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March 17, 2009

Charlene Frizzera
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Washington, D.C. 20201

Re: **Comments on CMS-1561-IFC – Interim Final Rule, "Medicare Program; Changes to the Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) by Certain Provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), 74 *Federal Register* 2873 (January 16, 2009)**

I. Introduction

Invacare Corporation is submitting comments in response to the Centers for Medicare and Medicaid Services (CMS) January 16, 2009 Interim Final Rule (IFR), "*Medicare Program; Changes to the Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) by Certain Provisions of the Medicare Improvements for Patients and Providers Act of 2008* (MIPPA), published in the *Federal Register* on January 16, 2009. The IFR implements certain MIPPA provisions that delay implementation of Round 1 of the competitive bidding program; requires CMS to conduct a second Round 1 competition in 2009; and mandates certain changes for both the Round 1 rebid and subsequent rounds of the program, including a process for providing feedback to suppliers regarding missing financial documentation and requiring contractors to disclose to CMS information regarding subcontracting relationships.

On February 10, 2009, CMS issued a Notice of a proposed delay for the effective date of this interim final rule requesting public comments on a proposed 60-day delay in the effective date of the IFR to allow the new Administration time to review the rule and its consequences. Invacare responded to the notice with comments, most of which are still germane and which we will discuss again here for your convenience. Recently, CMS announced that it would delay the effective date of the IFR until April 18, 2009 in response to the public comments and reiterated its request for comments on the IFR.

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Invacare Corporation is the global leader in the manufacture of the broadest product offering of innovative home medical equipment (HME) that promotes recovery and active lifestyles. Based in Elyria, Ohio, Invacare manufactures and sells to home medical equipment (HME) providers a broad array of products, including manual and power wheelchairs, other mobility aides such as canes and crutches; respiratory products such as new oxygen technology, oxygen concentrators, portable oxygen systems, nebulizer compressors and respiratory disposables; sleep therapy products; home care beds; low air loss therapy products; bath safety products; and patient transport equipment. The majority of this equipment falls under the definition of "durable medical equipment" as defined under Part B of the Medicare Program.

II. Summary of Comments

We believe that the agency's rush to implement this interim final rule without providing any opportunity for meaningful public comment will result in another disastrous bid round later this year. While CMS may have complied with the technical "letter of the MIPPA law," it has failed to comply with the "spirit of the MIPPA law" by not making any substantive improvements to the bid process. Last year, Congress intervened to legislatively delay implementation of the bid program due to serious concerns with beneficiary access to quality items, and the negative impacts on DME providers. CMS has made no substantive changes in its competitive bid rule to address these concerns. In fact, in the IFR CMS states that if will make no changes to the methodologies it used previously to select bid winners and to calculate the pivotal bid amount. Without substantive changes to fundamental decisions, CMS will encounter the identical fundamental flaws when it rolls out this next bidding round. We strongly urge the new Administration and CMS to take a closer examination of *why* the bid program resulted in bad outcomes, and address these by making substantive modifications to the bid program. We provide a number of recommendations later in our comments.

Based on what we witnessed of the 2008 implementation of the bid program, we know that competitive bidding eliminates 75 to 90 percent of homecare providers in a marketplace; lowers quality and access to care for seniors and people with disabilities; reduces competition and limits choice by shutting out the majority of qualified providers. Given the fundamental flaws that we have witnessed with the 2008 bid process, CMS must retract the IFR, provide a reasonable opportunity for the industry and other stakeholders to discuss with the agency necessary bid program improvements and incorporate those into a new rulemaking which would allow a meaningful and appropriate public comment period. It is only through a collaborative process that sincerely involves the industry and other stakeholders that CMS will be able to craft and implement a bid program that minimizes beneficiary access issues. For these reasons, we strongly urge CMS to retract the IFR, and establish a process that will maximize the possibility that the bid program will be successful.

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III. Impact Analysis, Manufacturer Impact and Creditor Issues

According to the Regulatory Impact Analysis in CMS' April 2007 Final Regulation implementing the competitive acquisition program, about half of the suppliers would not be selected as contract suppliers; approximately 70 percent of suppliers submitting bids were not selected as contract suppliers. The adverse impact was in fact far greater than CMS had anticipated. Since non-contract suppliers are not likely to be able to sustain their businesses based upon the remaining items that are not included in competitive bidding, the adverse impact to the industry and the resulting loss in beneficiary choice will be dramatic.

As the largest worldwide manufacturer of home medical equipment, Invacare extends credit to literally thousands of entities that are Medicare DMEPOS suppliers in the United States. CMS' Regulatory Impact Analysis does not include the costs and impacts on creditors such as Invacare; probably the largest creditor to the HME industry. The stark reality is that competitive bidding may well force up to 70 percent of the current suppliers to go out of business. Aside from the direct impacts of these "losing" entities, the direct financial impact on Invacare is potentially huge. As a creditor, Invacare has no information to understand or rationally predict which suppliers will be contract suppliers and which will not. As a result, Invacare will be significantly negatively impacted by the implementation of competitive bidding. Invacare strongly recommends that CMS consider these impacts on the economy, and modify the bid program to minimize these impacts. If CMS insists on implementing the program, one way to minimize the significant negative impacts to the industry would be to phase in product categories and bid areas.

IV. Competitive Bidding and the New Oxygen Payment Rules

The IFR does not address how recent dramatic changes to the Medicare oxygen benefit impact competitive bidding. MIPPA repealed the transfer of ownership requirement for oxygen equipment and instead caps Medicare payment for oxygen after Medicare has paid 36 monthly rental payments. Under the new rules, when patient equipment "caps", providers must continue servicing those patients for as long as an additional 24 months with no further compensation from Medicare except for oxygen contents and possibly a small maintenance payment in 2009. Providers also remain responsible for patients who cap even though the patient moves out of the provider's service area. CMS issued this onerous new rule on October 30, 2008 well before the January 16th publication date of the IFR.

These unprecedented new requirements imposed on oxygen suppliers must be addressed by CMS as they impact the competitive bid program. Patients who require oxygen often travel or move to or from competitive bidding areas (CBAs). Will contract suppliers be required to service beneficiaries who move away from the competitive bidding area (CBA), and if so under what terms? Conversely, will contract suppliers be required to accept patients who move into the CBA? Similarly, CMS will not pay for emergency service for equipment that has capped. What responsibilities will contract suppliers have

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for patients who visit the CBA? Providers have no information on how CMS will apply these new policies in the context of the competitive bidding program and therefore will not be able to factor into their bids the costs associated with servicing Medicare oxygen patients.

V. Improving the Bid Program - Examples of Necessary Competitive Bidding Program Improvements

Following are just a few specific examples of necessary bid program improvements that should be specifically addressed in any new bidding round:

A. Eliminate the Arbitrary Bid Price Ceiling

CMS should not artificially limit bids by disqualifying bids above the current fee schedule amount for an item. Otherwise, the competition is not truly competitive based on market prices. Instead, CMS should adopt the methodology used in the demonstration projects in Polk County and San Antonio.

Invacare strongly opposes the proposal that suppliers cannot submit a bid that is above the current allowable. Section 1847(b)(2)(A)(iii) of the Act prohibits awarding contracts to any entity for furnishing items unless the total amounts to be paid to contractors in a competitive bidding areas are expected to be less than the total amounts that would otherwise be paid. To meet this requirement, CMS proposes not to accept any bid for an item that is higher than the current fee schedule. This would require that the bid amount be equal to or less than the current fee schedule. Invacare strongly disagrees with this proposal because it places artificial constraints on a process that is trying to be designed to harness market forces. If CMS is truly using competitive bidding as a way to understand the price the market will bear, then CMS must allow suppliers to submit their lowest possible bid. Given the many new requirements associated with providing the items and related services under the bid program, bids may rationally and realistically be greater than the current fee schedule amount for the particular item. Given the fact that the majority of suppliers will be incurring new costs of accreditation, and the fact that in the last few years reimbursement has been cut significantly for many of the major product categories (*e.g.*, 36 month payment cap on oxygen, etc.), and some products have increased suppliers' documentation costs (e.g., power mobility device documentation requirements), it is highly likely that bids for certain product categories may realistically be at a rate that is higher than the current allowable.

CMS can still meet the "assurance of savings" requirement through alternative means. If bids received are higher than the current allowable, CMS should choose not to include that particular item or product category in the competitive bid program, because that is a strong indicator that savings are unlikely. Requiring that the bid be equal to or less than the fee schedule as a requirement of the Request For Bids artificially restricts bidding. Instead, CMS should allow suppliers to bid based on the true costs associated with each bid item. CMS can then use this information to determine whether the savings is adequate to justify awarding contracts for these items. The "assurance of savings"

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requirement would be met when CMS only included items for which the winning bid amount were less than the current allowable.

B. Providers With a Proven Track Record Should Be Given Preference

The definition of a qualified bidder must be amended to state that no bids will be permitted in a bidding area unless the provider has an existing physical facility there already or has experience providing the item/service or experience providing that bid area or can show proof from a lending institution or bank commitment that will allow the supplier to build the facility and stock it with proper inventory there to begin serving the entire CBA on the implementation date of the program. At a minimum, bidders with experience providing the item/service or with an existing physical facility in the CBA should be given preference over those bidders that do not have that experience or physical location.

C. Minimize "Gaming" of the Bidding Process

In an effort to prevent "gaming" of the bidding system, CMS should require that suppliers are paid at the payment rates for which they bid. A supplier offered a contract would be required to accept the contract unless there are unforeseen circumstances requiring the supplier to decline a contract. This will prevent non-local suppliers from submitting bids in an attempt to "practice" for bidding; it will prevent suppliers from skewing final results because they have no intention of accepting the contract; and it will prevent suppliers from submitting bids at unreasonably low levels in an effort to "stay alive" but rely on other provider bids to raise the final set price.

The use of a median of winning bids to set the price is not a methodology that has been tested in other industries; there is a potential for bidders to be reimbursed less than their bid. As a result of the proposed bidding methodology, some providers could incorrectly bid low to assure a contract, with the knowledge that the payment will be higher than their bid. This represents a potentially dangerous payment scenario for the homecare provider industry, and this is precisely what occurred during the 2008 bid process.

Within the bidding system, either the payment amount determined from the median of the winning bids or a provider's actual bid (if lower than the median) should be the limiting factor when determining what a provider will be paid for a DME item that has been competitively bid. This would reduce the number of problematic low bids.

A potentially more viable bidding methodology would be to produce a payment amount from the average *of all of the bids*; the companies closest to but lower than the average bid get the contracts, and the total number of companies getting contracts can still be determined by capacity, moving down from the average. This would reduce the effect of incorrectly made low bids. Moreover, this is the methodology that the Obama Administration has proposed for competitive bidding for Medicare managed care plans.

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VI. Procedural Issues with Interim Final Rule

The agency's rush to issue this rule has prevented any meaningful opportunity for suppliers and other stakeholders to provide comment and input based upon the implementation of the bid program in 2008. In fact, there is no valid or legal justification for CMS' rapid issuance of this Interim Final Rule. Interim Final Rules are reserved for situations where the agency must move very quickly for public safety reasons - no such reasons exist here. In fact, the Administrative Procedures Act requires federal agencies to follow normal rulemaking procedures that include issuing a proposed rule, soliciting public comments, considering those comments and then issuing a final rule. Exceptions to this process are limited to circumstances when the agency finds that procedure "impracticable, unnecessary, or contrary to public interest." (5 U.S.C. 553(b)(3)(B)). The interim final rule process is essentially an emergency procedure and should be used sparingly. CMS has not demonstrated that there exists an "emergency" that would justify the waiver of notice and comment with respect to this rule. In fact, waiving notice and comment by publishing an interim final rule in this case is contrary to the public interest because of the rule's potential impact on beneficiaries and Part B suppliers.

Interim Final Rules provide no meaningful opportunity for public comment because such rules go into effect just 30 days after publication, regardless of the comments the agency receives. There is no obligation for the agency to respond to comments or incorporate any changes in a subsequent final rule.

CMS is rushing to implement the new rule without providing any meaningful opportunity for input and comment. Moreover, the agency's rush to implement a new regulation is counter to Congress' intent when it delayed the competitive bidding program as part of MIPPA. Congress delayed the bid program and specified certain reforms that must be achieved after receiving many examples of the serious problems the bid program would cause; particularly its restriction of beneficiaries' access to quality local providers and homecare business closures or bankruptcies across the country. An interim final rule does not allow impacted parties time to meaningfully review and comment on the regulatory changes proposed by the government.

The home care community has expressed its keen interest in working with CMS to review the mechanics of all aspects of the bidding program. However, CMS has not capitalized on the only existing mechanism -- the Program Advisory and Oversight Committee (PAOC) -- to seek or incorporate feedback on aspects of the program. In fact, since MIPPA was passed, CMS disbanded the PAOC, which was created to provide the agency with concrete, real-world guidance on the development and implementation of the bidding program. CMS only announced a new PAOC on the date it issued this Interim Final Rule, but has not convened the PAOC to provide a public forum for comment on the bid program. There has been no public forum for CMS to collect comment from affected parties since CMS implemented the initial bid sites in 2008.

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VII. Miscellaneous Comments

A. Need For Product Standards

Without any quality, performance or technical standards in place for all items potentially included in competitive bidding except for power wheelchairs and power-operated vehicles, CMS is creating a program that will result in substantially inferior products. During PAOC meetings, CMS has identified a process whereby it would monitor on a retrospective basis the actual brand items of bid products that are provided to beneficiaries in a CBA. This burdensome process would be administratively impossible to monitor and, CMS has no measures to determine whether the items provided meet any particular standards.

As a way to ensure that beneficiaries are able to continue to receive quality items and related services, Invacare strongly recommends that CMS establish a process for each item subject to competitive bidding that ensures that products that contract suppliers provide are of similar quality compared to products provided in non-bid areas. Specifically, CMS needs to establish quality standards for products as CMS did for power wheelchairs and POVs. Regardless of the level of complexity, there will be durability, performance and other measures to ensure a certain level of product integrity and quality. As CMS did with power wheelchairs and POVs, CMS needs to work with the relevant manufacturers to establish these standards. Once the standards are established, manufacturers would apply for code verification; the HCPCS code designation would require the product to meet those specific standards. This would ensure that beneficiaries only have access to items of acceptable integrity and quality standards; it would resolve the quality issue at the front end, obviating CMS' need to track from every contract supplier, an itemization of all the products provided to beneficiaries in the CBA.

B. Need for HCPCS Code Refinement

In order for DMEPOS suppliers to submit bids for individual HCPCS codes, there must be a narrow range of technology defined by each HCPCS code. That specificity simply does not exist with the majority of HCPCS codes. We therefore recommend that CMS refine its HCPCS code system for each product category it intends to include in a competitive bidding program. To ensure that HCPCS codes are refined with sufficient specificity, that refinement must be done in consultation with stakeholders, including manufacturers, suppliers, physicians and other clinicians, and consumers. If CMS fails to refine the HCPCS code system for product categories it intends to include in competitive bidding, suppliers will not be able to provide intelligent bid information for each code; because suppliers cannot anticipate the specific future needs of beneficiaries for specific items that will fall with one HCPCS code.

C. Single payment amounts should be indexed by the CPI-U

Round 1 of the bidding program provided for no annual payment update during the three-year contract period. This decision was made by CMS during its initial rulemaking.

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CMS indicated that suppliers must include potential price increases as part of their bids. However, this is an unrealistic assumption for CMS to make given the rapidly changing dynamics of the economy. CMS should index the single payment amount by the CPI-U as other non-competitively bid items are. The MIPPA legislation restored a CPI-U for certain DMEPOS items beginning in 2009 and therefore supports the fact that providers' costs for labor, fuel and other operating expenses continue to rise.

D. CMS must create an appeals mechanism and bid transparency for suppliers participating in competitive bidding.

The Secretary should establish an administrative and judicial appeals process for DMEPOS suppliers similar to that which is available to other aggrieved providers in the Medicare program.

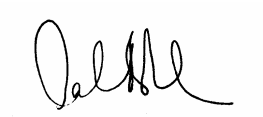
E. How will CMS evaluate supplier compliance with state laws?

Based upon the 2008 biding experience, many winning suppliers did not meet the licensure requirements for states where they won bids. In fact, many of these winning bidders had to go back and retroactively apply for state licensure. First, bidders must demonstrate that they are in compliance with all applicable state laws in the bid areas for which they are bidding. Second, CMS must have an effective mechanism to validate that the bidder does in fact meet the applicable state laws.

VIII. Conclusion

Thank you for the opportunity to provide comments on this important proposed regulation. Invacare is happy to discuss these issues in further detail. Please contact Cara Bachenheimer at 440-329-6226, or via electronic mail at cbachenheimer@invacare.com.

Sincerely,



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