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MEDICARE

CMS Has Addressed Some Implementation Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program for the Round 1 Rebid

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Highlights

Highlights of GAO-10-1057T, a testimony before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives

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Why GAO Did This Study

To reduce spending on durable medical equipment (DME) and related items, under federal law the Centers for Medicare & Medicaid Services (CMS) is phasing in, with several rounds of bidding, a competitive bidding program (CBP) for certain DME and other items. Because of numerous concerns, the Medicare Improvements for Patient and Providers Act of 2008 (MIPPA) terminated the CBP round 1 supplier contracts and required CMS to repeat the CBP round 1, the rebid that began in 2009.

In November 2009, GAO issued the report *Medicare: CMS Working to Address Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program* (GAO-10-27) that documented problems in CMS's implementation of CBP round 1. This statement discusses some of the problems GAO identified and how CMS has or plans to address them in the ongoing CBP rebid bidding process, particularly (1) the bid submission information provided to suppliers, (2) the electronic bid submission system, and (3) the bid disqualification notification process.

For the 2009 report, GAO reviewed data provided by CMS and relevant laws and regulations, and interviewed CMS officials. For this statement, GAO also obtained select information on how CMS addressed the CBP round 1 problems identified in GAO's report by reviewing agency documents and interviewing CMS officials in August and September 2010.

View GAO-10-1057T or key components.
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What GAO Found

In the November 2009 report on CBP round 1, GAO noted that problems with the bidding process included poor timing and lack of clarity in bid submission information and the inability to inform suppliers of missing financial documentation. Several times after the CBP round 1 bid window opened, CMS provided new bidding information and clarified other bidding information. The bid window was also extended beyond the initial deadline. These changes made it more difficult for suppliers to submit correct bids. CMS improved implementation of these steps in the bidding process for the CBP round 1 rebid. For example, for the CBP round 1 rebid, CMS provided bidding information to suppliers prior to the bid window opening, including the rebid's request-for-bid instructions, which were available to potential bidding suppliers for over 2 months before the bid window opening. CMS also provided clearer financial documentation instructions and additional financial documentation tools to guide suppliers in the CBP round 1 rebid. For example, the request-for-bid instructions included a chart that more clearly explained which documents were to be submitted by the supplier's business type, for example, a sole proprietorship. CMS also conducted a financial document review during the round 1 rebid, which informed suppliers whether their bid submission was missing required financial documents. Of the 321 suppliers that were notified they had missing documentation, only 14 did not subsequently submit the missing documents.

As CMS acknowledged, suppliers had difficulty entering bidding information in the bid submission system used in CBP round 1 and its user guide was not sufficiently detailed. CMS developed a new electronic bid submission system for the CBP round 1 rebid. CMS officials told us that the new system did not have significant operational issues and only a few suppliers experienced minor problems.

GAO found that CMS had not effectively notified all suppliers about the opportunity for a postbidding review process in CBP round 1. To address GAO's 2009 recommendation that the agency effectively notify all suppliers of all aspects of the CBP round 1 rebid and future rounds, including any process to review disqualifications, CMS officials stated that the agency plans to notify the losing suppliers of the disqualification reasons by sending each of these suppliers a letter that will explain the process for asking questions or expressing concerns. Officials also stated that in the course of responding to suppliers' questions or concerns, if CMS determines an error was made, it is possible that the supplier may be offered a contract.

In commenting on the information presented in this testimony, CMS officials stated they appreciated GAO noting the administrative improvements to the competitive bidding process the agency made for the round 1 rebid. The officials further stated that they believe that CMS made many improvements to the CBP.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss the Medicare[1] competitive bidding program for selected durable medical equipment (DME) and certain other items.[2] My testimony today is focused on how the Centers for Medicare & Medicaid Services (CMS)[3] is addressing bidding process problems we identified during round 1 of the competitive bidding program—conducted from 2007 to 2008—in our November 2009 report,[4] and steps CMS has taken to address those problems for the program's round 1 rebid bidding process, which is currently under way. Competitively determined Medicare payments for items and services covered under the round 1 rebid will be effective on or after January 1, 2011.

In 2009, Medicare spent $8.1 billion on DME, other items, and related supplies.[5] Since 1989, Medicare has paid for most DME through fee schedules. Medicare payment for DME is generally equal to 80 percent of the lesser of either the supplier's actual charge or the Medicare fee schedule for a particular item or service.[6] Both we and the Department of Health and Human Services' (HHS) Office of Inspector General have reported that Medicare and its beneficiaries have sometimes paid higher-

[1]Medicare is the federal health insurance program that currently serves about 46.3 million elderly and disabled individuals.

[2]DME is equipment that serves a medical purpose, can withstand repeated use, is generally not useful in the absence of an illness or injury, and is appropriate for use in the home. Items covered by the competitive bidding program include selected DME and related supplies and enteral nutrients and related equipment and supplies.

[3]CMS is an agency within the Department of Health and Human Services that has responsibility for administering the Medicare program.

[4]See GAO, *Medicare: CMS Working to Address Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program*, GAO-10-27 (Washington, D.C.: Nov. 6, 2009). Other related GAO products are listed at the end of this statement.

[5]Other items include prosthetic devices (other than dental), which are defined as devices needed to replace body parts or functions, such as artificial limbs, enteral nutrition, and cardiac pacemakers, and orthotic devices, which are defined as providing rigid or semirigid support to weak or deformed body parts or restricting or eliminating motion in a diseased or injured part of the body, such as leg, arm, back, and neck braces. Medicare-reimbursed supplies are items that are used and consumed with DME, such as drugs used for inhalation therapy, or that need to be replaced frequently (usually daily), such as surgical dressings.

[6]Medicare adjusts fee schedules for DME for each state, reflecting geographic price differences which are subject to national floor and ceiling limits.

than-market rates for various medical equipment and supply items.[7] These overpayments increase costs to both Medicare and its beneficiaries.[8] As we have previously stated, competitive bidding can reduce Medicare program payments by providing an incentive for suppliers to accept lower payment amounts for items and services to retain their ability to serve Medicare beneficiaries and potentially increase their market share.[9]

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003,[10] required CMS to phase in a competitive bidding program (CBP) for DME suppliers. CMS contracted with Palmetto GBA to implement the CBP bidding and contract award process and with Maricom to develop a Web-based electronic bid submission system. CBP round 1 was conducted in 2007 and 2008 for 10 competitive bidding areas.[11] For the bidding, CMS chose certain DME items in 10 product categories—generally high cost and high volume items and services—that were most likely to result in

[7]GAO, *Medicare: Competitive Bidding for Medical Equipment and Supplies Could Reduce Program Payments, but Adequate Oversight Is Critical*, GAO-08-767T , (Washington, D.C.: May 6, 2008); GAO, *Medicare: Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies*, GAO-04-765, (Washington, D.C.: Sept. 7, 2004); Department of Health and Human Services Office of Inspector General, *A Comparison of Prices for Power Wheelchairs in the Medicare Program*, OEI-03-03-00460 (Washington, D.C.: April 2004); and Janet Rehnquist, Inspector General, Department of Health and Human Services, *Medicare Reimbursement for Medical Equipment and Supplies*, testimony before the Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, and Education, 107th Cong., 2nd sess., June 12, 2002.

[8]In general, Medicare beneficiaries pay 20 percent of the Medicare reimbursement rate for DME after reaching their annual deductible.

[9]GAO-08-767T.

[10]Pub. L. No. 108-173 § 302(b), 117 Stat. 2066, 2224 (2003) (codified, as amended, at 42 U.S.C. § 1395w-3). In this statement, we refer to the competitive acquisition program as the competitive bidding program.

[11]To begin the program's national phase-in, the CBP round 1's 10 competitive bidding areas were chosen from the largest metropolitan statistical areas (MSA). The 10 CBAs had to be selected from the largest MSAs. The 10 CBAs were Charlotte (Charlotte-Gastonia-Concord, North Carolina and South Carolina); Cincinnati (Cincinnati-Middletown, Ohio, Kentucky, and Indiana); Cleveland (Cleveland-Elyria-Mentor, Ohio); Dallas (Dallas–Fort Worth–Arlington, Texas); Kansas City (Kansas City, Missouri and Kansas); Miami (Miami–Fort Lauderdale–Miami Beach, Florida); Orlando (Orlando-Kissimmee, Florida); Pittsburgh (Pittsburgh, Pennsylvania); Riverside (Riverside–San Bernardino–Ontario, California); and San Juan (San Juan–Caguas–Guaynabo, Puerto Rico).

Medicare savings if competitively acquired.[12] The round 1 suppliers submitted bids for supplying one or more of these 10 DME product categories in 1 or more of the 10 competitive bidding areas. There were 6,374 bids submitted by 1,010 suppliers. In March 2008, CMS began offering contracts to winning suppliers to provide DME to Medicare beneficiaries. The contracts between CMS and suppliers became effective on July 1, 2008.

Round 1's bid submission and contract award processes raised concerns about the CBP implementation. Therefore, on July 15, 2008, implementation of the CBP round 1 was stopped—after 2 weeks—by the enactment of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), which terminated the contracts already awarded to suppliers, delayed the program's restart, and required CMS to repeat the competition for CBP round 1 in 2009[13]—referred to in this statement as the CBP round 1 rebid.[14] MIPPA also imposed additional criteria for how CMS should conduct later CBP rounds, including the round 1 rebid and subsequent rounds that will expand the CBP to additional areas.[15]

[12]CBP round 1's 10 product categories were oxygen supplies and equipment; standard power wheelchairs, scooters, and related accessories; complex rehabilitative power wheelchairs and related accessories; mail-order diabetic supplies; enteral nutrients, equipment, and supplies; continuous positive airway pressure devices, respiratory assist devices, and related supplies and accessories; hospital beds and related accessories; negative pressure wound therapy pumps and related supplies and accessories; walkers and related accessories; and support surfaces (limited to group 2 mattresses and overlays—pressure reducing support surfaces for persons with or at high risk for pressure ulcers—in the Miami and San Juan CBAs only).

[13]Pub. L. No. 110-275, § 154, 122 Stat, 2494, 2560 (2008) (codified, as amended, at 42 U.S.C. § 1395w-3).

[14]To ensure budget neutrality, that is, to compensate for the loss of the projected savings from the CBP's round 1 delay, beginning January 1, 2009, MIPPA reduced the national Medicare reimbursement payments by 9.5 percent nationally for items and services that had been included in CBP round 1.

[15]CMS issued an interim final rule implementing these MIPPA provisions. Centers for Medicare & Medicaid Services, *Medicare Program: Changes to the Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) by Certain Provisions of MIPPA*, 74 Fed. Reg. 2873 (Jan. 16, 2009). In this rule, CMS clarified that with the exception of the new provisions in this rule, the CBP final rule published on April 10, 2007, *Medicare Program: Competitive Acquisition for Certain DMEPOS and Other Issues*, 72 Fed. Reg. 17, 992, would continue to govern implementation of the CBP for DME and other items.

Our November 2009 report documented round 1 implementation problems. We found, for example, that CMS did not provide suppliers with timely and clear bid submission information, used an inadequate electronic bid submission system, and did not have a process to inform bidders of missing financial documentation—42 percent of all submitted bids were disqualified due to incomplete financial documentation. In our report, we recommended that if CMS decides to review suppliers' disqualified bids during the round 1 rebid and future rounds, it should notify all suppliers of any such process, give suppliers equal opportunity for such reviews, and clearly indicate how suppliers can request a review.

In October 2009, CMS began the CBP round 1 rebid process.[16] The bid window closed in December 2009. There were 6,215 complete bids submitted by 1,011 bidding suppliers. On July 1, 2010, CMS announced the competitively determined DME single payment amounts, which are the new payment amounts that Medicare will pay for each item covered under the CBP. These payments will replace the applicable fee schedule amounts for the selected DME items in the competitive bidding areas. Under the round 1 rebid, CMS estimated that compared to the 2009 Medicare fee schedule, the volume-weighted reduction in CBP's single payment amounts for items averaged 32 percent. Under round 1, the estimated payment reductions compared to the 2008 Medicare fee schedule averaged 26 percent.[17] CMS also announced on July 1, 2010, that it would begin mailing contract offers to winning suppliers.[18] CMS officials informed us that 1,287 bids are included in the initial wave of contract offers. CMS

[16]In the CBP round 1 rebid, the product categories were revised to delete the negative pressure wound therapy category and to exclude group 3 complex rehabilitative power wheelchairs from the entire CBP, and to delete San Juan (San Juan–Caguas–Guaynabo, Puerto Rico) as a competitive bidding area.

[17]According to CMS officials, the savings estimate for each combination of competitive bidding area and product category was derived by multiplying the difference between the 2009 Medicare fee schedule for each item in the product category and the CBP-derived single payment amounts by the item's percentage share of the total number of units represented by all items in the product category provided by Medicare in 2008. In both CBP round 1 and the CBP round 1 rebid, the items in the mail-order diabetic supplies product category had the largest reductions, with the difference between the single payment amounts and the Medicare fee schedule averaging 43 and 56 percent, respectively.

[18]CMS officials informed us that if any winning supplier offered a CBP round 1 rebid contract decides not to accept the contract, it is possible that a losing supplier may later be offered the contract. The Palmetto GBA CBP Web site—www.dmecompetitivebid.com—provided suppliers a fact sheet on contract supplier obligations. Contract suppliers are winning suppliers that enter into a contract with CMS to provide specific items in the area for which the suppliers submitted a competitive bid.

officials also stated that they plan to announce the winning suppliers that accepted contracts in September 2010.[19]

In my testimony today, I will discuss problems we identified in the round 1 competitive bidding process and how CMS has or plans to address the problems in the ongoing rebid bidding process regarding (1) providing suppliers with bid submission information, (2) use of an electronic bid submission system, and (3) the bid disqualification notification process.

For our 2009 report, we reviewed data provided by CMS and Palmetto GBA; reviewed federal laws, regulations, and policies concerning the bidding and contract award processes; reviewed documents from the CBP round 1 bidding process, and interviewed CMS and Palmetto GBA officials about the CBP round 1 bid process and efforts to resolve problems that arose. For this testimony, we also obtained information on CMS responses to problems we identified in our 2009 report by reviewing agency documents and interviewing CMS officials. We also reviewed the available materials provided on the CMS and Palmetto GBA CBP Web sites and analyzed the results from the inquiries from suppliers received by the Palmetto GBA customer service center. We shared the information in this statement with CMS officials. Our work was performed in accordance with generally accepted government auditing standards for the 2009 report from June 2008 through September 2009 and for this testimony from August through September 2010. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[19]CMS plans to begin the CBP round 2 competitive bidding process in 2011. The Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 6410, 124 Stat. 119, 773 (2010) increases the number of round 2 competitive bidding areas from 70 to 91 of the largest MSAs, accelerating the CBP's implementation and its projected savings.

Problems Were Identified in the CBP Round 1 Bidding Process in Providing Suppliers with Bid Submission Information, but Some Improvements Were Made in the CBP Round 1 Rebid Process

For CBP round 1, we found problems with the bidding process, including poor timing and lack of clarity in bid submission information and CMS's inability to inform suppliers of missing financial documentation. In comparison with CBP round 1, CMS provided CBP round 1 rebid bidding information to suppliers earlier, and its financial documentation instructions were clearer and suppliers were notified of missing documentation. CMS also added program information about determining suppliers' capacity, and provided directories to inform suppliers about state licensure requirements.

CMS Had Difficulty Providing Clear Bidding Information to Suppliers in CBP Round 1, but Improved Its Communication about Bidding Information for the CBP Round 1 Rebid

CMS had difficulty providing clear bidding information in CBP round 1. For example, CMS provided new bidding information several times after the bid window opened, such as announcing the 10 financial measures used to evaluate the financial viability of bidding suppliers; clarified CBP round 1's bidding information in response to supplier confusion, such as providing additional explanatory information concerning the request-for-bid instructions; and extended the bid window deadline. These changes in bidding information made it more difficult for suppliers to submit correct bids.[20] CMS and Palmetto GBA acknowledged that during CBP round 1 suppliers did not always understand the request-for-bid instructions. The instructions were not available to suppliers until the day the bid window opened. During the first 2 months of the bid window, while suppliers were preparing their bid submissions, Palmetto GBA held informational bidder conference calls on how to submit bids and maintained audio recordings on the CBP Web site for a limited time. Questions also were not organized by subject matter, and while the Web site had a frequently asked questions section, it was difficult for suppliers to determine when questions had been added.

[20]The CBP round 1 bid window was extended three times resulting in a 4-month-long window. Although suppliers could revise their bid submissions throughout the bid window, when additional information was provided those that believed they had submitted completed bids had to review them to ensure that they were still correct.

CMS improved its communication with suppliers about bidding information for the CBP round 1 rebid. For example, CMS provided suppliers with bidding information before the bidding window opened on October 21, 2009, so that bid window extensions were not needed.[21] Prior to the bid window opening, the rebid's request-for-bid instructions had been available to potential bidding suppliers for over 2 months, since August 3, 2009, and CMS had already held seven informational bidder conference calls.[22] Transcripts, audio recordings, and PowerPoint presentations from the calls were available on the Palmetto GBA CBP Web site throughout the round 1 rebid. CMS made two minor clarifications to the CBP round 1 rebid instructions.[23] First, on the day the bid window opened, CMS provided the actual bid submission deadlines, including the covered document review date,[24] and provided further instructions on how a supplier needed to approve a bid in the online bidding system and would submit the required hard copy financial documents. Second, on November 17, 2009, CMS clarified that the financial statements for the last operating year that suppliers were required to submit as part of their bids could be for either calendar or fiscal years.

For the CBP round 1 rebid, Palmetto GBA maintained suppliers' frequently asked questions on the CBP's Web site by topic. The questions were provided for three topics—Bidding Guidelines, Bidding Process, and Payment Policies—and dated in chronological order, unlike in CBP round 1, so suppliers could more easily determine when new ones were

[21]The CBP round 1 rebid's bid window was open for 60 days—October 21 through December 21, 2009. Under federal law and implementing regulations, subject to few exceptions, suppliers furnishing DME and other items on or after October 1, 2009, must have submitted evidence of accreditation to CMS and beginning October 2, 2009, suppliers must submit a surety bond when enrolling in Medicare, making a change in ownership, or responding to a re-enrollment request. For the round 1 rebid, CMS required suppliers to submit evidence of accreditation and surety bonds prior to submitting their bids. During CBP round 1, suppliers could submit bids even if their accreditation was still pending.

[22]CMS held an eighth special open door forum after the bid window opened to respond to suppliers' questions about the competitive bidding process.

[23]Before the bid window opened, CMS changed the instructions on August 24, 2009 to provide a link to the Financial Documents Chart in the Required Hardcopy Documents section of the CBP Web site, http://www.dmecompetitivebid.com/.

[24]MIPPA and implementing regulations defined the covered document review date as the later of (1) 30 days before the final date for the close of the bid window or (2) 30 days after the bid window opens. During the CBP round 1 rebid, CMS was required to notify eligible suppliers of missing financial documentation within 45 days of the covered review date. The CBP round 1 rebid's review date was November 21, 2009.

posted on the Web site. The Web site also has a "What's New" section to allow suppliers to find any new CBP information, for example, information for the suppliers that were offered contracts, such as the form to request that business locations be added or removed from their contracts.[25]

Unclear CBP Round 1 Financial Documentation Instructions Led to Many Bid Disqualifications, but CBP Round 1 Rebid Instructions Were Clearer

In our 2009 report, we found that financial documentation instructions were sometimes unclear in CBP round 1. CMS acknowledged that during CBP round 1 many suppliers had particular difficulty complying with the financial documentation[26] requirements and that the statement of cash flow—described as a statement of changes in financial position—was the document most often missing. We found that CMS's CBP round 1 financial documentation instructions did not clearly address differences among supplier business types—for example, a sole proprietorship business versus a publicly traded national corporation—and among the financial documents needed to submit a bid for each type. Because business types could not easily be cross-referenced to the request-for-bid instructions, suppliers were at risk of submitting incomplete or inaccurate financial documentation. We also found that CMS's CBP round 1 request-for-bid instructions had inconsistent information about the requirements for the credit report and credit score submission. For example, the bid submission form stated that a credit rating and score—rather than using the term credit report—had to be submitted. Near the end of the bid window, Palmetto GBA then issued a "required document reminder" that all bidders had to submit both a credit report and a credit score.

For the CBP round 1 rebid, CMS clarified financial documentation instructions by providing additional tools to guide suppliers through the bid submission process.[27] The request-for-bid instructions included a chart—Required Financial Documents by Business Type—that more clearly explained which documents were to be submitted by business type. For example, the chart specified which portions of a supplier's tax return were required based on its business type such as a sole proprietorship.

[25]In addition, Palmetto GBA again had a customer service center to field inquiries from suppliers and individuals before, during, and after the bid window closed—7,637 phone and written inquiries had been made as of June 30, 2010.

[26]Financial documentation means a financial, tax, or other document required to be submitted in order to meet CMS's financial standards for the CBP.

[27]For the CBP round 1 rebid, suppliers were required only to submit 1 year of financial documentation instead of 3 years as was required in round 1.

The chart also included a credit report column that stated bidders must submit a "Credit Report with numerical score completed within 90 days of bid submission," and the bid instructions included the same description. To further assist suppliers to provide the correct financial documents, the instructions included a Required Financial Documents appendix with sample documents and more specific explanations of the income statement, balance sheet, statement of cash flow, revenue and expense portion of the tax return, and the credit report, along with a Checklist of Required Hardcopy Documents for Bid Submission.

For the CBP round 1 rebid, CMS officials told us they notified bidding suppliers that submitted their hard copy financial documents by the round's covered review date of any missing documents, as required by MIPPA.[28] Once notified, suppliers had 10 business days to submit their missing documentation.[29] CMS officials told us that 791 suppliers submitted their financial documentation by the CBP round 1 rebid covered document review date and 321 were notified that they had missing documentation. Fourteen suppliers did not subsequently submit the missing documents and their bids were disqualified. For this review, tax record documents were the most often missing financial documentation.

[28]The CBP round 1 rebid's covered review date was November 21, 2009. During the CBP round 1 rebid, CMS was required to notify eligible suppliers of missing financial documentation within 45 days after the end of the covered document review date. For future rounds, CMS must notify eligible suppliers of missing financial documentation within 90 days after the end of the covered document review date.

[29]This process only applies to the timely submission of financial documentation and does not apply to any determination by CMS as to the accuracy or completeness of the documentation submitted or whether the documents meet applicable financial requirements.

In CBP Round 1, Questions Were Raised about CMS's Ability to Estimate the Capacity of Suppliers to Furnish DME Items, but CMS Added a Systematic Method to Estimate Supplier Capacity for the CBP Round 1 Rebid

In CBP round 1, questions were raised about the capacity of some suppliers to fulfill their awarded contracts on day one of the CBP's contract period, including whether they had experience providing the DME product category, had business locations in the competitive bidding areas, and could expand their businesses, if needed, to supply all Medicare beneficiaries in their competitive bidding areas. CMS officials told us that the CBP's Program Advisory and Oversight Committee (PAOC)[30] raised concerns that suppliers new to a competitive bidding area, new to a DME product category, or that reported high capacity figures would not be able to increase reported capacity in time to meet the projected demand for the DME items in the competitive bidding areas.

To address the concerns, CMS officials told us that the agency added a systematic method of reviewing suppliers' capacity and expansion plans for the CBP round 1 rebid.[31] CMS developed a three-step method to determine whether a supplier new to a product category or a competitive bidding area or an experienced supplier that reported high capacity figures would be able to increase capacity to meet the projected demand for the DME items.[32] The three steps were as follows:

- First, CMS determined whether the total capacity of all experienced suppliers in the competitive bidding area reporting modest growth projections and eligible for a competitive bidding program contract offer could meet the projected demand for items in the contract's first year. If the capacity from these experienced suppliers was sufficient to cover the item demand on day one of the program, then the capacity offered by any

[30]The PAOC members were appointed by the HHS Secretary to advise CMS on implementing the CBP.

[31]CMS and Palmetto GBA provided a fact sheet explaining how a supplier should estimate its capacity to provide each item being bid to ensure that suppliers winning contracts could sustain this level of capacity throughout the entire competitive bidding area for the contract period. The sheet also explained that suppliers new to a product category, or new to a competitive bidding area, or that otherwise plan to increase their capacity beyond their current levels must submit expansion plans as part of their bid submissions.

[32]CMS officials told us that the ability of grandfathered suppliers or suppliers that are exempt from the CBP to cover a certain percentage of the beneficiary demand was not considered in reviewing contract suppliers' ability to meet demand on day one of the program. The CBP round 1 rebid fact sheets stated that grandfathered suppliers are suppliers that are not awarded a competitive bidding contract for furnishing oxygen and oxygen equipment or rented DME in a competitive bidding area and that decide to be grandfathered suppliers for the Medicare beneficiaries to whom they are furnishing these DME items at the time the CBP takes effect.

additional suppliers with expansion plans and eligible for a contract offer was considered surplus capacity and no further review was conducted.

- Second, if the total capacity of the experienced suppliers identified in step one did not meet the projected demand for the first year of the contract, then CMS reviewed the expansion plans provided by the new and high-growth or high-volume suppliers to verify their capacity to furnish the items. The expansion plan review involved an in-depth examination of the supplier's financial information, specifically to verify whether the supplier had the liquid assets and available credit needed to expand capacity. If the verified capacity from these suppliers with expansion plans was sufficient to meet demand, CMS determined that the suppliers eligible for a CBP contract offer had the ability to meet demand on day one of the program.

- Third, if the results of the first two steps indicated that more suppliers were needed to meet demand on day one of the program, CMS made more suppliers eligible for a CBP contract offer.

  As of September 10, 2010, CMS had not disclosed how many capacity evaluations were conducted during the CBP round 1 rebid.

In CBP Round 1, CMS Awarded Some Contracts to Suppliers That Were Not Yet Licensed, but CMS Provided Directories to Inform Suppliers of State Licensure Requirements in the CBP Round 1 Rebid

In 2009, we found that some suppliers that won CBP round 1 contracts were not yet licensed in states where they would be operating. For the CBP round 1 rebid, CMS further clarified the state licensure requirement, stating that suppliers must be licensed for the product category in the competitive bidding area in which they are bidding, and if a competitive bidding area covers more than one state, the supplier needs to obtain applicable licensure in all states. In order to better inform suppliers about these licensure requirements, CMS and Palmetto GBA provided licensure state directories for the 11 states included in the CBP round 1 rebid competitive bidding areas. The directories, which served only as guides for suppliers, provided a list of licenses required by each state for each product category for suppliers with a physical location in that state.[33] Suppliers without a physical location in the state but that would be providing DME items and services to Medicare beneficiaries in the state were directed to consult the appropriate state licensing agency; contact information for those agencies was also provided. The suppliers were required to file copies of applicable state licenses with the National

[33]The directories list, for example, licensure for a home medical device retail license and a respiratory care practitioner license.

Supplier Clearinghouse—which processes Medicare enrollment applications by DME suppliers—prior to submitting a bid.

Electronic Bid Submission System Used in CBP Round 1 Had Operational Problems, and CMS Developed a New Bid System for the CBP Round 1 Rebid

CMS acknowledged that CBP round 1's competitive bid submission system—CBSS—had operational problems that affected suppliers' ability to submit their bids. These problems included, for example, loss of bid submission data caused by CBSS security features that automatically logged suppliers out after 2 hours and that timed out suppliers if there was no activity for 30 minutes, and cases when CBSS was unavailable because of unscheduled downtimes. Additionally, CBSS did not have a "cut and paste" function and manual data reentry was time-consuming and increased the risk of suppliers inputting incorrect data that could disqualify a bid. CMS officials also acknowledged that the CBSS user guide was not very detailed or user friendly.

CMS developed a new electronic bid submission—DBidS—for the CBP round 1 rebid. DBidS was designed to address CBSS's specific deficiencies by being more user friendly and easier for suppliers to navigate and providing a logical flow of the requested data, as well as detailed bidding instructions in user-friendly language. Suppliers were provided a DBidS reference guide on the DMEPOS Competitive Bidding Program Web site that included screen shot explanations for the bid submission Forms A and B.[34] It also has a "copy and paste" function for the transfer of certain data and many data-saving points to minimize loss of data. Suppliers could have more than one employee access DBidS at the same time, but to control data input DBidS will not allow more than one employee to input the same data at the same time. DBidS has status indicators to indicate whether the bidding forms are "complete," "incomplete," or "pending approval," and has links in the system to direct suppliers to the incomplete data. CMS officials told us that DBids did not have significant operational issues and only a few suppliers experienced minor problems.

[34]Suppliers submit two forms as part of their bid submission—Form A, which is the bid application, and Form B, which is the bidding form.

CMS Did Not Effectively Notify All Suppliers about the Postbidding Review Opportunity in CBP Round 1, and Plans to Communicate with All Losing Suppliers in the CBP Round 1 Rebid after Contract Suppliers are Announced

In CBP round 1, CMS sent notification letters to both the winning and losing suppliers before announcing the final winning suppliers that accepted contracts for the CBP. The letters sent to suppliers that had bids disqualified included an attachment using seven general reason codes to explain the grounds for the disqualifications.[35] Disqualified bids were ineligible to compete on price and were not considered for a contract award. During CBP round 1, CMS also conducted a postbidding review process through which the agency considered concerns raised by losing suppliers and in some cases, reversed decisions to disqualify the bids of certain suppliers. We found that CMS had not effectively notified suppliers about the opportunity for this postbidding review process. To improve future rounds of the CBP, we recommended in our 2009 report that if CMS decides to conduct a review of disqualification decisions made during the CBP round 1 rebid and future rounds, CMS should notify all suppliers of any such process, give suppliers equal opportunity for such reviews, and clearly indicate how they can request a review. CMS agreed with our recommendation.

For the CBP round 1 rebid, CMS sent notification letters to winning suppliers beginning in July 2010.[36] CMS officials informed us that after the CBP round 1 rebid contracting process is completed, CMS plans to send letters to all disqualified suppliers with the reasons why their bids were disqualified.[37] CMS officials said the letters will explain the process by which suppliers may ask questions and express concerns. CMS officials also stated that in the course of responding to such questions or concerns, if CMS determines an error was made, it is possible that a CBP contract may be offered to the supplier.

[35]By the end of CBP round 1's initial bid review, almost half of the bids submitted were disqualified (3,143 of 6,374 submitted). A bid could be disqualified for more than one reason. Nearly 9 of every 10 disqualified bids (86 percent of the 3,143) did not submit complete financial documentation. Twenty-two percent of the bids were disqualified for noncompliance with accreditation requirements; that is, they failed to receive accreditation by the deadline established by CMS. Two percent of the bids were disqualified because the bidding suppliers did not meet supplier financial standards; that is, in CMS's judgment, they were unlikely for financial reasons to be able to fulfill their contract obligations.

[36]CMS informed us that they sent letters to winning suppliers in July 2010, extending offers to enter into a contract with CMS to provide selected DME. These suppliers must respond to CMS, by either accepting or declining to enter into these contracts. Once CMS has heard from all these suppliers, CMS will finalize the contracts and determine whether there are sufficient numbers of contracted suppliers. CMS officials informed us that they expected to complete this contracting process later in September.

[37]CMS officials told us that there are 11 disqualification reasons for the CBP round 1 rebid.

As required by MIPPA, we will study the CBP round 1 rebid, including, for example, the program's impact on Medicare beneficiary access to items and services and on DME small business suppliers. Our study is to be completed no later than one year after the CBP round 1 rebid's Medicare competitively determined payments are first made, which become effective for covered items and services on January 1, 2011.

Agency Comments

In commenting on the information presented in this testimony, CMS officials stated they appreciated GAO noting the administrative improvements to the competitive bidding process the agency made for the round 1 rebid. The officials further stated that they believe that CMS made many improvements to the CBP. CMS also provided technical comments that we incorporated as appropriate.

Mr. Chairman, this concludes my prepared statement. I would be happy to answer any questions you or other members of the subcommittee may have.

Appendix I: GAO Contact and Staff Acknowledgments

GAO Contact

For further information about this statement, please contact Kathleen M. King at (202) 512-7114 or kingk@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement.

Staff Acknowledgments

In addition to the contact named above, key contributors to this testimony were Martin T. Gahart, and Christie Motley, Assistant Directors; Lori Achman; Kye Briesath; Krister Friday; Thomas Han; Erica Pereira; Hemi Tewarson; Opal Winebrenner; and Charles Youman.

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