

A Primer on Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and DMEPOS Competitive Bidding

September 19, 2012

TABLE OF CONTENTS:

EXECUTIVE SUMMARY 3

WHAT DOES DMEPOS MEAN? 5

HOW IS DMEPOS USED AND WHY IS IT IMPORTANT? 6

HOW ARE DMEPOS PRODUCTS REPORTED AND BILLED? 7

HOW DID DMEPOS COMPETITIVE BIDDING UNDER MEDICARE COME ABOUT? 7

WHAT HAS HAPPENED UNDER THE DMEPOS COMPETITIVE BIDDING PROGRAM OVER THE LAST FEW YEARS? 8

ARE ALL DMEPOS PRODUCTS SUBJECT TO COMPETITIVE ACQUISITION UNDER MEDICARE? 11

WHAT ARE SOME OF THE IMPLICATIONS OF DMEPOS COMPETITIVE ACQUISITION OR BIDDING FOR MEDICARE BENEFICIARIES? 12

DOES THE HCPCS CODING SYSTEM USED TO BILL FOR DMEPOS PRODUCTS LEAD TO ADDITIONAL CONCERNS? 14

WHAT HAPPENS NEXT ON DMEPOS COMPETITIVE ACQUISITION? 14

A Primer on Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and DMEPOS Competitive Bidding

Executive Summary

The acronym “DMEPOS” (durable medical equipment, prosthetics, orthotics, and supplies) refers to a wide range of products meeting diverse health care needs. These include blood glucose monitoring systems for managing diabetes, hospital beds for home use, wheelchairs, oxygen equipment, artificial arms and legs, back and neck braces, enteral and parenteral nutrition, special pads and mattresses to prevent pressure or decubitus ulcers, and continuous positive airway pressure (CPAP) devices for treating obstructive sleep apnea, a condition that causes individuals to stop breathing several times during the night.

Congress in 2003 mandated a Medicare competitive acquisition (bidding) program for certain DMEPOS products. The program was slated to begin on July 1, 2008, in 10 competitive bidding areas (CBAs). However, in response to concerns of patient and supplier stakeholders, section 154 of the Medicare Improvements for Patients and Providers Act (MIPPA) retroactively delayed the start of the program and made other important changes to the underlying statute.

In October 2009, the Centers for Medicare & Medicaid Services (CMS) opened a 60-day bid window for the Round 1 Rebid in 9 areas of the country for 9 product categories. On July 1, 2010, the agency announced that the payment amounts derived from the Round 1 Rebid would reduce Medicare prices for these products, on average, by 32 percent. CMS entered into contracts with “winning” suppliers and the new program began on January 1, 2011. In the summer and fall of 2010, CMS developed additional regulations relating to future rounds of the DMEPOS competitive bidding program.

In January 2012, CMS opened the bidding process for Round 2 of the DMEPOS competitive bidding program in 91 additional metropolitan statistical areas (MSAs). In this round, CMS is also beginning a national mail order competitive bidding program for diabetes testing supplies. And in fall 2012, CMS is slated to conduct the Round 1 Recompete, a new competition in the nine areas where DMEPOS competitive bidding originally began. For the Round 1 Recompete, CMS is using much broader product categories, which include an array of products not typically furnished by any single supplier today, and also competitively bidding many additional products.

DMEPOS competitive bidding has a number of implications for Medicare beneficiaries, including the following:

- Medicare beneficiaries in affected CBAs will only be able to obtain competitively bid products from a limited number of winning (or contract) suppliers under the program (unless their current supplier is temporarily grandfathered).
- Medicare officials thus far also have rejected the notion that they should select winning suppliers in a way that assures that they will be dispersed geographically across an entire CBA, thereby providing some degree of convenient access to Medicare beneficiaries no matter where they live in the CBA.
- Beneficiaries requiring several different types of competitively bid DMEPOS products no longer may be able to obtain all the products they need from a single supplier.
- Medicare officials might not select enough winning suppliers to meet beneficiary needs in a particular CBA.
- Winning DMEPOS suppliers could restrict the range of DMEPOS products they choose to offer to Medicare beneficiaries. Current deficiencies in the HCPCS coding system further complicate the “product choice” situation.

A key question is whether Medicare beneficiaries will, over time, end up experiencing serious access or quality of care problems as a result of the new competitive bidding program. While CMS believes that a relatively low beneficiary complaint volume during Round 1 and no obvious increases in such indicators as beneficiary mortality and emergency room use are sufficient to suggest that beneficiaries are not being harmed, serious criticisms levied by neutral competitive bidding experts would appear to warrant a much more comprehensive assessment.

A Primer on Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and DMEPOS Competitive Bidding

What does DMEPOS mean?

For Medicare purposes, **durable medical equipment (DME)** means equipment that:

- Can withstand repeated use;
- Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years;
- Is used primarily and customarily to serve a medical purpose;
- Generally is not useful to a person in the absence of illness or injury; and
- Is appropriate for use in the home.

DME includes a wide range of products, such as:

- Alternating pressure pads, mattresses and lambs wool pads (also known as support surfaces);
- Blood glucose monitors or meters;
- Canes;
- Commodes;
- Continuous positive airway pressure (CPAP) devices;
- Crutches;
- Hospital beds (for home use);
- Infusion pumps;
- Intermittent positive pressure breathing machines;
- Oxygen equipment;
- Traction equipment;
- Vaporizers;
- Ventilators;
- Walkers; and
- Wheelchairs.

These products may be obtained on a rental and/or purchase basis.

The term “**prosthetics and orthotics**” (**P&O**) refers to “leg, arm, back, and neck braces [orthotics], and artificial legs, arms and eyes [prosthetics], including replacements if required because of a change in the patient’s physical condition” (Section 1861(s)(9) of Medicare law).

The term “**prosthetic devices**” (sometimes used interchangeably with the term “prosthetics” and sometimes viewed as a subset of “prosthetics”) corresponds to “prosthetic devices (other than dental) which replace all or part of an internal

body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens” (Section 1861(s)(8) of Medicare law). Other examples of prosthetic devices include:

- Cardiac pacemakers;
- Breast prostheses for postmastectomy patients; and
- Enteral and parenteral nutrition therapy.

The term “**supplies**” (**S**) refers to items necessary for the effective use of DME. Good examples are:

- Oxygen; and
- The test strips compatible with a patient’s blood glucose monitor or meter.

DMEPOS products not yet subject to competitive bidding are generally paid under one of several Medicare fee schedules established in Medicare statute.

How is DMEPOS used and why is it important?

DMEPOS products meet a wide range of Medicare beneficiary needs. Below are just a few examples.

- Medicare beneficiaries with diabetes use a **blood glucose monitor** (durable medical equipment), **compatible test strips, and lancets** (both considered supplies) to prick a finger or other body site, obtain a small blood sample, and check their blood sugar on the schedule recommended by their physician, which can be as often as three or more times a day. Test results help Medicare beneficiaries and their doctors manage their diabetes.
- A **CPAP device** (durable medical equipment) is used to treat obstructive sleep apnea (OSA), a condition that causes individuals to stop breathing several times during the night. If left untreated, OSA disturbs normal sleep patterns, leading to daytime drowsiness that can cause accidents with motor vehicles and machinery. Medicare beneficiaries with OSA also face significant risks for cardiovascular disease and other ailments.
- Patients with serious chronic obstructive lung disease and other pulmonary conditions need to receive supplemental **oxygen** (durable medical equipment and supplies) through one of several different types of devices, both stationary and portable.

- **Hospital beds, wheelchairs, and walkers** (all durable medical equipment) make it possible for ill or injured patients to compensate for their condition or injury, stay in their own homes, and preserve as much independence as possible. These products, especially hospital beds and wheelchairs, vary in their design and functionality, meaning that a Medicare beneficiary's specific needs must be assessed in selecting the product best able to meet those needs.
- **Enteral nutrition products** (considered prosthetic devices), administered through a nasogastric tube placed via the nose into the stomach or a percutaneous tube placed directly through the skin into the stomach or small intestine, provide essential nutrients to patients on a temporary or longer-term basis when they cannot otherwise get an adequate amount of nourishment by mouth. The inability to eat or swallow normally may be due to neurological problems such as stroke, brain injury, multiple sclerosis, polio, and Parkinson's disease, or physical problems such as trauma to the head and neck, cancers of the oral cavity or throat, and complications of spinal surgery.
- **Support surfaces**, such as mattress replacement systems constructed of foam, air, gel, or water (durable medical equipment), help prevent or treat pressure or decubitus ulcers in bedridden patients, including those with limited mobility and those recovering from serious operations. If left untreated, pressure ulcers can lead to serious, even life-threatening complications, including localized infection, pain, depression, abscess and sinus tract formation, osteomyelitis (bone infection), blood poisoning (septicemia), and even maggot infestation.

How are DMEPOS products reported and billed?

- DMEPOS suppliers use Healthcare Common Procedure Coding System (HCPCS) codes, a standardized set of alpha-numeric codes maintained by the Centers for Medicare & Medicaid Services (CMS).
- For example, a blood glucose monitor or meter is generally reported using HCPCS code E0607. A CPAP device is reported using HCPCS code E0601. And a hospital bed, variable height, hi-low, with any type of side rails, with mattress is described by HCPCS code E0255.

How did DMEPOS competitive bidding under Medicare come about?

- In 2003, the Congress decided to make a significant change in Medicare payment policy for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Section 302 of the Medicare Prescription Drug,

Improvement, and Modernization Act of 2003 (MMA) mandated a Medicare competitive acquisition (competitive bidding) program for DMEPOS.

- The program was slated to begin on July 1, 2008, for selected DMEPOS product categories in 10 competitive bidding areas (CBAs).
- Medicare officials had completed the Round 1 bidding process, selected winning or contract suppliers, and begun the program. However, in response to concerns of patient and supplier stakeholders, section 154 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), enacted on July 15, 2008, retroactively delayed the start of the competitive acquisition program, nullified the results of the Round 1 bidding process, and made other important changes to the underlying statute. CMS subsequently conducted a Round 1 Rebid process.

What has happened under the DMEPOS competitive bidding program over the last few years?

Round 1 Rebid. On January 1, 2011, CMS implemented DMEPOS competitive bidding in the same CBAs specified for the original Round 1 bidding (minus Puerto Rico). These areas are:

1. Charlotte-Gastonia-Concord (North Carolina and South Carolina);
2. Cincinnati-Middletown (Ohio, Kentucky and Indiana);
3. Cleveland-Elyria-Mentor (Ohio);
4. Dallas-Fort Worth-Arlington (Texas);
5. Kansas City (Missouri and Kansas);
6. Miami-Fort Lauderdale-Pompano Beach (Florida);
7. Orlando-Kissimmee (Florida);
8. Pittsburgh (Pennsylvania); and
9. Riverside-San Bernardino-Ontario (California).

For the Round 1 Rebid, the competitively bid categories of items and services were the same as those originally specified for Round 1 (minus negative pressure wound therapy and group 3 complex rehabilitative power wheelchairs). These categories are:

1. Oxygen, oxygen equipment, and supplies;
2. Standard power wheelchairs, scooters, and related accessories;
3. Group 2 complex rehabilitative power wheelchairs and related accessories;
4. Mail-order diabetic supplies;
5. Enteral nutrients, equipment and supplies;

6. Continuous positive airway pressure (CPAP) devices, respiratory assist devices (RADs), and related supplies and accessories;
7. Hospital beds and related accessories;
8. Walkers and related accessories; and
9. Support surfaces (Group 2 mattresses and overlays)—in Miami-Ft. Lauderdale-Pompano Beach, FL only.

On July 1, 2010, CMS announced that the payment amounts derived from the Round 1 Rebid would produce prices that, on average, would be 32 percent lower than amounts paid under the DMEPOS fee schedules. On November 3, 2010, CMS released the list of 356 suppliers that had agreed to enter into a total of 1,217 contracts with CMS to provide various items and services in the nine areas initially subject to DMEPOS competitive bidding.

Round 2. During the summer and fall of 2010, CMS completed rulemaking related to future rounds of the DMEPOS competitive acquisition program. A final rule unveiled on November 2, 2010, addressed the following issues:

- Division of the Chicago, Los Angeles and New York metropolitan areas into smaller CBAs;
- The addition of 21 metropolitan statistical areas to Round 2, as required by the Affordable Care Act, for a total of 91 areas that would be included in the Round;
- Creation of a national mail order competitive bidding program for diabetic testing supplies, with the first competition to occur at some unspecified date after 2010;
- A requirement that bidding suppliers of diabetic testing supplies in Round 2 and beyond demonstrate that their bid covers at least 50 percent of all types of diabetic testing strips, as mandated by MIPPA;
- A prohibition against contract suppliers of diabetic testing strips influencing or incentivizing Medicare beneficiaries to change their brand of glucose monitor and test strips; and
- A formal appeals process for DMEPOS competitive bidding contract suppliers in cases where a contract is proposed for termination due to breach of contract.

In a September 26, 2010, letter, nearly 170 economists and other competitive bidding experts concluded that CMS' DMEPOS competitive bidding program was seriously flawed and that the program "over time may degenerate into a race to the bottom in which suppliers become increasingly unreliable, product and service quality deteriorates, and supply shortages become common." In June 2011, an expanded group of 244 competitive bidding experts, including four Nobel laureates, wrote to the White House urging modifications to Medicare's

competitive bidding program. To date, however, CMS has refused to make any substantive changes to the program.

In September 11, 2012, testimony before a subcommittee of the House Small Business Committee, CMS reported that the DMEPOS competitive bidding program produced about \$202 million in Medicare savings in the first year of operation and is projected to save Medicare about \$25.7 billion between 2013 and 2022, with an additional \$17.1 billion in savings for beneficiaries during this period through lower Medicare Part B premiums and cost sharing.

At the same hearing, however, Peter Cramton, Professor of Economics at the University of Maryland and a competitive bidding expert, labeled Medicare's DMEPOS competitive bidding program "fatally flawed" and called particular attention to the following problems:

The use of non-binding bids together with setting the price equal to the median of the winning bids provides a strong incentive for low-ball bids--submitting bids dramatically below actual cost. This leads to complete market failure in theory and partial market failure in the lab. Another problem is the lack of transparency. For example, bidder quantities are chosen arbitrarily by CMS, enabling a wide range of prices to emerge that have no relation to competitive market prices.

Round 2 of the DMEPOS competitive bidding program opened on January 30, 2012, with a 60-day bid window. This round covers 91 additional MSAs, including the largest MSAs in the country, Chicago, Los Angeles, and New York. According to CMS, with this expansion, the competitive bidding program will cover approximately 50 percent of Medicare beneficiaries. It also includes a national mail order program for diabetes testing supplies (rather than establishing a competitive bidding program for this product category in each MSA, as was done under the Round 1 Rebid). Round 2 product categories generally track those for the Round 1 Rebid except that standard manual wheelchairs, standard power wheelchairs, and scooters have been combined to form a new expanded standard mobility device product category. In addition, support surfaces are being bid throughout all Round 2 areas, and a new product category for Negative Pressure Wound Therapy (NPWT) Pumps and Related Supplies and Accessories has been added.

Round 1 Re compete. On August 16, 2012, CMS announced the bidding timeline for the "Round 1 Re compete," a new competition in the nine MSAs where DMEPOS competitive bidding was first implemented. For the Round 1 Re compete, CMS adopted only six product categories, most of which are broad, often combining what had been separate categories under Round 1. For example, CMS adopted a General Home Equipment and Related Supplies and

Accessories product category, which includes hospital beds and related accessories, support surfaces, transcutaneous electrical nerve stimulation (TENS) devices, commode chairs, patient lifts, and seat lifts. CMS also adopted a Respiratory Equipment and Related Supplies and Accessories product category, which includes oxygen and oxygen equipment, CPAP devices and RADs, and even standard nebulizers. CMS also combined the walker and wheelchair/scooter categories. CMS retained separate product categories for enteral nutrients, equipment and supplies, and for NPWT pumps and related supplies and accessories. CMS also added a new External Infusion Pumps and Supplies product category.

The Round 1 Recompete product categories also expanded the scope of the competitive bidding program by including many DMEPOS products that were not included in either Round 1 or Round 2 of the competitive bidding program. In a number of cases, the Round 1 Recompete product categories combine products not typically furnished by any single DMEPOS supplier in the marketplace today.

For example, suppliers furnishing oxygen and oxygen equipment do not necessarily furnish CPAP devices and RADs or nebulizers. Yet, CMS has combined those products into a single category. Similarly, a supplier furnishing insulin pumps today would not also furnish the many other products included in the External Infusion Pumps and Supplies category. Nonetheless, under CMS bidding rules, a supplier must bid on and be willing to and capable of furnishing all products included in a product category.

Are all DMEPOS products subject to competitive acquisition under Medicare?

No. Items eligible for competitive acquisition currently include:

- Durable medical equipment other than class III devices;¹
- Supplies necessary for the effective use of durable medical equipment other than inhalation drugs;
- Enteral nutrients, equipment and supplies; and
- Off-the-shelf orthotics².

The MMA further allowed the Secretary to phase in the DMEPOS competitive acquisition program by beginning with “the highest cost and highest volume

1 Class III devices sustain or support life, are implanted, or present potential unreasonable risk and are subject to premarket approval, the most stringent regulatory control.

2 Off-the-shelf orthotics require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit a beneficiary.

items and services or those items and services that the Secretary determines have the largest savings potential.” Note that while reference is routinely made to DMEPOS competitive acquisition or bidding, prosthetics (P) are not subject to competitive bidding and enteral nutrients, equipment and supplies are the only prosthetic devices (also P) that are.

In a final rule published on April 10, 2007, CMS specifically acknowledged that diabetic shoes and inserts, prosthetics for the foot, splints and casts, prosthetic devices that aid vision (that is, post-cataract eyeglasses and contacts), surgical dressings, and parenteral nutrients, equipment and supplies are not among the products eligible for DMEPOS competitive acquisition. Customized items are also excluded from competitive acquisition.

What are some of the implications of DMEPOS competitive acquisition or bidding for Medicare beneficiaries?

- **Medicare beneficiaries in affected CBAs will only be able to obtain competitively bid products from a limited number of winning (or contract) suppliers under the program (unless their current supplier is temporarily grandfathered).** This means that many beneficiaries will no longer be able to obtain affected products from their usual or the closest supplier, such as their local pharmacy. And, physicians and other referral agents may no longer be able to refer their patients to the DMEPOS suppliers they customarily and confidently recommend.
- **Medicare officials thus far also have rejected the notion that they should select winning suppliers in a way that assures that they will be geographically dispersed across an entire CBA, thereby providing some degree of convenient access to Medicare beneficiaries no matter where they live in the CBA.** For example, if the Washington, DC metropolitan area were a CBA, it would obviously be important to select winning suppliers from a wide range of jurisdictions, rather than simply assume that suppliers in say Montgomery County, Maryland or Fairfax County, Virginia adequately and conveniently could meet beneficiary needs for the entire metropolitan area.
- **In certain instances, beneficiaries requiring several different types of competitively bid DMEPOS products no longer may be able to obtain all the products they need from a single supplier** since different suppliers may be selected as contract suppliers for different product categories.

- **Medicare officials might not select enough winning suppliers to meet beneficiary needs in a particular CBA.** An earlier Medicare effort to use a competitive bidding process for DMEPOS was canceled by Congress. Medicare officials had selected some suppliers located outside the CBA and other suppliers lacking previous experience in providing the DMEPOS product category for which they had been selected. According to CMS, 24 percent of DMEPOS suppliers selected as contract suppliers following the Round 1 Rebid process previously had not furnished contract items in the area(s) they were chosen to serve.
- **Winning DMEPOS suppliers could restrict the range of DMEPOS products they choose to offer to Medicare beneficiaries.** This is more likely to occur given Medicare’s decision to set the payment amount for each HCPCS code at the midpoint (median) of the array of winning bids, meaning that fully half of the winning bidders for each HCPCS code will be paid less than the amount they bid for products described by that HCPCS code. This payment outcome might prompt some winning suppliers to offer only products with minimal functionality or low acquisition costs in order to continue to operate under the Medicare competitive acquisition program.

Under two Medicare DMEPOS competitive bidding demonstration projects, DMEPOS payments were not based on the median of winning bids, but an adjustment factor was applied in order to minimize having Medicare payments set below the prices bid by winning suppliers. The table shown below provides a simple, hypothetical example of what the current median-based payment amounts can mean for “winning” suppliers. In this hypothetical case, the mid-point of the “winning” bids is \$24.00, and “winning” suppliers #4 and #5, respectively, would end up being paid about 8 and 14 percent below what they bid).

	Bid for Item A
“Winning” supplier #1	\$20.00
“Winning” supplier #2	\$22.00
“Winning” supplier #3	\$24.00
“Winning” supplier #4	\$26.00
“Winning” supplier #5	\$28.00
Single Payment Amount	\$24.00

- **Medicare beneficiaries who travel will face significant burdens.** This is because Medicare officials expect a beneficiary needing a DMEPOS product while traveling away from home and finding themselves in a CBA

to be able to: (1) know which DMEPOS products are subject to competitive bidding in that CBA; (2) identify and locate contract (winning) suppliers for that item; and (3) determine which of these suppliers offer the specific brand of product needed by the beneficiary. This seems both unrealistic and excessively complicated for beneficiaries.

Does the HCPCS coding system used to bill for DMEPOS products lead to additional concerns?

Yes. Current deficiencies in the HCPCS coding system further complicate the “product choice” situation.

- In some cases, a single HCPCS code describes a wide range of products with significantly different functionalities. For example, a single code applies to nearly all blood glucose monitors and another HCPCS code covers all the related test strips. However, blood glucose testing systems vary considerably in terms of their functionality. And, a brand of test strips is only compatible with its corresponding brand of blood glucose monitor; test strips are not interchangeable. Thus, if a winning supplier under Medicare’s competitive acquisition program chose to offer only a restricted set of test strip brands under HCPCS code A4253, beneficiaries now using non-compatible brands of blood glucose monitors would not be able to obtain replacement test strips for these non-compatible brands from that supplier. They might even end up suffering the disruptive effects of switching to a different brand of blood glucose meter.
- Problems with HCPCS coding were one reason why the Congress directed CMS to exclude negative pressure wound therapy from the Round 1 rebid process. As it now stands, a single HCPCS code, E2402, is used to describe a wide array of negative pressure wound therapy pumps, and a single HCPCS code, A6550, is available to describe a wide array of wound care dressing sets for negative pressure wound therapy.

What happens next on DMEPOS competitive acquisition?

For Round 2, CMS plans to announce the single payment amounts (that is, the payment amounts derived from the competitive bidding process) for the products subject to competitive bidding in fall 2012 and to begin contracting with “winning” bidders. The “winning” (contract) suppliers, including national mail order companies furnishing diabetes testing supplies, are slated to be announced in spring 2013, and the payment rates resulting from the competitive bidding process will take effect beginning July 1, 2013.

For the Round 1 Recompete, bidding will close on or about December 14, 2012. The “winning” (contract) suppliers will be announced in Fall 2013 and implementation of new supplier contracts and Medicare payment rates is slated to take effect on or about January 1, 2014.

What will be the impact on Medicare beneficiaries? Will they experience access or quality of care problems as a result of the Medicare DMEPOS competitive acquisition program? While CMS believes that a relatively low beneficiary complaint volume during Round 1 and no obvious increases in such indicators as beneficiary mortality and emergency room use are sufficient to suggest that beneficiaries are not being harmed, serious criticisms levied by neutral competitive bidding experts would appear to warrant a much more comprehensive assessment. Moreover, the significantly broader product categories being used for the Round 1 Recompete will essentially force specialized suppliers to furnish an array of products for which they have little or no expertise or experience is especially concerning. Medicare’s DMEPOS competitive bidding program should be fully evaluated to assess the overall impact of the program on beneficiaries.