



September 25, 2006

Mr. Herb Kuhn  
Director, Center for Medicare Management  
Centers for Medicare and Medicaid Services  
7500 Security Blvd.  
Baltimore, MD 21244-1850

RE: Changes to Medicare Payment for Oxygen Equipment, Oxygen Contents, and Capped Rental Durable Medical Equipment; Proposed Rule (CMS-1304-P).

Dear Mr. Kuhn:

I represent a group of home care providers through membership in our organization. On behalf of our membership, I respectfully submit comments on the Changes to Medicare Payment for Oxygen Equipment, Oxygen Contents, and Capped Rental Durable Medical Equipment, Proposed Rule (CMS-1304-P). The VGM Group represents over 3000 small to mid sized independently owned and operated durable medical equipment suppliers. The make up of our membership mirrors the make up of what makes our great country what it is today, the entrepreneur who can make a difference in someone's life.

Chronic Obstructive Pulmonary Disease (COPD), the fourth leading cause of death in the United States, is an incurable disease that affects more than 24 million adults. Approximately 1.5 million emergency department visits were made in the year 2000 with that number increasing annually as the prevalence of COPD increases year over year. Emergency department visits and more importantly, hospitalization is costlier to the Medicare system than providing oxygen therapy to beneficiaries in their home. In order for Medicare to realize its savings goals is to decrease the spending of hospitalization and emergency room visits, not by reducing reimbursement and coverage for long term oxygen therapy. A copy of the data fact sheet as published by the U.S. Department of Health and Human Services is provided for your perusal.

It is understood that the proposed rule (CMS-1304-P) is in response to the Deficit Reduction Act of 2005 that was signed into law by the President on February 8, 2006. Section 5101 of the DRA amends the provisions of the Social Security Act that govern Medicare payment for home oxygen therapy and rental of certain items of durable medical equipment. The burden and impact to Medicare beneficiaries as a result of the DRA of 2005 and subsequently the proposed rule changes (CMS-1304-P) has a significant impact on the overall health of the beneficiary in addition to limiting the service capabilities of the equipment provider.

Prior to the passage of the Deficit Reduction Act of 2005, oxygen and oxygen equipment was reimbursed on a continuous rental provided the beneficiary met Medicare's criteria for coverage. The equipment provider was responsible for providing equipment, service, support and other services that improved quality of life and ensured the proper working order of the equipment the beneficiary was utilizing. The regulations per the DRA of 2005 will transfer ownership of the oxygen equipment to the beneficiary after 36 continuous months of rental. After 36 months, Medicare will pay for oxygen contents as required by the equipment being utilized by the beneficiary.



In all respect, it is appreciated the task you were forced into by the passage of the DRA of 2005. The challenges you are faced with to ensure budget neutrality of any changes proposed and implemented by CMS. In regards to CMS Proposed Rule CMS-1304-P, there are many items of concern for the beneficiary and the supplier as it relates to providing oxygen equipment, oxygen and services. Based on the proposed rule, there are five major areas of concern related to the proposal. Those areas are as follows:

- Limits beneficiary access to ambulatory oxygen
- Limits beneficiary access to innovation and new technology
- Limits beneficiary access to freedom of relocation
- Limits beneficiary access to choice of suppliers
- Limits beneficiary access to twenty four hour service, maintenance and support

Additionally, there are still unanswered questions as it relates to reimbursement of on-going supplies. The absence of reimbursement codes for items that are routinely provided today, such as nasal cannulas, humidifiers, regulators, conserving devices, oxygen tubing and filters, to name a few of the routine items provided under the current system.

### **Limits beneficiary access to ambulatory oxygen**

The provisions for post 36 month transfer of ownership of ambulatory oxygen is not sufficient with the services provided by an oxygen therapy provider. The rule states that a provider would have to transfer ownership of all oxygen cylinders that are used by a beneficiary during the initial 36 months of continuous use period. The need to transfer cylinders that are located in a patient's home and those located at the provider to the patient generates additional tracking and additional purchasing requirements by the home care provider to be in compliance with the proposed rule. The current method of providing a beneficiary with gaseous cylinders for use during ambulation then replacing the empty cylinders with full cylinders and further re-filling the empty cylinders to be used by another beneficiary provides optimal use of cylinders. Under the proposed rule, the provider will have to spend additional monies to provide a beneficiary with ambulatory oxygen. In addition post 36 months; the amount of reimbursement for providing ambulatory oxygen is not sufficient to cover the expense of providing ambulatory oxygen. The delivery costs, the cost of contents, the record keeping and the type of delivery driver required to make deliveries are just a few of the costs associated with providing ambulatory oxygen. With a total monthly reduction in the reimbursement for ambulatory oxygen, the provision on what equipment must be transferred to a patient in conjunction with the federal and local laws regarding the handling of oxygen, the amount of reimbursement presented in the proposed rule is not sufficient to meet the needs and demands of the beneficiary. In addition, the amount of ambulatory oxygen varies greatly from week to week, month to month. There is no solutions post 36 months to any requirement that a beneficiary may need additional ambulatory oxygen.

The component in the proposed rule that mandates that "... 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. This policy would apply to both gaseous and liquid oxygen stationary equipment and portable systems." {Pages 69 and 70 of the proposed rule} This rule in itself will preclude a provider who currently practices "milk canning" for liquid oxygen from providing liquid oxygen to a beneficiary. Milk



Canning is the process in which a provider picks up an empty liquid oxygen reservoir and replaces it with a full reservoir and refills the empty reservoir picked up at a beneficiary for another beneficiary to maximize inventory. Liquid oxygen reservoirs cost approximately 30 times more than a gaseous oxygen cylinder and would prohibit a provider due to cost constraints for providing this modality to a beneficiary.

### **Limits beneficiary access to innovation and new technology**

Under current conditions if new technology or innovative equipment is introduced to the market place, a beneficiary and their chosen provider are able to review this equipment to determine if a change in modality would be beneficial to the patient. Under the proposed rule, it would be cost prohibitive to a provider to continually change modalities of equipment that is being utilized by a beneficiary. As an example, under current rules, new technology is introduced to the market during the 35<sup>th</sup> month of a beneficiary's continuous service, the beneficiary contacts their provider and the provider determines this new technology would benefit the patient. Under the proposed rule, the provider would not be able to provide this new technology for one months of reimbursement, regardless of cost. In addition, the amount of reimbursement differences between the payment classes is not sufficient to cover the differences in acquisition costs between the various modalities.

### **Limits beneficiary access to freedom of relocation**

The proposed rule states that oxygen therapy will be reimbursed for 36 continuous months and then ownership of the equipment would transfer to the beneficiary. If a beneficiary needs to relocate from one service area to another service area during the initial 36 months of continuous use period, a provider in the new area would need to provide the oxygen equipment. The provider in the new area is expected to provide oxygen equipment at something less than 36 months and would then have to transfer ownership of the equipment to the beneficiary. A supplier in the new area would not have any access to knowing how many months remain on the initial 36-month period without having access to the common working file. The proposed rule states that the current provider or beneficiary is responsible for finding a new supplier. This should be limited to the beneficiary since it is the choice of the beneficiary to relocate and not necessarily that of the supplier.

### **Limits beneficiary access to choice of suppliers**

Under the current CMS Rules, a beneficiary is able to call their current supplier and ask them to remove their equipment and contact another supplier to bring equipment for their perusal. Under the proposed rule and the transfer of ownership provision, the beneficiary would be limited in their ability to switch from one supplier to another should service not be acceptable to the beneficiary. Under the proposed rule, the beneficiary who contacts provider "B" to replace their existing equipment would do so at less than full reimbursement rates and therefore may opt not to replace the beneficiary's current supplier. This will force a beneficiary into staying with their current supplier because another supplier would not be able to provide the necessary therapy and products for the number of remaining months under the initial 36-month period. A supplier who is contacted to repair a concentrator post 36-month transfer of ownership would be hesitant in accepting a new claim if they do not know how much has



been provided under the beneficiary's current file. Without access to the common working file, the beneficiary would be limited to contacting the supplier who provided the initial repair and / or equipment.

**Limits beneficiary access to twenty four hour service, maintenance and support**

Under the current rule, a beneficiary is able to contact their current provider 24 hours per day, seven days per week with any questions or issues they have concerning their therapy. The proposed rule doesn't have a provision for a provider to continue providing this service post 36-months. Due to the fact that a beneficiary may not be covered and a provider doesn't have access to the common working file, a beneficiary may be asked to pay for this service in advance prior to a provider issuing a beneficiary any type of service. The beneficiary would then be required to file the correct paperwork necessary to be reimbursed. Under the current rule, the beneficiary's current provider is required to maintain twenty-four hour service and provider service to their beneficiary's upon being contacted by the beneficiary. Without funding for this provision in the proposed rule, this service will be eliminated for the beneficiary post 36-month transfer of ownership of medical equipment.

Other issues the proposed rule failed to clarify or identify as real issues beneficiary's face are as follows:

- 1) How does a beneficiary who resides in one state during one part of the year and another state during another part of the year receive service and the therapy they need?
- 2) What back-up oxygen equipment is required and how would a provider be reimbursed for having this back-up oxygen equipment with the beneficiary?
- 3) How would a supplier know how much was spent on repairs for a beneficiary? Without knowing how much was already spent on repairs for beneficiary owned equipment a supplier would be liable for replacing the equipment should the repairs they were contracted on pushes the spending limit over the threshold.
- 4) The tracking requirements initiated by the proposed rule adds additional expense to the supplier to ensure compliance with the rule should it go into affect.
- 5) The amount of reimbursement over the proposed oxygen classes would create a decrease in overall spending by CMS as opposed to budget neutral. The amount of reimbursement spread among the classes would have to be revisited in order to make this budget neutral.

Thank you for the opportunity to provide these comments.

Sincerely,

Tom Pontzius  
President