

Round One DME Competitive Bidding Must be Suspended And Changes Made Prior to Expansion of the Program

Pride Mobility request that Congress strongly communicate to HHS Secretary Michael Leavitt support for the immediate suspension of the implementation of Round One of the Medicare competitive bidding program for durable medical equipment, orthotics, prosthetics and supplies (DMEPOS). The Centers for Medicare and Medicaid Services (CMS) has improperly rejected over 200 qualified Medicare providers from the first stage of the program due to procedural flaws, operational problems and other irregularities that call into question the manner in which competitive bidding is being implemented. As a result, providers of home medical equipment will be prevented from doing business with Medicare for frequently provided products and services subject to competitive bidding.

Without adequate procedural controls, CMS is rushing to implement the program in ten metropolitan areas around the country and with equal haste is moving forward to expand the program under Round Two in another 70 areas across the country in 2009. Plans for Round Two are proceeding without a thorough examination of the serious, systemic problems being encountered now in Round One. Unless Congress exercises oversight and delays the implementation of Round One, fundamental mistakes will be imbedded in the program and perpetuated in Round Two of competitive bidding.

The problems being encountered in Round One are fundamental to the competitive bidding process and are undermining a number of goals that Congress identified in establishing the program. The program is currently scheduled to be implemented in the first 10 areas on July 1, 2008, which is when providers, manufacturers, and most importantly Medicare beneficiaries will feel the negative impact of the program and consequences of the actions now being taken by CMS.

Prior to any further plans to expand the program beyond the initial 10 areas Congress must require an independent thorough review and analysis of Round One that evaluates the following:

- Do Medicare beneficiaries have meaningful choices of providers and access to medical equipment?
- Beneficiary experiences under the program based on surveys of beneficiary complaints and grievances.
- Analysis of steps that should be taken to ensure beneficiary access to quality products and services, and the clinical care and treatment impact by product category in each CBA.
- Impact on small business in each CBA and steps taken to ensure they have an opportunity to be considered for participation in the program.
- Analysis of clinical outcomes for Medicare beneficiaries in each CBA.
- Effect of competitive bidding on the selection and utilization of particular products compared to the period two years prior to implementation and the impact of such selection and utilization on patient care.

Background:

The Medicare Modernization Act of 2003 mandated that CMS begin implementation of a durable medical equipment orthotics and supplies (DMEPOS) competitive bidding program for certain DMEPOS items and services in 10 of the largest metropolitan statistical areas (MSAs) in 2007, 70 additional areas in 2009, and be expanded to other areas as early as 2010. This statute includes provisions that fundamentally change the way that Medicare pays for these items under Part B of the Medicare program. Instead of a fee schedule, bids submitted by DMEPOS providers will establish new payment amounts.

The first 10 areas (CBAs) where the program is scheduled to be implemented July 1, 2008 include:

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| 1. Charlotte, NC (parts of SC) | 6. Miami, FL |
| 2. Cincinnati, OH | 7. Orlando, FL |
| 3. Cleveland, OH | 8. Pittsburgh, PA |
| 4. Dallas, TX | 9. Riverside, CA |
| 5. Kansas City, MO (parts of KS) | 10. San Juan, Puerto Rico |

The following 10 DME product categories are included in Round 1: Oxygen and oxygen equipment, standard power wheelchairs and accessories, complex rehab power wheelchairs and accessories, mail order diabetic supplies, enteral nutrition, CPAP/RAD, hospital beds, negative pressure wound therapy, walkers, and support surfaces (Miami and San Juan).

On March 21, CMS notified all bidding home medical equipment providers of the competitive bidding results. Many providers received notices that they had been disqualified from participating. A considerable number of those notified contest the grounds by which they have been disqualified. In many cases, they have supporting documentation indicating that they were improperly removed from participation in the program. If it is found that a provider was erroneously excluded from the program the result will be inaccurate single payment amounts for the CBA in the product categories the provider bid and contract bid winners making contract signing decisions based on invalid information.

The competitive bidding law does not permit DME providers to appeal decisions made by CMS during the provider selection process. The CBIC and CMS have indicated that they will review all disqualified provider claims; however, they have not indicated what their next steps will be.

Overview of errors and program flaws based on initial provider contracting process:

Pride Mobility has been contacted by many providers who attempted to participate in Round One of the competitive bidding program but were disqualified for various reasons. The following points provide an overview of key areas of serious concern:

1. Providers have been disqualified based on CMS/CBIC errors and for non-substantive reasons.

Numerous mistakes and flaws in CMS' management of the provider selection process have resulted in improper disqualifications.

Example: CMS cites a provider's improper or insufficient financial documentation as the basis for numerous provider disqualifications. A number of these providers have reviewed the documentation submitted to CMS and many appear to be in full compliance with the requirements. These providers have been eliminated from participation in the competitive bidding program because of these errors.

Example: A power wheelchair provider was disqualified because they bid less than their product cost for certain non-covered or rarely used codes. It is common business practice in competitive bidding programs for a company to use some items as "loss leaders" to secure a contract. Employing this practice for a small number of bid items should not result in a company's bid for the complex rehab device category being disqualified.

Unfortunately, CMS has stated that there is No:

- 1) Independent review of the CMS supplier selection process;
- 2) Independent review of criteria used to include or exclude providers from the program; or
- 3) Process for providers who believe that they have been improperly disqualified from the program to appeal the CMS determination.

2. **CMS has been unwilling to share meaningful data to fully assess the impact of the program on providers and beneficiaries. The entire implementation phase of the program has been veiled in secrecy and in all aspects failed to meet customary standards of government transparency.**

Providers with long-standing ties to a community, in many cases, did not win bids in their core product categories and they will likely face severe financial pressure that is likely to result in closing the business. The reduction in qualified providers will force many hospitals, clinics, physician's offices and vulnerable beneficiaries to find and receive care from a new provider that they may have no relationship with. Pride has learned that the Cleveland Clinic, the University of Pittsburgh and the University of Michigan were not selected as contract providers. It is likely that discharge planners for these hospitals will be significantly burdened when trying to transition beneficiaries from the hospital to the home setting, which could result in longer hospital stays and a significant increase in Part A expenditures.

The single payment amount for items within the complex rehab category are, in some instances, identical across the CBAs, raising questions about the validity of the bids. The formula that CMS applied in order to determine the single payment amount ultimately relies on a median of selected bids. Statistically, the odds of the exact same number being the median number in multiple CBAs are extremely small.

Specific information requested by the industry, which CMS has yet to release:

- 1) The number of individual providers who submitted bids in the competitive bidding areas (to determine if CMS has accurately anticipated demand for services and items);
- 2) The methodology it used to judge the financial condition of prospective contract providers (to ensure that CMS understands the various business models common to DME providers);
- 3) The financial criteria used to evaluate providers (again, to ensure that CMS understands the various business models common to DME providers); and
- 4) De-identified provider bid data (to validate CMS' calculation of the new single payment amounts).

In response to repeated requests for this information, CMS has refused to provide this data citing that the agency is in the "contracting" or "procurement" phase. Using this logic, CMS will never release this data and be held accountable for the implementation of this program since it will always be in either the "contracting" or "procurement" phase of competitive bidding.

3. **CMS must resolve provider disqualifications from Round One in a transparent manner and thoroughly educate stakeholders about impending changes.**

CMS indicated they have "instituted a rigorous quality assurance program for all aspects of bid evaluation including a multifaceted review of the hard copy documentation submitted in support of bids." CMS has not; however, indicated what the resolution process will be for providers who were deemed disqualified in error, if the single payment amount would be recalculated, and if contract award winners would be given another opportunity to reevaluate their decision based on a recalculation.

If additional contract bid winners are added CMS must recalculate the median to establish accurate single payment amounts and allow all contract bid winners the opportunity to reevaluate their contract.

CMS states that they are "in the process of preparing an extensive education and outreach campaign to ensure that beneficiaries, providers, referral agents and other stakeholders are aware of the impending changes on the provision of and payment for certain DMEPOS in competitive bid areas." While the education and outreach process began in a piecemeal fashion in early April, 90 days is an insufficient amount of time to educate beneficiaries, providers, referral agents and other stakeholders so that they are fully informed of the changes that will become effective on July 1.

4. Beneficiaries will face disruptions in service and reduced quality.

Beneficiaries who have come to rely on their long-standing provider may be required to switch providers in order for their products and services to continue to be a covered benefit after July 1. Further, a significant challenge for beneficiaries will be obtaining competitively bid products from multiple and unfamiliar contract providers, depending on the home medical equipment items and services they need. This stands in stark contrast with their ability today to receive services from a provider of their choice.

Beneficiaries who require the use of a complex rehab power wheelchair will likely soon begin to experience difficulty in securing the most appropriate product to address their medical needs due to the greater than 60 day cycle from initial evaluation to delivery for this complex equipment. Providers who lost bids will be reluctant to provide the product because if the date of service (delivery) is on or after July 1, a non-contract provider (non-bid winner) will not be paid for the product. In addition, many providers who won the bids do not yet have operations in place to handle these patients.

Hospital discharge planners may be required to arrange for products and services from multiple providers, some of which may not be local or experienced, which is likely to result in a delay of discharge and increased in patient care costs.

Providers may substitute products with lower quality and less expensive equipment and reduce the non-equipment services they historically provided as part of the package of home medical equipment and services. For example, on-call service and in-home training, adjustments or preventative maintenance visits may be curtailed or eliminated altogether. This is likely to occur as providers strive for ways to reduce operating costs.

In addition, Medicare beneficiaries will be unable to find a supplier willing to repair their power wheelchairs because contract providers are not required to service the items they sell, the single payment amounts on replacement parts are unreasonably low and noncontract providers are not only under no obligation to service the power wheelchair, they will not be able to afford to repair them..

5. Medicare Program will experience increased costs.

The provision of Durable Medical Equipment products and services is the slowest growing sector of the Medicare budget and has been proven to be the most cost effective method of care for Medicare beneficiaries. While the expected cost savings associated with the new single payment amounts will save the Medicare program and beneficiaries under their Part B benefits this savings is expected to be off-set by a significant increase in Part A expenditures for ambulance services, hospital emergency room visits, extended in-patient days in the hospital or skilled nursing facilities and additional physician's fees.

Within the Complex Rehab product category 4 of the 10 CBAs show actual savings (less non-covered items) of less than 10%. This is hardly enough to warrant the imposition and high administrative costs of a complicated bureaucratic competitive bidding scheme with the potential for harming people with disabilities who rely on their power wheelchair to remain active in their home and communities.

When implemented the competitive bidding program will have a limited number of suppliers in a particular CBA. Those providers that have been left out will either have to adapt their business accordingly, discontinue selling products that were subject to bidding or more likely close their doors altogether. This will create a situation where there is a bare minimum number of suppliers in a CBA needed to service the beneficiary population in a particular category. If after a period of time, several "winning" providers realize that they can no longer adhere to the program and voluntarily pull out, it may create a situation where there are only a few providers left after all other providers have vacated the

business. This could create a situation where the remaining providers would no longer be able to handle the capacity, would create a monopoly with no one left in the area to foster competition and lower prices and would not be subject to competitive bidding when the area is rebid in three years. Beneficiaries would then be at the mercy of these remaining providers, where cost and access would almost assuredly be negatively impacted.

Conclusion:

CMS is heading into uncharted territory with the implementation of a Medicare competitive bidding program where the government discriminates against who can provide items and services to Medicare beneficiaries. CMS has an obligation to determine whether the bidding program will be effective and achieve the goals that were originally intended and expected. Based on CMS's failure to adequately respond to questions about the program and the errors and program flaws that have been identified, Pride strongly requests that lawmakers urge CMS to delay round one immediately and stop plans to expand the program to 70 more areas until a thorough review and analysis of Round 1 is conducted which evaluates the following:

- Do Medicare beneficiaries have meaningful choices of providers and access to medical equipment?
- Beneficiary experiences under the program based on surveys of beneficiary complaints and grievances.
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