Caring that Feels Right at Home

Filed Electronically

March 17, 2009

Charlene Frizzera
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: **Medicare Program; Changes to the Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) by Certain Providers; 74 Fed. Reg. 2873 (January 16, 2009)**

Dear Acting Administrator Frizzera:

The American Association for Homecare (AAHomecare) submits the following comments on the interim final rule implementing changes to the national competitive bidding program for certain items of durable medical equipment and supplies (collectively "DME"). The Centers for Medicare and Medicaid Services (CMS) published the interim final rule (IFR) in the Federal Register on January 16, 2009. Subsequently, on February 10, 2009, CMS published a notice requesting public comments on a proposed 60-day delay in the effective date of the IFR[1] to allow the new Administration time to review the rule and its consequences.[2] AAHomecare responded to the notice with comments, some 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 in response to the public comments and reiterated its request for comments on the IFR.

[1]74 Fed. Reg. 6557 (February 10, 2009).

[2] CMS published the notice in response to a directive from Executive Office of the President, Office of Management and Budget (OMB), dated January 20, 2009. Specifically, OMB instructed agency heads and acting heads to consider extending for 60 days the effective date of regulations that have been published in the *Federal Register* but that have not yet taken effect so that agencies may review questions of law and policy posed by those regulations. Memorandum for the Heads and Acting Heads of Executive Departments and Agencies from Peter Orszag, Director, OMB, January 20, 2009.

I. Background

AAHomecare is the national trade association representing the homecare community. The Association represents health care providers and manufacturers that serve the medical needs of millions of Americans who require oxygen equipment and therapy, mobility assistive technologies, medical supplies, sleep therapy technologies, inhalation drug therapy, home infusion, and other home medical equipment, therapies, services, and supplies in their homes. Our 600 members reflect a broad cross-section of the homecare community including national, regional, and local providers operating approximately 3,000 locations in all 50 states.

In light of our members' experiences with the first round of the competitive bidding program and our longstanding experience as an association with the competitive bidding program's design and implementation, AAHomecare is uniquely positioned to comment on the IFR and other aspects of the program. Based on what we know of the program as it has been implemented so far, we know that competitive bidding:

- Eliminates approximately 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;
- Ignores the fact that the home medical sector is the slowest-growing portion of Medicare;
- Fails to understand the reality of how home medical equipment and services are provided.

Importantly, we are extremely concerned with the processes CMS used to implement this important and complex new program. Competitive bidding for DMEPOS represents a radical departure from the traditional fee-for-service Medicare DMEPOS benefit. Rather than proceed cautiously given the size and complexity of this undertaking, CMS rushed the program's implementation, ignoring the advice of the Program Advisory and Oversight Committee (PAOC) and leaving providers with little time to digest and understand the new rules.

Round One of the bidding program was so fraught with delays, conflicting guidance and systems failures that ultimately Congress postponed the program in order to protect beneficiary access to quality DME services. Section 154(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), was intended to give CMS time to revise the program. Congress and the Administration anticipated that a new regulatory process would take as long as 24 months, giving the Agency ample opportunity to solicit feedback from stakeholders on what program changes to make.

We have been disappointed to see that instead of making the most of the opportunity for productive action created by MIPPA, CMS chose expediency instead and avoided any public dialogue on how to improve the program. In issuing the IFR, CMS adhered to the "letter" of the law under MIPPA rather than proceeding under the "spirit" of the law as Congress had intended.

Moreover, soon after Congress passed MIPPA, CMS went so far as to disband the PAOC. While the PAOC has now been reconstituted, it has not yet met to review the problems that hampered the initial roll-out of the program or to consider any public input on the changes mandated under MIPPA.

In light of the history of this program, we strongly recommend that CMS withdraw the IFR and proceed with a notice and comment rulemaking that addresses the implementation issues that we discuss more fully below.

II. COMMENTS

A. CMS Should Withdraw The IFR And Issue A Proposed Rule

1. The Rulemaking Procedure Was Inadequate

New Financial Documentation Requirements

CMS sidestepped all of the important procedural protections inherent in rulemaking by publishing an IFR with an effective date approximately *one month before* the deadline for submitting comments. The preamble to the IFR states that formal rulemaking is unnecessary because the statutory requirements of §154(b) are self-implementing. We disagree that the IFR meets the Administrative Procedure Act exemption from public rulemaking for self-implementing statutes. Although the IFR for the most part adopts the statutory language of §154(b), it also revises the requirement that bidders must submit financial documentation for the three previous years. In the future, only one year of financial documentation will be required.

Some providers might hold the view that it is easy to falsify one year's worth of financial statements when compared to three, while others might welcome streamlining the paperwork burden imposed on small bidders. Obviously these viewpoints represent important competing interests since fraud of this type places the program at risk, whereas small providers are legitimately concerned about their ability to compete effectively. We believe that these competing interests can only be resolved through a notice and comment procedure.

Competitive Bidding and the New Oxygen Reimbursement Rules

The IFR also does not address how recent 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 for the IFR.

Despite the unprecedented requirements imposed on providers by these new rules, CMS did not address their impact on the implementation of competitive bidding for oxygen and oxygen equipment when it published the rules implementing MIPPA. Patients who require oxygen often travel or move to or from competitive bidding areas (CBAs). Will contract providers be required

to service beneficiaries who move away from the competitive bidding area (CBA), and if so under what terms? Conversely, will contract providers 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 providers have 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.

The implementation questions surrounding oxygen reimbursement and competitive bidding reveal the fundamental flaws affecting this program. CMS issued a final rule on competitive bidding that addressed only the broad framework of the program while giving itself vast discretion to evaluate bidders on subjective factors such as quality or financial soundness based on criteria that were not identified in the rule. Instead, many of the substantive requirements for bidding were issued informally – either verbally during CMS contractor teleconferences or through written questions and answers posted on the contractor's website, completely by-passing the rulemaking process. [3]

This method of disseminating bidding instructions, *i.e.*, a combination of contractor teleconferences and posted Q & A's, resulted in conflicting or incorrect guidance leading to a confusing series of retractions and clarifications that required providers to spend significant time and resources monitoring updates and program changes. Although the contractor's customer service staff was available to answer providers' *individual* questions, there did not seem to be criteria to determine which questions and answers were published on the website for the benefit of the public. In other words, CMS issued important and substantive competitive bidding rules *via* sub-regulatory process that was not subject to appropriate oversight by Congress or the scrutiny that comes from a public comment period.

In the preamble to the IFR, CMS clearly states that the Agency will issue additional guidance on competitive bidding *via* a sub-regulatory process. Once again CMS can avoid meaningful oversight of this program by engaging in less than full notice and comment rulemaking. Providers must understand what factors to consider when submitting their bids for oxygen, and they should have an opportunity to weigh in on how CMS will address oxygen reimbursement in the context of competitive bidding. The answers to these questions are far too important to be relegated to contractor teleconferences or FAQs posted on a contractors' website. These questions must be addressed on the record in a notice and comment proceeding.

2. CMS Did Not Analyze The Impact Of The MIPPA Reimbursement Cuts On Competitive Bidding

MIPPA imposed a 9.5 percent (%) payment reduction in the fee schedule amount for all competitively bid items. The 9.5% cut became effective January 1, 2009. In other words, homecare providers paid for the Round One delay by absorbing an across-the-board Medicare payment reduction in addition to the de facto payment reductions imposed under the new oxygen

[3] For example, the rules do not specify the threshold of financial standards bidders must meet to be awarded a contract. Instead, CMS published various financial ratios on the contractor's website but never explained how the standards would be applied.

policies. This steep drop in reimbursement for competitively bid items, most of which constitute the backbone of a provider's scope of service, will no doubt have repercussions on competitive bidding and the viability of small business providers who must now absorb additional payment reductions as well as face the possibility of losing their businesses through competitive bidding.

Notwithstanding this obvious connection, CMS did not examine the ramifications of the 9.5% cut on future rounds of competitive bidding in its Regulatory Flexibility Act analysis of the IFR. Instead, CMS stated that it did not have to address the 9.5% cut in the IFR because the payment cuts were implemented *via* sub-regulatory Medicare program instructions, rather than in the IFR, once again undermining the checks and balances inherent in the rulemaking process.

B. CMS Has Not Addressed The Basic Flaws That Became Evident During Round One

CMS has not explored the reasons why Round One did not move forward. Instead, as we stated above, CMS strictly limited itself to implementing the letter of the law under MIPPA rather than considering what Congress had intended as the spirit of the law. Specifically, the preamble to the IFR states that formal rulemaking is unnecessary because §154(b) is self-implementing. Even assuming that this is correct (which we dispute as we noted above), we believe that Congress and the public had a reasonable expectation that CMS would revisit these problems and at least try to correct them. At a minimum, CMS should have convened the PAOC to analyze the following troubling questions:

- There was significant variation in bid rates for the exact same product billing codes across bidding areas, conversely a number of allowables were identical in different MSAs;

- Homecare companies that had no experience providing patients with a product category, or that were not previously serving the MSA, were offered winning contracts;

- There was no transparency related to the evaluation of the bidding packages. CMS has never come forth with its methodology to review a complex bidding package;

- CMS has never explored the financial impact the program would have on a company that previously provided the full complement of bid items to Medicare beneficiaries but "won" only one or two product categories;

- CMS has never evaluated why large companies who can reasonably be assumed to have economies of scale, stronger purchasing power, and the ability to determine costs more accurately than smaller companies were not the predominant "winners."

Further, in taking this position, CMS completely ignores the factual context which prompted Congress to delay Round One in the first place. First, when contract awards were announced, many providers were told that their bids were disqualified because they had not submitted some or all of the required financial information. Providers that believed they were disqualified unfairly had no explicit avenue to redress their concerns. The CMS review process, managed by

a contractor, lacked any written rules or guidelines, apparently leaving the decision making to the contractor's discretion. In many cases, the outcome of a review turned on luck and the persistence of the provider. Eventually, some disqualified providers were awarded contracts after the contractor determined their bid submissions had been complete all along.

More importantly, many winning bidders were not capable of accepting beneficiaries throughout a CBA contrary to program rules. In an informal test of the program, 133 referrals made to winning providers in six of the bidding areas resulted in:

- Over half of referrals to contracted providers were turned down for various reasons related to their inability to serve the patients;

- Over 60 percent of referrals for patient services that were made to contracted providers resulted in untimely delivery; providers responded that they could not provide same day service (same-day is expected by referral agents); and

- Over 40 percent of referrals could not be serviced due to contracted providers' inability to service patient's zip codes or not answering the telephone at all.

This informal data-gathering also revealed significant beneficiary access issues. For example:

- In Miami, pulmonologists reported being told that oxygen services could not be delivered for 2-3 days by winning contractors. Prior to July 1, standard delivery times had been 2-4 hours;

- In Riverside, CA, 100 percent of out-of-state contract winners for CPAP/Bi-level sleep therapy equipment had rejected referrals, stating that they "don't service the area" or "that's too far";

- In Kansas City, 27 percent of referrals (i.e., orders) placed for walkers, enteral, oxygen or CPAP equipment and services had resulted in contract providers refusing those referrals because they could not service the area or did not have the equipment.

    - Five of the 11 contract suppliers contacted in the Kansas City CBA had no local office; this was the reason offered in two of the turndowns. The remaining providers stated they could only drop-ship the products and that it could take between several days and two weeks;

    - An out-of-state contract provider from California told Kansas City and Pittsburgh referral sources that they were not sure they could supply a walker to patients in those CBAs, but if so, it would be shipped by UPS and could take 10-12 days to deliver;

    - One enteral nutrition contract provider said they only supply nursing homes–not homecare patients;

    - One provider for the walker product category said they only service one small town in Kansas and cannot accept referrals across the Kansas City metro area.

- In Charlotte, based on 23 referrals that were transmitted to contract providers for CPAP, enteral, liquid oxygen and oxygen equipment and services, contract providers said "no" 30 percent of the time, and another 30 percent of referral contacts resulted in no answer at the business' phone number. Of the 30 percent of oxygen referrals turned down by winning providers in Charlotte:

    - 57 percent of the refusals were due to an out-of-state, contract provider <u>not having a state license</u> to provide oxygen in North Carolina;

    - 14 percent were due to the patient being located "too far" away in the CBA;

    - 28 percent were due to the provider not having the product in-house or having decided not to provide liquid oxygen--despite the Medicare mandate that providers supply all HCPCS products.

    - All out-of-state winners for CPAP intended to drop-ship the devices to patients in North Carolina which is a <u>clear violation of the North Carolina State Respiratory Care Board.</u>

The *only* reason for delaying Round One was to give CMS and providers the opportunity to identify and correct the implementation flaws that had plagued the "first" Round One. Congress believed that §154(b) would effectively delay a new Round One for a period of at least 18 months, which would be adequate to address the problems that had been identified up to that point. For example, Representative Pete Stark, the sponsor of the legislation in the House, introduced H.R. 6252 (later incorporated into MIPPA as Sec. 154(b)) to delay Round One. The Congressman stated:

> Without Congressional intervention, the flawed program begins on July 1, 2008. The bill we're introducing today ***delays implementation of the competitive bidding program for 18 months to provide the Centers on Medicare and Medicaid Services (CMS) with the time to create an improved program*** based on standards laid out in this legislation.[4]

Similarly, Senator Charles Grassley introduced legislation with a sense of the Senate provision to delay the competitive bidding program for 18 months. The Grassley bill stated:

> Implementation of ***competitive bidding*** for durable medical equipment, prosthetics, orthotics, and supplies ***should be delayed by 18 months to***

[4] Statement on Introduction of Legislation to Delay Medicare's DME Competitive Bidding: Cong. Rec. 1221 (Emphasis supplied).

> ***address concerns and ensure beneficiaries continued access to quality medical equipment and supplies***.[5]

In fact, at the time it was passed, §154(b) was widely understood by both its supporters and opponents as intended to delay competitive bidding for at least 18 months to give CMS an opportunity to make changes to the program.[6] CMS was fully engaged at every stage of the negotiations and understood, in full, the spirit of what Congress wanted to accomplish but instead chose to apply a narrow and technical approach to implementing MIPPA.

C. Issues For Future Rulemaking

1. Considerations For Competitively Bidding Diabetic Supplies

When it passed MIPPA, Congress was especially concerned that Medicare beneficiaries with diabetes continue to have access to the products and services that are available to them before competitive bidding. Round One bidding for diabetic supplies resulted in a 43% reduction to the Medicare allowable for these products. Many of the contract providers in this product category were small providers who were not prepared to take on greater volumes of business. Further, given the size of the reduction from the allowable, it was a foregone conclusion that these providers would be required to limit their product offerings to beneficiaries. In future bidding, providers in this product category will be required to factor in the 9.5% payment cut imposed on competitively bid items.

It is widely recognized that the growing incidence of diabetes in the United States is a significant public health issue. Medical costs attributed to diabetes include $27 billion for care to directly treat diabetes, $58 billion to treat the portion of diabetes-related chronic complications that are attributed to diabetes, and $31 billon in excess general medical costs. The largest components of medical expenditures attributed to diabetes are hospital inpatient care (50% of total cost), diabetes medication and supplies (12%), retail prescriptions to treat complications of diabetes (11%), and physician office visits (9%).[7] Recent estimates are that approximately 9 million individuals over the age of 65 have been diagnosed with diabetes and this number is expected to keep growing giving the aging of the population, better methods of detection and decreasing mortality rates, among other factors.[8]

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[5] Statements on Introduced Bills and Joint Resolutions 154 Cong. Rec. S5525-01, S5528. (Emphasis supplied).

[6] In a statement supporting the President's veto of MIPPA, Representative Joe Barton stated:

> The bill before us, if the veto is not sustained, would delay-and I'm being charitable to use that verb-the reform of competitive bidding for durable medical equipment. It would delay that for 18 months, which in all probability would kill a program that would save billions and billions of dollars if implemented.

Medicare Improvements for Patients and Providers Act of 2008-Veto Message from the President of the United States (H. DOC. NO. 110-131) 154 Cong. Rec. H6520-04, H6521).

[7] Economic Costs of Diabetes in the U.S. in 2007, American Diabetes Association, 2007, p.596

[8] *Id*. p.597

These alarming projections speak against a policy that reduces access to appropriate diabetes equipment and supplies in order to control the costs inherent in the monitoring and treatment of this disease. Appropriate monitoring, supplies and equipment can effectively prevent more serious – and costly – complications for individuals with diabetes and reduce the staggering burden of this disease. CMS should proceed cautiously in this area and delay any bidding of this product category until it is sure that beneficiaries will have access to adequate access and choice of products as well as necessary education and care management services. We believe CMS has the authority and discretion to alter the product and Healthcare Common Procedure Coding System (HCPCS) code selection subject to bidding.

III. CONCLUSION

In summary, we believe that CMS should immediately withdraw the IFR and issue a proposed rule that solicits public comments on the implementation of MIPPA and other modifications and improvements to the program. Specifically, CMS should convene the PAOC as well as solicit comments on its proposal to revise financial documentation requirements and explain, in detail, its plans for implementing the new oxygen rules under the program, and provide an analysis of the combined impact of a 9.5% payment reduction and competitive bidding on small businesses.

CMS should also review the factors that hampered an effective roll-out of Round One and address how it proposes to prevent their recurrence. When MIPPA is viewed in light of the factual context that prompted Congress to enact this legislation, we believe that Congress did not expect CMS to avoid these issues by publishing an IFR.

Thank you for providing us with the opportunity to comment on this important rule. Please feel free to contact me at (703) 535-1888 or Walter Gorski, AAHomecare's Vice President for Government Relations at (703) 535-1894 should you have any questions.

Sincerely,

Tyler J. Wilson
President and Chief Executive Officer
American Association for Homecare