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**BY HAND DELIVERY**

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

**Re: CMS—1304—P: "Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment; Proposed Rule"—COMMENTS ON "PROVISIONS OF THE PROPOSED REGULATIONS"**

Dear Administrator McClellan:

On behalf of our client, Rotech Healthcare Inc. ("Rotech" or the "Company"), we submit these comments on the proposed rule to implement certain provisions of the Deficit Reduction Act of 2005 ("DRA") regarding Medicare reimbursement for oxygen equipment and capped rental durable medical equipment ("DME").[1] Rotech is concerned about a number of the proposed revisions and appreciates the opportunity to offer its comments and recommendations.

Rotech provides a wide range of respiratory therapy equipment, including oxygen concentrators, liquid oxygen systems, portable oxygen systems, ventilator therapy systems, nebulizer equipment, and sleep disorder breathing therapy systems, for rental or sale. The Company's principal customers are older patients with breathing disorders, such as chronic obstructive pulmonary diseases, chronic bronchitis, emphysema, obstructive sleep apnea and other cardiopulmonary disorders. As such, the Company has a considerable interest in ensuring that the continued needs of its customers are met.

We recognize that the agency's proposed rule seeks to implement major changes to how the Centers for Medicare and Medicaid Services ("CMS") pays for oxygen equipment and capped rental DME supplied to Medicare beneficiaries. Specifically, CMS seeks to implement changes prescribed by section 5101 of the DRA, requiring that the beneficiary take ownership of oxygen equipment after a continuous rental period of 36 months.[2] For beneficiaries receiving

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1 *See* 71 Fed. Reg. 44082 (Aug. 3, 2006) (proposed oxygen provisions to be codified at 42 C.F.R. pt. 414).

2 *See* Deficit Reduction Act of 2005, § 5101(b), Pub. L. No. 109-171 (Jan. 8, 2006).

oxygen equipment on December 31, 2005, the 36-month rental period began on January 1, 2006. For beneficiaries who began to rent oxygen equipment on or after January 1, 2006, the 36-month rental period commences at the time they begin to rent the equipment.[3]

What is most concerning to Rotech is that in conjunction with implementing the DRA's mandates to cap rental periods, CMS has proposed to amend reimbursement levels for oxygen and oxygen equipment and to promulgate rules regarding repair and maintenance in a manner that ignores the fact that companies like Rotech supply not only oxygen, but a whole host of other services and supplies that are required by manufacturers and accrediting bodies and are necessary for patient safety. CMS's proposed monthly payments for oxygen contents are so low that they will be insufficient to cover the cost of delivery of the oxygen, not to mention the cost of regular maintenance or the provision of necessary supplies. Because a supplier is required under the proposal to continue to furnish oxygen for the period of medical necessity at such dramatically lower payment rates, CMS has essentially required that suppliers provide beneficiaries with free goods and services for as long as they require oxygen. By requiring suppliers to provide oxygen, supplies and regular maintenance, and by not paying suppliers sufficiently in return, CMS's proposed reimbursement structure would deter suppliers from furnishing oxygen to beneficiaries and, worse, might restrict beneficiary access to oxygen.

Accordingly, Rotech offers the following comments and recommendations for CMS's consideration:

(1) **Do not implement proposed reimbursement cuts for oxygen contents that are not budget neutral.** Although CMS specifically notes in the preamble to the proposed rule that it is prohibited from creating separate classes of payment for oxygen unless any such change is "budget neutral," the agency's proposed cuts in reimbursement threaten not to be budget neutral. Rotech urges the agency to refrain from implementing the changes. In the alternative, the Company suggests that CMS (1) work with the oxygen industry to develop payment levels that attain budget neutrality and (2) upwardly adjust the monthly payment for portable oxygen equipment and contents.

(2) **Include the cost of required maintenance and supplies in the monthly reimbursement of oxygen after title transfers.** If CMS does implement its proposed changes to reimbursement, it should take into account certain implications of the oxygen industry. For instance, reimbursement amounts need to cover the costs of (1) required monthly maintenance of oxygen equipment, and (2) supplies dispensed in conjunction with oxygen therapy (*e.g.*, masks, tubes, filters and humidifier bottles) that are necessary for the oxygen equipment to properly function and for patient safety. As drafted, for as long as a beneficiary requires oxygen, suppliers would be required to provide such maintenance services and replacements of necessary supplies for free. The result for beneficiaries will be a reduction in the number of suppliers that furnish oxygen

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3 *See* 71 Fed. Reg. at 44093.

and an overall restriction in available oxygen.

(3) **Provide more explanation for its proposed reimbursement amounts.** CMS has not provided adequate justifications for its decision to apportion 65% of the $156 payment for oxygen contents to stationary oxygen contents and 35% of the payment to portable oxygen contents. As such, it is difficult for affected entities to comment on this proposal.

(4) **Do not require suppliers to transfer title to oxygen tanks to beneficiaries.** CMS should also consider revisiting the proposed requirement that title to oxygen tanks will transfer to beneficiaries. This proposal creates an unnecessary burden on suppliers to keep track of thousands of tanks, virtually all of which are interchangeable and identical.

(5) **Revisit the 60% threshold for determining when a supplier must replace oxygen equipment.** CMS should not adopt its proposal that a supplier be required to replace equipment once accumulated repair costs exceed 60% of the cost to replace the equipment. CMS explains that the 60% threshold is based on a similar provision for artificial limbs. But, the two products are not comparable in that an artificial limb, unlike oxygen equipment, does not require regular servicing and maintenance. In addition, whereas oxygen equipment requires a host of additional supplies in order to properly function, artificial limbs do not. CMS has also not defined "replacement cost" and how such cost would be calculated.

(6) **Account for situations in which the supplier does not hold title to the oxygen equipment.** CMS should acknowledge in its policies those situations in which title is not held by a supplier that rents oxygen equipment to beneficiaries. It is common practice for a supplier to rent equipment from a manufacturer and never itself hold title to the equipment.

(7) **Take into consideration situations in which beneficiaries fail to pay required deductibles and copayments.** Under the proposal, oxygen suppliers are required to transfer the title of oxygen equipment to beneficiaries, regardless of whether they have paid required deductibles and copayments. Rotech believes that CMS should consider adopting special policies for discrete situations, including those where beneficiaries fail to make coinsurance payments under Part B.

(8) **Provide limits to a beneficiary's ability to switch suppliers.** CMS should impose restrictions on a beneficiary's ability to switch suppliers at will in order to prohibit beneficiaries from "shopping around" and delaying the start of the beneficiary ownership period. The Company suggests that CMS clarify that a new 36-month rental period begin each time a beneficiary switches suppliers or relocates. In conjunction with this rule, CMS should also impose safeguards (for instance, limits on the number of times a beneficiary can switch suppliers) that prevent beneficiaries from gaming the system.

(9) **Loosen the requirement regarding published assignment information.** CMS should not adopt its proposal to post assignment statistics for each supplier on its website. If it decides to proceed with publication, CMS should coordinate this effort with suppliers to ensure correct information is distributed to the public.

(10) **Do not implement the agency's proposed reimbursement changes at this time.** The oxygen industry has already been subjected to a variety of significant price cuts, and CMS should allow sufficient time to assess whether these cuts result in cost savings, which would eliminate the need for further payment adjustments.

Below are more detailed explanations of each of the Company's comments.

## I. CMS SHOULD NOT IMPLEMENT ANY CHANGES TO PAYMENT RATES WITHOUT FURTHER ASSURANCES OF BUDGET NEUTRALITY.

*Payment for Oxygen Contents for Beneficiary-Owned Oxygen Equipment; Classes of Oxygen and Oxygen Equipment*

Rotech urges the agency not to implement its proposed oxygen payment rates because they do not adequately account for budget neutrality. CMS is expressly prohibited from establishing new, separate payment rates for classes of oxygen and oxygen equipment if these new payment rates result in expenditures that are more or less than the expenditures that would have been made if such actions had not been taken.[4] In fact, in the preamble to the proposed rule, the agency specifically notes its intention to be budget neutral in cutting monthly reimbursement for oxygen.[5] In the alternative, CMS should work with the oxygen industry to ensure that payment levels are budget neutral.

### 1. *CMS Proposal*

In the proposed rulemaking, CMS has indicated that Medicare beneficiaries generally use four categories of oxygen systems:

- 69% of beneficiaries use both a stationary concentrator and a portable system that requires delivery of oxygen;
- 5% use a stationary system that requires delivery of oxygen and a portable system that requires delivery of oxygen;
- 24% use a stationary concentrator only; and

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4 *See* 42 U.S.C. § 1395m(9)(D) (2006).

5 *See* 71 Fed. Reg. at 44104.

- 2% use only a stationary system that requires delivery of oxygen.[6]

Medicare currently makes two separate payments for beneficiaries who use both stationary and portable systems during the rental period: (1) a "stationary payment" for the rental of stationary equipment, delivery of stationary oxygen contents and delivery of portable oxygen contents and (2) a separate add-on payment for the portable equipment.[7] CMS also makes monthly payments during the period of beneficiary ownership for (1) stationary and portable oxygen contents together (for beneficiaries who use both stationary and portable equipment or stationary equipment alone) and (2) portable oxygen contents (for beneficiaries who use portable equipment alone).[8] The current average monthly payment amounts are as follows: (1) $199 for stationary equipment and contents; (2) $32 for portable add-on; (3) $156 for stationary and portable oxygen contents; and (4) $21 for portable contents only.

CMS proposes to establish a new class and monthly payment amount for oxygen-generating portable oxygen equipment (*i.e.*, portable concentrators).[9] CMS proposes a higher monthly payment amount ($64) in lieu of the regular $32 portable add-on to account for increased costs to the supplier of furnishing the more expensive portable concentrator systems.[10] CMS selects $64 as a monthly payment amount based on the agency's calculations of long-term savings stemming from the fact that portable concentrator equipment will not require the proposed $55 monthly payment for portable oxygen contents.

CMS also proposes to segregate the monthly payment amount for oxygen contents into two categories: one payment for stationary oxygen contents for beneficiary-owned equipment and one payment for portable oxygen contents for beneficiary-owned equipment.[11] Currently, the combined average monthly payment amount of $156 for furnishing oxygen contents for beneficiary-owned stationary and portable systems includes payment for both stationary contents and portable contents. This combined payment results in Medicare reimbursement of portable oxygen contents, even when the beneficiary does not use portable oxygen equipment. The CMS proposal would split the $156 payment into a $101 payment for stationary oxygen contents and a $55 payment for portable oxygen contents. CMS indicates that it proposed a higher rate ($101 or 65% of $156) for stationary oxygen contents because stationary equipment requires delivery of larger, heavier oxygen cylinders or vessels—a more difficult, time-consuming, laborious and fuel-consuming task than delivery of smaller portable oxygen cylinders. Payment for the portable oxygen would be at a lower rate ($55 or 35% of $156).[12]

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6 *See id.* at 44095.

7 *See id.*

8 *See id.*

9 *See id.* at 44096.

10 *See id.*

11 *See id.*

12 *See id.* at 44096-97.

In addition, the agency intends to reduce the current monthly payment amount for stationary oxygen equipment and content during the rental period from $199 to $177.[13] CMS indicates that this cut was planned to attain budget neutrality. CMS believes that the reduction in the stationary payment is needed to offset the increased payments for the other changes.[14]

2. *Rotech Comments and Recommendations*

Rotech believes that CMS's proposed payment classes and payment amounts will not achieve budget neutrality as mandated by Congress and contemplated by CMS. The Company's understanding of industry analyses is that Medicare expenditures under the proposed reimbursement structure would differ markedly from expenditures under the current structure.[15] Because CMS cannot establish new, separate payment rates for classes of oxygen and oxygen equipment if these payment rates result in Medicare expenditures that are more or less than the expenditures which would have been made if such actions had not been taken, the agency should proceed cautiously with this life-sustaining benefit.[16] As such, Rotech urges CMS not to implement its proposed changes to oxygen reimbursement.

In the alternative, if CMS does decide to revise classes of products and implement reduced payment levels, the agency should recalculate Medicare expenditures under the new plan and develop payment rates that are truly budget neutral. Most critically, as noted above, CMS proposes to eliminate the joint stationary and portable payment and to create one monthly payment for stationary oxygen and one monthly payment for portable oxygen. To do this, CMS intends to split the $156 joint payment into a $101 payment for stationary oxygen contents and a $55 payment for portable oxygen contents. Rotech believes that this and other adjustments should be made in consultation with industry experience and only after detailed data is obtained for costs of all services at issue are obtained.

In addition, if CMS recalculates Medicare expenditures under the new plan and determines that an upward adjustment in payment levels is needed to attain true budget neutrality, Rotech contends that any such adjustment in payment levels should, at minimum, be made to the proposed payment rates for monthly portable oxygen equipment and contents (both during and subsequent to the capped rental period). The Company believes that any new payment level—even if, for example, derived by splitting the joint payment for both stationary and portable contents as has been proposed by the agency—must consider the economies

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13 *See id.* at 44097.

14 *See id.*

15 In addition, it appears that CMS's assumptions about Medicare expenditures on oxygen do not correlate with industry experience and require reassessment. For example, in its Regulatory Impact Analysis, the agency notes that current Medicare monthly payment rates for oxygen are significantly higher than the average payment made by the largest medical center operated by the U.S. Department of Veterans Affairs ("VA"). *See id.* at 44104 (noting an average per-patient Medicare payment of $7,164 over 5 years and an average VA payment of $1,435 over 5 years). As a large contractor with the VA, however, Rotech has considerable data and experience showing that VA payments for oxygen have been consistently greater than Medicare payments on a per-patient basis.

16 *See* 42 U.S.C. § 1395m(9)(D).

achieved by deliveries of both stationary and portable oxygen. Further, supporting the trend towards greater beneficiary usage of portable equipment serves to benefit beneficiaries' ability to live more independently. As described further below, the proposed rates are insufficient for continued necessary regular maintenance and servicing, replacement of supplies or the delivery of oxygen to beneficiaries. In fact, based on the proposed low rates in conjunction with the fact that suppliers are now required to furnish oxygen to beneficiaries for the period of medical necessity, CMS is essentially requiring that suppliers furnish tank after tank of free portable oxygen to beneficiaries. To avoid this inequitable result, Rotech strongly urges that any amounts to be added to attain budget neutrality should be added to the portable oxygen payment.

## II. IF CMS DOES IMPLEMENT THE PROPOSED CHANGES TO PAYMENT AMOUNTS FOR OXYGEN EQUIPMENT, THE AGENCY SHOULD ADJUST ITS FINAL RULE TO ACCOUNT FOR IMPLICATIONS ON THE OXYGEN INDUSTRY.

*Payment for Oxygen, Oxygen Equipment and Capped Rental DME*

### A. CMS payment levels should account for required maintenance of oxygen equipment and for supplies provided to beneficiaries in conjunction with oxygen therapy.

CMS's proposed monthly payment—$55 for portable oxygen contents and $101 for stationary oxygen contents—during the period of beneficiary ownership does not account for most of the costs associated with home oxygen therapy. Specifically, the agency does not account for (1) regular maintenance required by manufacturer guidelines and accreditation organizations or (2) the ongoing replacement of supplies used with oxygen equipment. As currently drafted, the proposed rule mandates that oxygen suppliers furnish free regular maintenance and replace supplies at virtually no charge. Suppliers of equipment that use oxygen concentrators will not receive any monthly payment for maintenance or supplies after title transfers; however, they will still be required to perform regular maintenance. CMS has proposed a reimbursement structure that does not reimburse suppliers for their services once beneficiaries own the equipment. Oxygen suppliers face a difficult decision—provide oxygen, maintenance and supplies for nothing or withdraw from the program altogether. Unfortunately, most suppliers will choose to withdraw rather than to go unpaid, and Medicare beneficiaries might have their ability to obtain oxygen supplies reduced substantially.

Clearly, these are unintended consequences of the proposal. CMS should provide payments sufficient to cover the costs of the mandatory services and supplies in addition to the monthly oxygen content payment. We propose that the agency either consult with the oxygen industry to assess the actual costs of maintenance and servicing of equipment or develop a study in conjunction with the industry that would provide data on maintenance and servicing costs, or both.

#### 1. *Comments and Recommendations Regarding Maintenance*

It cannot be overstated that the total cost of providing oxygen therapy in the home includes more than the cost of equipment and the cost of oxygen contents. Suppliers also

perform patient intake, preparation and delivery, scheduled and unscheduled maintenance, patient assessment, training and education, ongoing patient support (including costs associated with oxygen fills, disposable supply items and delivery).[17] In particular, oxygen suppliers like Rotech must perform regular servicing and maintenance on oxygen equipment, such as changing filters and checking oxygen levels being dispersed to the patient. For Rotech and other oxygen suppliers, this regular maintenance takes place in the patient's home, on average, every 90 days.

This regular maintenance is required by manufacturer warranties and guidelines. Many manufacturers of products supplied by Rotech require the Company to make the following maintenance and service checks every 90 days:

- Check exterior for damage and cleanliness,
- Check hours and compare to manufacturer's recommendations for compressor preventative maintenance,
- Check flow meter for accuracy,
- Check oxygen concentration,
- Check internal and exterior filters,
- Ensure that alarms are activated with appropriate settings and are sufficiently audible with respect to distances and competing noise within the unit or home environment, and
- Perform any additional requirements.

Annually, manufacturers require Rotech to check and clean the interior of the device of dust or debris. Manufacturers also require the Company to perform maintenance every 5,000 hours, which includes replacement of filters and checking of compression in addition to interior cleaning of the device. This type of maintenance, which requires disassembly of the device, must be performed at the supplier's facility and not in the patient's home. To provide this maintenance, the supplier incurs the additional costs of picking up equipment and providing loaner equipment.

Regular maintenance is also required by industry accreditation standards. Specifically:

- The Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") requires that an oxygen supplier plan for the effective selection, delivery, setup and maintenance of equipment provided to patients. This includes: (1) selecting and acquiring equipment; (2) delivering equipment; (3) setting up equipment;

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[17] *See* Morrison Informatics, Inc., *A Comprehensive Cost Analysis of Medicare Home Oxygen Therapy* (June 27, 2006), *available at* http://www.aahomecare.org/associations/3208/files/Morrison%20Oxygen%20Cost%20Study%20Report%20June%2027%202006.pdf.

(4) maintaining equipment; (5) providing an appropriate backup system; (6) appropriately receiving and storing equipment; (7) monitoring and acting on equipment hazard notices and recalls, including notifying patients, staff and prescribing physicians as appropriate; (8) monitoring and reporting incidents in which a medical device is connected to the death, serious injury, or serious illness of any individual, as required by the Safe Medical Devices Act of 1990; and (9) reporting within the organization and investigating equipment management problems, failures and user errors.

- JCAHO also requires that medical equipment be maintained, tested and inspected by: (1) performing routine and preventive maintenance at defined intervals and according to manufacturers' guidelines; (2) inspecting all medical equipment between patient uses; and (3) doing basic safety, operational and functional checks on equipment according to organization policy and manufacturers' guidelines.[18]

In addition, maintenance and servicing requires that the Company incur additional administrative and overhead costs. Supplying oxygen does not simply involve collecting tanks, filling them and delivering them. Rotech and other oxygen suppliers must take the following actions to be able to supply oxygen: (1) maintain all Federal, state and local licensure and permits to supply oxygen, (2) maintain a Medicare supplier number, (3) maintain the proper equipment inventory to fill orders on an expeditious basis, (4) maintain an adequate inventory of repair parts and disposable supplies for equipment, (5) incur freight and postage costs, (6) maintain appropriate physical facility space, (7) create and distribute appropriate signage and safety instructions at the facility, (8) operate telephone lines and answering services to provide after-hours accessibility, (9) maintain liability insurance, (10) purchase or lease general office equipment and supplies, (11) purchase or lease vehicles for delivery, (12) fuel delivery vehicles, (13) maintain computer systems and suppliers, (14) oversee and supervise employees in a variety of fields (e.g., management, billing, clinical, patient service technicians, customer service representatives, etc.), (15) pay for and maintain employee insurance (e.g., Group Health, Worker's Compensation, etc.), (16) make payroll taxes and pension contributions, (17) train employees and (18) pay for clinical employees' licensure fees. This extensive list of overhead costs does not address every facet of the oxygen supply business that a supplier like Rotech must take into consideration and pay for in order to keep furnishing oxygen to Medicare beneficiaries. The virtual lack of reimbursement by Medicare means that suppliers like Rotech cannot offset their administrative costs of doing business, making it even more difficult to continue supplying beneficiaries.

There is also another practical problem with CMS's proposed rule. The agency has noted that it expects beneficiaries and caregivers to perform routine maintenance, "such as testing, cleaning, regulating, changing filters and general inspection."[19] CMS states that "the beneficiary

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[18] *See generally* Joint Commission on Accreditation of Healthcare Organizations, *Patient Equipment Management Standards*.

[19] 71 Fed. Reg. at 44099.

and/or caregiver should be very knowledgeable regarding the routine maintenance required for the item."[20] The Company believes that CMS should reassess these assumptions for several reasons. First, suppliers are in a better position than beneficiaries to take care of routine maintenance—suppliers deal with this equipment on a routine basis and have the expertise and resources to provide quality maintenance in an expeditious manner. Second, maintenance frequently requires disassembling and reassembling the equipment and such procedures can only take place in the supplier's facility. This means a disruption in oxygen service for the beneficiary. It is safer for the beneficiary if the supplier—i.e., the maintenance expert—perform the necessary servicing, thereby keeping the period of disruption to a minimum.

Finally, and most importantly, it is simply unsafe to transfer the responsibility for maintenance and servicing to oxygen-dependent beneficiaries, as CMS suggests. Many of these services require moving or opening of the equipment—strenuous activities for weak, oxygen-needy patients. Rotech cannot emphasize strongly enough its patients' conditions. The Company's patients lack the capacity to take on even the smallest of tasks. Many are so vulnerable that they can barely get out of bed, let alone drive to an oxygen supplier to drop off equipment for servicing or perform the physically exerting maintenance themselves. Although some of Rotech's patients have caregivers, in many instances these caregivers are elderly spouses and are just as sick as the patients. For these reasons, CMS should recognize that it is simply unsafe to impose the responsibility for maintaining this equipment on beneficiaries.

Because suppliers must furnish regular maintenance pursuant to industry accreditation requirements and manufacturer guidelines and for the safety of its patients, Rotech urges CMS to amend the monthly payment to cover such services. As noted above, the proposed payment methodology for oxygen—$55 or $101 per month for portable and stationary oxygen contents, respectively—cannot cover regular maintenance. More troubling is that suppliers do not receive any monthly payment for oxygen concentrators, yet they are still required to provide these maintenance services.[21] The proposed oxygen reimbursement structure, therefore, simply does not sufficiently reimburse oxygen suppliers. Furthermore, by requiring suppliers to provide oxygen for the period of medical necessity, the agency's proposed rule essentially imposes a requirement for free services to be provided to Medicare beneficiaries indefinitely. Should these *de facto* requirements take effect, suppliers may choose to withdraw from the program, limiting beneficiary access to oxygen. Rotech therefore urges CMS not to reduce current reimbursement levels.

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20 *Id.*

21 The need for appropriate payments for the services was recognized in the recently-released report on home oxygen therapy by the Office of Inspector General ("OIG"). The OIG acknowledges that its study on additional cost savings if the oxygen concentrator capped rental period is 13 months has not accounted for maintenance and servicing payments. According to the OIG, accounting for these factors would "likely result in lower savings than our estimate." *See* U.S. Department of Health & Human Services, Office of Inspector General, Medicare Home Oxygen Equipment: Cost and Servicing, Report No. OEI-09-04-00420, at 15 (September 2006).

2. *Comments and Recommendations Regarding Supplies*

In addition to the ongoing maintenance of oxygen equipment, oxygen suppliers must also furnish beneficiaries with supplies necessary to make the equipment function. In particular, a supplier must provide a beneficiary with new tubing every month and new oxygen masks, if applicable, every 2-3 months. Humidifier bottles, if applicable, also require changing each month. This regular supply replacement schedule—which is above and beyond the actual furnishing of oxygen contents—is necessary for patient safety and to avoid infection.

Here as well, the proposed rule fails to account for the costs incurred for the supplies and the delivery of the supplies. The proposed rule requires the $55 or $101 monthly payment for oxygen to be stretched to cover not only the oxygen itself, but the supplies needed to deliver the oxygen to the patient. For oxygen systems with concentrators, suppliers would receive no payment for these supplies. Again, the low payment rates in conjunction with the requirement that the supplier furnish oxygen for the period of medical necessity serve to create a *de facto* mandate that suppliers furnish filters, masks, tubes, and humidifier bottles free of charge to beneficiaries for an unlimited period of time. It is inappropriate to require companies like Rotech to provide these necessary supplies to beneficiaries and not pay for them.

CMS should revisit its analysis of what is being provided to beneficiaries both during and after the capped rental periods and ensure adequate payment for these supplies. If it does not, Medicare suppliers may no longer be able to service this population, and Medicare beneficiaries will be in jeopardy of losing access to oxygen.

B. The agency's proposed payment rates for oxygen contents do not even cover the cost of gas used to fuel oxygen delivery trucks.

Rotech is also troubled by the agency's proposal because it does not appropriately and fully account for the cost of delivering oxygen contents in creating the $55 and $101 monthly payments. Specifically, CMS has assumed that, once title transfers, a beneficiary will own two sets of tanks and that these very tanks will be refilled once every month.[22] In fact, Rotech—and other oxygen suppliers—furnish oxygen as needed by the patient and not according to a set monthly schedule. This means multiple trips to many patients' homes per week to furnish many more than two sets of oxygen tanks. The $55 and $101 payments do not cover the cost of these multiple deliveries and are so minimal that they translate to free delivery of oxygen. Unfortunately, CMS's proposed payment levels will act as a deterrent to the industry and therefore run the risk of depleting the pool of oxygen suppliers available to service Medicare beneficiaries, particularly those residing in rural areas.

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22 *See* 71 Fed. Reg. at 44095. Here CMS states, "Customary practice by suppliers for refilling oxygen contents is to deliver to the beneficiary cylinders filled with contents and take back the empty cylinders to the supplier's place of business to refill the oxygen contents. Under [the agency's] proposal, title would transfer for *both* sets of cylinders, *meaning the ones that are being used by the beneficiary for the month and the ones that the supplier refills in its business location and delivers for use during the next subsequent month.*" (emphasis added).

Although CMS indicates that it will consider the cost of delivery in calculating reimbursement levels for oxygen contents,[23] the agency has based its considerations on an underestimate of the level of oxygen consumed by patients. Beneficiaries use anywhere from 2 to 10 or more tanks of oxygen *per week*, and Rotech and other oxygen suppliers are required to maintain enough oxygen in the home as is medically necessary.[24] When a patient needs oxygen, he or she calls the Company, and the Company delivers the oxygen. This means that a Medicare beneficiary could (and, in most cases does) go through *more than* two sets of cylinders in a week. Accordingly, the Company frequently makes more than one delivery per patient per week. Not only does this go beyond CMS's contemplated two-cylinder model, but the cost of the Company's delivery—personnel wages, oxygen refilling costs, and fuel—for one week's worth of oxygen is not covered by the $55 or $101 payments, which are designed to cover the Company for the entire month for one patient.

In sum, the monthly payment—which must cover regular maintenance and servicing, overhead and supplies—must also be stretched further to cover the cost of delivery. Frankly, the payment cannot stretch this far. The effect is a CMS directive that oxygen suppliers provide free delivery of oxygen to beneficiaries. This is an inequitable result.

Rotech suggests that CMS delay setting new rates until it has gathered sufficient data to identify the costs of oxygen services—both during and after the capped rental period. This can be accomplished, for example, through a study to determine the monthly average consumption of oxygen contents among Medicare beneficiaries. A methodology may be adopted to address payments for outliers. Because the first title transfers for oxygen equipment are not slated to take place until January 1, 2009, CMS has ample time to conduct such a study.

Rotech also suggests that CMS consider establishing a delivery fee for each time a supplier delivers oxygen. As proposed and as noted above, the $55 or $101 per month payments will not even cover the cost of gas—let alone the items being delivered. The U.S. Department of Health and Human Services Office of Inspector General ("OIG") has even recently noted that the monthly payment for "contents . . . does not vary based on the amount of oxygen a beneficiary requires" and that "[t]his payment may not adequately reimburse suppliers" for refills and "related services" once a beneficiary takes title to the equipment.[25] Such low reimbursement levels act to deter suppliers from continuing operating in the oxygen industry, thereby diminishing beneficiary access to oxygen—particularly in rural areas. The ultimate unintended result is a greatly reduced supply of oxygen to Medicare beneficiaries. A delivery fee would

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23 *See id.* at 44097.

24 Rotech's experience with oxygen delivery differs significantly from the OIG's findings in its recently released report on home oxygen therapy. In particular, the Company delivers multiple tanks of oxygen each week to a substantial number of beneficiaries. Rotech believes that the OIG's findings that "[s]uppliers deliver cylinders *once every 3 months*" and that "[a]mong beneficiaries who rented concentrators for 1 year or more, 65 percent received *two or fewer cylinders from their suppliers in the first year of rental*" is off the mark and inconsistent with industry experience. *See* U.S. Department of Health & Human Services, Office of Inspector General, Medicare Home Oxygen Equipment: Cost and Servicing, Report No. OEI-09-04-00420, at 12 (emphasis added).

25 *See id.* at 14 (specifically referencing the monthly payment for portable oxygen contents).

help to offset these costs and compensate suppliers for their services.

## III. THE AGENCY SHOULD PROVIDE A MORE DETAILED JUSTIFICATION FOR ITS PROPOSED REIMBURSEMENT CUTS.

In addition to the proposed monthly payment for oxygen not covering maintenance, supplies or delivery, CMS has not provided adequate notice for affected entities to comment fully on its decision to split the $156 payment for oxygen contents into two separate payments. Specifically, in splitting the $156 payment for both stationary and portable oxygen contents, CMS proposes to apportion 65% of the payment (or approximately $101) to stationary oxygen contents and 35% of the payment (or approximately $55) to portable oxygen contents. It is unclear how CMS decided to use a 65/35 split. The agency does note:

> The 65/35 split is based on our understanding that there are higher costs associated with delivering stationary tanks (cylinders of gaseous oxygen and vessels of liquid oxygen) which are approximately twice as large as the portable tanks. Such costs include supplier overhead costs, including the costs to purchase, maintain, and dispatch trucks, obtain insurance, and purchase fuel. The 65/35 split is intended to account for the difference in costs associated with the size of the tanks. Larger tanks take up more space on the trucks, take longer to fill, are harder to move, and result in increased fuel costs.[26]

CMS does not quantify, however, the higher costs of stationary tank delivery and how these higher costs warrant 65% of the $156 combined oxygen payment. Accordingly, the 65/35 split appears to be selected arbitrarily. Rotech submits that the result is an inadequate basis on which affected parties can provide comments that are useful to the agency.

## IV. TITLE TO OXYGEN TANKS SHOULD NOT TRANSFER TO BENEFICIARIES.

*Payment for Oxygen, Oxygen Equipment and Capped Rental DME*

CMS proposes that, during the rental period, a supplier cannot provide different equipment from that which was initially furnished to the beneficiary.[27] Different equipment can be provided if one of the following exceptions applies: (1) the equipment is lost, stolen, or irreparably damaged; (2) the equipment is being repaired while loaner equipment is in use; (3) there is a change in the beneficiary's medical condition such that the equipment initially furnished is no longer appropriate or medically necessary; or (4) the carrier determines that a change in equipment is warranted.[28] The Company urges the agency to reconsider this proposal or to add an exception for oxygen cylinders and vessels.

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26 71 Fed. Reg. at 44097.

27 *See id.* at 44094.

28 *See id.*

Transferring title to oxygen tanks is impracticable and contrary to industry practice. As it currently works, when Rotech or another oxygen supplier receives a call from a patient in need of oxygen, the delivery personnel take full cylinders from inventory and deliver them to the patient's home, where they pick up the empty cylinders and return them to inventory. Indeed, these cylinders are, for the most part, completely interchangeable. Under the proposal, a supplier would be required to use the exact same cylinders for each beneficiary and to track the cylinders at a supplier's refilling warehouse, where the cylinders of hundreds or thousands of other beneficiaries' identical, completely fungible tanks are stored and awaiting refilling. This is an overly burdensome and unnecessary process. So long as a beneficiary has access to oxygen—a current supply and refills—there is no need for the beneficiary to "own" or have an interest in any particular cylinders. Consequently, we ask that the agency revise its proposal to address this issue.

## V. CMS SHOULD RECONSIDER ITS PROPOSAL THAT A SUPPLIER REPLACE BENEFICIARY-OWNED EQUIPMENT IF THE COSTS OF REPAIRS EXCEED 60% OF THE REPLACEMENT COST OF THE ITEM.

*Payment for Replacement of Beneficiary-Owned Oxygen Equipment, Capped Rental Items, and Associated Supplies and Accessories*

CMS has proposed that a supplier of oxygen equipment or capped rental items would be required to replace beneficiary-owned equipment at no cost to the beneficiary or to the Medicare program if: (1) the total accumulated cost to repair the item after transfer of title to the beneficiary exceeds 60% of the "replacement cost" and (2) the item has been in continuous use for less than its reasonable useful lifetime.[29] CMS believes that this protects the beneficiary from receiving substandard equipment. CMS does note, however, that exceptions to this rule may be granted by the agency or the applicable carrier, citing the example of a supplier not being responsible for replacing an item in need of repair due to beneficiary neglect or abuse.[30]

To define "accumulated costs" of repairs, CMS uses the example of a capped rental item that can be replaced for $1,000 (the total fee schedule payments after 13 rental months) and for which title has transferred. If Medicare pays a total of $500 for 3 repairs necessary to make the item functional, and a fourth repair costing $200 is needed in order to make the item functional, the accumulated costs for repair in this case will equal $700, which exceeds $600 or 60% of the $1,000 cost to replace the item. In this example, the supplier would be required to furnish a replacement item.[31]

Rotech notes the following problems with CMS's approach. First, CMS assumes that an item is no longer useful after being subjected to numerous repairs. To the contrary, each time it is repaired, the repaired item can function as well as a brand new item. Second, by looking at the

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29 *See id.* at 44100. Medicare would not pay for the replacement of beneficiary-owned oxygen equipment or capped rental items covered by a manufacturer's or supplier's warranty.

30 *See id.*

31 *See id.*

accumulated costs of repairs, a supplier is motivated to keep its overall repair costs low. The result could be a string of cheap, quick fixes that slow repair costs from accumulating to the 60% replacement threshold rather than a potentially necessary and expensive overhaul of the equipment. The unintended consequence is Medicare beneficiaries being exposed to substandard repairs. Third, CMS indicates that it will look at "replacement cost" when determining when a replacement will be required. However, CMS does not define "replacement cost." It is unclear whether this means the original cost to Medicare of the equipment being replaced or the fair market value of the item. CMS must provide a definition for this term.

Finally, Rotech questions CMS's use of 60% of the replacement cost as the threshold for replacement. CMS notes that the 60% threshold is "consistent with the threshold repair costs that can result in the replacement of prosthetics (artificial limbs) in accordance with section 1834(h)(1)(G) of the Act."[32] The agency states that this threshold "should apply to oxygen equipment and capped rental items as well, because artificial limbs, like these items, are built to withstand repeated use."[33] Unlike artificial limbs, however, oxygen equipment has many associated supplies such as tubes, canulas, filters, and masks, among others. These items must also be regularly replaced. In addition, artificial limbs do not undergo regular maintenance every 90 days to 6 months, as oxygen equipment does. It is unclear whether the cost of replacing oxygen supplies or the cost of maintaining oxygen equipment will be included in the cumulative 60% threshold.

Rotech offers three suggestions:

- First, CMS should eliminate the 60% analysis altogether. Oxygen suppliers have an ethical obligation to their patients, who depend upon them for oxygen, to ensure that equipment works properly and safely.

- Second, CMS should look at the cost of each incident of repair rather than the accumulation of repairs. CMS appears to taking an approach similar to the concept of "totaling" a car—*i.e.*, the total cost to repair damage after a car accident is more than the total value of the car. When one "totals" a car, it occurs in a single event. Instead of looking at a number of repairs, CMS should determine whether the equipment is so damaged and so in need of repair that it is more reasonable and practical to pay for a new piece of equipment. Just as a car owner makes the same analysis after a car accident, the agency should do the same when a piece of equipment is in need of repair.

- Finally, CMS should define "cost of replacement" by using a definable value, such as fair market value or the original price of the equipment being replaced.

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32 *Id.*

33 *Id.*

## VI. CMS SHOULD ADAPT ITS POLICIES REGARDING THE TRANSFER OF TITLE TO ACCOUNT FOR SITUATIONS IN WHICH A SUPPLIER DOES NOT OWN THE EQUIPMENT.

*Payment for Oxygen, Oxygen Equipment and Capped Rental DME*

The proposed changes are impracticable under one very prevalent scenario in the oxygen industry. Many suppliers of oxygen do not own the equipment. Instead, these suppliers lease the equipment from manufacturers and then furnish the equipment to patients, including Medicare beneficiaries. Consequently, once suppliers of such items are required to transfer title of the equipment to Medicare beneficiaries, they will not be legally permitted to do so. Only the manufacturer of the equipment—the actual owner—would be able to transfer title. The 36 month rental cap, however, fails to address this quite common problem, and the result is a *de facto* requirement that oxygen suppliers must own the oxygen equipment they rent to beneficiaries—suppliers cannot lease the equipment. We urge CMS to provide significant revisions to the regulations to account for this prevalent occurrence.

## VII. CMS SHOULD ACCOUNT FOR SITUATIONS IN WHICH BENEFICIARIES HAVE FAILED TO MAKE COINSURANCE PAYMENTS.

*Payment for Oxygen, Oxygen Equipment and Capped Rental DME*

Rotech notes that another prevalent situation that CMS should consider in implementing the DRA's title transfer requirements is a common failure by beneficiaries to pay deductible and copayment amounts. (This does not include instances where deductibles and copayments are waived due to a beneficiary's bona fide financial hardship.) Suppliers—not to mention beneficiaries—are faced with a dilemma because they recognize that oxygen is life-sustaining and must be furnished. The inequitable result of the title transfer requirement is that suppliers must hand over equipment to beneficiaries who have neglected to pay their fair share.

Rotech believes that CMS needs to find a solution to this situation. We recommend three options. First, CMS could provide an exception to the title transfer requirement if a beneficiary has failed to pay his or her coinsurance for a significant period (such as more than 6 months) across the course of the 36-month rental period. Second, once title transfers, CMS could take responsibility for attempting to collect the amount of missed copayments from the beneficiary. Third, CMS can pay the supplier's bad debt (as is currently done for other provider types) for the amount of missed deductibles and copayments. Any of these potential solutions will alleviate the inequity of providing valuable equipment to a beneficiary when the beneficiary has not paid his or her deductible and/or coinsurance.

## VIII. CMS SHOULD IMPOSE RESTRICTIONS ON BENEFICIARIES' ABILITY TO SWITCH SUPPLIERS.

*Payment for Oxygen, Oxygen Equipment and Capped Rental DME*

CMS has proposed a handful of exceptions to the requirement that title to oxygen equipment transfer to the beneficiary after 36 months of continuous use. These exceptions

include (1) cases where a beneficiary relocates on either a temporary or permanent basis to an area outside the normal service area of the initial supplier and (2) cases where the beneficiary chooses to obtain equipment from a different supplier, among others. In other words, if the beneficiary moves, he or she can switch suppliers. More importantly, if the beneficiary simply chooses to do so, he or she can switch suppliers. No reason is required to be provided.[34]

Rotech believes that this proposal has created a dilemma for suppliers. CMS does not indicate (1) whether a new rental agreement with a new supplier restarts a full 36-month rental period, thereby delaying the transfer of title to the beneficiary, or (2) whether the new supplier will be required to take over the rental period where the previous supplier ended. If the rental period is restarted, beneficiaries could take advantage of the exceptions to "shop around" and to perpetually delay the transfer of title from taking effect. It cannot be overlooked that many beneficiaries may not want to hold title to the equipment, which might mean responsibility for regular maintenance and service, among other obligations.

If the proposed changes require the new supplier (after the beneficiary has moved or chosen to switch suppliers) to take over the rental period where the previous supplier ended, the result is inequitable. Specifically, a supplier might be required to provide a brand new piece of equipment to a beneficiary for 10 months of the 36 months, for instance. This *de facto* diminished reimbursement could deter suppliers from offering services to Medicare beneficiaries and diminish beneficiary access to oxygen supplies.

Consequently, Rotech urges CMS to specify that a new 36-month period begin. In conjunction with this provision, CMS should also include safeguards—such as limits on the number of times a patient can switch providers—to prevent beneficiaries from gaming the system and delaying the transfer of title.

## IX. CMS SHOULD NOT FINALIZE ITS PROPOSAL TO POST ASSIGNMENT STATISTICS FOR EACH SUPPLIER ON ITS WEBSITE.

*Payment for Oxygen, Oxygen Equipment and Capped Rental DME Items*

In its proposed rule, CMS notes that intends to post information on a CMS website indicating supplier-specific information on oxygen equipment and capped rental items. This information could include (1) the percentage of beneficiaries for whom each supplier accepted assignment during a prior period of time and (2) the percentage of cases in which the supplier accepted assignment during the beneficiary's entire rental period.[35] Although we understand that CMS wants to require disclosure of assignment information to inform the beneficiary about potential out-of-pocket payments, we would urge CMS to refrain from posting assignment information on a public website. First, CMS does not indicate how often it will make such postings and how it will verify the accuracy of its postings. Second, the result might be an inaccurate picture of a supplier's assignment history—suppliers could choose not to accept

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34 *See id.* at 44094.

35 *See id.* at 44094-95.

assignment for a variety of reasons, which a basic percentage will not demonstrate. Rotech recommends that, if CMS does intend to post such information, the agency should give suppliers 30 days notice as well as an opportunity to review information prior to posting and to correct erroneous information or identify the risks posed by erroneous information.

## X. CMS SHOULD NOT IMPLEMENT FURTHER DECREASES IN REIMBURSEMENT LEVELS FOR OXYGEN AND OXYGEN EQUIPMENT WITHOUT ASSESSMENT OF THE IMPACT OF RECENT REDUCTIONS.

*Payment for Oxygen Contents for Beneficiary-Owned Oxygen Equipment; Classes of Oxygen and Oxygen Equipment.*

In recent years, the oxygen industry has been made subject to a variety of pricing cuts, and the agency has not allowed sufficient time to pass for the impact of these cuts to ripen. As such, it is impossible to tell what effect each of the price changes will have on the oxygen industry or on CMS's cost savings. CMS should therefore not implement its proposed changes to the oxygen reimbursement methodology.

At the outset, Rotech is concerned that CMS is proposing payment reductions without allowing sufficient time to pass after prior cuts—taken only recently—may be evaluated to determine whether such prior cuts have resulted in sufficient cost savings. The Company notes that if the proposed pricing changes for oxygen take effect, the Federal government will have sought to cut reimbursement levels for oxygen three times in as many years. Specifically, as detailed above, section 5101(b) of the DRA establishes the 36-month limit on monthly payments for stationary and portable oxygen equipment furnished on or after January 1, 2006. Monthly rental payments for affected items terminate after a period of continuous use of 36 months, at which point the supplier transfers title for the stationary and/or portable oxygen equipment to the beneficiary.[36] The cap on the rental period for oxygen alone should result in significant cost savings. Only nine months have passed since the effective date (January 1, 2006) of these caps. Because the cost savings of these caps will not be felt until January 2009 (at the earliest) for oxygen equipment, it is simply premature to subject the industry to further reimbursement decreases at this time.

In addition, section 302(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") reduces the fee schedule amounts of certain items of DME, including oxygen and oxygen equipment.[37] Under the MMA price reduction, Medicare payment amounts for oxygen are decreased by the percentage difference between the amount of payment otherwise determined for 2002 and the median amount of payment under the Federal Employee Health Benefits Program ("FEHBP"), as determined by the OIG.[38] According to an OIG report, in 2002, FEHBP median payments were approximately 12.4% less than Medicare

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36 *See* Deficit Reduction Act of 2005, § 5101(b).

37 *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-73, Section 302(c) (2003).

38 *See id.*

payments for stationary home oxygen equipment and approximately 10.8% less than Medicare payments for portable home oxygen equipment.[39] In other words, oxygen suppliers have already been subject to substantial reimbursement cuts. CMS has also noted that significant savings have been achieved through these reductions.[40]

Moreover, CMS only recently proposed the competitive acquisition program for DMEPOS, which will most likely include oxygen and oxygen equipment. This will, once more, reduce reimbursement to oxygen suppliers. Again, however, it is difficult to determine the effect of the competitive acquisition plan, which is not expected to be implemented until late 2007, on cost savings to Medicare.

Importantly, CMS does not need to take the position that it must further reduce oxygen payments at this juncture. First, the future relevance of the agency's proposed monthly payments is uncertain at best. Identical bills introduced in the U.S. House of Representatives in May and the U.S. Senate in August—both entitled the Home Oxygen Patient Protection Act of 2006[41]—seek to amend Medicare Part B to restore the pre-DRA treatment of ownership of oxygen equipment. If passed, these bills would require CMS to withdraw its proposed monthly payments for oxygen contents after title transfers, as these payments would become irrelevant if title does not transfer. Second, CMS has approximately three years to determine whether further price cuts are necessary, because the diminished monthly payments for oxygen contents will not go into effect until 2009 at the earliest. As such, there is no reason to rush the process—CMS should make a careful study of the issue over the course of the next three years before deciding to further reduce oxygen payments.

Simply put, the full impact of the 36-month cap and other recent reimbursement changes remains unknown. CMS should allow sufficient time to pass after the implementation of the DRA's 36-month rental cap, the MMA's FEHBP price reduction and the proposed competitive acquisition program to determine whether these initiatives will achieve significant savings for the Federal government without compromising beneficiary access to oxygen. Suppliers, in turn, should be afforded sufficient time to determine the full impact of these changes on their ability to continue to provide oxygen services to beneficiaries.

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39 *See* U.S. Department of Health & Human Services, Office of Inspector General, Medicare and FEHB Payment Rates for Home Oxygen Equipment, Report No. OEI-09-03-00160, at i (March 2005).

40 In the Regulatory Impact Analysis section of the proposed competitive acquisition rule, CMS recognizes that prices have fallen for certain DMEPOS suppliers, specifically pointing out the 2005 reductions in oxygen supplies. *See* 71 Fed. Reg. 25654, 25693 (May 1, 2006).

41 *See* Home Oxygen Patient Protection Act of 2006, H.R. 5513, 109th Cong. (2006); *see also* Home Oxygen Patient Protection Act of 2006, S. 3814, 109th Cong. (2006).

LATHAM & WATKINS LLP

Thank you for considering Rotech's comments regarding the agency's proposed changes to oxygen reimbursement regulations. Should you have any questions or comments, I can be reached at (202) 637-2200.

Sincerely,

Stuart S. Kurlander /MEW

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Of LATHAM & WATKINS LLP

Cc: Rotech Healthcare Inc.

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September 22, 2006

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BY HAND DELIVERY

The Honorable Mark McClellan
Administrator
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 – Home Health Medicare Prospective Payment System Rate Update for Calendar Year 2007 and Deficit Reduction Act of 2005 Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment: Proposed Rule**

Dear Dr. McClellan:

On behalf of the American Association for Respiratory Care (AARC), I am pleased to submit comments on the proposed rule published in the *Federal Register* on August 3, 2006, to update the home health prospective payment rate for calendar year 2007 and to implement provisions of the Deficit Reduction Act (DRA) of 2005 regarding Medicare payment for oxygen and oxygen equipment and capped rental durable medical equipment. The AARC is the national professional association representing over 40,000 respiratory therapists who treat high-risk patients with chronic conditions such as asthma and chronic obstructive pulmonary disease (COPD), including emphysema and chronic bronchitis.

The AARC is most concerned with the health and safety of Medicare beneficiaries who are on long-term oxygen therapy. We recognize that the Centers for Medicare and Medicaid Services (CMS) has no leeway in implementing the DRA provisions that mandate transfer of ownership of oxygen and oxygen equipment to the beneficiary after 36 months of continuous use; however, we are nonetheless worried about those beneficiaries who may not be able to undertake routine maintenance and repair on their own due to various physical and mental impairments.

While CMS has taken certain safeguards to protect Medicare beneficiaries once transfer of ownership takes place, we believe the proposed rule falls short of fully recognizing the dangers to Medicare beneficiaries' health and safety that may be a consequence of the responsibilities they must now assume as owners of the oxygen equipment.

Our specific comments on the proposed rule are outlined below. They focus only on the DRA provisions regarding changes to payment and ownership of oxygen and oxygen equipment and capped rental durable medical equipment (DME) items.

**Background**

Home oxygen is critical to approximately one million Medicare beneficiaries who suffer from respiratory illnesses such as COPD. These beneficiaries require oxygen therapy for their long-term survival and well-being. COPD, which includes chronic bronchitis, asthmatic bronchitis and emphysema, has been defined as the physiologic finding of nonreversible pulmonary function impairment.[1] COPD is the 4th leading cause of death in the world and the only leading cause of death for which both prevalence and mortality are rising.[2] COPD afflicts approximately 14-16 million people in the United States, and it is estimated that there may be an additional 16 million that have early disease but have yet to be diagnosed.[3]

Disease progression in COPD often leads to the development of stable but chronic hypoxemia, which is commonly treated with long-term oxygen therapy (LTOT). For over 30 years, LTOT in the home has been a standard and accepted treatment for patients with severe COPD demonstrating stable, chronic hypoxemia. Oxygen is the only non-invasive therapy shown to prolong the life of COPD patients with severe hypoxemia, as was evidenced in the two major randomized, controlled studies in this area. The well-known and frequently referenced *Nocturnal Oxygen Therapy Trial* (NOTT)[4] and the British Medical Research Council report on domiciliary oxygen use[5] set the scientific basis for the use of LTOT in the treatment of chronic hypoxemia. Both of these studies demonstrated significant mortality improvement with prolonged oxygen therapy. LTOT is the only available non-surgical therapy demonstrated to prolong survival in patients with COPD and chronic hypoxemia.

## "Provisions of the Proposed Regulations"

### G. Payment for Oxygen, Oxygen Equipment and Capped Rental DME Items

- **CMS has not incorporated enough safeguards to protect beneficiaries in the transition from rental to ownership of their oxygen equipment.**

The DRA of 2005 revises substantially long-standing Medicare policies covering payment for oxygen and oxygen equipment. For the first time, Medicare beneficiaries who have always rented their oxygen equipment and had their routine maintenance and

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[1] Centers for Disease Control and Prevention – MMWR: Surveillance Summaries. August 2, 2002/Vol. 51/No. SS-6.
[2] Global Strategy for the Diagnosis, Management and Prevention of Chronic Obstructive Lung Disease. Global Initiative for Chronic Obstructive Lung Disease (GOLD) – Executive Summary Updated 2003.
[3] Good, JT, Petty TL. Frontline Update in Chronic Obstructive Pulmonary Disease. Snowdrift Pulmonary Conference, Inc. 2004.
[4] Nocturnal Oxygen Therapy Group. Continuous or nocturnal oxygen therapy in hypoxemic chronic obstructive lung disease: a clinical trial. *Ann Intern Med* 1980;93(3):391-398.
[5] Report of the Medical Research Council Working Party. Long-term domiciliary oxygen therapy in chronic hypoxic cor pulmonale complicating chronic bronchitis and emphysema. *Lancet* 1981;1:681-685.

servicing provided by a home medical provider (HME) will be faced with new challenges in understanding the myriad of safety warnings and instructions on how to care for the equipment themselves.

In an effort to safeguard beneficiaries during the transition from rental to ownership of their oxygen equipment, CMS has proposed several new supplier requirements in an effort to safeguard the beneficiary from unwarranted practices. These safeguards include requiring a supplier who furnishes rented oxygen equipment or a capped rental item in the first month to continue furnishing the item throughout the entire rental period, not allowing suppliers to switch out equipment except under specified circumstances, and requiring a supplier to disclose its intentions regarding assignment for the entire rental period.

There are no requirements, however, that the supplier continue to provide services to the beneficiary once title of the oxygen equipment has been transferred. While Medicare will continue to pay for reasonable and necessary maintenance and servicing, it will be up to the beneficiary to shop around for another supplier in the event the current one chooses not to continue providing such services. The AARC believes this puts the beneficiary at a distinct and unfair disadvantage at a time when they are most vulnerable. Elderly and sick patients on long-term oxygen face significant challenges on a day-to-day basis. Those who will continue to be on oxygen beyond the 36-month period have established over time a relationship and confidence with the professionals that have provided oxygen and oxygen equipment services during the rental period. That they could be faced with the added burden of trying to find another HME supplier only exacerbates the situation. The AARC believes that additional safeguards are warranted to protect the beneficiary.

**Recommendation 1**

**CMS should add additional safeguards to protect the beneficiary if their initial supplier chooses not to continue a relationship with them after title transfer of the oxygen equipment.**

For those initial suppliers **only** that decide to discontinue service once title of the oxygen equipment transfers to the beneficiary, the AARC recommends that CMS add a new paragraph in §414.226 (g) requiring the supplier that furnishes the oxygen equipment throughout the rental period to notify the beneficiary no later than 3 months before the end of the rental period that the supplier will no longer continue to provide services once the transfer of title takes place. This will give the beneficiary adequate notice and time to find another comparable supplier and will not leave a gap in their service once ownership takes place.

We do not believe it is unreasonable for CMS to add this additional safeguard. The current DME Quality Standards establish certain "consumer services", but they do not address this issue.

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

- **Medicare beneficiaries on long-term care oxygen have serious health problems that could affect their ability to understand and take responsibility for routine maintenance and servicing of their oxygen equipment.**

The AARC is concerned about Medicare beneficiaries' physical and mental capabilities to conduct routine maintenance and service on their oxygen equipment once the supplier transfers ownership of the equipment to the beneficiary.

CMS acknowledges in the proposed rule that concerns have been raised regarding the ability of beneficiaries to obtain maintenance and servicing of their equipment once they own it. In fact, CMS states that the concerns are unfounded because Medicare has traditionally paid for reasonable and necessary maintenance and servicing and will continue to do so, and the beneficiary will not be "on his or her own" to secure these services and to submit payment claims for them. The AARC believes CMS has over-simplified the situation and that the health and safety of the beneficiary could be at risk.

*The average Medicare beneficiary on long-term oxygen suffers from advanced disease and disability.*

According to recent survey data[6], the profile of the average Medicare beneficiary receiving oxygen therapy at home is the following:

- Average age: 73: Thirty percent are 80 or older. Fifty-eight percent female.
- More than 1 in 4 patients on home oxygen use it for more than 36 months.[7]
- About 1 in 4 patients qualify for both Medicare and Medicaid.
- Three out of 4 oxygen patients use a combination of oxygen systems such as a concentrator and a portable gas system.
- Fifty-six percent suffer from Chronic Obstructive Pulmonary Disease – a progressive, debilitating disease and the fourth leading cause of death in the United States.
- Nine percent suffer from congestive heart failure; 7 percent suffer from hypoxemia; 3 percent suffer from emphysema; 1 percent suffers from asthma.
- Patients experience a reduced capacity to cope with Activities of Daily Living (ADLs).[8]

It is important for CMS to understand fully the serious and debilitating illnesses that require patients to be on long-term oxygen therapy. Many live alone, are unable to drive, have poor eyesight, hearing impairments and other health complications such as arthritis. Caregivers are frequently aged spouses with similar physical and mental issues. Few are able to perform simple troubleshooting of their equipment with a professional speaking to

[6] American Association for Homecare 2006 survey of oxygen providers
[7] 2006 Survey by the Council for Quality Respiratory Care
[8] Bestall JC, et al. Usefulness of the Medical Research Council dyspnoea scale as a measure of disability in patients with chronic obstructive pulmonary disease. *Thorax*. 1999;54:581-586

them over the phone, requiring home visits to assure the equipment is functioning and/or to determine if replacement is required.

Patients prescribed home oxygen therapy suffer from an advanced level of disease and disability that requires treatment for the rest of their lives. As noted in the "Background" section, COPD is a very progressive disease, which becomes more debilitating with time. It is the fourth leading cause of death in the US (behind heart disease, cancer and stroke) and is projected to be the third leading cause of death for both males and females by the year 2020.[9] COPD is the third leading reason for at-home care (after congestive heart failure and stroke.)[10] As with any chronic progressive disease, effective treatment is an on-going process requiring consistent re-assessment, monitoring/trending, and changes in modalities and/or prescriptions to meet the changes and aging that naturally occur.

*Patients with COPD and CHF have reduced capacity to cope with Activities of Daily Living (ADLs)*

There have been numerous clinical studies published in peer-reviewed journals that have studied the correlation between Activities of Daily Living (ADLs) and patients with severe COPD who are on long-term oxygen therapy. For example, a 2005 study[11] published in *Chest* sought to distinguish the disabling effects of COPD, congestive heart failure (CHF) and diabetes mellitus using a scale of basic activities of daily living (BADL) (e.g., the basic capacity of persons to care for themselves) and instrumental activities of daily living (IADL), which refer to higher levels of performance such as managing money and taking medicine. The purpose of the study was to demonstrate using the BADL-IADL scale that CHF, COPD and diabetes mellitus affect physical function differently. The study concluded that COPD was associated with a distinctive pattern of disability expressed by loss of selected BADL-IADL. Correlates of dependency in IADL in COPD were older age, cognitive impairment, widowhood and comorbidity.

In a 1997 study, Okubadejo, et al[12], concluded that "patients with severe chronic obstructive pulmonary disease and broadly similar health status using long-term oxygen therapy who tend to have more severe airways obstruction were less independent in activities of daily living than those not requiring long-term oxygen therapy." The study showed that reduced independence was due to the extent of airflow limitation, depression and poor health as opposed to restrictions in movements imposed by a stationary oxygen device. Another study conducted in 1999 by S Small and M Lamb[13], concluded that participants with COPD or asthma described fatigue "as an unrelenting feeling of tiredness that was associated with labored breathing and that limited their ability to perform meaningful daily activities."

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[9] http://www.copd-international.com/library/statistics.htm

[10] http://www.lungsandiego.org/copd/adults_stats.asp

[11] 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

[12] 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

[13] Small A, Lamb M. Fatigue in chronic illness: the experience of individuals with chronic obstructive pulmonary disease and with asthma. *J Adv Nurs* 1999;30:469-78.

*Cognitive impairment is common among elderly patients with COPD and CHF*

Other studies focus on cognitive impairment in patients with COPD and CHF. A recent study showed that cognitive impairment was a key feature of CHF in the elderly[14]. According to the study, patients were assessed and tested for the following cognitive domains: attention, visual-spatial intelligence, verbal attainment, verbal and visuo-spatial memory. The results demonstrated that cognitive impairment is common among CHF patients and seems to be causally related to CHF severity, depression and hypertension.

Another study conducted in 1998[15] was designed to identify the predictors of cognitive decline in patients with hypoxemic COPD on continuous therapy. The findings showed 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. The onset of depression rather than baseline depressive symptoms seems to be a risk factor for cognitive decline." Another study published in *Chest*[16] in 1997 found that the decline of verbal memory parallels that of the overall cognitive function in COPD patients and is due to the impairment of both active recall and passive recognition of learned material. Poor adherence to medication regimen was significantly associated with abnormal delayed recall score (82.3% versus 36% in subjects with normal delayed recall, $p<0.008$).

Last, in order to characterize the neuropsychologic profile of patients with hypoxic-hypercapnic COPD, patients with COPD were compared to normal adults, normal elderly adults, patients with Alzheimer-type dementia and multi-infarct dementia.[17] The discriminate analysis of cognitive test scores in this study showed that 48.5% of patients with COPD had a specific pattern of cognitive deterioration characterized by a dramatic impairment in verbal and verbal memory tasks, well-preserved visual attention, and diffuse worsening of other functions.

- **Beneficiary responsibility for routine maintenance and serving of oxygen equipment could have serious consequences.**

*Certain "routine" oxygen services require trained and qualified personnel*

We use the examples above to illustrate the significance of the physical and mental disabilities associated with respiratory illnesses requiring long-term oxygen use. That the supplier must now transfer ownership of the oxygen equipment to the Medicare beneficiary after 36 months of continuous use has significant consequences for the beneficiary. Although CMS will continue to pay for reasonable and necessary maintenance and servicing for parts and labor not covered by the manufacturer's warranty, the beneficiary will now be responsible for routine maintenance and servicing

[14] Trojano L, et al. Cognitive impairment: a key feature of congestive heart failure in the elderly. *J Neurol* 2003; 250(12):1456-63.
[15] Incalzi RA, et al. Predicting cognitive decline in patients with hypoxemic chronic obstructive pulmonary disease. *Respir Med* 198; 92:527-533.
[16] Incalzi RA, et al. Verbal memory impairment in COPD: Its mechanisms and clinical relevance. *Chest* 1997; 112:1506-1513.
[17] Incalzi RA, et al. Chronic obstructive pulmonary disease: an original model of cognitive decline. *Am Rev Respir Dis* 1993; 148:418-420.

of the equipment that has heretofore been performed by the DME supplier. CMS describes certain routine maintenance or periodic servicing of purchased equipment as "testing, cleaning, regulating, changing filters, and general inspection of beneficiary-owned DME that can be done by the beneficiary or caregiver.

Since certain routine maintenance services are currently performed by home oxygen providers as part of the monthly rental fee, we are concerned that beneficiaries will have difficulty knowing which services will continue to be paid by Medicare and which services will not. Services currently provided by HME suppliers that could be in jeopardy of non-Medicare payment include but are not limited to the following:[18]

- Verifying the purity of the oxygen delivered to the patient. This procedure is performed regularly by a respiratory therapist or specially trained technician using calibrated oxygen analyzing technologies. Without this verification, a patient could be unknowingly receiving sub-therapeutic levels of oxygen. Such an incident may adversely and severely affect the patient's medical condition, requiring emergency care and/or hospitalization.

- The oxygen flow is the "dose" of the drug prescribed. Utilizing a flow verification device, a respiratory therapist or specially trained technician regularly verifies the actual prescription being delivered to the patient. As with many other medications, too little is ineffective and too much can be potentially fatal for some patients.

- Verification of alarm system functions assures the patient and/or caregivers will be awakened to place the patient on a back-up oxygen system should the home lose electricity or the oxygen concentrator fails to operate properly.

- Internal and external filter systems must be regularly checked and replaced. A respiratory therapist or specially trained technician normally cleans and replaces the filters in accordance with the manufacturer's specifications, often a requirement to retain the manufacturer's warranty.

- Disposable oxygen accessories, such as humidifiers, supply tubing, filters, nasal cannulas, trach masks, corrugated tubing, in-line adaptors, and other miscellaneous devices are needed to deliver the prescribed oxygen to the patient. These disposable components require frequent replacement and are included in the current monthly rental fee paid by Medicare.

- Ensuring that patients can adequately manage their oxygen in the event of natural or man-made emergencies that effect or damage their homes. This includes but is not limited to 24-hour, seven-day per week on-call and emergency support of all home oxygen patients.

[18] http://www.aarc.org/headlines/home_oxygen_issue/letter.html

Given the severe health status of patients receiving long-term oxygen therapy, the AARC is concerned that it is unlikely the elderly patient will be able to manage concentrator maintenance issues such as liter flow settings, filters and humidifier jars (manual dexterity); alert lights and liter flow settings (visual impairment); alarms (hearing impairment); and preventative maintenance (memory impairment). Patients with these impairments will be unable to ensure that they are getting their prescribed oxygen liter flow without help.

*Oxygen equipment is complex and can cause serious injury if improperly maintained and serviced.*

While oxygen and oxygen equipment has not been categorized in the past as the type of equipment requiring frequent and substantial servicing, we would point out that it is more technically complex than other types of DME (e.g., those categorized as inexpensive equipment, customized items, wheelchairs, prosthetic and orthotic devices) and lack of proper maintenance and servicing of oxygen equipment can cause serious injury or produce life-threatening outcomes.

The Food and Drug Administration's (FDA) web site[19] reports frequent adverse events experienced by patients using various types of oxygen equipment. To illustrate how easy it is to encounter serious problems with oxygen equipment, we have provided below several examples for CMS' information.

***Event Type: Life Threatening***

During 2003, the patient accepted delivery on a portable oxygen concentrator that functioned well for the first month and then stopped. The unit operates from an on-board 12-volt battery powered electrical scheme, has a cable and transformer for hours current charging and a 12-volt direct input cable for automobile use. Battery life is 50 minutes. Unit has no battery charging or capacity gauges. The first breakdown was full failure to recharge electrically, either from house current or 12-volt sources within vehicles. A friend with a cylinder of oxygen from a local clinic rescued the patient.

The manufacturer insisted the patient return the unit to their factory, but no "loaner" or temporary-use machine was available. When the unit was returned, it emitted a faint odor similar to burning electrical insulation. The patient telephoned the factory for advice. Engineering did not return their call. At about the 90-day point, the unit became and continues to be undependable in the sense that it has some intermittent fault in the charging circuit. Presently the unit cannot be depended on for more than 15 minutes service. Performance and charging are certainly affected by cold weather. The binary penchant for partial charging to half capacity or charging for 2 minutes, then stopping, causes a life-threatening situation for the next user. The charging cycle must be carefully monitored or a death could result.

[19] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM

***Event Type: Injury***

A patient using a c41 stationary liquid oxygen system encountered a problem with the equipment. The homecare provider (HCP) was contacted and proceeded to troubleshoot over the phone. During the process of filling the portable unit from the reservoir, the two units became frozen together. The HCP instructed the patient to apply warm water to the connection, disengage and then re-engage the unit and wait for any ice that formed to thaw. The patient was able to disengage the portable unit approximately 30 minutes after these steps were taken. The patient again contacted the HCP and reported that the quick connect of the reservoir had frozen open after removing the portable unit and was leaking oxygen. Approximately 45 minutes after this call the patient's wall furnace ignited. The fire department was called and extinguished the home. The patient was hospitalized for smoke inhalation. The house sustained damage.

***Event Type: Malfunction***

A patient experienced nausea and wooziness during a 3-hour car trip while using an oxygen concentrator, which alarmed for a "call provider error." The patient ignored the alarm. He did not have a backup oxygen supply with him. He called an emergency medical service and was provided oxygen from a bottle, resulting in improved spo02. The patient, however, was hospitalized for mild arterial fibrillation and released the next day.

In the "Injury" example, the unit is being held by the patient's insurance carrier for investigation and had not been made available to the manufacturer for evaluation at the time the event was reported. It can be surmised from the report that the problem was exacerbated by the patient's lack of adherence to the safety information provided with the equipment, although he did contact the HCP when problems with the equipment occurred. In the "Malfunction" example, the device was evaluated by the manufacturer and found to be producing oxygen at a concentration of 80%, which is below the specification of 87%. The device data log indicated that the device had alarmed properly when concentration dropped below 82%. Instructions to notify the HCP if the "low oxygen" alarm persists and to have a back-up oxygen supply available are stated in the patient manual. The patient did not follow these instructions, but it is possible that the device may have contributed to the event, although that was not confirmed. In the "Life Threatening" example, it is believed that the unit did not deliver the liters per minute indicated on the selector switch, but there is no flow meter able to confirm such suspicion. There was no follow-up report on the manufacturer's evaluation.

After receiving 12 reports in which regulators used with oxygen cylinders have burned or exploded, the FDA and the National Institute for Occupational Safety and Health put out a public health notification in June 2006 warning that the improper use of certain gaskets/washers in regulators used with oxygen cylinders is a major factor in both the ignition and severity of fires which occurred during emergency medical use or during routine equipment checks.

The purpose of highlighting these events is to show the complexity of various types of oxygen equipment and that in spite of the fact that patients may have been provided instructions on their safety and use, there is no guarantee that once they have been given the information they will either remember it or adhere to it. That any one of the many instructions in the owners' manual goes unheeded could cause serious injury to the patient, damage to their home, or even death.

**Recommendation 2**

**CMS should require suppliers to re-train beneficiaries (and/or their caregivers) on the services they will need to perform on the equipment at the time they transfer ownership and to verify in writing that the beneficiary/caregiver has actually performed the tasks for which they will be responsible to ensure that they are capable of doing so.**

As evidenced by the FDA adverse event reports, patients do not always understand the instructions they are given about the safety and hazard aspects of their oxygen equipment, nor do they necessarily follow them. While qualified professionals, often respiratory therapists, provide basic training and instructions at the time of set up, there are no assurances or a requirement for verification that the beneficiary understands the instructions or is able to perform certain routine functions short of actually demonstrating that they can do so. Once beneficiaries own their oxygen equipment, it will become even more important they understand their ownership responsibilities and are able to perform them.

CMS states in its proposed rule "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 recommend that CMS add an additional safeguard in §414.226 (g) by requiring the supplier at that the time of transfer to re-train the beneficiary and/or caregiver with respect to information regarding preparation of formulas, features, routine use, troubleshooting, cleaning, maintenance, safety considerations, and infection control.

These requirements are currently contained in the DME Quality Standards; however, the supplier is only required to verify that the beneficiary received the instructions and information at the time of setup, not they he or she understood them or could perform them. The fact that instructions were provided is meaningless unless the person(s) receiving the instructions is capable of carrying them out. Further, if the beneficiary does not perform routine checks and maintenance soon after being provided the instructions, it is likely that they will be forgotten or misunderstood when it time to actually perform them. During the rental period, the beneficiary often relies on the professional expertise of the supplier to ensure that proper servicing and maintenance is performed. Re-training the beneficiary at the time of transfer and **verification in writing** by the supplier that the beneficiary and/or caregiver can actually carry out the tasks could prevent serious injuries or even life-threatening situations in the future.

- **CMS' assumption that beneficiaries will be fully knowledgeable about the routine servicing and maintenance of their equipment by the time ownership transfer occurs has been oversimplified.**

CMS maintains that after receiving the manufacturer's information about their equipment, and "after becoming familiar with the equipment during the 13- or 36-month rental period, the beneficiary or caregiver should be very knowledgeable regarding the routine maintenance required for the item." The AARC strongly disagrees with this assumption. We believe it is highly unlikely that the average Medicare beneficiary

profiled earlier in our comments will have the wherewithal to effectively remember all of the complicated routine checks and servicing required for ensuring proper functioning of the various types of oxygen equipment prescribed by their physician.

It cannot be overstated that equipment utilized to deliver home oxygen therapy is technically complex and varies based on the type, brand and model used to deliver the prescribed liter flow. Although each manufacturer may have unique specifications for the various types and models it produces, there are a number of common issues associated with the management of home oxygen technologies, including but not limited to the items outlined below.

- Oxygen concentrators are an electrically operated, mechanical gas filtering and separation system that must be cleaned and checked regularly for the system to operate correctly. Over time, the sieve beds (nitrogen filters) eventually deplete or become contaminated, greatly reducing the ability to absorb nitrogen, and therefore, inhibiting the ability to produce a therapeutic level of prescription oxygen. Currently, home medical equipment providers are obligated to ensure the safety and performance of the oxygen devices they rent.

- Compressed gas cylinder systems, which are commonly used for emergency back-up and portability, use a regulator or pulse-dose oxygen delivery device (e.g., an oxygen conserving device) to deliver oxygen to the patient. The cylinders have a very limited supply of oxygen that depletes quickly (i.e., a few hours) as the patient utilizes the contents of the tank. Compressed gas cylinders need to be refilled frequently. In addition to regular re-filling, all compressed gas cylinders must undergo periodic safety testing as mandated by the Department of Transportation (DOT) and FDA.

- Liquid oxygen systems, which often utilize electronic or pneumatic pulse dosing systems to deliver the prescribed oxygen liter flow, require consistent refills, even if not used. If the oxygen equipment is purchased for the patient, a home liquid oxygen system will still require refilling 2 to 5 times per month, depending on the patient's oxygen prescription and the type of system. Liquid oxygen is a hazardous material and the DOT and FDA closely regulate the transport and home filling liquid oxygen system.

Any malfunction, misuse, or failure of the equipment and/or supplies may result in a non-therapeutic oxygen percentage or inappropriate oxygen liter flow, compromising the physician's prescription and goal to maintain the patient's stable condition. Ineffective treatment will result in the deterioration of the patient's condition (in some cases a sudden and rapid exacerbation.) Without routine equipment maintenance, monitoring the equipment will become increasingly ineffective and/or suddenly cease to operate. Either scenario places the patient in a potentially unrecognized, yet significantly, compromised position.

Under the rental-type arrangement, necessary and routine maintenance and servicing of the oxygen equipment is currently performed by the supplier and covered and paid for in the monthly rental fee. Beneficiaries have relied on these professional services and trusted their expertise to ensure the safe and effective use of their equipment. Because of the complexities of various types of oxygen equipment, the AARC does not believe that the patient will be as knowledgeable about their equipment as CMS surmises when it comes to knowing what they will be expected to take care of once they own the equipment. This is particularly true for those beneficiaries that use more than one type of equipment and suffer from various disabilities and forms of cognitive impairment.

**Recommendation 3**

**CMS should require the supplier to provide the beneficiary with a list of "routine" services for which Medicare will no longer make payment once title of the equipment transfers to the beneficiary.**

The AARC recommends that CMS add an additional safeguard in §414.226 (g) that requires the supplier to put in writing the services they will no longer perform under the new provisions and for which the beneficiary will now be responsible. This requirement could be simplified by the development of a standard format for each type of equipment that the supplier need only check off the list. There should be no doubt in the beneficiaries mind as to what they need to do to maintain the equipment, because any negligence on their part could have serious repercussions. We request that CMS discuss this issue more fully and provide additional information in the final rules.

In addition to the above recommendation, we suggest that suppliers maintain on their websites, or CMS on its "Medicare.gov" website, the same type of checklist; that is, routine periodic services that Medicare will no longer cover once title of the equipment transfers to the beneficiary and that the beneficiary will be expected to perform on his or her own. We have listed above various services that are currently performed and are frankly unclear which ones CMS will determine are "routine." We believe there will be much confusion during the transition phase and the fact that the beneficiary and/or caregiver can access information in more than one place or format can be helpful. We recognize, of course, that a significant number of the Medicare beneficiaries on long-term oxygen are too sick and disabled to undertake or even understand computer technology. That is why we feel is it essential for suppliers to provide beneficiaries at the time of title transfer a written checklist of their services for which Medicare will no longer provide payment.

As discussed above, we believe there will be many instances where a beneficiary simply will not be able to undertake the routine services for which they will now be responsible in order to properly maintain their oxygen equipment. Since Medicare will not pay for services such as "testing, cleaning, regulating, changing filters and general inspection" of the equipment, the beneficiary needs to be clearly informed as to what this means in the way of responsibilities that they will now have to provide that were heretofore performed by the HME supplier. For a variety of reasons, not the least of which are safety concerns, we believe that a number of beneficiaries may elect to hire a third party to perform these

types of routine tasks rather than attempt to undertake such services themselves. In those cases, the beneficiary needs to understand clearly that they must bear the cost.

The underlying factors behind the changes in payment for oxygen and oxygen equipment are that Medicare has continued to pay for equipment well past its initial cost and, as a result, beneficiaries have continued to pay unnecessary coinsurance as part of the rental fee. Under the proposed changes, the government will no longer spend money over and above what it originally would have paid, nor will beneficiaries have to pay the monthly co-payment amount for the rental e.g., around $40 per month. While the assumption is that everyone saves, the AARC believes the reality will be that some Medicare beneficiaries could end up spending more once they own their own equipment. The potential for this scenario only adds to their already stressful burdens.

## General Comments Regarding Changes to Payment for Oxygen and Oxygen Equipment

- **The proposed rule does not provide enough clarity and specificity for stakeholders and Medicare beneficiaries alike to fully recognize the impact on Medicare beneficiaries when the final provisions become effective.**

Given the recent changes in the Medicare program with respect to the new provisions for prescription drug coverage under Medicare Part D, Medicare beneficiaries have been inundated with information and the need to make informed decisions. Now they will be asked to understand their new responsibilities for taking care of their oxygen equipment. Granted, the process will not become effective until 2009 at the earliest, but the complexity of oxygen equipment and the services associated with it, including the fact that each different type of equipment carries with it different safety and routine maintenance requirements, will surely be overwhelming for the average Medicare beneficiary receiving long-term home oxygen therapy to comprehend.

### Recommendation 4

**CMS should develop a list of "Frequently Asked Questions" specific to oxygen and oxygen equipment payment to assist beneficiaries in understanding the significance of the new provisions and their impact on the beneficiary.**

We recommend that CMS develop a specific category of "Frequently Asked Questions" directly related to oxygen equipment on its "Medicare.gov" web site. We have attached a list of questions (**see Appendix A**) that cover some of the issues that we believe will be of interest to beneficiaries once the new payment for oxygen and oxygen equipment provisions become final. Of course, we expect this listed to be expanded as additional questions and issues occur.

## Summary

Implementation of the DRA provisions affecting payment for oxygen and oxygen equipment can have significant consequences for Medicare beneficiaries on long-term home oxygen therapy. The physical and mental capacity of these patients and the potential health and safety risks that could occur once they own their own equipment are key issues that need to be addressed.

Beneficiaries on continuous oxygen, most of who suffer from COPD, are elderly and very sick patients who are unable to carry out many of the normal activities of daily living. Further, serious cognitive impairments can cause an inability to understand the complex instructions and need for routine maintenance and servicing that heretofore have been performed by highly professional and trained personnel. Unlike other DME, various types of oxygen equipment are technically complex and carry with them strong warnings of safety hazards. Serious injuries or even life threatening situations can occur if the beneficiary is not able to understand or perform correctly the routine services they may have to undertake in the future.

In the proposed rule, CMS has added certain safeguards to protect Medicare beneficiaries once transfer of ownership takes place. We believe these requirements fall short of fully recognizing a variety of unintended consequences that may result once the provisions become final. For example, there is no requirement that the supplier continue to service the beneficiary's equipment once title of ownership transfers to the beneficiary or a timeframe by which the supplier should notify the beneficiary of change. In these situations, CMS should add additional safeguards to ease the transition by requiring the supplier to notify the beneficiary at least 3 months in advance of transfer if they are not going to keep servicing the equipment. We believe it is reasonable for the beneficiary to have an adequate amount of time to find another comparable supplier without leaving a potential gap in coverage.

AARC is most concerned about the physical and mental capabilities of patients on long-term oxygen use to perform even the most menial tasks. Of particular concern, is the beneficiary's ability to perform routine servicing once they own their oxygen equipment. Instructions and training on their equipment are only currently provided only at the time of set-up and delivery and the beneficiary is not required to demonstrate use of the equipment once they are trained. Therefore, we recommend that CMS require the supplier to re-train the beneficiary on use of their equipment at the time of transfer as an additional safeguard. Also, at that time, CMS should require the supplier to verify in writing that the beneficiary is capable of performing the required routine maintenance by having the beneficiary/caregiver actually perform the tasks.

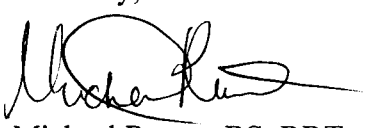
Although the new oxygen payment provisions are supposedly designed to save money for the Medicare program and the beneficiary as well, we believe a number of beneficiaries may hire a third party to perform the routine maintenance tasks that will otherwise transfer to the beneficiary to ensure there is no chance for error that could result in serious injury or death. In the end, these beneficiaries may likely pay more for home oxygen therapy than they are paying under the current provisions.

CMS states that the beneficiary should be fully knowledgeable about their oxygen equipment after 36 months of continuous use (or 13 months for capped rental). AARC disagrees with this assumption. We believe there will be a lot of confusion about what is and is not covered once transfer occurs. Therefore, we recommend CMS require suppliers to provide the beneficiary with a written list of which services Medicare will no longer pay for once transfer of ownership is complete. This information should also be posted on the supplier's website or even the "Medicare.gov" website.

The proposed rule leaves a lot of questions to be answered. We highly recommend that CMS provide additional detail in the final rule in defining "routine services" for oxygen equipment. Oxygen equipment is more complex that other types of DME and some services that may be considered "routine" should continue to be performed by trained and professional personnel. It would also be helpful for CMS to establish on its "Medicare.gov" website a list of "Frequently Asked Questions" that pertain specifically to payment for oxygen and oxygen equipment. This action can assist beneficiaries (and caregivers) in knowing how the new provisions may affect them in the near future. AARC has provided an initial list of questions for CMS' consideration.

We appreciate the opportunity to provide these comments and hope that CMS will consider our recommendations to ensure beneficiaries' health and safety are protected once final regulations become effective. If you have any questions about our comments or desire additional information, please call Cheryl West, Director of Government Affairs, at 972-243-2272.

Sincerely,



Michael Runge, BS, RRT
President

**APPENDIX A**

## List of Frequently Asked Questions

1. How do I know if the oxygen concentrator is functioning properly and is putting out the correct amount of oxygen?
2. If I call my supplier and it is not time for Medicare to pay for servicing, will I have to pay the supplier? How much can the company charge me?
3. Are pocket flow meters that determine adequate oxygen flow for concentrators considered a covered supply?
4. How do I know if my humidifier is working correctly? It is plastic and wears out. Will I have to pay for the replacement of it or is that a supply that Medicare will pay for?
5. Who do I call if the electricity goes out and my concentrator stops working? Will I have to pay for the supplier to bring in a backup? Will I have to pay for the backup equipment? How long could I keep the backup equipment?
6. If I live with someone who smokes tobacco or I live in a high pollution area, I will have to change out the cotton filters more than the recommended 3 months, probably every month. Will Medicare cover the cost of the new filters when the changes are required this frequently?
7. I spend several months a year away from my primary residence. Do I need to pack up my oxygen equipment and ship it to my temporary residence? Will another supplier at my destination provide me my oxygen equipment? Will I have to buy it from them, or can I rent it from them? Will Medicare cover any of these costs? How much can the supplier charge me if I have to rent it?
8. While I am away from my primary residence, will Medicare still cover the supplies from the supplier I am using temporarily?
9. What if my medical condition changes and I need a different type of oxygen equipment? Will I be able to get it? Will I have to pay for it, or will the 36-month rental period start again?
10. How will I be assured that I have the information I need to take care of my equipment?
11. Will my supplier have a 24-hour hotline in case I need assistance after normal business hours?
12. Can I hire another company to take care of the routine maintenance on my oxygen equipment if I cannot take care of it myself as long as I pay for the service?
13. How will I know which services Medicare will pay for once I own my own equipment?
14. Will my supplier continue to service my equipment once I own it? If not, how will I know to find another supplier?

GENTIVA®

September 25, 2006

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

RE: CMS-1304-P

Dear Dr. McClellan:

Gentiva Health Services (Gentiva), the nation's largest comprehensive provider of homecare services including home health and hospice, is pleased to have this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule entitled "Home Health Prospective Payment System Rate Update for Calendar Year 2007." We specifically are very interested and supportive of the CMS initiative to refine the home health quality measures and to complement the measures with health information technology. Gentiva believes the implementation of new evolved measures with appropriate technology will further improve home health's role in the continuum of care for treating acute needs of patients and providing important disease management for chronic illnesses.

As the Medicare and Medicaid programs grapple with increasing costs related to the aging population, new technologies, and lack of care coordination between providers, home health services provide an unique opportunity to be relied upon more for acute care, disease management services and long term care.

Our care under the Medicare program is uniquely positioned to provide symptom management services for the chronically ill and support their treatment through education and self-management of their disease that we believe has long sustaining power for better outcomes. Home health is also well-positioned to provide acute care services in the home without the need for institutional care. *Home health services, therefore, are cost-effective, clinically-efficacious and patient-preferred. It is an important solution to the Medicare financial dilemma.*

The development of new quality measures should help to support and promote our unique Medicare role with the appropriate use of technology. Gentiva has written a white paper that outlines the areas we believe would be most beneficial for new measure

development. The specific areas include: heart failure, Diabetes, falls risk, medication management, and pressure ulcers. An important additional component is our ability to keep the patient from being hospitalized. This component relates to those patients whose care in the home acts as a substitution for facility-based services with the same or better outcomes and for less cost to the overall Medicare program. Also, this component relates to home health care that does not require the patient to be re-hospitalized.

Since quality measures and the use of health information technology are a top priority for Gentiva, our company has established an internal clinical outcome group to further explore areas of possible evidence-based criteria and the best approaches for ensuring excellent and sustainable clinical outcomes. As you are well area, there is virtually no evidence based measures for home health services. But of the areas of importance to us, we did find some interesting research.

**Heart Failure:**
In May 2004, the National Institutes of Health released a study that highlighted the impact on the continuum of care when homecare is utilized with elderly heart-failure patients. When heart-failure patients received specialized nursing care throughout their hospital stay and at home following hospital discharge, the patients reported a better quality of life and fewer hospital readmissions. The use of this combined care resulted in a 38% savings in Medicare costs.

The NIH stated that the higher level of care actually saved taxpayers an average of $4,845 per patient or 37.6% savings over a twelve month period by avoiding additional institutional care. Within this demonstration project advanced practice nurses were used. One could surmise that similar or better savings could be realized within the episodic payment methodology of traditional home health care that focuses on patients remaining safe and independent in their homes.

A survey by Duke University Medical Center also found that heart disease patients who receive home visits by a health care professional after hospital discharge reported better quality of life than those who received no visits. Patients were contacted approximately nine months after discharge from the hospital and were asked to complete a questionnaire. Thirty-four percent of patients who have suffered myocardial infarct (a heart attack) who received home health care reported that their health status was "much better," compared to 19 percent who did not receive home health care. Bypass patients who received home health care felt "much better" 49 percent of the time, compared to 45 percent for those who didn't.

Similar success stories have been observed at Gentiva Health Services through our specialized program for congestive heart failure patients. Of the 104 Gentiva cardiopulmonary patients who were reviewed, less than 3% required rehospitalization during or after our home health interventions. Likewise, less than 8% of the cardiopulmonary patients visited the emergency room 16 weeks after discharge.

The Gentiva patients overwhelmingly had better self-management of their heart failure condition. Ninety-seven percent of the patients were able to explain the actions of their medications 16 weeks after discharge. Likewise, ninety-nine percent of the patients were able to recognize the signs and symptoms of their illness within 16 weeks following their discharge from our services.

A critical initial step in treating CHF patients in the home is working with the patient to help them better manage their own illness. There are evidenced-based criteria that have been applied in other settings for self-management techniques that are especially associated with home care.

***Health Information Technology:*** Gentiva has found that this particular diagnosis and the associated treatment options can be augmented with the use of both low and high technology in the home. The type and timing of the technology required is an important factor. A patient with more severe symptoms may require a telemonitoring program. These patients should be eased into self-monitoring and the use of low technology devices (a simple blood pressure cuff for home use). The use of technology in home care has been shown to help reduce rehospitalizations. It is important to note that this use of technology is a tool used by the professional to help teach the patient to become more compliant with disease self-management, and cannot replace the importance of clinical care by professionals.

**Diabetes:**
The American Diabetes Association estimates that 18.2 million people in the United States, or 6.3% of the population, have diabetes. Of those 18.2 million, an estimated 13 million have been diagnosed with diabetes. Another 5.2 million people, however, are unaware that they have the disease. The direct and indirect medical expenditures attributed to diabetes in 2002 were estimated at $132 billion. Institutional care was the largest component of health care costs related to diabetes and comprised 41% of the cost. Outpatient care comprised $20 billion in 2002 and comprised 15% of the total cost of diabetes. Another $17.5 billion comprises outpatient medication and supplies.

Although no concrete data is yet available on the cost savings and clinical effectiveness of home care in regards to the care of diabetic patients, some comparison could be made

to that of congestive heart failure in that patient education is the important factor in the treatment and management of these illnesses. The home environment is a perfect setting for patients to learn how to manage their illness in the safety and familiar surroundings of their homes. Home care does and should continue to play a dynamic role in self management for the diabetic while continuing to reduce hospitalization of these patients.

***Health Information Technology:*** Once again, similar to congestive heart failure, Medicare patients are likely to benefit from the use of appropriate telemonitoring devices when they suffer with Diabetes. Telemonitoring is not for all Medicare beneficiaries but does play an important role in caring for patients with chronic illnesses.

**Falls Risk in the Home:**
According to the National Institutes of Health, falls are the leading cause of fatal and non-fatal injuries in persons over 65, and about half of those falls can be attributed to a balance disorder. A 1997 study in the New England Journal of Medicine concluded that falls among older people are a "strong predictor" of placement in a skilled nursing facility, and interventions that prevent falls may delay or reduce the frequency of nursing home admissions, and presumably a decline in health.

The AARP Public Policy Institute estimates the direct cost of falls in individuals over 65 in 2000 alone was $16.4 billion, with about 48% of that cost borne by Medicare. A 1998 study of people 72 and older found that the average cost of a fall injury was nearly $20,000. By 2020, it is estimated that the annual cost of all fall injuries to Americans over 65 is expected to reach $43.8 billion.

Gentiva served on the Medicare Payment Advisory Commission's expert panel that reviewed best practices for falls risk and wound care. For falls risk, Gentiva provided insight to our comprehensive specialty program that includes a multi-system, home-based approach to evaluation and treatment of balance dysfunction. To date, we have observed better outcomes related to falls prevention with over 3,000 Gentiva Safe Strides patients.

**Medication Management:**
The Institute for Safe Medication Practices estimates that 2 million people are hospitalized every year due to the use of prescription drugs and another 1.3 million people have injuries as a result of medication errors. Similarly, the Journal of Research in Pharmaceutical Economics states that 28% of all hospitalizations are the direct result of medication errors. The impact is staggering for all consumers, payers and providers. The American Medical Association states that $75 billion is spent on preventable hospitalizations due to medication misuse.

Home care services play a pivotal role in improving the quality of life for patients and reducing health care costs related to proper medication management. The home care clinician interacts with the physician and/or pharmacist to ensure proper medication and medication interactions. The clinician then interacts with the patient to ensure proper use, educate the patient on actions, potential side effects, contraindications, storage and self-administration and seeks to assist the patient in compliance with the medication regimen.

**Risk of Pressure Ulcers:**
More than 1 million individuals develop pressure ulcers each year, and there are approximately 1.5 to 3 million adults living with pressure ulcers in the United States according to the Wound Ostomy and Continence Nurses Society. The WOCN's "Guideline for Prevention and Management of Pressure Ulcers" states that the health care costs associated with treating pressure ulcers are $2.2 to $3.6 billion in acute care settings. Further, the report states that the mean cost per hospital admission for patients who develop a pressure ulcer as $37,288. The above cost estimates are most likely underreported as pressure ulcers are not reportable conditions. On CMS' home health compare site, during the third quarter of 2005, the percentage of patients who experienced an increase in the number of pressure ulcers during a home health episode was 1% nationally.

Homecare plays a critical role in assessing the patient for potential risk of developing pressure ulcers. Whether or not the patient is referred to home care through hospitals, physicians, the community or other post-acute care provider, home care should help reduce the health care spend by assessing patients for risk of pressure ulcers and providing intervention as indicated. Home care would reduce payer costs, intervene clinically and prevent additional complications for the patient.

***Health Information Technology:*** For accurate assessment and communication or the status of pressure ulcers, the best technology available includes a digital photograph of the wound. A picture of the wound would be transmitted securely to the physician or evaluated by a wound specialist to support care coordination and to ensure progress toward goals is sustained.

One other important health information technology is a point-of-care device whether in PDA form or tablet or lap top. The point-of-care devices should be utilized for all patients and are beneficial for better overall organization, information exchange, clinical resources and ultimately treatment of the patient. One caveat is like any technology, the devices are being modified as adoption of better services is being applied.

Gentiva believes very strongly in the adoption of health information technology. Health information technology helps to ensure quality of care and providers who have bravely sought the adoption of new technologies should be commended for their efforts. New technologies enter into the markets and need to be researched and evaluated. Our clinicians are our top priority to be sure that they approve of the new technologies, find them useful and believe that the technologies are beneficial to our patients. The process of seeking our clinician approval through a pilot test that is time-consuming and costly as we ultimately make additional modifications following the pilot test. But it is important for better clinical care of our patients. As CMS seeks to encourage other providers to implement new technologies, it is important to recognize providers who have been on the forefront of testing and implementing the new technologies, and have been developing better ways to care for Medicare beneficiaries.

Finally, Gentiva appreciates CMS seeking to evolve the OASIS tool. OASIS has been very successful in promoting better efficiencies within home health agencies through its focus on clinical outcomes, data collection, and resource use. And because of its implementation, the home health industry is learning new ways to treat our patients. We do, however, believe it is now time for it to be refined. Gentiva joined with the national associations and providers in offering suggestions for possible changes to the OASIS tool. We support the industry recommendations.

As CMS seeks to develop new quality measures, Gentiva also supports some broad considerations. They include:

- Be meaningful to patients, providers, payers, and other stakeholders;
- Show the value of home health services in care and to the overall healthcare system;
- Represent aspects of care that are under the control of the home health agency while the patient is receiving our services;
- Be evidence-based and/or risk-adjusted and achieve reasonable norms or reliability and validity testing as appropriate for the type of measure; and,
- Seek to implement in the least burdensome way for providers.

Gentiva believes that through the proper use of new quality measures in the above areas and the appropriate use of health information technology, home health services will promote quality care, efficiency, save federal dollars, and satisfy the needs and wishes of our patients by allowing them to remain in their own homes.

Thank you for initiating further discussion on quality measure development and implementation of health information technology. Gentiva is very interested in continuing to help and support CMS on both initiatives. If you should need further information or assistance, please do not hesitate to contact me at (703) 340-1633.

Sincerely,

Mara Benner

Mara Benner
Vice President, Government Affairs

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## Teeters, Margaret A. (CMS/OSORA)

**From:** Sharon Fowler [sfowler@inspiremed.com]
**Sent:** Wednesday, September 27, 2006 10:28 AM
**To:** Teeters, Margaret A. (CMS/OSORA)
**Subject:** [CMS-1304-P] Comments
**Importance:** High
**Attachments:** LET CMS-1304-P.doc

Dear Ms. Teeters;
Attached please find a copy of the comments I submitted on 9/22/06 per your request. Please feel free to contact me if you have questions.
Sincerely,

Sharon E. Fowler, RRT, RCP
General Manager
INSPIRE Medical Equipment & Svcs., Inc.
34 Rogers Road, Haverhill, MA 01835
sfowler@inspiremed.com
Tel 978-372-2290
Fax 978-372-2292

September 22, 2006

Department of Health and Human Services
Centers for Medicare & Medicaid Services

RE: [CMS-1304-P] Comments

To Whom It May Concern,

I am writing to you first as a Registered Respiratory Therapist who has been serving patients in their homes since 1982 and second as a founding partner of Inspire Medical Equipment & Services, Inc. I am commenting because I believe the NPRM proposals are poorly conceived and if enacted as currently written will create hardships to both beneficiaries and home oxygen providers.

Let me start by stating that acquisition costs for oxygen equipment and supplies are only a fraction of our overall costs and that the financial assumptions of the Deficit Reduction Act do not account for our costs of labor, facilities, utilities, vehicles, fuel, and administration of services. While it is true that the acquisition costs for oxygen concentrators have declined in recent years, all of our overhead expenditures have increased significantly.

Regardless of these increases, we have made the sacrifices necessary to continue to provide service to home patients 24 hours/day, 7 days/week. The proposed rule makes no provision for back-up/emergency oxygen supplies that are currently provided to our patients and are a requirement of accreditation. We are required to provide "3 times the response time" for use in the event of equipment malfunction and power failures. It appears to me that at the time of transfer of title of the concentrator the back-up oxygen supply (we use M-60 cylinders which provide 14 hours of oxygen @ 2 L/M) would have to be removed OR the beneficiary would have to pay for the cylinder, regulator, and stand on a rental basis and/or agree to a Service Contract to ensure an emergency oxygen supply and after hours services as needed. If home oxygen patients do not have back up oxygen supplies, they may call ambulances to go to emergency rooms for oxygen during extended power outages or when the concentrator fails. I do not believe that this is a desired outcome of this proposal, and thus an amendment should be made to ensure that back-up oxygen supplies are provided.

Furthermore, if title transfer of cylinders is to be included with transfer of a concentrator I have numerous concerns. First, we are required to track hydrostatic test dates for cylinders by the DOT. Aluminum cylinders must be tested every 5 years. Second, if cylinders are to be tracked by patient name it will create labeling issues currently not covered by the FDA, nor software programs by which serial and lot numbers are tracked. And what is the expected "after-market" life of these cylinders. Once the beneficiary no longer needs them, where will they go? eBay? Waste disposal? Garage sales? What happens to the tracking then. Oxygen cylinders are deemed "hazardous material" but DOT and FDA enforcement will be hampered once these items are in the public domain and no longer controlled by a gas supplier. It is conceivable that cylinders may be transferred amongst family members and filled by non-medical gas sources.

It is also unclear how many cylinders will be allotted to each beneficiary and of what size? If they need more or less portable cylinders post title transfer, how will that be addressed?

Apparently, beneficiaries are expected to clean, test, and maintain the concentrator. Does this mean that CMS plans to provide liter meters and oxygen analyzers to beneficiaries after the title of ownership is transferred?

If the concentrator is not maintained properly, or if the beneficiary attempts to repair the device or have it serviced by an unauthorized dealer the warranty will be voided.

Also, it seems that there is an assumption that concentrators have a five year warranty. That is no longer true. Every concentrator we own has a three year warranty, and now the manufactures have begun issuing notices that these warranties will be non-transferable. Thus, even if the beneficiary ends service with a new unit, the warranty will expire at the time of title transfer.

If concentrator servicing and repairs exceed 60% of the equipment's value the item is to be replaced. This is unreasonable because the CMS service fees have not been increased in approximately 10-15 years - even though our costs for parts and labor have increased. Thus, we will be unable to provide service or repair at the current rates, forcing beneficiaries to find a repair service on their own. And if another company provides service and repair, and does not have a Medicare Supplier Number, we should not be expected to replace the unit at the 60% threshold since we will have no way of verifying that the work performed was necessary or properly done. CMS is asking us to provide another unit without further compensation through no fault of our own. In the current system, we are held responsible for all maintenance and service and are required by accreditation to keep detailed records of the service history. But once the title transfers to the beneficiary we will loose control of the device service history and should not be expected to replace devices at no charge.

Respiratory Therapists are required to perform an initial assessment and patient/client instruction for home oxygen patients by the state of Massachusetts. It is also part of our service to provide follow-up visits by Respiratory Therapists based on the identified needs of a Care Plan or upon the written order of a physician. This is currently provided without charge to the beneficiary; however professional hourly fees based at a fair market value will be charged to the beneficiary for any visits needed post title transfer. Given the fixed income of the majority of our clients, we expect the level of care and monitoring in the home to decline because of this.

Oxygen accessory supplies such as regulators, carts/stands, nasal cannulas, tubing, adapters, connectors, humidifiers, and filters are all supplied as part of the rental agreement. Our patients are instructed to change their nasal cannula weekly. What quantity of supplies will be allowed to the patient and in what time frame? Will delivery or shipping charges be included or charged to the beneficiary?

If you require any further information please contact me directly at 978-372-2290.

Respectfully yours,

Sharon E. Fowler, RRT, RCP
General Manager

MINNESOTA HOME CARE ASSOCIATION
*The voice for home care in Minnesota*

**Comments to CMS regarding Inflation Update**

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

Re: Home Health Inflation Update and Other Payment Changes

The Minnesota HomeCare Association (MHCA) is a statewide, nonprofit association whose purpose is to promote the delivery of quality health care and supportive services in a variety of home living environments. The association believes home care should be an integral part of the health care system and be available to anyone who needs it.

MHCA represents approximately 260 home care agency members who provide hands-on care to Minnesota residents in their homes. MHCA includes in its membership all types of agencies: county public health nursing services, hospital- and nursing home-based programs, proprietary, and private nonprofit. About two-thirds are located in greater Minnesota, and one-third are in the seven-county metropolitan area.

We understand the need to regulate reimbursement for health care. However, we have several concerns about the planned inflation update for home health. Please consider the following comments and recommendations regarding the home health inflation update.

1. Home care providers should receive their full Medicare market basket update for 2007 and each subsequent year.
2. Indefinitely retain the five percent rural add-on for home health services delivered in rural areas.
3. Retain or increase the current outlier payment structure.

Rationale:

- Home care staff travel substantial distances to care for home care clients. With the increase in transportation costs over the past year, providers have had to pay a significant increase in mileage reimbursement. With the home health worker shortage, providers must reimburse workers at a reasonable rate in order to retain staff. These costs are not faced by hospitals and other institutions that furnish care in a single location.
- The nation is shifting to a community health model for health care delivery. The rapidly increasing cost to deliver home care (increasing costs for labor, transportation, workers' compensation, health insurance premiums, compliance with the Health Insurance Portability and Accountability Act, HHABN changes and other regulatory requirements, technology enhancements including telehealth, emergency and bioterrorism preparedness, and systems changes to adapt to the

prospective payment system) makes it imperative that the Centers for Medicare & Medicaid Services use the most accurate and timely data available to establish the annual inflation update for home health agencies. Current reimbursement levels have failed to adequately cover the rising costs of providing care.

- Home is the most cost-effective setting in which to provide care, and studies indicate it is also where most individuals prefer to receive their health care.
- Since the inception of the Medicare home health prospective payment system in 2000, home health agencies have not received a full market basket increase, but instead received either a reduced market basket increase or a freeze in payment. Home health agencies have experienced market basket reductions in seven of the last nine years.
- Home health agencies are already in financial jeopardy as a result of Medicaid cuts and inadequate Medicare Advantage and private payment rates.

The circumstances noted above have had a substantially negative impact on home health agencies' ability to deliver care and services to clients. To mitigate the negative impact on home health and the subsequent use of more expensive health care settings, it is vitally important to increase the market basket update and retain the 5% rural add on. Thank you for the opportunity to provide comments on the inflation update for home health. Please carefully consider the recommendations for future implementation.

Sincerely,

Dori Finch
Chair, MHCA Medicare Team

Neil Johnson
MHCA Executive Director