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Report to Congressional Requesters

November 2009

MEDICARE

CMS Working to Address Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program

GAO-10-27

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Highlights

Highlights of GAO-10-27, a report to congressional requesters

Why GAO Did This Study

In 2007, Medicare spent $8.3 billion for durable medical equipment (DME) and related supplies. To reduce spending, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required that the Centers for Medicare & Medicaid Services (CMS) phase in, with several rounds of bidding, a large-scale competitive bidding program (CBP) for certain DME and other items. DME suppliers began bidding in round 1 of the CBP on May 15, 2007. After contracts were awarded, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), was enacted on July 15, 2008. Because of numerous concerns MIPPA delayed the program, terminated supplier contracts, and required CMS to begin the CBP round 1 rebid in 2009. GAO was asked to report on (1) the results of CBP round 1, (2) the major challenges CMS had in conducting CBP round 1, and (3) the steps CMS has taken to improve future CBP rounds. GAO reviewed CMS data and relevant laws and regulations, and interviewed officials from CMS and its contractors, and DME suppliers and professional associations.

What GAO Recommends

GAO recommends that if CMS decides to conduct reviews of disqualified bids, CMS should notify all suppliers of this process, giving suppliers equal opportunity for such reviews and clearly indicate how to request them. CMS agreed with GAO's recommendation.

View GAO-10-27 or key components.
For more information, contact Kathleen M. King at (202) 512-7114 or kingk@gao.gov.

What GAO Found

About a quarter of the bids submitted during CBP round 1 resulted in awarded contracts. The contracts were in effect until terminated by MIPPA on July 15, 2008. Of the 6,374 bids submitted by 1,010 suppliers, half were disqualified before competing on price. Bids were most often disqualified for missing financial documentation or noncompliance with accreditation requirements. In nearly two-thirds of CBP round 1's price competitions—in which suppliers submitted bids to deliver items for a specific product category within a specific competitive bidding area (CBA)—the number of suppliers decreased by at least half. The largest decreases in suppliers were in the Miami CBA. CMS estimated that the reduction in Medicare payments for items acquired as a result of CBP round 1 would have averaged 26 percent when compared to payments under the Medicare fee schedule.

CBP's round 1 presented several challenges to suppliers, including poor timing and lack of clarity in bid submission information, a failure to inform all suppliers that losing bids could be reviewed, and an inadequate electronic bid submission system. CMS provided some clarifying information about bidding after the bid window opened, repeatedly extended the bid window deadlines, and provided updated guidance to bidders throughout the bid window. The information CMS provided to suppliers about bidding requirements was sometimes unclear and inconsistent, particularly regarding financial documentation. CMS did not effectively notify suppliers of its postbidding review process. Because some suppliers were not aware of the review process, they missed the opportunity to have their disqualified bids reviewed. CMS found that some bids had been incorrectly disqualified. Finally, several problems with the electronic bid submission system, including data losses from automated logouts and unscheduled downtimes, made it difficult for some suppliers to submit bids.

CMS has taken several steps to improve the bidding process for the round 1 rebid and subsequent rounds of the CBP. CMS is implementing MIPPA provisions to notify suppliers of missing financial documentation and create a CBP ombudsman. It has reduced financial documentation requirements and revised the request for bid instructions to make it clearer and more understandable. It is also developing a new electronic bidding submission system, the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies bidding system (DBidS), which the agency claims will address the deficiencies of the system used for round 1. Bidding for the round 1 rebid began in late October 2009.

The CBP has the potential to produce considerable benefits, including reducing overall Medicare spending for DME and limiting potential fraud through increased scrutiny of suppliers. Although challenges may be expected for any new program, problems occurred in round 1 because of poor communication by CMS and an inadequate bid submission system.

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Abbreviations

BBA	Balanced Budget Act of 1997
CBA	competitive bidding area
CBES	Competitive Bidding Evaluation System
CBP	competitive bidding program
CBSS	Competitive Bid Submission System
CMS	Centers for Medicare & Medicaid Services
CY	calendar year
DBidS	Durable Medical Equipment, Prosthetics, Orthotics, and Supplies bidding system
DME	durable medical equipment
HHS	Department of Health and Human Services
IT	information technology
MIPPA	Medicare Improvements for Patients and Providers Act of 2008
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
PAOC	Program Advisory and Oversight Committee

GAO
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United States Government Accountability Office
Washington, DC 20548

November 6, 2009

The Honorable Max Baucus
Chairman
Committee on Finance
United States Senate

The Honorable Henry A. Waxman
Chairman
The Honorable John D. Dingell
Chair Emeritus
Committee on Energy and Commerce
House of Representatives

The Honorable Charles B. Rangel
Chairman
Committee on Ways and Means
House of Representatives

In 2007, Medicare—the federal health insurance program that currently serves about 45 million elderly and disabled individuals—spent $8.3 billion on durable medical equipment (DME), prosthetics, orthotics, and related supplies.[1] Both we and the Department of Health and Human Services's (HHS) Office of Inspector General have reported that Medicare and its beneficiaries have sometimes paid higher than market rates for various

[1]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. DME includes items such as wheelchairs, hospital beds, and walkers. Prosthetic devices (other than dental) are defined as devices needed to replace body parts or functions such as artificial limbs, enteral nutrition, and cardiac pacemakers. Orthotic devices 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.

medical equipment and supply items.[2] In 1997, Congress required the Centers for Medicare & Medicaid Services (CMS)—the agency that administers the Medicare program—to test competitive bidding for selected DME and other items and services through demonstration projects.[3] The demonstrations were conducted from 1999 to 2002 and showed that competitive bidding would save Medicare money.

Competitive bidding can reduce Medicare payments for DME and close the disparity with prices paid by others for the same items. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required that CMS implement a competitive acquisition program for DME and certain other items.[4] CMS was required to phase in the competitive bidding program (CBP) in 2007 in 10 competitive bidding areas (CBA).[5] The CBP would be expanded in future rounds. CBP round 1 began when the bid window opened May 15, 2007. In May 2008, CMS announced the final winning suppliers, and contracts with winning suppliers took effect July 1, 2008.

[2]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); Office of Inspector General, Department of Health and Human Services, *A Comparison of Prices for Power Wheelchairs in the Medicare Program*, OEI-03-03-00460 (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.

[3]Balanced Budget Act of 1997 (BBA), Pub. L. No. 105-33, § 4319(a), 111 Stat. 251, 392 (1997). This competitive bidding was designed to provide a new way to set fees for Medicare Part B items and services specified by CMS.

[4]Pub. L. No. 108-173 § 302(b), 117 Stat. 2066, 2224 (2003) (codified, as amended, at 42 U.S.C. § 1395w-3). Items and services covered by the competition were DME and related supplies, off-the-shelf orthotics, and enteral nutrients and related equipment and supplies. In this report, we refer to the competitive acquisition program as the competitive bidding program.

[5]The 10 CBAs had to be selected from the largest metropolitan statistical areas. 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).

Some DME suppliers and trade associations raised concerns about the CBP round 1, questioning several aspects of CMS's bid submission and contract award processes. They also questioned whether some winning suppliers could provide the volume of items and services their contracts required and whether contracts should have been awarded to suppliers that had no prior business presence in a CBA. Two congressional hearings addressed these concerns in May 2008.[6]

On July 15, 2008, the CBP round 1 was stopped when the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 was enacted.[7] MIPPA delayed the CBP, terminated the contracts already awarded by CMS to suppliers in round 1, and required CMS to repeat the competition for round 1 CBP in 2009—the CBP round 1 rebid. To ensure budget neutrality, that is to compensate for the loss of the projected savings from the CBP, beginning January 1, 2009, MIPPA reduced national Medicare reimbursement payments by 9.5 percent nationally for items and services that had been included in the CBP round 1.[8] 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.[9]

As CMS prepares to implement the CBP round 1 rebid, you asked us to report on (1) the results of the CBP round 1, (2) the major challenges CMS had in conducting the CBP round 1, and (3) the steps CMS has taken to improve future CBP rounds.

To determine the results of the CBP round 1, we reviewed data from CMS and Palmetto GBA—the contractor CMS selected to implement the CBP bidding and contract award process—about the number of suppliers participating in round 1 of the CBP process, the number of submitted bids,

[6]Hearings on CBP were held by the House of Representatives's Committee on Ways and Means, Subcommittee on Health, on May 6, 2008, and the Committee on Small Business, Subcommittee on Rural and Urban Entrepreneurship, on May 21, 2008.

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

[8]House of Representatives's Committee on Ways and Means, Subcommittee on Health, hearing on Medicare's DMEPOS Competitive Bidding Program (May 6, 2008).

[9]MIPPA also changed the CBP phase-in dates to 2009 for the round 1 rebid in 9 CBAs, to 2011 for round 2 in 70 additional CBAs, and after 2011 for additional CBAs (or after 2010 for national mail order items and services).

and the bids' outcomes. We interviewed and obtained information from CMS and Palmetto GBA officials about the Competitive Bid Submission System (CBSS), an electronic database used by suppliers to submit part of their bid application, including information about covered system testing and data processing procedures. We also reviewed the instructions provided to bidding suppliers about entering data into the CBSS. We interviewed Palmetto GBA officials about the Competitive Bidding Evaluation System (CBES), a repository of bid data including financial data entered by Palmetto GBA personnel and documentation of Palmetto GBA actions, as well as about the system's data transfer and data entry protocols. We compared data published by CMS with the data provided to us and followed up with the appropriate officials to resolve any discrepancies. We assessed the reliability of round 1 data by interviewing or reviewing information from CMS and Palmetto GBA officials and determined that the data were sufficiently reliable for the purposes of this report. We did not independently evaluate CMS's estimates of beneficiary demand, which relied on 2005 and 2006 DME claims data, the most recent data available to it at the time, nor did we evaluate CMS's estimates of projected savings as the result of the CBP round 1.

To determine the major challenges CMS had conducting the CBP round 1, we reviewed relevant federal laws, regulations, and policies concerning the bidding and contract award processes. We interviewed CMS and Palmetto GBA officials about the bid submission process, including the CBSS, the bid evaluation and contract award processes, and the CMS and Palmetto GBA postbidding review. We reviewed CMS and Palmetto GBA bid submission instructions and related materials, communications to suppliers during the bid window, and information on how CMS and Palmetto GBA evaluated bids and awarded contracts. We also reviewed information related to the Program Advisory and Oversight Committee (PAOC), whose members are appointed by the HHS Secretary to advise CMS on implementing the CBP. We reviewed PAOC meeting materials, interviewed members about their role and input into the development of round 1, and attended a committee meeting on June 16, 2008. We also interviewed national and state DME trade associations and a small number of randomly selected suppliers about the CBP bidding and contract award processes.

To determine the steps that CMS has taken to improve the bidding process for future CBP rounds, we reviewed applicable CBP provisions in relevant MIPPA sections and implementing regulations, PAOC Federal Register notices, and interviewed CMS and Palmetto GBA officials. We also interviewed Maricom officials and reviewed available documentation

related to the development, testing, and proposed implementation of the new electronic bid submission system—the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies bidding system (DBidS)—to be used for the round 1 rebid. We attended a June 4, 2009, meeting at which CMS updated the current PAOC about the process changes that have been implemented or proposed for the CBP round 1 rebid. We did not assess the reliability or functionality of DBidS, but we reviewed the processes established by CMS and its contractors for testing and accepting such systems. (See app. I for more detailed information on our methodology.)

We conducted this performance audit from June 2008 to September 2009 in accordance with generally accepted government auditing standards. 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.

Background

Most Medicare beneficiaries participate in Medicare Part B, which helps pay for certain DME and other equipment and supplies.[10] This includes, for example, wheelchairs, walkers, oxygen, and hospital beds. In 2007, Medicare spent a total of $430.3 billion. Of that, $8.3 billion was spent on DME and other medical equipment and supplies covered under Part B.[11]

Medicare DME Payments

Since 1989, Medicare has paid for DME through fee schedules. These fee schedules are based on the average amount that suppliers charged on Medicare claims in 1986 and 1987 for individual DME items adjusted for inflation.[12] Medicare uses a fee schedule for each state to reflect

[10]In addition to DME, Medicare Part B covers certain physician services, outpatient hospital, laboratory, and other services. Beneficiaries who enroll in Part B pay a monthly premium and have an annual deductible—$135 in 2009. Under Part B, Medicare generally pays the supplier 80 percent of the lesser of the actual charge or fee schedule amount for a covered item or service and the Medicare beneficiary pays the supplier the remaining 20 percent, once the beneficiary's annual deductible has been met.

[11]This Medicare Part B total does not include the amount of coinsurance or deductibles paid by Medicare beneficiaries or administrative expenses. Medicare Part C also helps pays for DME covered under Medicare Advantage health plans, which are operated by private companies.

[12]In general, DME fee schedule rates are subject to national floor and ceiling limits, and updated annually by the consumer price index for all urban consumers.

geographical price differences. The applicable state fee schedule is determined by the beneficiary's residence, not the DME supplier's location.

Medicare generally pays the lesser of either the supplier's actual charge or the Medicare fee schedule amount for the item or service. For suppliers, Medicare assignment—accepting Medicare's reimbursement amount for an item as payment in full and limiting the amount the beneficiary can be billed for that item—is optional. If a supplier agrees to assignment, then Medicare generally pays 80 percent of the amount to the supplier and the Medicare beneficiary is responsible for paying the supplier the remaining 20 percent (referred to as the coinsurance payment), once the beneficiary's annual deductible has been met. If the supplier does not accept assignment, the supplier is not limited to charging the beneficiary 20 percent of the Medicare reimbursement for that item or service and the beneficiary can be billed for whatever balance is due.

History of DME Competitive Bidding Payment Reform

The Balanced Budget Act of 1997 required CMS to test competitive bidding as a new way to set payment rates for Part B services and supplies selected by CMS.[13] CMS conducted three CBP demonstration projects, two in Florida (1999–2002) and one in Texas (2000–2002). Evaluations of the demonstration projects estimated that they saved nearly $9.4 million.[14]

About a year after the demonstrations ended, the MMA was enacted, requiring CMS to implement a broader CBP in 2007.[15] Changing the long-standing policy that any qualified provider be allowed to participate in Medicare, the MMA provided that generally only suppliers who were

[13]The BBA authorized CMS to implement up to five competitive bidding demonstration projects in no more than three metropolitan statistical areas over a 3-year period. Pub. L. No. 105-33, § 4319(a), 111 Stat. 251, 392 (1997).

[14]Medicare expenditures for medical equipment and supplies provided by demonstration participants decreased by about $7.5 million, and corresponding beneficiary cost sharing for the medical equipment and supplies decreased by about $1.9 million.

[15]Pub. L. No. 108-173, § 302(b), 117 Stat. 2066, 2224 (2003) (codified, as amended, at 42 U.S.C. § 1395w-3). Under the MMA, CMS could include DME and medical supplies, off-the-shelf orthotics, and enteral nutrients and related equipment and supplies. CMS was required to establish competitive acquisition areas, phasing in the CBP program beginning with 10 of the largest metropolitan statistical areas in 2007, and more in later years. CMS also could phase in the CBP beginning with the highest cost and volume items and services or those that had the largest savings potential.

awarded contracts could be reimbursed by Medicare for providing covered Part B items and services in the selected areas. The MMA imposed certain criteria that CMS was required to follow—for example, eligible suppliers had to meet quality and financial standards, the total amount to be paid to contractors was expected to be less than would be paid otherwise, access of beneficiaries to multiple suppliers in their area must be maintained, and CMS must consider the ability of suppliers to meet the anticipated needs of beneficiaries in the covered geographic area. CMS was also required to ensure that small suppliers would be considered. The MMA required the establishment of the PAOC to advise CMS on various aspects of the CBP, including financial and quality standards.[16] The MMA also prohibited any administrative or judicial review of the designation of CBP's CBAs, the selection of items and services, the establishment of payment amounts, the bidding structure and number of contract suppliers selected, the awarding of contracts, and the phase-in of the CBP. CMS published a final rule, effective on June 11, 2007, governing implementation of the CBP.[17]

CMS contracted with Palmetto GBA to implement the CBP bidding and contract award process and with Maricom to develop the Web-based CBSS. CMS established the bidding process and approved policies and procedures developed by Palmetto GBA. CMS implemented the CBP in 10 CBAs which were among the largest statistical metropolitan areas.[18] CMS chose the items and services to include in round 1 by focusing on the highest cost and highest volume items and services with the largest

[16]PAOC members included representatives of: beneficiaries and consumers, physicians and providers, DME manufacturers, suppliers, certification and quality standards, and federal and state programs.

[17]CMS, *Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Final Rule*, 72 Fed. Reg. 17,992, 18,055-56 (Apr. 10, 2007). In this report, we refer to this rule as "the CBP final rule." CMS officials informed us that the agency determined that the Federal Acquisition Regulation (FAR) did not apply to contracts awarded by CMS to suppliers because these contracts did not contemplate the acquisition of goods for the federal government.

[18]The CBP does not apply to items and supplies covered by Medicare Advantage health plans.

potential for savings. It selected 10 product categories,[19] with 371 unique items and services; spending for those product categories in the 10 CBP CBAs accounted for about 9 percent of total Medicare spending on those product categories in 2006. Within the 10 CBAs, the product categories chosen accounted for 48 percent of Medicare's spending for DME, prosthetics, orthotics, and related supplies that year.

On July 15, 2008, MIPPA was enacted, which terminated the CBP contracts awarded during round 1. MIPPA reinstated Medicare reimbursement based on the Medicare fee schedule for all items and services included in CBP round 1, subject to a 9.5 percent reduction nationally for 2009.[20] MIPPA also required that CMS implement the CBP round 1 rebid in 2009, and imposed additional criteria for this rebid and later rounds.[21] CMS issued an interim final rule implementing these MIPPA provisions.[22]

The CBP Round 1 Competitive Bidding Process

The competitive bidding process had several steps: bidder registration, bid submission, bid review, winner selection, setting Medicare payment amounts, and contract offers (see fig. 1). To participate in CBP round 1, DME suppliers must have met enrollment, quality, and financial standards, obtained all the state and local licenses required to provide the relevant services, and been accredited by a CMS-approved accrediting

[19]The 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, and 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).

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

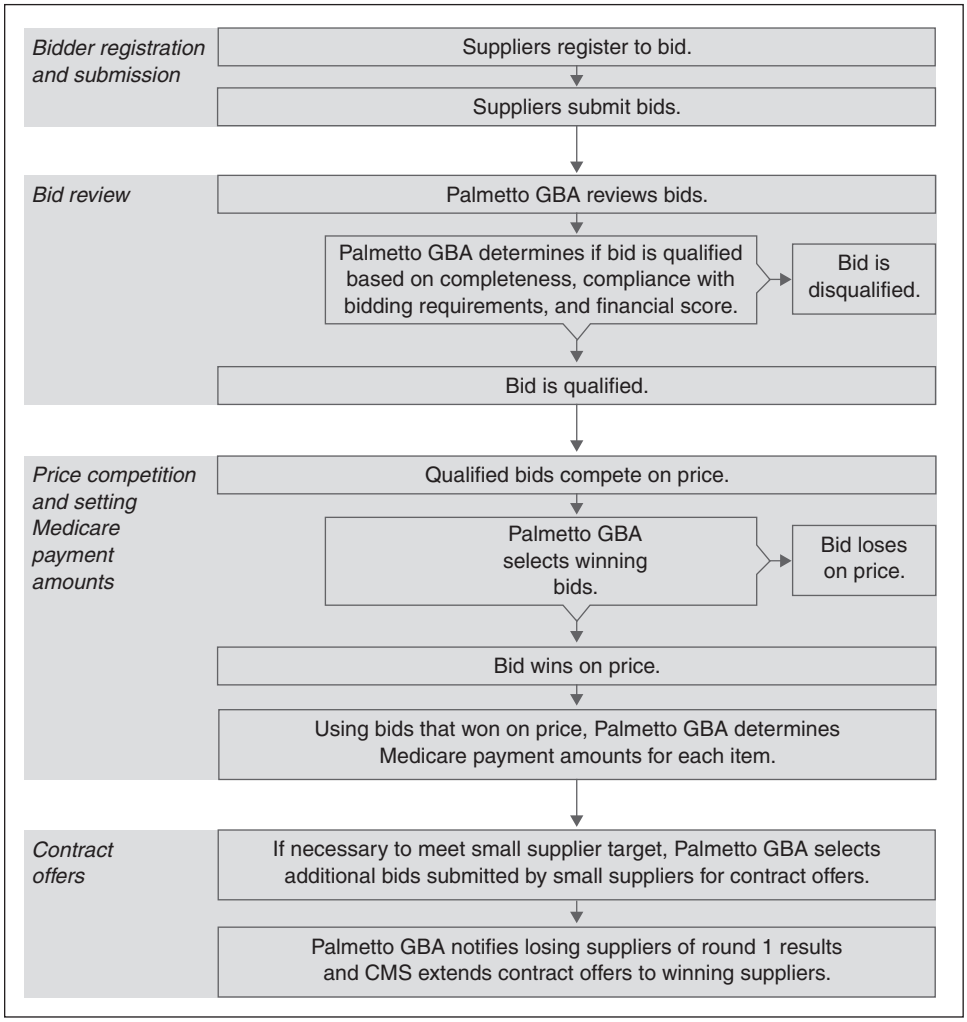
[21]For example, MIPPA required that CMS notify bidding suppliers of missing financial documentation.

[22]CMS, *Medicare Program: Changes to the Competitive Acquisition of Certain DMEPOS by Certain Provisions of MIPPA*, 74 Fed. Reg. 2873 (Jan. 16, 2009). CMS clarified that, with the exception of the new provisions in this rule, the CBP final rule published in April of 2007 would continue to govern the CBP. In this report, we refer to this rule as the "interim final rule."

organization.[23] In addition, bids for each item had to be bona fide—that is, not higher than the Medicare fee schedule but not lower than the supplier's cost.

[23]For a list of Medicare enrollment standards applying to all DME suppliers, see 42 C.F.R. § 424.57(c). For a list of quality standards applying to all DME suppliers, see http://www.cms.hhs.gov/MedicareProviderSupEnroll/Downloads/DMEPOSAccreditationStandards.pdf (downloaded on March 19, 2009).

Figure 1: CBP Round 1 Process



Source: GAO based on information provided by CMS.

Bidder registration. The first step in the CBP bidding process was bidder registration. Suppliers had to register with a CMS identity management and authentication system to gain access to the CBSS. Suppliers registered in the CBSS as one of three types of bidding entities: a

supplier with a single location, multiple suppliers sharing common ownership or control, or 2-20 small suppliers forming a network.[24]

Bid submission. For purposes of the CBP, a bid was an offer by a supplier to furnish all items within a product category throughout the entire CBA. The bid had to include a proposed price for each item in the product category. The number of items in a product category ranged from 3 to 142.[25] A bid package consisted of two electronic forms, A and B, and documents specified in the request-for-bid instructions and in other communication with suppliers. Hard copies of the documents had to be submitted to Palmetto GBA. Form A requested information about suppliers, including Medicare billing numbers, addresses, ownership, current or prior sanctions, and accreditation status.[26] Each Form B required suppliers to disclose annual revenues for the product category in each CBA; estimates of the number of item units currently provided and that could be provided in the future for that product category in that CBA; expansion plans; and item prices, models, and manufacturers. Each Form B constituted one bid—that is, suppliers had to submit a separate form for each product category in each CBA. Suppliers could submit a Form B for any product category up for bid in any CBA.[27] Hard-copy documents required to complete the bid package included financial documents, proof of accreditation status, letters of intent to enter into agreements with subcontractors, network agreements, and statements certifying the accuracy of the submissions. Financial documentation requirements included 3 years of annual financial statements, selected forms from the

[24]The CBSS registration process allowed only one supplier to register per bidding entity. A bidding entity could be one or more suppliers associated with one or more bids.

[25]For example, in the walker and related accessories category, there were 17 items, including a folding wheeled walker with adjustable or fixed height, a walker seat attachment, and a replacement handgrip.

[26]A bidding entity completed one Form A, regardless of how many suppliers made up the bidding entity or how many bids were associated with the bidding entity.

[27]Commonly owned or controlled suppliers were required to submit a single bid to furnish a product category in a CBA. Two or more suppliers are commonly owned if one or more of them has an ownership interest totaling at least 5 percent of the other supplier. A supplier controls another supplier if one or more of its owners is an officer, director, or partner in the other.

last three annual tax returns, and credit reports and credit scores for a 90-day period ending close to the date of the bid's submission.[28] (See table 1.)

Table 1: Required Financial Documents for CBP Round 1

Financial document as described in request-for-bid instructions	Request-for-bid instructions' term definitions
Compiled balance sheet (Statement of Financial Position)	The balance sheet and statement of financial position terms were defined as: Balance sheet: The position statement, that is, it presents the cumulative financial position of a firm at a specific date. The balance sheets reports financial position in terms of the basic economic model of the enterprise: Assets = Creditors' Equity + Owners' Equity. Statement of financial position: An alternative term for the term "balance sheet." The financial position of an enterprise at a particular time comprises its assets, liabilities, and owners' equity and the relationship among them, plus contingencies, commitments, and other financial matters that pertain to the enterprise at the time.
Statement of Cash Flow (Statement of Changes in Financial Position)	Term was not defined.
Statement of Operations (Income Statement)	Income statement: Reports on the results of an entity's operations for a given period of time as opposed to a specific point in time.
Schedule C from 1040 Tax Return (Profit and loss statement)	No further description provided.
Schedule L from 1065, U.S. Return of Partnership Income (limited partnerships and partnerships)	No further description provided.
Schedule L (balance sheet) from corporate tax return (corporations)	No further description provided.
10-K filing reports with Securities and Exchange Commission (publicly traded companies)	No further description provided.
Current credit report and credit score	Terms were not defined.

Source: CMS.

Note: Data are from CMS's *Instructions for Completing Bid Forms for Medicare DMEPOS Competitive Bidding Program* (May 2007).

Bid review. After the bid window closed, Palmetto GBA began to review the bids. It determined whether each bid package was complete, compliant with bidding requirements, and whether the submitting supplier's financial score satisfied a minimum threshold to qualify to

[28]New suppliers were required to submit projected financial documents to substitute for any year for which they did not have past financial information because they were not suppliers of DME and other items.

compete on price.[29] The financial score was determined using criteria developed by CMS for this purpose including suppliers' credit scores and 10 financial measures—described by CMS as standard accounting measures. (See table 2.) If the bid package was complete, compliant with bidding requirements, and the submitting supplier had a financial score that was equal to or greater than the minimum threshold, the bid qualified to compete on price. But before comparing prices, Palmetto GBA also reviewed each qualified bid's capacity projections—the supplier's ability to provide the volume of items claimed in the bid in light of the supplier's historical capacity, expansion plans, and financial score. It adjusted some bids' capacity projections according to certain guidelines.[30]

Table 2: Ten Financial Measures Used to Determine a Supplier's Financial Score, CBP Round 1

Financial measure	Description provided to suppliers
Current ratio	Current assets / current liabilities
Collection period	Accounts receivable / sales x 360
Working capital	Current assets – current liabilities
Accounts payable to sales	Accounts payable / net sales
Quick ratio	(Cash + accounts receivable) / current liabilities
Current liabilities to net worth	Current liabilities / net worth
Quality of earnings	Cash flow from operations / (net income + depreciation)
Operating cash flow to sales	Cash flow from operations / (revenue – adjustment to revenue)
Return on sales	Net income / sales
Sales to inventory	Net sales / inventory

Source: CMS.

[29]If the bidding entity was other than a single supplier, the financial scores of each supplier making up the bidding entity were combined into a score for the bidding entity.

[30]If the supplier had a low financial score, the supplier's projected capacity was limited to historical capacity. If the supplier did not have a low score but reported projected capacity as less than historical capacity, projected capacity was adjusted upward to historical capacity. If the supplier's projected capacity for the product category was 20 percent or more of expected beneficiary demand, projected capacity was limited to 20 percent of expected beneficiary demand for purposes of the bid review process only.

Winner Selection. Palmetto GBA used several steps to identify the winning bids based on price. Item prices submitted by competing suppliers were compared using a composite pricing methodology. A bid's composite price was calculated as each item's price multiplied by an item weight summed across all items in the product category. Table 3 illustrates the calculation for three hypothetical bids' composite prices in a product category containing three items. Each weight is based on the item's share of units billed to Medicare in 2006 as a percentage of all of the units for the product category billed to Medicare nationwide that same year.

Table 3: Bid Composite Price Calculation for a Product Category with Three Items

	Item A		Item B		Item C		Composite price
Item weight	0.5		0.3		0.2		
Supplier 1 bid	$1.00 x 0.5	+	$4.00 x 0.3	+	$1.00 x 0.2	=	**$1.90**
Supplier 2 bid	3.00 x 0.5	+	3.00 x 0.3	+	2.00 x 0.2	=	**$2.80**
Supplier 3 bid	2.00 x 0.5	+	3.00 x 0.3	+	2.00 x 0.2	=	**$2.30**

Source: GAO.

For each auction—a competition by qualified suppliers to deliver all items within a single product category in a single CBA—Palmetto GBA ordered the bids by composite price from lowest to highest.[31] Starting with the bid with the lowest composite price, Palmetto GBA calculated the cumulative projected capacity of the competing bids. Palmetto GBA identified the bid where cumulative projected capacity met or exceeded CMS's estimated beneficiary demand as the pivotal bid (see table 4). In table 4, the pivotal bid was submitted by Supplier 9 with a composite price of $7.64, since cumulative supply (1,765 units) reached CMS's estimated demand (1,500 units) at that bid. If projected beneficiary demand could not be met by qualified suppliers, a pivotal bid could not be established and the auction was considered nonviable.[32] Otherwise, bids with composite prices equal to or less than the pivotal bid were winners on the basis of price.

[31]CBP round 1 consisted of 92 auctions. Though there were 10 CBAs and 10 product categories in round 1, support surfaces (group 2 mattresses and overlays) were only bid in Miami and San Juan.

[32]When an auction was declared nonviable, the DME items in the product category in that CBA would continue to be paid according to the Medicare DME fee schedule and all Medicare enrolled DME suppliers would continue to be allowed to submit DME claims for these items in that CBA. In CBP round 1, seven auctions were declared nonviable.

Table 4: Determining the Pivotal Bid

Bids	Composite price (ordered)	Each bid's projected capacity	Cumulative projected capacity	Estimated beneficiary demand: 1,500	Pivotal bid
Supplier 15 bid	$4.00	400	400	Does not meet	
Supplier 6 bid	$5.70	320	720	Does not meet	
Supplier 1 bid	$5.76	200	920	Does not meet	
Supplier 7 bid	$5.87	100	1,020	Does not meet	
Supplier 12 bid	$6.20	245	1,265	Does not meet	
Supplier 10 bid	$6.21	200	1,465	Does not meet	
Supplier 9 Bid	**$7.64**	**300**	**1,765**	**Meets**	✓
Supplier 3 bid	$9.75	400	2,165		
Supplier 2 bid	$9.89	100	2,265		

Source: GAO.

Setting Medicare single payment amounts. Bids that won on price were used to establish Medicare's single payment amounts for each item in the auction.[33] For each item, Palmetto GBA ordered these winning bids' price offers for each item from lowest to highest. The median price offered for that item would be Medicare's payment for that auction item in that CBA. The use of the median in setting the item's single payment amount meant that Medicare's payment amount could be less than or more than a particular winning supplier's actual bid for an item. Because CBP payments may only be paid on assignment, Medicare would pay the supplier 80 percent of the single payment amount for an item and the beneficiary would be responsible for the remaining 20 percent.

Contract offers. In addition to winning on price, small suppliers' bids could also win if there were an insufficient number of small suppliers that won on price alone.[34] Before the initial set of contract offers, Palmetto GBA determined whether CMS's target—that 30 percent of the qualified suppliers be small suppliers—had been met by small suppliers winning on price. In the auctions where the goal had not been met, Palmetto GBA moved up the composite pricing order, above the pivotal bid, for small suppliers only as a means to include additional small suppliers. These

[33]The same DME items could have different single payment amounts in different CBAs.

[34]CMS defined small suppliers as those that generate gross revenue of $3.5 million or less in annual receipts including Medicare and non-Medicare revenue.

additional small suppliers would then be offered contracts, in addition to those suppliers whose bids won on price alone. In March 2008, CMS and Palmetto GBA notified suppliers of the auction results and CMS extended contract offers to winning suppliers. In May 2008, CMS announced the suppliers that had accepted contracts for the 3-year CBP contract period from July 1, 2008, through June 30, 2011.[35] However, MIPPA, which was enacted on July 15, 2008, terminated the CBP round 1 contracts.

About One-Quarter of Bids Resulted in Contracts Generating Significant Potential Savings

About one-quarter of the bids submitted during CBP round 1 resulted in awarded contracts. Of the 6,374 bids submitted by 1,010 suppliers, half were disqualified before competing on price—most often for missing financial documentation or noncompliance with accreditation requirements. Nearly two-thirds of the 85 auctions saw the number of suppliers decrease by 50 percent or more compared to the number of suppliers billing Medicare for the product category in 2006. CMS estimated that the volume-weighted reduction in Medicare's payment amounts for round 1 would have averaged 26 percent.

About One-Quarter of the Submitted Bids Resulted in Contracts, but Almost Half Were Disqualified for Missing Financial Documentation

Once the contract award process was completed, 22 percent of the bids submitted (1,372 of 6,374) resulted in contracts between CMS and suppliers to provide DME and other items to Medicare beneficiaries.[36] (See table 5 for step-by-step results.) CMS initially extended contract offers for 1,335 bids.[37] Contracts were offered to additional suppliers when some winners rejected the contract offers associated with 86 bids, as well as after CMS reversed Palmetto GBA's determinations to disqualify 27 bids. Winning suppliers may have rejected contracts because the CBP single payment amounts were less than the item prices the supplier had bid.

[35]The contract period for diabetes mail-order supplies was July 1, 2008, through March 31, 2010.

[36]Three percent of the bids competed in seven nonviable auctions. Of the 178 bids submitted for the nonviable auctions, 81 were qualified.

[37]CMS entered into these contracts with suppliers, which, among other things, required suppliers to deliver all items in a product category throughout a CBA.

Table 5: CBP Round 1 Bid Counts by Process Step

Process step	Number of round 1 bids	Percentage of total bids reviewed
1. Bid review		
Bids reviewed	6,374	100
Bids disqualified on first review	(3,143)	49
Bids qualified but rejected because auction deemed nonviable	(65)	1
2. Winner selection		
Qualified bids used to determine pivotal bids	3,166	50
Bids that lost on price	(1,831)	29
Bids that won on price or were contracts with small suppliers added to meet 30 percent target, or both	1,335	21
3. Contract offers		
Initial round of contract offers	1,335	21
Additional offers extended	137	2
4. Contract outcomes		
Total contract offers made	1,472	23
Contract offers rejected	(86)	1
Acceptances in nonviable auctions that were withdrawn	(14)	<1
Final contracts	1,372	22

Source: Palmetto GBA.

Note: Numbers in parentheses are decreases.

By the end of 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. (See table 6.) 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. Disqualified bids were ineligible to compete on price and were not considered for a contract award.

Table 6: Number and Percentage of CBP Disqualified Bids by Reason for Disqualification

Reason for bid disqualification	Bids disqualified for this reason	Percentage of bids disqualified
One or more suppliers lacked required financial documentation	2,698	86
No suppliers were accredited by a CMS-approved accreditation organization for the product category	681	22
A bid price for one or more items was deemed not bona fide	230	7
One or more suppliers did not meet enrollment standards for supplier billing privileges	120	4
Suppliers sharing common ownership or management were competing in the same auction	104	3
One or more suppliers did not meet financial standards	48	2
Bid submitted by a network did not meet all network requirements	3	<1

Source: GAO based on information provided by CMS.

Note: Percentages add to more than 100 because bids could be disqualified for more than one reason.

In the preamble to the CBP final rule, CMS acknowledged that the number of suppliers would decrease as the result of competitive bidding.[38] In 2006, the median number of suppliers per CBA for a product category was 31.[39] For the 2 weeks the CBP contracts were effective, the median number of suppliers fell to 14, or 55 percent less than the number in 2006.[40] Nearly two-thirds of the auctions conducted during CBP round 1 had decreases in the number of suppliers of 50 percent or more. (See app. II for auction-specific detail.) Mail-order diabetic suppliers had the largest decrease (88 percent) while walkers and related accessories had the smallest decrease. One of the 10 product categories, negative pressure wound therapy pumps, had an increase in the number of suppliers as the result of CBP. Compared to the other nine CBAs, the Miami CBA had the largest number of suppliers in eight of nine product categories in 2006 and had the greatest decreases in suppliers after CBP round 1.[41] The median number of

[38]72 Fed. Reg. at 18077.

[39]This number includes only those suppliers submitting at least $10,000 worth of claims to Medicare for the product category within the CBA for dates of service between January 1, 2006, and December 31, 2006.

[40]Only those suppliers that had entered into CBP contracts with CMS as of June 11, 2008, are included.

[41]Miami was the only CBA with CBP contracts for group 2 support surfaces in 2008, so it was not possible to compare changes in the number of suppliers between Miami and the other CBAs.

suppliers across the 10 product categories decreased 87 percent in the Miami CBA.

CMS Generally Met the Small Supplier Representation Goal

In 76 of the 85 auctions, at least 30 percent or more of the suppliers that were awarded contracts were small. Small suppliers represented at least 57 percent of all suppliers registered on CBSS and 63 percent of the winning suppliers (see table 7).[42] Because small suppliers submitted fewer bids on average, slightly less than half (48 percent) of all bids resulting in contracts were from small suppliers.

Table 7: CBP Round 1 Contract Awards by Supplier Size

Size of suppliers	Number of registered suppliers	Percentage of registered suppliers	Number of registered suppliers awarded contracts	Percentage of registered suppliers awarded contracts
Small supplier	574	57	208	63
Large supplier	300	30	121	37
Unknown[a]	136	13	NA	NA
Total	**1,010**	**100**	**329**	**100**

Source: GAO based on information provided by CMS.

Notes: NA means not applicable. These suppliers did not submit sufficient financial information to determine their gross revenues and were disqualified. These suppliers were not eligible for contract awards.

[a]Palmetto GBA was unable to classify the size for 136 registered suppliers and 746 of their bids because the suppliers did not include income statements or revenue information with their bid package.

[42]If the suppliers of unknown size were excluded from calculating the percentage of total suppliers, small suppliers would have represented 66 percent of the total instead of 57 percent.

CMS Estimated a 26 Percent Reduction in CBP Single Payment Amounts Compared to the Medicare Fee Schedule

CMS estimated that, compared to the 2008 Medicare fee schedule, the volume-weighted reduction in Medicare's payment amounts for items acquired under CBP round 1 would have averaged 26 percent.[43] (See app. III for specifics by CBA and product category.) The items in the mail-order diabetic supply category had the largest reductions, with differences between the CBP single payment amounts and the Medicare fee schedule averaging 43 percent. CBP single payment amounts were reduced the least for items in the complex rehabilitative power mobility devices and negative pressure wound therapy pumps categories—on average, 15 and 16 percent lower than the 2008 Medicare fee schedule.

CMS Had Difficulty Providing Bidders with Clear, Timely Information, and Its Electronic Bid Submission System Was Problematic

CMS's implementation of CBP round 1 presented several challenges to suppliers. Some bid submission information was poorly timed and unclear, confusing suppliers about bidding requirements and compelling some to revise and resubmit their bids. In addition, the CBSS experienced several problems that made submitting bids difficult. CMS did not notify all suppliers of its postbidding review process, which reinstated some bids that CMS found to have been incorrectly disqualified. While the PAOC alerted CMS to potential challenges for round 1, some were not resolved before the bid window opened.

[43]According to CMS officials, the savings estimate for each combination of CBA and product category was derived by multiplying the difference between the 2008 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 2006, the same weights used in estimating composite prices in 2007.

CMS Provided Bidding Information to Suppliers after the Bid Window Opened and Extended the Window Deadlines Three Times

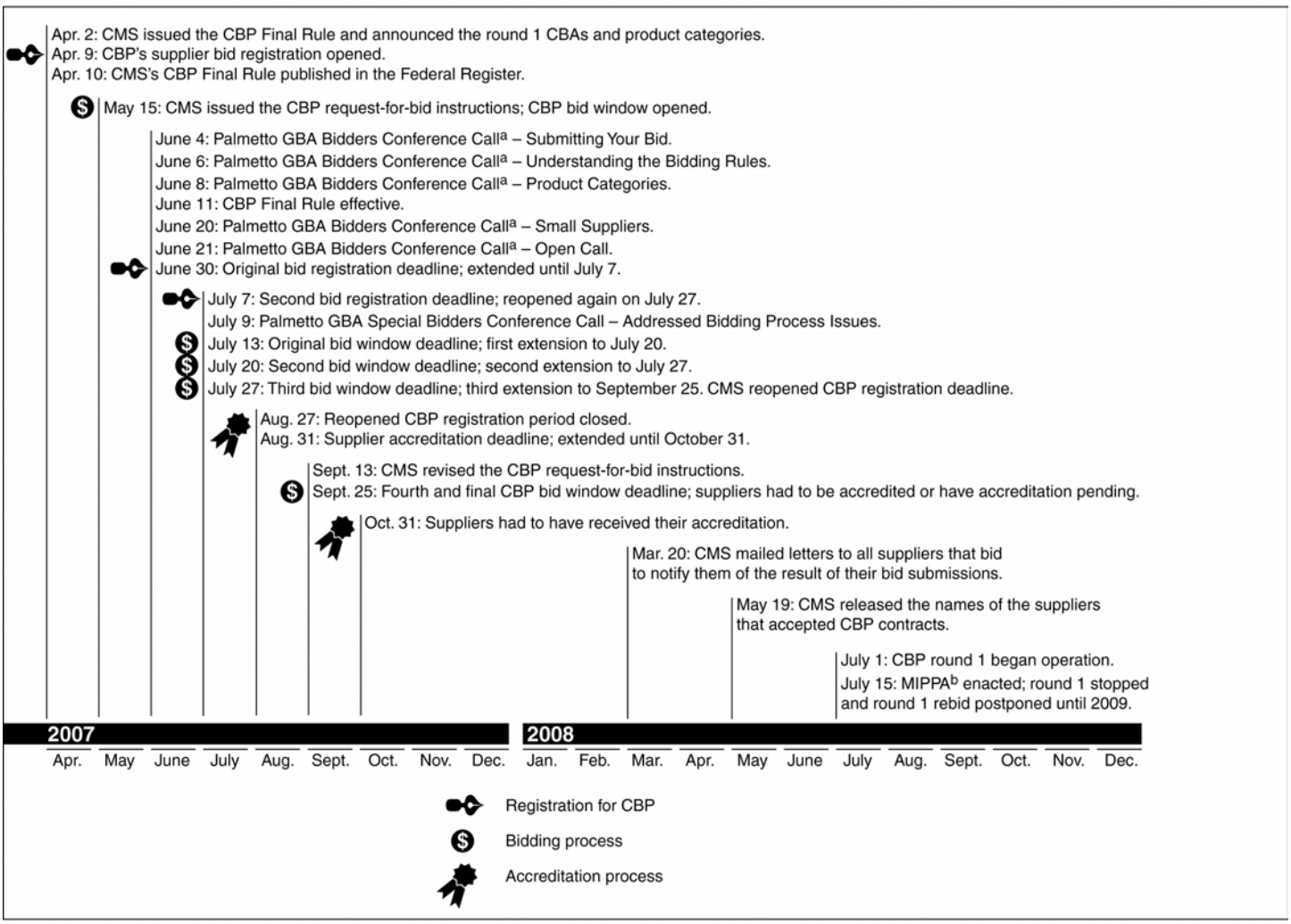
CMS clarified CBP bidding information after the bid window opened and extended the bid window deadlines three times—actions making it more difficult for suppliers to submit correct bids. (See fig. 2.) While the CBP request-for-bid instructions, posted the day that the bid window opened, were only revised once,[44] CMS and Palmetto GBA provided additional information explaining the instructions throughout the bid window.[45] Although suppliers could revise their submissions throughout the bid window, when additional information was provided those that believed they had submitted completed bids had to review them to ensure they were still correct. For example, if a supplier revised any of its financial documentation, it had to resubmit the entire financial documentation package and certification statement in hard copy.[46]

[44]CMS revised the request-for-bid instructions on September 13, 2007—about 2 weeks before the CBP bid window closed on September 25, 2007—and posted the revision on Palmetto GBA's Web site. The revised instruction informed suppliers that it was their responsibility to ensure that they had submitted a complete package of all required hardcopy documents to Palmetto GBA, and that their CBSS homepage would indicate whether the package had been received, but "this does not mean that the package is necessarily accurate, completeness [sic] or meets CMS criteria." The original instructions had stated that suppliers' bid submissions would be reviewed by Palmetto GBA for completeness beginning 10 business days before the bid window closed. Suppliers also received a listserv message—a message sent to multiple e-mail addresses on a subscriber mailing list—from CMS that stated Palmetto GBA "will not be able to notify bidders of any specific missing documentation or otherwise provide confirmation of the accuracy or completeness of the hard-copy documentation." The message did not indicate that it was a revision of the request-for-bid instructions. (In its agency comments to this report, CMS told us that it also notified suppliers by individual e-mails.)

[45]Throughout the bid window, CMS continued to provide additional information about the bidding process; for example, on May 25, 2007—10 days after the bid window opened—CMS announced the 10 financial measures that would be used to evaluate the financial viability of bidding suppliers. During the original 60-day bid window, Palmetto GBA conducted six bidder conference calls—three within the first 30 days—to provide more information about the bidding process. The calls were conducted to help suppliers understand the request-for-bid instructions that were released the day the bid window opened. The first three calls—conducted about 3 weeks after the bid window opened and within 5 days of each other—focused on how suppliers should submit a bid, understanding bidding rules, and the product categories. The next two calls—conducted on consecutive days—focused on the bidding provisions specific to small suppliers, and an open call to allow suppliers to ask CBP questions—were held less than a month before the first bid window deadline of July 13, 2007. The sixth and last call—to address bidding process issues—was held 4 days before the July 13 deadline.

[46]The supplier's signed certification statement applied to all bid information submitted electronically or in hard copy. The request-for-bid instructions explained that the statement certified that the financial documents included—which were not prepared as part of a tax return—were accurate and had been prepared on an accrual or cash basis of accounting.

Figure 2: CBP Round 1 Timeline, 2007-2008



Source: GAO analysis of CMS data.

[a]CMS conducted bidder conference calls to inform potential bidders about the bidding process.

[b]Medicare Improvements for Patients and Providers Act of 2008.

CMS's bid window extensions resulted in a 4-month bid window, open May 15, 2007, through September 25, 2007—about 2-½ months longer than originally planned. A first 1-week extension was announced on June 29, 2007—about a week after the open bidder conference call to respond to suppliers' questions. Palmetto GBA and CMS then conducted a special 30-minute bidder conference call on July 9, 2007, to address suppliers'

concerns about CBSS data losses from an automated logout security feature that caused suppliers to lose unsaved information. CMS announced the second 1-week extension from July 20, 2007, to July 27, 2007. On July 27, 2007, CMS announced a third, 2-month deadline extension to September 25, 2007, and explained there would be a targeted period to address suppliers' remaining questions and requested that suppliers e-mail their questions to Palmetto GBA by August 10, 2007.

CMS allowed suppliers to submit CBP bids while their DME accreditation was pending, and when the final bid window extension was made, the accreditation deadline was also extended. Although CMS had encouraged suppliers to begin the accreditation process before the bid window opened, some suppliers were submitting bids while completing their accreditation process. A CMS official told us that some suppliers did not appreciate or understand the amount of information needed before the accrediting organizations could conduct an accreditation site visit.

Whether suppliers had the required DME state licenses was to be determined as part of the accreditation process. However, CMS acknowledged that it checked supplier licenses after contract offers were made and Palmetto GBA officials acknowledged that some suppliers were awarded CBP contracts even though they did not have the necessary state licenses at the time contracts were awarded.[47]

CMS's Competitive Bidding Submission Information Was Sometimes Unclear, Particularly for Financial Documentation

CMS and Palmetto GBA acknowledged that suppliers did not always understand the request-for-bid instructions.[48] CMS provided guidance to suppliers through the CBP final rule and the request-for-bid instructions, and CMS and Palmetto GBA provided additional information throughout the bid window through multiple sources. These sources included the Palmetto GBA Web site and its frequently asked questions section,[49] bidder conference calls, CMS and Palmetto GBA listservs, and the Palmetto GBA

[47]After contract awards were announced, two state DME associations told us that they found some winning suppliers did not have the necessary state licenses.

[48]CMS and Maricom developed the request-for-bid instructions; Palmetto GBA provided comments and recommendations.

[49]CMS officials told us that more than 90 percent of the frequently asked questions were posted on the Palmetto GBA Web site during the bid window. The CMS Web site had links to the Palmetto GBA Web site and to medicare.gov, the official Web site for Medicare beneficiaries.

customer service center.[50] We found that these sources sometimes had unclear or inconsistent information about the bidding instructions, including the specialty supplier definition, how to estimate supplier capacity, and how to complete bid application Forms A and B. (See app. IV for examples.) Some suppliers told us that Palmetto GBA service center employees could not answer their questions and one supplier told us it was uncomfortable using the center because it was unsure the information provided was correct.

CMS also acknowledged that many suppliers had particular difficulty complying with the financial documentation requirement. A supplier told us, for example, that it was a wholly owned subsidiary of a parent company and did not understand which financial documentation requirements in the request-for-bid instructions applied to it. A CMS official told us that some suppliers did not understand that they had to provide all of the required financial documents, and that the statement of cash flow—described as a statement of changes in financial position—was the document most often missing. We also found that CMS's 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 supplier type.[51] Because business types did not easily link to the request-for-bid instructions, suppliers were at risk of submitting incomplete or inaccurate financial documentation.

We found that CMS's request-for-bid instructions had inconsistent information about the requirements for a credit report and credit score. The Form A bid instructions for financial information discussed different

[50]CMS also had fact sheets available on its Web site concerning post-CBP bidding issues such as the grandfathering of certain suppliers who may continue to provide items and services even if they had not been awarded a contract under CBP and how items would be repaired or replaced.

[51]On the bid submission Form A, suppliers self-identified themselves as one of eight supplier types— business corporation, professional organization, sole proprietorship, franchise, general partnership, publicly traded company, joint venture, or other. Different categories were used in the request-for-bid instructions. There suppliers were described for financial documentation purposes as suppliers that submitted individual tax returns that include business taxes, limited partnerships and partnerships, suppliers that submit corporate tax returns, suppliers that are publicly traded companies, new suppliers, and suppliers submitting an individual bid and also being part of a network. Only the publicly traded company term was used in both.

types of suppliers and their financial documents in six paragraphs. In two paragraphs—for suppliers that submit individual tax returns that include business taxes and for suppliers that submit corporate tax returns—the instructions stated that those supplier types had to submit a current credit report but stated nothing about a credit score. In the remaining four paragraphs—for limited partnerships, publicly traded suppliers, new suppliers, and networks—nothing was stated about either a credit report or a credit score. The bid submission Form A 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 on September 13, 2007, Palmetto GBA issued a "required document reminder" that stated that all bidders, regardless of their business structure, had to submit both a credit report and a credit score.

CMS Feedback to Suppliers on Bid Disqualification Reasons Were Vague and Incomplete

The feedback that CMS provided to suppliers that had bids disqualified because of bid submission deficiencies was vague.[52] CMS provided suppliers that had bids disqualified with seven general reason codes to explain the grounds for the disqualifications. (See table 8.) The suppliers with disqualified bids received letters dated March 20, 2008, from Palmetto GBA with attachments that indicated which reason code or codes applied for each CBA and each product category for which the supplier submitted a bid.[53]

[52]CMS had stated in the preamble to the CBP final rule, that given the expected bid volume, logistics, and time constraints, it would not be administratively feasible to provide losing suppliers individual bid debriefing meetings to discuss the inadequacies of their bid.

[53]Suppliers that had bids that failed on price and suppliers that were offered contracts for their winning bids also received notification letters dated March 20, 2008.

Table 8: CMS's CBP Bid Disqualification Reason Codes and Descriptions, CBP Round 1

Reason code	Reason code description
BSE-1	Bidder did not meet enrollment standards specified in 42 C.F.R. 424.57(c).
BSE-2	Bidder did not submit a bona fide bid that complies with all the terms and conditions contained in the request for bids (RFB).
BSE-3	Bidder did not meet applicable quality standards developed by CMS in accordance with § 1834(a) (20) of the Social Security Act / was not accredited by a CMS-approved accreditation organization.
BSE-4	Bidder did not submit along with its bid the applicable financial documentation specified in the request for bids (RFB).
NR-1	Bidder did not meet network requirements.
CO-1	Bidder did not submit a single bid for commonly-owned or controlled suppliers.
FS-1	Bidder did not meet financial standards.

Source: CMS and Palmetto GBA.

The reason codes provided as feedback may not help a supplier understand how to resolve its bid issues for future CBP rounds. For example, if a supplier's bid did not provide all required financial documentation, it was disqualified under the BSE-4 reason code. (See table 9.) The BSE-4 reason code does not inform the supplier which financial document or documents were not submitted. Likewise, if the supplier did not meet the financial standards, the bid was disqualified under the FS-1 reason, and the supplier would not know the standard or standards it had not met. In addition, CMS did not always provide a supplier with all reasons why a bid was disqualified. Palmetto GBA officials told us that suppliers were informed of an accreditation disqualification reason (BSE-3) if it was the bid's only disqualifying reason. If a supplier was disqualified both for a reason code other than BSE-3 and for not being accredited, the supplier would not have been informed about the accreditation reason.

Table 9: Text of One Disqualified Bid Letter's Attachment Information

Competitive bidding area	Product category
	Oxygen Equipment and Supplies
Charlotte-Gastonia-Concord, NC-SC	**BSE-4**

Source: CMS and Palmetto GBA.

CMS Postbidding Review Process Was Not Effectively Communicated to Suppliers and Was Inconsistent with CMS's Earlier Interpretation of Its Authority to Conduct Such Reviews

CMS conducted a postbidding review process through which the agency reversed Palmetto GBA's decision to disqualify the bids of certain suppliers. Specifically, Palmetto GBA and CMS reviewed a total of 1,935 bids from 357 suppliers from March 21, 2008, through July 9, 2008.[54] They only reviewed the disqualified bids of suppliers who contacted them with questions or requested a review.[55] As a result of this review, CMS determined that 10 suppliers had 58 bids incorrectly disqualified; the agency subsequently offered CBP contracts to 7 of these suppliers for 27 bids.[56]

CMS did not effectively communicate to suppliers that they had an opportunity to have disqualified round 1 bids reviewed. CMS officials informed us that the agency made a decision on or about March 5, 2008, as part of a quality assurance process, to permit Palmetto GBA to review disqualified bids after suppliers received their March 20, 2008, letters notifying them of their disqualifications.[57] After the letters were sent to suppliers on March 20, 2008, CMS officials told us that suppliers learned

[54]CMS officials confirmed that bid reviews took an average of 34 days to complete and suppliers were notified of the results of their bid reviews from April 21 through August 28, 2008. Palmetto GBA acknowledged that because of the volume of challenges, the time required for review and the fact that no time frame was specified, the reviews continued after July 1, 2008, the implementation date of the CBP program.

[55]CMS informed us that the 290 suppliers with disqualified bids who did not call Palmetto GBA or CMS with questions or request a review did not receive one.

[56]These 10 suppliers had been disqualified for (1) failing to submit required financial documentation, (2) failing to be appropriately accredited, (3) having a bid price for one or more items that was not bona fide, or (4) sharing common ownership or management when competing in the same auction. The incorrectly disqualified suppliers were offered contracts if they had bids equal to or less than the pivotal bid or were needed to meet the small-supplier participation goal.

[57]CMS officials stated that Palmetto GBA reviewed disqualified bids and made recommendations as to whether the disqualification determination should be overturned; those recommendations were subsequently reviewed and acted upon by CMS.

about the bid review opportunity if they contacted Palmetto GBA with questions about their bids,[58] participated in an April 2008 CMS Open Door Forum[59] about the CBP program, or attended the June 16, 2008 PAOC meeting.[60] CMS and Palmetto GBA, however, did not provide any written notification explaining this review process to suppliers prior to or after they were informed of their bid disqualifications, and some suppliers were not aware of this opportunity for review. For example, two suppliers informed us that they were unaware that a postbidding review was an option. Another supplier informed us that the company's bids were disqualified and when he called Palmetto GBA to follow up, he was informed that there would be a review and response in 30 days, but he had not received a response as of March 25, 2009. An additional supplier informed us that in response to his inquiries, CMS stated that there was no formal appeal process.

Moreover, the postbidding review was inconsistent with CMS's earlier interpretation of its authority to conduct such reviews. Before soliciting bids for round 1, the agency determined that it would not have the authority to review the results of bid evaluations. The MMA prohibited administrative and judicial review of certain round 1 determinations, including the awarding of contracts, the bidding structure, and number of contractors selected.[61] Neither the MMA nor its legislative history defined the phrase "administrative review." In the preamble to the CBP final rule, however, CMS interpreted this provision as prohibiting review of the

[58]The March 20, 2008, letters to suppliers stated that "If you have any questions, please contact the customer service center at 877-577-5331."

[59]CMS periodically conducts open door forums for DME suppliers using telephone conference calls. The forums offer suppliers an opportunity for live dialogue with CMS officials about policy and program-related issues. Participants may call in without having to register. Once posted on the CMS Web site, forum replays are available for 30 days.

[60]A CMS official stated at the PAOC meeting on June 16, 2008, that suppliers had been informed there was a bid review process and that they could contact Palmetto GBA to request their bids be reviewed. A meeting summary was not posted to the CMS Web site until August 2009, but it did not make any references to the postbid review process. As of September 10, 2009, no transcript of the June 16, 2008, meeting had been posted.

[61]The MMA stated, "there shall be no administrative or judicial review under [42 U.S.C. § 1395ff, § 1395oo], or otherwise, of … the awarding of contracts … or the bidding structure and number of contractors selected…". Pub. L. No. 108-173, § 302, 117 Stat. 2066, 2224 (2003) (codified, as amended, at 42 U.S.C. § 1395w-3(b)(10)). CMS subsequently incorporated this prohibition in its regulations implementing the CBP. 42 C.F.R. § 414.424.

results of bid evaluations.[62] CMS did not explicitly address such a review or any reversals of bid disqualifications elsewhere in its regulations or other policy guidance. In the preamble, CMS also recounted that commenters requested that it establish a grievance and review process for suppliers.[63] Among other things, commenters also expressed concern about the potential for errors in disqualifying suppliers and requested that CMS provide an opportunity for review to confirm the accuracy of these disqualifications.[64] In response to these comments, CMS indicated that it did not have the authority to review the outcome of bid evaluations. Specifically, it cited the prohibition on administrative or judicial review, explaining that Congress enacted this prohibition to avoid any delay or disruption in the implementation of the program as a result of challenges brought by bidders.

In response to our inquiries during this evaluation, CMS officials informed us that the postbidding review process was not an administrative review prohibited by statute, but rather a quality assurance measure. In our view, CMS's characterization of the postbidding review process as a quality assurance measure does not fully address the inconsistency with the agency's earlier position that it did not have the authority to conduct such a review. In the preamble to the CBP final rule, CMS advised that it would notify losing bidders but would not provide debriefings due to logistics, volume of bidders, and time constraints. As an alternative, CMS explained that the agency would conduct an extensive education and outreach program for suppliers and was developing a quality assurance program. But the postbidding review process was distinct from the specific quality assurance steps that CMS described it would take in the preamble to the

[62]72 Fed. Reg. at 18055-56. In the CBP final rule, CMS did provide for one situation in which contracts could be awarded to losing suppliers. Specifically, subsequent to the awarding of contracts, CMS may award additional contracts when there is a need for additional contract suppliers to meet beneficiary demand for a particular product category. 42 C.F.R. § 414.414(i). During round 1, CMS awarded contracts to some suppliers who were deemed qualified but who lost their bids on price; these actions were separate and distinct from the postbidding review process described above.

[63]For example, while acknowledging the statutory prohibition on administrative review, two commenters asserted that it did not preclude the establishment of a process that would give suppliers an opportunity to communicate with CMS regarding grievances and seek redress.

[64]For example, numerous commenters recommended that CMS implement a procedure for debriefing suppliers that were not selected and provide an opportunity for a review to determine, at a minimum, whether an error on the part of CMS or its contractors was the reason that the supplier was not selected.

CBP final rule.[65] In addition to its own quality assurance system, CMS indicated that Palmetto GBA would implement a quality assurance program, but did not elaborate on the form this program would take.[66] However, the agency's response to commenters rejected any suggestion of a postbidding review citing prohibitions under federal law. CMS officials have since informed us that the language in the CBP final rule was ambiguous, thereby not precluding it from conducting the postbidding review to be considered a quality assurance measure. Even if that were the case, CMS did not provide any clarifying guidance to suppliers that explicitly informed disqualified suppliers of the opportunity for a postbidding review. Instead CMS made its March 5, 2008, decision to conduct these reviews about 2 weeks before suppliers were mailed notice of their bid disqualifications. The notification simply stated that suppliers could call customer service with questions, and CMS and Palmetto GBA conducted these reviews only for suppliers who contacted them or requested a review.

CMS's CBP Electronic Bid Submission System Had Information Technology Operational Problems

After the CBP round 1 bid window closed, CMS acknowledged that the CBSS had information technology (IT) operational problems that affected suppliers' ability to submit their bids.[67] CMS also acknowledged that loss of bid submission data was a major problem for suppliers. During the early part of the bid window, a CBSS security feature automatically logged a supplier out of the system after 2 hours, which caused some suppliers to lose data.[68] Another security feature timed suppliers out of CBSS if there was no activity for 30 minutes. To address suppliers' concerns with the CBSS's bid submission data losses, CMS and Palmetto GBA conducted a special bidder conference call July 9, 2007.

[65]CMS specifically defined these quality assurance steps as allowing bidders to submit electronic bids and providing suppliers with a 60-day open bidding period during which they could change, update, or correct their bid packages before certifying their final submissions.

[66]In the preamble, CMS noted that Palmetto GBA would implement an auditing system and quality assurance program to monitor and ensure that it accurately recorded and calculated information provided by suppliers.

[67]CMS presented this information at the PAOC meeting held October 11, 2007.

[68]Later in the bid window, the CBSS time-out period was extended to 12 hours.

Some suppliers stated that the CBSS was difficult to use, which impeded their ability to submit a bid. CMS officials acknowledged that the CBSS user guide was not very detailed or user friendly. Some error messages also used technical language that suppliers did not understand. In addition, CBSS required data to be manually reentered for the same product category in multiple CBAs because the CBSS did not have a "cut and paste" function. The data reentry was time-consuming and increased the risk of suppliers' inputting incorrect data that could disqualify a bid.

CMS officials stated that there were cases when the CBSS was unavailable to suppliers to submit their bids. CMS explained that CBSS had unscheduled downtimes that inconvenienced the suppliers, particularly those working in CBSS at the time. According to CMS, privacy and security rules required that each user ID and password allow only one user to access the CBSS at a time. However, the system did not have the controls to prevent multiple users from attempting to do so. When this scenario did occur, the system became inaccessible for all user IDs and passwords. A supplier told us that it had to wait until nonworkday hours to access the CBSS to submit its bids. On the last day of the bid window, CBSS was unavailable for several hours.

CMS's Program Advisory and Oversight Committee Provided Input to Address Supplier Challenges, but Not All Challenges Were Addressed

Although a CMS official said that the original PAOC was generally helpful to CMS in developing and implementing CBP round 1 and that it provided CMS with assistance in the overall design of the program, two members of the original PAOC and three DME trade association representatives told us that CMS did not always use the PAOC effectively. Though the PAOC provided input to CMS to address potential supplier challenges during the development and implementation of CBP round 1, some issues raised were not fully resolved,[69] such as concerns about missing or lost financial documentation, the absence of a formal CMS bid review process, the concern that small suppliers would be disadvantaged, and that the supplier quality standards were not finalized before the CBP round 1 bid window opened. One PAOC member stated that although the PAOC's role was to advise and to oversee the CBP, members were not provided enough information and opportunities to provide feedback to fulfill these responsibilities. One PAOC member also reported having insufficient time to discuss and react to the CMS and Palmetto GBA presentations and expressed dissatisfaction at not being able to formulate or vote on recommendations. A CMS official stated that the PAOC had cochairs—one CMS official and one industry representative—to encourage mutual collaboration. However, the two PAOC members said this approach was not effective because the CMS cochair had a greater role on the committee than the industry cochair.

[69]During its 4 years, the PAOC met seven times beginning in 2004 through 2008. The PAOC held four meetings in 2004 and 2005 where CMS presented CBP options being considered—for example, for selecting the items for competitive bidding, organizing the items into product category groups, establishing supplier capacity and beneficiary demand estimates, calculating single payment amounts, and ensuring the participation of small suppliers. After CMS published a proposed rule for implementing CBP round 1 in May 2006, 71 Fed. Reg. 25,654, the PAOC met for the fifth time, May 22–23, 2006, to provide feedback on the proposed implementation process. About a year and a half later, the PAOC met for the sixth time on October 11, 2007—16 days after the CBP bid window closed. At this meeting, CMS updated the PAOC on the CBP round 1 bidding. The PAOC's seventh meeting, June 16, 2008, was held 2 weeks before the contracts awarded to suppliers in CBP round 1 took effect. PAOC members were briefed by CMS and Palmetto GBA on the CBP process and CMS's CBP round 1 education and monitoring activities, and were asked for their feedback for improving the next CBP round. CMS provided meeting summaries, agendas, and presentation materials for the first five meetings on the CMS Web site. The summaries for the last two PAOC meetings—held on October 11, 2007, and June 16, 2008—were not available on CMS's Web site until August 2009. A Palmetto GBA official stated that Palmetto GBA was responsible for preparing the meeting summaries of the last three PAOC meetings. Meeting transcripts, though available for all of the meetings held through 2008, have not been posted on the CMS Web site.

CMS Has Taken Several Steps to Improve Future Rounds of the CBP, Including Implementing MIPPA Provisions and Addressing IT Operational Problems

CMS has taken several steps to improve future rounds of the CBP. It issued an interim final rule in 2009 to implement certain provisions of MIPPA that affect the round 1 rebid. It has taken several additional actions to make the round 1 rebid bidding process easier for suppliers to navigate and the bidding information easier to understand. CMS's new bid submission system, DBidS, may address the IT operational deficiencies that occurred during round 1. Finally, though MIPPA extended the termination date of the PAOC, CMS disbanded the original PAOC and appointed new members to the current PAOC to provide new expertise and input for the round 1 rebid.

CMS Has Implemented Certain MIPPA Provisions

CMS's interim final rule, effective April 18, 2009,[70] implemented certain MIPPA provisions, including changes that CMS is required to make for the CBP round 1 rebid and future rounds.[71]

- **Notification of missing financial documentation**. CMS will notify and provide feedback about any missing financial documentation to bidding suppliers that submit their required financial documentation within a time period known as the covered document review date.[72] Once notified, suppliers will have 10 business days to submit the missing documentation.[73]

[70]The original effective date of CMS's interim final rule was February 17, 2009, but CMS issued a Federal Register notice on February 19, 2009, that delayed the effective date until April 18, 2009. 74 Fed. Reg. 7653 (Feb. 19, 2009).

[71]74 Fed. Reg. 2873.

[72]Financial documentation means a financial, tax, or other document required to be submitted in order to meet CMS's financial standards for the CBP. MIPPA and implementing regulations define 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 round 1 rebid, CMS is 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.

[73]42 C.F.R. §§ 414.402, 414.414. MIPPA provided, however, that 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.

- **Subcontractor information**. Suppliers that enter into CBP contracts with CMS must disclose (1) each subcontracting arrangement the supplier enters into to provide items and services covered under its CBP contract and (2) whether the subcontractor meets accreditation requirements, if applicable.[74] The supplier must provide this information to CMS within 10 days of entering into a CBP contract and within 10 days of entering any subcontracting arrangement subsequent to the award of the contract.[75]

  In addition to the changes specifically required under the interim final rule, MIPPA also included other changes to the CBP.[76]

- **Accreditation deadline**. Suppliers, including subcontractors, providing items or services on or after October 1, 2009, must have submitted evidence of accreditation prior to this date.[77]

- **CBP ombudsman**. A competitive acquisition ombudsman, within CMS, must be appointed by the HHS Secretary to respond to CBP questions and complaints made by suppliers and individuals. The ombudsman must submit an annual report detailing CBP-related activities to Congress.[78]

- **PAOC extension**. The termination date for the PAOC is extended from December 31, 2009, to December 31, 2011.[79]

Additional CMS Actions to Improve the Round 1 Rebid

CMS has made several additional changes for the CBP round 1 rebid in response to problems that occurred during CBP round 1. First, to reduce the burden on bidding suppliers providing financial documentation, CMS, as stated in the preamble to the interim final rule, will require suppliers to submit 1 year of documentation instead of 3 years, which CMS now

[74]See 42 U.S.C. § 1395m(a)(20)(F)(i) for accreditation requirements.

[75]42 C.F.R. § 414.422.

[76]Pub. L. No. 110-275, § 154, 122 Stat. 2494, 2560 (2008).

[77]42 U.S.C. § 1395m(a)(20)(F)(i). This requirement is not limited to suppliers and subcontractors participating in the CBP and instead applies to any supplier and subcontractor providing items and services to Medicare beneficiaries on or after October 1, 2009. According to CMS, suppliers that are not accredited by September 30, 2009, will be barred from participating in Medicare.

[78]42 U.S.C. § 1395w-3(b)(3)(f).

[79]42 U.S.C. § 1395w-3(c)(2).

believes is adequate to determine a supplier's financial soundness. The request-for-bid instructions now provides a chart that lists the required financial documents by supplier type. For example, the chart distinguishes the financial documentation required for a sole proprietorship versus a corporation. In addition to the chart, the rebid's request-for-bid instructions also include a sample of a completed income statement, balance sheet, statement of cash flow, and corporate tax return.

Second, CMS announced the timeline for the round 1 rebid bid window in advance, and to improve the quality and availability of information to bidding suppliers, CMS launched an intensive bidder education campaign to provide suppliers with all the information necessary to submit a complete bid during the round 1 rebid bid window. According to CMS, the request-for-bid instructions has been made clearer and more understandable. A Palmetto GBA official said that, if necessary, the request-for-bid instructions will be updated until the bid window closes, although CMS will notify suppliers if the bidding instructions are revised or clarified during the bid window.[80] Furthermore, to ensure that suppliers can easily locate the most current CBP information, CMS will date every page, article, and frequently asked question so that suppliers know when new information has been posted.

As in CBP round 1, suppliers may enter into subcontracting arrangements with other suppliers to provide items and services covered under their CBP contract to eligible Medicare beneficiaries. However, CMS clarified that subcontractors may be used only to purchase inventory, deliver and instruct on the use of Medicare-covered items, and repair rental equipment. Contract suppliers are responsible for furnishing items and services in compliance with physicians' orders and Medicare rules and guidelines. These services include coordination of care with physicians, submitting claims on behalf of beneficiaries, assuming ownership and responsibility for equipment furnished to beneficiaries, and ensuring product safety.

In addition, the original PAOC was concerned that suppliers new to a product category were given the same consideration as experienced suppliers during CBP round 1. For this reason, a CMS official announced

[80]Any revision regarding financial documentation could cause challenges for suppliers seeking to meet the covered document review date because suppliers have a limited time period within the bid window to submit financial documentation to meet this date and CMS has a specified time period to provide notification to suppliers on missing documentation.

at the June 4, 2009, PAOC meeting that the agency is now considering whether to apply a different standard to evaluate the capacity of suppliers new to a DME product category. CMS later explained the new proposal to us. For the CBP, all suppliers, both new and experienced, estimate the number of items they can provide to meet the projected demand of beneficiaries for a product category in a CBA. Currently, a supplier must meet a minimum threshold based on CMS's determination of its financial strength in order for CMS to continue to evaluate its bid. If a supplier meets that threshold, it is then evaluated against a second threshold to determine whether CMS will accept the supplier's estimate of its ability to expand its current capacity. CMS is proposing that the second threshold be higher for suppliers new to a product category than for experienced suppliers. According to a CMS official, new suppliers that did not meet the second higher threshold could still be offered a contract, although the proposal would generally result in awarding more contracts to suppliers with experience.

Suppliers participating in the round 1 rebid must have all local and state licenses for a product category in a CBA at the time of bid submission in order to be considered for a CBP contract. According to CMS, this is not a change from CBP round 1. However, there were issues during the first round that complicated licensure verification. CMS and Palmetto GBA acknowledged and some trade association representatives told us that some suppliers were offered CBP contracts during CBP round 1 for product categories for which they were not properly licensed. Therefore, for the round 1 rebid, CMS has further clarified the licensure requirement, stating that suppliers must be licensed for the product category in the CBA in which they are bidding and if a CBA covers more than one state, the supplier needs to obtain applicable licensure in all states. To ensure that the licensure requirement is met, CMS is improving quality assurance checks to confirm that suppliers are properly licensed prior to accepting suppliers' bids in the CBP round 1 rebid.

On January 2, 2009, CMS published a final rule, effective March 3, 2009, to implement a statutory requirement that certain DME suppliers post a $50,000 surety bond.[81] In responding to comments on the rule, CMS stated that the surety bond is designed to reduce the amount of money that is lost

[81]CMS, *Medicare Program: Surety Bond Requirement for Suppliers of DMEPOS*, 74 Fed. Reg. 166 (Jan. 2, 2009). The BBA had required the Secretary to impose a surety bond for at least $50,000 as a condition of suppliers becoming eligible to bill Medicare for the provision of DME and other items to beneficiaries.

due to fraudulent or abusive billing schemes by suppliers. Existing Medicare suppliers had until October 2, 2009, to comply, and as of May 4, 2009, new suppliers were required to post the bond as a condition of their enrollment in Medicare.[82] Suppliers that participate in the rebid will have to comply with the surety bond requirement.

To Address CBSS Operational Deficiencies, CMS Is Developing a New Bid Submission System

According to CMS system and Palmetto GBA personnel, the agency developed a new IT system to replace the CBSS and correct the operational problems that were identified. This system, DBidS, was developed in accordance with the agency's defined system development process and was designed to address the operational deficiencies identified with CBSS. DBidS software testing, including user testing, was completed in August 2009 and CMS management has accepted and approved the system for operation.

CMS system development is guided by its Integrated IT Investment and System Life Cycle Framework, which prescribes steps, activities, and documents required to develop CMS IT systems. For example, the framework describes processes to be followed in developing, validating, and agreeing on requirements for system features and capabilities. It also describes required testing, including user acceptance testing, which validates that business requirements are met, as well as performance and stress testing, in which large volumes of input data or simulated concurrent users are introduced to determine levels beyond which the system will fail. Finally, it describes the operational review that the agency must perform to determine whether to accept and approve the system for operation.[83] According to experts in the software development field,[84]

[82]Under limited circumstances, CMS may exempt from the surety bond requirement (1) government-operated suppliers, (2) state-licensed orthotic and prosthetic personnel, (3) physicians and nonphysician practitioners in private practice, and (4) physical and occupational therapists in private practice.

[83]In addition, CMS policy includes a requirement that contracts for system development efforts be performed by an IT contractor that meets or exceeds a specific maturity level as measured using the Software Engineering Institute Capability Maturity Model Integration®. According to CMS, IT contractor compliance with such maturity standards and methodologies signifies a greater capability to perform software development and integration activities in a repeatable and consistently high-quality manner. According to a published assessment reported by the institute, the DBidS development contractor meets the minimum level of maturity established by CMS policy.

[84]Software Engineering Institute, *Understanding and Leveraging a Supplier's CMMI® Efforts: A Guidebook for Acquirers*, CMU/SEI-2007-TR-004 (Pittsburgh PA: March 2007).

having a defined process increases the likelihood of a successful system development, although it does not guarantee it.

In accordance with the framework, CMS officials assessed CBSS business requirements and reviewed these with the contractors to establish a new set of baseline requirements for DBidS. The agency used these requirements to develop a design for the system, which was reviewed by CMS in 2008. Based on this design, the system was developed and testing began.

On May 29, 2009, CMS began advising all DME suppliers to update their National Supplier Clearinghouse files to ensure that they contained correct and current information. CMS stated that this was especially important for suppliers planning to bid in the round 1 rebid because it would enable them to avoid the registration issues that occurred during CBP round 1 because some of the information in the suppliers' National Supplier Clearinghouse files did not match the information that was submitted into the Individuals Authorized Access to CMS Computer Systems.[85] In May 2009, a CMS official stated that DBidS was designed to address specific deficiencies identified in CBSS; it is designed to be more user friendly and easier for suppliers to navigate, and it is to provide a logical flow of the data that are requested, as well as detailed bidding instructions in user-friendly language. It is to have status indicators to indicate whether the bidding forms are "complete," "incomplete," or "pending approval," and links in the system to direct suppliers to the incomplete data. In addition, CMS said that DBidS will have a "copy and paste" function for the transfer of certain data and many data-saving points to minimize loss of data. DBidS is expected to also allow a supplier to have more than one employee access DBidS at the same time, but to control data input the

[85]The Individuals Authorized Access to CMS Computer Systems is an application that provides authentication of authorized users for the supplier and support communities of DBidS.

system will not allow more than one employee to input the same data at the same time.[86]

In addition to the DBidS changes to address specific deficiencies identified in CBSS, CMS also recognized that more thorough testing of CBSS might have prevented certain systems deficiencies. As of August 2009, CMS has completed testing DBidS, including two changes to correct a critical defect[87] and addressed the policy requirement that all suppliers be accredited. As of September 2009, CMS has accepted DBidS for operation and agency officials indicated that previous deficiencies have been satisfactorily addressed. However, until DBidS is put into operation its effectiveness in correcting these deficiencies is unknown.

CMS Changed PAOC Membership to Solicit New Expertise and Input

On October 2, 2008, CMS formally announced that because of the length of the MIPPA extension, and because the PAOC was to perform additional duties, the agency had ended the terms of service for the original PAOC members, and was soliciting nominations for new individuals to serve on the PAOC.[88] On January 15, 2009, CMS announced the 17 new members of the current PAOC who were chosen because of their expertise in a broad range of issues, including quality standards, accreditation, and Medicare beneficiary issues.[89] Although CMS stated that this PAOC was to review the bidding process for the round 1 rebid and consider all of the MIPPA

[86]CMS said that the authorized official who registers in the Individuals Authorized Access to CMS Computer Systems and DBidS should authorize a backup and an end user to ensure that an official in the organization will be able to access DBidS. The authorized official must be listed on the supplier's Medicare enrollment form and must register through the Individuals Authorized Access to CMS Computer Systems and DBidS. Once CMS verifies the supplier organization and personal information entered, CMS will mail the authorized official a temporary password and identification number. The official can then authorize a backup. They are authorized to input data, approve Form A, and certify Form B. They can also authorize an end user, an employee of the supplier, to input data.

[87]According to CMS, a critical defect renders the whole system nonoperational, corrupts critical system data or information, or makes it impossible to continue with testing because of the severity of the error.

[88]CMS, *Medicare Program: Request for Nominations for the Program Advisory and Oversight Committee for the Competitive Acquisition of Durable Medical Equipment and Other Items*, 73 Fed. Reg. 57363 (Oct. 2, 2008).

[89]The current PAOC membership includes representatives of Medicare beneficiaries and consumers, physicians and other practitioners, suppliers, organizations that help to establish professional standards, financial standards experts, DME industry associations, and manufacturers.

changes, CMS did not schedule the first meeting until June 4, 2009, 4-½ months after CMS had issued its interim final rule for public comment to implement the MIPPA provisions on January 16, 2009. Like the original PAOC, the current PAOC is cochaired by a CMS official and a DME industry representative.[90]

Similar to the meetings of the original PAOC, the June 4, 2009, PAOC meeting included several presentations by CMS officials with limited time allowed at the end of each for PAOC member discussion. The presentations included information concerning DBidS; CBP requirements and bidder responsibilities; suppliers' financial documentation, licensure, accreditation, and subcontracting requirements; new supplier issues; mail-order diabetic supplies; and the tentative timeline for the CBP round 1 rebid implementation. Although a CMS official told PAOC members that they were encouraged to continue to provide individual feedback, advice, and suggestions during the meeting and additionally by e-mail for CMS's consideration, as with the original PAOC meetings, CMS did not ask the PAOC to provide recommendations that would reflect input from the committee as a whole. Although CMS had not conducted PAOC meetings by teleconference previously, the agency held a three-hour teleconference on July 21, 2009, to solicit the current PAOC members' feedback and suggestions on (1) determining beneficiary demand, (2) assessing bidding suppliers' ability to meet the demand, and (3) reviewing regulations for change of ownership and the sale of contracts. A four-page meeting summary was posted on CMS's Web site in August 2009, but a transcript has not been posted. We cannot determine at this time the degree to which the PAOC members' input will be reflected in CMS's implementation of the round 1 rebid.

Conclusions

If wholly adopted, competitive bidding could reduce Medicare payments for DME, help close the disparity with prices paid by others for the same items and services, and also help reduce improper payments. It also represents a change from Medicare's long-standing policy that any qualified provider can participate in Medicare because it authorizes CMS to select suppliers to participate in Medicare, based in part on CMS's scrutiny of their financial documents and other bid submission materials.

[90]The CMS cochairs on each of the PAOCs, the Director of CMS's Center for Medicare Management, were not listed on either PAOC's membership roster.

CBP round 1 was the first time that both CMS and DME suppliers participated in a large-scale DME competitive bidding process. Some challenges may be expected for a new program, but problems occurred, in part because of poor communication by CMS and an inadequate electronic bid submission system. CMS was aware of these problems as the bidding unfolded and extended the original bid window as it attempted to correct them. The agency worked to address these problems before the round 1 rebid began.

DBidS, the new electronic bid submission system developed by CMS and Maricom, could be an improvement if it successfully addresses the deficiencies identified in the system used for round 1 as CMS claims it will. CMS's implementation of the MIPPA requirement that the agency provide feedback on the status of suppliers' financial documentation may help reduce the number of bids disqualified for inadequate financial documentation. And the agency's implementation of the statutory requirements that all suppliers, including subcontractors, provide evidence of accreditation by October 1, 2009, and that suppliers generally must post surety bonds may help ensure that only legitimate suppliers are enrolled in Medicare and therefore are eligible to bid. To address the concerns that suppliers have the experience to provide the DME items they win contracts for, before they can submit bids, suppliers will also have to be accredited and licensed for each DME product category and CBA in which they bid. In addition, CMS's early announcement of the timeline for the rebid and the revised request-for-bid instructions gave suppliers more time to decide whether to participate in the rebid and to begin preparing their bids before the window opens.

Despite CMS's actions to improve the program, difficulties may still arise in the round 1 rebid and future rounds. Because CMS did not effectively notify suppliers of the postbidding review conducted in round 1, some suppliers missed the opportunity to have their disqualified bids reviewed. Unless CMS commits to effectively notifying all bidders of any review of disqualified bids, if it decides to allow such a process in future rounds of the CBP, CMS will not be able to ensure that all bidding suppliers have an equal opportunity to request a postbid review.

Recommendation for Executive Action

To improve future rounds of the competitive bidding program for DME, we recommend that the Administrator of CMS take the following action:

- If CMS decides to conduct a review of disqualification decisions during the 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.

Agency Comments and Our Evaluation

In written comments on a draft of this report, HHS agreed with our recommendation that it effectively notify all suppliers of all aspects of the CBP. This would include any process to review bid disqualifications. CMS said it believes that suppliers should have the opportunity to raise questions or concerns about the competitive bidding process, including disqualification decisions. We found that CMS did not effectively notify suppliers about its postbid review of disqualified bids which resulted in some bid disqualifications being overturned in round 1 of the CBP. HHS also commented that we had not identified concerns with the overall structure and design of the CBP. However, such an analysis was beyond the scope of this report.

HHS noted that it had a different perspective on some aspects of our report. The agency commented that the number of suppliers with CBP contracts did not account for the number of locations where DME items and services might be available in the CBAs. Our work focused on the number of suppliers participating in the CBP process, the number that were disqualified, and the number that were awarded contracts. We used the same contract supplier definition as CMS, which did not include the number of locations. We did not analyze whether there were enough locations to provide adequate Medicare beneficiary access during the CBP's 2-week operation.

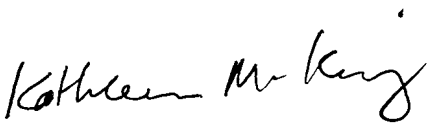
HHS suggested that our statement that about half of the submitted bids were disqualified before competing on price creates the impression that additional suppliers would have won if they submitted bids that complied with the terms and conditions of the request-for-bid instructions. However, we believe our characterization is accurate because bids were first reviewed for completeness, compliance with bidding requirements, and financial score. The agency also argued that it relied heavily on the PAOC for the design and implementation of the CBP. But as we stated in the report, two original PAOC members and three trade association representatives told us that CMS did not always use the PAOC effectively. Our review of PAOC meeting transcripts also found members who were dissatisfied with how the PAOC was used.

Finally, we revised the report according to HHS's comment that a reduction in the number of suppliers was an expected result of the CBP, but not a goal of the program. As we noted in the report draft, the CBP was structured to allow only suppliers with winning bids that accepted contracts to provide DME items and services, in contrast to Medicare's long-standing policy that any qualified provider can participate in Medicare.

HHS provided additional technical comments which we incorporated as appropriate. HHS's written comments are reprinted in appendix V.

As we agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from its date. We are sending copies of this report to the Secretary of Health and Human Services. The report will also be available at no charge on our Web site at http://www.gao.gov.

If you or your staffs have any questions about this report, please contact me 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 report. GAO staff who made major contributions to this report are listed in appendix VI.



Kathleen M. King
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Appendix I: Scope and Methodology

To assess the Centers for Medicare & Medicaid Services's (CMS) implementation of round 1 of the competitive bidding program (CBP), we reviewed federal laws and regulations. We also interviewed officials from CMS and Palmetto GBA—the contractor CMS selected to implement the CBP bidding and contract award process—about the results of the bid submission and review processes, CMS's major challenges in implementing CBP round 1, and the actions taken to improve future CBP rounds.

To determine the results of the CBP round 1, we reviewed data from CMS and Palmetto GBA about the number and characteristics of suppliers participating in the CBP process, number and characteristics of bids submitted, and the bids' outcomes. We reviewed the Competitive Bid Submission System (CBSS) User Guide, and instructions for entering data. We interviewed and obtained information from officials from CMS and Palmetto GBA about the CBSS, including system testing and data processing. We asked Palmetto GBA officials about data transfers from the CBSS to the Competitive Bidding Evaluation System (CBES), an application designed by Palmetto GBA to automate specific portions of the bid evaluation process that contained bid data, financial data entered by Palmetto GBA personnel, and documentation of Palmetto GBA actions. We asked them about CBES data checks, quality control, data entry procedures, and security. We interviewed CMS officials about the criteria and procedures for disqualifying bids, identifying winning bids, and calculating single payment amounts. We reviewed information CMS provided to the Program Advisory and Oversight Committee (PAOC) about this process and its results. We compared data published by CMS with the data provided to us and followed up with the appropriate officials to resolve discrepancies. We assessed the reliability of round 1 data by reviewing information from or interviewing CMS and Palmetto GBA officials and determined that the data were sufficiently reliable for the purposes of this report. We did not evaluate the reliability of CMS estimates of beneficiary demand for durable medical equipment (DME) which relied on 2005 and 2006 DME claims data, the most recent data available to them at the time, nor did we evaluate CMS's estimates of projected savings as the result of round 1.

To determine the major challenges CMS had in conducting CBP round 1, we interviewed CMS and Palmetto GBA officials and reviewed information provided to suppliers, including CBP bid submission instructions and related materials, bidder conference call transcripts, and CMS's and Palmetto GBA's CBP Web sites. We reviewed these materials for inconsistencies. We also reviewed an internal document provided by

Palmetto GBA about its implementation of the CBP round 1. We interviewed two PAOC members concerning whether CMS used the PAOC effectively and to gain insight about the committee's role in advising CMS about the implementation of the CBP and establishing standards for suppliers that bid in round 1. We reviewed transcripts and meeting summaries of the seven PAOC meetings to assess the concerns and feedback that the members provided about potential supplier issues and challenges. We also interviewed CMS and Palmetto GBA officials and reviewed documentation about CBSS's operational problems.

We interviewed 12 suppliers about their experiences with CBP. We interviewed 4 suppliers that were not offered a contract, 4 suppliers that accepted a CBP contract, and 4 suppliers that rejected their CBP contract offer. The suppliers were randomly selected from CMS's list of suppliers that bid in CBP round 1. Because we interviewed a small number of suppliers, our findings from these interviews are not generalizable to all suppliers. In addition, we interviewed representatives from national and state industry trade associations representing DME suppliers—the American Association for Homecare, the National Association of Independent Medical Equipment Suppliers, the Florida Association of Medical Equipment Services, and the Ohio Association of Medical Equipment Services. We also reviewed testimony from three congressional hearings including two 2008 hearings about the CBP implementation[1] and a 2009 congressional hearing on the CBP's impact on small business,[2] in which a CMS official discussed the results of CBP round 1, and six representatives of various DME associations and interest groups discussed the effect that the CBP had on their businesses and professions.

To analyze the postbidding review authorized by CMS and conducted by Palmetto GBA, we interviewed CMS and Palmetto GBA officials about the development and implementation of the review process and reviewed its results. We also reviewed relevant federal laws and regulations and

[1]House of Representatives, Committee on Ways and Means, Subcommittee on Health, Hearing on "Medicare's Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program," May 6, 2008, and House of Representatives, Committee on Small Business, Subcommittee on Rural and Urban Entrepreneurship, Hearing on "Competitive Bidding for Durable Medical Equipment," May 21, 2008.

[2]House of Representatives, Committee on Small Business, Subcommittee on Rural Development, Entrepreneurship, and Trade, Hearing on "The Impact of Competitive Bidding on Small Businesses in the Durable Medical Equipment Community," February 11, 2009.

interviewed CMS officials and attorneys representing the Department of Health and Human Services (HHS), CMS division.

To determine the steps that CMS has taken to improve the bidding process for future CBP rounds, we reviewed relevant federal laws and regulations, PAOC Federal Register notices, and CMS press releases related to the PAOC. We interviewed CMS and Palmetto GBA officials about the actions they have taken and intend to take to improve the CBP bidding process during the CBP round 1 rebid. We also attended the June 4, 2009, PAOC meeting at which CMS provided updates of the process changes and modifications that it made for the round 1 rebid.

In addition, we interviewed Maricom officials and reviewed available documentation related to the development, testing, and proposed implementation of the new electronic bid submission system—Durable Medical Equipment, Prosthetics, Orthotics, and Supplies bidding system (DBidS)—that will be used during the CBP round 1 rebid. We did not assess the reliability or functionality of DBidS, but we reviewed the processes established by CMS and its contractors for testing and accepting such systems.

We conducted this performance audit from June 2008 to September 2009 in accordance with generally accepted government auditing standards. 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.

Appendix II: Change in Numbers of Suppliers by CBP Product Category and CBA: 2006-2008

Product category	Competitive bidding area (CBA)										
	Charlotte	Cincinnati	Cleveland	Dallas	Kansas City	Miami	Orlando	Pittsburgh	Riverside	San Juan	Median
Oxygen Supplies and Equipment											
Calendar year (CY) 2006 suppliers[a]	39	45	38	133	41	488	71	47	53	NA	47
Competitive bidding program (CBP) contract suppliers	18	18	22	36	17	43	34	22	18	INS	22
Percent change in number of suppliers	-54	-60	-42	-73	-59	-91	-52	-53	-66	NA	-53
Standard Power Wheelchairs, Scooters and Related Accessories											
CY 2006 suppliers	30	19	18	92	18	91	27	12	72	34	29
CBP contract suppliers	11	13	12	24	14	18	13	11	19	6	13
Percent change in number of suppliers	-63	-32	-33	-74	-22	-80	-52	-8	-74	-82	-54
Complex Rehabilitative Power Wheelchairs and Related Accessories											
CY 2006 suppliers	27	21	20	74	19	101	21	11	49	NA	21
CBP contract suppliers	10	7	6	11	4	6	6	5	8	INS	6
Percent change in number of suppliers	-63	-67	-70	-85	-79	-94	-71	-55	-84	NA	-71
Mail-Order Diabetic Supplies											
CY 2006 suppliers	118	101	93	150	96	294	87	79	68	129	99
CBP contract suppliers	10	15	12	15	10	18	12	12	7	13	12
Percent change in number of suppliers	-92	-85	-87	-90	-90	-94	-86	-85	-90	-90	-88

Product category	Competitive bidding area (CBA)										
	Charlotte	Cincinnati	Cleveland	Dallas	Kansas City	Miami	Orlando	Pittsburgh	Riverside	San Juan	Median
Enteral Nutrients, Equipment and Supplies[b]											
CY 2006 suppliers	48	47	67	100	34	338	47	50	67	NA	50
CBP contract suppliers	12	11	14	13	13	29	21	10	19	INS	13
Percent change in number of suppliers	-75	-77	-79	-87	-62	-91	-55	-80	-72	NA	-74
Continuous Positive Airway Pressure Devices, Respiratory Assist Devices and Related Supplies and Accessories											
CY 2006 suppliers	34	28	32	72	24	172	46	29	32	13	32
CBP contract suppliers	18	13	17	26	15	33	23	15	17	15	17
Percent change in number of suppliers	-47	-54	-47	-64	-38	-81	-50	-48	-47	15	-47
Hospital Beds and Related Accessories											
CY 06 suppliers	33	29	33	103	21	160	30	35	45	NA	33
CBP contract suppliers	13	12	12	51	15	43	29	15	32	INS	15
Percent change in number of suppliers	-61	-59	-64	-50	-29	-73	-3	-57	-29	NA	-55
Negative Pressure Wound Therapy Pumps and Related Supplies and Accessories											
CY 06 suppliers	1	2	1	3	NA	242	4	2	2	NA	2
CBP contract suppliers	10	8	9	16	INS	15	14	6	5	INS	10
Percent change in number of suppliers	900	300	800	433	NA	-94	250	200	150	NA	375
Walkers and Related Accessories											
CY 06 suppliers	15	18	21	34	8	42	18	18	12	9	18
CBP contract suppliers	8	10	10	20	14	25	16	14	12	17	14
Percent change in number of suppliers	-47	-44	-52	-41	75	-40	-11	-22	0	89	-22

Product category	Competitive bidding area (CBA)										
	Charlotte	Cincinnati	Cleveland	Dallas	Kansas City	Miami	Orlando	Pittsburgh	Riverside	San Juan	Median
Support Surfaces (group 2 mattresses and overlays)[c]											
CY 06 suppliers	NA	NA	NA	NA	NA	417	NA	NA	NA	NA	417
CBP contract suppliers	NA	NA	NA	NA	NA	37	NA	NA	NA	INS	37
Percent change in number of suppliers	NA	NA	NA	NA	NA	-91	NA	NA	NA	NA	-91
Change in median number of suppliers											
Median CY 06 suppliers	33	28	32	92	23	207	30	29	49	24	31
Median CBP contract suppliers as of 6/11/08	11	12	12	20	14	27	16	12	17	14	14
Percent change in median number of suppliers	-67	-57	-63	-78	-38	-87	-47	-59	-65	-40	-55

Source: Centers for Medicare & Medicaid Services (CMS).

Notes: The source for CY 2006 data was the Statistical Analysis Durable Medical Equipment Regional Carrier claims data based on the 6-byte base supplier number, for dates of service from January 1, 2006, to December 31, 2006. GAO calculated the medians and percent changes in median numbers of suppliers. INS means that the estimated capacity of suppliers submitting qualified bids or accepting contracts was insufficient to meet projected demand. NA means not applicable.

[a]This table identifies the total number of suppliers that provided services in each competitive bidding area (CBA) for each product category in CY 2006 with allowed charges for items in the product category greater than $10,000 and the number of suppliers awarded CBP contracts in round 1 as of June 11, 2008.

[b]Enteral nutrients, equipment, and supplies are used to provide food through a tube placed in the nose, the stomach, or the small intestine.

[c]Group 2 mattresses and overlays of the support surfaces product category are pressure-reducing support surfaces for persons with large or multiple pressure ulcers.

Appendix III: Percentage Differences between 2008 Medicare Fee Schedule and CBP Round 1 Single Payment Amounts

	Competitive bidding area (CBA)[a]										
Product category	**Charlotte**	**Cincinnati**	**Cleveland**	**Dallas**	**Kansas City**	**Miami**	**Orlando**	**Pittsburgh**	**Riverside**	**San Juan**	**Product category average**
Oxygen Supplies and Equipment	30	30	27	23	25	29	32	28	22	INS	27
Standard Power Wheelchairs, Scooters and Related Accessories	20	15	18	21	12	30	25	17	27	25	21
Complex Rehabilitative Power Wheelchairs and Related Accessories	10	19	17	19	10	18	20	10	11	INS	15
Mail-Order Diabetic Supplies	43	43	43	37	42	41	42	48	57	36	43
Enteral Nutrients, Equipment and Supplies[b]	25	29	28	26	20	30	25	29	22	INS	26
Continuous Positive Airway Pressure Devices, Respiratory Assist Devices and Related Supplies and Accessories	31	33	33	25	30	30	31	31	24	20	29
Hospital Beds and Related Accessories	31	36	32	25	25	29	31	30	20	INS	29

	Competitive bidding area (CBA)[a]										
Product category	**Charlotte**	**Cincinnati**	**Cleveland**	**Dallas**	**Kansas City**	**Miami**	**Orlando**	**Pittsburgh**	**Riverside**	**San Juan**	**Product category average**
Negative Pressure Wound Therapy Pumps and Related Supplies and Accessories	9	15	18	20	INS	20	23	18	7	INS	16
Walkers and Related Accessories	25	34	24	30	24	31	29	32	30	10	27
Support Surfaces (group 2 mattresses and overlays)[c]	NA	NA	NA	NA	NA	36	NA	NA	NA	INS	36
Average of all auctions											**26**

Source: Centers for Medicare & Medicaid Services (CMS).

Notes: GAO reformatted a CMS table distributed at the June 16, 2008 Program Advisory and Oversight Committee meeting.

INS means that the estimated capacity of suppliers submitting qualified bids or accepting contracts was insufficient to meet projected demand. NA means not applicable. No auctions were conducted for these product category and CBA combinations.

[a]Except for the last column, the data reflect volume-weighted average savings within an auction. According to the CMS, the savings rate was derived by multiplying the difference between the 2008 Medicare fee schedule for each item in a product category in a CBA and the item's CBP-derived single payment amount by the same weights used to calculate composite prices for the product category. CMS projected the overall savings for round 1 at approximately 26 percent annually to the Medicare program and Medicare beneficiaries. The averages in the last column are unweighted. GAO did not make a determination as to whether or not this methodology is an accurate measure of true savings to the Medicare program.

[b]Enteral nutrients, equipment, and supplies are used to provide food through a tube placed in the nose, the stomach, or the small intestine.

[c]Group 2 mattresses and overlays of the support surfaces product category are pressure-reducing support surfaces for persons with large or multiple pressure ulcers.

Appendix IV: Omitted and Conflicting Information in Written Instructions on Submitting a Bid for CBP Round 1

The examples below are taken from two competitive bidding program (CBP) documents that provided written information for suppliers about how to submit a bid and information on bidding requirements. The documents are from a Web-based seminar, or webinar, posted on the Palmetto GBA Web site on April 30, 2007, and the request-for-bid instructions posted on the same Web site on May 15, 2007.

Table 10: Examples of Conflicting and Omitted Information, CBP Round 1

Topic	Source	Summary of what was stated in the instruction	GAO comments	Implications
Number of Form A's required to complete a bid submission	Webinar and request-for-bid instructions	Told suppliers to complete one Form A per competitive bidding area (CBA) per bidding entity.	Inconsistent with a bidder conference call on June 4, 2007. The correct answer is that a bidding entity had to only complete one Form A regardless of the number of CBAs or product categories being bid.	Suppliers had only limited opportunities to obtain the correct information from Palmetto GBA: (1) to join the bidder conference call on June 4, 2007; (2) read the call's transcript posted on the Palmetto GBA website; or (3) call the Palmetto GBA customer service center. The webinar and request- for-bid instructions, posted on the Palmetto GBA Web site throughout the bid window, were not corrected.
On how to estimate capacity	Webinar	Referred suppliers to column D of the printed version of Form B as well as to a separate document called the Product Category chart to determine the type of units to use in reporting total estimated capacity. column D contained the definition of a unit for purposes of pricing an item.	Conflicting and incomplete information. Column D did not describe the units to use in reporting total estimated capacity while the Product Category chart did.	If winning suppliers estimated capacity on units other than the type of unit specified in the Product Category chart, the cumulative capacity for the auction's winning suppliers would have been incorrect.[a]
	Request-for-bid instructions	Told suppliers to estimate the number of units of each item that the bidding entity currently furnishes to Medicare beneficiaries plus any additional capacity the bidding entity would be capable of providing per item.	Incomplete. Information needed for correctly reporting expanded capacity, for example, time period to use in reporting, payer source of units to include in reporting, and geographic area to use, were omitted. Source also did not identify the type of units to use for each item or direct the supplier to a source for the correct unit to use in reporting current or expanded capacity.[b]	If winning suppliers did not similarly report expanded capacity for the same item in a product category, the cumulative capacity for the auction's winning suppliers would have been incorrect.[a]

Topic	Source	Summary of what was stated in the instruction	GAO comments	Implications
On finding each item's price limit	Webinar and request-for-bid Instructions	Omitted.	Incomplete. While both documents indicated that an item's bid cannot exceed the Medicare fee schedule, neither document directed suppliers to a source of information for the bid limit.	Submission of one or more item prices in excess of the Medicare fee schedule would have resulted in the exclusion of the bid from competing for the product category.[c]

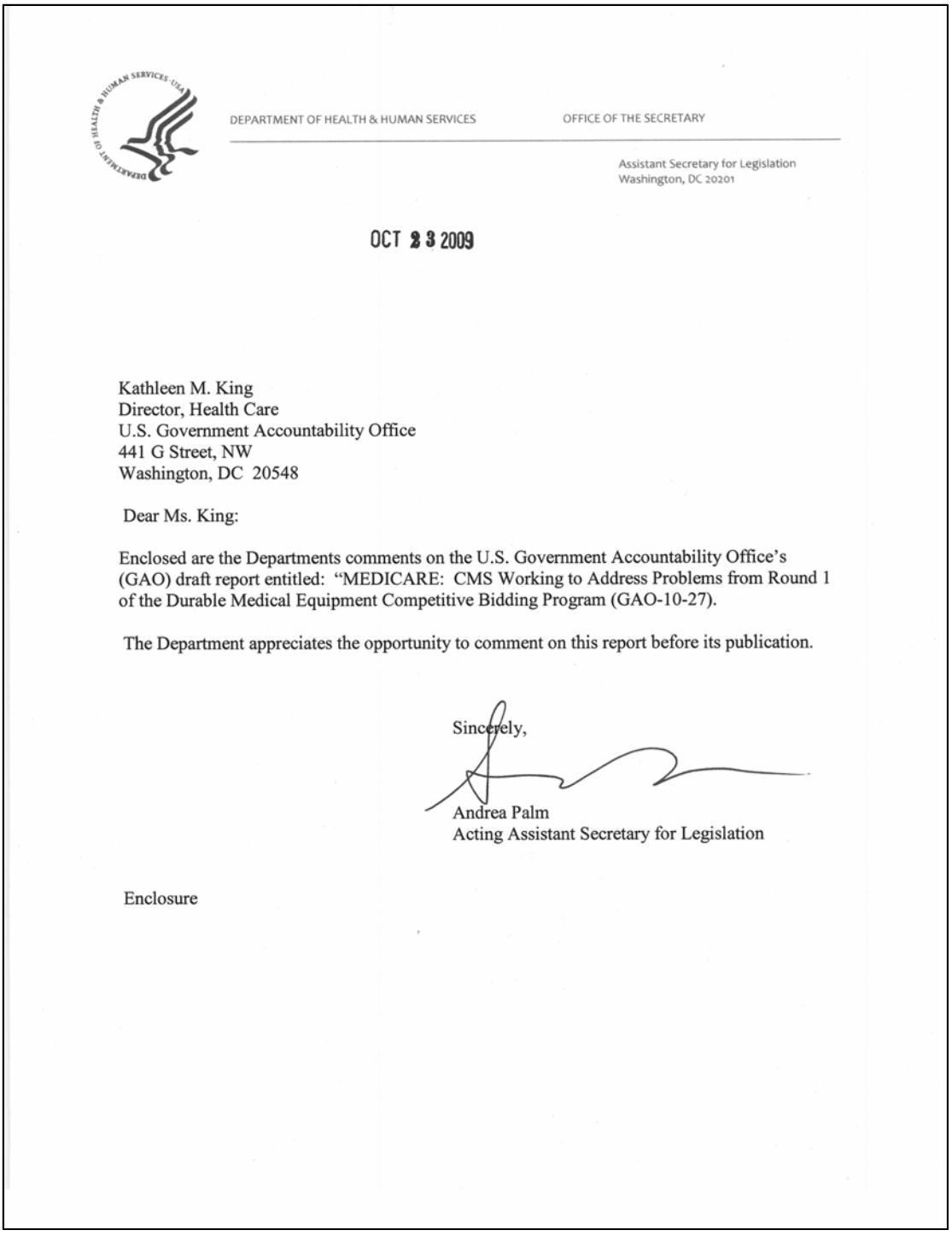
Source: GAO analysis of information provided by Centers for Medicare & Medicaid Services (CMS) and Palmetto GBA.

[a]Cumulative capacity, combined with CMS estimates of beneficiary demand, determine the pivotal bid, the number of winning suppliers based on price, and, indirectly, single payment amounts. Also, because bidding suppliers did not report the unit used to report expanded capacity, Palmetto GBA would have been unable to detect these types of errors.

[b]Out of 371 items subject to competitive bidding, 275 may be furnished and paid for as new or used equipment or on a rental basis.

[c]This information was also omitted from the data entry screen of the electronic bid submission system.

Appendix V: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

OCT 23 2009

Kathleen M. King
Director, Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Ms. King:

Enclosed are the Departments comments on the U.S. Government Accountability Office's (GAO) draft report entitled: "MEDICARE: CMS Working to Address Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program (GAO-10-27).

The Department appreciates the opportunity to comment on this report before its publication.

Sincerely,

Andrea Palm
Acting Assistant Secretary for Legislation

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: OCT 22 2009

TO: Andrea Palm
Acting Assistant Secretary for Legislation

FROM: Charlene Frizzera
Charlene Frizzera
Acting Administrator

SUBJECT: Government Accountability Office's Draft Report: "CMS Working to Address Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program" (GAO-10-27)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO) draft report entitled, "CMS Working to Address Problems from Round 1 of the Durable Medical Equipment (DME) Competitive Bidding Program." The report recognized CMS' efforts to refine certain features of the program based upon changes in the law and upon the Agency's experience from Round 1 of the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program. We are pleased that the GAO identified no concerns with the overall structure and design of the program and recognized its potential benefits.

As mentioned in the draft report, the Department of Health and Human Services' (DHHS) Office of Inspector General and the GAO have both reported that CMS could reduce program payments for various medical and supply items for which Medicare pays higher than market rates. Congress mandated the development and implementation of a competitive bidding program for certain items of DMEPOS in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The law required that the program be phased in, beginning in 10 Metropolitan Statistical Areas (MSAs) in the first round, expanding to additional MSAs and areas throughout the United States after this initial phase.

After conducting the required competition, CMS implemented the new competitive bidding program in 10 competitive bidding areas (CBA) for 10 categories of DMEPOS, with payments based on the competitively bid single payment amounts beginning July 1, 2008. However, in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), enacted July 15, 2008, Congress delayed the competitive bidding program retroactive to July 1, 2008, and required CMS to make certain changes to the program.

Since the enactment of the MIPPA, CMS has been actively working toward effective implementation of the Round 1 re-bid. On January 16, 2009, CMS issued an interim final rule with comment period (IFC) modifying the program to conform to the MIPPA changes. The IFC became effective on April 18, 2009. CMS announced the bidding timeline, created a new on-line bid submission system, and initiated an aggressive bidder education program well in advance of

bidding, which is scheduled to open October 21, 2009. The Agency's operational modifications to the program, along with the MIPPA reforms, are expected to result in a bidding process that is easier for suppliers to navigate, and that ultimately will benefit Medicare beneficiaries.

While we appreciate the GAO's acknowledgement of CMS' preparations for the Round 1 re-bid, we do have a different perspective, in some cases, on various components of the program discussed in the report. For instance, CMS designed the Program Advisory and Oversight Committee (PAOC) discussions to encourage individual members with different backgrounds and perspectives to provide feedback and advice, in contrast to the consensus approach, which GAO seems to prefer. CMS also relied heavily on the PAOC members' advice in the design and implementation of the program leading up to 2008. Just a few examples of their suggestions adopted by CMS include: including a process to ensure that bids are bona fide; permitting any enrolled supplier to repair equipment; and requiring submission of certain financial documents.

In addition, we disagree with the GAO's assertion that an underlying purpose of the program is to reduce the number of suppliers, though we recognize that the natural result of the competition is that fewer contracts are awarded than suppliers that bid. We would also like to note that CMS was required to ensure that projected beneficiary demand was met when awarding contracts to suppliers. We also find that the manner in which some of the data from 2008 is presented in the report is very misleading. We note that the number of contract suppliers (entities) does not represent the number of store fronts or locations within an area that are available to serve beneficiaries, nor does it account for the large number of non-contract suppliers that received professional exemptions or that chose to be grandfathered suppliers, allowing many beneficiaries to continue receiving equipment from their current supplier. This must be taken into account when considering the total number of supplier locations available to serve beneficiaries under the program.

GAO Recommendation

If CMS decides to conduct a review of the disqualification decisions during the round 1 re-bid 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 Response

We agree that all suppliers should receive notice about all aspects of the competitive bidding program and note that all Round 1 bidders were specifically advised in writing of the opportunity to ask questions about their bid results. CMS continues to believe that suppliers should have the opportunity to raise questions or concerns about the competitive bidding process, including disqualification decisions. Further, we also continue to believe that the competitive bidding program statute and regulations permit us to conduct quality assurance checks during the course of responding to bidders' questions as part of our other extensive quality assurance efforts. We remain committed to answering suppliers' questions and will continue to ensure that all suppliers are sufficiently informed about opportunities for the Round 1 re-bid and future rounds.

The CMS looks forward to implementing the Round 1 re-bid of the program along with the many improvements discussed in this report. We appreciate the opportunity to comment on this report.

Appendix VI: GAO Contact and Staff Acknowledgments

GAO Contact

Kathleen M. King, (202) 512-7114 or kingk@gao.gov

Acknowledgments

In addition to the contact named above, key contributors to this report were Martin T. Gahart, Assistant Director; Carrie Davidson; Neil Doherty; JoAnn Martinez; Christie Motley; Michelle Paluga; Hemi Tewarson; Keo Vongvanith; Timothy Walker; Opal Winebrenner; Suzanne Worth; and Charles Youman.

Related GAO Products

Medicare: Covert Testing Exposes Weaknesses in the Durable Medical Equipment Supplier Screening Process. GAO-08-955. Washington, D.C.: July 3, 2008.

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.

Medicare: Improvements Needed to Address Improper Payments for Medical Equipment and Supplies. GAO-07-59. Washington, D.C.: January 31, 2007.

Medicare Payment: CMS Methodology Adequate to Estimate National Error Rate. GAO-06-300. Washington, D.C.: March 24, 2006.

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Medicare: CMS Did Not Control Rising Power Wheelchair Spending. GAO-04-716T. Washington, D.C.: April 28, 2004.

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