



# Medicare Durable Medical Equipment: The Competitive Bidding Program

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## Summary

The Medicare Supplementary Medical Insurance Program (Part B) currently covers a wide variety of durable medical equipment, prosthetics, orthotics, and other medical supplies (DMEPOS) if they are medically necessary and are prescribed by a physician.

Durable medical equipment (DME) is equipment that (1) can withstand repeated use, (2) has an expected life of at least three years (effective for items classified as DME after January 1, 2012), (3) is used to serve a medical purpose, (4) generally is not useful in the absence of an illness or injury, and (5) is appropriate for use in the home. Examples include hospital beds, blood glucose monitors, and wheelchairs. Prosthetic and orthotic devices (PO) are items that replace all or part of an internal body organ, such as colostomy bags, as well as such items as leg braces and artificial legs, arms, and eyes. Medicare also covers some items or supplies (S), such as disposable surgical dressings that do not meet the definition of DME or PO.

Medicare generally pays for most DMEPOS on the basis of fee schedules. Medicare pays 80% of the fee schedule amount, while the beneficiary is responsible for the remaining 20%, plus any unmet deductible. Unless otherwise specified by Congress, fee schedule amounts are updated yearly by a measure of inflation and economy-wide productivity. However, studies by federal agencies have shown that Medicare pays above-market prices for certain items of DME. Such overpayments may be due partly to the fee schedule mechanism of payment, which does not reflect market changes, such as new and less-expensive technologies, changes in production or supplier costs, or geographic price variations.

Congress enacted legislation to establish a Medicare competitive acquisition program (competitive bidding) under which prices for selected DMEPOS sold in specified areas are determined by suppliers' bids rather than fee schedules. The first round of the program began on July 1, 2008, but was suspended due to implementation concerns. Suppliers submitted new bids for the first round "rebid," and payments based on winning suppliers' bids went into place in the first nine areas on January 1, 2011. Round 2 is set to begin in 91 additional areas on July 1, 2013. The process for re-competing the contracts for Round 1 has started, and payments based on winning bids are expected to be in place on January 1, 2014. Starting in 2016, the Secretary of Health and Human Services (the Secretary) is required to either expand competitive bidding to additional areas, or apply information gained from the program to adjust fee schedule amounts in remaining areas.

Competitive bidding has been shown to decrease Medicare payments for DMEPOS, leading to savings for Medicare and lower beneficiary cost sharing. Evidence from the competitive bidding demonstration and the Round 1 Rebid also suggests, based on evaluations of the program thus far, that competition did not deteriorate beneficiary access to DMEPOS, or the quality and product selection available to them.

In general, the technical implementation concerns that halted the 2008 competition appear to have been addressed, however, concerns over the auction methodology have been raised, drawing into question whether the competitively bid payments are an accurate reflection of the market for DMEPOS. Finally, the competitive bidding program will result in fewer suppliers being allowed to sell competitively bid items to Medicare beneficiaries, though all suppliers may continue to sell non-competitively bid items to beneficiaries and may repair competitively bid and non-competitively bid DMEPOS.

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## Background

The Medicare Supplementary Medical Insurance Program (Part B) currently covers a wide variety of durable medical equipment, prosthetics, orthotics, and other medical supplies (DMEPOS) if they are medically necessary and are prescribed by a physician.<sup>1</sup> Medicare beneficiaries who are prescribed an item of DMEPOS obtain it from a DMEPOS supplier, who then bills Medicare for reimbursement.

Durable medical equipment (DME) is equipment that (1) can withstand repeated use, (2) has an expected life of at least three years (effective with respect to items classified as DME after January 1, 2012), (3) is used to serve a medical purpose, (4) generally is not useful in the absence of an illness or injury, and (5) is appropriate for use in the home.<sup>2</sup> Examples include hospital beds, blood glucose monitors, and wheelchairs. The benefit also includes related supplies, such as drugs and biologicals that are necessary for effective use of the product. Prosthetics (P) replace all or part of a body organ, such as colostomy bags, pacemakers, and breast prostheses for post-mastectomy patients. Orthotics (O) are artificial or mechanical aids, such as braces, to prevent or assist movement of weak or injured joints or muscles, and include leg, arm, back, and neck braces. Medicare also covers some items or supplies (S), such as disposable surgical dressings when used in conjunction with DMEPOS.

According to the National Health Expenditure Accounts, Medicare spending on DME in CY2011 represented 20% of all spending on DME; over half of DME spending (55%) is paid out-of-pocket.<sup>3</sup> Medicare Part B program expenditures for DMEPOS were \$7.8 billion in CY2011.<sup>4</sup> There were approximately 98,000 active DMEPOS suppliers in the United States in May 2012; approximately half of those suppliers (50,000) had total allowed Medicare payments of greater than \$10,000 between May 2011 and May 2012.<sup>5</sup> Approximately one in three beneficiaries uses DMEPOS in a given year.<sup>6</sup>

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<sup>1</sup> Social Security Act §1862(a)(1)(A). For an overview of the Medicare program, see CRS Report R40425, *Medicare Primer*. Medicare Advantage (MA or Part C) plans must also provide required DMEPOS under the same coverage criteria as Part B. However, MA plans do not participate in the competitive bidding program, as discussed in more detail in this report.

<sup>2</sup> Social Security Act §1861(n). 42 C.F.R. §414.202.

<sup>3</sup> The estimate of the proportion of DME spending paid by Medicare is based on a CRS analysis of the National Health Expenditure Accounts data. This estimate includes spending from Medicare Part B and Part C (Medicare Advantage or MA). <http://www.cms.hhs.gov/nationalhealthexpenddata/>. The proportion of DME spending paid by Medicare, the recipient (out-of-pocket), or other payers, may vary for any particular DMEPOS supplier.

<sup>4</sup> Centers for Medicare & Medicaid Services, Office of Legislation. This estimate does not include beneficiary cost sharing and only represents DMEPOS spending under Part B. If estimates of DMEPOS spending from Medicare Advantage are included along with estimates of beneficiary cost sharing, Medicare DMEPOS spending was \$14.3 billion for 2010, <http://www.hhs.gov/asl/testify/2012/09/t20120911a.html>. However, because encounter data for MA are not yet available, the estimates of DMEPOS spending in the MA program are based on extrapolations from Part B.

<sup>5</sup> Centers for Medicare & Medicaid Services, Office of Legislation.

<sup>6</sup> Kathleen Sebelius, Report to Congress: Evaluation of the National Competitive Bidding Program for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, U.S. Department of Health and Human Services, August 15, 2011, p. iii, [http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/DHHS\\_DME\\_RTC\\_August\\_2011.pdf](http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/DHHS_DME_RTC_August_2011.pdf).

Medicare generally pays for most DMEPOS on the basis of fee schedules. A fee schedule is a list of Medicare payments for specific items and services, which are calculated according to statutorily specified formula and take into account the actual amount of care (or items) provided. Medicare pays 80% of the fee schedule amount, while the beneficiary is responsible for paying the remaining 20% (co-insurance), in addition to any unmet deductible.<sup>7</sup> Unless otherwise specified by Congress, fee schedule amounts are updated each year by a measure of price inflation and economy-wide productivity.<sup>8</sup> However, investigations by the Government Accountability Office (GAO)<sup>9</sup> and the Office of the Inspector General (OIG)<sup>10</sup> in the Department of Health and Human Services (HHS) have shown that Medicare pays above-market prices for certain items of DME. Such overpayments may be due partly to the fee schedule mechanism of payment, which does not reflect market changes, such as new and less-expensive technologies, changes in production or supplier costs, or variations in prices in comparable localities.

The Medicare program and beneficiaries are disadvantaged when Medicare pays above-market prices for DMEPOS. First, the higher payments result in an otherwise greater amount of Part B (Supplementary Medical Insurance) program payments, which are financed primarily through general tax revenues and beneficiary premiums.<sup>11</sup> Second, the beneficiaries who use DMEPOS pay more; though the proportion of co-insurance paid by beneficiaries remains at 20%, the higher fee schedule payment means the beneficiary co-insurance results in a higher dollar amount. Third, the payment differential between market prices and Medicare payments for DMEPOS make fraud “particularly lucrative, further attracting bad actors to the system.”<sup>12</sup> However, legitimate Medicare participating suppliers and DMEPOS manufacturers are advantaged by the higher Medicare prices, which may, in part, enable less efficiently run businesses to remain in business.

Following competitive bidding demonstrations required by the Balanced Budget Act of 1997 (P.L. 105-33, BBA 97),<sup>13</sup> the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108-173, MMA) required the Secretary of HHS to establish a competitive acquisition

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<sup>7</sup> See CRS Report R40425, *Medicare Primer*. Outside of the competitive bidding program, DMEPOS supplier are not required to accept assignment; assignment is an agreement between CMS and the supplier that the supplier will accept the Medicare approved amount as payment in full. If a DMEPOS supplier does not accept assignment, Medicare does not limit the amount that the supplier can bill the beneficiary for covered items. In such a case, the beneficiary would also be responsible for any amount above the fee schedule amount. Suppliers in the competitive bidding program must accept assignment.

<sup>8</sup> Fee schedule updates are calculated from changes in the Consumer Price Index for all Urban Consumers (CPI-U). For more information on how Medicare pays for DMEPOS under the fee schedule methodology, as well as how Medicare pays for other items and services, see CRS Report RL30526, *Medicare Payment Updates and Payment Rates*.

<sup>9</sup> See General Accounting Office (GAO) report, “Medicare Payments for Oxygen,” May 15, 1997, GAO-97-120R.

<sup>10</sup> See HHS Office of the Inspector General report, “Comparison of Prices for Negative Pressure Wound Therapy Pumps,” March 2009, OEI-02-07-00660; HHS Office of the Inspector General report, “Medicare Home Oxygen Equipment: Cost and Servicing,” September 2006, EOI-09-04-00420; HHS Office of the Inspector General report, “Medicare and FEHBP Payment Rates for Home Oxygen Equipment,” March 2005, EOI-09-03-00160; Testimony of the Inspector General of Health and Human Services before the Senate Subcommittee on Labor, HHS, Education, Committee on Appropriations, June 12, 2002. <http://www.oig.hhs.gov/testimony/docs/2002/020611fin.pdf>. Congressional action to reduce or eliminate the payment updates for certain items of DMEPOS since the publication of these studies and testimony may have reduced the differences between the prices paid by CMS and those of other purchasers.

<sup>11</sup> See CRS Report R41436, *Medicare Financing*.

<sup>12</sup> Testimony of Daniel R. Levinson, Inspector General, U.S. Department of Health and Human Services, before the House Committee on Energy and Commerce, Subcommittee on Health, September 15, 2010, [http://oig.hhs.gov/testimony/docs/2010/testimony\\_levinson\\_09152010.pdf](http://oig.hhs.gov/testimony/docs/2010/testimony_levinson_09152010.pdf).

<sup>13</sup> The competitive bidding demonstrations are described in more detail in Appendix A.

program (also known as competitive bidding) under which prices for selected DMEPOS sold in specified areas would be determined not by a fee schedule, but by suppliers' bids. A bid represents the amount a DMEPOS supplier is willing to accept to provide specified items or services to a Medicare beneficiary. The first round of the competitive bidding program began on July 1, 2008, but was suspended, contracts dissolved, and a rebid required due to implementation concerns. Between October and December 2009, DMEPOS suppliers submitted new bids for nine categories of equipment in nine competitive bidding areas; payments based on the bids of winning suppliers went into effect on January 1, 2011 (referred to in this report as Round 1 Rebid).<sup>14</sup> Payment amounts based on Round 2 of competitive bidding are scheduled to take effect in 91 additional metropolitan areas on July 1, 2013, for a slightly modified set of nine equipment categories; Round 2 also includes a competition for mail order diabetic testing supplies, which applies to the entire nation.<sup>15</sup> Because the contracts signed with winning bidders are limited to three years, the process to "Recompete" for the contracts in Round 1 areas has already started. Payments based on the re-compete are expected to go into effect on January 1, 2014.<sup>16</sup>

This report describes the DMEPOS competitive bidding program, including how winning bidders are chosen and how payments for equipment are determined. It summarizes evaluations of the first round of the program. Finally, it discusses issues for congress and recently introduced legislation. The text box below provides a brief legislative history; a more detailed legislative history can be found in the **Appendix**.

#### **Brief Legislative History**

**The Balanced Budget Act of 1997** (P.L. 105-33, BBA97) required the Secretary of Health and Human Services to establish competitive bidding demonstration projects. Areas were to be selected based on availability and accessibility of suppliers, and on the likelihood that savings could be realized by competitive bidding. The Secretary was permitted to limit the number of winning suppliers.

**The Medicare Prescription Drug, Improvement, and Modernization Act of 2003** (P.L. 108-173, MMA) required the Secretary to establish a DMEPOS competitive bidding program to be phased-in in successive rounds starting in 10 areas (later amended to 9 areas) and expanding to 70 additional areas (later amended to 91 additional areas) and a national mail order program.

**The Medicare Improvements for Patients and Providers Act of 2008** (P.L. 110-275, MIPPA) halted the first round of competition, required the first round to be "Rebid," and put into place notification requirements if certain financial information was missing from the bid. It also required a one-time national fee-schedule reduction of 9.5% on items competitively bid in Round 1, which made this provision of the bill budget neutral.<sup>17</sup>

**The Patient Protection and Affordable Care Act** (P.L. 111-148, ACA, as amended) requires the Round 2 competition to be expanded from 70 additional areas to 91 areas. It also requires the Secretary to extend the program, or apply competitively bid rates to remaining areas by 2016.

**The American Taxpayer Relief Act of 2012** (P.L. 112-240, ATRA) requires the Secretary to apply payment rates from the national mail order competitive bidding program for diabetic supplies to non-mail order diabetic supplies and reduce the fee schedule payments for diabetic supplies prior to the implementation of competitively bid rates.

<sup>14</sup> The Competitive Bidding Implementation Contractor (CBIC) maintains a website with detailed information about the Round 1 Rebid. <http://www.dmecompetitivebid.com/palmetto/cbicrd1rebid.nsf/DocsCat/Home>.

<sup>15</sup> See CBIC site for Round 2. <http://www.dmecompetitivebid.com/palmetto/cbicrd2.nsf/DocsCat/Home>.

<sup>16</sup> See CBIC site for Round 1 Recompete. <http://www.dmecompetitivebid.com/palmetto/cbicrd1recompete.nsf/DocsCat/Home>.

<sup>17</sup> Personal communication with the Congressional Budget Office.

## Description of the Program

This section describes the statutory and regulatory requirements of where competitive bidding takes place, what items are included (or excluded), how winning bidders are determined, and how the payments for the competitively bid items (single payment amounts) are determined. It includes a discussion of the concerns of small suppliers. Often the authorizing statutes for the competitive bidding program are broad, allowing or requiring the Secretary to determine the specific policies under this program.

### Where Does Competitive Bidding Take Place?

The statutes require the Secretary to establish and implement the DMEPOS competitive bidding program and specify a phase-in schedule, and areas to be excluded from competition. Round 1 was originally to take place in 10 of the largest metropolitan statistical areas (MSAs) based on a competition in 2007, but the law was later amended to require the competition to take place in nine MSAs in 2009 (in what is referred to as the Round 1 Rebid).<sup>18</sup> Round 2 was originally to take place in 80 areas in 2009, but was later expanded to 91 additional areas for a competition in 2011.<sup>19</sup> The statutes also require a national mail order competition is to take place after 2010.<sup>20</sup> The Secretary is required to extend the program or apply competitively bid rates to remaining areas by 2016.<sup>21</sup> The Secretary is required to exclude certain areas from competition before 2015: (1) rural areas, (2) MSAs not selected for Round 1 or Round 2 with a population of less than 250,000, and (3) areas with low population density within an MSA that is otherwise selected. The Secretary is allowed to subdivide MSAs of greater than 8 million people into separate DMEPOS competitive bidding markets. The statutes, otherwise, give the Secretary authority to determine competitive bidding areas.

The Secretary described the methodology to be used to implement the competitive bidding program (including the choice of competitive bidding areas) in a final rule published on April 10, 2007.<sup>22</sup> Competitive Bidding Areas (CBAs) for Round 1 were determined through a multi-step process. First, the 50 MSAs with the largest population were identified. Second, of those MSAs, the 25 with the highest DMEPOS allowed charges in CY2004 were identified and retained for consideration. Third, a score was calculated for each of the 25 MSAs based on (1) DMEPOS charges per Medicare beneficiary, and (2) the number of suppliers per Medicare beneficiary receiving an item of DMEPOS, with equal weight being given to each factor. The MSAs were ranked according to that score. Fourth, the three largest MSAs by population size were eliminated from consideration for the first round of the program due to the complexity of implementing the

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<sup>18</sup> Social Security Act §1847(a)(1)(D). Puerto Rico was excluded from the first round of competition (SSA §1847(a)(1)(D)(i)(III)). See Appendix A for detail. The dates in the statutes have been interpreted by the administration as the dates when the bidding process (supplier registration and submission of bids) takes place; payments based on the bids of winning suppliers often go into effect in the following year.

<sup>19</sup> CMS announced the Round 2 bidding timeline and began the bidder education program in November of 2011.

<sup>20</sup> As with other items in the competitive bidding program, the statutes do not specify which items are to be included in the mail order competition.

<sup>21</sup> Social Security Act §1834(a)(1)(F)(iii).

<sup>22</sup> The Centers for Medicare & Medicaid Services, "Medicare Program: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues," *72 Federal Register* 17992-18090, April 10, 2007.



program in such large areas.<sup>23</sup> Fifth, MSAs in areas served by two DME Medicare Administrative Contractors (DME MACs) were excluded, also due to complexity. Sixth, the top MSAs were selected to be CBAs as long as no state had more than two CBAs. **Table 1** shows the Round 1 areas.

According to the final rule, the process for identifying Round 2 areas was substantially the same. The scoring criteria were the same; however, more recent data were used. Also, the three largest MSAs and MSAs that cross the DME MAC boundaries were not excluded. Round 2 areas are shown in **Table 2**.

The statute did not require the boundaries of a CBA to be the same as that of the MSA. CMS could add counties, parishes, or zip codes outside of an MSA to the CBA if all of the following applied: (1) the area was contiguous to the MSA; (2) the area was not otherwise a part of a different CBA; (3) the area was competitive as evidenced by high use of DMEPOS, significant expenditures, or a large number of suppliers; and (4) the area was part of the normal market area for the DMEPOS suppliers. The final rule did not identify the boundaries of the CBAs, but that information is available on the implementation contractor's website.<sup>24</sup>

### **DMEPOS Competitive Bidding and Medicare Advantage**

Medicare Advantage (MA or Medicare Part C) is an alternative way for Medicare beneficiaries to receive covered benefits. Under MA, private health plans are paid a per-person amount to provide all Medicare covered benefits (except hospice) to beneficiaries who enroll in their plan. In general, MA plans ensure provider access, in part, by maintaining a list (or network) of medical providers, hospitals, and suppliers with whom they have contractual agreements and from whom plan enrollees can receive covered medical care.

Medicare Advantage plans do not participate in the DMEPOS competitive bidding program. Payments to network suppliers for covered DMEPOS items and services provided to MA plan enrollees are determined through a negotiation between the MA plan and the network supplier, and may differ from Medicare fee schedule amounts and the competitively bid payment amounts. However, there are circumstances when an MA plan enrollee may seek services outside of the plan network, such as emergency care. In such circumstances, the MA plan is required to pay the provider/supplier the Medicare required payment, which would be the payment determined under competitive bidding in the competitive bidding area.

DMEPOS suppliers who fail to become contracted suppliers in the DMEPOS Competitive Bidding Program may still be able to become part of an MA plan's (contracted) network of providers, and sell Medicare covered items to MA plan enrollees.

**Table 1** and **Table 2** show the number and percentage of Medicare beneficiaries and Medicare Advantage enrollees in each Round 1 and Round 2 competitive bidding area, respectfully. The percentage of beneficiaries enrolled in MA in each CBA varies from a high of 63% in Pittsburgh, PA, to a low of 9% in Baltimore-Towson, MD.

The final rule also established a nationwide mail order competitive bidding program. CMS analyses found over 60% of Medicare expenditures on diabetic supplies, for example, were furnished by mail order.<sup>25</sup> The payments based on the national competition for mail order diabetic supplies are to start on July 1, 2013.<sup>26</sup>

<sup>23</sup> This provision eliminated New York, Los Angeles and Chicago from the first round of competition. These areas are included in Round 2 of the competitive bidding program.

<sup>24</sup> [http://www.dmecompetitivebid.com/cbic/cbic.nsf/\(pages\)/home\(pages\)/home](http://www.dmecompetitivebid.com/cbic/cbic.nsf/(pages)/home(pages)/home).

<sup>25</sup> *Federal Register*, vol. 72, no. 68, April 10, 2007, p. 18018.

<sup>26</sup> The national mail order competition for diabetic testing supplies is to take place in all ZIP codes in all parts of the United States, including the 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa. <http://www.dmecompetitivebid.com/palmetto/cbicrd2.nsf/DocsCat/> (continued...)

**Table I. The Nine Round 1 Rebid/Recompete Competitive Bidding Areas (CBAs) with Total Medicare and Medicare Advantage Enrollment Estimates, 2013**

| Competitive Bidding Area                | Estimated Total Medicare Beneficiaries | Estimated Number and Percent Enrolled in Medicare Advantage (not subject to DMEPOS competitive bidding) | Estimated Number and Percent of Medicare Beneficiaries in original Medicare <sup>a</sup> |
|---|--|---|--|
| Charlotte-Gastonia-Concord, NC-SC       | 240,000                                | 50,000 (21%)  | 190,000 (79%)  |
| Cincinnati-Middletown, OH-KY-IN         | 338,000                                | 126,000 (37%)   | 212,000 (63%)  |
| Cleveland-Elyria-Mentor, OH             | 381,000                                | 139,000 (37%)   | 242,000 (63%)  |
| Dallas-Fort Worth-Arlington, TX         | 740,000                                | 208,000 (28%)   | 532,000 (72%)  |
| Kansas City, MO-KS                      | 312,000                                | 85,000 (27%)  | 227,000 (73%)  |
| Miami-Fort Lauderdale-Pompano Beach, FL | 941,000                                | 462,000 (49%)   | 479,000 (51%)  |
| Orlando-Kissimmee, FL                   | 330,000                                | 120,000 (36%)   | 210,000 (64%)  |
| Pittsburgh, PA                          | 491,000                                | 307,000 (63%)   | 184,000 (37%)  |
| Riverside-San Bernardino-Ontario, CA    | 538,000                                | 278,000 (52%)   | 260,000 (48%)  |

**Sources:** Table created by CRS based on information from the Centers for Medicare & Medicaid Services, [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/dme\\_ref\\_agt\\_factsheet\\_icn900927.pdf](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/dme_ref_agt_factsheet_icn900927.pdf); Medicare and Medicare Advantage enrollment data, <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAAdvPartDENrolData/MA-State-County-Penetration.html>; and the Census Bureau's Historical Delineation File for 2005. This data reflects information available at the time CBAs were announced, <http://www.census.gov/population/metro/data/defhist.html>.

- a. Original Medicare consists of Part A (Hospital Insurance) and Part B (Supplementary Medicare Insurance). Individuals entitled to Part A and enrolled in Part B may receive their Medicare covered benefits through a private health plan in the Medicare Advantage (MA) program. MA enrollees are not subject to the Competitive Bidding Program. The Secretary will conduct the Recompete of the Round 1 competition in the same CBAs. Estimates are based on county-level Medicare and MA enrollment in April 2013, summed for the metropolitan statistical area, and rounded to the nearest one thousand. Areas with low population density within a CBA are required to be excluded from competition; such areas are not reflected in the enrollment estimates above.

### DMEPOS Competitive Bidding in Rural Areas

Starting July 1, 2013, Medicare beneficiaries living in all areas of the United States, including rural areas, will be subject to the National Mail Order Competition for Diabetic Supplies; this means that beneficiaries *who choose to receive their Medicare covered diabetic supplies through mail order* will be required to order those supplies from a contract supplier. Beneficiaries may choose to receive their covered diabetic supplies from either a mail order, or non-mail order supplier. Beneficiaries living in rural areas are not subject to the Round 1 or Round 2 competitions for other DMEPOS items (such as oxygen equipment and supplies, or wheelchairs), and may choose to receive their Medicare covered supplies from any Medicare participating supplier. Starting in 2016, the Secretary is required to either extend competitive bidding to additional areas, or use information gained from competitive bidding to adjust the fee schedule rates. The Secretary has not yet published information about how that will be done.

(...continued)

Competitive%20Bidding%20Areas.

**Table 2. The 91 Round 2 Competitive Bidding Areas (CBAs) with Total Medicare and Medicare Advantage Enrollment Estimates, 2013**

| Competitive Bidding Area              | Estimated Total Medicare Beneficiaries | Estimated Number and Percent Enrolled in Medicare Advantage (not subject to DMEPOS competitive bidding) | Estimated Number and Percent of Medicare Beneficiaries in original Medicare <sup>a</sup> |
|---------------------------------------|--|---|--|
| <b>West</b>                           |  |   |  |
| Albuquerque, NM                       | 141,000                                | 67,000 (48%)  | 74,000 (52%)   |
| Bakersfield-Delano, CA                | 100,000                                | 34,000 (35%)  | 65,000 (65%)   |
| Boise City-Nampa, ID                  | 92,000                                 | 42,000 (45%)  | 50,000 (55%)   |
| Colorado Springs, CO                  | 87,000                                 | 24,000 (28%)  | 63,000 (72%)   |
| Denver-Aurora-Broomfield, CO          | 330,000                                | 156,000 (47%)   | 174,000 (53%)  |
| Fresno, CA                            | 118,000                                | 31,000 (27%)  | 86,000 (73%)   |
| Honolulu, HI                          | 158,000                                | 74,000 (47%)  | 84,000 (53%)   |
| Las Vegas-Paradise, NV                | 267,000                                | 99,000 (37%)  | 168,000 (63%)  |
| Los Angeles-Long Beach-Santa Ana, CA  | 1,680,000                              | 719,000 (43%)   | 961,000 (57%)  |
| Oxnard-Thousand Oaks-Ventura, CA      | 121,000                                | 34,000 (28%)  | 87,000 (72%)   |
| Phoenix-Mesa-Glendale, AZ             | 601,000                                | 254,000 (42%)   | 347,000 (58%)  |
| Portland-Vancouver-Hillsboro, OR-WA   | 330,000                                | 178,000 (54%)   | 152,000 (46%)  |
| Sacramento-Arden-Arcade-Roseville, CA | 336,000                                | 141,000 (42%)   | 195,000 (58%)  |
| Salt Lake City, UT                    | 124,000                                | 47,000 (38%)  | 77,000 (62%)   |
| San Diego-Carlsbad-San Marcos, CA     | 432,000                                | 180,000 (42%)   | 252,000 (58%)  |
| San Francisco-Oakland-Fremont, CA     | 659,000                                | 272,000 (41%)   | 387,000 (59%)  |
| San Jose-Sunnyvale-Santa Clara, CA    | 239,000                                | 84,000 (35%)  | 155,000 (65%)  |
| Seattle-Tacoma-Bellevue, WA           | 482,000                                | 160,000 (33%)   | 322,000 (67%)  |
| Stockton, CA                          | 92,000                                 | 29,000 (32%)  | 63,000 (68%)   |
| Tucson, AZ                            | 176,000                                | 80,000 (46%)  | 95,000 (54%)   |
| Visalia-Porterville, CA               | 54,000                                 | 6,000 (12%)   | 47,000 (88%)   |
| <b>Midwest</b>                        |  |   |  |
| Akron, OH                             | 124,000                                | 57,000 (46%)  | 67,000 (54%)   |
| Chicago-Joliet-Naperville, IL-IN-WI   | 1,325,000                              | 139,000 (11%)   | 1,185,000 (89%)  |
| Columbus, OH                          | 257,000                                | 109,000 (42%)   | 148,000 (58%)  |
| Dayton, OH                            | 154,000                                | 66,000 (43%)  | 88,000 (57%)   |
| Detroit-Warren-Livonia, MI            | 737,000                                | 197,000 (27%)   | 541,000 (73%)  |
| Flint, MI                             | 81,000                                 | 24,000 (30%)  | 57,000 (70%)   |
| Grand Rapids-Wyoming, MI              | 122,000                                | 53,000 (43%)  | 69,000 (57%)   |
| Huntington-Ashland, WV-KY-OH          | 64,000                                 | 16,000 (24%)  | 49,000 (76%)   |
| Indianapolis-Carmel, IN               | 251,000                                | 59,000 (23%)  | 193,000 (77%)  |

*Medicare Durable Medical Equipment: The Competitive Bidding Program*

| <b>Competitive Bidding Area</b>             | <b>Estimated Total Medicare Beneficiaries</b> | <b>Estimated Number and Percent Enrolled in Medicare Advantage (not subject to DMEPOS competitive bidding)</b> | <b>Estimated Number and Percent of Medicare Beneficiaries in original Medicare<sup>a</sup></b> |
|---|---|--|--|
| Milwaukee-Waukesha-West Allis, WI           | 248,000                                       | 80,000 (32%)   | 167,000 (68%)  |
| Minneapolis-St. Paul-Bloomington MN-WI      | 452,000                                       | 238,000 (53%)  | 213,000 (47%)  |
| Omaha-Council Bluffs, NE-IA                 | 124,000                                       | 26,000 (21%)   | 98,000 (79%)   |
| St. Louis, MO-IL                            | 475,000                                       | 136,000 (29%)  | 340,000 (71%)  |
| Toledo, OH                                  | 113,000                                       | 40,000 (36%)   | 72,000 (64%)   |
| Wichita, KS                                 | 95,000  | 15,000 (16%)   | 81,000 (84%)   |
| Youngstown-Warren-Boardman, OH-PA           | 124,000                                       | 56,000 (46%)   | 67,000 (54%)   |
| <b>South</b>                                |   |  |  |
| Asheville, NC                               | 98,000  | 19,000 (19%)   | 80,000 (81%)   |
| Atlanta-Sandy Springs-Marietta, GA          | 643,000                                       | 188,000 (29%)  | 455,000 (71%)  |
| Augusta-Richmond County, GA-SC              | 93,000  | 24,000 (25%)   | 70,000 (75%)   |
| Austin-Round Rock-San Marcos, TX            | 190,000                                       | 44,000 (23%)   | 146,000 (77%)  |
| Baltimore-Towson, MD                        | 423,000                                       | 40,000 (9%)  | 383,000 (91%)  |
| Baton Rouge, LA                             | 116,000                                       | 46,000 (40%)   | 70,000 (60%)   |
| Beaumont-Port Arthur, TX                    | 65,000  | 20,000 (31%)   | 45,000 (69%)   |
| Birmingham-Hoover, AL                       | 202,000                                       | 81,000 (40%)   | 121,000 (60%)  |
| Cape Coral-Fort Myers, FL                   | 147,000                                       | 43,000 (29%)   | 105,000 (71%)  |
| Charleston-North Charleston-Summerville, SC | 105,000                                       | 17,000 (16%)   | 88,000 (84%)   |
| Chattanooga, TN-GA                          | 100,000                                       | 29,000 (29%)   | 72,000 (71%)   |
| Columbia, SC                                | 118,000                                       | 21,000 (18%)   | 96,000 (82%)   |
| Deltona-Daytona Beach-Ormond Beach, FL      | 120,000                                       | 50,000 (42%)   | 70,000 (58%)   |
| El Paso, TX                                 | 107,000                                       | 45,000 (42%)   | 62,000 (58%)   |
| Greensboro-High Point, NC                   | 126,000                                       | 52,000 (41%)   | 74,000 (59%)   |
| Greenville-Mauldin-Easley, SC               | 115,000                                       | 32,000 (28%)   | 83,000 (72%)   |
| Houston-Sugar Land-Baytown, TX              | 663,000                                       | 216,000 (33%)  | 447,000 (67%)  |
| Jackson, MS                                 | 85,000  | 17,000 (20%)   | 68,000 (80%)   |
| Jacksonville, FL                            | 219,000                                       | 51,000 (23%)   | 168,000 (77%)  |
| Knoxville, TN                               | 134,000                                       | 51,000 (38%)   | 83,000 (62%)   |
| Lakeland-Winter Haven, FL                   | 125,000                                       | 52,000 (42%)   | 73,000 (58%)   |
| Little Rock-North Little Rock-Conway, AR    | 120,000                                       | 18,000 (15%)   | 103,000 (85%)  |
| Louisville-Jefferson County, KY-IN          | 223,000                                       | 54,000 (24%)   | 169,000 (76%)  |
| McAllen-Edinburg-Mission, TX                | 85,000  | 21,000 (25%)   | 64,000 (75%)   |
| Memphis, TN-MS-AR                           | 189,000                                       | 37,000 (20%)   | 152,000 (80%)  |

*Medicare Durable Medical Equipment: The Competitive Bidding Program*

| <b>Competitive Bidding Area</b>                    | <b>Estimated Total Medicare Beneficiaries</b> | <b>Estimated Number and Percent Enrolled in Medicare Advantage (not subject to DMEPOS competitive bidding)</b> | <b>Estimated Number and Percent of Medicare Beneficiaries in original Medicare<sup>a</sup></b> |
|--|---|--|--|
| Nashville-Davidson-Murfreesboro-Franklin, TN       | 230,000                                       | 85,000 (37%)   | 145,000 (63%)  |
| New Orleans-Metairie-Kenner, LA                    | 189,000                                       | 92,000 (49%)   | 97,000 (51%)   |
| North Port-Bradenton-Sarasota, FL                  | 192,000                                       | 49,000 (25%)   | 144,000 (75%)  |
| Ocala, FL  | 96,000  | 34,000 (35%)   | 62,000 (65%)   |
| Oklahoma City, OK                                  | 190,000                                       | 38,000 (20%)   | 152,000 (80%)  |
| Palm Bay-Melbourne-Titusville, FL                  | 128,000                                       | 43,000 (33%)   | 85,000 (67%)   |
| Raleigh-Cary, NC                                   | 141,000                                       | 26,000 (18%)   | 115,000 (82%)  |
| Richmond, VA                                       | 201,000                                       | 37,000 (19%)   | 163,000 (81%)  |
| San Antonio-New Braunfels, TX                      | 314,000                                       | 112,000 (36%)  | 201,000 (64%)  |
| Tampa-St. Petersburg-Clearwater, FL                | 553,000                                       | 248,000 (45%)  | 305,000 (55%)  |
| Tulsa, OK  | 155,000                                       | 44,000 (28%)   | 111,000 (72%)  |
| Virginia Beach-Norfolk-Newport News, VA-NC         | 247,000                                       | 37,000 (15%)   | 210,000 (85%)  |
| Washington-Arlington-Alexandria, DC-VA-MD-WV       | 673,000                                       | 70,000 (10%)   | 603,000 (90%)  |
| <b>Northeast</b>                                   |   |  |  |
| Albany-Schenectady-Troy, NY                        | 154,000                                       | 58,000 (38%)   | 96,000 (62%)   |
| Allentown-Bethlehem-Easton, PA-NJ                  | 155,000                                       | 39,000 (25%)   | 116,000 (75%)  |
| Boston-Cambridge-Quincy, MA-NH                     | 745,000                                       | 121,000 (16%)  | 623,000 (84%)  |
| Bridgeport-Stamford-Norwalk, CT                    | 141,000                                       | 30,000 (21%)   | 111,000 (79%)  |
| Buffalo-Niagara Falls, NY                          | 226,000                                       | 121,000 (54%)  | 105,000 (46%)  |
| Hartford-West Hartford-East Hartford, CT           | 209,000                                       | 52,000 (25%)   | 157,000 (75%)  |
| New Haven-Milford, CT                              | 148,000                                       | 39,000 (26%)   | 109,000 (74%)  |
| New York-Northern New Jersey-Long Island, NY-NJ-PA | 2,900,000                                     | 747,000 (26%)  | 2,153,000 (74%)  |
| Philadelphia-Camden-Wilmington, PA-NJ-DE-MD        | 985,000                                       | 267,000 (27%)  | 718,000 (73%)  |
| Poughkeepsie-Newburgh-Middletown, NY               | 105,000                                       | 16,000 (15%)   | 89,000 (85%)   |
| Providence-New Bedford-Fall River, RI-MA           | 299,000                                       | 83,000 (28%)   | 216,000 (72%)  |
| Rochester, NY                                      | 196,000                                       | 119,000 (60%)  | 77,000 (40%)   |
| Scranton-Wilkes-Barre, PA                          | 123,000                                       | 30,000 (24%)   | 94,000 (76%)   |
| Springfield, MA                                    | 131,000                                       | 27,000 (21%)   | 104,000 (79%)  |
| Syracuse, NY                                       | 119,000                                       | 34,000 (29%)   | 85,000 (71%)   |
| Worcester, MA                                      | 133,000                                       | 45,000 (34%)   | 88,000 (66%)   |

**Source:** Table created by CRS based on information from the Centers for Medicare & Medicaid Services, [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/dme\\_ref\\_agt\\_factsheet\\_icn900927.pdf](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/dme_ref_agt_factsheet_icn900927.pdf); Medicare and Medicare Advantage enrollment data, <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/MA-State-County-Penetration.html>; and the Census Bureau's Historical Delineation File for 2005. This date reflects information available at the time CBAs were announced, <http://www.census.gov/population/metro/data/defhist.html>.

- a. Original Medicare consists of Part A (Hospital Insurance) and Part B (Supplementary Medicare Insurance). Individuals entitled to Part A and enrolled in Part B may receive their Medicare covered benefits through a private health plan in the Medicare Advantage (MA) program. MA enrollees are not subject to the competitive bidding program. Round 2 also includes a nationwide competition for mail order diabetic supplies which applies to beneficiaries in original Medicare in all areas of the United States, Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa. Estimates are based on county-level Medicare and MA enrollment in April 2013, summed for the metropolitan statistical area, and then rounded to the nearest one thousand. Areas with low population density within a CBA are required to be excluded from competition; such areas are not reflected in the enrollment estimates above.

## What Items Are Included in Competitive Bidding?

The Secretary is authorized to phase in competitive bidding first among the items with the highest cost, highest volume, or those with the greatest savings potential.<sup>27</sup> The program may include Medicare covered items of DME, enteral nutrients,<sup>28</sup> and off-the shelf orthotics which require minimal self-adjustment for appropriate use and do not require expert trimming, bending, molding, assembling, or customized fitting.<sup>29</sup> Certain items are statutorily excluded from the competitive bidding program, including inhalation drugs, parenteral nutrients,<sup>30</sup> equipment and supplies, Group 3 complex rehabilitative power wheelchairs<sup>31</sup>, and class III medical devices defined as those that sustain or support life, are implanted, or present potential unreasonable risk.<sup>32</sup> The Secretary is also authorized to exempt items that would not result in significant savings.

The final rule specified that CMS would consider the following when determining the items to be included in the program:

- Annual Medicare DMEPOS allowable charges,
- Annual growth in expenditures,
- Number of suppliers,

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<sup>27</sup> Social Security Act §1847(a)(1)(B)(ii). The Secretary is also authorized by §1847(b)(7) to take into consideration the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage for individuals.

<sup>28</sup> Enteral nutrition is nourishment given through a tube directly into the stomach or small intestine, and used when an individual cannot ingest, chew, or swallow food but can digest it and absorb nutrients.

<sup>29</sup> Social Security Act §1847(a)(2). Note that the DMEPOS competitive bidding program is not statutorily authorized to include prosthetics.

<sup>30</sup> Parenteral nutrition is a way of supplying nutrition into a person's vein, thus bypassing the digestive system. It is used when a person's intestines are obstructed, or when the small intestines cannot absorb nutrition properly.

<sup>31</sup> Power wheelchairs are divided into groups based on their performance with respect to speed, range (distance it can travel), height of vertical obstruction it can climb, and the weight it can hold. Group 3 power wheelchairs must meet a higher level of performance than Group 2 or Group 1 chairs. For a summary of wheelchair classifications, see, <http://oig.hhs.gov/oei/reports/oei-04-07-00403.pdf>.

<sup>32</sup> Social Security Act §1847(a)(2). Negative Pressure Wound Therapy items and services were also excluded from the first round of competition as specified in the Social Security Act §1847(a)(1)(D)(i)(IV).

- The savings for the item during the DMEPOS demonstrations, and <sup>33</sup>
- Reports and studies conducted by the Office of the Inspector General, and the Government Accountability Office.

Items with the highest allowable charges and highest annual growth in expenditures would receive the highest priority. **Table 3** shows the categories of items included in Round 1 (Rebid), Round 2, and the Recompete in Round 1 areas.

Similar items (or items used to treat related medical conditions) are grouped together in product categories. For example, oxygen supplies and equipment are combined into a single category and any supplier who wants to provide oxygen supplies in a CBA must bid on every item within the category. The number of items in a category can vary from less than a half a dozen to over 100 items. All items are defined by a Healthcare Common Procedure Coding System (HCPCS) code.<sup>34</sup> A supplier may bid for one or more categories. The categories vary by bidding round. In general, the Round 1 Recompete included more broadly defined categories. For example, hospital beds and support services were separate categories for Round 1 Rebid, and Round 2, but they are combined into a single category for Round 1 Recompete. As another example, walkers were a single category in Round 1 Rebid, and Round 2, but they are combined with standard power and manual wheelchairs, and scooters to create a broader mobility equipment category for the Round 1 Recompete.

**Table 3. Categories of Items Included in the DMEPOS Competitive Bidding for Round 1 Rebid, Round 2, and the Recompete of Round 1**

| Categories  | Round 1<br>Rebid (prices<br>effective<br>January 2011) | Round 2<br>(prices to be<br>effective<br>July 2013) | Round 1<br>Recompete<br>(prices to be<br>effective<br>January 2014) |
|---|--|---|---|
| Enteral Nutrients, Equipment and Supplies   | √  | √   | √   |
| External Infusion Pumps and Supplies  |  |   | √   |
| General Home Equipment  |  |   |   |
| Hospital Beds and Related Accessories   | √  | √   |   |
| Support Surfaces (Group 2 mattresses and overlays)  | Miami, FL<br>Only                                      | √   |   |
| Hospital Beds and Related Accessories, Group 1 and 2 Support Surfaces, Transcutaneous Electrical Nerve Stimulation (TENS) devices, Commode Chairs, Patient Lifts, and Seat Lifts* |  |   | √   |
| Mail Order Diabetic Supplies  |  |   |   |
| Metropolitan Area Competition   | √  |   |   |
| National Competition  |  | √   |   |

<sup>33</sup> The final rule noted that the results of the DMEPOS demonstrations would be used with caution. The final rule recognized that the demonstration projects took place over three years prior to the publication of the final rule and policy changes in the MMA, which required CMS to modify some fee schedule amounts based on comparisons with other payers, could contribute to smaller savings from the competitive program.

<sup>34</sup> <http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html?redirect=/medhcpcsgeninfo/>.

| Categories  | Round 1<br>Rebid (prices<br>effective<br>January 2011) | Round 2<br>(prices to be<br>effective<br>July 2013) | Round 1<br>Recompete<br>(prices to be<br>effective<br>January 2014) |
|---|--|---|---|
| <b>Mobility Equipment</b>   |  |   |   |
| Standard Power Wheelchairs, Scooters, and Related Accessories   | √  |   |   |
| Standard Power and Manual Wheelchairs, Scooters, and Related Accessories  |  | √   |   |
| Standard Power and Manual Wheelchairs, Scooters, Related Accessories, and Walkers <sup>a</sup>  |  |   | √   |
| Complex Rehabilitative Power Wheelchairs and Related Accessories (Group 2)  | √  |   |   |
| Walkers and Related Accessories   | √  | √   |   |
| Negative Pressure Wound Therapy (NPWT) Pumps and Related Supplies and Accessories   |  | √   | √   |
| <b>Respiratory Equipment</b>  |  |   |   |
| Continuous Positive Airway Pressure (CPAP), Respiratory Assist Devices (RADS), and Related Accessories and Supplies   | √  | √   |   |
| Oxygen Supplies and Related Accessories   | √  | √   |   |
| Oxygen, Oxygen Equipment, and Supplies; Continuous Positive Airway Pressure (CPAP) Devices and Respiratory Assist Devices (RADs) and Related Supplies and Accessories; and Standard Nebulizers <sup>a</sup> |  |   | √   |

**Source:** Table created by CRS based on information from the CMS Competitive Bidding Implementation Contractor (CBIC). <http://www.dmecompetitivebid.com/palmetto/cbicrd1rebid.nsf/DocsCat/Product%20Categories>, <http://www.dmecompetitivebid.com/palmetto/cbicrd2.nsf/DocsCat/Product%20Categories>, <http://www.dmecompetitivebid.com/palmetto/cbicrd1recompete.nsf/DocsCat/Product%20Categories>.

**Notes:** Suppliers bid for all items in a category, and a contract for a category includes all items in the category. The actual items included in each category are identified by Healthcare Common Procedure Coding System (HCPCS) codes on the website of the CBIC.

- a. The CBIC product category sheet indicates that the category includes these items; it may not be an exhaustive list.

## How Are Winning Suppliers Determined?

To be selected as a winning supplier, a supplier must first meet eligibility requirements, and then the supplier's bid must be selected as a winning bid based on the price competition. In limited circumstances, non-winning suppliers are allowed to sell competitively bid items, and certain suppliers are exempt from the program, as discussed below.



## **Eligibility to Be a Winning Supplier**

The Secretary may only award contracts to suppliers under the competitive bidding program if the following requirements are met:<sup>35</sup>

- The supplier must be accredited by a CMS approved national accrediting organization.<sup>36</sup>
- The supplier must meet applicable financial standards specified by the Secretary.<sup>37</sup>
- The total amount to be paid to contracts in competitive bidding areas is expected to be less than amounts that would be paid under the fee schedule methodology.
- Beneficiaries have a choice of multiple suppliers in each area.

Additionally, suppliers must be in good standing with an active Medicare provider number, meet all applicable state licensure requirements,<sup>38</sup> and be ready to provide services on the first day of the contract period.<sup>39</sup>

The Secretary may limit the number of winning bidders in an area to the number needed to meet projected demand.<sup>40</sup>

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<sup>35</sup> Social Security Act §1847(b)(2).

<sup>36</sup> In general, as of September 30, 2009, all DMEPOS suppliers are required to meet quality standard requirements for Medicare Accreditation. See, <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html>.

<sup>37</sup> A description of the financial measures used by the Secretary can be found on the CBIC website: <http://www.dmecompetitivebid.com/palmetto/cbicrd2.nsf/docsCat/Round%20~Bidding%20Suppliers~Bid%20Evaluation~Financial%20Measures?open>.

<sup>38</sup> A letter from CMS to Tennessee Senators and Representatives indicates that certain winning suppliers in Tennessee did not have the proper licenses to serve the state. CMS has voided 30 out of 98 contracts held by suppliers serving Tennessee competitive bidding areas. <http://www.help.senate.gov/newsroom/press/release/?id=cb248dfc-7114-410f-a739-170f12bb0602&groups=Ranking>. Additionally, the American Association of Homecare filed suit against the Secretary of Health and Human Services to halt the DMEPOS Competitive Bidding Program. *Am. Ass'n for Homecare v. Sebelius*, Complaint (D.D.C. filed June 19, 2013). On June 27, 2013, the court denied the motion for a temporary restraining order to block implementation of the program.

<sup>39</sup> See Fact Sheet on Eligibility Requirements from the CBIC website: [http://www.dmecompetitivebid.com/Palmetto/Cbic.Nsf/files/R2\\_Fact\\_Sheet\\_Eligibility\\_Requirements.pdf/\\$File/R2\\_Fact\\_Sheet\\_Eligibility\\_Requirements.pdf](http://www.dmecompetitivebid.com/Palmetto/Cbic.Nsf/files/R2_Fact_Sheet_Eligibility_Requirements.pdf/$File/R2_Fact_Sheet_Eligibility_Requirements.pdf). CBIC documentation states that suppliers bidding in Round 2 must submit evidence of state licensure to the CMS contractor on or before May 1, 2012, which is after the Round 2 bid deadline of March 30, 2012, <http://www.dmecompetitivebid.com/palmetto/cbicrd2.nsf/docsCat/Round%20~Important%20Dates~Timeline?open&expand=1&navmenu=Important^Dates|>.

<sup>40</sup> Social Security Act §1847(b)(4).

## Selection of Winning Suppliers

The Secretary published the methodology for determining winning suppliers in the final rule published on April 10, 2007.<sup>42</sup> All suppliers in a competitive bidding area who meet the eligibility requirements may bid to supply an entire product category. The supplier must submit a bid for each item included in a product category, and provide an estimate of the amount of product they could supply at that price.<sup>43</sup> For each product category bid that a supplier submits, a “composite bid” is calculated. The composite bid is a method for aggregating a supplier’s bid for all of the items in a category into a single bid for the entire product category. To calculate the composite bid, the bid for each item in the category is multiplied by a weight, and then summed for the category. The weight of the item is based on the national utilization of each item relative to other items in the category. Once the composite bids for each supplier are calculated, they are ranked smallest to largest. The capacity of the bidders is compared to the estimated demand in the CBA. A pivotal bid is identified as the composite bid where the expected combined capacity of the bidders is sufficient to meet the demand in the area. All suppliers with composite bids at or below the pivotal bid are then offered contracts to provide the category of goods to Medicare beneficiaries in the CBA. Suppliers who are offered contracts are not required to sign them.

### **Can a Supplier from Outside of the Competitive Bidding Area Bid in the CBA?**

In certain circumstances, a supplier from outside of a CBA may bid in a CBA. The supplier must have at least one physical location that meets the requirements to be an eligible bidder, including having been accredited and meeting financial standards specified by the Secretary. For Round 2, bidders did not need to meet state licensure requirements *at the time of bidding*, but they were required to submit copies of all applicable state licenses on or before May 1, 2012. Some state laws may not require a DMEPOS supplier to have a physical storefront in a state in order to qualify for applicable licenses; as long as the supplier meets the requirements, the supplier can bid in the CBA. Alternatively, a bidder may rely on licensed subcontractors to serve a CBA that crosses state lines if the bidder does not otherwise have licensure in all state included in the CBA.<sup>41</sup>

All suppliers with composite bids above the pivotal bid are denied contracts, with one exception. CMS established a target that 30% of winning bidders in a CBA should be small suppliers, defined as a supplier that generates gross revenues of \$3.5 million or less in annual receipts. If less than 30% of suppliers are small suppliers, CMS will offer a contract to the small supplier with the lowest composite bid that was above the pivotal bid. That supplier may have a contract to participate in the CBA if it agrees to accept the payment amounts paid to all other suppliers in

<sup>41</sup> [http://www.dmecompetitivebid.com/Palmetto/Cbic.Nsf/files/R2\\_Fact\\_Sheet\\_Eligibility\\_Requirements.pdf/\\$File/R2\\_Fact\\_Sheet\\_Eligibility\\_Requirements.pdf](http://www.dmecompetitivebid.com/Palmetto/Cbic.Nsf/files/R2_Fact_Sheet_Eligibility_Requirements.pdf/$File/R2_Fact_Sheet_Eligibility_Requirements.pdf); and [http://www.dmecompetitivebid.com/cbic/cbicrd1.nsf/files/Fact\\_Sheet\\_Eligibility\\_Requirements.pdf/\\$File/Fact\\_Sheet\\_Eligibility\\_Requirements.pdf](http://www.dmecompetitivebid.com/cbic/cbicrd1.nsf/files/Fact_Sheet_Eligibility_Requirements.pdf/$File/Fact_Sheet_Eligibility_Requirements.pdf).

<sup>42</sup> The Centers for Medicare & Medicaid Services, “Medicare Program: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues,” 72 *Federal Register* 17992-18090, April 10, 2007.

<sup>43</sup> CMS uses historic claims data and financial documents submitted in the bid to evaluate the projected capacity of each supplier. For purposes of the bidding process, no supplier is assumed to be able to serve more than 20% of projected beneficiary demand. This allows more bidders to be winning bidders. Once winning bidders are serving the market, their market share is limited only by their ability to compete on quality of service, equipment selection, and other non-price factors. See, [http://www.dmecompetitivebid.com/Palmetto/Cbicrd2.Nsf/files/R2\\_Fact\\_Sheet\\_Capacity\\_and\\_Expansion\\_Plan.pdf/\\$File/R2\\_Fact\\_Sheet\\_Capacity\\_and\\_Expansion\\_Plan.pdf](http://www.dmecompetitivebid.com/Palmetto/Cbicrd2.Nsf/files/R2_Fact_Sheet_Capacity_and_Expansion_Plan.pdf/$File/R2_Fact_Sheet_Capacity_and_Expansion_Plan.pdf).

the CBA. This continues until 30% of suppliers for each product category are small suppliers or there are no other small suppliers to offer contracts to.<sup>44</sup>

**Can a Winning Supplier Sell Their Contract?**

A supplier cannot sell its competitive bidding contract, but the statutes recognize that suppliers may engage in business mergers or acquisitions.<sup>45</sup> The Secretary's approval is required before a competitive bidding contract can be transferred when a DMEPOS supplier's business is changing ownership.<sup>46</sup>

In very limited circumstances, a supplier who is not a winner in the competition may still be able to sell competitively bid items in the CBA. When a supplier does not win a contract to provide grandfathered items—items paid on a rental basis and for which the supplier had already entered a rental period prior to the start of the competitive bidding program—that supplier may finish the rental period for those items if the supplier agrees to accept a specified payment, which in most circumstances is the competitive bidding payment. For example, oxygen equipment is paid by Medicare on a

36-month rental basis. If the competitive bidding program started after a beneficiary had rented their equipment for six months, and the beneficiary's supplier had not won a competitive bidding contract to sell oxygen equipment in the CBA, the supplier could finish out the remaining 30 months of the rental period if it agreed to the single payment amount.<sup>47</sup> A supplier who does not win a contract to supply a category of items may enter into a subcontracting agreement with a winning supplier<sup>48</sup> or, with the Secretary's approval, may be able to purchase the business of a winning supplier.<sup>49</sup>

Certain providers are exempted from competitive bidding altogether. Physicians or other practitioners may furnish off-the-shelf orthotics or certain items of DME to their own patients as part of their medical service. Likewise, hospitals may furnish off-the-shelf orthotics or certain items of DME to their own patients during admission or on the date of discharge.<sup>50</sup>

In addition, any supplier in a competitive bidding area can be paid by Medicare to repair beneficiary owned equipment, even if that equipment is otherwise included in a competitive bidding product category.<sup>51</sup>

<sup>44</sup> *Federal Register*, vol. 72, no. 68, April 10, 2007, p. 18071.

<sup>45</sup> Social Security Act § 1847(b)(6)(C).

<sup>46</sup> [http://www.dmecompetitivebid.com/Palmetto/Cbicrd2.Nsf/files/R2\\_Fact\\_Sheet\\_CHOW.pdf/\\$File/R2\\_Fact\\_Sheet\\_CHOW.pdf](http://www.dmecompetitivebid.com/Palmetto/Cbicrd2.Nsf/files/R2_Fact_Sheet_CHOW.pdf/$File/R2_Fact_Sheet_CHOW.pdf)

<sup>47</sup> See,

<http://www.dmecompetitivebid.com/palmetto/cbicrd2.nsf/docsCat/Round%20~Grandfathering%20Information~About%20Grandfathering?open>.

<sup>48</sup> Social Security Act § 1847 (b)(3)(C).

[http://www.dmecompetitivebid.com/Palmetto/Cbic.Nsf/files/R2\\_Fact\\_Sheet\\_Subcontracting.pdf/\\$File/R2\\_Fact\\_Sheet\\_Subcontracting.pdf](http://www.dmecompetitivebid.com/Palmetto/Cbic.Nsf/files/R2_Fact_Sheet_Subcontracting.pdf/$File/R2_Fact_Sheet_Subcontracting.pdf).

<sup>49</sup> Social Security Act § 1847(b)(6)(C).

<http://www.dmecompetitivebid.com/palmetto/cbicrd2.nsf/docsCat/Round%20~Contract%20Suppliers~Change%20of%20Ownership?open>.

<sup>50</sup> Social Security Act § 1947(a)(7).

<sup>51</sup> If a beneficiary is renting equipment from a supplier, the Medicare rental payment for that equipment includes the cost of any repairs to that equipment. If the equipment is owned by the beneficiary, Medicare will cover repairs to the medically necessary equipment if the equipment is no longer covered under the manufacturer's warranty. See Medicare Learning Network, *The Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program: Repairs and Replacements*, Department of Health and Human Services, Centers for Medicare & (continued...)

The names of winning suppliers are published on the website of the Competitive Bidding Implementation Contractor.<sup>52</sup>

## How Are Payments Determined?

The payment (“single payment amount”) for each competitively bid item supplied to a beneficiary whose permanent residence is in a CBA<sup>53</sup> is based on the median of the bids for that item among all suppliers who won contracts to provide a category of goods in the process described directly above. This means that half of all winning suppliers will be paid a single payment amount that is less than what they bid for any one item, while half of suppliers are paid an amount that is more than what they were willing to accept to provide any one item. The single payment amount is calculated for each item included in a category, which means that it is possible that a winning bidder may be paid more than its bid for some items in the category, and paid less than its bid for other items in the category; some suppliers may be paid consistently more than they were willing to accept for items in the category, while some suppliers may find the single payment amounts to be consistently lower than what they bid. The winning suppliers know the single payment amounts before they are offered a competitive bidding contract.

Suppliers who accept contracts under the competitive bidding program must accept assignment; this means that suppliers must agree to accept the single payment amount as payment in full. The Medicare payment will equal 80% of the applicable single payment amount, while the beneficiary is responsible for the remaining 20% and any unmet deductible. (Outside of the competitive bidding program, assignment is optional for Medicare-participating DMEPOS suppliers. For suppliers who do not accept assignment, Medicare does not place any restrictions on the amount that those suppliers can bill beneficiaries for covered items. In such a case, the beneficiary would also be responsible for any amount above the fee schedule payment.)

### Does Sequestration Apply to the Competitive Bidding Program?

Provisions in the Budget Control Act of 2011 (P.L. 112-25, BCA) impact Medicare payments in 2013. The BCA established a Joint Select Committee on Deficit Reduction and tasked it with providing to Congress by November 23, 2011, recommendations on ways to reduce the deficit over the subsequent 10 years. When the committee did not provide the recommendations, this triggered a government-wide sequestration process to reduce federal spending beginning in 2013. Payments for most Medicare benefits will be subject to a maximum 2% reduction each year from March 2013 through 2021. Medicare payments for DMEPOS, including those in CBAs, will be reduced by 2% for dates-of-service, or start dates for rental equipment or multi-day supplies, on or after April 1, 2013. The 2% reduction does not apply to beneficiary cost-sharing; the beneficiary pays 20% of the pre-sequestration amount, plus any unmet deductible.

Certain items of DME are rented over a period of 36 months (oxygen) or no more than 13 months (items including hospital beds, nebulizers, and

(...continued)

Medicaid Services, ICN 905283, March 2013, [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/dme\\_repair\\_replacement\\_factsheet\\_icn905283.pdf](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/dme_repair_replacement_factsheet_icn905283.pdf).

<sup>52</sup> See <http://www.dmecompetitivebid.com/palmetto/cbic.nsf/DocsCat/Home>.

<sup>53</sup> If a beneficiary lives in a CBA but needs an item of DME while traveling outside of the CBA, the beneficiary would be able to obtain that item outside of the CBA from a non-contracted provider. The payment for that item would be based on the payment relevant in the CBA. For example, if the beneficiary was to receive an item that is a competitively bid item in the CBA where that beneficiary lives, then the supplier outside of the CBA would be paid the single-payment competitively bid amount. If the beneficiary was to receive an item that was not a competitively bid item, the supplier would be paid the fee schedule amount relevant for the beneficiary’s permanent address.

wheelchairs). A grandfather provision allows beneficiaries who live in a CBA to maintain their established rental agreements for specified items with suppliers who do not win competitive bidding contracts if the supplier agrees to the payment conditions. The supplier would have to agree to accept a specified payment amount, which, in general, is the single payment amount.<sup>54</sup>

The final rule for the Competitive Bidding Program also established additional safeguards and payment adjustments. For example, the final rule established a minimum number of monthly rental payments for oxygen and oxygen equipment, and capped rental items if a beneficiary chooses to switch from a non-contract supplier to a contract supplier. The final rule also included provisions for various payment adjustments, including an adjustment to address changes in the health care procedure and coding system (HCPCS) codes that classify items of DME, or to account for beneficiaries for whom Medicare is their secondary insurance.

## **Small Supplier Considerations**

The Secretary is required to “take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program” when developing procedures related to bids and awards of DMEPOS contracts.<sup>55</sup> The Secretary found that the majority of suppliers of DMEPOS met the Small Business Administration's definition of a small business—a business with less than \$6.5 million in annual receipts. A CMS analysis of claims data published in the final rule indicated that 90% of suppliers had Medicare allowable charges of less than \$1 million in CY2003.<sup>56</sup>

The final rule includes several provisions that would increase the likelihood that small suppliers would be able to participate in the program. Those include the following:

- Multiple suppliers are selected for each CBA, thus increasing the chance that the smaller providers would be able to participate.
- Separate bidding competitions are conducted for each product categories, which may encourage small businesses that specialize in a type of equipment to apply.
- The Centers for Medicare & Medicaid Services conducted focus groups with small suppliers to gain information about ways to facilitate their participation in the program. These groups also discussed the quality standards and the accreditation process. The results of the focus groups were presented to the Program Advisory and Oversight Committee.
- The Centers for Medicare & Medicaid Services established a new definition of "small suppliers" as Medicare DMEPOS suppliers that generates gross revenues of \$3.5 million or less in annual receipts.

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<sup>54</sup> For Round 1 Rebid, the payment amount for certain grandfathered items, such as oxygen, was the single payment amount, but for other specified items, the payment was that under the existing rental agreement. See 42 C.F.R. §414.408(j).

<sup>55</sup> Social Security Act §1847(b)(6)(D). The Secretary is also required to take into account the needs of small suppliers when determining if a supplier meets the applicable financial standards necessary for awarding a contract. Social Security Act §1847(b)(2)(A)(ii).

<sup>56</sup> The Centers for Medicare & Medicaid Services, "Medicare Program: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues," 72 Federal Register 17992-18090, April 10, 2007.

- The Centers for Medicare & Medicaid Services established a target number of DMEPOS small suppliers participating in each competitive bidding program of 30% or more.

For Round 1 Rebid, 51% of the winning suppliers were small suppliers.<sup>57</sup> For Round 2, they make up 63% of contract suppliers.<sup>58</sup>

## Oversight of the Competitive Bidding Program

The Secretary has broad authority to administer the Medicare program and to undertake research, studies, and other initiatives, either directly or through contracts or authorized grant or demonstration programs. The Centers for Medicare & Medicaid Services has primary responsibility for administration of the Medicare program. In addition to the Secretary's general administrative and oversight authority, several specific provisions in Section 1847 of the Social Security Act, which authorizes the Competitive Bidding Program, require formation of an advisory body, an additional ombudsman's office, and various program evaluations, as described below. In addition, Congress, in its oversight capacity, has held several hearings examining the implementation and functioning of the Competitive Bidding Program.<sup>59</sup>

### Program Advisory and Oversight Committee

As required by Section 1847(c) of the Social Security Act, the Secretary established a Program Advisory and Oversight Committee (PAOC), which provided advice to the Secretary with respect to (a) implementation of the competitive bidding program; (b) establishment of financial standards; (c) data collection requirements for efficient management of the program; (d) development of proposals for efficient interaction among manufacturers, providers of services, suppliers, and individuals; and (e) establishment of quality standards. PAOC also performed other functions the Secretary specified. The committee was terminated on December 31, 2011, as required by law.<sup>60</sup> Membership information and notes from PAOC meetings are available on the CMS website.<sup>61</sup>

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<sup>57</sup> The Centers for Medicare & Medicaid Services, *Competitive Bidding Update—One Year Implementation Update*, April 17, 2012, p. 2, <http://www.cms.gov/medicare/medicare-fee-for-service-payment/dmeposcompetitivebid/downloads/competitive-bidding-update-one-year-implementation.pdf>.

<sup>58</sup> <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-Releases/2013-Press-Releases-Items/2013-04-092.html>.

<sup>59</sup> Recent hearings include the following: U.S. Congress, House Committee on Ways and Means, Subcommittee on Health, *Hearing on Medicare's Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program*, 110<sup>th</sup> Cong., 2<sup>nd</sup> sess., May 6, 2008, <http://waysandmeans.house.gov/calendar/eventsingle.aspx?EventID=232364>; U.S. Congress, House Small Business Committee, Subcommittee on Healthcare and Technology, *Medicare's Durable Medical Equipment Competitive Bidding Program: How are Small Suppliers Faring?*, 112<sup>th</sup> Cong., 2<sup>nd</sup> sess., Sept. 11, 2012, <http://smallbusiness.house.gov/calendar/eventsingle.aspx?EventID=307385>; U.S. Congress, House Committee on Ways and Means, Subcommittee on Health, *Medicare Durable Medical Equipment Competitive Bidding Program*, 112<sup>th</sup> Cong., 2<sup>nd</sup> sess., May 9, 2012, <http://waysandmeans.house.gov/calendar/eventsingle.aspx?EventID=293769>.

<sup>60</sup> Social Security Act §1847(c)(5).

<sup>61</sup> [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Program\\_Advisory\\_and\\_Oversight\\_Committee\\_PAOC.html](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Program_Advisory_and_Oversight_Committee_PAOC.html).

## Ombudsman's Office

The Secretary was required to establish a Competitive Acquisition Ombudsman (CAO) within CMS to respond to complaints and inquiries made by suppliers and individuals related to the competitive bidding program.<sup>62</sup> The CAO works in coordination with the Office of the Medicare Beneficiary Ombudsman to submit an annual report to Congress on the activities of the office.<sup>63</sup>

## Evaluations of Round 1 Rebid

Several required evaluations of the Competitive Bidding Program have been published, while some required evaluations are still outstanding, as discussed below.

### CMS Evaluation

On April 17, 2012, CMS released an evaluation of the first year of the Round 1 Rebid. The Round 1 Rebid included 1,217 contracts awarded to 356 individual suppliers, 51% of whom were small suppliers. CMS found that, overall, the competitive bidding program reduced expected expenditures for selected DMEPOS by over 42%, taking into account reductions in the prices paid by Medicare and changes in utilization, though savings percentages varied by product category and competitive bidding area. Real-time monitoring of claims data, and factors such as hospital admissions, emergency room visits, physician visits, and admissions to skilled nursing facilities both before and after implementation of the program, for both competitive bidding areas and non-CBA comparator locations, found “no disruptions in access to needed supplies ... and no negative health consequences to beneficiaries as a result of competitive bidding.”<sup>64</sup> The CMS analysis of inquiries and complaints received by the regional offices, 1-800 Medicare, and to the Competitive Acquisition Ombudsman's office found a high number of inquiries about the program during 2011 (127,466), but a much smaller number of complaints (151) defined as “inquiries that express dissatisfaction with the program and cannot be resolved by a call center operator.”<sup>65</sup>

### GAO Evaluation

In May of 2012, the Government Accountability Office (GAO) released an evaluation of the first year of the program.<sup>66</sup> GAO was required to examine and report to Congress on the following

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<sup>62</sup> Social Security Act §1847(f).

<sup>63</sup> The 2010 Report to Congress, released on June 1, 2012, is the most recent report available. [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Downloads/CAO\\_2010\\_Report\\_to\\_Congress.pdf](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Downloads/CAO_2010_Report_to_Congress.pdf).

<sup>64</sup> The Centers for Medicare & Medicaid Services, *Competitive Bidding Update—One Year Implementation Update*, April 17, 2012, p. 1, <http://www.cms.gov/medicare/medicare-fee-for-service-payment/dmeposcompetitivebid/downloads/competitive-bidding-update-one-year-implementation.pdf>.

<sup>65</sup> The Centers for Medicare & Medicaid Services, *Competitive Bidding Update—One Year Implementation Update*, April 17, 2012, pp.5-6, <http://www.cms.gov/medicare/medicare-fee-for-service-payment/dmeposcompetitivebid/downloads/competitive-bidding-update-one-year-implementation.pdf>.

<sup>66</sup> U.S. Government Accountability Office, *Medicare: Review of the First Year of CMS's Durable Medical Equipment Competitive Bidding Program's Round 1 Rebid*, GAO-12-693, May 2012, <http://www.gao.gov/assets/600/590712.pdf>.

issues: (1) outcomes of the rebid process including disqualifications and contracts awarded, (2) the effects of the rebid on DME suppliers, (3) how the rebid affected beneficiary access to and satisfaction with DME, (4) the extent to which bidding affected utilization, and (5) the costs to CMS of implementing the program, and to the suppliers for participating. Among the findings of the report are the following:

- Nearly the same number of suppliers bid in Round 1 Rebid as had bid in Round 1. The initial bid review resulted in fewer disqualifications in the Round 1 Rebid (30% of bids disqualified) compared to Round 1 (almost 50% of bids were disqualified). About 20% of the bids submitted were awarded contracts in Round 1 Rebid, which was similar to the proportion that won contracts on Round 1 (22%).
- “Although the majority of suppliers with disqualified bids that contacted CMS with questions were found to have been correctly disqualified, some suppliers were later found to have incorrectly disqualified bids and were offered contracts.”
- Many suppliers still had difficulty complying with bid submission requirements, and had particular difficulty submitting accurate financial documentation.
- Four percent of the original contract suppliers had their contracts terminated or cancelled in the first 10 months of the program; an additional 2% of contract suppliers changed ownership.
- In January 2011, 58% of suppliers who had billed for grandfathered products the month before chose to become grandfathered suppliers. That percentage decreased to 22% by December 2011 as the rental periods for grandfathered items expired.
- About 31% of contract suppliers reported that they had subcontracts with other suppliers within the first 8 months of the program.
- “There were 43 distinct contract suppliers new to a product category, and 44 new to a competitive bidding area – each were about 12 percent of the 356 original contract suppliers awarded contracts.”
- “Although CMS’s monitoring activities have limitations, they indicate that beneficiary access and satisfaction have not been affected by competitive bidding.”
- Data suggest decreases in some DME utilization; however, pre-competitive bidding utilization may not have been at the appropriate level.
- CMS’s estimated savings to the Medicare program and beneficiaries are “significantly higher” than the cost of implementing the program. CMS estimated the average cost for a supplier to submit a bid was \$2,303.16.

## **OIG Evaluation**

The Office of the Inspector General (OIG) examined the extent to which suppliers were soliciting physicians to prescribe specific brands or modes of DMEPOS in the competitive bidding program in order to maximize their revenue. The OIG found that most physicians did not specify the brand of DMEPOS in the prescription (thus allowing the supplier to choose the brand), and of those



physicians who did prescribe a brand or mode, most were not solicited by the supplier to change it.<sup>67</sup>

The OIG is also statutorily required to evaluate the conduct of competitive bidding and how the subsequent single payment amounts were determined; however, this report has not yet been released.<sup>68</sup>

## Issues for Congress

Several issues have been voiced in regard to the Competitive Bidding Program that may raise questions about its long-term viability, or whether the prices established through competitive bidding reflect the market for those products.

### Pool of Suppliers

One concern raised about the Competitive Bidding Program is whether it would reduce the number of DMEPOS suppliers leading to higher bids in subsequent rounds of bidding. More specifically, because Medicare is such an important part of some DMEPOS suppliers' businesses, if a supplier doesn't win a contract (or multiple contracts), the supplier may be unable to stay in business. In the next round of bidding, there could be fewer suppliers competing in the market, which could lead to higher bids, and higher payments for DMEPOS.

There are several things to consider with respect to this issue. First, prices may rise in subsequent rounds of bidding for reasons other than a reduction in the number of suppliers. In the demonstration for the competitive bidding program held in Polk County, Florida between 1999 and 2002, the prices for urological supplies increased between the first and second round. "Once the demonstration got underway, some urological suppliers discovered they had bid too low to cover costs [and bid higher in the second round of competition]."<sup>69</sup>

Another consideration is the relatively low barriers to enter the DME business. Though DMEPOS suppliers must comply with more enrollment requirements than previously, such as accreditation requirements and surety bonds, they are not required to undergo the extensive licensure and credentialing required of some other Medicare participating providers, such as physician practices and hospitals.<sup>70</sup> If subsequent rounds of competitive bidding resulted in substantially higher prices, it is likely that the higher prices would encourage new businesses to compete. However, if

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<sup>67</sup> Stuart Wright, Deputy Inspector General for Evaluations and Inspections, *Limited Supplier Solicitation of Prescribing Physicians Under Medicare DMEPOS Competitive Bidding Program*, Department of Health and Human Services, Office of Inspector General, OEI-06-11-00081, December 2012, <https://oig.hhs.gov/oei/reports/oei-06-11-00081.pdf>.

<sup>68</sup> Social Security Act §1847(a)(1)(E).

<sup>69</sup> Tommy G. Thompson, Secretary, *Final Report to Congress: Evaluation of Medicare's Competitive Bidding Demonstration for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies*, Department of Health and Human Services, 2004, p. 4, [http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/CMS\\_rtc.pdf](http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/CMS_rtc.pdf).

<sup>70</sup> Daniel R. Levinson, Inspector General, *Testimony before the House Committee on Energy and Commerce, Subcommittee on Health*, U.S. Department of Health & Human Services, September 15, 2010, pp. 1-2, [http://oig.hhs.gov/testimony/docs/2010/testimony\\_levinson\\_09152010.pdf](http://oig.hhs.gov/testimony/docs/2010/testimony_levinson_09152010.pdf).

this were to happen, it is possible that new market entrants might not be the same businesses that had been in the market previously.

## **“Non-binding” or Revocable Bids<sup>71</sup>**

When “non-binding” or revocable bidding is used, suppliers can place bids without their bids being enforceable against them (i.e., the bid-taker generally has no legal recourse if the bidder fails to enter a contract with the bid-taker based on the terms of the bid). The use of non-binding bidding has been criticized on various grounds, including on the grounds that bidders submit “bids they ha[ve] no intention of paying ... merely to guarantee they w[i]n,”<sup>72</sup> and then, having won, determine whether or not it is to their advantage to enter a contract based on the terms of their bid. These concerns may have particular force in the DME context, where the use of non-binding bidding *and* “median pricing,” discussed below, could potentially combine to result in bidders submitting unrealistically low bids in an attempt to obtain a highly valued contract.<sup>73</sup>

In letters to the President<sup>74</sup> and Congress,<sup>75</sup> hundreds of economists, computer scientists, and engineers have suggested that using non-binding bids and median pricing will lead to “complete market failure in theory.”<sup>76</sup> In addition, in a study published in the *Quarterly Journal of Economics*, a simplified experimental auction using 12-16 university students as auction participants found that auctions conducted using non-binding bids and median pricing resulted in “low-ball bids,” while auctions conducted with binding bids and prices set at market-clearing levels tended to reveal bidders’ “true costs.”<sup>77</sup> Results from this very small economics experiment suggest that aspects of the DMEPOS competitive bidding program could encourage bidders to submit possibly unreasonably low bids.

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<sup>71</sup> The legal analysis in this section was written by (name redacted), Legislative Attorney, Congressional Research Service.

<sup>72</sup> Donovan Bezer, “The Inadequacy of Surety Bid Bonds in Public Construction Contracting,” *Public Contract Law Journal*, vol. 40, no. 1 (2010), pp. 87-146, at pg. 110 (internal citations omitted). Other potential issues with non-binding or revocable bids are also noted (e.g., penalty-free withdrawal after bid opening gives the reneging bidder(s) a “free look” at pricing and related information that other bidders had to “pay” for through the disclosure of valuable private data and, thus, could result in a smaller pool of bidders in future auctions). *See id.* at pg. 115. However, some of these concerns would appear to be inapposite in the DME context given CMS’s contracting practices. For example, CMS does not publicly disclose bidders’ prices at bid opening, as is often the case when the government conducts sealed bidding. For more on bidding in the context of the Federal Acquisition Regulation, see generally 48 C.F.R. §14.402-1(a) (“The bid opening officer ... shall ... [,] if practical, read the bids aloud to the persons present.”).

<sup>73</sup> Such bidders could, for example, offer prices below their actual costs of performance, knowing that they would be expected to perform not at their own price, but at a price which is the median of accepted bidders. There may, however, be limits on how low a bidder might wish to go, even in the case of nonbinding bids, since federal contracting officers may generally reject bids that are “unreasonable as to price” (either overall price, or price on individual line items). *See* 48 C.F.R. §14.404-2(f). Bids from suppliers who are found to be nonresponsible (e.g., lack the financial resources to perform the contract) may generally also be rejected. 48 C.F.R. §14.404-2(i). *See also* 42 C.F.R. §414.414(b)(4).

<sup>74</sup> <http://www.cramton.umd.edu/papers2010-2014/further-comments-of-concerned-auction-experts-on-medicare-bidding.pdf>.

<sup>75</sup> The letter is reproduced, in part, in the testimony of Dr. Peter Cramton to the House Committee on Small Business on September 11, 2012. [http://smallbusiness.house.gov/uploadedfiles/9-11\\_cramton\\_testimony.pdf](http://smallbusiness.house.gov/uploadedfiles/9-11_cramton_testimony.pdf).

<sup>76</sup> <http://www.cramton.umd.edu/papers2010-2014/further-comments-of-concerned-auction-experts-on-medicare-bidding.pdf>.

<sup>77</sup> Brian Merlob, Charles R. Plott, and Yuanjun Zhang, “The CMS Auction: Experimental Studies of a Median-Bid Procurement Auction with Nonbinding Bids,” *Quarterly Journal of Economics*, May 2012, pp. 793-827.

However, while there is apparent unanimity with regards to the economic arguments here, there may be legal and empirical reasons to question the potential benefits of expressly barring the withdrawal of bids for a certain time period after their submission.<sup>78</sup> The Federal Acquisition Regulation (FAR), which generally governs the acquisition of goods and services by executive branch agencies,<sup>79</sup> helps illustrate how the withdrawal of bids is generally handled by federal agencies and the courts. The FAR broadly permits the modification or withdrawal of bids after their submission, but prior to bid opening.<sup>80</sup> In contrast, in the period between bid opening and contract award, the FAR generally permits agencies to grant requests for modification or withdrawal of a bid only if there is “clear and convincing evidence” of both (1) a mistake’s existence and (2) evidence of the bidder’s intended bid, and certain other conditions are met.<sup>81</sup> The FAR’s approach here arguably reflects the case law, which has generally found that bidders may, in certain circumstances, be entitled to equitable relief from the obligation to enter contracts based on the terms of their bids.<sup>82</sup> In particular, courts have developed what some commentators have referred to as the “law of mistaken bids,”<sup>83</sup> which can be seen as somewhat different than the common law of contracts.<sup>84</sup> While the law of mistaken bids can be quite complicated, it would generally support the rescission of bids in cases of (1) *mutual mistakes*, that is, mistakes common to both parties;<sup>85</sup> (2) *unilateral mistakes* by the bidder that are patent or obvious on their face;<sup>86</sup>

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<sup>78</sup> It should also be noted that at least one early case took the view that “government agents should be allowed a reasonable time after the opening of bids before they [i.e., the bids] are allowed to be withdrawn,” even when the auction rules did not expressly provide that bids would be binding. See *Scott v. United States*, 44 Ct. Cl. 524, 527 (1909). The court reached this conclusion, in part, because of the differences between the government and private contract parties. *Id.* (“The agents of the Government stand upon a different footing from private individuals in the matter of advertising for the letting of contracts on behalf of the United States. They have no discretion. They must accept the lowest or highest (in the case of sales) responsible bid, or reject all and readvertise.”).

<sup>79</sup> For more on the FAR, see generally CRS Report R42826, *The Federal Acquisition Regulation (FAR): Answers to Frequently Asked Questions*, by (name redacted) et al. The FAR is codified in Parts 1 to 53 of Title 48 of the *Code of Federal Regulations*, and all citations to the FAR in this report are to Title 48.

<sup>80</sup> 48 C.F.R. §14.303(a) (requiring only that “notice is received in the office designated in the solicitation not later than the exact time set for opening of bids”).

<sup>81</sup> 48 C.F.R. §14.407-3(a) & (b). In addition, if a correction would result in displacing one or more lower bids, the existence of the mistake and the bid actually intended must be “ascertainable substantially from the invitation and the bid itself.” 48 C.F.R. §14.407-3(a). There are separate—and even more stringent limitations—on rescission and reformation of contracts after their award. See generally 48 C.F.R. §14.407-4.

<sup>82</sup> See Ernest M. Jones, “The Law of Mistaken Bids,” *University of Cincinnati Law Review*, vol. 48, no. 1 (1979) (“Of the four mistaken bid cases known to have been decided prior to 1900, each denied relief. Thereafter, except for the 1930’s, when relief was granted in only three of eight cases, a trend of granting judicial relief to mistaken bidders has continued since the 1900 decision of the United States Supreme Court in *Moffett, Hodgkins & Clark Co. v. City of Rochester*.”). See also *Balt. Cnty. v. John K. Ruff, Inc.*, 375 A.2d 237, 239 (Md. 1977) (“[T]he blundering bidder may be relieved in equity of his obligation created at law by his bid and deposit, and this is true even though the bid was submitted to a public body under a statute declaring the bid to be irrevocable and providing for the forfeiture of the deposit.”).

<sup>83</sup> Ernest M. Jones, “The Law of Mistaken Bids,” *University of Cincinnati Law Review*, vol. 48, no. 1 (1979) at pp. 43-83.

<sup>84</sup> See, e.g., Donovan Bezer, “The Inadequacy of Surety Bid Bonds in Public Construction Contracting,” *Public Contract Law Journal*, vol. 40, no. 1 (2010) at 134 (“[T]he first edition of *Williston’s Law of Contracts* recognized that the customary practice by which offer and acceptance are communicated in a bidding forum clashes with the common law’s understanding of how parties express their willingness to contract in other settings.”).

<sup>85</sup> Compare *Rash v. United States*, 360 F.2d 940 (Ct. Cl. 1966) (rescission granted where both contractor and government believed contractor purchased improved land and the land was, in fact, unimproved) with *In re Roundtree*, 44 B.R. 772, 773-74; 1984 Bankr. LEXIS 4571, at \*4-\*5 (1984) (requiring the bidder to comply with the terms of its bid because the alleged mistake was a unilateral one).

<sup>86</sup> Compare *Peerless Cas. Co. v. Hous. Auth. of Hazelhurst*, 228 F.3d 376, 381 (5<sup>th</sup> Cir. 1955) (holding that, where there (continued...))

and (3) certain other unilateral mistakes, particularly if they involve “clerical” or mathematical errors.<sup>87</sup> Mistakes in judgment, in contrast, are generally not excused,<sup>88</sup> unless enforcement of the bid’s terms is seen as unconscionable.<sup>89</sup> Moreover, even if the bidder’s failure to execute a contract based on its bid is not excused, the government is generally only entitled to damages in an amount equivalent to the difference in price between the withdrawn bid and the next lowest-priced bid.<sup>90</sup>

Beyond providing that bids may not be revoked for a period of time after being offered,<sup>91</sup> agencies often also require that bidders must submit security with their bids to guarantee that they will, if selected, execute a contract to perform the work according to the terms of their bid. Examples of such securities include cash deposits, cashier’s checks, certified checks, letters of credit, and *bid bonds* (i.e., written instruments executed by a bidder (the principal) and a second party (the surety) to ensure fulfillment of the principal’s obligation to a third party (i.e., the bid-taker) to enter a contract based on the terms of the bid). Bid bonds are used by the federal government, particularly with construction contracts. However, the FAR generally authorizes the use of bid bonds only when performance and payment bonds are also required,<sup>92</sup> and at least some underwriters reportedly decline to issue bid bonds for contracts that do not require performance and payment bonds.<sup>93</sup> In addition, and perhaps more significantly, the surety on the bond may assert all defenses available to the principal except personal ones (e.g., insanity, infancy).<sup>94</sup> Moreover, although the bid bond and the bid are distinct legal instruments,<sup>95</sup> courts often decline to require forfeiture of the bond where the bidder can assert a mistake that would permit

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(...continued)

is a reasonable excuse for the error and the government knows of the mistake, the contractor may have the bid rescinded in equity) *and* *Tyra v. Cheney*, 152 N.W. 835 (Minn. 1915) (“One cannot snap up an offer or bid knowing that it was made in mistake.”) *with* *Wender Presses, Inc. v. United States*, 343 F.2d 961 (Ct. Cl. 1965) (mistake not patent).

<sup>87</sup> See, e.g., *E. Porter County Sch. Corp. v. Gough, Inc.*, 965 N.E.2d 684 (Ind. Ct. App. 2012); *Balaban-Gordon Co. v. Brighton Sewer Dist.*, 67 Misc. 2d 76, 1971 N.Y. Misc. LEXIS 1370 (N.Y. Misc., August 9, 1971); *Boise Junior College Dist. v. Mattefs Constr. Co.*, 92 Ida. 757 (1969); *M.F. Kemper Constr. Co. v. Los Angeles*, 235 P.2d 7 (Cal. 1951); *Sch. Dist. of Scottbluff v. Olson Constr. Co.*, 45 N.W.2d 164 (Neb. 1950).

<sup>88</sup> See, e.g., *Buffalo Mun. Hous. Auth. v. Gross Plumbing & Heating Co.*, 172 A.D.2d 1030, 1030 (N.Y. App. Div. 1991) (excusing bidder’s mistake because it “was clerical and not judgmental in nature”).

<sup>89</sup> See, e.g., *Peerless Cas. Co.*, 228 F.2d at 381 (court noting that its ruling, which found that the bidder was not liable to forfeit its bid bond, was “made without reluctance between ... affirmance would result in an unjust enrichment of the appellee Housing Authority”); *City of Florence v. Powder Horn Constrs., Inc.*, 716 P.2d 143, 144 (Colo. App. 1985) (“We believe that such a policy [i.e., strictly enforcing bids] is unduly restrictive in that it denies the application of equitable principles in meritorious cases, including the principle of unjust enrichment.”).

<sup>90</sup> See, e.g., *Road Comm’n v. Union Constr. Co.*, 339 P.2d 421, 423 (Utah 1959) (state suffered no disadvantage other than taking the next lowest bid).

<sup>91</sup> Even when binding bids are called for, the bid-taker’s power of acceptance will lapse after a period of time. See e.g., *Fraser Public Schools Dist. v. Kolon*, 193 N.W.2d 64 (1971).

<sup>92</sup> See 48 C.F.R. §28.101-1(a) (“A contracting officer shall not require a bid guarantee unless a performance bond or a performance and payment bond is also required.”).

<sup>93</sup> See, e.g., David K. Kerr, “Does Issuance of a Bid Bond Constitute a Performance Commitment?” 15 *Forum* (1979/80), pp. 465-80, at pg. 467.

<sup>94</sup> See, e.g., *Peerless Cas. Co.*, 228 F.2d at 381 (if the bidder is not liable, neither is the surety); *Balaban-Gordon Co. v. Brighton Sewer Dist.*, 342 N.Y.S.2d 435, 438 (App. Div. 1973) (“If the bid may be rescinded, the bid bond must be cancelled.”).

<sup>95</sup> See Donovan Bezer, “The Inadequacy of Surety Bid Bonds in Public Construction Contracting,” *Public Contract Law Journal*, vol. 40, no. 1 (2010) at 121 (expressing the view that bid bonds could be enforced, even if the bid is not, because it is a separate agreement).

rescission of the bid.<sup>96</sup> The DMEPOS competitive bidding program does not require suppliers to submit bid bonds with their bids.

It is also important to note that, even when binding bids are required, the bidder's obligation to enter a contract corresponding to the terms of its bid is generally distinguishable from the bidder's obligation to perform as required under the terms of that contract.<sup>97</sup> In other words, even if the bidder fulfills its obligation to enter into a contract, it could still potentially fail to perform as required by the contract (whose terms are based, in part, on the terms of its bid). If a contractor were to default, the government could potentially recover monetary damages. However, its ability to compel the contractor to perform as required in the contract is arguably limited.<sup>98</sup> *Specific performance*—or a court order to perform as required in a contract—is granted primarily in cases involving real property or unique items, not in cases involving commercial items or the performance of services.<sup>99</sup> In addition, the DMEPOS contracts require the winning bidder(s) to perform repeatedly over time, and the quality of their performance could potentially vary by task or time. This means that a bidder who enters into a contract with CMS—as the result of either binding or nonbinding bids—could still have opportunities to underperform on that contract, either by providing poor customer service or by engaging in activities that would violate its contract with CMS. Binding bids would not, per se, protect against this type of underperformance.

Finally, there is empirical support for the argument that non-binding bids may be more of a problem in theory than in practice, given that the percentage of bidders who were offered contracts and accepted them was above 90% for each of Round 1 (stopped by MIPPA), Round 1 Rebid, and Round 2. Further, of those suppliers who signed contracts for Round 1 Rebid (the only round for which evaluation data are available), only 4% were terminated by CMS or voluntarily cancelled by the suppliers in the first 10 months of the program.<sup>100</sup>

## Median Versus Market Clearing Price

The price for each item is set at the median (or middle) of all the winning bids for the item. This means that the single payment amount for any particular good will be set below the amounts that

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<sup>96</sup> See, e.g., *Peerless Cas. Co.*, 228 F.2d at 381 (“[R]eading the bid and the bid bond together, we can see no liability on the bond against the principal ... and absent any liability of the principal there is not, as we have noted, any liability of the surety.”).

<sup>97</sup> Donovan Bezer, “The Inadequacy of Surety Bid Bonds in Public Construction Contracting,” *Public Contract Law Journal*, vol. 40, no. 1 (2010) at 130 (“The universe of potential occurrences between winning a bid and completing the job—changes in the contractor’s finances, requests for changes to the scope of the project, weather, etc.—is complex.”).

<sup>98</sup> *Laclede Gas Co. v. Amoco Oil Co.*, 522 F.2d 33, 39-40 (8<sup>th</sup> Cir. 1975) (“It is axiomatic that specific performance will not be ordered when the party claiming breach of contract has an adequate remedy at law,” including monetary damages). *But see Hamlet v. Hayes*, 641 S.E.2d 115, 118 (Va. 2007) (concluding that specific performance is a proper remedy for breach of a contract that explicitly provided for specific performance).

<sup>99</sup> *Compare Structural Polymer Group, Ltd. v. Zoltek Corp.*, 2006 U.S. Dist. LEXIS 88479 (E.D. Mo., Dec. 7, 2006) (declining to grant specific performance where the evidence suggested that plaintiffs had successfully “covered” with somewhat different products in the past) *with LAK, Inc. v. Deer Creek Enters.*, 1986 U.S. Dist. LEXIS 18270 (E.D. Mich., Oct. 31, 1986) (granting specific performance in a case involving real property).

<sup>100</sup> U.S. Government Accountability Office, *Medicare: Review of the First Year of CMS's Durable Medical Equipment Competitive Bidding Program's Round 1 Rebid*, GAO-12-693, May 2012, p. 28, <http://www.gao.gov/assets/600/590712.pdf>.

half of the bidders said was the minimum amount they were willing to accept to provide the good. Generally in auctions, prices are set at the highest bid for the good among all winning bidders necessary to fulfill the market.

As discussed above, there is some experimental evidence to suggest that median pricing (coupled with “non-binding bids”) leads to “low-ball” bids that may not be sustainable in the long run.

The extent to which this point is problematic depends, in large part, on the distribution of the bids for each item. If the range between the highest winning bid for the item, and the lowest winning bid for the item is narrow, then setting the price at the median rather than the market clearing price would mean the difference of a small amount on a particular item and may not be problematic for even the supplier who had the highest winning bid. While the bid data have not been released by CMS, the fact that most successful bidders who were offered contracts accepted them, and that a small proportion of those suppliers who accepted contracts subsequently withdrew from the program suggests that suppliers did not view the difference between the price they bid and the price they were offered as sufficiently large that they should reject the price offered by CMS.

At an April 1, 2011, meeting at the University of Maryland, Tom Bradley from the Congressional Budget Office indicated that CMS had chosen to offer contracts to more suppliers than would meet the estimated market demand over the three-year period. In so doing, setting the price at the median, rather than market clearing price (for this larger group of suppliers) means that the single payment amounts may have been, in CMS’s judgment, set closer to what might be considered a reasonable approximate of the market clearing price for enough suppliers to fulfill the market. And though the early reports of the Round 1 Rebid showed little market disruption and were being viewed by CMS as successful, the imprecise, and somewhat arbitrary methodology used to set prices would, over the long run (which was not defined), fail.<sup>101</sup>

With respect to CMS’s decision to allow a greater number of suppliers than needed to clear the market, there are two potential arguments in favor of this approach. First, one could view CMS’s decision to select more suppliers than needed to serve a market as a conservative approach to running the program, in that if suppliers failed to perform, their failure would be less likely to disrupt the market. Second, suppliers’ estimates of the amount of product they could supply to the market is in no way guaranteed to be their market share once the program begins and suppliers once selected, do not compete for Medicare beneficiaries based on price. Therefore, allowing more suppliers in the market than would be strictly necessary to meet estimated demand may mean a more rigorous non-price competition among suppliers.

## Quality

Some have argued that quality is not enough of a consideration in the competitive bidding program, and that suppliers’ attempts to reduce cost will result in lower quality equipment and customer service.

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<sup>101</sup> <http://vimeo.com/21942973>—Video of the final panel from an April 1, 2011 meeting on the competitive bidding program held at the University of Maryland.

All suppliers—both contract suppliers and non-contract suppliers—must meet accreditation requirements.<sup>102</sup> In part, accreditation requires that suppliers have leadership and systems in place to address aspects of the business such as financial management, human resources, customer service, performance management (such as the measurement of the frequency of billing and coding errors), and product safety. The accreditation requirements also describe specific supplier responsibilities with regard to (1) consulting with the prescribing physician to confirm the prescription and incorporate pertinent information into the beneficiary’s file, (2) delivery and set-up of the equipment, (3) training and instruction for the beneficiary or their caregiver(s), and (4) follow-up services consistent with the type of equipment and services provided. There are additional accreditation requirements for suppliers who supply respiratory equipment, wheelchairs, and certain orthotics or prosthetics.

Specific to the competitive bidding program, quality was examined as part of the assessment of the Competitive Bidding Demonstration Programs<sup>103</sup> that took place from 1999 to 2002. With respect to quality and product selection, beneficiary surveys showed high satisfaction with suppliers under the demonstration projects. Supplier surveys showed that products provided to beneficiaries changed little during the demonstration. Though it did not show up in either of the surveys, anecdotal reports pointed to issues surrounding urological supplies and wheelchair fitting and delivery. These instances were isolated, and “eventually self-correcting”<sup>104</sup> through a new round of bidding, changes in ordering documentation, and increased experience of the referral agents (such as hospital discharge planners) in directing beneficiaries to selected suppliers.<sup>105</sup>

Finally, since the prices of competitively bid items are determined through the competitive bidding process, and contract suppliers must accept the single payment amounts as payment in full, winning suppliers will be competing on quality of customer service and product selection to gain market share.

## Proposed Legislation

Four bills have been introduced in the 113<sup>th</sup> Congress to amend the Competitive Bidding Program.

The Small Supplier Fairness in Bidding Competition Act of 2013 (H.R. 27) was introduced on January 3, 2013. The bill would repeal the DMEPOS competitive bidding program, effective upon enactment, and require the Secretary to submit a report to the House Committee on Small Business and the Senate Committee on Small Business and Entrepreneurship on the impact of competitive bidding on small clinical laboratories, among other provisions.

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<sup>102</sup> <http://cms.hhs.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/DMEPOSAccreditationStandardsCMB.pdf>

<sup>103</sup> The demonstration projects authorized by the Balanced Budget Act of 1997 are discussed in more detail in Appendix A of this report.

<sup>104</sup> Tommy Thompson, *Final Report to Congress: Evaluation of Medicare’s Competitive Bidding Demonstration for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies*, Department of Health and Human Services, 2004, [http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/CMS\\_rtc.pdf](http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/CMS_rtc.pdf), p. 10.

<sup>105</sup> Tommy Thompson, *Final Report to Congress: Evaluation of Medicare’s Competitive Bidding Demonstration for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies*, Department of Health and Human Services, 2004, [http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/CMS\\_rtc.pdf](http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/CMS_rtc.pdf).

The Medicare DMEPOS Market Pricing Program Act of 2013 (H.R. 1717) was introduced on April 24, 2013. The bill would require the Secretary to repeal the DMEPOS competitive bidding program, and establish a Market Pricing Program (MPP) to determine the prices of selected DMEPOS under Medicare Part B. The design parameters for the program, the conducting of the auctions, and other requirements, would be contracted out, based on criteria specified in the bill. The auctions for DMEPOS would be live auctions, and would be based on a reference item for each category. The prices of all other items in a category would be determined by their value relative to the representative item, as calculated by the contractor. Two items would be auctioned in each area and the winners of those auctions would be required to sign two-year contracts; the market-clearing prices resulting from those auctions would be applied to similar markets, with modifications, and, in general, any supplier willing to accept the MPP-determined price (for a product category that was not auctioned in the suppliers' area) could sell those products.

Additionally, the Secretary would be required to re-establish the Program Advisory and Oversight Committee (PAOC) for two years; the PAOC was originally established to provide advice to the Secretary on implementation of the competitive bidding program. Certain provisions of the competitive bidding program would also apply to the MPP, including the requirement that the OIG evaluate the bidding methodology, the supplier feedback requirement for missing financial documentation, and provisions determining the contents of contracts.

A portion of the cost of terminating the competitive bidding program and establishing the MPP would be paid through fee schedule reductions and rescission of budget authority in discretionary accounts, programs, projects, and activities (other than those in the Department of Defense or the Department of Veteran's Affairs.)

On June 14, 2013, H.R. 2375 was introduced. The bill would delay for at least six months the implementation of Round 1 Recompete and Round 2 of the competitive bidding program and national mail order program for diabetic supplies.

On June 27, 2013, S. 1265 was introduced. The bill would delay implementation of Round 2 in Tennessee. The Secretary would be required to terminate contracts for Round 2 winning suppliers in Tennessee and to rebid those contracts. The bill would also impose penalties on the implementation contractor for specified errors including awarding a contract to a DMEPOS supplier in Tennessee that did not meet state licensing requirements.

The Congressional Budget Office (CBO), responsible for preparing cost estimates of legislation pursuant to the Congressional Budget Act of 1974, has not yet issued cost estimates for the bills.



## **Appendix. A Selected History of DMEPOS Competitive Bidding Legislation, Demonstrations and Implementation**

The following is a legislative history of the DMEPOS Competitive Bidding Program, with descriptions of selected evaluations and congressional hearings for context.

### **The Balanced Budget Act of 1997 (BBA97, P.L. 105-33)**

Competitive bidding for DMEPOS was introduced in the BBA97, which required the Secretary to establish five three-year competitive bidding demonstration projects. Suppliers competed for contracts to furnish Medicare beneficiaries with selected items and services. The BBA97 required the Secretary to select areas for the demonstrations based on the availability and accessibility of suppliers, and on the likelihood that savings could be realized by competitive bidding. The Secretary was permitted to limit the number of winning suppliers. If the demonstrations decreased Medicare spending, the Secretary could expand the projects to other areas.

### **Demonstrations in Texas and Florida**

Three demonstrations were conducted in two different sites.<sup>106</sup> The first demonstration site was Polk County, FL. The Centers for Medicare & Medicaid Services (CMS) reviewed bids from 30 different suppliers for both quality and value. Based on these bids, Medicare established new payment rates for five categories of products: oxygen supplies and equipment, hospital beds and accessories, surgical dressings, enteral nutrition equipment and supplies, and urological supplies. To ensure beneficiary access and a choice of suppliers, between 4 and 13 suppliers were selected for each category (with 16 winning suppliers in total). New rates took effect on October 1, 1999. This phase of the demonstration, which ended in September 2001, saved the Medicare program and beneficiaries an estimated 16%-17% on covered items. A second round of bidding took place in Polk County in early 2001. The bidding was conducted on the same product categories minus enteral nutrition. Again, 16 winners were chosen to participate, of whom half had participated in the previous round. The prices went into effect on October 1, 2001. The Polk County demonstration ended September 30, 2002. This second round of the demonstration resulted in estimated savings of approximately 20%.

A second demonstration site in a three-county area around San Antonio, TX, began on February 1, 2001. The project covered oxygen supplies, hospital beds, manual wheelchairs, non-customized orthotic devices (including “off-the-shelf” items such as braces and splints), and certain nebulizer inhalation drugs used to treat lung disease and other conditions. Fifty-one suppliers were selected. This project saved Medicare and beneficiaries an estimated 20% over predicted expenditures before its termination in December 2002.

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<sup>106</sup> Tommy Thompson, *Final Report to Congress: Evaluation of Medicare’s Competitive Bidding Demonstration for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies*, Department of Health and Human Services, 2004, [http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/CMS\\_rtc.pdf](http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/CMS_rtc.pdf).

A final report to Congress by the Secretary of HHS evaluated the DMEPOS demonstrations by criteria including (1) Medicare expenditures, (2) beneficiary access, and (3) quality and product selection.

- Overall, the demonstrations in both sites saved an estimated 19% over what would have been paid under existing fee schedules. The demonstration reduced Medicare payments by an estimated \$7.5 million and beneficiary payments by \$1.9 million over the three-year period.
- Analyses of beneficiary and supplier surveys, and site visits, suggested that the demonstrations had little to no impact on access to goods and services, with one exception. Polk County, FL, experienced a decline in the use of portable oxygen equipment. These results were further analyzed using claims data, which confirmed a 3 percentage point decline in portable oxygen use overall, and a 12 percentage point decline among new users. Though it is possible that the demonstration could have induced suppliers to save money by reducing access to portable machines, there may have been other contributing factors, including an oxygen policy change coinciding with the initiation of the Polk County demonstration, which tightened Medicare eligibility for portable oxygen. Conversely, the San Antonio, TX, site did not show a decline in portable oxygen use.
- With respect to quality and product selection, beneficiary surveys showed high satisfaction with suppliers under the demonstration projects. Supplier surveys showed that products provided to beneficiaries changed little during the demonstration. Though it did not show up in either of the surveys, anecdotal reports pointed to issues surrounding urological supplies and wheelchair fitting and delivery. These instances were isolated, and “eventually self-correcting”<sup>107</sup> through a new round of bidding, changes in ordering documentation, and increased experience of the referral agents (such as hospital discharge planners) in directing beneficiaries to selected suppliers.

## **Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L. 108-173)**

MMA was signed into law on December 8, 2003. MMA required the Secretary to establish a competitive acquisition program (otherwise known as the competitive bidding program) for durable medical equipment.<sup>108</sup> The Secretary was permitted to first phase in items and services with the highest cost and highest volume, or those items and services that the Secretary determined had the largest savings potential. The Secretary could exempt items and services for which competitive bidding was not likely to result in significant savings.<sup>109</sup> When establishing competitive bidding areas, the MMA gave the Secretary the authority to exempt rural areas and

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<sup>107</sup> Tommy Thompson, *Final Report to Congress: Evaluation of Medicare’s Competitive Bidding Demonstration for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies*, Department of Health and Human Services, 2004, [http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/CMS\\_rtc.pdf](http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/CMS_rtc.pdf), p. 10.

<sup>108</sup> MMA substantially amended Section 1847 of the Social Security Act with the new competitive acquisition authority.

<sup>109</sup> MMA exempted specific items from inclusion in the program (1) inhalation drugs, (2) parenteral nutrients, equipment, and supplies, and (3) class III devices. Class III devices are typically those that support or sustain life.

areas with low population density within urban areas that are not competitive, unless a significant national market existed through mail order for a particular item or service.<sup>110</sup> MMA established a phase-in schedule as follows: 10 of the largest metropolitan statistical areas (MSAs) in 2007, 80 of the largest MSAs in 2009, and remaining MSAs after 2009.<sup>111</sup>

The Secretary was given the authority to establish a process where a physician could prescribe a particular brand or mode of delivery of an item or service within a particular healthcare procedure code (HCPCS) if the physician determined that doing so would avoid an adverse medical outcome for the beneficiary, although this could not affect the amount of payment otherwise applicable.

The MMA established certain requirements for the program. Specifically, contracts could only be awarded in an area if the following conditions were met:

- entities met quality standards established by the Secretary;
- entities met financial standards specified by the Secretary, taking into account the needs of small providers;
- total amounts paid under the contracts were expected to be less than otherwise paid; and,
- beneficiary access to multiple suppliers was maintained.

Contracts are subject to terms and conditions specified by the Secretary and must be re-competed at least every three years. The Secretary is required to award contracts to multiple entities submitting bids in each area for an item or service but has the authority to limit the number of contractors in a competitive bidding area to the number needed to meet projected demand for covered items and services.

Payment for competitively priced items and services must be based on bids submitted and accepted. The Secretary determines a single payment amount for each item or service in each competitive bidding area. Medicare payment is 80% of the payment amount, with beneficiaries paying the remaining 20% (after meeting the Part B deductible). Payment for any item or services can be made only on an “assignment-related” basis, which means that the supplier bills Medicare and accepts Medicare payment as payment in full.<sup>112</sup> The use of advanced beneficiary notice<sup>113</sup> is not precluded by this program.

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<sup>110</sup> Later legislation (MIPPA, P.L. 110-275) *requires* the Secretary to exempt certain areas, such as rural areas, prior to 2015. The Secretary’s decision criteria for choosing competitive bidding areas are summarized in the body of this report. CMS announced the competitive bidding areas for Round 1 and Round 2 of the program, as of February 2010. [http://www.cms.hhs.gov/DMEPOSCompetitiveBid/01a\\_MSAs\\_and\\_CBAs.asp#TopOfPage](http://www.cms.hhs.gov/DMEPOSCompetitiveBid/01a_MSAs_and_CBAs.asp#TopOfPage).

<sup>111</sup> The proposed rule for the program was published in the *Federal Register* on May 1, 2006. Two final rules were published in the *Federal Register* on August 18, 2006, and April 10, 2007. The first round of bidding closed on September 25, 2007, and the competitive bidding program started on July 1, 2008. The contracts were terminated, and the program was delayed by P.L. 110-275, as explained below. A rebid of the first round started in October 2009 and payment rates based on the rebid were used in the Round 1 areas starting on January 1, 2011.

<sup>112</sup> Outside of competitive bidding areas, assignment is optional and balanced billing limits do not apply.

<sup>113</sup> An advance beneficiary notice is given to a beneficiary when a supplier believes that Medicare may not cover the particular item. If Medicare does not cover the item and payment is not made, the beneficiary is liable for the payment to the supplier.

In establishing the categories and products subject to bidding, the Secretary can consider the clinical efficiency and the value of specific items within health care procedure codes, including whether some items have a greater therapeutic advantage to individuals. Small suppliers must have an opportunity to be considered for participation in the program. The Secretary cannot pay for items furnished by a contractor unless the contractor has submitted a bid to supply the item and the contract has been awarded. Certain provisions of the Federal Acquisition Regulation<sup>114</sup> that are necessary for the efficient implementation of this program can be waived, except confidentiality of information.

A Program Advisory and Oversight Committee with members appointed by the Secretary provided advice to the Secretary regarding the implementation of the program, data collection requirements, proposals for efficient interaction among manufacturers and distributors of the items and services, providers, and beneficiaries, the establishment of quality standards, and other functions specified by the Secretary. MMA sunset the committee on December 31, 2009.<sup>115</sup>

In a final rule for MMA published April 10, 2007, the Secretary described the methodology CMS uses in implementing the competitive bidding program. It includes descriptions of how CMS determines (1) competitive bidding areas, (2) items to be included in the program, (3) the winning suppliers, and (4) the payments for items. It includes considerations for small businesses.<sup>116</sup> A summary of the final rule can be found in the body of this report.

## **Implementation Concerns**

Congress held several hearings during which equipment suppliers and their representatives expressed concern about the Competitive Bidding Program and how it was being implemented.<sup>117</sup> Concerns about *implementation* focused on the following:

- supplier and beneficiary education,
- the system for submitting bids,
- rejection of bids based on missing information, and
- basis of calculations for winning bids and payment amounts.<sup>118</sup>

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<sup>114</sup> The Federal Acquisition Regulation governs acquisitions by the Executive Branch, in general.

<sup>115</sup> Subsequent legislation (MIPPA, P.L. 110-275) delayed the sunset of this committee until December 31, 2011.

<sup>116</sup> CMS, "Medicare Program: Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues," 72 *Federal Register* 17992-18090, April 10, 2007.

<sup>117</sup> U.S. Congress, House Committee on Ways and Means, Subcommittee on Health, *Hearing on Medicare's Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program*, 110<sup>th</sup> Cong., 2<sup>nd</sup> sess., May 6, 2008, <http://waysandmeans.house.gov/calendar/eventsingle.aspx?EventID=232364>. <http://www.gpo.gov/fdsys/pkg/CHRG-110hhr47175/html/CHRG-110hhr47175.htm>; The U.S. Congress, House Small Business Committee, Subcommittee on Healthcare and Technology, also held hearings just prior to the Round 1 implementation date, but testimony and transcripts are not available on the committee website.

<sup>118</sup> In his statement before the House Committee on Ways and Means, Tom Ryan from the American Association of Homecare referred to these implementation concerns. The testimony includes other concerns not specifically addressed in this report including the number of suppliers who will be prohibited from participating in Medicare under the competitive bidding program, reductions in services for beneficiaries, reductions in quality of equipment and services, and the potential burden on beneficiaries to coordinate their DMEPOS needs between several winning bidders. <http://www.gpo.gov/fdsys/pkg/CHRG-110hhr47175/html/CHRG-110hhr47175.htm>.

One concern was that there was not sufficient education for suppliers, and that some suppliers who wanted to bid may not have been able to navigate the bidding process or may have had to revise their bids. A subsequent analysis by GAO confirmed that “CMS had difficulty providing bidders with clear, timely information.”<sup>119</sup> GAO also found that CMS had not notified all suppliers of its post-bidding review process, discussed in more detail below.

Suppliers also argued that they should have been the ones to help educate the beneficiary community but were not asked to do so. CMS disagreed with this position and indicated that they had had “extensive communication” with beneficiaries, partner groups (the local Area Agencies on Aging, the State Health Insurance Assistance Programs [SHIPS]), beneficiary advocacy groups and other local organizations, providers (doctors, social workers, discharge planners and others), and DMEPOS suppliers. CMS indicated that supplier education started prior to the publication of the final rule and began formally on April 2, 2007.

Another concern was that the system for submitting bids was “primitive, cumbersome and fraught with problems resulting in excessive data input time and loss of submitted data. Frequently the system was non-operational and inaccessible.” CMS acknowledged difficulties with the online bidding system and indicated that the bidding window was extended to allow suppliers time to submit bids.

Suppliers expressed concern that some bids may have been rejected due to misplaced or overlooked documentation or rejected based on “financial stability” reasons without clarification about what that meant. CMS indicated that they reexamined bids that the implementation contractor had disqualified due to missing documentation to confirm that the packages were incomplete. CMS confirmed that it did not disclose exactly how the financial information was used to judge or score each bidder. A subsequent GAO analysis found that the CMS post-bid review process had not been effectively communicated to suppliers or consistently applied to bids. A post-bid review was conducted only on bids of suppliers who had contacted CMS with questions about their disqualification. As a result of the post-bid review, CMS found that 58 bids from 10 suppliers had been incorrectly disqualified (out of 1,935 bids from 357 suppliers reviewed); of these, 7 suppliers (submitting 27 bids) were ultimately offered contracts.<sup>120</sup>

## **Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, P.L. 110-275)**

The Medicare Competitive Bidding Program for DMEPOS started on July 1, 2008, in 10 designated competitive bidding areas, but when MIPPA became law on July 15, 2008, it stopped the program, terminated all contracts with suppliers, and required the Secretary to rebid the first round of the program in 2009.<sup>121</sup> MIPPA also includes provisions designed to address some of the

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<sup>119</sup> U.S. Government Accountability Office, *Medicare: CMS Working to Address Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program*, GAO-10-27, November 2009, p. 20, <http://www.gao.gov/new.items/d1027.pdf>.

<sup>120</sup> The GAO report also identified some questions about whether the post-bid review was an “administrative review” explicitly prohibited under the MMA, or whether it was a “quality assurance measure” which would not be explicitly prohibited under authorizing legislation. U.S. Government Accountability Office, *Medicare: CMS Working to Address Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program*, GAO-10-27, November 2009, pp. 27-30, <http://www.gao.gov/products/GAO-10-27>.

<sup>121</sup> Section 154, of MIPPA which delayed the competitive bidding program and made other changes, was first (continued...)

implementation issues identified in congressional hearings. The Congressional Budget Office (CBO) indicated that these provisions “will not have substantial budgetary effects” because the program delay and other changes were paid for through a decrease in payments for Medicare DMEPOS.<sup>122</sup> The following is a detailed description of the provisions in MIPPA that amended the Competitive Bidding Program for DMEPOS.

### **Termination of Contracts and Delay in Implementation**

MIPPA terminated all contracts awarded for Round 1 of the competitive bidding program and prohibited payments based on those contracts. To the extent that there were damages as a result of the terminations, MIPPA directed damages to be paid from the Federal Supplementary Medical Insurance (Part B) Trust Fund. The Secretary was required to conduct a new Round 1 competition in 2009. Previously identified competitive bidding areas for Round 1 (except Puerto Rico) and items and services (except negative pressure wound therapy and complex rehabilitative power wheelchairs) were to be included in the competition. MIPPA precluded suppliers from seeking administrative or judicial review of the contract termination for Round 1.

MIPPA delayed Round 2 until 2011. It also clarified that Round 2 *added 70* new competitive bidding areas to the program (resulting in 80 total areas), as identified by the Secretary as of June 1, 2008. The provision gave the Secretary the authority to subdivide an area with a population of at least 8 million for the purposes of the program.

MIPPA delayed when the Secretary can expand the program beyond the original 80 locations by two years (after 2011 instead of after 2009) except for national mail order items, which can be implemented after 2010. Prior to 2015, in expanding the program after the first two rounds, the Secretary is prohibited from expanding competitive bidding (other than national mail order) into the following locations (1) rural areas, (2) MSAs of fewer than 250,000 if not previously selected, and (3) areas with low population density within MSAs that are otherwise selected for competitive bidding.

MIPPA delayed the Secretary’s authority to use information from the program to adjust the payments for items and services in areas that are not competitive bidding areas by two years (from January 1, 2009, to January 1, 2011). Prior to exercising this authority, the Secretary must promulgate regulations describing the method to be used in adjusting rates.

### **Fee Schedule Reductions for Round 1 Items and Services**

The two-year delay in the program was paid for through reductions in the fee-schedule update. Specifically, MIPPA reduced the 2009 fee schedule update by 9.5% for all items, services, and related accessories identified prior to July 1, 2008, as part of Round 1 of the competitive bidding program. This reduction applied to *all areas*, regardless of whether the area was a competitive bidding area or not. For any item or service that was *not* identified as part of Round 1, the 2009 fee schedule update was the increase in the consumer price index (CPI-U) (the same as current

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(...continued)

introduced as H.R. 6252, the Medicare DMEPOS Competitive Acquisition Reform Act of 2008.

<sup>122</sup> Congressional Budget Office, *Cost Estimate of H.R. 6331, Medicare Improvements for Patients and Providers Act of 2008*, July 23, 2008, p. 6, <http://www.cbo.gov/ftpdocs/95xx/doc9595/hr6331pgo.pdf>.

law). For 2010 through 2013, the fee schedule update was the increase in the CPI-U. MIPPA had required a 2% increase in the fee schedule update for competitively bid items in 2014 (in addition to CPI-U), but the increase above the CPI-U was eliminated in the Patient Protection and Affordable Care Act (ACA, P.L. 111-148, as amended).

### **New Assessments and Opportunities for Feedback on Implementation**

The original authorizing legislation required several reports to evaluate program implementation. MIPPA required an additional evaluation, expanded the scope of one evaluation, and created an ombudsman's office for competitive acquisition, as described below.

The OIG must assess the process CMS used to conduct the competitive bidding program, and the pricing determinations used as the basis for the pivotal bid amounts and single payment amounts. This will be done to verify calculations for Rounds 1 and 2, as well as subsequent rounds.

MIPPA delayed a required GAO evaluation of the competitive bidding program from January 1, 2009, to no later than one year after the first date that payments are made under the program. MIPPA expanded the scope of the study to include an analysis of (1) beneficiary access to items and services including the impact on access of awarding contracts to bidders that did not have a physical presence in the area where they received the contract or had not previously provided the product category they were contracted to provide; (2) beneficiary satisfaction with the program and cost savings; (3) costs to the suppliers of participating in the program and recommendations on ways to reduce those costs without compromising quality standards or savings to Medicare; (4) the impact of the program on small businesses; (5) the impact on use of different items and services within the same Healthcare Common Procedure Coding System (HCPCS) code; (6) the costs to CMS, including payments to contractors, for administering the program compared to administration of the fee schedule, in comparison with relative savings of the program; (7) the impact on access, Medicare spending, and beneficiary spending of any difference in treatment for diabetic testing supplies depending on how the supplies are furnished; and, (8) other topics as the GAO determines appropriate.

### **Notification of Certain Missing Documents**

The Secretary must notify bidders if certain documents (covered documents)<sup>123</sup> are missing from their bids as of a specified date (the covered document review date). If the supplier receives a notice from the Secretary of missing covered documents and submits those documents to the Secretary, the Secretary is prohibited from rejecting the bid on the basis that the documents had been missing or had not been submitted on a timely basis. However, it does not prohibit the Secretary from rejecting the bid on another basis. The notification process only applies to the *timely* submission of documents and does not apply to determinations of the accuracy, completeness, or whether they meet other applicable requirements.

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<sup>123</sup> Only certain documents are subject to the notification process. Covered documents are defined as financial, tax or other documents required as part of a bid in order to meet financial standards; covered documents do not include other documents such as the bid itself, or accreditation documentation.

## **Accreditation**

MIPPA required all DMEPOS suppliers (directly or as a subcontractor) to submit evidence of accreditation by October 1, 2009. MIPPA identified a group of health care professionals for which the accreditation requirement did not apply unless the Secretary were to determine that the standards were designed specifically to be applied to those professionals. In addition, the Secretary had the authority to exempt other professionals from the accreditation requirement if the Secretary determined that licensing, accreditation, or other mandatory quality requirements applied to those professionals. MIPPA identified some of the professionals that might be subject to the provision, including physicians; physical or occupational therapists; physicians assistants; nurse practitioners; clinical nurse specialists; orthotists; and prosthetists. MIPPA specified that the added authority should not be construed as preventing timely implementation of the first round of the program.

MIPPA required contracted suppliers to inform the Secretary of each subcontractor and whether the subcontractor met accreditation requirements.

## **Additional Studies**

MIPPA required the Secretary to evaluate the HCPCS code for negative pressure wound therapy to ensure accurate reporting and billing for items and services under that code.<sup>124</sup>

Starting in the second round of the program, suppliers must demonstrate that their bid covers over 50% (or more as specified by the Secretary) of all types of diabetic test strips in use (in the aggregate and taking into account the volume of the different types of test strips). The volume of the types of test strips in use could be determined with data (such as marketing data) as recognized by the Secretary. The Inspector General was required to conduct a study to determine the types of diabetic test strips by volume that could be used to make this determination, and submit the report prior to the start of Round 2.

## **Items Exempt from Competition**

MIPPA exempted off-the-shelf orthotics and other durable medical equipment and medical supplies from competitive bidding when furnished by physicians or other practitioners (as defined by the Secretary) to their own patients as part of their professional service, or by a hospital to its own patients during an admission or on the date of discharge.

## **The Patient Protection and Affordable Care Act (ACA, P.L. 111-148, as Amended)**

The Patient Protection and Affordable Care Act became law on March 23, 2010. Section 6410 of ACA expands the number of areas that begin competitive bidding in Round 2 of the program from 70 to 91 MSAs. The 21 additional MSAs will be the next largest MSAs by population. The

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<sup>124</sup> The Healthcare Common Procedure Coding System (HCPCS) level II is a set of alpha-numeric codes for medical items or services. A HCPCS code can identify a broad category of similar items or services, or can identify a very specific item or service.



Secretary is also required to extend the program, or apply competitively bid rates, to remaining areas by 2016. The Congressional Budget Office (CBO) estimated that this provision would save Medicare \$0.3 billion for FY2010-FY2014 and \$1.4 billion for FY2010-FY2019.<sup>125</sup>

Section 3109 of ACA extended to January 1, 2011, the accreditation deadline for all pharmacies not participating in competitive bidding. Effective January 1, 2011, ACA also exempts certain pharmacies from the accreditation requirements, although all pharmacies will still be required to meet accreditation requirements to qualify for competitive bidding. The CBO score is \$0.0 billion for FY2010-FY2014 and \$0.0 billion for FY2010-FY2019.<sup>126</sup>

## **The American Taxpayer Relief Act of 2012 (ATRA, P.L. 112-240)**

The American Taxpayer Relief Act of 2012 requires the payments for diabetic supplies determined under the mail order competitive bidding program to also be applied to non-mail order diabetic testing supplies. In addition, within 30 days of enactment, but before payments based on competitive bidding are applied, the Secretary was required to recalculate and apply new payment rates to non-mail order diabetic supplies taking into account a 9.5% reduction in the payment update for 2009 that did not apply to those items in 2009. The CBO score is a \$0.6 billion savings for both FY2013-FY2017 and FY2013-FY2022.<sup>127</sup>

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<sup>125</sup> The CBO score on ACA, as amended, may be found at <http://www.cbo.gov/ftpdocs/113xx/doc11379/Manager'sAmendmenttoReconciliationProposal.pdf>.

<sup>126</sup> The CBO score on ACA, as amended, may be found at <http://www.cbo.gov/ftpdocs/113xx/doc11379/Manager'sAmendmenttoReconciliationProposal.pdf>. For more information, see CRS Report R41196, *Medicare Provisions in the Patient Protection and Affordable Care Act (PPACA): Summary and Timeline*.

<sup>127</sup> See, CRS Report R42944, *Medicare, Medicaid, and Other Health Provisions in the American Taxpayer Relief Act of 2012*.

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