Medicare Durable Medical Equipment: The Competitive Bidding Program

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August 6, 2010

Congressional Research Service
7-5700
www.crs.gov
R41211

CRS Report for Congress
Prepared for Members and Committees of Congress

c11173008

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) is used to serve a medical purpose, (3) generally is not useful in the absence of an illness or injury, and (4) 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. Unless otherwise specified by Congress, fee schedule amounts are updated each year by a measure of price inflation. However, investigations 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 locations.

Congress has enacted legislation to establish a Medicare competitive acquisition program (competitive bidding) under which prices for selected DMEPOS sold in specified areas would be determined not by a fee schedule, but by suppliers' bids. The first round of the competitive bidding program began on July 1, 2008, but was halted, due to implementation concerns. DMEPOS suppliers submitted new bids for the first round "rebid" in late October of 2009. The bidding window closed in December of that same year. Under current estimations by the Centers for Medicare and Medicaid Services (CMS), the program will start in January of 2011 in nine metropolitan areas.

Competitive bidding has been shown to decrease prices for DMEPOS, which could lead to savings for the Medicare program and lower cost sharing for the beneficiaries who use the items and services. Evidence from the competitive bidding demonstration also suggests that competition did not deteriorate beneficiary access to DMEPOS, or the quality and product selection available to them.

However, opponents may note that the implementation has been problematic, with poor communication and an inadequate bid submission system. It remains to be seen whether new legislative requirements (MIPPA, P.L. 110-275) and administration efforts will result in the effective implementation of the program. Finally, the competitive bidding program will result in fewer suppliers participating with Medicare. In general, Members of Congress often closely scrutinize or fail to support programs that have the potential to adversely affect companies or beneficiaries in their districts.

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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.[1]

Medicare covered durable medical equipment (DME) is equipment that (1) can withstand repeated use, (2) is used to serve a medical purpose, (3) generally is not useful in the absence of an illness or injury, and (4) is appropriate for use in the home.[2] Examples include hospital beds, blood glucose monitors, and wheelchairs. The benefit also includes related supplies, such as drugs and biologicals that are necessary for the effective use of the product.

Prosthetic and orthotic devices (PO) are items that replace all or part of an internal body organ, such as colostomy bags, pacemakers, and breast prostheses for postmastectomy patients, as well as such items as leg, arm, back, and neck 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.

As of April 2009, there were approximately 107,000 DMEPOS suppliers in the United States with Medicare billing privileges. Medicare expenditures for DMEPOS were $10.6 billion for CY2008. In FY2009, approximately 9.85 million Medicare beneficiaries used Medicare-covered DMEPOS.[3] According to the National Health Expenditure Accounts, Medicare spending on DMEPOS in CY2007 represented 28% of all spending on DMEPOS.[4]

Medicare generally pays for most DMEPOS on the basis of fee schedules. Unless otherwise specified by Congress, fee schedule amounts are updated each year by a measure of price inflation.[5] However, investigations by the Government Accountability Office (GAO)[6] and the Office of the Inspector General (OIG)[7] 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.

[1] Section 1862(a)(1)(A) of the Social Security Act.

[2] Section 1861(n) of the Social Security Act.

[3] Centers for Medicare and Medicaid Services, Office of Legislation.

[4] This is based on a CRS analysis of the National Health Expenditure Accounts. http://www.cms.hhs.gov/nationalhealthexpenddata/.

[5] The Consumer Price Index for all Urban Consumers (CPI-U).

[6] See General Accounting Office (GAO) report, "Medicare Payments for Oxygen," May 15, 1997, GAO-97-120R.

[7] See 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.

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 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 halted, contracts dissolved, and a rebid required due to implementation concerns. DMEPOS suppliers submitted new bids for the first round in late October of 2009. The bidding window closed in December of that same year. CMS estimates the program will start in January of 2011.

This report provides the legislative history of the Medicare DMEPOS Competitive Acquisition Program. It summarizes suppliers' implementation concerns and outlines various responses to those concerns: administrative responses, GAO analysis of implementation issues, and subsequent legislation to amend the program.

The Balanced Budget Act of 1997 (P.L. 105-33, BBA)

Competitive bidding for DMEPOS was introduced in the BBA, 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 BBA 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.[8] The first demonstration site was Polk County, FL. The Centers for Medicare and 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%.

[8] 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.

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 about 20% over predicted expenditures before its termination in December 2002.

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 $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. 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"[9] 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 (P.L. 108-173, MMA)

MMA was signed into law on December 8, 2003. MMA requires the Secretary to establish a competitive acquisition program for durable medical equipment.[10] The Secretary is permitted to

[9] 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, p. 10.

[10] MMA substantially amended Section 1847 of the Social Security Act with the new competitive acquisition authority.

first phase in items and services with the highest cost and highest volume, or those items and services that the Secretary determines have the largest savings potential. The Secretary may exempt items and services for which competitive acquisition would not be likely to result in significant savings.[11] When establishing competitive acquisition areas, the MMA gives the Secretary the authority to exempt rural areas and areas with low population density within urban areas that are not competitive, unless a significant national market exists through mail order for a particular item or service.[12] 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.[13]

Rental agreements for covered DME will be fulfilled regardless of whether the supplier wins a contract to serve the area. Also, the Secretary is given the authority to establish a process where a physician would be able to prescribe a particular brand or mode of delivery of an item or service within a particular healthcare procedure code (HCPCS) if the physician determines 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 establishes certain requirements for the program. Specifically, contracts can only be awarded in an area if the following conditions are met:

- entities meet quality standards established by the Secretary;
- entities meet financial standards specified by the Secretary, taking into account the needs of small providers;
- total amounts paid under the contracts are expected to be less than otherwise paid; and
- beneficiary access to multiple suppliers is 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 acquisition 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 acquisition area. Medicare payment is 80% of the payment amount, with beneficiaries paying the remaining 20% (after meeting the Part B deductible). Payment for any

[11] 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.

[12] 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 **Appendix** to this report. CMS announced the competitive acquisition 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.

[13] 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 is slated to begin in January 2011.

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.[14] The use of advanced beneficiary notice[15] is not precluded by this program.

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[16] 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 provides 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.[17]

In a final rule for MMA published April 10, 2007, the Secretary described the methodology CMS will use in implementing the competitive bidding program. It includes descriptions of how CMS will determine (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.[18] A summary of the final rule can be found in the **Appendix** to this report.

Implementation Concerns

Congress held several hearings during which equipment suppliers and their representatives expressed concern about the Competitive Acquisition Program and how it was being implemented.[19] Concerns about *implementation* focus on the following:

- Supplier and beneficiary education.
- The system for submitting bids.

[14] Outside of competitive bidding areas, assignment is optional and balanced billing limits do not apply.

[15] 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.

[16] The Federal Acquisition Regulation governs acquisitions by the Executive Branch, in general.

[17] Subsequent legislation (MIPPA, P.L. 110-275) delayed the sunset of this committee until December 31, 2011.

[18] 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.

[19] 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*, 110th Cong., 2nd sess., May 6, 2008, http://waysandmeans.house.gov/Hearings/hearingDetails.aspx?NewsID=10346; The House Small Business Committee also held hearings. The Committee website does not include hearing transcripts or witness testimony, but video clips of portions of the hearings are available on U-Tube.

- Rejection of bids based on missing information.
- Basis of calculations for winning bids and payment amounts.[20]

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."[21] GAO also found that CMS had not notified all suppliers of its postbidding 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.[22] 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 Program [SHIPS]), beneficiary advocacy groups and other local organizations, providers (doctors, social workers, discharge planners and others), and DMEPOS suppliers.[23] 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."[24] CMS acknowledged difficulties with the online bidding system and indicated that the bidding window was extended to allow suppliers time to submit bids.[25]

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.[26] 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

[20] 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://waysandmeans.house.gov/Hearings/Testimony.aspx?TID=1967.

[21] 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.

[22] http://waysandmeans.house.gov/Hearings/Testimony.aspx?TID=1967.

[23] Testimony of Kerry Weems, Acting Administrator for CMS on DMEPOS Competitive Bidding Program before the House Committee on Ways and Means, May 6, 2008. http://waysandmeans.house.gov/Hearings/Testimony.aspx?TID=1965.

[24] Testimony of Tom Ryan, American Association of Home Care on DMEPOS Competitive Bidding Program before the House Committee on Ways and Means, May 6, 2008. http://waysandmeans.house.gov/Hearings/Testimony.aspx?TID=1967.

[25] See the transcript to the May 6, 2008, Ways and Means hearing. http://waysandmeans.house.gov/hearings.asp?formmode=view&id=7569.

[26] Testimony of Tom Ryan, American Association of Home Care on DMEPOS Competitive Bidding Program before the House Committee on Ways and Means, May 6, 2008. http://waysandmeans.house.gov/Hearings/Testimony.aspx?TID=1967.

used to judge or score each bidder.[27] 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.[28]

Lastly, suppliers were concerned that the process CMS used to determine how many bidders were needed to supply a particular market and the calculation of the winning bid amounts were not clear.[29] Though these issues were not addressed by CMS at the hearing, the final rule to MMA implementing the DMEPOS Competitive Acquisition program explains that process, as discussed in the **Appendix**.

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

The Medicare Competitive Acquisition 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.[30] MIPPA also includes provisions designed to address some of the 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.[31] The following is a detailed description of the provisions that amended the Competitive Acquisition Program for DMEPOS.

Termination of Contracts and Delay in Implementation

MIPPA terminated all contracts awarded for the first round 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 Trust Fund. The Secretary was required to conduct a new round 1 competition

[27] See the transcript to the May 6, 2008, Ways and Means hearing. http://waysandmeans.house.gov/Hearings/transcript.aspx?NewsID=10346.

[28] 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/new.items/d1027.pdf.

[29] Testimony of Tom Ryan, American Association of Home Care on DMEPOS Competitive Bidding Program before the House Committee on Ways and Means, May 6, 2008. http://waysandmeans.house.gov/Hearings/Testimony.aspx?TID=1967.

[30] Section 154, of MIPPA which delayed the competitive bidding program and made other changes, was first introduced as H.R. 6252, the Medicare DEMPOS Competitive Acquisition Reform Act of 2008.

[31] 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.

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 delays the second round of bidding until 2011. It also clarifies that round 2 *adds 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 gives the Secretary the authority to subdivide an area with a population of at least 8 million for the purposes of the acquisition program.

MIPPA delays 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) metropolitan statistical areas (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 acquisition.

MIPPA delays the Secretary's authority to use information from the program to adjust the payments for items and services in areas that are not competitive acquisition 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 acquisition program. This reduction applied to *all areas*, regardless of whether the area was a competitive acquisition 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 law). For 2010 through 2013, the fee schedule update will be the increase in the CPI-U; this will apply to all items and services outside competitive bidding areas. For 2014, the fee schedule update will be the increase in the CPI-U plus 2 percentage points for items and services that (1) had received a 9.5% fee schedule reduction in 2009, (2) had not been subject to a payment adjustment based on the Secretary's authority to adjust payments outside of competitive areas based on data from competitive acquisition, and (3) were not part of a competitive bidding area.[32] For all other items and services, the update for 2014 will be the increase in the CPI-U.

[32] Subsequent legislation (PPACA, P.L. 111-148) eliminated the 2% update for specified items in 2014. CRS Report R41196, *Medicare Provisions in the Patient Protection and Affordable Care Act (PPACA): Summary and Timeline.*

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 Inspector General 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 acquisition program from January 1, 2009, to not later than one year after the first date that payments are made under the program. MIPPA expanded the scope of the study, which must include (1) an analysis of 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) an analysis of beneficiary satisfaction with the program and cost savings; (3) an analysis of 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) an analysis of the impact of the program on small businesses; (5) an analysis of the impact on use of different items and services within the same Healthcare Common Procedure Coding System (HCPCS) code; (6) an analysis of 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) an analysis of 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.

A competitive acquisition ombudsman must be established within CMS to respond to complaints and inquiries made by suppliers and individuals. The new ombudsman may be within the office of the Medicare Beneficiary Ombudsman. The new ombudsman must submit a yearly report to Congress.

Notification of Certain Missing Documents

The Secretary must notify bidders if certain documents (covered documents[33]) 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 or completeness, or whether they meet other applicable requirements.

[33] 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 has the authority to exempt other professionals from the accreditation requirement if the Secretary determines that licensing, accreditation, or other mandatory quality requirements applied to those professionals. MIPPA identified some of the professionals that may 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 requires contracted suppliers to inform the Secretary of each subcontractor and whether the subcontractor met accreditation requirements.

Deadline Adjustments to Account for Delay in Implementation

MIPPA delayed a required GAO evaluation of the program from January 1, 2009, to not later than one year after the first date that payments are made under the program, as mentioned above.

MIPPA delayed the termination of the Program Advisory and Oversight Committee by three years (December 31, 2009, to December 31, 2011). It delayed by two years the due date of a report by the Secretary on the savings, decreased cost sharing, access to and quality of items and services, and satisfaction of individuals involved with the competitive acquisition program (July 1, 2011, instead of July 1, 2009). It delayed by three years the due date of a report by the Inspector General on the extent to which (if any) suppliers of covered items were soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability.

Additional Studies

MIPPA requires 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.[34]

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 must 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 the second round of the program.

[34] 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.

Items Exempt from Competition

MIPPA exempted off-the-shelf orthotics and other durable medical equipment and medical supplies from competitive acquisition 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 (P.L. 111-148, PPACA)

The Patient Protection and Affordable Care Act became law on March 23, 2010. Section 6410 of PPACA 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 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.[35]

Section 3109 of PPACA extends to January 1, 2011, the accreditation deadline for all pharmacies not participating in competitive bidding. Effective January 1, 2011, PPACA 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.[36]

Current Timeline

CMS published a tentative implementation time line for the round 1 rebid. The following are selected dates from that timeline.[37] CMS has met this timeline thus far.

- October 21, 2009—CMS opens 60-day bid window for round 1 rebid.
- November 21, 2009—Covered document review date for bidders to submit financial documentation.
- December 21, 2009—60-day bidding window closes.
- July 2010—CMS announces single payment amounts and begins contracting process.
- September 2010—Target date for CMS to announce contract suppliers and begin contract supplier education campaign.

[35] The CBO score on PPACA combined with the Reconciliation Act, may be found at http://www.cbo.gov/ftpdocs/113xx/doc11379/Manager'sAmendmenttoReconciliationProposal.pdf.

[36] The CBO score on PPACA combined with the Reconciliation Act, 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*.

[37] For the full implementation time line, see http://www.cms.gov/DMEPOSCompetitiveBid/01A0_Timeline.asp#TopOfPage.

- Fall 2010—Target date for CMS to begin education campaign for suppliers, referral agents, and beneficiaries.
- January 1, 2011—Target date for implementation of Medicare DMEPOS Competitive Bidding Program Round 1 Rebid contracts and prices.

On July 2, 2010, CMS announced the single payment amounts for items and services included in the round 1 rebid for each of the nine competitive bidding areas. The single payment amount for an item or service is based on the median of the bids for that item among all winning bidders in that area. Therefore, the single payment amounts for the same item may vary between areas. Overall, the payment amounts under competitive bidding are projected by CMS to result in average savings of 32% compared to the current fee schedule prices.[38]

Legislation Introduced in the 111th Congress

Prior to the passage of PPACA, H.R. 3790 was introduced on October 13, 2009. H.R. 3790 would repeal the DMEPOS competitive bidding program and would require specified reductions to the fee schedule updates:

- For 2010 through 2012, the bill would require a quarter of a percentage point reduction in the fee schedule amounts for all items except complex rehabilitative power wheelchairs classified as group 3 or higher, which would increase by CPI-U.
- For 2013, the bill would require a fee schedule update of CPI-U for items.
- For 2014, the bill would require a fee schedule update of CPI-U for items except complex rehabilitative power wheelchairs classified as group 3 or higher, which would increase by CPI-U plus 2 percentage points.
- For 2015, the bill would require a half of a percentage point reduction in the fee schedule amounts for all items except complex rehabilitative power wheelchairs classified as group 3 or higher, which would increase by CPI-U.

The Congressional Budget Office (CBO), which prepares cost estimates of legislation pursuant to the Congressional Budget Act of 1974, has not yet issued a cost estimate of this legislation. Therefore, it is unclear whether or not this bill is budget neutral.

No other legislation specifically amending the DMEPOS competitive bidding program has been introduced.

[38] http://www.cms.gov/DMEPOSCompetitiveBid/01A1_Announcements_and_Communications.asp#TopOfPage. For information about specific single payment amounts, see http://www.dmecompetitivebid.com/Palmetto/Cbic.nsf/files/SPA_All_Product_Categories.pdf/$File/SPA_All_Product_Categories.pdf?Open&cat=Suppliers~Single%20Payment%20Amounts.

Concluding Observations

Studies have shown that Medicare pays above-market prices for certain items of DME. Competitive bidding has been shown to decrease those prices as evidenced during the Medicare demonstrations and the first round of the program. Decreased prices mean (1) Medicare pays less out of the Part B trust fund for covered services, (2) beneficiaries who pay 20% cost sharing on DMEPOS will pay less, and (3) the Part B premiums paid by all beneficiaries, which are generally set at 25% of estimated Part B expenditures might also be lower, though the effect on Part B premiums is likely to be very small.[39]

Evidence from the competitive bidding demonstrations also suggests that competition did not deteriorate beneficiary access to DMEPOS, or the quality and product selection available to them.

Competitive bidding may also result in less fraud and abuse partly because there will be fewer suppliers to oversee, but also because the bidding process requires a greater level of oversight.

However, opponents may note that implementation has been problematic with poor communication and an inadequate bid submission system. It remains to be seen whether new legislative requirements (MIPPA, P.L. 110-275) and administration efforts will result in effective implementation of the program.

Finally, the competitive bidding program will result in fewer suppliers participating with Medicare. In general, Members of Congress have often closely scrutinize or fail to support supported programs that have the potential to adversely affect companies or beneficiaries in their districts.

[39] For more information on Medicare Part B premiums, see CRS Report R40082, *Medicare: Part B Premiums*.

Appendix. Summary of Regulation

In a final rule to the MMA (P.L. 108-173) published April 10, 2007, the Secretary described the methodology CMS will use in implementing the DMEPOS Competitive Acquisition program. It included descriptions of how CMS will determine (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.[40]

Determination of Competitive Bidding Areas

The statute required CMS to establish and implement the DMEPOS Competitive Bidding Program and specified a phase-in schedule, which was amended by subsequent legislation.

The final regulation outlined a multi-step process for selecting the Competitive Bidding Areas (CBAs) for the first round of the program. First, the 50 MSAs with the greatest population size in the United States 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. The score was based on (1) DMEPOS charges per Medicare beneficiary in CY2004, and (2) the number of DMEPOS suppliers per Medicare beneficiary receiving an item of DMEPOS in CY2004, 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 program in such large areas.[41] Fifth, MSAs in areas served by two DME Medicare Administrative Contractors (DME MAC) were excluded, also due to complexity. Sixth, the top six MSAs were selected to be CBAs as long as no state had more than two CBAs. Finally, CMS ensured that each DME MAC region contained at least one CBA. The final rule did not name the CBAs for the first or second round of the program, but this information is available through the program implementation contractor.[42] The first 10 MSAs for the Competitive Bidding Program are as follows:

- Charlotte-Gastonia-Concord, NC-SC.
- Cincinnati-Middletown, OH-KY-IN.
- Cleveland-Elyria-Mentor, OH.
- Dallas-Fort Worth-Arlington TX.
- Kansas City, MO-KS.
- Miami-Fort Lauderdale-Miami Beach, FL.
- Riverside-San Bernardino-Ontario, CA.

[40] The Centers for Medicare and 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.

[41] This provision eliminated New York, Los Angeles and Chicago from the first found of the competitive bidding program. However, the final rule does not eliminate them from participation in the second round.

[42] http://www.dmecompetitivebid.com/cbic/cbic.nsf/(pages)/home.

- Orlando-Kissimmee, FL.
- Pittsburgh, PA.
- San Juan-Caguas-Guaynabo, PR.

According to the final rule, the process for identifying the 80 MSAs to participate in the second round of the program would be substantially the same. The scoring criteria would be the same; however, newer data would be used. Also, the three largest MSAs and MSAs that cross the DME MAC boundaries would not be excluded.

The statute gave CMS the authority to exempt certain rural areas or areas with a low population density within MSAs, unless those areas comprise a significant mail order market. The final rule stipulated that CMS must use its authority to exempt areas if data analyses show that areas are not competitive as demonstrated by one or more of the following: low number of DMEPOS items or low allowable charges relative to similar areas; low number of suppliers relative to similar areas; or a low number of Medicare beneficiaries relative to similar areas.

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 apply: (1) the area is contiguous to the MSA; (2) the area is not otherwise a part of a different CBA; (3) the area is competitive as evidenced by high use of DMEPOS, significant expenditures, or a large number of suppliers; and (4) the area is 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.[43]

The final rule also established a nationwide, or region-wide, mail order competitive bidding program. CMS analyses found over 60% of Medicare expenditures on diabetic supplies, for example, were furnished by mail order.[44]

Determination of Items to Be Included in the Program

The MMA authorized CMS to phase in competitive bidding first among the items with the highest cost, highest volume, or those with the greatest savings potential. Certain items were specifically excluded from the competitive bidding program, including inhalation drugs, parenteral nutrients, equipment and supplies, and class III medical devices defined as those that sustain or support life, are implanted, or present potential unreasonable risk.

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.
- The savings for the item during the DMEPOS demonstrations.[45]

[43] http://www.dmecompetitivebid.com/cbic/cbic.nsf/(pages)/home.

[44] *Federal Register*, vol. 72, no. 68, April 10, 2007, p. 18018.

- 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. The final rule did not publish the items to be included in the competitive program, but they are available on the implementation contractor's website.[46]

Similar items are grouped together in product categories. A supplier must submit a bid for every item included in the product category. A supplier may bid for one or more groups of items.

Determination of Winning Suppliers in a Competitive Bidding Area

All suppliers in a competitive bidding area who meet quality and financial requirements may bid to supply an entire product category of DME items. The product categories are groupings of items used to treat a related medical condition. For example, oxygen supplies and equipment are combined into a single group and any supplier who wants to provide oxygen supplies in a CBA must bid on every item within the category and provide an estimate of the amount of product that could be supplied. For each product category bid that a supplier submits, a "composite bid" is calculated. The composite bid is a weighted average of the items within the category where the weight is based on historic Medicare claims. The composite bids 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 would be sufficient to meet the demand in the area. All suppliers with composite bids at or below the pivotal bid would be offered contracts to provide the category of goods to Medicare beneficiaries in the CBA. There must be at least two winning bids. All suppliers with composite bids above the pivotal bid would be denied contracts, with one exception. CMS established a target that 30% of suppliers 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 single payment amounts paid to all other suppliers in 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.[47]

Determination of Payment for Competitively Bid Items

The payment for each competitively bid item supplied to a beneficiary whose permanent residence is in a CBA[48] is based on the median of the bids for that item among all suppliers who

(...continued)

[45] 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 ago 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.

[46] http://www.dmecompetitivebid.com/cbic/cbic.nsf/(pages)/home.

[47] *Federal Register*, vol. 72, no. 68, April 10, 2007, p. 18071.

[48] If a beneficiary lives in a CBA but needs an item of DME while traveling outside of the CBA, the beneficiary would (continued...)

won contracts to provide a category of goods (such as oxygen supplies and equipment, or hospital beds and related supplies) within the CBA. The single payment amount must be less than the current fee schedule amount.

The Medicare payment for a competitively bid item is based on an assignment-related basis equal to 80% of the applicable single payment amount, less any unmet Part B deductible. The beneficiary pays the remaining 20% of the applicable single payment amount.

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 particular rate. For competitively bid items requiring frequent or substantial servicing, or for oxygen or oxygen equipment, the grandfathered supplier would have to agree to accept the single payment amount determined under the competitive bidding program. For all other items under the competitive bidding program, the grandfathered supplier would have to agree to accept the payment based on the existing rental agreement.

The final rule established additional safeguards and payment adjustments. For example, the final rule establishes 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 provider to a contract provider. The final rule also includes 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.

Provisions for Small Businesses

The MMA required CMS to take steps to ensure that small suppliers have an opportunity to be considered for participation in the DMEPOS Competitive Bidding Program. Also, the MMA stipulated that the needs of small suppliers are to be taken into account with respect to financial standards.

CMS found that the majority of suppliers of DMEPOS were considered small businesses under 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. Most Medicare DMEPOS suppliers would likely be categorized as "small businesses" under this definition.

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

(...continued)

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.

- The selection of multiple suppliers for each CBA, thus increasing the chance that the smaller providers would be able to participate.
- Separate bidding competitions for product categories, which may encourage small businesses that specialize in a type of equipment to apply.
- 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 definition of "small suppliers" as Medicare DMEPOS suppliers that generate gross revenues of $3.5 million or less in annual receipts.
- Established a target number of DMEPOS small suppliers participating in each competitive bidding program—30%—as discussed above.
- The ability of small suppliers to establish networks for bidding purposes so that small providers could work together to provide all of the items in a bid category throughout the entire CBA.[49]

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[49] The final rule indicated that many commenters believed the proposed rule on the requirements necessary for networking to be too complex. Some commenters considered the burdens of this process so great that it was not a beneficial option for some small providers.