require suppliers to provide the beneficiary with necessary information and instructions on how to use DME items safely and effectively. We believe that after receiving this information, and after becoming familiar with the equipment during the 13 or 36-month rental period, the beneficiary and/or caregiver should be very knowledgeable regarding the routine maintenance required for the item. All non-routine maintenance of beneficiary owned oxygen equipment and capped rental items which would need to be performed by authorized technicians would be covered as reasonable and necessary maintenance and servicing.* CMS proposes to shift much of this burden on the patient. There should be an affirmative requirement that manuals be provided to the patient. A non-medical person should also easily understand these manuals. It should not be incumbent upon the patient to need to secure such manuals from the supplier, manufacturer or from a website. In addition, patients will need training at the end of the rental period and both patients and their caregivers must be able to demonstrate an understanding of the operation of the equipment. Documentation should be required to demonstrate proof of this training.

Moreover, what will occur after the 36-month rental period is over and the title transfer has taken place? Is it the expectation that the suppliers will continue to perform this routine service? Will patients need to rely on the good will of their supplier to perform this service? Do suppliers to need to bear these costs without payment? Will patients be required to pay for this service directly? If the latter is the case, we are concerned that this would provide a disincentive to

patients to seek service of their equipment, resulting in potential harm to the patient, and almost certainly, increased hospitalizations.

The American Lung Association believes that suppliers should perform regular inspections and testing of this equipment. Suppliers should be inspecting concentrators at least every 60 days. For liquid and gaseous systems, suppliers should be inspecting the equipment when delivering refilled tanks.

In conclusion, the 36-month capped rental system still is a cause of significant concern to the American Lung Association. In moving forward with this rulemaking, we respectfully request that CMS reevaluate the approach to routine maintenance, service and testing so as not to place an additional burden on the patient and caregiver.

Thank you for consideration of our comments.

Sincerely,

John L. Kirkwood
President and CEO

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

Organization : **Coalition of Respiratory Care Manufacturers**

Category : **Device Association**

Issue Areas/Comments

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See Attachment for comments to Provisions of the Proposed Regulations, section G-L.

CMS-1304-P-59-Attach-1.DOC

COALITIONS OF

Enteral Nutrition Manufacturers
Respiratory Care Manufacturers
Wheelchair Seating Manufacturers
Wound Care Manufacturers

#59

Sent Via Electronic Transmission

September 25, 2006

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1304-P
PO Box 8014
Baltimore, MD 21244-8013

Re: Comments Regarding CMS-1304-P: Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 Changes to the Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment; Proposed Rule

Dear Dr. McClellan,

The Coalitions of Respiratory Care Manufacturers, Wound Care Manufacturers, Enteral Nutrition Manufacturers, and Wheelchair Seating Manufacturers ("Coalitions") respectfully submit the following comments on the CMS-1304-P proposed rule. Our comments will reflect the order that the issues were presented in the proposed rule. While the majority of our comments refer to oxygen, we also have concerns relating to provisions of the Deficit Reduction Act that impact the Medicare beneficiaries who use capped rental devices. Many of the issues that we have concerns about and our recommendations are echoed in many of our members' comments such as Sunrise Medical and Inogen.

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

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

Implementation Date

The proposed regulation states that the effective date of January 1, 2007 will be for all claims for oxygen and capped rental items. Although this may be acceptable for certain capped rental items, the timeframe for the oxygen equipment provisions is inadequate. There are significant decisions that must be made by beneficiaries and medical equipment providers that simply cannot be accomplished in the two months prior to a January 1, 2007 effective date. In addition, tasks performed by the providers such as reviewing their patient mix, determining the appropriate patients for the new technologies, securing funding for the capital investment in the new equipment and deploy that equipment all before January 1, 2007 cannot be accomplished in two months.

Recommendation:

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

Furnishing Services for Entire Period of Medical Need

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

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

payment every 6 months once the cap is reached. For oxygen, the current system continues to make payments for the entire period of medical need with no time limitation.

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

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

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

Replacing Equipment Once the Rental Agreement has Commenced

We have concerns with CMS's meaning of "modality." The proposed rule appears to misuse the well-established clinical definition of "modality" in favor of a generic use of the term tied to specific categories of equipment. When clinicians consider oxygen modalities, there are traditionally three categories:

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

In the proposed regulation, rather than consider oxygen modalities the way that clinicians define them, CMS will create new payment categories and redistribute reimbursement among certain "new" and existing categories of oxygen equipment. For example, the regulation discusses new payment categories for transfilling units and portable oxygen concentrators and equates these to payments for "new" modalities. From a clinical viewpoint, these are not new modalities but rather new technologies. For example, compressed gas is often used for portable oxygen needs and is provided in cylinders that

traditionally have been filled at the medical equipment provider's place of business. New technologies are now available for patients to fill their cylinders at home, still a compressed gas modality, using a transfilling system. CMS recognizes the evolution of technology with this proposed regulation by creating a category for transfilling technology; however, both the traditional cylinder method and the transfilling systems are commonly considered "compressed gas" modalities by the clinical community.

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

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

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

Medical Necessity Exception for Equipment Changes
We recognize that CMS delegates the authority for determining medical necessity criteria to the Durable Medical Equipment Program Safeguard Contractors (DME PSC). The proposed rule delineates an exception for medically necessary changes; however, it is the local coverage determination (LCD) that will provide the details of this provision. We are very concerned that the LCD will not be published in time to allow clinicians, beneficiaries and providers an adequate public comment and notice period.

Medicare contractors typically make medical necessity determinations and delineate the coverage and documentation requirements for such in their LCDs. In developing medical necessity requirements for modality changes, CMS should take into consideration the medical benefit that a change in equipment type may provide in terms of ambulatory ability and participation in activities of daily living. One common reason for patients to choose lighter, more portable oxygen delivery systems is for the increase in mobility these systems afford. In the case of oxygen patients, this is not simply a "lifestyle" choice.

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

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

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

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

H. PAYMENT FOR OXYGEN CONTENTS FOR BENEFICIARY-OWNED EQUIPMENT

Title Transfer of Oxygen Equipment

We disagree with the requirement that providers must transfer both the cylinders at use in the beneficiary's home and an equivalent number of cylinders used for exchange. Requiring title transfer of two sets of cylinders – those used in the home and those maintained at the provider's business – is a considerable depletion of assets and a significant financial burden for the provider. Furthermore, the logistical issues of assigning specific cylinders to specific beneficiaries will require tracking systems that are not currently utilized and will result in further financial expenditures to implement.

Recommendation:

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

Safety Issues Associated with Beneficiary-Owned Equipment

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

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

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

Prior to the DRA, a legal mechanism existed to pursue sellers who technically did not have title to oxygen equipment (i.e., prior to DRA title transfer, the home equipment provider held title). Often manufacturers and providers confronted sellers where ownership was unclear. When

confronted by the homecare providers' Legal or Compliance departments, the seller usually stated that he/she bought left over equipment at an elderly neighbor's garage sale, or they retracted the sale of an item for which they could not produce a valid receipt. EBay sellers have begun transporting used oxygen cylinders through United Parcel Service (UPS), FedEx and other air carriers without the Transportation Safety Administration's (TSA) or the Federal Aviation Administration's (FAA) knowledge.

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

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

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

Recommendation:

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

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

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

I. CLASSES OF OXYGEN AND OXYGEN EQUIPMENT

Appropriateness of Payment Structure (p. 73)

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

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

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

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

visits, we believe the proposed add-on fee of $10 per month or a total of $360 for the life of the asset is inadequate. On average, transfilling units cost $2,500 - $3,000 and portable oxygen concentrators are similarly priced, averaging approximately $2,500 - $3,500.

Recommendation:
Given the high acquisition cost of this equipment, CMS should reconsider the proposed fee schedule for these new technologies and increase reimbursement to accurately reflect the cost of the equipment and provide reasonable incentives for continued development of these types of technology. The Coalition members are interested in working with CMS to help determine the appropriate reimbursement in order to maintain budget neutrality.

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

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

Recommendation:

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

J. PAYMENT FOR MAINTENANCE AND SERVICING OF OXYGEN AND OXYGEN EQUIPMENT AND CAPPED RENTAL ITEMS

Access to Providers Willing to Provide Maintenance and Service
CMS asserts that "[W]e are not aware of instances where beneficiaries have encountered problems in finding providers to provide maintenance and service of beneficiary-owned DME." This statement is followed by CMS' stated belief that under the new payment

system, beneficiaries will continue to encounter no problems when seeking maintenance and service. We believe this assumption is erroneous.

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

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

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

Recommendation:

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

Failure to Account for Value of Clinical Services

While there is discussion in the proposed rule regarding payment for maintenance and service, there is no provision for reimbursement of after-hour, emergency or clinical services after the 36th month rental payment. The value of the home care provider to the physician community in these situations should not be underestimated. It is not

uncommon for a physician to ask a home oxygen provider to conduct an in-home clinical patient assessment on a long-term oxygen patient so that the licensed homecare clinician can listen to breath sounds, discuss the patient's level of adherence to the physician's prescribed regimen, and document other findings in a summary to be provided to the physician. These in-home clinical assessments are extremely important to ensuring high quality care for patients. However, this activity is sustainable only if CMS establishes a new code and an appropriate reimbursement rate. Patient assessment, training, education and monitoring currently comprise nine percent of providers' total costs of caring for patients. Providers cannot provide these assessments without fair reimbursement rates because they would constitute an illegal inducement and raise other fraud and abuse concerns.

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

Definition of Maintenance and Service (p. 90)
CMS issued conflicting guidelines as to what will be reimbursed by the program once the title for oxygen equipment transfers to the patient. In one section, CMS stated that beneficiaries or their caregiver would be able to perform routine maintenance (p. 91) and includes "testing...regulating." Shortly after (p. 92), CMS indicates that if special tools are required to perform that maintenance – tools which patients would not typically own, such as an oxygen analyzer – then reimbursement would be provided by Medicare to the provider (p. 92). These two statements appear to be in conflict since testing and regulating oxygen equipment both require specialized tools.

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

While the simple task of cleaning an external filter may seem easy to the able individual, experience shows that they are complex for many Medicare-age beneficiaries. In fact, as

reported by many of our dealer-customers, few are able to perform simple troubleshooting of their equipment despite professional guidance via phone and require home visits to assure the equipment is functioning properly. CMS only needs to recall the decision "requiring" beneficiaries to change their own power wheelchair batteries. That decision by the Durable Medical Equipment Regional Carriers (DMERCs) was reversed after learning from medical equipment providers that, despite what seems like a simple task, beneficiaries often reversed polarity on the batteries and ruined the electronics on the chair.

Recommendation:

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

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

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

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

In addition, oxygen technology and capped rental service and maintenance HCPCS codes should be developed with a corresponding fee schedule to be used by suppliers.

Warranty Repair

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

Recommendation:

The Coalition members will work with CMS to provide further information about our product's warranties and their limitations. CMS should obtain warranty information from other manufacturers in order to craft maintenance and service and replacement policies

that benefit both the beneficiary and the provider and ensure that critical services are available.

We appreciate the opportunity to comment on this proposed rule and would welcome the chance to discuss our comments and concerns in greater detail at your convenience.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director

Submitter : Mrs. Tammy Zelenko **Date:** 09/25/2006

Organization : Advacare Home Services, Inc.

Category : Health Care Industry

Issue Areas/Comments

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

The proposed changes to the ownership of oxygen equipment, which would transfer ownership to the beneficiary will not ensure that proper testing and maintenance of the equipment is being done on a regular basis. This could cause the patient to receive over or under medication, since oxygen is a drug. The concern of asking the sick, weak, and inexperienced patient to take care of changing filters, tubing, cannualas, and back-up systems is not a realistic approach to providing care in the home.

Our beneficiaries struggle daily just to make ends meet, and by adding this additional burden to them will ultimately lead to higher costs or shifting costs from the Part B benefit to the Part A benefit, which will be caused by patients not getting the proper level of oxygen, therefore ending up in their local hospitals emergency room. The services that the Home Medical and Respiratory companies provide are just that... a service. We are in a service industry, and the equipment purchase only represents about 28% of what our operational costs make up.

We will not be able to provide the ongoing service level to these patients, which includes 24/7 days a week emergency service should the equipment break down or there are power outages. The Home Medical Equipment industry is a solution to health care, because we allow the patients to be discharged out to the hospital quicker and recover at home with loved ones.

I urge you to review the analysis of your cost savings by ensuring that you have considered all of the costs associated with providing a quality service to your beneficiaries.

Submitter : **Ms. Jacquelyn McClure** **Date: 09/25/2006**

Organization : **The MED Group**

Category : **Other Health Care Provider**

Issue Areas/Comments

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See attachment, MEDDRAComments, for comments to Medicare Program; Home Health prospective Payment Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 (DRA) Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment; Proposed Rule [CMS-13040P] RIN 0938-AN76.

CMS-1304-P-61-Attach-1.DOC

#61

THE MED GROUP

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]

The MED Group (MED) respectably submits the following comments in response to the Centers for Medicare and Medicaid Services' (CMS') request for comments to the above captioned proposed rule. The MED Group is a nationwide network of independently owned home medical equipment and rehab technology companies. We have approximately 250 member companies with over 800 operating location across the country. Our member companies provide products and services to hundreds of thousands of Medicare beneficiaries within their local communities. Please visit www.medgroup.com for more information on our organization and membership.

We also are members of and serve on the Board of Directors of the American Association for Homecare (AAH).

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

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

THE MED GROUP
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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.

The MED members agree that it is worth examining 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, 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

[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.

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 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

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[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.

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]

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

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% of supplier's costs. These administrative and support costs include: obtaining patient information and related

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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] Cite to Morrison study.

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.

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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.

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 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.

2. 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, The MED Group 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

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[22] DMEPOS Quality Standards published at: cite to 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).

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]

Our 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. The MED Group, and I personally, have 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

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[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.

[27] Lewin at _____

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 equipment over another will be arbitrary. We at MED are 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 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

[28] 42 U.S.C. §1395u(b)(B)(i)(ii).
[29] Cite to APA

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 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 our member 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. But our membership, 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

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

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. MED 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.

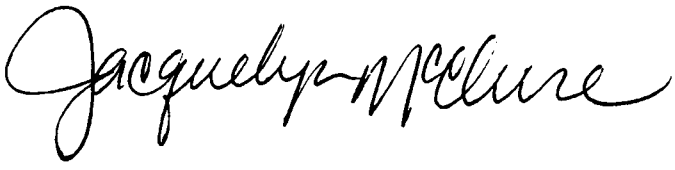
[34] 42 U.S.C. §1395m(a)(1), 2006.
[35] §1128b ___.

III. CONCLUSION

Thank you for your detailed review of these comments and those submitted by the industry associations. As 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.

The MED Group stands ready to work collaboratively with CMS on this matter and other Medicare DMEPOS issues. Please do not hesitate to contact me directly if we can be of further assistance.

Sincerely,



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