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Via Electronic Mail
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September 25, 2006

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

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

Dear Dr. McClellan,

Care Medical and Rehabilitation Equipment, Inc., is pleased to submit comments on CMS' Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment; Proposed Rule [CMS-1304-P]. Established in 1970, Care Medical is an independent, family-owned and operated company that has grown to include ten branch locations throughout Oregon and Washington states. Care Medical specializes in home medical equipment and

services, including medical oxygen, ventilators and sleep apnea products and has been serving the needs of the Pacific Northwest for over 35 years.

Introduction

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

Care Medical agrees 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.

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.[1] 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.[2] The clinical course of COPD is characterized by chronic disability with intermittent acute exacerbations that

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

[2] 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.

occur more often during the winter months. The World Health Organization has projected that COPD will rank fifth in 2020 as a global burden of disease.[3]

COPD is a progressive disease that often compounds and adversely impacts several other disease processes including diabetes, congestive heart failure, sleep apnea and coronary artery disease. Long-term oxygen therapy is the *only* treatment proven to treat the pulmonary destruction caused by COPD.

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.[4] 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. While oxygen therapy is the #1 expenditure by Medicare under the Durable Medical Equipment (DME) benefit, it represents a minute fraction of overall Medicare expenditures and is significantly less than spending on inpatient and physician services. In 2004, there were an estimated 1.4 million Medicare beneficiaries receiving oxygen therapy resulting in expenditures of over $2 billion dollars.

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. Care Medical is concerned that the rules being contemplated will restrict access to new technologies, create safety issues, impose a financial burden on suppliers 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.

Overall Comments

The proposals in the NPRM are based on a flawed policy that will create unnecessary hurdles to access for Medicare beneficiaries. We understand that the DRA dictates the transfer of ownership of oxygen equipment and capped rental DME to beneficiaries at the end of the

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

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

statutory period of continuous use. The DRA is based on faulty assumptions about the range of administrative and support services that providers furnish to beneficiaries who receive medical equipment and the cost of furnishing those services. In fact, the acquisition cost for oxygen equipment is only a small component of the overall cost of furnishing oxygen therapy to Medicare beneficiaries safely and effectively.

The most comprehensive data on the cost of furnishing home oxygen to Medicare beneficiaries shows that equipment acquisition costs are only a small portion of the overall cost to service beneficiaries. A recent study by Morrison Informatics found that equipment acquisition was only 28% of a provider's total cost for servicing Medicare beneficiaries. Morrison collected and analyzed data from homecare providers that collectively serve more than 600,000 Medicare beneficiaries receiving oxygen therapy in their homes. This large sample represents more than half of the Medicare population receiving oxygen therapy at home. The study found that nearly three-quarters (72%) of the cost of providing home oxygen therapy to Medicare patients represent services, delivery, and other administrative and support services that benefit patients. Only about one-quarter, 28%, of the cost represents oxygen equipment.
Moreover, the provisions of the NPRM compound the problems inherent in the DRA requirement that title to oxygen equipment transfer to beneficiaries after 36 consecutive rental months. Patients may find it difficult to change providers or oxygen modalities, especially in months 37-60. Patients with high mobility requirements may experience the most difficulty changing suppliers or oxygen modalities. Physicians who want to change their patient's oxygen regimen may likewise experience difficulty.

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 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.

Grandfather Beneficiaries Receiving Oxygen before January 1, 2007

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

the NPRM should not apply to any beneficiary receiving Medicare covered oxygen on December 31, 2006, although the DRA transfer of ownership will apply to these beneficiaries.

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. One of the stated goals of the regulation is to create new product classes that promote the use of new technologies such as portable concentrators and transfilling systems. We agree with this objective; however, there are significant decisions that must be made by beneficiaries and medical equipment suppliers that simply cannot be accomplished in the two months prior to a January 1, 2007 effective date. This is a crucial point, given the restrictions outlined in later sections that limit the circumstances in which a supplier may change equipment once a patient has been accepted for services. In effect, the supplier must analyze their patient mix, determine the appropriate patients for the new technologies, secure funding for the capital investment in the new equipment and deploy that equipment all before January 1, 2007. Those tasks simply cannot be accomplished in two months.

Recommendation:

We recommend that CMS allow a grace period for implementation of the section outlining when suppliers may change equipment. Permit suppliers, with beneficiary consent, to change equipment without proof of medical necessity for claims with dates of service prior to June 30, 1997. This recommendation would provide for implementation of the new payment rates and product classes but not penalize beneficiaries and suppliers who have to make complex oxygen equipment decisions on the currently proposed short timeframe.

Ownership Issues for Oxygen and DME

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

a) Providers would have to track equipment by serial number in order to make sure that the beneficiary receives title to the equipment that was delivered on the first day of continuous use. This will be very difficult for providers to track internally if the concentrator or another type of equipment is brought into the facility for repairs. Importantly, larger providers may have regional or even national distribution centers which stock and service equipment. Other providers may use contractors to service equipment.

b) It is not clear how the "break in service" rules will apply to oxygen equipment. Will CMS simply apply the existing break in service rules to oxygen? There are a number of situations in which a beneficiary may have a short term need for oxygen that should not be included in the period of continuous use.

c) Similarly, CMS did not respond to AAHomecare's question on 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.

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

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

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. Care Medical believes that title to backup equipment does not transfer under the coverage rules established by the oxygen LCD. The LCD states that backup equipment is non-covered because it is provided solely for the convenience of the beneficiary. Under the LCD, Medicare will not pay for backup oxygen equipment because the equipment is not medically necessary. To the extent that CMS has not made any rental payments for the backup equipment, and because the equipment is not medically necessary, title to the equipment should not transfer to the beneficiary under the DRA.

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 supplier, that supplier 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 supplier – 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 supplier's service area. While correct that a beneficiary may choose a new supplier when they relocate either on a temporary or permanent basis, even the current payment model is problematic for capped rental items. Suppliers 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 supplier 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 supplier 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 supplier 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 supplier's 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 supplier 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 supplier with each passing month in a rental arrangement.

Recommendation:
CMS should develop a reimbursement mechanism that allows for payments to a new supplier when a beneficiary chooses to relocate or elects to have services delivered by a new supplier. The new supplier 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 supplier.

Replacing Equipment Once the Rental Agreement has Commenced

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

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

1. Liquid oxygen
2. Compressed gas

3. Oxygen extraction from room air (i.e., concentrator)

In the proposed regulation, rather than consider the oxygen modalities in the way that clinicians define them, CMS proposed to create new payment categories and redistribute reimbursement among certain "new" and existing categories of oxygen equipment. For example, the regulation discusses new payment categories for transfilling units and portable oxygen concentrators and equates these to payments for "new" modalities.

From a clinical viewpoint, these are not new modalities but rather new technologies. For example, compressed gas is often used for portable oxygen needs and is provided in cylinders that that traditionally have been filled at the medical equipment supplier'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 suppliers can change "modalities," would seem to be at odds with the stated intent of CMS to encourage adoption of the new technologies.

Recommendation:
CMS must clarify their interpretation of "modality" in the final rule. Assuming it is not the clinical community's definition, CMS must define the specific circumstances when patients may be changed from one type of equipment 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 category to another (i.e., delivered cylinders vs. cylinders self-filled in the home); and,
b. Payment policy that allows for full reimbursement when the patient changes from one equipment type to another, even if that change occurs during the first 36 months of rental.

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. Medical literature has thoroughly documented the benefit to pulmonary patients of increased activity levels.

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:

a) 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;
b) How providers will be reimbursed for changing equipment;
c) Specific documentation requirements for both the supplier 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[5], it appears impossible that the DME PSCs will be able to meet a January 1, 2007 implementation date.

Periods of Continuous Use

Continuous Use for New or Additional Equipment Redefined

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

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

Secondly, there has been a long-standing "break in service" policy that if an interruption in service exceeds 60 consecutive days (plus the days remaining in the rental month in which the need ceases), the provider may submit a new prescription and medical necessity information, along with an explanation for the interruption, and begin a new period of rental.[6] There is no discussion in the proposed regulation regarding CMS' intention to retain this continuous use policy.

Recommendation:

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

CMS should also clarify if the current definition of "break in service" will apply under the new DRA provisions.

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

[6] CMS Internet Only Manual, Pub. 100-4, *Medicare Claims Processing Manual*, Ch. 20, §30.5.4

Acceptance of Assignment

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. 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.[7] 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.

As noted in the propose rule, current Medicare regulations regarding assignment allow suppliers to choose whether to accept assignment on a claim-by-claim basis or on all claims. CMS proposes that in order to allow a beneficiary to make an informed choice, the supplier must disclose to the beneficiary its intentions regarding whether it will accept assignment of *all*

[7] Cite to APA

monthly rental claims during the period of medical necessity, up to and including the 36th month in the case of oxygen equipment or the 13th month in the case of capped rental items. In a subsequent section (p. 67), CMS states an intention to post information on the CMS and/or Medicare contractor web site "...the percentage of cases in which the supplier accepted assignment during the beneficiary's entire rental period." This later statement appears to contradict the earlier provision requiring that, once a supplier agrees to accept assignment, it must be for all claims during the period of medical need.

Recommendation:
CMS must clarify in the final regulation whether a supplier may accept assignment for a portion of the rental period. For example, can a supplier accept assignment for the first 15 months of an oxygen equipment rental and file non-assigned claims for the remaining 21 months, assuming the supplier complied with the requirement to fully disclose to the beneficiary at the start of the rental agreement the extent of their financial liability during the period of medical need? Allowing this type of assignment arrangement would still further the stated intent to create reasonable rules for suppliers and ensure that beneficiaries have the information necessary to make informed choices.

Payment for Oxygen Contents For Beneficiary-Owned Equipment

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

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

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

FDA Issues
The proposal that title to equipment would transfer to the cylinder or vessel currently in use by the beneficiary as well as the one being refilled by the supplier 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 a specific set of cylinders/vessels. Suppliers also have specific labeling requirements imposed under FDA and DOT rules that would be difficult for them to comply with under the NPRM proposal. In other words, the equipment could not be labeled with the beneficiary's name.
Currently, 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 manufacturer's specification. The medical oxygen provider should be reluctant to assume responsibility for a cylinder or liquid oxygen container that is not under its control under these circumstances.

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.

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 supplier 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 suppliers 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 supplier of contents. The new supplier 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 supplier 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 suppliers 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, something required for accredited providers must comply with the infection control requirements of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or other accrediting organizations.[8] 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, suppliers 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.

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

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.
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.
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.

Classes of Oxygen and Oxygen Equipment

Appropriateness of Payment Structure

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 suppliers." 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 supplier 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.

Title Transfer for Transfilling Equipment

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

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

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

All three types of equipment provide oxygen directly to the patient. Furthermore, two of the three transfilling units on the market today are combined stationary concentrators and transfill units that deliver oxygen directly to the patient. There is only one transfill product that serves solely as an oxygen transfilling device - Sunrise Medical/DeVilbiss' iFill®. The iFill® system is

unique in that it operates independently from a stationary concentrator. In other words, a beneficiary can have a stationary concentrator in their living room and fill oxygen cylinders with an iFill® unit located in a spare bedroom. It does not provide oxygen directly to the patient like other "dual use" units in the marketplace today.

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

Recommendation:

a. CMS has the authority to interpret statutory language in the manner described above and should do so in order to be consistent with long-standing definitions of oxygen equipment.

b. Transfill technology is a significant capital investment for medical equipment providers and transfer of title should not occur at the end of the 36-month rental period. For those products that serve solely as a transfilling device, allowing continued provider ownership of the equipment past 36 months will afford providers the opportunity to reissue transfilling units to another beneficiary when the unit is no longer medical necessary. This would result in the provider gaining the benefit of potential re-coupment of acquisition costs. We believe the provider community would support the loss in revenue resulting from leaving the unit in the beneficiary's residence without compensation past 36 months in exchange for retaining ownership of the unit.

c. Products included in HCPCS code K0738 should be restricted to those products that meet the definition of the code. Specifically, a home compressor that is used to fill oxygen cylinders and not "dual use" devices (i.e., devices that are both a stationary concentrator and transfilling device).

d. A new HCPCS code should be created to describe "dual use" devices. Creation of a new HCPCS code to describe these devices will allow CMS and its contractors to distinguish which devices will not undergo title transfer. We recommend Kxxx1 with the following descriptor:
Kxxx1 – Stationary gaseous oxygen system, rental, dual use, includes stationary concentrator component and capability to fill portable oxygen cylinders, includes portable containers, regulator, flow meter, humidifier, cannula or mask and tubing.

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.

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

Recommendation:

a. As noted above, CMS should re-evaluate the distribution of payments among the various classes of equipment and support the transition to newer technologies such as portable oxygen concentrators and transfilling systems through higher reimbursement in those product categories.

b. CMS should develop a long-term reimbursement strategy for gaseous and liquid content payments that furthers the goal of encouraging transition to newer technologies. This must be a long-term goal since providers currently have patients utilizing older technologies and require increased payment support to continue servicing those patients until physician education can be accomplished.

c. Since the type of oxygen therapy utilized by the beneficiary is often driven by the physician, CMS should work to educate physicians about the benefits of newer technologies and encourage the movement of oxygen therapy away from older, more expensive equipment models.

Billing for Equipment Repairs

Billing for repairs needs to be addressed through the issuance of new codes. In addition there should be a code for the more extensive testing and maintenance that oxygen equipment requires.

Also billing for repairs will require specific guidance on the type of documentation that CMS expects on claims for repairs. Currently there is not a high volume of repairs because oxygen has been a continuous rental and most beneficiaries have chosen to continue to rent capped rental equipment. CMS and the Medicare administrative contractors (MACs) should be prepared for an increase in the volume of claims for repairs. 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.

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 "We are not aware of instances where beneficiaries have encountered problems in finding suppliers 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 service standards for suppliers of home oxygen therapy. We are unclear why the government would completely reverse its position, not recognizing the need for the many critical support services that home oxygen suppliers provide to patients. Specifically, the OIG found: "The importance of support services, such as equipment and patient monitoring, for oxygen concentrator patients is critical for the proper functioning of the equipment as well as the effectiveness of the therapy it provides."

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.

require specialized tools.

Even "routine" tasks are often complicated for many seniors, especially those with COPD and

make unnecessary repairs in order to recover lost revenue is fallacious. CMS presents no evidence that unnecessary repairs occur today. Moreover, given the historic inadequacies of Medicare's fee schedule for parts and labor, there is no basis for the belief that this will occur under the new rules imposed by the DRA.

Calculation of 60% Replacement Rule

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

Recommendation:

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

Audits

Providers should not be subject to overpayments and re-coupment actions after title to equipment has transferred to the beneficiary. The MACs and PSCs need to bring their audit activity current so the audit activity occurs within the period of continuous use absent evidence of fraud or other wrongful conduct on the part of the provider.

Conclusion

Care Medical appreciates the opportunity to comment on the proposed regulations for oxygen equipment and capped rental items of DME. Care Medical is committed to protecting the welfare – both health and financial – of the beneficiaries we serve. We believe our analysis of the proposed regulation and the recommendations made are well-reasoned and consistent with a beneficiary-centric mission. Should you have further questions, please do not hesitate to contact me.

Sincerely,
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Mark E. Miller, Ph.D., Executive Director

September 22, 2006

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

Re: File Codes CMS-1304-P.
Sections D. and F.

Dear Dr. McClellan:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit these comments on CMS's proposed rule entitled *Medicare program: Home Health Prospective Payment System Rate Update for Calendar Year 2007*, Federal Register Vol. 71, No. 149, pages 44085-44092 (August 3, 2006). In this letter our comments are on measuring quality and the wage index in home health. We appreciate your staff's ongoing efforts to administer and improve the home health payment system, particularly considering the agency's competing demands.

Reporting on Quality

MedPAC supports CMS's plans to expand the quality measure set to include process measures. We have published work that discusses process measures in home health, focusing on fall prevention and wound care practices. (http://www.medpac.gov/publications/congressional_reports/Jun06_Ch05.pdf.) The discussion concludes that the practices listed in Tables 1 and 2 should be considered for development into process measures for the care of falls and wounds.

Table 1. Pressure wound practices

Improve assessment	○ Assess skin from head to toe ○ Assess wound at each visit ○ Photograph wound as part of the record
Improve treatment	○ Offload pressure ulcers ○ Maintain moist wound bed as appropriate ○ Develop a turning schedule or increase mobility as appropriate ○ Use infection control techniques ○ Educate caregivers regarding infection control
Develop physician contact protocols	○ Contact physician at first sign of infection ○ Contact physician if wound does not respond to treatment within 2 weeks

Table 2. Fall prevention practices

Use a standard, multifactor tool	○ Include patients' fall history ○ Include a medication inventory
Use validated techniques to measure fall risk	○ Measure postual hypotension ○ Measure balance deficits by asking patient to stand on one foot for 10 seconds
Link assessment tool to appropriate follow-up activities	Follow-up could include: ○ Contacting physician about medications that increase fall risk ○ Referring patient to a physical or occupational therapist ○ Initiating gait training, balance training or strength training

These measures could complement the process measures being developed by CMS and elsewhere for other important health conditions, such as chronic disease or other functions such as medication management.

Home Health Wage Index

The rule proposes to use the pre-floor pre-reclassification hospital wage index for home health as has been done in the past and solicits comments about new methods to establish wage index values for areas without hospitals.

For rural Massachusetts, for example, the rule proposes using last year's value of 1.0216. It also discusses an alternative: the average of the rural wage indexes for the New England Census Division.

However, these indexes range from .8410 in Maine to 1.1753 in Connecticut. Because this range is so broad, the Census region average does not seem to be a reasonable approximation of the wages in any of the constituent rural areas.

An alternative that CMS could consider is using BLS wage data to derive a ratio of rural Massachusetts' wages to wages in an urban MSA in Massachusetts (Boston, for example) for the mix of workers hospitals employ. That ratio could then be multiplied by the current Boston MSA wage index to derive an estimated wage index for rural Massachusetts.

MedPAC appreciates your consideration of these comments. If you have any questions, or require clarification of our comments, please feel free to contact Mark Miller, MedPAC's Executive Director, at (202) 220-3700.

Sincerely,

Glenn M. Hackbarth
Chairman