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November 2014

MEDICARE

Bidding Results from CMS's Durable Medical Equipment Competitive Bidding Program

GAO-15-63

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GAO Highlights

Highlights of GAO-15-63, a report to the Subcommittee on Health, Committee on Ways and Means, House of Representatives

Why GAO Did This Study

To achieve Medicare savings for DME, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 required that CMS implement the CBP for certain DME. The first completed CBP round—the round 1 rebid—operated in nine competitive bidding areas. CMS reported total savings of more than $580 million at the end of the round 1 rebid's 3-year term due to lower payments and decreased utilization. GAO previously reported on the implementation of the CBP round 1 rebid (GAO-12-693).

GAO was asked to continue to monitor the CBP as it expands to subsequent rounds. In this report, GAO examines (1) bidding process results for the round 1 recompete, round 2, and national mail-order program, and how they compare to the concluded round 1 rebid results, and (2) how SPAs for selected HCPCS codes common to the round 1 rebid, round 1 recompete, round 2, and national mail-order program compare.

To examine bidding process results, GAO analyzed data from CMS and its CBP contractor related to bidding suppliers, contract awards, and the post-bid review process. To assess how SPAs for 28 HCPCS codes common to all CBP rounds (using selected high-cost, high-utilization codes identified by CMS) and all 8 HCPCS codes common to the round 1 rebid and national mail-order program compare, GAO identified, averaged, and compared these codes to one another and to the average 2010 Medicare fee-for-service payment amounts for the same codes.

View GAO-15-63. For more information, contact Kathleen King at (202) 512-7114 or KingK@gao.gov.

What GAO Found

The Medicare competitive bidding program (CBP) for durable medical equipment (DME) is administered by the Centers for Medicare & Medicaid Services (CMS) within the Department of Health and Human Services (HHS). Under the CBP, only competitively selected contract suppliers can furnish certain DME items (such as oxygen supplies and hospital beds) at competitively determined prices to Medicare beneficiaries in designated competitive bidding areas. Contracts awarded in CBP's round 1 rebid were effective on January 1, 2011, and ended on December 31, 2013. The CBP is currently operating as the round 1 recompete in the same nine competitive bidding areas as the round 1 rebid (with contracts awarded effective January 1, 2014, through December 31, 2016), as round 2 in an additional 100 competitive bidding areas (with contracts awarded effective July 1, 2013, through June 30, 2016), and as the national mail-order program for diabetic testing supplies (competed at the same time as the round 2 contracts, with the same effective contract dates).

GAO found that a similar percentage of bidding suppliers—between 30 and 43 percent—were awarded contracts in the round 1 rebid, round 1 recompete, and round 2. Fewer bidding suppliers—7 percent—were awarded a contract in the national mail-order program. Although the percentages of bids submitted that resulted in contracts varied by round, the reasons for bid disqualification—such as unacceptable financial documentation or failure to meet all state licensure requirements—were generally similar across CBP rounds. Many bidding suppliers benefited from submitting their paperwork by a certain date—known as the covered document review date—after which CMS informed them of any missing financial documentation and allowed them the opportunity to provide it. CMS identified suppliers during its post-bid review process that were disqualified incorrectly, and some suppliers with initially disqualified bids were ultimately offered a contract. In each round, no more than 3 percent of contract suppliers were new to both a product category and a competitive bidding area.

GAO found that the single payment amounts (SPA) for 28 selected Healthcare Common Procedure Coding System (HCPCS) codes common to the round 1 rebid, round 1 recompete, and round 2 generally decreased through all CBP rounds as compared to the average Medicare 2010 fee-for-service payment for the same codes. For a majority of the codes, the largest overall decreases occurred in round 1 rebid average SPAs compared to the average Medicare 2010 fee-for-service payments for the same codes, with relatively smaller SPA decreases in subsequent rounds. The extent to which average SPAs changed varied by type of HCPCS code. For example, average SPAs decreased in each CBP round for three selected hospital bed HCPCS codes, but average SPAs significantly varied from one round to the next for three selected standard power wheelchair HCPCS codes. Average SPAs for the 8 HCPCS codes included in the national mail-order program also decreased or remained steady compared to those in the round 1 rebid. For example, SPAs for two codes associated with glucose monitoring test strips and lancets decreased by at least 50 percent from the round 1 rebid average SPA to the national mail-order program SPA.

In commenting on a draft of this report, HHS stated that it anticipates CBP will provide substantial savings for the Medicare Trust Fund and beneficiaries.

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Abbreviations

CBP	competitive bidding program
CMS	Centers for Medicare & Medicaid Services
CPAP	continuous positive airway pressure devices
DME	durable medical equipment
DMEPOS	durable medical equipment, prosthetics, orthotics, and related supplies
HCPCS	Healthcare Common Procedure Coding System
HHS	Department of Health and Human Services
NSC	National Supplier Clearinghouse
RAD	respiratory assist devices
SPA	single payment amount

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November 7, 2014

The Honorable Kevin Brady
Chairman
The Honorable Jim McDermott
Ranking Member
Subcommittee on Health
Committee on Ways and Means
House of Representatives

In 2013, Medicare—a federal health insurance program—spent an estimated $11 billion in fee-for-service payments for durable medical equipment (DME), prosthetics, orthotics, and related supplies for beneficiaries.[1] The Medicare program is administered by the Centers for Medicare & Medicaid Services (CMS) within the Department of Health and Human Services (HHS). Most Medicare beneficiaries enroll in Medicare Part B,[2] which helps pay for DME items and supplies, such as oxygen, wheelchairs, hospital beds, walkers, orthotics, prosthetics, and supplies if they are medically necessary and prescribed by a physician. Medicare beneficiaries typically obtain these items from suppliers, which submit claims for payment to Medicare on behalf of beneficiaries.

[1]Individuals may qualify for Medicare if they are aged 65 and older, are under 65 and disabled, or have been diagnosed with certain conditions such as end-stage renal disease and amyotrophic lateral sclerosis (also known as Lou Gehrig's disease). Collectively, DME, prosthetics, orthotics, and related supplies are referred to as DMEPOS. 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, including, for example, wheelchairs and hospital beds. Prosthetic devices (other than dental) are needed to replace body parts or functions, such as artificial limbs and cardiac pacemakers. Orthotic devices provide rigid or semi-rigid support for weak or deformed body parts or restrict or eliminate 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. For this report, the term DME refers to the DMEPOS items included in the Medicare DME competitive bidding program.

[2]Medicare Part B helps pay for certain physician, outpatient hospital, laboratory, and other services, and medical equipment and supplies. Medicare beneficiaries are required to pay a monthly premium for Part B coverage and an annual deductible. In general, beneficiaries also pay 20 percent—the coinsurance—of the Medicare fee schedule payment rate after reaching their annual Medicare Part B deductible.

Historically, Medicare has paid eligible claims from all enrolled DME suppliers based on a fee schedule amount for each type of item.[3]

To achieve savings in the Medicare program's DMEPOS spending and to address DMEPOS fraud concerns, Congress, through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, required CMS to phase in a competitive bidding program (CBP) for DME and other items.[4] Under CBP, DME suppliers that are competitively selected and awarded contracts can furnish certain DME items to Medicare beneficiaries in designated competitive bidding areas.[5] The competition process also determines the payments—referred to as the single payment amounts (SPA)—for each DME item included in the CBP. Each DME item is identified by a Healthcare Common Procedure Coding System (HCPCS) code.[6]

CBP has been implemented through several rounds, each operating in particular areas and for particular time frames. CBP's first 3-year competition round—the round 1 rebid—awarded contracts to suppliers in nine competitive bidding areas that were effective from January 1, 2011, through December 31, 2013.[7] In anticipation of the expiration of the round 1 rebid contracts, in 2012 CMS held a new competition for CBP contracts for the same nine competitive bidding areas as the round 1

[3]Medicare fee schedules are adjusted for each state, reflecting the geographic price differences that are subject to national floor and ceiling payment limits.

[4]Pub. L. No. 108-173, § 302(b), 117 Stat. 2066, 2224-30 (2003) (codified, as amended, at 42 U.S.C. § 1395w-3).

[5]A competitive bidding area is either a metropolitan statistical area or a part thereof. Metropolitan statistical areas are designated by the Office of Management and Budget and include major cities and the suburban areas surrounding them.

[6]HCPCS codes are used by suppliers to submit claims for Medicare payments. The codes identify a category of DME items, for example, walkers, but can encompass a broad range of items that serve the same general purpose but vary in price and characteristics.

[7]Beginning in 2007, CMS conducted the first CBP competition—referred to as round 1—and awarded contracts effective July 1, 2008, to suppliers. The Medicare Improvements for Patients and Providers Act of 2008, however, terminated the round 1 contracts on July 15, 2008, and required CMS to repeat the competition in 2009—referred to as the round 1 rebid. Pub. L. No. 110-275, § 154(a), 122 Stat. 2494, 2560-3 (2008) (codified, as amended, at 42. U.S.C. § 1395w-3). In 2009, CMS began the CBP round 1 rebid bidding process and awarded contracts in nine competitive bidding areas that were effective from January 1, 2011, through December 31, 2013.

rebid, referred to as the round 1 recompete. The round 1 recompete contracts became effective on January 1, 2014. CBP round 2 contracts became effective on July 1, 2013, in 100 competitive bidding areas that were not included in the round 1 recompete. CBP contracts for the national mail-order program for diabetic testing supplies were competed at the same time as the round 2 contracts, and also became effective on July 1, 2013.[8]

CMS reported total savings of more than $580 million at the end of the round 1 rebid's 3-year term due to lower payments and decreased utilization. In 2012 we reported that the round 1 rebid was generally implemented successfully.[9] You asked us to continue to monitor the CBP as it expands to subsequent rounds. For this engagement, we continue our monitoring of CBP bidding results by reporting (1) bidding process results for the ongoing round 1 recompete, round 2, and national mail-order program, and comparing them, to the extent possible, to round 1 rebid results; and (2) how SPAs for selected HCPCS codes common to the round 1 rebid, round 1 recompete, round 2, and national mail-order program compare.

To review bidding results for the round 1 recompete, round 2, and national mail-order program, we analyzed data from CMS concerning the number of suppliers that bid and won in each round and the results of CMS's post-bid review process. We also reviewed feedback that CMS provided to bidding suppliers to explain reasons for bid disqualifications. To the extent possible, we compared these results to the round 1 rebid bidding results that we reported in 2012 to determine similarities and differences between the results of the completed round 1 rebid and the ongoing round 1 recompete, round 2, and national mail-order program.

To determine how SPAs for selected HCPCS codes compare among the rounds, we compared average Medicare 2010 fee-for-service payments and average SPAs for certain HCPCS codes common to the concluded

[8]During the round 1 rebid, CMS awarded 2-year contracts to mail-order diabetic testing supplies suppliers, which expired December 31, 2012. CMS expanded the mail-order competition nationally, as permitted under federal law.

[9]See GAO, *Medicare: Review of the First Year of CMS's Durable Medical Equipment Competitive Bidding Program's Round 1 Rebid*, GAO-12-693 (Washington, D.C.: May 9, 2012). For a list of other reports we have issued on Medicare DME, see the *Related GAO Products* page later in this publication.

round 1 rebid and the ongoing round 1 recompete and round 2.[10] We also compared average Medicare 2010 fee-for-service payments to average SPAs for eight HCPCS codes included in the national mail-order program and the round 1 rebid.[11] We selected the 2010 Medicare national fee-for-service payment schedule because 2010 was the year prior to the start of the CBP round 1 rebid contracts on January 1, 2011. For the round 1 rebid, CMS determined there were 34 HCPCS codes that represented the top 80 percent of the Medicare DMEPOS HCPCS codes that were high cost, high utilization, or both.[12] Of these 34 items, 28 are common to the CBP round 1 rebid, round 1 recompete, and round 2, and 3 are diabetic testing supply codes common to both the round 1 rebid and the national mail-order program.[13] Our analysis compared the average Medicare 2010 fee-for-service payments to the average SPAs using the appropriate CBP code modifiers for each of the HCPCS codes.[14] We calculated average Medicare 2010 fee-for-service payment amounts for the 28 HCPCS codes common to CBP rounds as well as the 8 mail-order diabetic testing supply codes common to the round 1 rebid and national mail-order program by obtaining each HCPCS code's individual Medicare 2010 fee-for-service payment amount in each of the 48 continental states and the District of Columbia and averaging those equally weighted payment amounts into one average Medicare 2010 fee-for-service payment amount for each code. We used payments only within the continental states and the District of Columbia because Alaska and Hawaii are not subject to Medicare's fee-for-service payment amount ceiling and floor limits. For the four HCPCS codes for enteral nutrients—to provide feeding through a tube into the stomach or small intestine—included in our analysis, no Medicare payment averaging was necessary, as Medicare sets national payment amounts for enteral nutrition items and services.

[10]CBP SPAs are required to be less than or equal to the Medicare fee-for-service payment amount for the same item.

[11]Mail-order diabetic testing supply codes were not included in the round 1 recompete and round 2; therefore these rounds were not included in our analysis of these codes.

[12]See GAO-12-693 for the full list of the 34 HCPCS codes.

[13]The CBP round 1 rebid's complex rehabilitative power wheelchairs product category was excluded from the subsequent CBP round 1 recompete and round 2, so the 3 complex rehabilitative power wheelchair HCPCS codes that were included in the top 80 percent list were excluded from our analysis.

[14]HCPCS code modifiers for the CBP items include NU for a new item, RR for a rental item, UE for a used item, and KL for a mail-order diabetic testing supply item.

To calculate an average CBP SPA for each HCPCS code included in our analysis, we averaged the reported SPAs across all competitive bidding areas included in each CBP round. We used the average SPAs because a HCPCS code's SPA is determined for each competitive bidding area; therefore, the SPA for the same item in the same round may differ among competitive bidding areas. For the 28 common HCPCS codes, we compared the average SPAs for the round 1 rebid, round 1 recompete, and round 2 to each other and to the average 2010 Medicare fee-for-service payment for the same codes. For the eight diabetic testing supply HCPCS codes, we compared the average SPAs for mail-order diabetic testing supplies in the round 1 rebid to SPAs for the national mail-order program, and to the 2010 average Medicare fee-for-service payments for the same mail-order codes.[15]

To assess the reliability of the data we received from CMS, we identified and reviewed outliers in the data and followed up with CMS officials to clarify and resolve any discrepancies. We also reviewed publicly available SPAs and compared them to the average SPAs we calculated. We determined that these data were sufficiently reliable for the purposes of this report.

We conducted this performance audit from May 2014 through November 2014 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 based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings based on our audit objectives.

[15]Because the national mail-order program sets nationwide SPAs, no averaging was necessary to determine SPAs for this program.

Background

CBP Contract Supplier Eligibility and Bidding Process

CMS and its CBP implementation contractor—Palmetto GBA—administer and implement the CBP and its bidding rounds.[16] In each CBP round, suppliers can bid for one or more included product categories in multiple competitive bidding areas.[17] To be eligible to submit bids in a CBP round, suppliers must be eligible to bill Medicare for DME,[18] must have met Medicare enrollment and quality standards,[19] must have a surety bond,[20] and must be accredited and licensed.

After a round's bidding period closes, Palmetto GBA reviews the bids to determine whether each supplier's bid submission is complete and complies with the bidding requirements and whether each supplier's financial score meets the CBP minimum financial standard threshold for financial viability to be eligible to compete on price. If a supplier's bid meets all these requirements, it is considered a qualified bid and can then compete on price. Before comparing bid prices, Palmetto GBA reviews each qualified bid's estimated capacity projections—a supplier's anticipated ability to provide the volume of items claimed in the bid in light of that supplier's historical capacity, expansion plans, and financial score. Palmetto GBA then takes several steps to compare prices and identify the winning bids.

- The DME bid item prices submitted by suppliers with qualified bids are reviewed using a methodology to calculate a composite bid for each

[16]Palmetto GBA is also referred to as the competitive bidding implementation contractor.

[17]For the CBP, CMS chose certain DME items in product categories—generally high-cost and high-volume items and services—that were most likely to result in Medicare savings if competitively acquired.

[18]To be eligible to bill Medicare for DME, suppliers must have an active National Supplier Clearinghouse (NSC) number. The NSC is the CMS contractor responsible for processing Medicare enrollment applications for DMEPOS suppliers.

[19]For all DMEPOS suppliers, the Medicare enrollment standards are listed at 42 C.F.R. § 424.57(c), and the Medicare quality standards are listed at https://www.cms.gov/medicareprovidersupenroll/10_DMEPOSsupplierstandards.asp (accessed on Sept. 23, 2014).

[20]Certain DMEPOS suppliers are required to post a $50,000 surety bond for each business location. Surety bonds are designed to reduce the amount of money lost due to fraudulent or abusive billing schemes by suppliers.

product category to allow for a comparison of prices among the qualified bids.[21]

- Once the composite bid prices have been calculated, the bids are ordered by the lowest to the highest composite bid price in each product category in each competitive bidding area.
- After the composite bid prices are ordered, Palmetto GBA calculates the cumulative projected capacity of the competing bids—which indicates the capacity that each supplier projects it could furnish for the product category throughout an entire competitive bidding area each year.
- Beginning with the lowest composite price, Palmetto GBA moves up the ordered bid list to identify the bid where the suppliers' cumulative projected capacity meets or exceeds CMS's estimated beneficiary demand; this bid is referred to as the pivotal bid.
- Qualified bids with composite prices that are equal to or less than the pivotal bid are determined to be winning suppliers and are used to establish the CBP round's SPAs for each item in a product category in a competitive bidding area. Specifically, for each item, the winning bids' price offers are ordered from lowest to highest, and the median price offered by these suppliers for that item becomes the item's SPA. The CBP SPAs are required to be less than or equal to the Medicare fee-for-service payments for the same items.

CMS takes steps to ensure beneficiary access and choice. CMS tries to award at least five contracts in each product category in each competitive bidding area.[22] To help meet this goal, CMS caps the estimated projected capacity of any single supplier to 20 percent of the total projected beneficiary demand for each product category, in each competitive bidding area, regardless of the capacity estimated by the supplier in its

[21]A composite bid is determined by summing all of the weights assigned to each item in a product category—with each item weight calculated using national beneficiary utilization data for that item compared to the other items within that product category.

[22]If there are five suppliers with qualified bids, CMS will award at least five contracts in each product category in each competitive bidding area. If there are fewer than five suppliers with qualified bids, CMS must award contracts to at least two suppliers if the suppliers have sufficient capacity to satisfy beneficiary demand in the product category in the competitive bidding area.

bid.[23] CMS also takes steps to ensure that small suppliers are awarded CBP contracts by having a target that 30 percent of the qualified suppliers in each product category in each competitive bidding area are small suppliers as defined for CBP.[24] In instances when the small supplier target is not initially met, CMS may award contracts to additional small suppliers after the agency has determined the number of suppliers needed to meet or exceed CMS's estimated beneficiary demand.

CMS offers the winning suppliers CBP contracts that the suppliers may accept or reject. A CBP contract includes all the product category and competitive bidding area combinations that a supplier has won for the round. If the supplier accepts its contract offer, it must agree to accept Medicare assignment—to be paid 80 percent of the relevant CBP SPA—for the CBP-covered items included in its contract.[25] Generally, CBP's contracts are for a 3-year period.

CBP Rounds and Product Categories

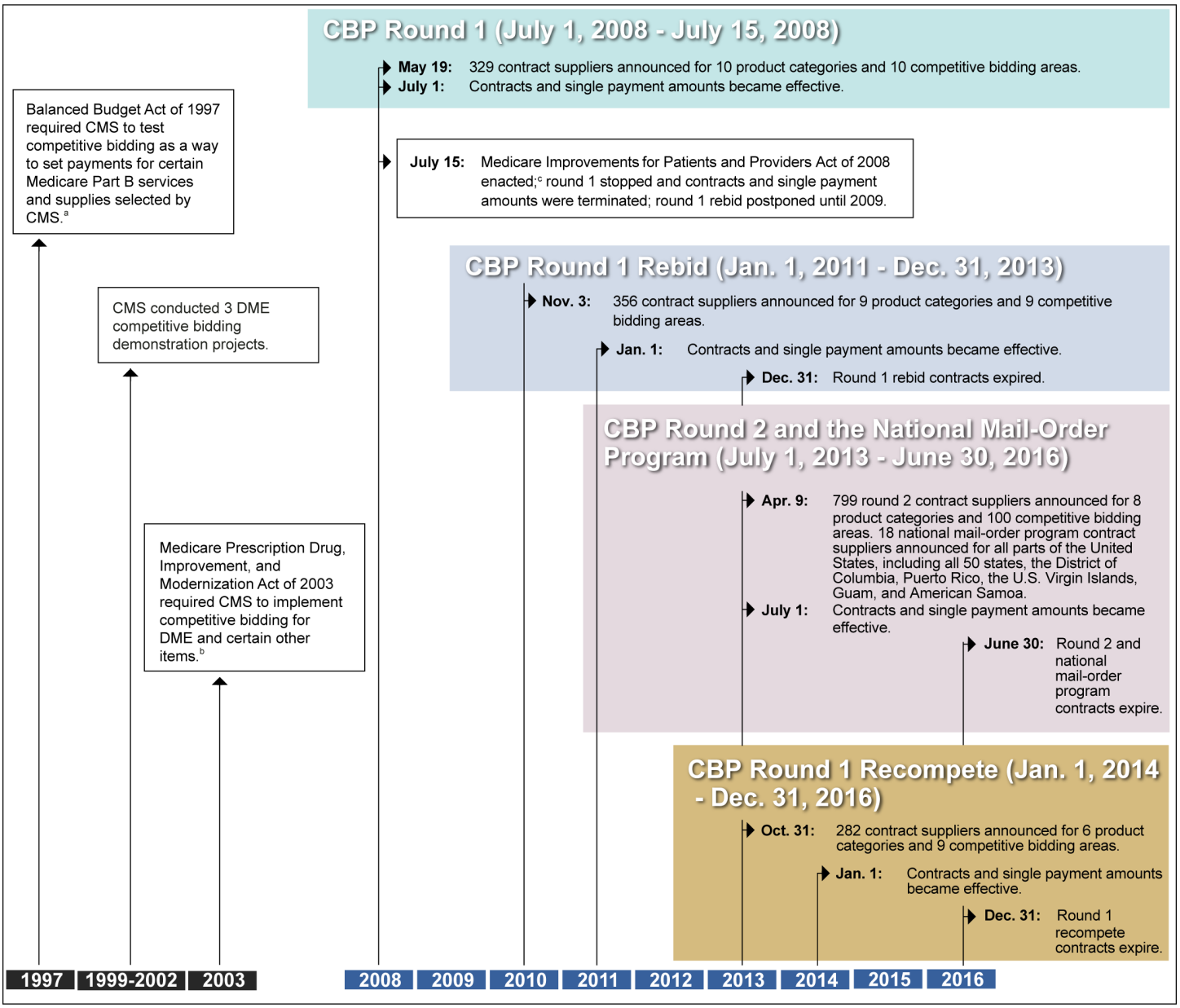
CMS is required by law to recompete the CBP contracts at least once every 3 years. Before a round's contracts expire, CMS conducts another bidding process for the new round. (See fig. 1 for CBP's legislative and program implementation timeline.)

[23]Capping a supplier's estimated projected capacity to 20 percent does not limit the number of items a supplier can furnish, if awarded a CBP contract, and suppliers may be able to furnish more than 20 percent of the beneficiary demand in a product category in a competitive bidding area.

[24]For CBP, CMS defined a small supplier as one that generates gross revenue of $3.5 million or less in annual receipts, including both Medicare and non-Medicare revenue. A qualified supplier is a bidder that has met certain requirements, including having been found financially sound and having its bids used to determine a round's SPAs and to select the contract suppliers.

[25]If a supplier agrees to assignment, then Medicare generally pays 80 percent of the amount to the supplier and the beneficiary is responsible for paying the supplier the remaining 20 percent, or the coinsurance payment, once the beneficiary's annual Medicare deductible is met. Under CBP, contract suppliers must agree to assignment, meaning that they will be paid 80 percent of the CBP SPA for the item involved. The CBP SPA that a contract supplier receives is determined by the Medicare beneficiary's residence, not the supplier's business location.

Figure 1: Timeline for CMS Implementation of the Competitive Bidding Program (CBP) for Durable Medical Equipment (DME), 1997-2016



Source: GAO analysis of CMS data. | GAO-15-63

[a]Pub. L. No. 105-33, § 4319(a), 111 Stat. 251, 392-4 (1997) (codified, as amended, at 42 U.S.C. § 1395w-3).

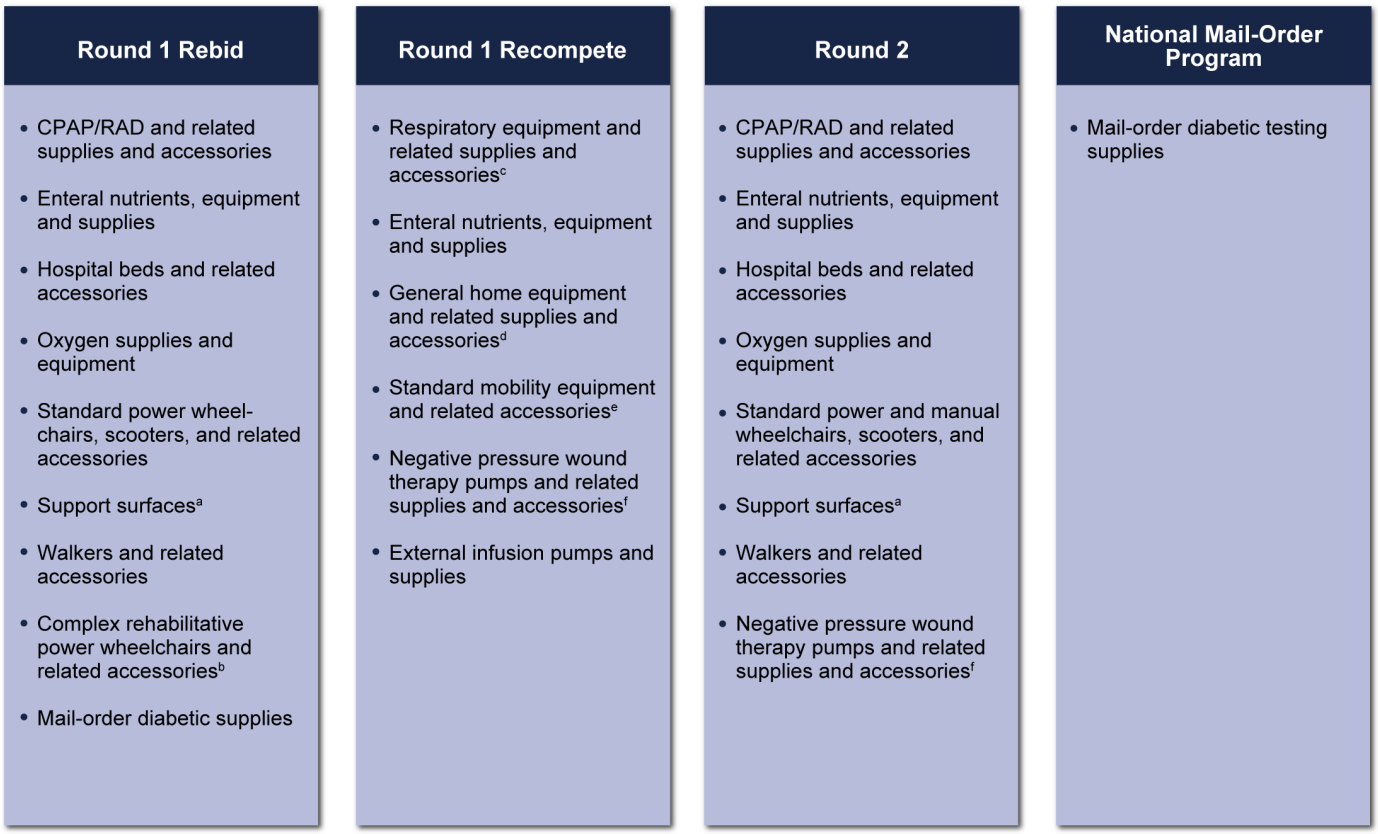
[b]Pub. L. No. 108-173, § (302)(b), 117 Stat. 2066, 2224-30 (2003) (codified, as amended, at 42 U.S.C. § 1395w-3). Items and services covered by the competition were DME and related supplies, off-the-shelf orthotics, and enteral nutrients and related equipment and supplies).

[c]Pub. L. No. 110-275, § 154(a)(2), 122 Stat. 2494, 2560-3 (2008) (codified, as amended, at 42 U.S.C. § 1395w-3).

Several product categories remained the same since the CBP round 1 rebid was implemented, but CMS also made some changes for the round 1 recompete and round 2. (See fig. 2.) The round 1 rebid contracts and SPAs were effective January 1, 2011, through December 31, 2013.[26] The rebid operated in nine competitive bidding areas and included nine DME product categories.

[26]The CBP round 1 rebid contracts for the mail-order diabetic testing supplies product category ended December 31, 2012.

Figure 2: CMS Durable Medical Equipment Product Categories by Competitive Bidding Program Round



Source: GAO analysis of CMS data. | GAO-15-63

[a]Support surfaces are pressure-reducing support surfaces for persons with or at high risk for pressure sores. The support surfaces product category includes group 2 mattresses and overlays, and for the round 1 rebid was only included in the Miami competitive bidding area.

[b]The complex rehabilitative power wheelchairs and related accessories product category was limited to group 2 power wheelchairs with power options.

[c]The respiratory equipment and related supplies and accessories product category includes oxygen; oxygen equipment and supplies; continuous positive airway pressure devices (CPAP), respiratory assist devices (RAD), and related supplies and accessories; and standard nebulizers.

[d]The general home equipment and related supplies and accessories product category includes hospital beds and related accessories, group 1 and 2 support surfaces, transcutaneous electrical nerve stimulation devices, commode chairs, patient lifts, and seat lifts.

[e]Standard mobility equipment and related accessories includes walkers, standard power and manual wheelchairs, scooters, and related accessories.

[f]Negative pressure wound therapy uses pumps that apply controlled negative or subatmospheric pressure to care for ulcers or wounds that have not responded to traditional wound treatment methods.

The round 1 recompete contracts and SPAs were effective January 1, 2014, and will expire on December 31, 2016. The recompete operates in the same nine competitive bidding areas as the concluded round 1 rebid,[27] but the product categories differ. The round 1 recompete does not have the round 1 rebid's complex rehabilitative power wheelchairs or the mail-order diabetic supplies program categories, and has some new categories the rebid did not.

The round 2 contracts and SPAs were effective July 1, 2013, and will expire on June 30, 2016. This round operates in 100 competitive bidding areas and includes eight DME product categories. (See app. I for the 100 competitive bidding areas of round 2.)

The national mail-order program contracts and SPAs were effective July 1, 2013, and will expire June 30, 2016. The program operates in the 50 states, the District of Columbia, American Samoa, Puerto Rico, and the U.S. Virgin Islands, and includes the same eight mail-order diabetic testing supply HCPCS codes as the round 1 rebid. Unlike the round 1 rebid, a supplier's diabetic testing supply bid must demonstrate that the supplier would cover at least 50 percent, by sales volume, of all types of diabetic test strips on the market. Additionally, suppliers must be paid the national mail-order program SPA for diabetic testing supply items regardless of whether they are furnished by mail or non-mail order.[28]

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

[28]Under the American Taxpayer Relief Act of 2012, diabetic testing supplies furnished on or after July 1, 2013, are paid at the same CBP SPAs as the diabetic testing supply items included in the national mail-order program, regardless of whether they are furnished by mail-order or non-mail order. Pub. L. No. 112-240, § 636, 126 Stat. 2313, 2356 (2013).

CBP Bidding Process Results for the Round 1 Recompete, Round 2, and National Mail-Order Program Are Generally Similar to Round 1 Rebid Results

We found that a similar percentage of bidding suppliers were awarded contracts in the round 1 rebid, round 1 recompete, and round 2, but not in the national mail-order program. The percentages of all bids reviewed that resulted in CBP contracts varied across CBP rounds, and the reasons that bids were disqualified were generally similar across CBP rounds. Many suppliers benefited from CMS's review of their financial documentation by submitting their paperwork by a certain date before the bid window closed—known as the covered document review date—which gave suppliers a chance to receive CMS feedback on whether they were missing any financial documentation, and the opportunity to provide any missing documentation. CMS identified suppliers that were disqualified incorrectly during its post-bid review process, and some suppliers with disqualified bids were ultimately offered a contract. In each round, few suppliers were new to both a product category and a competitive bidding area.

The Percentage of Bidding Suppliers Awarded a Contract Was Similar in All Rounds Except for the National Mail-Order Program

In all CBP rounds except the national mail-order program, the percentage of all bidding contract suppliers that were awarded a contract was between 30 and 43 percent.[29] Specifically, in the round 1 rebid, 35 percent of the 1,011 bidding suppliers were awarded a contract; in the round 1 recompete, 43 percent of the 660 bidding suppliers were awarded a contract. Sixty percent of the suppliers awarded a round 1 recompete contract had previously been awarded at least one contract in the round 1 rebid. In round 2, 30 percent of the 2,641 bidding suppliers were awarded a contract. Fewer suppliers—7 percent of the 245 bidding suppliers—were awarded a contract in the national mail-order program. (See table 1.)

[29]CMS tries to award at least five contracts in each product category in each competitive bidding area. According to CMS, the agency initially offered at least five contracts, and at least five were accepted by suppliers for each product category and competitive bidding area included in the round 1 rebid, round 1 recompete, and round 2. However, a total of three round 2 contracts were later voided due to licensure issues in the negative pressure wound therapy product category across 3 of the 100 competitive bidding areas. Therefore, there were a total of four contract suppliers for that product category in each of those three round 2 competitive bidding areas.

Table 1: CMS Durable Medical Equipment (DME) Competitive Bidding Program (CBP) Contract Awards by Bidding Supplier Size for the Round 1 Rebid, Round 1 Recompete, Round 2, and National Mail-Order Program

	Number of bidding suppliers	Percentage of bidding suppliers	Number of suppliers awarded contracts	Percentage of suppliers awarded contracts by supplier size
Round 1 rebid[a]				
Small suppliers	619	61%	219	62%
Large suppliers	340	34	137	38
Unknown	52	5	0	0
Total	**1,011**	**100**	**356**	**100**
Round 1 recompete[b]				
Small suppliers	381	58	163	58
Large suppliers	258	39	119	42
Unknown	21	3	0	0
Total	**660**	**100**	**282**	**100**
Round 2[c]				
Small suppliers	1,653	63	504	63
Large suppliers	850	32	296	37
Unknown	138	5	0	0
Total	**2,641**	**100**	**799**	**100**
National mail-order program[c]				
Small suppliers	121	49	6	33
Large suppliers	113	46	12	67
Unknown	11	5	0	0
Total	**245**	**100**	**18**	**100**

Source: CMS data. | GAO-15-63

Notes: CMS has a target that 30 percent of the qualified suppliers in each product category in each competitive bidding area are small suppliers, as defined for CBP. Categories characterizing size are based on revenue reported on suppliers' financial documents. Small suppliers reported gross revenues of $3.5 million or less in both Medicare and non-Medicare revenues, and large suppliers reported more than $3.5 million in both Medicare and non-Medicare revenues. Bidders that did not report this information or submitted bid packages with missing financial documents are categorized as unknown.

[a]The number of CBP round 1 rebid contracts that were awarded as of November 3, 2010—the date that CMS announced contract winners.

[b]The number of round 1 recompete contracts that were awarded as of October 31, 2013—the date that CMS announced contract winners.

[c]The number of round 2 contracts and national mail-order program contracts that were awarded as of April 9, 2013—the date that CMS announced contract winners.

As in the round 1 rebid, CMS met its 30 percent target for small supplier participation in subsequent CBP rounds. Specifically, 58 percent of the suppliers awarded a contract in the CBP round 1 recompete were small,

as were 63 percent of the suppliers awarded a contract in round 2 and 33 percent of the suppliers awarded a contract in the national mail-order program.

Percentages of Bids That Resulted in Contracts Varied across Rounds, but Reasons for Bid Disqualifications Were Generally Similar

The percentages of total bids submitted that resulted in contracts between CMS and suppliers were very similar in the round 1 recompete and round 2—29 percent and 28 percent, respectively. These percentages were higher than the round 1 rebid, at 20 percent, and significantly higher than the national mail-order program, at 7 percent.

Ten percent or less of the contract offers CMS made to bidding suppliers in the round 1 recompete, round 2, and national mail-order program were rejected by suppliers. Specifically, for the round 1 recompete, 111, or 10 percent, of the 1,108 bids that resulted in contract offers made to suppliers as of October 31, 2013—the date that CMS announced contract winners—were rejected. For round 2, 1,232, or 8 percent, of the 14,740 bids that resulted in offers made to suppliers as of April 9, 2013—the date that CMS announced contract winners—were rejected. For the national mail-order program, 1 bid, or 5 percent, of the 19 bids that resulted in offers made to suppliers as of April 9, 2013—the date that CMS announced contract winners—was rejected. (See table 2.)

Table 2: CMS Durable Medical Equipment (DME) Competitive Bidding Program (CBP) Bid Counts by Process Step for the Round 1 Recompete, Round 2, and National Mail-Order Program

		Round 1 recompete[a]		Round 2[b]		National mail-order program[b]	
		Number of bids	Percentage of total bids reviewed	Number of bids	Percentage of total bids reviewed	Number of bids	Percentage of total bids reviewed
1.	**Bid review**						
	Bids reviewed	3,438	100%	48,424	100%	245	100%
	Bids disqualified on initial review[c]	(1,817)	52.9	(15,130)	31.2	(117)	47.8
2.	**Winner selection**						
	Qualified bids used to determine pivotal bids	1,621	47.1	33,294	68.8	128	52.2
	Bids that lost only on price	(513)	14.9	(18,451)	38.1	(109)	44.5
	Bids that won on price, bids from small suppliers added to meet the 30 percent target, or both	1,108	32.2	14,843	30.7	19	7.8
3.	**Contract offers**						
	Initial round of contract offers	1,100	32.0	14,654	30.3	15	6.1
	Contract offers rescinded by CMS after initial round[d]	(0)	0.0	(103)	0.2	(0)	0.0
	Additional contract offers extended[e]	8	0.2	189	0.4	4	1.6
4.	**Contract outcomes**						
	Total contract offers made	1,108	32.2	14,740	30.4	19	7.8
	Contract offers rejected by suppliers[f]	(111)	3.2	(1,232)	2.5	(1)	0.4
Bids resulting in contract awards		**997**	**29.0**	**13,508**	**27.9**	**18**	**7.3**

Source: GAO analysis of CMS data. | GAO-15-63

Notes: Numbers in parentheses are decreases. The number of bids submitted is higher than the number of bidding suppliers because suppliers could submit bids in multiple product categories and multiple competitive bidding areas.

[a]These bid counts by process step were current as of October 31, 2013—the date that CMS announced contract winners.

[b]These bid counts by process step were current as of April 9, 2013—the date that CMS announced contract winners.

[c]Some of the bids that were disqualified during the initial bid review would have lost on price had they not been disqualified for at least one other reason. Some bids that were disqualified during the initial bid reviews for the round 1 recompete, round 2, and national mail-order program were later found to have been disqualified incorrectly.

[d]CMS rescinded 103 round 2 contract offers because the suppliers were excluded based on their National Supplier Clearinghouse status.

[e]CMS extended additional contract offers to suppliers in specific product categories and competitive bidding areas. To meet capacity, CMS extended an additional 8 contract offers to suppliers for the round 1 recompete, 105 for round 2, and 4 for the national mail-order program. To meet its 30 percent target for small supplier participation, CMS extended an additional 83 contract offers for round 2. CMS also extended 1 additional contract offer for round 2 as a result of an accreditation override.

[f]CMS extended these contract offers, but the bidding suppliers did not accept them.

The percentage of bids that were disqualified in the initial bid review, and therefore not eligible to compete on price, was about the same in round 2 as in the round 1 rebid, but significantly higher in the round 1 recompete and the national mail-order program. In both the round 2 and the round 1 rebid, about 30 percent of bids submitted were disqualified in the initial bid review for at least one or more reasons. Therefore, about 70 percent of all bids submitted were qualified and used to determine pivotal bids, which were then used to establish SPAs for each item that was included in the CBP round 2 and round 1 rebid.[30] In both the round 1 recompete and the national mail-order program, about 50 percent of all bids submitted were qualified and used to determine pivotal bids, which were then used to establish SPAs for each item that was included in the round 1 recompete and national mail-order program. (See app. II for additional information regarding bid disqualifications for the round 1 recompete, round 2, and the national mail-order program.)

During the round 1 recompete, bids were disqualified, and thus not eligible to compete on price, for a number of reasons.[31] The highest percentage of bids disqualified during the round 1 recompete initial bid review, 32 percent, was related to unacceptable financial documentation—131 bidding suppliers submitted 584 incomplete or inaccurate bids. The second highest percentage of bids disqualified during the round 1 recompete, 28 percent, was related to state licensure requirements—185 bidding suppliers submitted 499 bids that did not meet all state licensure requirements.

As in the round 1 recompete, the highest percentage of bids disqualified during the round 2 initial bid review, 51 percent, was related to unacceptable financial documentation—524 bidding suppliers submitted 7,768 incomplete or inaccurate bids. The second highest percentage of bids disqualified during the round 2, 21 percent, occurred because 167

[30]Bids that won on price were used to establish Medicare's SPAs for each item in a product category in a competitive bidding area.

[31]CMS officials told us that after round 1 in 2008 they changed the way CMS reported bid disqualifications for subsequent rounds by establishing a CBP bid disqualification hierarchy that ranks a supplier's bid disqualifications on the basis of reason codes. CMS officials told us that although a supplier that had a bid disqualified for more than one reason was notified of all reasons, they counted a bid that was disqualified for more than one reason code only once—under the highest reason code of the hierarchy. If a bid was disqualified for any reason, but would have also lost on price, CMS included it under the "lost on price" reason code—the highest code of its hierarchy.

bidding suppliers submitted 3,149 bids that did not meet supplier financial standards.[32] In addition, 1,804 round 2 bids were disqualified because 254 bidding suppliers did not meet all state licensure requirements.[33]

Reasons for bid disqualifications in the national mail-order program were also similar to reasons in other CBP rounds. The highest percentage of bids disqualified during the national mail-order program, 70 percent, was related to 82 bids from 82 bidding suppliers that did not meet all state licensure requirements. The second highest percentage of bids disqualified, 30 percent, was related to 35 bids from 35 bidding suppliers with unacceptable financial documentation. The third highest percentage of bids disqualified, 15 percent, was due to 18 bids that did not comply with the diabetic test strips 50 percent compliance rule, which helps to ensure that Medicare beneficiaries have access to a wide variety of mail-order diabetic supplies.[34]

[32]According to CMS officials, for the round 1 recompete, round 2, and national mail-order program, CMS revised some of the 10 financial measures or ratios that were used in the round 1 rebid. Specifically, CMS deleted the quick ratio—(cash + accounts receivables)/current liabilities—and added the debt-to-equity ratio—total liabilities/shareholder's equity. CMS also included amortization in the quality-of-earnings ratio—cash flow from operations/ (net income + depreciation + amortization).

[33]In April 2014, the HHS Office of Inspector General reported that it was in the process of conducting a limited-scope review of the efficacy of CMS's procedures for ensuring supplier compliance with applicable licensure requirements for CBP round 2.

[34]As part of their CBP bid submission, bidding suppliers are required to complete a national mail-order 50 percent compliance form that demonstrates that their bid covers at least 50 percent, by volume, of all types of mail-order diabetic testing strips on the market.

Many Bidding Suppliers Benefited from Submitting Documents before the Covered Document Review Date

As they did in the CBP round 1 rebid, bidding suppliers in the round 1 recompete, round 2, and the national mail-order program continued to benefit from a provision in the Medicare Improvements for Patients and Providers Act of 2008. It requires that, for bidding suppliers that submit their financial documentation by a certain date—known as the covered document review date—CMS provide feedback about missing financial documentation.[35] (See table 3.)

Table 3: Financial Document Covered Review Date Results for CMS Durable Medical Equipment (DME) Competitive Bidding Program (CBP) Round 1 Recompete, Round 2, and National Mail-Order Program

Covered document review	Round 1 recompete	Round 2	National mail-order program
Total number of bidding suppliers notified that financial documentation was missing from their submission	72[a]	407	39
Number of notified bidding suppliers that subsequently submitted correct documentation	66	370	35
Number of notified bidding suppliers that did not provide the missing documentation	6	37	4
Number of notified bidding suppliers that resubmitted their documentation, but were ultimately disqualified for unacceptable (such as incomplete or inaccurate) documents	23	117	8
Number of bidding suppliers initially notified that they had missing financial documentation that were ultimately awarded a contract	22	106	10

Source: GAO analysis of CMS data. | GAO-15-63

[a]Some of the bidding suppliers in each round that were notified of missing financial documentation were small suppliers as defined by CMS—specifically, 42 bidding suppliers in the CBP round 1 recompete, 256 bidding suppliers in round 2, and 19 bidding suppliers in the national mail-order program.

For each currently operating CBP round, at least 69 percent of bidding suppliers submitted their financial documentation by the covered document review date. Specifically, 69 percent of bidding suppliers

[35]Financial documentation means a financial, tax, or other document required to be submitted in order to meet CMS's financial standards for the CBP. The Medicare Improvements for Patients and Providers Act of 2008 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. For CBP rounds beginning after the round 1 rebid, CMS must notify eligible suppliers of missing financial documentation within 90 days after the end of the covered document review date. This process applies only 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.

submitted their financial documentation by the covered document review date for the round 1 recompete, 70 percent for round 2, and 78 percent for the national mail-order program. In each round, between 16 and 22 percent of bidding suppliers that submitted their financial documentation by the covered document review date were notified that they were missing financial documentation. At least 90 percent of the bidding suppliers notified that they were missing financial documentation in the round 1 recompete, round 2, and national mail-order program submitted the correct documentation. Of those that submitted the correct documentation, between 29 and 33 percent of bidding suppliers in each round were ultimately awarded a contract.

The statement of cash flow was the most common reason that bidding suppliers were notified that their bids were missing financial documentation for the round 1 rebid.[36] This continued to be the most common reason for notification of missing financial documentation in subsequent CBP rounds. Specifically, of all suppliers that were notified of missing financial documentation, 60 percent of round 1 recompete, 51 percent of round 2, and 59 percent of national mail-order program bidding suppliers were missing a statement of cash flow.

CMS's Post-Bid Review Process Identified Bidding Suppliers That Were Disqualified Incorrectly

In each CBP round, CMS determined that some bidding suppliers that did not initially receive contract offers, but then requested a review of their bids, had been disqualified incorrectly.[37] Some bidding suppliers that requested a review were found to have incorrectly disqualified bids in all rounds for a variety of reasons. For example, a bidding supplier could

[36]See GAO-12-693.

[37]During CBP round 1, we reported that CMS did not communicate effectively to suppliers that they had an opportunity to have their round 1 bids reviewed. CMS officials told us that they conducted a post-bid review process for suppliers that contacted the agency with questions or requested a review and subsequently found that 10 of the 357 round 1 suppliers that had bids reviewed had been disqualified incorrectly. After reviewing the language that CMS provided to suppliers during CBP round 1, we determined that CMS did not communicate effectively to suppliers that they had an opportunity to have disqualified round 1 bids reviewed. As a result, in 2009, we recommended, and CMS agreed, that if CMS chose to conduct a review of disqualification decisions during the round 1 rebid and future bids, CMS should notify and give all suppliers an equal opportunity for review, and clearly indicate how suppliers can request a review. See GAO, *Medicare: CMS Working to Address Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program*, GAO-10-27 (Washington, D.C.: Nov. 6, 2009). CMS provided additional information for subsequent CBP rounds.

have been disqualified incorrectly for issues regarding unacceptable hardcopy financial documentation, because it was thought not to have the required license in the state or product category(ies) in which bids were submitted, or because its bid was deemed not bona fide.[38]

In the round 1 recompete, 36 of the 151 bidding suppliers that requested a review were found to have had bids disqualified incorrectly (24 percent). According to CMS, some of these suppliers were disqualified incorrectly because one accreditation organization erroneously reported them as not being accredited. Specifically, 73 bidding suppliers requested a review of 191 bids because they were notified that they had been disqualified for failing accreditation, and 23 bidding suppliers with 71 bids were found to have been disqualified incorrectly. Of those, 14 bidding suppliers were subsequently offered a contract because they were disqualified incorrectly for failing accreditation, and 9 additional suppliers were offered a contract because they were disqualified incorrectly for other reasons.

In round 2, 187 of the 2,641 total bidding suppliers requested a review, and 17 bidding suppliers (9 percent) were found to have had bids disqualified incorrectly. Of those, 13 bidding suppliers had 310 bids that were at or below the pivotal bid or were needed to meet CMS's target for small supplier participation, and were offered a contract. In the national mail-order program, 19 of 245 total bidding suppliers requested a review. Of those, 1 bidding supplier (1 percent) was found to have been disqualified incorrectly, because it had been erroneously shown as revoked or inactive by the NSC, and was subsequently offered a contract. (See table 4.)

[38]All bids must be bona fide, meaning that they cannot be higher than the Medicare fee schedule or lower than the supplier's cost. During the bid evaluation process, Palmetto GBA screens every bid to ensure that it is bona fide.

Table 4: Results of CMS Post-Bid Review Process for the Durable Medical Equipment (DME) Competitive Bidding Program (CBP) Round 1 Rebid, Round 1 Recompete, Round 2, and the National Mail-Order Program

Post-bid review	Round 1 rebid	Round 1 recompete	Round 2	National mail-order program
Total number of bids submitted	6,215	3,438	48,424	245
Total number of bidding suppliers	1,011	660	2,641	245
Total number of bidding suppliers that requested a review	99	151	187	19
Total number of bidding suppliers found to have had bids disqualified incorrectly	7	36	17	1
Percentage of bidding suppliers that requested a review that were found to have had bids disqualified incorrectly	7%	24%	9%	1%
Number of bidding suppliers offered a contract as a result of the post-bid review[a]	7	23	13	1

Source: GAO analysis of CMS data. | GAO-15-63

[a]Only suppliers that had bids equal to or less than the pivotal bids or were needed to meet the Centers for Medicare & Medicaid Services' target for small supplier participation were offered a contract.

Few Contract Suppliers Were New to Both a Product Category and a Competitive Bidding Area Prior to Being Awarded a Contract

Although some distinct suppliers were new to at least one product category or new to at least one competitive bidding area—that is, did not provide products or services in the area—few suppliers that were awarded CBP round 1 recompete, round 2, or national mail-order program contracts were new to both a product category and a competitive bidding area.[39] In both the round 1 recompete and the national mail-order program, about 1 percent of contract suppliers were new to both the product category and the competitive bidding area. In round 2, 12 distinct contract suppliers of the original 799 contract suppliers—about 2 percent—were new to both a product category and a competitive bidding area. This number and percentage were similar to those in the round 1 rebid, where 9 distinct contract suppliers of the original 356—about 3 percent—were new to both a product category and a competitive bidding area. (See table 5.)

[39]We determined the number of distinct suppliers since contract suppliers can be counted more than once if they are new to more than one product category or more than one competitive bidding area.

Table 5: Contract Suppliers with No Previous Experience in a Competitive Bidding Area, Product Category, or Both, for the CMS Durable Medical Equipment (DME) Competitive Bidding Program (CBP) Round 1 Rebid, Round 1 Recompete, Round 2, and National Mail-Order Program

	Round 1 rebid	Round 1 recompete	Round 2	National mail-order program
New to at least one product category	43	40	159	2
New to at least one competitive bidding area	44	60	258	1[a]
New to both a product category and a competitive bidding area	9	3	12	1[a]
Total contract suppliers per round	**356**	**282**	**799**	**18**

Source: GAO analysis of CMS data. | GAO-15-63

Note: As a contract supplier can be new to a product category and a competitive bidding area, some suppliers are counted more than once across rows.

[a]There is one competitive bidding area and product category for the national mail-order program.

Most Average SPAs for Common HCPCS Codes Decreased through CBP Rounds

Most of the average SPAs for high-cost, high-utilization HCPCS codes common to the round 1 rebid, round 1 recompete, and round 2 decreased through the CBP rounds. Average SPAs for the eight HCPCS codes included in the national mail-order program also decreased or remained steady compared to those in the round 1 rebid.

Average SPAs Decreased through CBP Rounds for Most of the 28 Selected HCPCS Codes Common to the Round 1 Rebid, Round 1 Recompete, and Round 2

Average SPAs for the 28 high-cost, high-utilization HCPCS codes common to the round 1 rebid, round 1 recompete, and round 2 generally decreased through CBP rounds,[40] compared to the average Medicare 2010 fee-for-service payments for the same codes.[41] The 28 codes were among the 34 high-cost and high-utilization DME HCPCS codes CMS identified and we discussed in our 2012 report.[42] (App. III, table 11, presents a full list of the 28 codes with descriptions as well as SPAs for all codes for each round and the corresponding average Medicare 2010 fee-for-service payment amounts.) Although average SPAs continued to decrease from one round to the next for a majority of the codes, the largest overall decreases across all rounds occurred in round 1 rebid average SPAs compared to the average Medicare 2010 fee-for-service payments for the same codes.

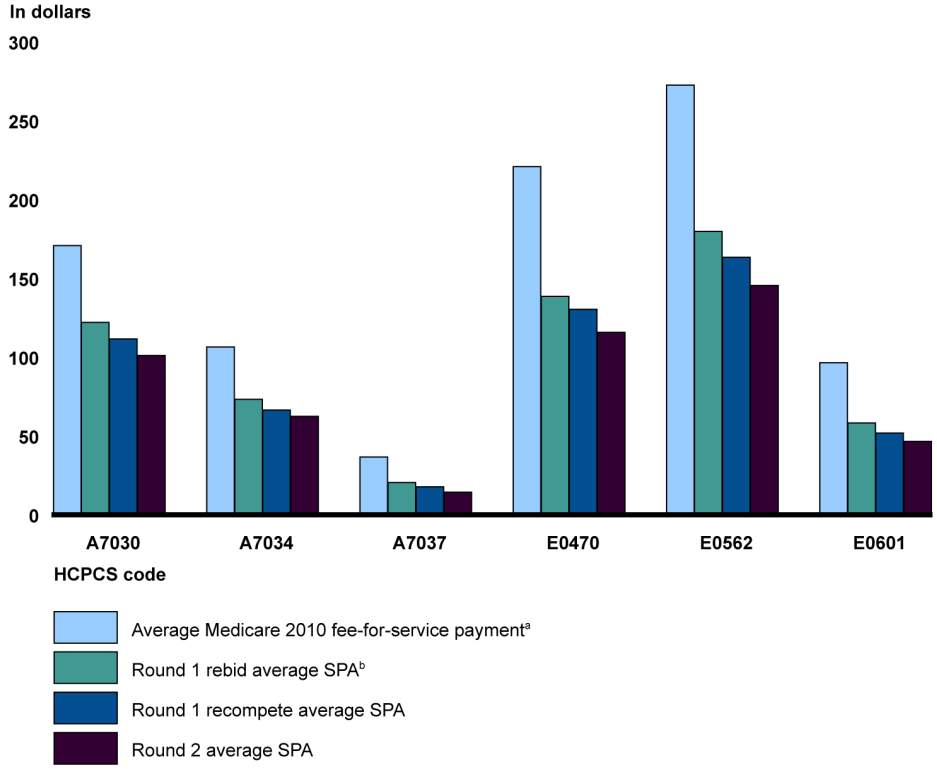
The extent to which average SPAs changed varied by type of HCPCS code. For example, SPAs for six selected HCPCS codes associated with continuous positive airway pressure devices (CPAP), respiratory assist devices (RAD), and related supplies and accessories decreased in each CBP round. (See fig. 3.)

[40]SPAs are determined by arraying the price offers in winning bids from lowest to highest and selecting the median price offered by the suppliers for an item. The median price becomes the SPA. SPAs can vary by competitive bidding area. To calculate an average SPA for each HCPCS code, we averaged the SPAs across all competitive bidding areas included in each round. For example, round 2 SPAs for respiratory assist devices (HCPCS code E0470) ranged from a low of $106.90 in the Northern New Jersey Metro competitive bidding area to a high of $138.85 in the Worchester, Massachusetts, competitive bidding area, and the average SPA was $115.75.

[41]The 2010 Medicare fee-for-service payment amount was used as a comparison point for this analysis because 2010 was the year that preceded the round 1 rebid, which resulted in contracts that were effective from January 1, 2011, through December 31, 2013. CBP SPAs are required to be less than or equal to the Medicare fee-for-service payment for the same item. We averaged Medicare fee-for-service payments for 2010 using payments within the continental states and the District of Columbia only, because Alaska and Hawaii are not subject to Medicare's fee-for-service payment amount ceiling and floor limits.

[42]See GAO-12-693. For our previous work on the CBP, we reported on the top 34 HCPCS codes that CMS identified as representing the top 80 percent high-cost and high-utilization codes for the round 1 rebid.

Figure 3: Comparison of Average Medicare 2010 Fee-for-Service Payments with CMS Competitive Bidding Program Rounds' Average Single Payment Amounts (SPA) for Selected Continuous Positive Airway Pressure Devices (CPAP), Respiratory Assist Devices (RAD), and Related Supplies and Accessories Codes



Source: GAO analysis of CMS data. | GAO-15-63

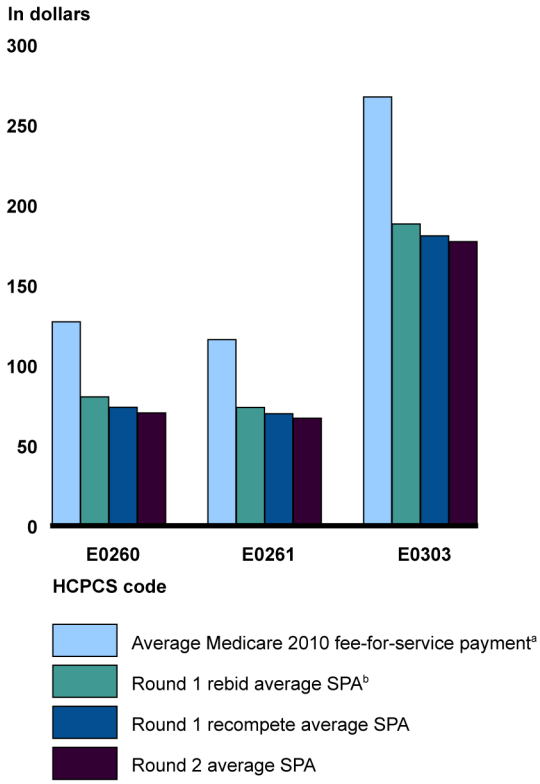
Notes: A7030 is a full face mask used with positive airway pressure device (each). A7034 is a nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap. A7037 is tubing used with positive airway pressure device. E0470 is a RAD, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device). E0562 is a humidifier, heated, used with positive airway pressure device. E0601 is a CPAP.

[a]The 2010 Medicare fee-for-service payment amount was used as a comparison point for this analysis because 2010 was the year that preceded the round 1 rebid, which resulted in contracts that were effective from January 1, 2011, through December 31, 2013. CBP SPAs are required to be less than or equal to the Medicare fee-for-service payment amount for the same item. We averaged Medicare fee-for-service payments for 2010 using payments within the continental states and the District of Columbia only, because Alaska and Hawaii are not subject to Medicare's fee-for-service payment amount ceiling and floor limits.

[b]SPAs are determined by arraying the price offers in winning bids from lowest to highest and selecting the median price offered by the suppliers for an item. The median price becomes the SPA. SPAs can vary by competitive bidding area. To calculate an average SPA for each Healthcare Common Procedure Coding System (HCPCS) code, we averaged the SPAs across all competitive bidding areas included in each round. For example, SPAs in round 2 for HCPCS code E0470 ranged from a low of $106.90 in the Northern New Jersey Metro competitive bidding area to a high of $138.85 in the Worchester, Massachusetts, competitive bidding area, and the average SPA was $115.75.

Similar to the pattern for the six selected CPAP and RAD HCPCS codes, the average SPAs also decreased in each CBP round for three selected hospital bed HCPCS codes. (See fig. 4.)

Figure 4: Comparison of Average Medicare 2010 Fee-for-Service Payments with CMS Competitive Bidding Program Rounds' Average Single Payment Amounts (SPA) for Selected Hospital Bed Codes



Source: GAO analysis of CMS data. | GAO-15-63

Notes: E0260 is a hospital bed, semi-electric (head and foot adjustment), with any type side rails, with mattress. E0261 is a hospital bed, semi-electric (head and foot adjustment), with any type side rails, without mattress. E0303 is a hospital bed, heavy duty, extra wide, with weight capacity greater than 350 pounds, but less than or equal to 600 pounds, with any type side rails, with mattress.

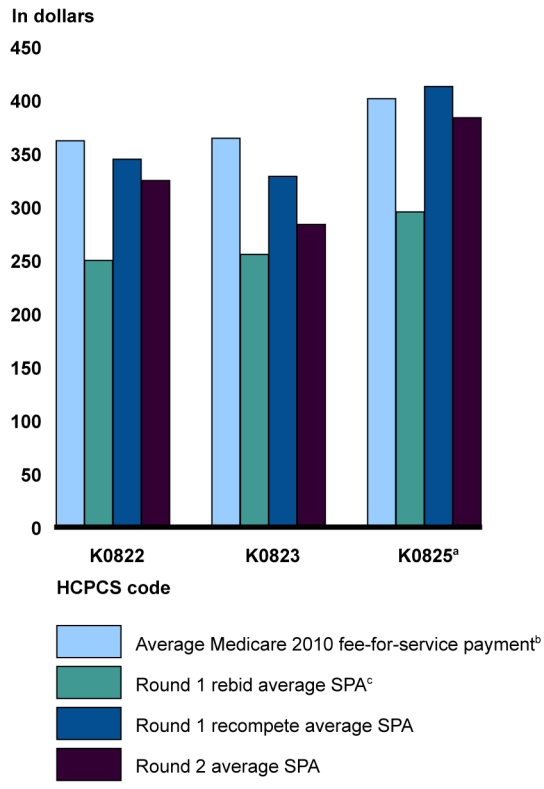
[a]The 2010 Medicare fee-for-service payment amount was used as a comparison point for this analysis because 2010 was the year that preceded the round 1 rebid, which resulted in contracts that were effective from January 1, 2011, through December 31, 2013. CBP SPAs are required to be less than or equal to the Medicare fee-for-service payment amount for the same item. We averaged Medicare fee-for-service payments for 2010 using payments within the continental states and the District of Columbia only, because Alaska and Hawaii are not subject to Medicare's fee-for-service payment amount ceiling and floor limits.

[b]SPAs are determined by arraying the price offers in winning bids from lowest to highest and selecting the median price offered by the suppliers for an item. The median price becomes the SPA. SPAs can vary by competitive bidding area. To calculate an average SPA for each Healthcare Common Procedure Coding System (HCPCS) code, we averaged the SPAs across all competitive bidding areas included in each round. For example, SPAs for round 2 for HCPCS code E0261 ranged from a

low of $58.67 in the Cape Coral-Fort Myers, Florida, competitive bidding area to a high of $91.62 in the Honolulu, Hawaii, competitive bidding area, and the average SPA was $67.04.

However, average SPAs for the three selected standard power wheelchair HCPCS codes had a different pattern. Average round 1 rebid SPAs for these HCPCS codes decreased an average of 29 percent from the average Medicare 2010 fee-for-service payment amounts. Average SPAs for the same HCPCS codes then increased by an average of 35 percent from the round 1 rebid to the round 1 recompete, but decreased by an average of 9 percent from the round 1 recompete to round 2. (See fig. 5.) Round 2 average SPAs for selected standard power wheelchair HCPCS codes, while higher than the round 1 rebid amounts, remained 12 percent lower, on average, than the average Medicare 2010 fee-for-service payments for the same codes.

Figure 5: Comparison of Average Medicare 2010 Fee-for-Service Payments with CMS Competitive Bidding Program Rounds' Average Single Payment Amounts (SPA) for Selected Standard Power Wheelchair Codes



Source: GAO analysis of CMS data. | GAO-15-63

Notes: K0822 is a power wheelchair, group 2 standard, sling/solid seat/back, patient weight capacity up to and including 300 pounds. K0823 is a power wheelchair, group 2 standard, captains chair,

patient weight capacity up to and including 300 pounds. K0825 is a power wheelchair, group 2 heavy duty, captains chair, patient weight capacity 301 to 450 pounds.

[a]The average SPA for K0825 in the round 1 recompete ($412.62) was higher than the average Medicare 2010 fee-for-service payment listed ($401.20), but it was not higher than the 2013 average Medicare fee-for-service payment amount ($620.59) for that item. CMS used the 2013 Medicare fee-for-service payments as a comparison point for determining whether SPAs in the round 1 recompete were less than or equal to Medicare fee-for-service payments for the same items.

[b]The 2010 Medicare fee-for-service payment amount was used as a comparison point for this analysis because 2010 was the year that preceded the round 1 rebid, which resulted in contracts that were effective from January 1, 2011, through December 31, 2013. CBP SPAs are required to be less than or equal to the Medicare fee-for-service payment amount for the same item. We averaged Medicare fee-for-service payments for 2010 using payments within the continental states and the District of Columbia only, because Alaska and Hawaii are not subject to Medicare's fee-for-service payment amount ceiling and floor limits.

[c]SPAs are determined by arraying the price offers in winning bids from lowest to highest and selecting the median price offered by the suppliers for an item. The median price becomes the SPA. SPAs can vary by competitive bidding area. To calculate an average SPA for each Healthcare Common Procedure Coding System (HCPCS) code, we averaged the SPAs across all competitive bidding areas included in each round. For example, SPAs in round 2 for HCPCS code K0822 ranged from a low of $285.49 in the Austin-Round Rock-San Marcos, Texas, competitive bidding area to a high of $388.59 in the Honolulu, Hawaii, competitive bidding area, and the average SPA was $324.53.

Average SPAs for Diabetic Testing Supply HCPCS Codes Decreased or Remained Steady from the Round 1 Rebid to the National Mail-Order Program

Eight diabetic testing supply HCPCS codes were common to the CBP round 1 rebid and the national mail-order program.[43] (See table 6.) Three of these codes were also included in the original 34 codes CMS determined to be high-cost, high-utilization HCPCS codes for the round 1 rebid.[44]

[43]Mail-order diabetic testing supplies were not included in the round 1 recompete because CBP's national mail-order program was implemented before the recompete. The national mail-order program competition took place at the same time as the round 2 competition.

[44]For the full list of 34 codes, see GAO-12-693. HCPCS codes A4253, A4256, and A4259 were included in the list of 34 codes CMS identified as representing the top 80 percent high-cost and high-utilization codes included in the CBP round 1 rebid, and were common to the round 1 rebid and national mail-order program.

Table 6: Healthcare Common Procedure Coding System (HCPCS) Codes and Descriptions for Mail-Order Diabetic Testing Supply Codes Common to the CMS Competitive Bidding Program (CBP) Round 1 Rebid and the National Mail-Order Program

HCPCS code[a]	Description
A4233	Replacement battery, alkaline (other than J cell), for use with medically necessary home blood glucose monitor owned by patient, each
A4234	Replacement battery, alkaline, J cell, for use with medically necessary home blood glucose monitor owned by patient, each
A4235	Replacement battery, lithium, for use with medically necessary home blood glucose monitor owned by patient, each
A4236	Replacement battery, silver oxide, for use with medically necessary home blood glucose monitor owned by patient, each
A4253[b]	Blood glucose test or reagent strips for home blood glucose monitor, per 50 strips
A4256[b]	Normal, low, and high calibrator solution/chips
A4258	Spring-powered device for lancet, each
A4259[b]	Lancets, per box of 100

Source: GAO analysis of CMS data. | GAO-15-63

[a]HCPCS codes under the diabetic testing supplies product category must also include the modifier "KL" at the end to indicate that these supplies were furnished by mail-order.

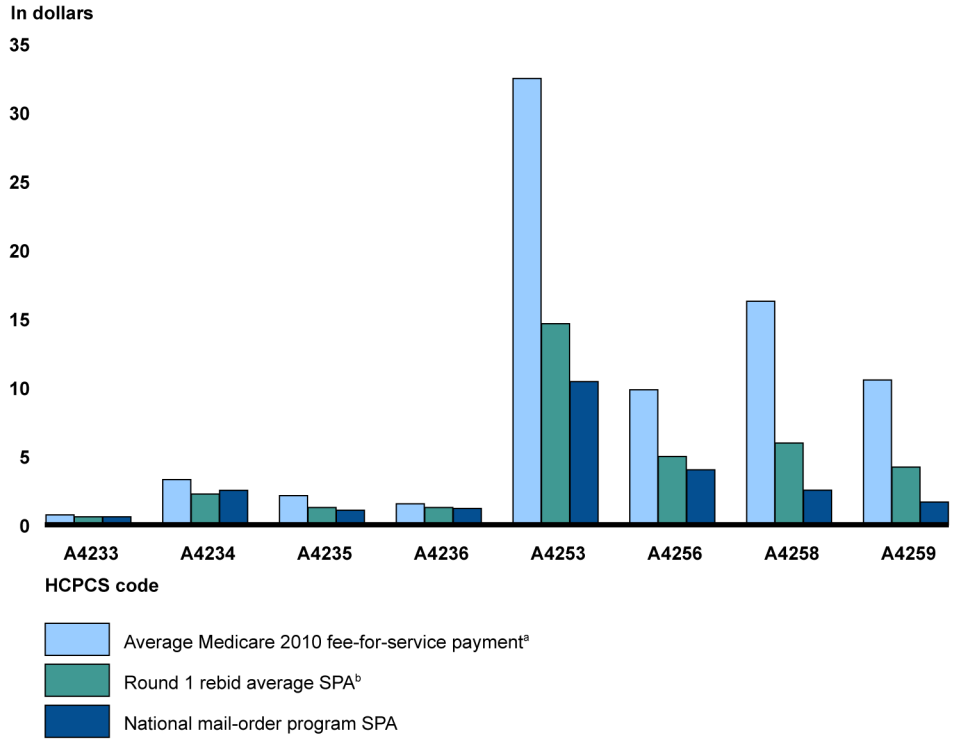
[b]These three codes were also part of the original 34 codes that CMS determined as representing the top 80 percent high-cost and high-utilization codes for the round 1 rebid.

Average SPAs for the eight common mail-order diabetic testing supply HCPCS codes decreased from the average 2010 Medicare mail-order fee-for-service payment amount to the round 1 rebid,[45] and decreased or

[45]The 2010 Medicare mail-order fee-for-service payment amount was used as a comparison point for this analysis because 2010 was the year that preceded the round 1 rebid, which resulted in contracts that were effective from January 1, 2011, through December 31, 2013. CBP SPAs are required to be less than or equal to the Medicare fee-for-service payment amount for the same item. We averaged Medicare mail-order fee-for-service payments for 2010 using payments within the continental states and the District of Columbia only, because Alaska and Hawaii are not subject to Medicare's fee-for-service payment amount ceiling and floor limits.

remained steady from the round 1 rebid to the national mail-order program.[46] (See fig. 6.)

Figure 6: Comparison of Average Medicare 2010 Mail-Order Fee-for-Service Payments with CMS Competitive Bidding Program Rounds' Average Single Payment Amounts (SPA) for Diabetic Testing Supply Codes



Source: GAO analysis of CMS data. | GAO-15-63

Notes: Healthcare Common Procedure Coding System (HCPCS) codes for mail-order diabetic testing supplies must include the modifier "KL" at the end to indicate that these supplies were furnished by mail-order. A4233 is a replacement battery, alkaline (other than J cell), for use with medically

[46]SPAs are determined by arraying the price offers in winning bids from lowest to highest and selecting the median price offered by the suppliers for an item. The median price becomes the SPA. SPAs can vary by competitive bidding area. To calculate an average SPA for each HCPCS code, we averaged the SPAs across all competitive bidding areas included in the round 1 rebid. For example, SPAs for the round 1 rebid for HCPCS code A4253 KL ranged from a low of $13.88 in the Riverside-San Bernadino-Ontario, California, competitive bidding area to a high of $15.62 in the Cleveland-Elyria-Mentor, Ohio, competitive bidding area, and the average SPA was $14.62. For the national mail-order program, CMS determined one SPA for each HCPCS code, so no averaging was necessary.

necessary home blood glucose monitor owned by patient, each. A4234 is a replacement battery, alkaline, J cell, for use with medically necessary home blood glucose monitor owned by patient, each. A4235 is a replacement battery, lithium, for use with medically necessary home blood glucose monitor owned by patient, each. A4236 is a replacement battery, silver oxide, for use with medically necessary home blood glucose monitor owned by patient, each. A4253 is blood glucose test or reagent strips for home blood glucose monitor, per 50 strips. A4256 is normal, low, and high calibrator solution/chips. A4258 is a spring-powered device for lancet, each. A4259 is lancets, per box of 100.

[a]The 2010 Medicare mail-order fee-for-service payment amount was used as a comparison point for this analysis because 2010 was the year that preceded the round 1 rebid, which resulted in contracts that were effective from January 1, 2011, through December 31, 2013. CBP SPAs are required to be less than or equal to the Medicare fee-for-service payment amount for the same item. We averaged Medicare mail-order fee-for-service payments for 2010 using payments within the continental states and the District of Columbia only, because Alaska and Hawaii are not subject to Medicare's fee-for-service payment amount ceiling and floor limits.

[b]SPAs are determined by arraying the price offers in winning bids from lowest to highest and selecting the median price offered by the suppliers for an item. The median price becomes the SPA. SPAs can vary by competitive bidding area. To calculate an average SPA for each code, we averaged the SPAs across all competitive bidding areas included in the round 1 rebid. For example, SPAs for the round 1 rebid for HCPCS code A4253 KL ranged from a low of $13.88 in the Riverside-San Bernadino-Ontario, California, competitive bidding area to a high of $15.62 in the Cleveland-Elyria-Mentor, Ohio, competitive bidding area, and the average SPA was $14.62. For the national mail-order program, CMS determined one SPA for each HCPCS code, so no averaging was necessary.

The extent of decrease in national mail-order program SPAs varied across HCPCS codes. (See app. III, table 12, for a list of all eight HCPCS codes with their corresponding average 2010 Medicare and CBP SPA amounts.) For example, average SPAs for three HCPCS codes associated with glucose monitoring test strips and lancets (A4253, A4258, and A4259)[47] decreased by more than 50 percent from the average Medicare 2010 mail-order fee-for-service payment to the round 1 rebid average SPA. Payments for two of these codes (A4258 and A4259) further decreased by 50 percent or more from the round 1 rebid average SPA to the national mail-order program SPA. However, average SPAs for two codes associated with replacement batteries for blood glucose monitors (A4233 and A4236)[48] decreased by less than 20 percent from the average Medicare 2010 mail-order fee-for-service payment to the round 1 rebid average SPA. Payments for these codes were steady in the

[47]A4253 is blood glucose test or reagent strips for home blood glucose monitor, per 50 strips. A4258 is a spring-powered device for lancet, each; and A4259 is lancets, per box of 100.

[48]A4233 is a replacement battery, alkaline (other than J cell), for use with medically necessary home blood glucose monitor owned by patients, each. A4236 is a replacement battery, silver oxide, for use with medically necessary home blood glucose monitor owned by patient, each.

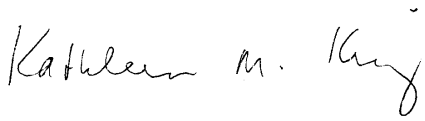
national mail-order program compared to the round 1 rebid, with minimal or no decrease in SPAs.

Agency Comments

HHS reviewed a draft of this report and provided written comments, which are reprinted in appendix IV. HHS also provided technical comments, which we incorporated as appropriate. In its general comments, HHS stated that it anticipates CBP will provide substantial savings for both the Medicare Part B Trust Fund and Medicare beneficiaries.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the Secretary of Health and Human Services and appropriate congressional committees. The report will also be available at no charge on our website at http://www.gao.gov.

If you or your staff 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 V.



Kathleen M. King
Director, Health Care

Appendix I: The 100 Competitive Bidding Areas Included in the CMS Competitive Bidding Program Round 2

Region and competitive bidding area	State
Midwest	
Akron, OH	Ohio
Central-Chicago Metro area	Illinois
Columbus, OH	Ohio
Dayton, OH	Ohio
Detroit-Warren-Livonia, MI	Michigan
Flint, MI	Michigan
Grand Rapids-Wyoming, MI	Michigan
Huntington-Ashland, WV-KY-OH	Kentucky
Indiana-Chicago Metro area	Indiana
Indianapolis-Carmel, IN	Indiana
Milwaukee-Waukesha-West Allis, WI	Wisconsin
Minneapolis-St. Paul-Bloomington, MN-WI	Minnesota
Northern-Chicago Metro area	Illinois
Omaha-Council Bluffs, NE-IA	Iowa
South-West-Chicago-Metro area	Illinois
St. Louis, MO-IL	Illinois
Toledo, OH	Ohio
Wichita, KS	Kansas
Youngstown-Warren-Boardman, OH-PA	Ohio
Northeast	
Albany-Schenectady-Troy, NY	New York
Allentown-Bethlehem-Easton, PA-NJ	New Jersey
Boston-Cambridge-Quincy, MA-NH	Massachusetts
Bridgeport-Stamford-Norwalk, CT	Connecticut
Bronx-Manhattan NY	New York
Buffalo-Niagara Falls, NY	New York
Hartford-West Hartford-East Hartford, CT	Connecticut
New Haven-Milford, CT	Connecticut
Nassau-Brooklyn-Queens-Richmond County Metro area	New York
North East NY Metro area	New York
Northern NJ Metro area	New Jersey
Philadelphia-Camden-Wilmington, PA-NJ-DE-MD	Delaware
Poughkeepsie-Newburgh-Middletown, NY	New York
Providence-New Bedford-Fall River, RI-MA	Massachusetts

Region and competitive bidding area	State
Rochester, NY	New York
Scranton—Wilkes-Barre, PA	Pennsylvania
Southern NY Metro area	New Jersey
Springfield, MA	Massachusetts
Suffolk County	New York
Syracuse, NY	New York
Worcester, MA	Massachusetts
South	
Asheville, NC	North Carolina
Atlanta-Sandy Springs-Marietta, GA	Georgia
Augusta-Richmond County, GA-SC	Georgia
Austin-Round Rock-San Marcos, TX	Texas
Baltimore-Towson, MD	Maryland
Baton Rouge, LA	Louisiana
Beaumont-Port Arthur, TX	Texas
Birmingham-Hoover, AL	Alabama
Cape Coral-Fort Myers, FL	Florida
Charleston-North Charleston-Summerville, SC	South Carolina
Chattanooga, TN-GA	Georgia
Columbia, SC	South Carolina
Deltona-Daytona Beach-Ormond Beach, FL	Florida
El Paso, TX	Texas
Greensboro-High Point, NC	North Carolina
Greenville-Mauldin-Easley, SC	South Carolina
Houston-Sugar Land-Baytown, TX	Texas
Jackson, MS	Mississippi
Jacksonville, FL	Florida
Knoxville, TN	Tennessee
Lakeland-Winter Haven, FL	Florida
Little Rock-North Little Rock-Conway, AR	Arkansas
Louisville/Jefferson County, KY-IN	Indiana
McAllen-Edinburg-Mission, TX	Texas
Memphis, TN-MS-AR	Arkansas
Nashville-Davidson—Murfreesboro—Franklin, TN	Tennessee
New Orleans-Metairie-Kenner, LA	Louisiana
North Port-Bradenton-Sarasota, FL	Florida
Ocala, FL	Florida

Region and competitive bidding area	State
Oklahoma City, OK	Oklahoma
Palm Bay-Melbourne-Titusville, FL	Florida
Raleigh-Cary, NC	North Carolina
Richmond, VA	Virginia
San Antonio-New Braunfels, TX	Texas
Tampa-St. Petersburg-Clearwater, FL	Florida
Tulsa, OK	Oklahoma
Virginia Beach-Norfolk-Newport News, VA-NC	North Carolina
Washington-Arlington-Alexandria, DC-VA-MD-WV	District of Columbia
West	
Albuquerque, NM	New Mexico
Bakersfield-Delano, CA	California
Boise City-Nampa, ID	Idaho
Colorado Springs, CO	Colorado
Denver-Aurora-Broomfield, CO	Colorado
Fresno, CA	California
Honolulu, HI	Hawaii
Las Vegas-Paradise, NV	Nevada
Los Angeles County	California
Orange County	California
Oxnard-Thousand Oaks-Ventura, CA	California
Phoenix-Mesa-Glendale, AZ	Arizona
Portland-Vancouver-Hillsboro, OR-WA	Oregon
Sacramento—Arden-Arcade—Roseville, CA	California
Salt Lake City, UT	Utah
San Diego-Carlsbad-San Marcos, CA	California
San Francisco-Oakland-Fremont, CA	California
San Jose-Sunnyvale-Santa Clara, CA	California
Seattle-Tacoma-Bellevue, WA	Washington
Stockton, CA	California
Tucson, AZ	Arizona
Visalia-Porterville, CA	California
Total	**100**

Source: GAO analysis of CMS data. | GAO-15-63

Note: Regions listed above are determined by the corresponding metropolitan statistical area. These are areas designated by the Office of Management and Budget that include major cities and the suburban areas surrounding them. By law, round 2 was required to be conducted in designated metropolitan statistical areas. On January 8, 2008, CMS announced 70 metropolitan statistical areas for round 2. Under the Patient Protection and Affordable Care Act, CMS was required to designate an

additional 21 areas for round 2, resulting in a total of 91 areas. 42 U.S.C. § 1395w-3(a)(1)(D)(ii). The round 2 competitive bidding areas are defined by specific ZIP codes related to a metropolitan statistical area, and may be the same size as, larger than, or smaller than the related metropolitan statistical area, depending on a variety of considerations. The competitive bidding area is the area wherein only contract suppliers may furnish competitively bid items to beneficiaries unless an exception is permitted by law. Metropolitan statistical areas with populations over 8 million may be subdivided into multiple competitive bidding areas. Most round 2 metropolitan statistical areas have only one competitive bidding area. However, the three largest metropolitan statistical areas (Chicago, Los Angeles, and New York) are subdivided into multiple competitive bidding areas, so there are a total of 100 competitive bidding areas.

Appendix II: Suppliers with Disqualified Bids in Currently Operating CMS Competitive Bidding Program Rounds

Bidding suppliers in the CBP round 1 recompete, round 2, and the national mail-order program had bids disqualified for a number of reasons. (See table 7, table 8, and table 9, respectively.)

Table 7: Number of Suppliers with CMS Durable Medical Equipment (DME) Competitive Bidding Program (CBP) Round 1 Recompete Disqualified Bids, by Reason for Disqualification as of October 31, 2013

Reason for bid disqualification	Bids disqualified during initial bid review	Percentage of bids disqualified[a]	Number of suppliers with a bid that was disqualified, for each reason
Unacceptable (incomplete or inaccurate) financial documentation[b]	584	32.1%	131
Did not meet all state licensure requirements[c]	499	27.5	185
Did not meet supplier financial standards[d]	189	10.4	32
Missing required hardcopy documentation[e]	116	6.4	21
Bid price for one or more product category items was deemed not bona fide[f]	266	14.6	111
Did not meet Medicare accreditation requirements[g]	502	27.6	222
National Supplier Clearinghouse (NSC) number was revoked or inactive[h]	61	3.4	14
Did not meet common ownership rules[i]	6	0.3	2
Did not meet network criteria[j]	0	0.0	0
Did not meet eligibility requirements to bid as a specialty supplier[k]	0	0.0	0
Invalid bid[l]	18	1.0	1

Source: CMS data as of October 31, 2013. | GAO-15-63

Notes: October 31, 2013, is the date that the Centers for Medicare & Medicaid Services (CMS) announced contract winners. Suppliers that were disqualified for more than one reason are counted in each reason code. Therefore, the number of bids disqualified and the number of suppliers disqualified may appear in multiple categories. In addition to the reasons for bid disqualifications above, CMS also established a "lost on price" category. According to CMS, 740 of the 1,817 total bids disqualified—41 percent—would also have lost on price had the bids not been disqualified for at least one other reason.

[a]Percentages add to more than 100 because a bid could have been disqualified for more than one reason.

[b]Suppliers failed to submit complete or accurate hardcopy financial documentation as required.

[c]Suppliers were responsible for meeting all applicable state licensure requirements for the product category for every state included in the competitive bidding area in which they submitted a bid.

[d]Supplier financial standards indicated that CMS believed that the supplier was unlikely for financial reasons to be able to fulfill its contract obligations.

[e]Suppliers failed to submit financial documentation in hardcopy as required.

[f]All bid prices could not be higher than the Medicare fee schedule but not lower than the cost to the supplier.

[g]Suppliers must have been accredited by a CMS-approved accreditation organization for the product categories in which they submitted bids.

[h]Suppliers must have had an active NSC number to be eligible to bill Medicare for DME.

[i]Commonly owned or controlled suppliers were required to submit a single bid to furnish a product category in a competitive bidding area.

[j]A network is a group of 2 to 20 small suppliers that collectively submit a bid as a single entity and must meet certain criteria.

[k]A specialty supplier is a skilled nursing facility or nursing facility that is awarded a competitive bidding contract to furnish competitively bid items only to its own residents to whom it would otherwise furnish Medicare Part B services.

[l]This category indicates a loss of eligibility prior to the arraying of bids because the supplier's Provider Transaction Account Number was either inactivated or revoked.

Table 8: Number of Suppliers with CMS Durable Medical Equipment (DME) Competitive Bidding Program (CBP) Round 2 Disqualified Bids, by Reason for Disqualification as of April 9, 2013

Reason for bid disqualification	Bids disqualified during initial bid review	Percentage of bids disqualified[a]	Number of suppliers with a bid that was disqualified, for each reason
Unacceptable (incomplete or inaccurate) financial documentation[b]	7,768	51.3%	524
Did not meet all state licensure requirements[c]	1,804	11.9	254
Did not meet supplier financial standards[d]	3,149	20.8	167
Missing required hardcopy documentation[e]	1,217	8.0	138
Bid price for one or more product category items was deemed not bona fide[f]	915	6.0	165
Did not meet Medicare accreditation requirements[g]	166	1.1	67
National Supplier Clearinghouse (NSC) number was revoked or inactive[h]	766	5.1	30
Did not meet common ownership rules[i]	30	0.2	8
Did not meet network criteria[j]	0	0.0	0
Did not meet eligibility requirements to bid as a specialty supplier[k]	0	0.0	0
Withdrew bid[l]	100	0.7	1

Source: CMS data as of April 9, 2013. | GAO-15-63

Notes: April 9, 2013, is the date that the Centers for Medicare & Medicaid Services (CMS) announced contract winners. Suppliers that were disqualified for more than one reason are counted in each reason code. Therefore, the number of bids disqualified and the number of suppliers disqualified may appear in multiple categories. In addition to the reasons for bid disqualifications above, CMS also established a "lost on price" category. According to CMS, 10,057 of the 15,130 total bids disqualified—66 percent—would also have lost on price had the bids not been disqualified for at least one other reason.

[a]Percentages add to more than 100 because a bid could have been disqualified for more than one reason.

[b]Suppliers failed to submit complete or accurate hardcopy financial documentation as required.

[c]Suppliers were responsible for meeting all applicable state licensure requirements for the product category for every state included in the competitive bidding area in which they submitted a bid.

[d]Supplier financial standards indicated that CMS believed that the supplier was unlikely for financial reasons to be able to fulfill its contract obligations.

[e]Suppliers failed to submit financial documentation in hardcopy as required.

[f]All bid prices could not be higher than the Medicare fee schedule but not lower than the cost to the supplier.

[g]Suppliers must have been accredited by a CMS-approved accreditation organization for the product categories in which they submitted bids.

[h]Suppliers must have had an active NSC number to be eligible to bill Medicare for DME.

[i]Commonly owned or controlled suppliers were required to submit a single bid to furnish a product category in a competitive bidding area.

[j]A network is a group of 2 to 20 small suppliers that collectively submit a bid as a single entity and must meet certain criteria.

[k]A specialty supplier is a skilled nursing facility or nursing facility that is awarded a competitive bidding contract to furnish competitively bid items only to its own residents to whom it would otherwise furnish Medicare Part B services.

[l]The supplier retracted the bids, and the bids were disqualified.

Table 9: Number of Suppliers with CMS Durable Medical Equipment (DME) National Mail-Order Program Disqualified Bids, by Reason for Disqualification, as of April 9, 2013

Reason for bid disqualification	Bids disqualified during initial bid review	Percentage of bids disqualified[a]	Number of suppliers with a bid that was disqualified, for each reason
Unacceptable (incomplete or inaccurate) financial documentation[b]	35	29.9	35
Did not meet all state licensure requirements[c]	82	70.1	82
Did not meet supplier financial standards[d]	11	9.4	11
Missing required hardcopy documentation[e]	11	9.4	11
Bid price for one or more product category items was deemed not bona fide[f]	0	0.0	0
Did not meet Medicare accreditation requirements[g]	0	0.0	0
National Supplier Clearinghouse (NSC) number was revoked or inactive[h]	3	2.6	3
Did not meet common ownership rules[i]	2	1.7	2
Did not meet network criteria[j]	0	0.0	0
Did not meet eligibility requirements to bid as a specialty supplier[k]	0	0.0	0
Test Strips 50 Percent Compliance Rule[l]	18	15.4	18

Source: CMS data as of April 9, 2013. | GAO-15-63

Notes: April 9, 2013, is the date that the Centers for Medicare & Medicaid Services (CMS) announced contract winners. Suppliers that were disqualified for more than one reason are counted in each reason code. Therefore, the number of bids disqualified and the number of suppliers disqualified may appear in multiple categories. In addition to the reasons for bid disqualifications above, CMS also established a "lost on price" category. According to CMS, 112 of the 117 total bids disqualified—96 percent—would also have lost on price had the bids not been disqualified for at least one other reason.

[a]Percentages add to more than 100 because a bid could have been disqualified for more than one reason.

[b]Suppliers failed to submit complete or accurate hardcopy financial documentation as required.

[c]Suppliers were responsible for meeting all applicable state licensure requirements for the product category for every state included in the competitive bidding area in which they submitted a bid.

[d]Supplier financial standards indicated that CMS believed that the supplier was unlikely for financial reasons to be able to fulfill its contract obligations.

[e]Suppliers failed to submit financial documentation in hardcopy as required.

[f]All bid prices could not be higher than the Medicare fee schedule but not lower than the cost to the supplier.

[g]Suppliers must have been accredited by a CMS-approved accreditation organization for the product categories in which they submitted bids.

[h]Suppliers must have had an active NSC number to be eligible to bill Medicare for DME.

[i]Commonly owned or controlled suppliers were required to submit a single bid to furnish a product category in a competitive bidding area.

[j]A network is a group of 2 to 20 small suppliers that collectively submit a bid as a single entity and must meet certain criteria.

[k]A specialty supplier is a skilled nursing facility or nursing facility that is awarded a competitive bidding contract to furnish competitively bid items only to its own residents to whom it would otherwise furnish Medicare Part B services.

[l]The supplier did not submit form or failed to meet the test strips 50 percent compliance rule.

Appendix III: High-Cost and High-Utilization CMS Competitive Bidding Program HCPCS Codes and Single Payment Amounts

In our 2012 report, we reported on the 34 HCPCS codes that CMS determined represented the top 80 percent of costs and utilization for the CBP round 1 rebid.[1] We determined that 28 of these codes were common to the round 1 rebid, round 1 recompete, and round 2.[2] (See table 10.)

Table 10: High-Cost, High-Utilization Healthcare Common Procedure Coding System (HCPCS) Codes Common to CMS Durable Medical Equipment Competitive Bidding Program Rounds, by Product Category

Product category	HCPCS code	Description
Continuous positive airway pressure devices, respiratory assist devices, and related supplies and accessories (CPAP/RAD)	A7030	Full face mask used with positive airway pressure device (each)
	A7034	Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap
	A7037	Tubing used with positive airway pressure device
	E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
	E0562	Humidifier, heated, used with positive airway pressure device
	E0601	Continuous airway pressure (CPAP) device
Enteral nutrients, equipment, and supplies	B4035	Enteral feeding supply kit; pump fed, per day; includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape
	B4150	Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
	B4152	Enteral formula, nutritionally complete, calorically dense (equal to or greater than 1.5 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
	B4154	Enteral formula, nutritionally complete, for special metabolic needs, excludes inherited disease of metabolism, includes altered composition of proteins, fats, carbohydrates, vitamins and/or minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
Hospital beds and related accessories	E0260	Hospital bed, semi-electric (head and foot adjustment), with any type side rails, with mattress
	E0261	Hospital bed, semi-electric (head and foot adjustment), with any type side rails, without mattress

[1]See GAO-12-693.

[2]Of the six codes excluded from our analysis, three are diabetic testing supply codes common to both the round 1 rebid and the national mail-order program and are presented in table 12 of this appendix. The other three codes were for complex rehabilitative power wheelchairs. The CBP round 1 rebid's complex rehabilitative power wheelchairs product category was excluded from the CBP round 1 recompete and round 2.

Product category	HCPCS code	Description
	E0303	Hospital bed, heavy duty, extra wide, with weight capacity greater than 350 pounds, but less than or equal to 600 pounds, with any type side rails, with mattress
Oxygen supplies and equipment	E0424	Stationary compressed gaseous oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
	E0439	Stationary liquid oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
	E1390	Oxygen concentrator, single delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate
	E1391	Oxygen concentrator, dual delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate (each)
	E0431	Portable gaseous oxygen system, rental; includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing
	E0434	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, contents gauge, cannula or mask, and tubing
Standard power wheelchairs, scooters, and related accessories	K0823	Power wheelchair, group 2 standard, captains chair, patient weight capacity up to and including 300 pounds
	K0822	Power wheelchair, group 2 standard, sling/solid seat/back, patient weight capacity up to and including 300 pounds
	K0825	Power wheelchair, group 2 heavy duty, captains chair, patient weight capacity 301 to 450 pounds
Support surfaces (group 2 mattresses and overlays)	E0277	Powered pressure reducing air mattress
	E0372	Powered air overlay for mattress, standard mattress length and width
	E0373	Non-powered advanced pressure reducing mattress
Walkers and related accessories	E0135	Walker, folding (pickup), adjustable or fixed height
	E0143	Walker, folding, wheeled, adjustable or fixed height
	E0156	Seat attachment, walker

Source: GAO analysis of CMS data. | GAO-15-63

For these 28 HCPCS codes, we determined the average single payment amount (SPA) for the round 1 rebid, round 1 recompete, and round 2, as well as the average Medicare 2010 fee-for-service payment amount.[3] (See table 11.) We also determined the average SPAs for diabetic testing

[3]The 2010 Medicare fee-for-service payment amount was used as a comparison point for this analysis because 2010 was the year that preceded the round 1 rebid, which operated from January 1, 2011, through December 31, 2013. CBP SPAs are required to be less than or equal to the Medicare fee-for- service payment amount for the same item. We averaged Medicare fee-for-service payments for 2010 using payments within the continental states and the District of Columbia only, because Alaska and Hawaii are not subject to Medicare's fee-for-service payment amount ceiling and floor.

supply codes included in the round 1 rebid and the national SPAs for the same codes in the national mail-order program, as well as the average Medicare 2010 mail-order fee-for-service payment amounts for these same codes. (See table 12.)

Table 11: Medicare Average 2010 Fee-for-Service Payment and Average Single Payment Amounts (SPA) for CMS Durable Medical Equipment Competitive Bidding Program Rounds for Selected Healthcare Common Procedure Coding System (HCPCS) Codes

			Average SPA[a]		
Product category and short HCPCS description	**HCPCS code**	**Medicare average 2010 fee-for-service payment[b]**	**Round 1 rebid**	**Round 1 recompete**	**Round 2**
Continuous positive airway pressure devices, respiratory assist devices, and related supplies and accessories (CPAP/RAD)					
CPAP full face mask	A7030	$170.72	$122.01	$111.52	$101.08
Nasal application device	A7034	106.46	73.28	66.47	62.45
Pos airway pressure tubing	A7037	36.68	20.49	17.72	14.32
RAD w/o backup non-inv intfc	E0470	220.85	138.54	130.40	115.75
Humidifier heated used w/ pap	E0562	272.60	179.73	163.31	145.50
CPAP device	E0601	96.43	58.23	51.86	46.60
Enteral nutrients, equipment, and supplies					
Enteral feed supp pump per d	B4035	11.30	7.50	5.79	5.98
Enteral formula (EF) complet w/ intact nutrient	B4150	0.65	0.46	0.40	0.40
EF calorie dense >/= 1.5kcal	B4152	0.54	0.40	0.33	0.33
EFspec metabolic noninherit	B4154	1.18	0.83	0.72	0.73
Hospital beds and related accessories					
Hosp bed semi-electr w/ matt	E0260	127.12	80.35	73.86	70.31
Hosp bed semi-electr w/o matt	E0261	116.05	73.72	69.81	67.04
Hosp bed hvy dty xtra wide	E0303	267.38	188.11	180.74	177.17
Oxygen supplies and equipment					
Stationary compressed gas O_2	E0424	173.17	116.16	95.74	93.07
Portable gaseous O_2	E0431	28.77	20.82	18.99	19.42
Portable liquid O_2	E0434	28.77	20.82	18.99	19.42
Stationary liquid O_2	E0439	173.17	116.16	95.74	93.07
Oxygen concentrator	E1390	173.17	116.16	95.74	93.07
Oxygen concentrator, dual	E1391	173.17	116.16	95.74	93.07

Product category and short HCPCS description	HCPCS code	Medicare average 2010 fee-for-service payment[b]	Average SPA[a]		
			Round 1 rebid	Round 1 recompete	Round 2
Standard power wheelchairs, scooters, and related accessories					
Pwc gp 2 std seat/back	K0822	361.77	249.64	344.44	324.53
Pwc gp 2 std cap chair	K0823	364.14	255.42	328.39	283.42
Pwc gp 2 hd cap chair	K0825	401.20	295.14	412.62	383.28
Support surfaces (group 2 mattresses and overlays)					
Powered pres-redu air mattress	E0277	626.65	319.75	285.51	235.18
Powered air mattress overlay	E0372	474.37	224.95	277.79	226.92
Non-powered pressure mattress	E0373	541.80	291.18	338.74	311.18
Walkers and related accessories					
Walker folding adjust/fixed	E0135	73.39	49.84	48.08	42.82
Walker folding wheeled w/o s	E0143	104.93	66.13	58.79	53.22
Walker seat attachment	E0156	22.63	14.84	15.11	14.66

Source: GAO analysis of CMS data. | GAO-15-63

Note: The HCPCS code descriptions listed are the short descriptions published by the Centers for Medicare & Medicaid Services. For full descriptions of each HCPCS code used in our analysis, see table 10 in this appendix.

[a]SPAs are determined by arraying the price offers in winning bids from lowest to highest and selecting the median price offered by the suppliers for an item. The median price becomes the SPA. SPAs can vary by competitive bidding area. To calculate an average SPA for each HCPCS code, we averaged the SPAs across all competitive bidding areas included in each round. For example, SPAs in round 2 for HCPCS code E0470 ranged from a low of $105.90 in the Northern New Jersey Metro competitive bidding area to a high of $138.85 in the Worchester, Massachusetts, competitive bidding area, and the average SPA was $115.75.

[b]The 2010 Medicare fee-for-service payment amount was used as a comparison point for this analysis because 2010 was the year that preceded the round 1 rebid, which resulted in contracts that were effective from January 1, 2011, through December 31, 2013. CBP SPAs are required to be less than or equal to the Medicare fee-for-service payment amount for the same item. We averaged Medicare fee-for-service payments for 2010 using payments within the continental states and the District of Columbia only, because Alaska and Hawaii are not subject to Medicare's fee-for-service payment amount ceiling and floor limits.

Table 12: Medicare Average 2010 Fee-for-Service Payment and Average Single Payment Amounts (SPA) for CMS Durable Medical Equipment Competitive Bidding Program Rounds for Selected Diabetic Testing Supply Healthcare Common Procedure Coding System (HCPCS) Codes

Diabetic testing supply HCPCS code description	HCPCS code[a]	Medicare average 2010 fee-for-service payment[b]	Round 1 rebid average SPA[c]	National mail-order program SPA[d]
Replacement battery, alkaline (other than J cell), for use with medically necessary home blood glucose monitor owned by patients, each	A4233	$0.72	$0.58	$0.58
Replacement battery, alkaline, J cell, for use with medically necessary home blood glucose monitor owned by patients, each	A4234	3.29	2.24	2.50
Replacement battery, lithium, for use with medically necessary home blood glucose monitor owned by patients, each	A4235	2.12	1.26	1.06
Replacement battery, silver oxide, for use with medically necessary home blood glucose monitor owned by patients, each	A4236	1.52	1.25	1.19
Blood glucose test or reagent strips for home blood glucose monitor per 50 strips	A4253[e]	32.46	14.62	10.41
Normal, low, and high calibrator solution/chips	A4256[e]	9.82	4.96	4.00
Spring-powered device for lancet, each	A4258	16.26	5.94	2.52
Lancets, per box of 100	A4259[e]	10.53	4.19	1.65

Source: GAO analysis of CMS data. | GAO-15-63

Notes: Mail-order diabetic testing supplies were not included in the round 1 recompete because CBP's national mail-order program was implemented before the recomplete. The national mail-order program competition took place at the same time as the round 2 competition.

[a]HCPCS codes under the diabetic testing supplies product category must also include the modifier "KL" at the end to indicate that these supplies were furnished by mail-order.

[b]The 2010 Medicare fee-for-service payment amount was used as a comparison point for this analysis because 2010 was the year that preceded the round 1 rebid, which resulted in contracts effective from January 1, 2011, through December 31, 2013. CBP SPAs are required to be less than or equal to the Medicare fee-for-service payment amount for the same item. We averaged Medicare fee-for-service payments for 2010 using payments within the continental states and the District of Columbia only, because Alaska and Hawaii are not subject to Medicare's fee-for-service payment amount ceiling and floor limits.

[c]SPAs are determined by arraying the price offers in winning bids from lowest to highest and selecting the median price offered by the suppliers for an item. The median price becomes the SPA. SPAs can vary by competitive bidding area. To calculate an average SPA for each HCPCS code, we averaged the SPAs across all competitive bidding areas included in the round 1 rebid. For example, SPAs for the round 1 rebid for HCPCS code A4253 KL ranged from a low of $13.88 in the Riverside-San Bernadino-Ontario, California, competitive bidding area to a high of $15.62 in the Cleveland-Elyria-Mentor, Ohio, competitive bidding area, and the average SPA was $14.62.

[d]For the national mail-order program, CMS determined one SPA for each HCPCS code, so no averaging was necessary.

[e]These codes were also part of the original 34 codes that CMS determined were the top 80 percent highest cost and utilization for the round 1 rebid.

Appendix IV: 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 29 2014

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

Dear Ms. King:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "Medicare: Bidding Results from CMS's Durable Medical Equipment Competitive Bidding Program" (GAO-15-63).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: MEDICARE: BIDDING RESULTS FROM CMS'S DURABLE MEDICAL EQUIPMENT COMPETITIVE BIDDING PROGRAM (GAO-15-63)

The Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on this draft report. HHS is committed to the continued success of the competitive bidding program (CBP) for durable medical equipment (DME).

The CBP uses market forces to help Medicare pay appropriately and lower beneficiary out-of-pocket expenses for DME items, while ensuring beneficiary access to quality items and services. In 2011, HHS successfully implemented the Round 1 Rebid of the CBP in nine metropolitan areas after making a number of improvements, including adopting new requirements from Congress, and after working closely with stakeholders. In July 2013, Round 2 of the CBP expanded to 91 additional areas, and we implemented a national mail-order program for diabetic testing supplies.

The program saved more than $580 million for beneficiaries and taxpayers in its first two years of operation, and is projected to save the Medicare Part B Trust Fund $25.8 billion and beneficiaries $17.2 billion over ten years. The program has also maintained beneficiary access to quality products from licensed and accredited suppliers. Monitoring data have shown a successful implementation with very few complaints and no negative impact on beneficiary health status.

As noted in the report, the Single Payment Amounts (SPAs) for 28 high-cost, high-utilization billing codes decreased significantly as compared to the average Medicare 2010 durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) fee schedule amount for the same codes. In some cases, SPAs for these items have decreased by over 50 percent from the Medicare 2010 DMEPOS fee schedule amounts.

This reduction in payment amounts reduces suppliers' incentive to fraudulently bill Medicare for DMEPOS and makes competitively bid items less attractive targets for fraud and abuse. In addition, all suppliers in the program must meet applicable licensure requirements, meet strict quality and financial standards, and be accredited by a national accreditation organization.

HHS expects that Medicare beneficiaries across the country will continue to benefit from this important program as it expands further. We thank GAO for their efforts on this issue and look forward to working with GAO on this and other issues in the future.

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

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Staff Acknowledgments

In addition to the contact named above, key contributors to this report were Martin T. Gahart, Assistant Director; Yesook Merrill, Assistant Director; Zhi Boon; Michelle Paluga; Roseanne Price; Hemi Tewarson; Opal Winebrenner; and Malissa G. Winograd.

Related GAO Products

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Medicare: Review of the First Year of CMS's Durable Medical Equipment Competitive Bidding Program's Round 1 Rebid. GAO-12-693. Washington, D.C.: May 9, 2012.

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Medicare: Issues for Manufacturer-level Competitive Bidding for Durable Medical Equipment. GAO-11-337R. Washington, D.C.: May 31, 2011.

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