



Committed to Preserving and Promoting Access, Choice and Value for Consumers of Ostomy and Urological Products

The Access & Care Coalition is comprised of not-for-profit organizations representing patients, consumers, and clinicians along with manufacturers and suppliers of ostomy and urological products who are committed to preserving and promoting access, choice and value.

There are approximately 1,000,000 individuals in the United States who rely on ostomy and/or urological devices to ensure proper health and to function at the highest level possible. Due to differing body shapes, physiology, and medical circumstances, there is no one-size-fits-all product that can meet everyone's needs. In fact, there is often the need for individuals to use several different types of devices during their lifetimes. Any attempt to systematically drive down costs – like Medicare's Competitive Bidding Program (CBP) – will result in constrained access, reduced choice, and decreased value to both the Medicare Program and its beneficiaries.

Government officials – both executive and legislative – tasked with determining what is the best and most effective policy regarding reimbursement for these devices should be guided by five criteria:

- **Harm of Commoditization**
- **Limited or No Savings Potential**
- **Reduction in Access and Choice**
- **Cost Shifting**
- **Previous Negative Outcomes**

COMMODITIZATION: Ostomy and urological products are specialized devices that can vary greatly from individual to individual.

- That's why there are more than 2,000 items produced by more than 100 manufacturers and offered by suppliers to the patient population.

- What works for one cohort of patients will, invariably, not work for others. Since these devices physically replace a critical and sensitive body function, the consequences to individuals of using inferior or incompatible devices is life-impacting to the patient and costly to providers, government agencies, and patients.
- The reduction in choice of products can and will cause debilitating and measurable negative health outcomes, both from a physical and psycho-social perspective. There is no middle ground with these products. They must work and work well for the beneficiary.

Whether intended or not, the practical outcome of reimbursing for these unique types of medical devices and products through an inflexible “competitive bidding” system is to create a market based on a least-common denominator platform resulting in the commoditization of products that immediately restricts access, reduces choice, and decreases value to both the Medicare Program and its beneficiaries. We know this to be a fact as CMS data has chronicled the restricted access, reduced choice, and decreased value regarding other DME products that have been subjected to Medicare’s Competitive Bidding Program this past decade.

LIMITED OR NO SAVINGS POTENTIAL: In 2016, Durable Medical Equipment-Prosthetics, Orthotics and Supplies (DMEPOS) represented approximately 1% of the total Medicare annual budget, or \$6.6B. Ostomy and Urological represent approximately 8% of all DME expenditures, or approximately \$500M. Extrapolating from the results of a competitive bidding demonstration project on urological products conducted in Polk County, Florida from 1999-2003, contained in the report “Evaluation of Medicare’s Competitive Bidding Demonstration for DMEPOS”, we could expect the following:

- Polk County Demonstration projected no more than an 8% decrease on urological costs under competitive bidding.
- This 8% “savings” is further offset by the cost of implementing the bidding scheme which consumed approximately 50% of the overall savings.
- Ostomy products are similar to urological products – particularly with regard to having much lower allowed charges than other DME -- and could be expected to yield a similar savings percentage.
- Although ostomy was not part of the Polk County Demonstration, individuals using ostomy products are similar– to individuals using urological products and would experience the same deleterious effects regarding constrained access, reduced choice, limited training, and concomitant health complications.

- These factors would drive up costs in other parts of Medicare resulting in little to no net savings to the overall Program, yet place beneficiaries in an inferior position vis-à-vis the current system.

REDUCTION IN ACCESS AND CHOICE: The application of competitive bidding to ostomy and urological products will necessarily result in a reduction of access to providers/suppliers and the number and type of products offered resulting in decreased choice for beneficiaries.

- Through the bid system, some beneficiaries will experience a reduction in the number of suppliers in their geographic area thus being deprived of professional service and availability of products in determining their individual product needs.
- Because of the variance in needs among the affected population, the unintended consequences of removing the one or few alternative products that work for an individual is one of the greatest concerns to beneficiaries.
- Suppliers will be economically forced to offer only those products that serve the highest percentage of the patient base that fit with the bid payment amounts resulting in the elimination of products that serve smaller percentages of beneficiaries, even though these products are medically necessary for these beneficiaries.
- The resulting decrease in products that may be offered also diminishes manufacturer incentive to invest in new research, technologies, design and innovation.

COST SHIFTING: Under competitive bidding, there will be a significant likelihood of cost-shifting within the Medicare Program.

- The constrained access to beneficiaries and the reduced choice of specific products due to competitive bidding will result in increased frequency of health complications – such as urinary tract infections (UTI's) in urology patients and peristomal skin conditions (PSC's) in ostomy patients – due to inferior or incompatible products.
- These outcomes will require additional medical treatment thus shifting costs from one part of the Program (DME) to other parts (Parts A & B) resulting in little to no savings or, potentially, additional costs to the overall Program.

PREVIOUS NEGATIVE OUTCOMES: There is perhaps no greater testament against the applicability of competitive bidding to these types of products than CMS's previous experience through a Demonstration Project in Polk County, Florida, between 1999 and 2002. Urological products were included as one of the five product categories for the Project which conducted

two rounds of bidding. The CMS-commissioned “Evaluation of Medicare’s Competitive Bidding Demonstration for DMEPOS,” issued in November 2003, included the following findings.

- Competitive bidding reduced the number of approved suppliers in Polk County during the term of the Demonstration Project -- in fact, the number of successful bidders dropped from 9 to 7 from Round 1 to Round 2;
- Some suppliers consolidated their urological products into one line to offset the reduction in reimbursements;
- Some suppliers employed/retained fewer employees in an effort to reduce costs which increased the need for service calls and extended waiting times, thereby decreasing access;
- There was also a measurable decline (22%) of training for urological product users;
- Because 3 of the 5 providers of urological supplies were located outside of Polk County, a shift to mailing supplies resulted in supplier staff not being available in person to provide training to beneficiaries when first receiving their supplies;
- Survey of suppliers noted that several of them had modified their inventories to carry lower quality/cost products to offset lower reimbursement rates;
- While the overall cost of urological products decreased by approximately 19 percent during the first bidding process, it was unsustainable, and the second bid increased significantly resulting in a less than 8 percent reduction overall;
- The reduction in the overall number of suppliers – including experienced suppliers – reduced competition and drove remaining suppliers to consolidate to one brand to obtain a more competitive price having a deleterious effect on product selection;
- Such deleterious effects would be more likely in product categories with low allowed charges and relatively few suppliers, such as urologicals;
- Urological products have much lower allowed charges than most other DME products, so it offers relatively little potential for Program savings;
- With the low number of suppliers participating in the program, competitive bidding may not be appropriate for product categories that are so small and have so few suppliers serving the market;
- Based on all the above factors, the Report concluded that, **“the product category of urological supplies is not as well-suited for competitive bidding”** as other DMEPOS categories.

CONCLUSION

For all these reasons outlined above, the cost containment and policy goals of expanding the Competitive Bidding Program to ostomy and urological products as defined by HHS/CMS would not be met and, therefore, any plan that contemplates expansion should be rejected.

Prepared by PHG/WMR; 8-23-18

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