

**VIA CMS website**

September 22, 2006

Honorable Mark B. McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1304-P  
Room 445-G  
Hubert M. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

***Reference: File Code CMS-1304-P - Comments Related to Proposed Rule re: 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 (July 28, 2006)***

Dear Dr. McClellan:

Thank you for the opportunity to provide written comments in response to the Notice of Proposed Rule Making (NPRM or Proposed Rule) related to the planned implementation of the Deficit Reduction Act of 2005 (DRA or Act). The Proposed Rule relates to the Centers for Medicare & Medicaid Services' (CMS) plans to implement the statutory directives associated with certain home medical equipment and services, home oxygen therapy and related services.

These comments are being submitted on behalf of the Oxygen Stakeholders Summit, a non-profit conference that involved a wide range of stakeholder groups and was held in June 2006. Attendees at the Summit were a diverse and representative team of stakeholders that included manufacturers of oxygen technology and accessories, homecare providers (representing large, small, public and private entities), non-profit patient advocacy organizations, non-profit clinical advocacy organizations and physician organizations dedicated to the advancement of pulmonary medicine in the United States. Approximately 75 attendees were present at the meeting, which was managed via a formal consensus-building method.

The purpose of the Summit was to bring the various stakeholders together to discuss the challenges presented by the Deficit Reduction Act of 2005 (DRA) and the possibility of developing a new philosophical and reimbursement approach to home oxygen therapy as covered under Medicare Part B. While the final consensus statement is still a work in progress, we were encouraged by the significant amount of consensus around the shared goals of:

- Preserving Medicare beneficiary access to home oxygen therapy and the right to choose a qualified home oxygen provider;
- Preserving prescribing physicians' right to choose a quality home oxygen provider for their patients and the oxygen modalities most appropriate for their patients' individual needs;
- Increasing patient and physician access to those oxygen modalities that offer patients portability and the ability to perform activities of daily living (ADLs) both inside and outside the home, as well as encouraging manufacturers to continue investing in the development of newer oxygen technologies;
- Recognizing that providers deliver more than just oxygen equipment to patients, but actually provide or perform a wide range of patient support services, administrative services, 24/7 on-call and emergency response services and clinical consultation to physicians and patients. The group acknowledges that many of these services are conducted "behind the scenes" and therefore are not often clearly visible to either beneficiaries or CMS.
- Ensuring that home oxygen providers adhere to quality, financial and compliance standards;
- Ensuring that Medicare fee schedules are appropriate and adequate in terms of providing a suitable amount of reimbursement necessary to cover providers' total costs of caring for Medicare beneficiaries not just those related to the procurement of the oxygen equipment itself; and
- Discussing other methods – outside of ongoing payment reductions for oxygen therapy – that CMS might realize savings related to the care of patients with Chronic Obstructive Pulmonary Disease (COPD), the fourth leading cause of death in the United States.

### **Shared Concerns Regarding the Proposed Rule on the DRA**

Although the Oxygen Stakeholder Summit attendees represent different segments in the industry, all share a number of concerns that are associated with the Proposed Rule. Since individual industry stakeholders will be affected more than others by various aspects of the Proposed Rule, we expect that those individual providers, advocacy groups and trade associations will submit their concerns directly to CMS.

The purpose of this letter is to outline seven (7) primary concerns that are shared by all industry stakeholders represented by the Summit. We outline each of the eight areas below.

**1. Existing patient choice of oxygen modalities will be restricted, especially from months 37-60 after a significant percentage of beneficiaries take ownership of their equipment.**

Our understanding from the Proposed Rule is that patients will only be able to obtain different equipment or modalities if a limited number of exceptions apply. Under the current system, if a patient chooses to try another oxygen modality, or if his/her physician prescribes a different system for him/her purely due to a change in activity, lifestyle, equipment weight or other needs, the alternate oxygen modality is provided by a home oxygen provider. A change in medical condition does not have to apply.

In the Proposed Rule, it appears that a patient will not have the right to change equipment for the reasons described above. A “change in medical condition” will have to apply, and that has not been defined in the Proposed Rule or statute. In addition, those patients who assume ownership of equipment at month 36 will be particularly restricted if they are not able to switch equipment for at least 23 months.

We urge CMS to more clearly define “change in medical condition” and provide for a method that allows patients some reasonable choice to change equipment when desired, without penalizing the home oxygen provider financially for doing so. In addition, CMS must give the DME MACs very clear guidance about how to process exceptions, since it is giving the DME MACs authority to do so for the very first time. If these exceptions are not managed correctly, such a restriction will increase patient dissatisfaction and be inconsistent with CMS’ stated goals of making new technologies and/or portable oxygen more available to patients in the future.

**2. Physician choice of oxygen modalities and homecare providers will be restricted for their patients, especially for patients who reach the 36<sup>th</sup> month and beyond.**

The same four exceptions described in section (1) above also limit physicians’ choice of oxygen modalities for their patients. If a patient does not meet the exception criteria associated with a “change in medical condition” (again, that criteria has not been published), he/she will not qualify for a different oxygen modality even if the physician chooses to prescribe it for him/her. The homecare provider cannot be expected to provide alternate modalities that might cost significantly more to acquire and provide if there is not going to be a corresponding different level of payment. With more flexibility in this area, CMS will also benefit from those situations where a patient moves from a higher cost modality to a lower cost one, as in the example where a patient reaches the terminal phase of COPD they may no longer require portability for ambulation. COPD is a progressive disease that often requires changes in oxygen therapy and technology, a practice discouraged by the Proposed Rule.

The 36-month cap and the Proposed Rule’s policies also make it difficult for a physician to select a different homecare provider for his/her patient in the event of the patient’s or the physician’s dissatisfaction with a particular homecare provider. If the patient has already reached the 32<sup>nd</sup> month of continuous rental and desires to change providers, the other providers are not likely to choose to accept the patient on to service if the patient only has four more rental months left. The receiving provider would be required to supply all-new oxygen equipment, accessories and services to the transferring patient and would not be able to cover those costs if only four months’ rental were left. This situation will also apply to patients who simply choose to move from one

area of the country to another, unless they are with a national provider with multiple locations. Even then, that provider will incur costs associated with the transfer from one location to another.

One way to solve this would be for CMS to allow the “36-month clock” to start over whenever there is a valid, documented reason for the patient to change providers. Regarding the changes in modalities, physicians should be able to prescribe changes in modalities for their patients without incurring a lot of extra administrative paperwork or negative financial consequences for oxygen providers.

### **3. The Proposed Rule is not budget neutral.**

Summit attendees support the general direction that CMS has taken in developing the Proposed Rule’s differential payment levels regarding oxygen modalities. Attendees might have categorized the oxygen modalities a bit differently than CMS’ approach, but in general, we understand CMS’ goals of increasing access to certain therapies.

However, various attendees of the Summit have evaluated the proposed rates found in the Proposed Rule and, using CMS’ own data published in this Proposed Rule as well as the one related to Competitive Bidding for DMEPOS, determined that the proposal is not budget-neutral as mandated by statute. The proposed rates appear to result in an actual reimbursement rate reduction of 10% starting in January 2007, which translates to approximately \$260 million that CMS could reallocate within the oxygen benefit. More detailed analyses of the lack of budget neutrality will likely be submitted by other stakeholders, so we will not provide that analysis in this document.

However, we do recommend that CMS reallocate the \$260 million that results from the proposed payment rates primarily into the area of portable oxygen. The rates that CMS has proposed for portable oxygen are inadequate to cover providers’ operating costs. By reallocating the \$260 million to portable oxygen, particularly in the post-36 month scenario, CMS would meet its goal of encouraging patient mobility while also appropriately paying providers for the service.

### **4. Increased legal liability associated with patient-owned equipment.**

As a group, Summit attendees are very concerned about laypersons being responsible for servicing, maintaining and disposing of their FDA-approved medical equipment. Physician members of the Summit advised that the patients impacted are typically frail, elderly, live alone and may not be able to perform even the most “routine” maintenance on their medical equipment.

Physicians already face time and financial challenges when caring for Medicare beneficiaries and cannot be expected serve in place of the oxygen providers staff to advise on the equipment’s performance and routine maintenance following the transfer of ownership. This is a service that homecare providers have always provided in a rental situation. Now that ownership transfers to the patients, we are unclear as to what services homecare providers will be expected to provide, especially those patients who will soon own their hospital beds, wheelchairs and patient lifts, since the service and maintenance fee that was paid to providers semi-annually to help cover the costs of 24/7 on-call and other services has been eliminated.

Summit attendees are also very concerned about the possibility for increased used, unsanitary, improperly maintained medical equipment to be resold or distributed to unsuspecting future patients. eBay and other Internet vehicles are already causing problems in this area, with the unregulated sale of used oxygen cylinders (presumably stolen from providers since they are rarely sold) and other devices. CMS must confer with the FDA to obtain clear rules and regulations on the resale of medical equipment.

**5. Repair and maintenance policies are not clear, and there are no standardized payment schedules for repair parts, labor or service.**

In the Proposed Rule, CMS states that in the past, patients who own equipment have not had any problems accessing service for repairs and maintenance. Yet, most providers will advise that a very small percentage of capped rental HME patients ever took ownership of their medical equipment, and since oxygen was not subject to such a provision, oxygen-dependent beneficiaries never needed to access such services. Providers simply exchanged the equipment in the patients' homes, and returned the malfunctioning equipment to the providers' warehouse for internal repairs (without any claim billed to Medicare). CMS could see a large increase in access issues once 90% more patients assume equipment ownership than in the past.

Additionally, the DME MACs and DMERC have confirmed that there is no single, standardized reimbursement schedule for DMEPOS repair parts, labor or other service. If CMS expects providers to repair patient-owned equipment as soon as February 2007 when the first patients who assume ownership of their capped rental HME are impacted, CMS must establish a standardized, fair and equitable fee schedule with industry input. We will assist the agency in any way possible.

**6. CMS must clarify a "change in medical condition" as it relates specifically to oxygen, continuous positive airway pressure (CPAP) devices, nebulizers and other respiratory/medical equipment.**

CMS refers repeatedly throughout the Proposed Rule to a "change in medical condition" for the patient, but the agency never defines that term. It is critical for the agency to consult with clinical and medical experts to define this term as it relates to several respiratory products and services subject to the DRA. As described in the oxygen example earlier in this document, patients often desire a different model or modality of a medical device, and a change in medical condition may not apply. For example, patients who require a CPAP device to treat Obstructive Sleep Apnea (OSA), may request a device with different features, noise level, size or other attributes. Patients who rely on a nebulizer may request one that is hand-held, portable or has other features.

We are also concerned about the CMS plan to provide the DME MACs with the authority to approve an exception. The DME MACs have never been in such a role before, and will require a significant amount of training and preparation in order to do so. Also, the Proposed Rule did not specify the clinical background, role or title of the person or persons at the DME MAC who would be authorized to approve such an exception. We request that only a licensed clinician or physician with experience in pulmonary or respiratory care be authorized to approve exceptions related to Part B respiratory equipment and services. Only a licensed clinician or physician should be able to approve exceptions for other home medical equipment exchanges, although the pulmonary/respiratory specialty need not apply to such devices as hospital beds, patient lifts, wheelchairs and other HME capped rental products/services.

In order to avoid a great deal of confusion and patient dissatisfaction upon the implementation of the final rule, we urge CMS to consult with pulmonologists from Washington, DC-based advocacy groups, home respiratory therapists and other clinical experts to develop standardized definitions of “change in medical condition” Members of our Summit stand ready to assist CMS and the DME MAC physicians in developing such criteria.

#### **7. Transition Period Needed to Ensure Ongoing Access While Changes Are Underway**

Again, we understand CMS’ goals in developing certain content of the Proposed Rule that was not explicitly stated in the DRA, such as the decision to propose oxygen modality-specific reimbursement rates. However, given the nearness of the new calendar year, and the fact that the final rule will not be published until at least November, we recommend that CMS institute a transition process. Such a process would allow patients, providers, manufacturers and physicians enough time to communicate the changes with other stakeholders and make changes in their medical practice, operations, manufacturing facilities, engineering plans, branch and billing operations. If a transition period is not allowed, we are concerned that the dramatic changes to the home oxygen therapy benefit -- brought about by the confluence of the 36-month cap, competitive bidding in 2007 and any payment changes CMS elects to implement – will have a disruptive effect on the entire industry and therefore not serve either patients or CMS well.

Thank you for the opportunity to submit these comments. If you have any questions, please feel free to contact the Oxygen Stakeholder Summit Organizing Committee through the American Association for Homecare’s Alexandria, Virginia office, at (703) 836-6263.

Respectfully Submitted,

Oxygen Stakeholder Summit Organizing Committee

*A multi-disciplinary group representing home oxygen providers, patient advocacy organizations, physicians practicing pulmonary medicine, manufacturers of home oxygen technologies and medical equipment, professional associations representing clinical respiratory practitioners*

American Association for Homecare  
Apria Healthcare  
Inogen Incorporated  
The MED Group  
National Emphysema/COPD Association  
National Association for Medical Direction of Respiratory Care  
National Home Oxygen Patients Association