

June 29, 2006

TO: The Centers for Medicare and Medicaid Services

RE: **CMS-1270-P**

FROM: The Sleep Manufacturers Alliance

The Sleep Manufacturers Alliance<sup>1</sup> includes nine device manufacturers which, under approval from the Food and Drug Administration, produce and sell diagnostic and therapeutic devices in the United States for the diagnosis and treatment of sleep disordered breathing, most notably obstructive sleep apnea. We welcome the opportunity to comment on the proposed regulations published in the May 1, 2006 *Federal Register* that address competitive acquisition for durable medical equipment.

**Overview:** There are several principles that must be incorporated into a successful competitive bidding program. First, it must ensure that the quality of care Medicare beneficiaries receive is not adversely impacted by this program. Secondly, the program must ensure that Medicare beneficiaries have access to the devices and supplies that are medically necessary for effective implementation of the treatment plan established by the physician and others. Thirdly, its administration should be relatively seamless to ensure that suppliers not only have all the information necessary to participate in the program but can do so without administrative burden to the suppliers. Lastly, it should achieve cost savings without impacting on the three principles cited above.

Another principle that should be woven into this proposed rule is an appreciation that, particularly in the arena of respiratory related devices (oxygen systems, CPAP devices, ventilators, etc.) these devices provide critically needed therapy for treatment of chronic illness. Without appropriate concurrent services to manage such respiratory-related devices, morbidity and mortality increase and associated health care costs increase.

As there are major components of the competitive bidding program that are not addressed at all or are addressed without specificity, we strongly recommend that any final rule addressing competitive bidding be published as an “interim final rule” to allow appropriate public comment on policies that are being proposed for the first time.

**Quality Standards for Suppliers of DME:** The primary goal of quality standards must focus on ensuring that Medicare beneficiaries receive the device(s) and supplies that are appropriate for the management of their illness. The proposed rule indicates that on the basis of a recommendation from PAOC, CMS will publish quality standards through program instructions. On the one hand, we find it problematic that CMS would choose to implement a statutorily mandated requirement through a simple instruction rather than the more formal mechanism of rulemaking through the *Federal Register* which would afford interested parties ample opportunity to comment. However, as these standards will apply to our customers who participate in the competitive bidding program, it is of paramount importance that CMS permit ample opportunity for public comment, whether

it be through the Federal Register rulemaking process or the less formal program memorandum process. .

Specifically, the proposed regulation states, “These standards will measure the effect of suppliers’ services on beneficiaries. The supplier quality standards will include product specific requirements that will focus on a consumer-directed model of service delivery for suppliers to improve beneficiary access to information about DMEPOS.” The term “product specific requirements” clearly would affect our products, and therefore the development of standards not subject to input from manufacturers of devices that are likely to be bid competitively is problematic.

Recommendation: We recommend that CMS create a transparent policy process with ample opportunity for public comments for final promulgation of “product specific requirements.”

**Implementation Contractor:** As device manufacturers, we maintain ongoing relationships and communications with the DMERCs and the SADMERC. While we are not opposed to CMS’ designation of competitive bidding implementation contractors (CBICs), we are unclear as to how the CBICs and DMERCs will interact in terms of development of policy, implementation of each other’s policies, and overall coordination by CMS central office. On the one hand, the CBIC(s) will prepare the requests for bids, perform bid evaluations, select qualified suppliers and set single payment amounts for all competitive bidding areas, and the CMS approach here seems logical. But the addition of “assist(ing) CMS and the DMERCs in monitoring program effectiveness, access and quality, “ the mix of responsibilities could be confusing and repetitive due to overlap of responsibilities, and costly to taxpayers.

The proposed rule is unclear in delineating specific responsibilities of existing and new contractor responsibilities, and therefore, without extensive clarification, it is unlikely that manufacturers as well as suppliers, providers and beneficiaries will know where to turn to address the myriad of issues that will arise related to competitive bidding.

Recommendation: we urge CMS to provide specific contractor responsibilities so that manufacturers, providers, physicians, and beneficiaries know where to address concerns regarding access, quality of care, etc.

### **Payment Basis:**

**Mail order programs under competitive bidding:** Our review of the proposed rule indicates that CMS will seek bids from mail order suppliers on ALL items of durable medical equipment, regardless of the fact those items might not be included in a nationwide or regional competitive bidding program. We strongly urge CMS to approach this aspect of competitive bidding very carefully to ensure that patient care, access to suppliers, etc., is not adversely impacted. In candor, we believe that because there is a wide range of items under the DME benefit, it would be wise to seek specific input from

the public and interested parties, including physicians, to determine what items can appropriately be distributed through mail order. Using the CMS example, items such as blood glucose test strips may be appropriate for mail order processing, but certainly CMS does not want to encourage shipping of oxygen cylinders or ventilators to Medicare beneficiaries. In the arena of respiratory related devices, one must not presume that, unlike a cane or walker, instruction on proper use is as simple as reading an instruction manual. In the case of CPAP, fitting of a proper mask is paramount to successful compliance with/adherence to a prescribed plan of care. To presume that the same mask is clinically appropriate ad infinitum and the patient's condition does not warrant a different kind of mask at some time during the ongoing course of treatment is extremely problematic.

It is also unclear as to the application of mail order in the context of initial order versus re-ordering of supplies. Clearly situations will arise where re-ordering via mail order may be appropriate, but this, too, must be carefully monitored to ensure that the beneficiary's needs have not changed. Ongoing involvement of health care providers is imperative to ensure that any mail order process does not adversely affect patient care.

Again, we urge extreme caution in selection of devices that can be handled through mail order and strongly request careful consultation with the respiratory medical community prior to any proposed rules related to mail order programs.

**Criteria for item selection:** We cannot help but seriously question the approach CMS has outlined for device selection for competitive bidding. Using CPAP as an example, Medicare data indicate that these devices account for 1.2% of all DME allowed charges, \$204.7 million in 2003. Assuming for the sake of discussion that Medicare believes it can save 5-10% of that amount through competitive bidding **if implemented nationally**, this would be a national savings of \$20 million. While we fully appreciate and support CMS' fiduciary role to act on the taxpayer's behalf in a responsible way, it is difficult to fathom that the costs associated with implementing the program would make the approach cost effective.

Specifically, CMS estimates that its aggregate savings in 2008 will be \$110 million. Using CMS' tables for the top 10 eligible DME policy group allowed charges, with the allowed charges of \$7.4 billion, savings of \$110 million signals to us a savings of 1.4% in 2008. To us, creation of a new bureaucracy including new Medicare contractors, and other obvious related financial as well as social costs, very well may not justify the return. We do appreciate CMS' need to implement a Congressionally mandated competitive bidding program, but it seems infinitely more logical to focus on product categories that will ensure savings that truly justify the associated costs. It is also important to emphasize the correlation between effective disease management for sleep disorder breathing and corollary reductions in other associated health care costs. Therefore, when one looks at the broad financial perspective, CPAP is not an appropriate category for competitive bidding!

**Opportunity for Networks:**

We support the concept of permitting suppliers to form their own networks. However, the use of networks must be very carefully structured to ensure that Medicare beneficiaries have appropriate access to Medicare suppliers. In theory, under the current structure, a Medicare beneficiary in Miami has dozens of suppliers from which to choose, and the implementation of competitive bidding will unquestionably reduce that number. Because such networks already exist for group purchasing, it is only reasonable to permit willing suppliers to form legal entities that will function to pass such savings on to the Medicare program as well as Medicare beneficiaries.

Specifically, we do note, however, that there appears to be a problematic limit on the size of such networks, as CMS proposes to limit market share to 20%. In fact, this could be discriminatory in its very nature if in fact large national suppliers can exceed the 20% threshold in their capacity. For example, if two national chains, as winning bidders, account for 75% of the threshold capacity identified by Medicare, what logic exists in limiting the network's capacity to 20%? Simply, why is one company permitted to function above the 20% threshold while a legal network of companies must be limited to 20% capacity? To us, it appears to be questionable legally as it discriminates against small suppliers and their ability to participate in the program. To reiterate, we support the option for suppliers to create networks, but we do not believe that limiting the market share of such networks to 20% is reasonable and, if implemented as proposed, would likely inhibit beneficiary access to a reasonable number of choices of suppliers.

### **Education and Outreach:**

We support the Agency's commitment to ensure that Medicare beneficiaries are thoroughly educated regarding this matter. Recent CMS experience unequivocally signals the need for aggressive, thorough, timely and accurate education of beneficiaries who will be impacted by competitive bidding.

### **Gap Filling:**

CMS recognizes that the current system does not readily address pricing of new technologies in the DME arena. We can identify numerous specific examples in the broad respiratory category where dramatic advances in sleep technology as well as oxygen delivery technology have quickly surpassed CMS' ability to code, let alone price these new technologies. We also recognize that, on occasion, there are either statutory or administrative limitations to pricing of new technologies, and it would be appropriate for CMS to recognize those limitations as well rather than espousing detailed analytical processes that would apparently usurp or replace other pricing structures already in place. Our comments, therefore, focus on the specific arena of pricing for competitive bidding as well as the broader issue of gap filling for all devices covered by the Medicare program.

**CMS's proposal for gap filling in the context of competitive bidding is especially problematic.** If a new code is established during a competitive bidding

cycle, CMS has stated that payment will be made at the rate for the current code until the end of that competitive bidding cycle. However, that rate may not be adequate / appropriate for a newer, more advanced technology. The CMS approach is likely to be a barrier to access to new technologies.

Additionally, of great concern to us is the statement, “we can use the technology assessment process at any time to adjust prices on or after January 1, 2007 that were previously established using the gap filling methodology if it is determined that those pricing methods resulted in payment amounts that do not reflect the cost of furnishing the item.” We interpret this to mean that technological assessment alone, to the exclusion of both price comparison and medical benefit assessment, can be used to re-price items that have payment rates established through the traditional gap filling methodology currently in place. We support use of those two assessment tools in the establishment of pricing for new technologies as well as re-pricing of existing technologies. Excluding those assessment tools is unacceptable.

To address “gap filling” in the broader context of Medicare outside of competitive bidding, we recommend that CMS develop a process that ensures Medicare contractors will solicit and review information from manufacturers that address product development as well as information from providers regarding costs associated with support, service and delivery of the device(s). Therefore, we believe it is more appropriate for CMS to promulgate a separate, free-standing rule addressing gap filling that would apply to devices in general, not just devices that may be subject to competitive bidding.

**Concluding comments:**

The Sleep Manufacturers Alliance believes that a competitive bidding program can be structured in such a way to ensure that the services associated with medical devices continues to be provided in a seamless, clinically appropriate manner. Likewise, we believe that such a program can achieve worthwhile savings to Medicare and, therefore, the taxpayer. We are not convinced, however, that the proposed program achieves those goals. Too much is left for decisionmaking through subsequent rulemaking, program memoranda, and processes that may not afford the public ample opportunity for comment. It is in that context that we have outlined the comments above. We are committed to working with CMS and would be glad to offer assistance in clarifying these matters for you if you so request.

If we can be of further assistance, please do not hesitate to contact Phillip Porte at 703-752-4353 or [Phil@GRQConsulting.com](mailto:Phil@GRQConsulting.com).

<sup>1</sup> Embla, Fisher & Paykel Healthcare, Invacare Corporation, Pro-Tech Services, Puritan Bennett, ResMed, Respironics, Sunrise Medical, VIASYS Healthcare