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Report to the Subcommittee on Health, Committee on Ways and Means, House of Representatives

March 2014

MEDICARE

Second Year Update for CMS's Durable Medical Equipment Competitive Bidding Program Round 1 Rebid

GAO Highlights

Highlights of GAO-14-156, 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. In 2008, the Medicare Improvements for Patients and Providers Act terminated the first round of supplier contracts and required CMS to repeat the CBP round 1—referred to as the round 1 rebid, resulting in the award of contracts to suppliers with CBP payments that began January 1, 2011.

GAO was asked to review issues concerning the rebid's second year of operation—2012. This report reviews the round 1 rebid's effects on (1) Medicare beneficiaries, (2) the market share of contract suppliers, and (3) all suppliers, including both contract and non-contract suppliers (the suppliers not awarded rebid contracts.) To examine the effects on Medicare beneficiaries, GAO compared Medicare claims data for 2011 and 2012 with that for 2010, the year before the round 1 rebid. GAO also examined other information about CMS's efforts to monitor the effects of the CBP, and interviewed DME industry representatives and officials from Medicare beneficiary organizations. To examine the effects on both contract and non-contract suppliers, GAO compared Medicare claims data for 2012 with that for 2010 and analyzed other data provided by CMS.

View GAO-14-156. For more information, contact Kathleen M. King at (202) 512-7114 or kingk@gao.gov.

MEDICARE

Second Year Update for CMS's Durable Medical Equipment Competitive Bidding Program Round 1 Rebid

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. Under the CBP, only competitively selected contract suppliers can furnish certain DME product categories (such as oxygen supplies and hospital beds) at competitively determined prices to Medicare beneficiaries in designated competitive bidding areas. The CBP's round 1 rebid was in effect for a 3-year period, from 2011 through 2013. It included nine DME product categories in nine geographic areas. For CBP monitoring purposes, CMS also selected nine comparator areas that were demographically similar to the rebid areas. GAO's analysis found that in 2012, the second year of the round 1 rebid:

- The number of beneficiaries furnished DME items included in the CBP generally decreased more in the CBP areas than in the comparator areas. For example, the number of beneficiaries furnished oxygen supplies decreased by about 22 percent in the CBP areas and by about 16 percent in the comparator areas. According to CMS, CBP may have reduced inappropriate usage of DME and these decreases do not necessarily reflect beneficiary access issues. Based on its monitoring tools, which include comparing changes in the health outcomes of beneficiaries in the CBP areas to those in the comparator areas, CMS has concluded that beneficiaries have not been affected adversely by the CBP.
- In general, a small number of contract suppliers had a large proportion of the market share in the nine competitive bidding areas. The top four contract suppliers generally accounted for a large proportion of the market in all CBP areas, although the top four suppliers for each product category were not the same in every competitive bidding area. CMS has reported that few contract suppliers had contracts terminated by the agency or voluntarily withdrew from Medicare.
- The total number of DME suppliers and Medicare allowed charges decreased more in the CBP areas than in the comparator areas. For example, the number of suppliers in the CBP areas with Medicare allowed charges of \$2,500 or more decreased, on average, 27 percent. In the comparator areas, supplier numbers decreased by 5 percent. The decreases in supplier numbers may reflect other factors, such as CMS's efforts to reduce Medicare DME fraud.

The round 1 rebid's first 2 years achieved Medicare cost savings of about \$400 million as estimated by CMS, and did not appear to have adversely affected beneficiary access to CBP-covered items. However, with CBP's national mail-order diabetic testing supplies program and expansion into an additional 100 bidding areas in July 2013, it will be important for CMS to continue its efforts to monitor the effects of the CBP.

In commenting on a draft of this report, HHS cited the results of CMS's monitoring of beneficiaries' access to CBP items as evidence that CBP has not adversely affected beneficiaries.

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Abbreviations

CAO CBP	competitive acquisition ombudsman competitive bidding program
CMS	Centers for Medicare & Medicaid Services
CPAP/RAD	continuous positive airway pressure devices and respiratory assist devices
CSR	customer service representative
DME	durable medical equipment
DMEPOS	durable medical equipment, prosthetics, orthotics, and related supplies
HCPCS	Healthcare Common Procedure Coding System
HHS NPWT	Department of Health and Human Services negative pressure wound therapy

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U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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March 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 2012, Medicare—a federal health insurance program—spent \$11.4 billion on durable medical equipment (DME),¹ prosthetics, orthotics, and related supplies for beneficiaries.² 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 participate in Medicare Part B,³ which helps pay for DMEPOS 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.

¹Medicare is for individuals aged 65 and older, individuals under age 65 with certain disabilities, and individuals diagnosed with end-stage renal disease.

²Collectively, DME, prosthetics, and 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 defined as devices needed to replace body parts or functions such as artificial limbs and cardiac pacemakers. Orthotic devices are defined as providing rigid or semi-rigid support for weak or deformed body parts or restricting or eliminating motion in a diseased or injured part of the body, such as leg, arm, back, and neck braces. Medicare-reimbursed supplies are items that are used and consumed with DME, such as drugs used for inhalation therapy, or that need to be replaced frequently (usually daily), such as surgical dressings. For this report, the term DME refers to the DMEPOS items included in the Medicare competitive bidding program (CBP).

³Medicare 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.

To achieve Medicare savings for DMEPOS and to address DMEPOS fraud concerns,⁴ Congress, through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,⁵ required CMS to phase in a competitive bidding program (CBP) for DME and other items. Under CBP, DME suppliers—referred to as contract suppliers—are competitively selected to furnish certain DME product categories to Medicare beneficiaries in designated competitive bidding areas.^{6,7} Suppliers not selected for a CBP contract are referred to as non-contract suppliers. Non-contract suppliers generally cannot furnish CBP-covered items, however, some of them may be grandfathered to continue to furnish some CBP-covered items to certain beneficiaries for a limited time or may act as subcontractors to contract suppliers.⁸

Beginning in 2009, CMS conducted a competition and awarded contracts to suppliers in nine competitive bidding areas for nine product

⁵Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 302(b), 117 Stat. 2066, 2224-30 (2003) (codified, as amended, at 42 U.S.C. § 1395w-3).

⁶A product category is a grouping of related items used to treat a similar medical condition.

⁷A competitive bidding area is either a metropolitan statistical area (MSA) or a part thereof. MSAs are designated by the Office of Management and Budget and include major cities and the suburban areas surrounding them.

⁸Grandfathered suppliers are suppliers that were not awarded a CBP contract but chose to continue to furnish certain CBP-covered rental items to beneficiaries who were their customers when CBP began in 2011, and who reside in the competitive bidding areas. Once the relevant rental period expires or the beneficiary involved decides to select a contract supplier, the grandfathered supplier can no longer provide the CBP-covered items and services to the beneficiary. Subcontractor suppliers enter into agreements with contract suppliers to furnish limited services to CBP-covered beneficiaries on behalf of the contract suppliers.

⁴In addition to CBP, CMS has implemented other Medicare fraud prevention efforts affecting DMEPOS suppliers including strengthening the enrollment process, such as by requiring suppliers to submit either their Social Security number or their employer identification number, and state licensing information; requiring all suppliers be accredited by a CMS-approved accrediting organization to ensure they meet certain quality standards; requiring suppliers to purchase surety bonds; making unannounced site visits for high risk suppliers; requiring fingerprint-based criminal history checks; and providing enhanced oversight for initial claims of suppliers. In 2012, CMS also implemented the Prior Authorization of Power Mobility Devices Demonstration in seven states to help ensure that a Medicare beneficiary's medical condition warrants a power wheelchair or scooter before it is furnished.

categories,^{9,10} referred to as the round 1 rebid.¹¹ According to CMS, CBP's round 1 rebid competitive bidding areas were selected, in part, because they had high utilization, suggesting that some utilization may have been unnecessary. About 2 million of Medicare's estimated 45 million beneficiaries reside in the nine competitive bidding areas.¹² The original 356 suppliers that were awarded CBP round 1 rebid contracts contract suppliers—were paid at the competitively determined payments for the CBP-covered DME items beginning on January 1, 2011. CMS

⁹The 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).

¹⁰The round 1 rebid's nine product categories were: (1) complex power wheelchairs (complex rehabilitative power wheelchairs and related accessories—limited to group 2—power wheelchairs with power options); (2) CPAP/RAD (continuous positive airway pressure devices, respiratory assist devices, and related supplies and accessories); (3) enteral (enteral nutrients, equipment, and supplies—to provide feeding through a tube into the stomach or small intestine); (4) hospital beds (hospital beds and related accessories); (5) mail-order diabetic supplies; (6) oxygen (oxygen supplies and equipment); (7) standard power wheelchairs (standard power wheelchairs, scooters, and related accessories); (8) walkers (walkers and related accessories); and (9) support surfaces (support surfaces limited to group 2 mattresses and overlays—pressure reducing support surfaces for persons with or at high risk for pressure ulcers—in the Miami competitive bidding area only.)

¹¹Beginning in 2007, CMS conducted a competition and awarded contracts effective July 1, 2008 to suppliers, referred to as the CBP round 1. The Medicare Improvements for Patient and Providers Act of 2008, however, terminated the contracts awarded during CBP round 1 on July 15, 2008, and required CMS to repeat the competition in 2009—referred to as the round 1 rebid. To compensate for the loss of the projected Medicare savings due to the termination and to ensure budget neutrality, the act also reduced Medicare payments for the DME items that had been included in the round 1 by 9.5 percent nationally. Pub. L. No. 110-275, § 154(a), 122 Stat. 2494, 2560-3 (2008) (codified, as amended, at 42 U.S.C. § § 1395w-3, 1395m(a)(14)).

¹²A beneficiary's permanent residence, which is the address provided by the individual to the Social Security Administration, determines whether the person is residing in a CBP competitive bidding area and is a CBP-covered beneficiary. Medicare beneficiaries who reside in CBP competitive bidding areas but are enrolled in Medicare Advantage plans, which are operated by private companies, are not covered by CBP. Beneficiaries who reside within a competitive bidding area are CBP-covered beneficiaries even if they travel outside their area. When CBP-covered beneficiaries travel outside their area, for example, to a non-CBP area, they may get CBP-covered DME items from any Medicare supplier, but the supplier will be paid the CBP single payment amount for the CBP-covered item.

estimated that the round 1 rebid saved Medicare and beneficiaries through lower coinsurance—about \$400 million in its first two years.¹³

In a 2012 report, we reported on the first year—2011—of CBP's round 1 rebid.¹⁴ We found that early data indicated that beneficiary utilization had decreased in some CBP product categories, but CMS's multiple monitoring activities generally indicated that beneficiary access and satisfaction had not been affected. You asked us to examine particular issues concerning the CBP round 1 rebid's second year—2012. In this report, we review (1) the extent to which Medicare beneficiaries have been affected by CBP's round 1 rebid, (2) the development of contract suppliers' market share in CBP's round 1 rebid, and (3) the extent to which all suppliers—including both contract and non-contract suppliers—have been affected by CBP's round 1 rebid.

To examine the extent to which beneficiaries have been affected by the CBP round 1 rebid, we analyzed changes in utilization of CBP-covered DME items by comparing Medicare claims data from 2010, the year prior to the CBP round 1 rebid, to post-CBP round 1 rebid claims data from 2011 and 2012.¹⁵ We used these data to determine whether the number of CBP-covered beneficiaries utilizing CBP-covered items and services increased or decreased in each month of 2011 and 2012 compared to the same month in 2010 for six of the round 1 rebid's nine product categories.¹⁶ We did these analyses for Medicare beneficiaries using CBP-covered items in both the nine competitive bidding areas and in the

¹³CMS told us that it derived the total savings by comparing 2010 to 2011 Medicare Part B allowed charges, which include Medicare program expenditures and beneficiary cost sharing, and is the actual change in Medicare expenditures.

¹⁴GAO, *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).

¹⁵We analyzed Medicare durable medical equipment claims for 2010, 2011, and 2012. We assigned these services to a month and year based on the claim "through date," which indicates the last date on the billing statement covering services rendered to the beneficiary.

¹⁶We did not include three round 1 rebid product categories in this analysis: (1) the mail-order diabetic testing supplies category because data are limited due to some beneficiaries switching to non-mail-order sources; (2) the complex power wheelchair category due to potential data reliability concerns reported by CMS; and (3) the support surfaces category because it was limited to only the Miami competitive bidding area in the round 1 rebid.

nine areas selected by CMS—referred to as comparator areas—in this report.^{17,18} We also examined how the CBP round 1 rebid may have affected Medicare beneficiary access to and satisfaction with selected DME items by analyzing 2011 and 2012 CBP inquiry data from the 1-800-MEDICARE beneficiary help line, and CBP complaint data, and interviewing CMS officials and officials from a sample of Medicare beneficiary advocacy groups.

To examine the development of contract suppliers' market share in the round 1 rebid, we obtained and analyzed quarterly Medicare claims data to review contract suppliers' Medicare market shares in 2011 and 2012 for six of the nine product categories in each competitive bidding area. To ensure that we captured all Medicare total allowed charges submitted by a distinct contract supplier that may have been doing business in several locations under different registered names, national provider identifier numbers, or provider transaction access numbers, we used the unique bidder number assigned by CMS to each distinct bidding supplier and combined all Medicare total allowed charges submitted under any other identifying numbers for each product category and competitive bidding

¹⁷Suppliers use a standardized coding system to submit claims for Medicare payments the Healthcare Common Procedure Coding System (HCPCS). HCPCS codes identify a category of like DMEPOS items, for example, walkers, but can encompass a broad range of items that serve the same general purpose but vary in price and characteristics. Medicare claims data include the HCPCS code, but do not identify the specific item's manufacturer, or brand or trade name. We included all CBP-covered HCPCS codes in five of the six product categories we analyzed. For the standard power wheelchair product category, our analysis includes only the 20 HCPCS codes that are unique to the standard power wheelchair product category. We did not include the other 86 HCPCS codes that are related to wheelchair accessories and repairs because they are also included in the complex wheelchair product category and CMS told us that data for that product category are unreliable.

¹⁸CMS selected the nine comparator areas as control groups for the nine competitive bidding areas for CMS's health outcomes real-time claims monitoring system and to conduct its round 1 rebid beneficiary satisfaction surveys. CMS chose comparator areas that have similar demographic profiles as the competitive bidding areas: (a) estimated total population size; (b) a proxy for the number of Medicare beneficiaries; and (c) the percentage of the population who are Medicare beneficiaries. The round 1 rebid's competitive bidding areas and their respective comparator areas were: (1) Charlotte and Virginia Beach (Virginia Beach, Virginia and North Carolina), (2) Cincinnati and Indianapolis (Indianapolis, Indiana), (3) Cleveland and Columbus (Columbus, Ohio), (4) Dallas and Houston (Houston, Texas), (5) Kansas City and Oklahoma City (Oklahoma City, Oklahoma), (6) Miami and Tampa (Tampa, Florida), (7) Orlando and Jacksonville (Jacksonville, Florida), (8) Pittsburgh and Detroit (Detroit, Michigan), and (9) Riverside and San Diego (San Diego, California.)

area.¹⁹ We then arrayed from highest to lowest all contract suppliers' individual Medicare total allowed charges for 2011 and 2012 combined and reviewed the individual market share of the top 4 suppliers for five product categories as well as the top supplier for the sixth product category in each competitive bidding area.²⁰ For each product category in each competitive bidding area, we also summed all other contract suppliers' individual Medicare total allowed charges to show their combined market share for each quarter of 2011 and 2012. Some Medicare total allowed charges were submitted by non-contract suppliers. We identified distinct non-contract suppliers, to the extent possible, by summing all the Medicare total allowed charges submitted under any national provider identifier number or provider transaction access number that were associated with one tax identification number for each product category in each competitive bidding area. Medicare total allowed charges submitted by non-contract suppliers were identified by their tax identification numbers because unique bidder numbers were not available.

To further determine the extent that contract suppliers may have been affected by the round 1 rebid, we asked CMS for information on how many CBP contract suppliers have had their CBP contracts terminated; have voluntarily withdrawn from Medicare, which results in CMS canceling their CBP contracts; or have acquired or been acquired by other DME suppliers. To determine whether there have been changes in the number of subcontractor suppliers and grandfathered suppliers in

¹⁹For purposes of this report, a Medicare allowed charge is the full amount that Medicare will pay for the item or service furnished under the fee schedule—the 80 percent to the supplier and the 20 percent the Medicare beneficiary is responsible for paying—as coinsurance. For the CBP round 1 rebid competitive bidding areas, the Medicare allowed charge is the single payment amount that Medicare pays for the CBP-covered item in the particular competitive bidding area—80 percent to the supplier and 20 percent as the beneficiary's responsibility.

²⁰Because some contract suppliers won a contract in one or more competitive bidding areas, while other contract suppliers won contracts in all nine competitive bidding areas, the four top contract suppliers for a product category may be different in each competitive bidding area. For example, the top four contract suppliers with the highest percentages of Medicare total allowed charges for the hospital bed product category may be different in the Orlando competitive bidding area than the top four contract suppliers in the Riverside competitive bidding area.

CBP areas,²¹ we obtained information from CMS on the number of CBP contract suppliers that subcontracted with other suppliers to help fulfill their CBP contracts, and the extent that grandfathered suppliers were still furnishing items and services to CBP-covered beneficiaries.

To examine the extent to which all suppliers-both contract and noncontract suppliers-may have been affected by the round 1 rebid, we obtained and analyzed CMS Medicare claims data for the nine competitive bidding areas and their nine comparator areas. We compared the number of suppliers with total Medicare allowed charges at two levels in the 18 areas using the allowed charge data for the third quarter 2010, and for the third guarter 2012, the comparable guarter in the round 1 rebid's second year. The third quarter of 2010 was the last one before the round 1 rebid contract suppliers were announced in November 2010 and before the DME marketplace began to adjust to CBP in the fourth guarter of 2010. For example, CMS officials told us that some suppliers furnished diabetic beneficiaries with additional testing supplies in late 2010 before the beneficiaries switched to contract suppliers in 2011. For this analysis, we included suppliers with at least one allowed charge for a beneficiary residing in any of the 18 areas for any Medicare DMEPOS fee-for-service HCPCS codes, excluding the prosthetic and orthotic codes as this category generally represents more individualized items needing to be fitted to a beneficiary and including the parenteral-intravenous nutrition—codes.²²

To assess the reliability of the data we received from CMS, we reviewed and identified outliers in the data, and followed up with CMS officials to clarify and resolve any discrepancies. We assessed the reliability of Medicare claims data from CMS's 100 Percent Standard Analytic Files by reviewing existing information about the data and the systems that produced them and performing appropriate electronic data checks. We

²¹For CBP, subcontractor suppliers may include a supplier that did not bid, that bid and lost, or that won a CBP contract and is also subcontracting with a contract supplier for a product category for which it did not win.

²²There is also a wide range of payments under the Medicare fee-for-service schedule for the prosthetic and orthotic category—from an inexpensive item at \$0.31 to an expensive item at \$99,584.93. In comparison, the most expensive item included in the CBP round 1 rebid is \$8,514.12 in the Cleveland competitive bidding area for a new group 2 complex rehabilitative wheelchair (HCPCS code K0840.)

determined that these data were sufficiently reliable for the purposes of this report.

We conducted this performance audit from August 2012 through March 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.

Background

Medicare traditionally has paid DMEPOS suppliers through fee schedule amounts based on suppliers' historical charges to Medicare.²³ The purpose of CBP is to improve how Medicare payment amounts are set by paying only competitively selected contract suppliers amounts based on competitive bids, thereby providing Medicare program savings and reducing Medicare beneficiaries' out-of-pocket expenses for DMEPOS items and services.

The CBP

CMS and its CBP implementation contractor—Palmetto GBA—administer and implement the CBP and its bidding rounds.²⁴ In each competitive bidding area included in a CBP bidding round, suppliers can bid for one or more product categories' CBP-covered items.²⁵ The suppliers' bids are evaluated based on the supplier's eligibility, financial status, and bid prices. From this evaluation, the CBP payments—referred to as single payment amounts—are determined for each CBP-covered item in each

²³The fee schedules are adjusted for each state, reflecting the geographic price differences that are subject to national floor and ceiling payment limits. The fee schedule payment is generally equal to 80 percent of the lesser of either the supplier's actual charge or the Medicare fee schedule for a particular item or service. In general, Medicare beneficiaries are responsible for paying the supplier the remaining 20 percent referred to as the coinsurance.

²⁴Palmetto GBA is also referred to as the competitive bidding implementation contractor or CBIC.

²⁵For a general explanation of the CBP process for bidding and selecting winning suppliers, see GAO-12-693; for a detailed explanation of the CBP bidding process steps, 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).

competitive bidding area, and the winning suppliers are selected.²⁶ Winning suppliers are then offered CBP contracts. If the supplier accepts its contract offer, it agrees to accept Medicare assignment on the CBPcovered items for the product category and in the competitive bidding area involved,²⁷ and to be paid the relevant CBP single payment amounts.

CMS was also required to take steps to ensure that small suppliers could be awarded CBP contracts, and accordingly set a target that 30 percent of the qualified suppliers in each product category in each competitive bidding area would be small suppliers as defined for CBP.²⁸ In instances where the small supplier target is not initially met, CMS may award additional small suppliers CBP contracts after the agency has determined the number of suppliers needed to meet or exceed CMS's estimated beneficiary demand. To help ensure beneficiary access and choice, CMS tries to award at least five contracts in each product category in each competitive bidding area.²⁹ CMS is required by law to recompete the CBP contracts at least once every three years. (See fig. 1 for CBP's legislative history and program implementation timeline.)

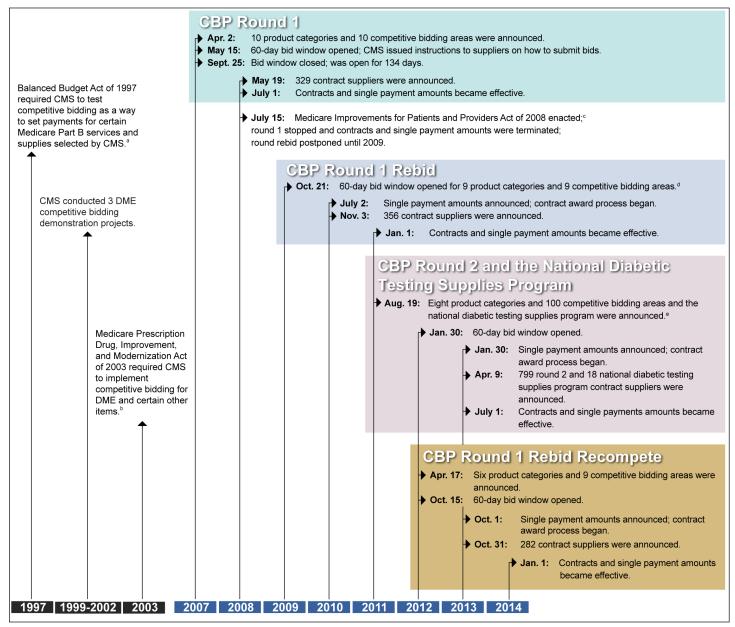
²⁸For CBP, CMS has defined a small supplier as one that generates gross revenue of \$3.5 million or less in annual receipts including both Medicare and non-Medicare revenue. A qualified supplier is a bidder that has met certain requirements, including having been found financially sound, and its bids will be used to determine the single payment amounts and to select the contract suppliers.

²⁹If 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 relevant product category in the competitive bidding area.

²⁶The CBP single payment amounts are required to be less than or equal to the Medicare fee-for-service payments for the same items.

²⁷For non-CBP suppliers, Medicare assignment—accepting Medicare's payment amount for an item as payment in full and limiting the amount the Medicare beneficiary can be billed for that item—is optional. If a supplier agrees to assignment, then Medicare generally pays 80 percent of the amount to the supplier and beneficiary is responsible for paying the supplier the remaining 20 percent or the coinsurance payment, once the beneficiary's annual Medicare deductible is met. If the supplier does not accept assignment, the supplier is not limited to charging the beneficiary 20 percent of the Medicare payment for the item or service, and the beneficiary can be billed for whatever balance is due.

Figure 1: Competitive Bidding Program Timeline, 1997-2014



Source: GAO analysis of data provided by the Centers for Medicare & Medicaid Services (CMS).

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

^bPub. 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 durable medical equipment (DME) and related supplies, off-the-shelf orthotics, and enteral nutrients and related equipment and supplies.

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

^dThe Medicare Improvements for Patients and Providers Act of 2008 and implementing regulations require CMS to notify suppliers of missing financial documentation if their bids are submitted within the covered document review date, which is 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 the round 1 rebid, CMS was required to notify eligible suppliers of missing financial documentation within 45 days after the end of the covered document review date. For other competitive bidding program (CBP) rounds, CMS is required to notify eligible suppliers of missing financial documentation within 90 days after the end of the covered document review date.

^eThe national mail-order competition includes all parts of the United States, including the 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa.

The CBP rounds include:

- Round 1 rebid. CMS awarded contracts to 356 contract suppliers for the provision of DME items and services in nine product categories in nine competitive bidding areas. The contracts took effect on January 1, 2011 and expired after three years on December 31, 2013, except for the mail-order diabetic testing supplies contracts, which expired on December 31, 2012.
- Round 2. Round 2 expands CBP to another 100 competitive bidding areas in 91 metropolitan statistical areas. The single payment amounts for covered items were effective July 1, 2013 under round 2 contracts. The round 2 product categories are the same as the round 1 rebid except for the addition of the negative pressure wound therapy (NPWT) category,³⁰ the deletion of the complex power wheelchairs and mail-order diabetic supplies categories, and the extension of the support surfaces category to all round 2 competitive bidding areas.³¹ The round 2 contracts are for a term of 3 years.
- **National mail-order diabetic testing supplies program**. The CBP national mail-order diabetic testing supplies program competition was conducted at the same time as round 2, and its competitively determined single payment amounts were effective July 1, 2013.³²

³²During 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.

³⁰NPWT uses pumps that apply controlled negative or subatomspheric pressure to care for ulcers or wounds that have not responded to traditional wound treatment methods.

³¹Support surfaces are pressure-reducing support surfaces for persons with or at high risk for pressure ulcers. In the round 1 rebid, the support surfaces product category was limited to only the Miami competitive bidding area.

Unlike in the round 1 rebid, suppliers bidding for the national program had to demonstrate that their bids would cover at least 50 percent, by sales volume, of all types of diabetic testing strips on the market.³³ These contracts are for a term of 3 years. Non-mail order Medicare payments are the same as the mail-order single payment amounts for the CBP-covered items.³⁴

• Round 1 recompete. In anticipation of the expiration of the round 1 rebid contracts, in 2012 CMS recompeted contracts for the nine round 1 rebid competitive bidding areas, referred to as the round 1 recompete. The round 1 recompete's six product categories differ from the round 1 rebid categories by adding infusion pumps,³⁵ NPWT pumps, deleting complex wheelchairs, and creating a new category that includes home equipment, such as hospital beds and commode chairs.³⁶ The recompete contracts have a 3-year term, with an effective date of January 1, 2014.

³⁵The round 1 recompete's six product categories are: (1) enteral nutrients, equipment, and supplies; (2) external infusion pumps and supplies; (3) general home equipment and related supplies and accessories (includes hospital beds and related accessories, group 1 and 2 support surfaces, transcutaneous electrical nerve stimulation—TENS—devices, commode chairs, patient lifts, and seat lifts); (4) NPWT pumps and related supplies and accessories (includes oxygen, oxygen equipment, and supplies; CPAP devices and RADs and related supplies and accessories; and standard nebulizers); and (6) standard mobility equipment and related accessories, scooters, and related accessories.)

³⁶Mail-order diabetic testing supplies were not included in the round 1 recompete because CBP's national mail-order diabetic supplies program was implemented before the recompete.

³³42 U.S.C. § 1395w-3(b)(10). As part of their CBP bid submissions, bidding suppliers complete a National Mail-Order 50 Percent Compliance form to indicate that the testing strip brands they intend to furnish meet the 50 percent requirement. For information on the Medicare market shares by type of mail-order diabetic testing strips, see HHS OIG report, *Medicare Market Shares of Mail Order Diabetic Testing Strips*, OEI-04-10-00130 (Washington, D.C.; Dec. 2, 2010).

³⁴Under the American Taxpayer Relief Act of 2012, diabetic testing supplies included in the CBP's national mail-order diabetes supplies program will be paid at the same CBP single payment amounts for both mail-order and non-mail-order (retail) supplies. This provision is effective for the supplies furnished on or after July 1, 2013, the implementation date for the program. Pub. L. No. 112-240, § 636, 126 Stat. 2313, 2356 (2013).

CBP Contract Supplier Terminations, Voluntary Withdrawals, and Changes in Ownership	A contract supplier may no longer participate in CBP if CMS terminates its contract, if it voluntarily withdraws from Medicare, or if it has experienced a certain type of change of ownership. CMS can terminate a contract supplier's CBP contract if a supplier fails to meet its contractual obligations. ³⁷ In that case, CMS may request that the supplier submit a corrective action plan, suspend or terminate the contract, preclude it from participating in CBP, or revoke its billing number. A contract supplier that has its CBP contract terminated may continue to operate as a Medicare supplier and submit Medicare claims for non-CBP covered items and services. Contract suppliers may choose to voluntarily withdraw from Medicare, and thus no longer be a Medicare supplier. Contract suppliers may also have a change in ownership that impacts their participation in CBP, but their CBP contracts may be transferred only under certain circumstances. A change in ownership, also referred to as a CHOW, may result in either (1) a new entity or company that did not exist before the merger or acquisition transaction; or (2) a successor entity or company that exists before the transaction. If a contract supplier, and continues to exist as it did before the transaction. If a contract supplier is negotiating an ownership change, the supplier must notify CMS in advance and CMS may award the CBP contract to the entity that merges with or acquires the contract supplier in certain circumstances. These circumstances include when the successor entity is acquiring the assets of the contract supplier and submits a signed agreement to CMS in advance of the acquisition stating that it will assume all obligations under the contract.
Beneficiary Sources for CBP Assistance	 Medicare beneficiaries residing in competitive bidding areas have several sources available to help them locate contract suppliers and receive assistance for CBP-related issues. CBP Online Contract Supplier Locator. To locate a CBP contract
	supplier, beneficiaries can use the CMS online supplier locator tool on CMS's Medicare website. ³⁸ The contract locator tool contains the
	³⁷ In general, a contract supplier enters into a single contract with CMS for the relevant CBP round, which covers all of the product category and competitive bidding area combinations awarded to and accepted by the contract supplier. Accordingly, if the contract is terminated, the contract supplier can no longer participate in CBP as individual product category and competitive bidding area combinations cannot be severed from the CBP contract.
	³⁸ The teel is leasted at www.medicare.gov/cupplier/

³⁸The tool is located at www.medicare.gov/supplier/.

names of the contract suppliers in each competitive bidding area, as well as the product categories for which they furnish CBP-covered items. Contract suppliers are responsible for submitting information regarding the specific brands of items they furnish in the upcoming quarter, and CMS uses this information to update the supplier locator.

- 1-800-MEDICARE Inquiries. CMS has directed beneficiaries to call its 1-800-MEDICARE beneficiary help line with CBP questions referred to by CMS as inquiries.³⁹ Callers are assisted by trained CBP customer service representatives (CSR) who use several scripts to answer general questions about CBP and specific product categories and assist beneficiaries in finding CBP suppliers.⁴⁰ If a beneficiary's inquiry cannot be addressed by the scripts, the CSR will forward the inquiry to an advanced-level CSR who will research the issue and respond to the beneficiary's inquiry.
- Palmetto GBA and CMS regional offices. Palmetto GBA, the CBP implementation contractor, investigates all beneficiary or supplier complaints related to alleged CBP contract violations.⁴¹ In addition, Palmetto GBA provides CBP-related information and updates through its website.⁴² Local Palmetto GBA staff are stationed in the competitive bidding areas and work with CMS regional staff to monitor CBP activities and identify and address any emerging issues. CMS also uses its regional offices as the focal point for calls that cannot be

⁴¹According to CMS officials, the National Supplier Clearinghouse investigates supplier standards violations and accreditation organizations investigate quality standards violations.

⁴²Information about the CBP is located on Palmetto GBA's website at http://dmecompetitivebid.com/palmetto/cbic.nsf/DocsCat/Home.

³⁹One phone call between a caller and a 1-800-MEDICARE CSR could result in one or more inquiries, since an inquiry is counted by the number of scripts that a CSR uses to respond to the call. As such, the number of inquiries could be higher than the number of distinct beneficiaries who called.

⁴⁰Scripts address topics that may arise during a beneficiary call to 1-800-MEDICARE regarding CBP, and cover issues such as urgent needs for new supplies, and beneficiaries who are unable to locate a contract supplier in their area. The scripts instruct CSRs how to assist beneficiaries; for example, when a CSR conducts a three-way call with a beneficiary and a contract supplier, the CSR will read a script that says, "My name is [CSR NAME] from 1-800-MEDICARE. I have a beneficiary on the line who is looking for [NAME THE SUPPLY]. His/her name is [BENEFICIARY NAME] and he/she called us because [REASON]. We are calling you because [EXPLAIN THE ISSUE AND WHAT THE SUPPLIER CAN DO TO HELP]."

	resolved by 1-800-MEDICARE; for example, the offices may assist when a CSR is unable to help a beneficiary find a contract supplier.
	• Competitive Acquisition Ombudsman (CAO) . The CMS CAO was created to respond to CBP-related complaints and inquiries made by suppliers and individuals, and works with CMS officials and contractors and Palmetto GBA to resolve them. The CAO is required to submit an annual report detailing CBP-related activities to Congress. ⁴³
CMS's CBP Monitoring Activities	CMS has implemented several activities to monitor whether beneficiary access or satisfaction have been affected by the implementation of CBP.
	 Inquiries and Complaints to 1-800-MEDICARE. CMS tracks all CBP-related inquiries to 1-800-MEDICARE. All calls are first classified as inquiries and CMS defines as a CBP complaint only those inquiries that cannot be resolved by any 1-800-MEDICARE CSR and is elevated to another entity, such as Palmetto GBA, CMS's regional offices, or the CAO for resolution.
	• Beneficiary Satisfaction Surveys. CMS conducted pre and post- implementation surveys to measure beneficiary satisfaction with CBP's round 1 rebid. The pre-implementation survey was conducted from June to August 2010, the first post-implementation survey was conducted from August to October 2011, and the second post- implementation survey was conducted in June 2013. CMS surveyed beneficiaries in the nine round 1 rebid competitive bidding areas, as well as the nine comparator areas.
	 National Claims History. CMS conducts daily monitoring of national Medicare claims data to identify utilization trends, monitor beneficiary access, address aberrations in services, and target potential fraud and abuse. CMS tracks health outcomes—such as hospitalizations, emergency room visits, physician visits, admissions to skilled nursing facilities, and deaths—for beneficiaries likely to use a CBP-covered product and who have used a CBP-covered product, in both competitive bidding areas and comparator areas to determine whethe

is required to submit an annual report to Congress that includes the CAO's findings and if appropriate, recommendations for improvements to the implementation of CBP. As of February 24, 2014, the CAO had issued an annual report to Congress only for 2009 and 2010.

health outcomes in the competitive bidding areas remain consistent with national trends. CMS posts quarterly reports of these health outcomes on its website.⁴⁴

- Form C. Each quarter, CMS requires contract suppliers to submit a Form C that lists the specific CBP-covered DME items they plan to furnish the following quarter—including the brand names and equipment models.⁴⁵ According to Palmetto GBA, this information is used to update the Medicare supplier directory tool and to evaluate beneficiary access to competitively bid items, as well as the quality of items and services.
- Secret shopping. CMS has conducted secret shopping calls in which individuals posed as beneficiaries and requested items, such as specific diabetic supplies from contract suppliers to determine whether the suppliers offer the supplies they claim to furnish. Secret shopping is conducted on a limited ad-hoc basis and may be done in response to specific complaints received, or to evaluate certain contract suppliers and monitor their performance and compliance with the terms of their CBP contracts.

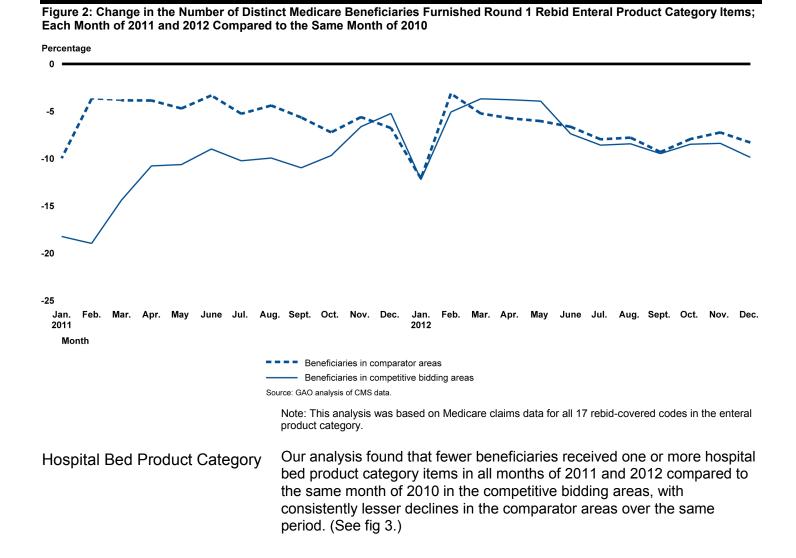
⁴⁴The health outcomes are available at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html.

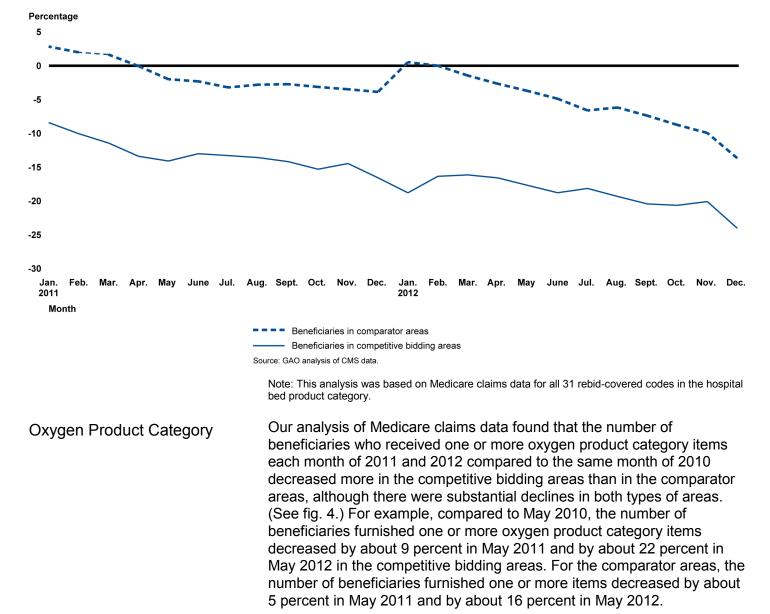
⁴⁵Contract suppliers are required to submit a Form C each quarter that describes every combination of competitive bidding area and product category covered by their contract. Failure to submit Form Cs may be considered a breach of contract and could result in CMS terminating a supplier's contract. According to Palmetto GBA, the contract supplier locator tool is posted with updated Form C product information within 30 days after the Form C submission deadline.

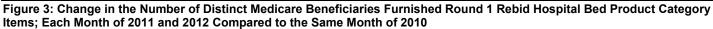
Medicare Claims Data Show Larger Decreases in Beneficiary Utilization in Competitive Bidding Areas than Comparator Areas, but Beneficiary Access Does Not Appear to Have Been Affected	Our analysis of Medicare claims data found that for five of the six product categories we examined, the number of distinct beneficiaries furnished CBP-covered items generally decreased more in the competitive bidding areas than in the comparator areas in each month of 2011 and 2012 compared to the same month of 2010. CMS continued several ongoing monitoring activities and reported that the CBP round 1 rebid did not affect beneficiary access and satisfaction in its second year. In addition, several Medicare beneficiary advocacy groups that we interviewed did not report widespread access issues among their members.
Medicare Claims Data Show Larger Decreases in Beneficiary Utilization in Competitive Bidding Areas than Comparator Areas	Our analysis of Medicare claims data found that the number of distinct beneficiaries furnished CBP-covered items generally decreased more in the nine competitive bidding areas than in the nine comparator areas in each month of 2011 and 2012 compared to the same month of 2010 for five of the six product categories we analyzed. ⁴⁶ However, the larger decreases in the number of beneficiaries furnished CBP-covered items in the competitive bidding areas do not necessarily indicate that CBP- covered beneficiaries did not receive needed DME. As CMS has reported, the CBP may have curbed previous inappropriate distribution of some CBP-covered items in competitive bidding areas.
Enteral Product Category	Our analysis found that fewer beneficiaries received one or more enteral product category items in each month of 2011 and 2012 compared to the same month of 2010. In 2012, the declines were roughly equivalent in the competitive bidding areas and the comparator areas. (See fig. 2.) For example, in the competitive bidding areas, the number of CBP-covered beneficiaries who received one or more items in May 2012 decreased by about 4 percent compared to May 2010. In the comparator areas, the

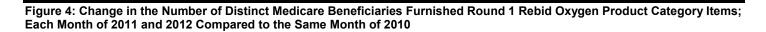
⁴⁶Our analysis used the 2010 utilization data for comparison because it was the year immediately prior to January 2011 when the CBP round 1 rebid began operating, but does not assume that 2010's utilization was the appropriate level for any of the CBP product categories.

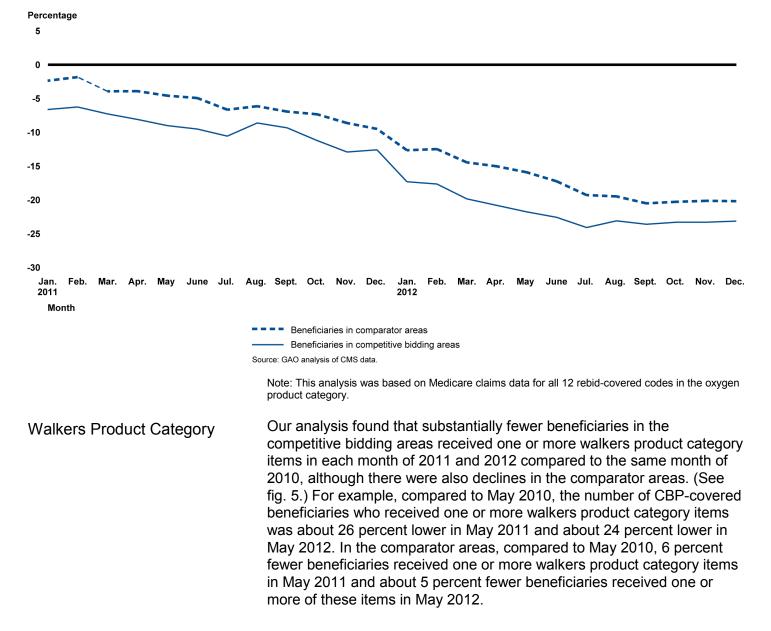
number of beneficiaries who received one or more items was about 6 percent lower in May 2012 compared to May 2010.

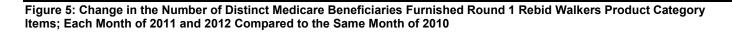


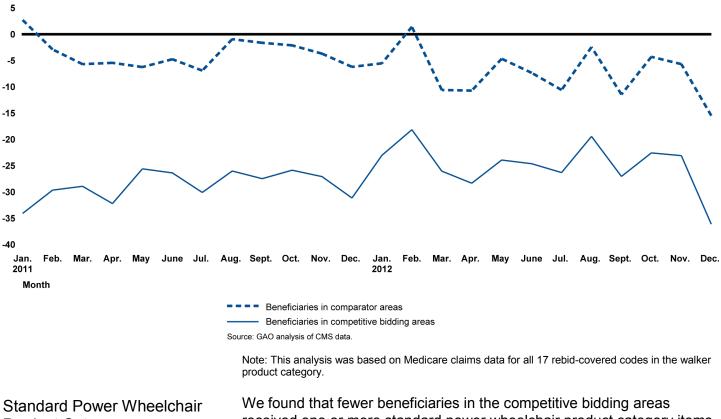












Standard Power Wheelchair Product Category

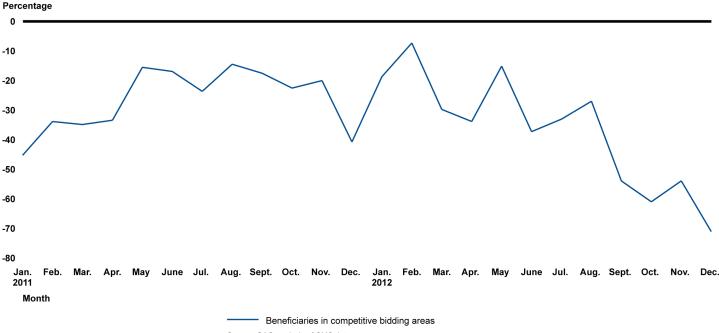
Percentage

We found that fewer beneficiaries in the competitive bidding areas received one or more standard power wheelchair product category items each month of 2011 and 2012 compared to the same month of 2010.⁴⁷ (See fig. 6.) For example, compared to May 2010, about 16 percent fewer beneficiaries in the competitive bidding areas received one or more standard power wheelchair product category items in May 2011 and about 15 percent fewer in May 2012. We did not include like information for the comparator areas because CMS changed the payment policy for standard power wheelchairs in non-competitive bidding areas only,

⁴⁷The analysis shown in Figure 6 includes only the 20 HCPCS codes that are distinct to the standard power wheelchair product category. We excluded the other 86 HCPCS codes that are related to wheelchair accessories and repairs because they are also related to the complex wheelchair product category and CMS told us that data for that product category are unreliable.

making a comparison to the competitive bidding areas difficult. This change in payment policy, which was effective January 1, 2011, eliminated the option for the lump sum purchase payment for standard power wheelchairs in all non-competitive bidding areas.

Figure 6: Change in the Number of Distinct Medicare Beneficiaries Furnished Certain Round 1 Rebid Standard Power Wheelchair Product Category Items; Each Month of 2011 and 2012 Compared to the Same Month of 2010



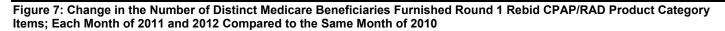
Source: GAO analysis of CMS data.

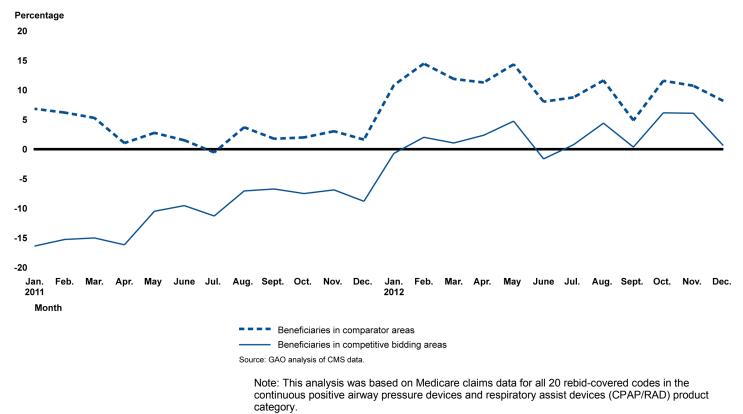
Note: This analysis was based on Medicare claims data for the 20 distinct rebid-covered codes in the standard power wheelchair product category.

CPAP/RAD Product Category We found that the difference in beneficiary utilization of CPAP/RAD product category items—used, for example, to treat sleep apnea—was greater between the competitive bidding areas and comparator areas in the beginning of the round 1 rebid, although the difference decreased over time. It was the only product category we analyzed that experienced a period of utilization increase in the competitive bidding areas and the comparator areas, although utilization was lower in the competitive

bidding areas.⁴⁸ (See fig. 7.) The number of distinct beneficiaries residing in the nine competitive bidding areas who received one or more of these items decreased in all months of 2011, but was higher in most months of 2012 compared to the same month of 2010. For example, the number of CBP-covered beneficiaries who received one or more CPAP/RAD product category items was about 10 percent lower in May 2011, but about 5 percent higher in May 2012. In contrast, utilization of CPAP/RAD product category items furnished to beneficiaries residing in the comparator areas generally increased in all months of 2011 and 2012 compared to the same month of 2010. For example, compared to May 2010, the number of comparator area beneficiaries who received these items was about 3 percent higher in May 2011 and about 14 percent higher in May 2012.

⁴⁸CMS officials told us they believe that the increase in utilization for the CPAP/RAD product category is not related to the CBP round 1 rebid because the increase also occurred in the comparator areas. Instead, they said that the increase may be related to an increase in the number of diagnoses for diseases that can be treated with CPAP/RAD product category items.





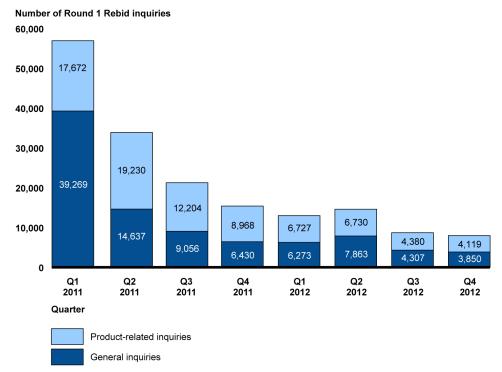
CMS Reports that Its Ongoing Monitoring Tools Indicate that CBP's Round 1 Rebid Has Not Affected Beneficiary Access and Satisfaction

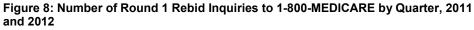
As it did in 2011, CMS continued several ongoing activities to monitor CBP's effects on beneficiaries in 2012.⁴⁹ CMS's activities included monitoring the number of CBP-related inquiries and complaints made to 1-800-MEDICARE and the health outcomes of CBP-covered beneficiaries in competitive bidding areas. CMS reported that the implementation of the CBP round 1 rebid did not result in beneficiary access issues in the first two years of the program. In addition, representatives of several Medicare beneficiary advocacy groups that we interviewed did not report that widespread access issues occurred.

⁴⁹As we previously reported, some of CMS's monitoring efforts have limitations, but in the aggregate, they provide useful information to CMS regarding beneficiary access and satisfaction. See GAO-12-693.

Total Number of Inquiries and Complaints Significantly Decreased in CBP's Second Year According to data provided by CMS, 1-800-MEDICARE received a total of 44,249 CBP-related questions—referred to by CMS as inquiries—in 2012, which was fewer than the 127,466 CBP-related inquiries reported in 2011. The total number of quarterly CBP-related inquiries to 1-800-MEDICARE ranged from a high of 56,941 in the first quarter of 2011 (17,672 product-related inquiries plus 39,269 general CBP inquiries) to a low of 7,969 in the fourth quarter of 2012 (4,119 product-related inquiries plus 3,850 general CBP inquiries). (See fig. 8.) The majority of total inquiries for both 2011 and 2012 were general in nature; for example, CMS officials told us that inquiries were related to questions about the program or finding a contract supplier. About 2 million beneficiaries reside in CBP round 1 rebid competitive bidding areas; the ratio of inquiries to 1-800-MEDICARE compared with CBP beneficiaries is approximately 1 inquiry for every 45 beneficiaries.⁵⁰

⁵⁰According to CMS officials, each beneficiary may make more than one call to 1-800-MEDICARE and each call would be classified as at least one inquiry. The ratio does not represent the percentage of beneficiaries who called 1-800-MEDICARE.



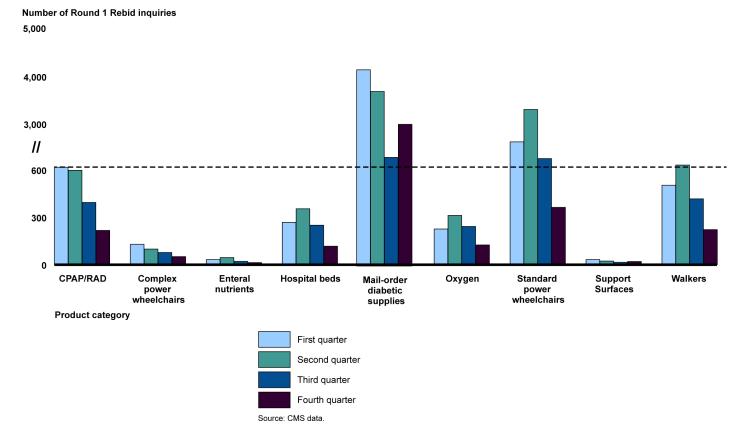


Source: GAO analysis of CMS data.

Notes: Product-related inquiries were related to a specific item or product category. According to CMS data, an increase in the number of inquiries in the second quarter of 2012 was attributed to an internal communication from the 1-800-MEDICARE beneficiary call center to its customer service representatives in May 2012 reminding them when it is appropriate to transfer beneficiaries to the competitive bidding program queue. Confusion resulting from the communication led to an increase in number of calls inappropriately transferred to the competitive bidding program queue.

As was also the case in 2011, CMS data showed that the majority of all CBP product-category specific inquiries to 1-800-MEDICARE—over 13,000 in 2012—were related to mail-order diabetic supplies. The enteral product category and support surfaces product category received the fewest number of inquiries. (See fig. 9.)

Figure 9: Number of Round 1 Rebid Product Category Inquiries to 1-800-MEDICARE by Quarter, 2012



All calls to 1-800-MEDICARE are initially classified as inquiries and only recorded as complaints if they cannot be resolved by a CSR.⁵¹ In 2012, CMS classified 43 CBP-related calls to 1-800-MEDICARE as complaints,

⁵¹CMS's definitions of an inquiry and a complaint may be an optimistic characterization of beneficiary calls. According to CMS officials, CSRs are able to address most beneficiary inquiries; therefore, the definition of inquiry covers the majority of calls to 1-800-MEDICARE. However, it is possible that CMS's definition of a complaint may not fully capture dissatisfaction and problems with CBP. For example, CMS would consider it an inquiry if a beneficiary called 1-800-MEDICARE to complain about a contract supplier, but was subsequently helped by the CSR to locate another contract supplier. Conversely, CMS would consider it a complaint if a contract supplier called 1-800-MEDICARE and asked a question about a CBP supplier's contract obligations that the CSR could not answer and had to refer to another entity.

which was a decline from 151 complaints in 2011. Among the 43 complaints, 13 complaints were specific to the walkers product category. which was almost more than twice the number of complaints associated with any of the other product categories. Twelve of the 13 complaints were related to a specific walker brand and model that can be billed under HCPCS code E0147, which has the highest single payment amount of all CBP-covered HCPCS codes included in the walkers product category.⁵² Some complainants reported that contract suppliers would not provide the specific walker brand and model prescribed by beneficiaries' physicians because the CBP single payment amount is lower than the cost of the item. According to Palmetto GBA data, in response to one complaint, it conducted secret shopping calls to two contract suppliers and was told by both that they did not carry the specific walker brand and model and could not obtain it. After Palmetto GBA explained the terms of their contracts, both contract suppliers then agreed to provide it.53 Half of these 12 complaints originated in the Miami competitive bidding area, where there was a decline in utilization for these walkers.

According to CMS, the agency continues to monitor national Medicare claims data to identify utilization trends, monitor health outcomes and beneficiary access, address aberrations in services, and target potential fraud and abuse. As part of this effort, CMS monitors a range of health outcomes—including deaths, hospitalizations, emergency room visits, physician visits, and admissions to skilled nursing facilities—for beneficiaries likely to use a CBP-covered item or who have used a CBP-covered item, in both competitive bidding areas and their comparator areas. In both 2011 and 2012, CMS's monitoring of health outcomes from national claims data indicated that CBP-covered beneficiaries continued to have access to necessary and appropriate CBP-covered items and supplies, and that health outcomes in the competitive bidding areas were

CMS Has Several Other Monitoring Efforts to Conduct CBP Program Oversight

⁵²HCPCS code E0147 is described as a heavy-duty, multiple-braking system, variable wheel resistance walker and is covered for beneficiaries who meet coverage criteria for a standard walker and who are unable to use a standard walker due to a severe neurologic disorder or other condition causing the restricted use of one hand.

⁵³Under the terms of their contracts, if a physician or other treating practitioner orders a specific brand and model to avoid an adverse medical outcome for a beneficiary, the contract supplier must provide that specific item, consult with the physician for a suitable alternative and obtain a revised prescription, or assist the beneficiary in locating a contract supplier who will furnish the needed item. If a supplier cannot obtain a revised prescription or locate another contract supplier to furnish an item, the contract supplier must furnish the item as prescribed.

consistent with national trends. However, as we previously reported,⁵⁴ while these outcomes are reassuring, they may not reflect other outcomes that did not require physician, hospital, or emergency room visits, such as whether beneficiaries received the DME item they needed on time, or whether health outcomes were caused by problems accessing CBP-covered DME.

CMS data show that the agency monitored beneficiary access by conducting more secret shopping calls in 2012 than it did in 2011—300 versus 32. According to that data, the highest number of secret shopping calls in 2012 involved the oxygen product category (109) and the second highest number of calls involved the walker product category (58). According to CMS officials, secret shopping calls were prompted by beneficiary and industry concerns expressed to CMS. For example, CMS officials told us that the agency received complaints that contract suppliers were not providing liquid oxygen equipment and specific walker models. According to these officials, when conducting secret shopper calls, CMS provides contract suppliers additional education on competitive bidding program and supplier quality standard requirements. CMS then conducts subsequent secret shopper calls to verify that the contract suppliers are adhering to the requirements.

CMS conducted a pre-CBP implementation survey in 2010 and post-CBP implementation survey in 2011 to measure beneficiary satisfaction with the CBP round 1 rebid's first year. According to CMS data, the agency obtained responses from at least 400 beneficiaries in each of the nine competitive bidding areas and nine comparator areas to collect beneficiary satisfaction ratings for six questions related to the beneficiary's initial interaction with DME suppliers, the training received regarding DME items, the delivery of the DME item, the quality of service provided by the supplier, the customer service provided by the supplier, and the supplier's overall complaint handling. According to CMS data, results of the pre-2010 and post-CBP 2011 implementation surveys showed that responses from beneficiaries were similar and generally

⁵⁴See GAO-12-693.

positive in both the competitive bidding areas and comparator areas.⁵⁵ CMS officials told us that CMS conducted a follow-up beneficiary satisfaction survey in June 2013 using the original survey questions and methodology, but as of November 20, 2013, survey results were not yet available.

Beneficiary Advocacy Groups We Interviewed Did Not Report Widespread CBP Beneficiary Access Concerns

We interviewed representatives from several beneficiary advocacy groups about their members' experiences with CBP, and whether they were aware of any CBP-related beneficiary access and choice issues that may have occurred among their members. The beneficiary groups represent beneficiaries with specific issues, such as those with diabetes and disabilities requiring wheelchairs. In general, these representatives either reported no or few concerns, or provided anecdotal examples of beneficiary access issues, such as difficulty obtaining wheelchair repairs, or difficulty locating contract suppliers. They did not indicate that their CBP-covered beneficiary members had been negatively affected by widespread access issues or concerns in the first two years of the CBP round 1 rebid.

⁵⁵The survey design had limitations because it did not capture responses from beneficiaries living in those locations who may have needed, but did not obtain, DME during the period; that is, if a beneficiary's access problems resulted in not receiving DME, that beneficiary would not be included in the survey. In addition, the survey's sampling methodology also did not ensure that all socio-economic groups were represented, so it does not confirm that all beneficiaries within an area had equal access. For more information about the CMS beneficiary satisfaction survey methodology and results, see GAO-12-693.

For the Round 1 Rebid Product Categories and Areas, a Small Number of Contract Suppliers Accounted for a Large Portion of the CBP Market Share in 2011 and 2012	For the round 1 rebid product categories we examined, a small number of contract suppliers accounted for a large portion of Medicare total allowed charges across 2011 and 2012. One contract supplier had a high percentage of the total market share for the standard power wheelchair product category across 2011 and 2012, but was terminated as a contract supplier in 2013. Few contract suppliers left the CBP through contract terminations, voluntarily withdrawing from Medicare, or having had a change in ownership.
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A Small Number of Contract Suppliers Accounted for a Large Portion of the Market Share

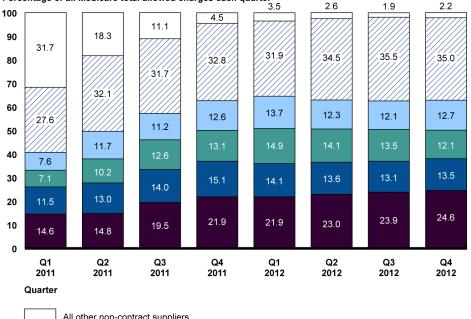
We examined the contract supplier market share development for six product categories in 2011 and 2012 and found that the trends for each product category were relatively consistent across the nine competitive bidding areas. For each product category, we illustrate typical market share development trends by showing examples from two competitive bidding areas. (See fig. 10 through fig. 21.) For five of the six product categories, we found that, in general, the top 4 suppliers—those with the highest individual Medicare total allowed charges across all quarters of 2011 and 2012—accounted for a large portion of the market in all competitive bidding areas, although the top 4 suppliers for each product category could vary by competitive bidding area.⁵⁶ In our examples, the top 4 suppliers' combined market share in the fourth quarter of 2012 ranged from 50 percent for the enteral product category in the Dallas competitive bidding area to 86 percent for the walkers product category in the Orlando competitive bidding area.

⁵⁶Because some contract suppliers may have won a contract for only one product category and competitive bidding area combination, while other contract suppliers may have won a contract with multiple category and area combinations, the contract suppliers for the same product category may differ in each competitive bidding area. For example, the top 4 contract suppliers with the highest percentages of Medicare total allowed charges for the hospital bed product category may be different in the Orlando competitive bidding area.

CPAP/RAD Product Category

Our analysis of Medicare claims data for the CPAP/RAD product category indicates that, in general, the market share among the top 4 contract suppliers increased steadily, the combined market share for the other contract suppliers' remained relatively consistent with some small increases, and the non-contract suppliers' combined market share decreased throughout 2011 and 2012. For example, in the Pittsburgh competitive bidding area, by the fourth quarter of 2012, the top 4 contract suppliers combined had about 63 percent of the market, while the other 10 contract suppliers combined had 35 percent of the market. (See fig. 10.) This is fairly similar to the contract supplier market share trend in the Cleveland competitive bidding area, where the top 4 contract suppliers combined had about 73 percent of the market and the other 8 contract suppliers combined had about 26 percent in the fourth quarter of 2012. (See fig. 11.)

Figure 10: Four Contract Suppliers with the Highest Individual Percentage of Medicare Total Allowed Charges for All 20 Round 1 Rebid CPAP/RAD Product Category Codes, Pittsburgh Competitive Bidding Area, 2011 and 2012



Percentage of all Medicare total allowed charges each quarter 3.5



Source: GAO analysis of CMS data.

Note: The figure includes each of the 4 contract suppliers with the highest percentages of Medicare total allowed charges for rebid-covered continuous positive airway pressure devices and respiratory assist devices (CPAP/RAD) product category codes across all 8 quarters of 2011 and 2012. For the "all other contract suppliers" group, we combined the other 10 contract suppliers' individual percentages of Medicare total allowed charges for the codes. For the "all other non-contract suppliers" group, we combined non-contract suppliers' individual percentages of Medicare total allowed charges for the codes. For the "all other non-contract suppliers" group, we combined non-contract suppliers' individual percentages of Medicare total allowed charges for the codes.

Figure 11: Four Contract Suppliers with the Highest Individual Percentage of Medicare Total Allowed Charges for All 20 Round 1 Rebid CPAP/RAD Product Category Codes, Cleveland Competitive Bidding Area, 2011 and 2012



Percentage of all Medicare total allowed charges each quarter

 All other non-contract suppliers

 All other contract suppliers

 Contract supplier #4

 Contract supplier #3

 Contract supplier #2

 Contract supplier #1

Source: GAO analysis of CMS data.

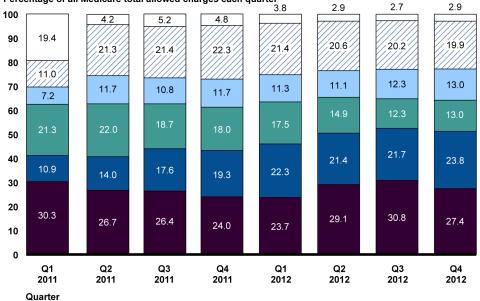
Note: The figure includes each of the 4 contract suppliers with the highest percentages of Medicare total allowed charges for rebid-covered continuous positive airway pressure devices and respiratory assist devices (CPAP/RAD) product category codes across all 8 quarters of 2011 and 2012. For the "all other contract suppliers" group, we combined the other 8 contract suppliers' individual percentages of Medicare total allowed charges for the codes. For the "all other non-contract suppliers" group, we combined non-contract suppliers' individual percentages of Medicare total allowed charges for the codes.

Enteral Product Category

Our analysis of Medicare claims data for the enteral product category indicates that, in general, the market share of the top 4 contract suppliers and all other contract suppliers combined remained relatively consistent or increased throughout 2011 and 2012. For example, in the Cincinnati competitive bidding area, the top 4 contract suppliers combined had about 70 percent or more of the market share throughout 2011 and 2012.⁵⁷ For that same time period, the other 10 contract suppliers combined generally had about 20 percent of the market in that area. (See fig. 12.) In the Dallas competitive bidding area, the top 4 contract suppliers combined had less of the market share—between about 43 to 55 percent each quarter of 2011 and 2012—while the other 20 contract suppliers had more of the market share each quarter. (See fig. 13.)

⁵⁷CBP's enteral nutrition product category cannot be grandfathered. CMS announced in December 2011 that Medicare claims submitted for maintenance and servicing of enteral nutrition pumps during 2011 would be paid if the non-contract supplier furnished the pump to a beneficiary in a competitive bidding area and the pump had been rented for at least 15 continuous months at the time of CBP's implementation on January 1, 2011. The supplier that provided the pump in the 15th month of the rental period is responsible for furnishing, maintaining, and servicing the pump—whether it is a contract supplier or not—until the pump is no longer medically necessary for the beneficiary or reaches the end of its reasonable useful lifetime.

Figure 12: Four Contract Suppliers with the Highest Individual Percentage of Medicare Total Allowed Charges for All 17 Round 1 Rebid Enteral Product Category Codes, Cincinnati Competitive Bidding Area, 2011 and 2012



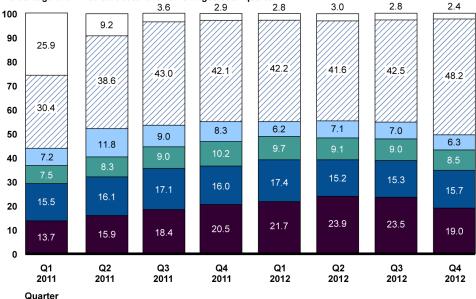
Percentage of all Medicare total allowed charges each quarter 3.8



Source: GAO analysis of CMS data.

Note: The figure includes each of the 4 contract suppliers with the highest percentages of Medicare total allowed charges for rebid-covered enteral product category codes across all 8 quarters of 2011 and 2012. For the "all other contract suppliers" group, we combined the other 10 contract suppliers' individual percentages of Medicare total allowed charges for the codes. For the "all other non-contract suppliers" group, we combined non-contract suppliers' individual percentages of Medicare total allowed charges for the codes.

Figure 13: Four Contract Suppliers with the Highest Individual Percentage of Medicare Total Allowed Charges for All 17 Round 1 Rebid Enteral Product Category Codes, Dallas Competitive Bidding Area, 2011 and 2012



Percentage of all Medicare total allowed charges each quarter



Source: GAO analysis of CMS data.

Note: The figure includes each of the 4 contract suppliers with the highest percentages of Medicare total allowed charges for rebid-covered enteral product category codes across all 8 quarters of 2011 and 2012. For the "all other contract suppliers" group, we combined the other 20 contract suppliers' individual percentages of Medicare total allowed charges for the codes. For the "all other non-contract suppliers' individual percentages of Medicare total allowed charges for the codes of Medicare total allowed charges for the codes.

Hospital Bed Product Category Our analysis of Medicare claims data for the hospital bed product category indicates that contract suppliers' percentages of Medicare total allowed charges increased steadily throughout 2011 and 2012 as noncontract suppliers' percentages of Medicare total allowed charges substantially decreased. In both the Riverside and Orlando competitive bidding areas, the top 4 contract suppliers accounted for more than 80 percent of the market by the fourth quarter of 2012, with the other contract suppliers totaling about 10 percent of Medicare total allowed charges in each of the areas. (See fig.14 and fig. 15.)

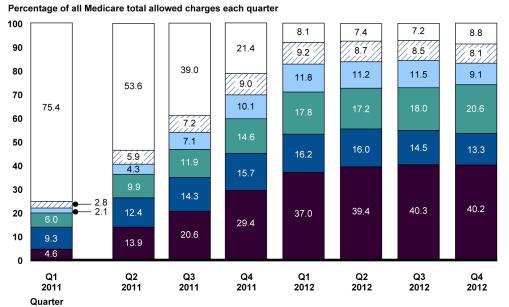


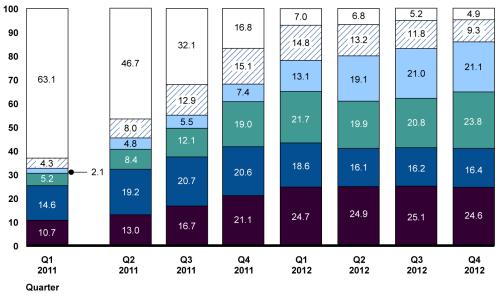
Figure 14: Four Contract Suppliers with the Highest Individual Percentage of Medicare Total Allowed Charges for All 31 Round 1 Rebid Hospital Bed Product Category Codes, Riverside Competitive Bidding Area, 2011 and 2012



Source: GAO analysis of CMS data.

Note: The figure includes each of the 4 contract suppliers with the highest percentages of Medicare total allowed charges for rebid-covered hospital bed product category codes across all 8 quarters of 2011 and 2012. For the "all other contract suppliers" group, we combined the other 6 contract suppliers' individual percentages of Medicare total allowed charges for the codes. For the "all other non-contract suppliers" individual percentages of Medicare total allowed charges of Medicare total allowed charges for the codes.

Figure 15: Four Contract Suppliers with the Highest Individual Percentage of Medicare Total Allowed Charges for All 31 Round 1 Rebid Hospital Bed Product Category Codes, Orlando Competitive Bidding Area, 2011 and 2012







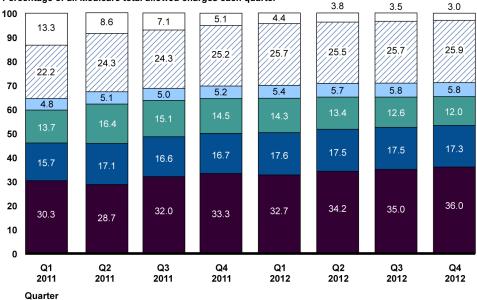
Source: GAO analysis of CMS data.

Note: The figure includes each of the 4 contract suppliers with the highest percentages of Medicare total allowed charges for rebid-covered hospital bed product category codes across all 8 quarters of 2011 and 2012. For the "all other contract suppliers" group, we combined the other 6 contract suppliers' individual percentages of Medicare total allowed charges for the codes. For the "all other non-contract suppliers" group, we combined non-contract suppliers' individual percentages of Medicare total allowed charges for the codes.

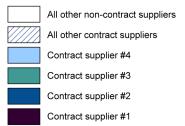
Oxygen Product Category

Our analysis of Medicare claims data for the oxygen product category indicates that the market share of the top 4 contract suppliers and all other contract suppliers combined remained relatively consistent or increased from the first quarter of 2011 to the fourth quarter of 2012. For example, in the Cleveland competitive bidding area, the top 4 suppliers had about 65 percent of the market in the first quarter of 2011 and about 71 percent of the market in the fourth quarter of 2012. (See fig. 16.) In the Kansas City competitive bidding area, the top 4 suppliers had about 71 percent of the market in the first quarter of 2011 and about 83 percent of the market in the fourth quarter of 2012. (See fig. 17.)

Figure 16: Four Contract Suppliers with the Highest Individual Percentage of Medicare Total Allowed Charges for All 12 Round 1 Rebid Oxygen Product Category Codes, Cleveland Competitive Bidding Area, 2011 and 2012

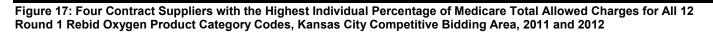


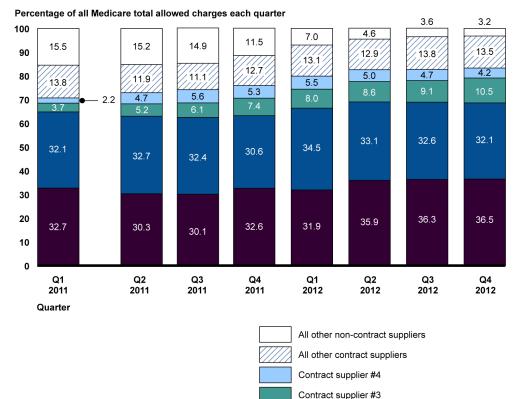
Percentage of all Medicare total allowed charges each quarter



Source: GAO analysis of CMS data.

Note: The figure includes each of the 4 contract suppliers with the highest percentages of Medicare total allowed charges for rebid-covered oxygen product category codes across all 8 quarters of 2011 and 2012. For the "all other contract suppliers" group, we combined the other 13 contract suppliers' individual percentages of Medicare total allowed charges for the codes. For the "all other non-contract suppliers' individual percentages of Medicare total allowed charges for the codes. For the "all other non-contract suppliers' individual percentages of Medicare total allowed charges for the codes.





Source: GAO analysis of CMS data.

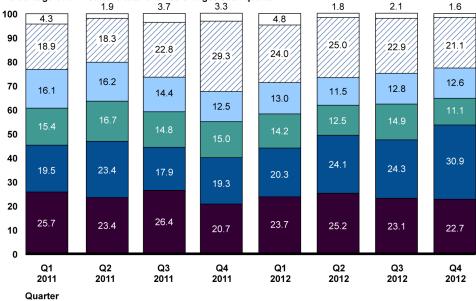
Contract supplier #2 Contract supplier #1

Note: The figure includes each of the 4 contract suppliers with the highest percentages of Medicare total allowed charges for rebid-covered oxygen product category codes across all 8 quarters of 2011 and 2012. For the "all other contract suppliers" group, we combined the other 8 contract suppliers' individual percentages of Medicare total allowed charges for the codes. For the "all other non-contract suppliers' individual percentages of Medicare total allowed charges for the codes.

Walkers Product Category

Our analysis of Medicare claims data for the walkers product category indicates that the market share of the top 4 contract suppliers and all other contract suppliers combined remained relatively consistent throughout 2011 and 2012. For example, in the Pittsburgh competitive bidding area, the top 4 contract suppliers combined had at least 65 percent of the total market share each quarter of 2011 and 2012. The other 11 contract suppliers combined had between about 20 to 30 percent of the market share each quarter over that time period. (See fig. 18.) The Orlando competitive bidding area showed a similar market share trend where the top 4 contract suppliers combined maintained at least 72 percent of the total market share each quarter of 2011 and 2012. The other 13 contract suppliers combined consistently had about 20 percent each quarter. (See fig. 19.)

Figure 18: Four Contract Suppliers with the Highest Individual Percentage of Medicare Total Allowed Charges for All 17 Round 1 Rebid Walkers Product Category Codes, Pittsburgh Competitive Bidding Area, 2011 and 2012



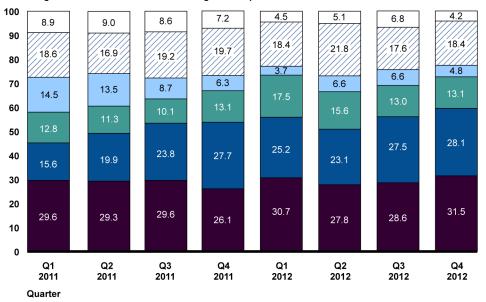
Percentage of all Medicare total allowed charges each quarter



Source: GAO analysis of CMS data.

Note: The figure includes each of the 4 contract suppliers with the highest percentages of Medicare total allowed charges for rebid-covered walkers product category codes across all 8 quarters of 2011 and 2012. For the "all other contract suppliers" group, we combined the other 11 contract suppliers' individual percentages of Medicare total allowed charges for the codes. For the "all other non-contract suppliers' individual percentages of Medicare total allowed charges for the codes of Medicare total allowed charges for the codes.

Figure 19: Four Contract Suppliers with the Highest Individual Percentage of Medicare Total Allowed Charges for All 17 Round 1 Rebid Walkers Product Category Codes, Orlando Competitive Bidding Area, 2011 and 2012



Percentage of all Medicare total allowed charges each quarter



Source: GAO analysis of CMS data.

Note: The figure includes each of the 4 contract suppliers with the highest percentages of Medicare total allowed charges for rebid-covered walkers product category codes across all 8 quarters of 2011 and 2012. For the "all other contract suppliers" group, we combined the other 13 contract suppliers' individual percentages of Medicare total allowed charges for the codes. For the "all other non-contract suppliers' individual percentages of Medicare total allowed charges for the codes of Medicare total allowed charges for the codes.

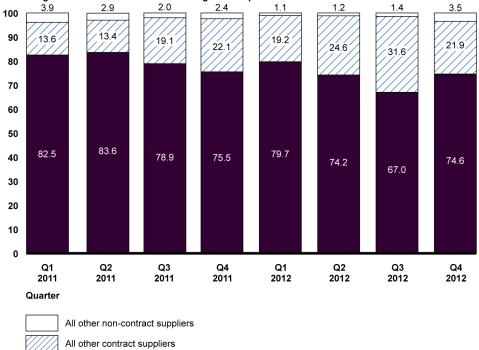
Our analysis of Medicare claims data for the standard power wheelchair product category indicates that the market share for the top contract supplier, The Scooter Store's Alliance Seating & Mobility Division (The Scooter Store), was very high in all quarters of 2011 and 2012 across all competitive bidding areas. Specifically, The Scooter Store had the highest individual supplier percent of all CBP-covered Medicare total allowed charges across all quarters of 2011 and 2012 combined for the standard

Standard Power Wheelchair Product Category power wheelchair product category in eight of the nine competitive bidding areas, and the second highest in the ninth competitive bidding area.⁵⁸ The Scooter Store's individual percentages of all Medicare total allowed charges in the fourth quarter of 2012 were: Pittsburgh (82 percent), Orlando (81 percent), Miami (75 percent), Riverside (72 percent), Cleveland (62 percent), Dallas (60 percent), Charlotte (48 percent), Kansas City (41 percent), and Cincinnati (37 percent).

In the Miami competitive bidding area, Medicare claims data show that The Scooter Store's highest individual percentage of all Medicare total allowed charges was about 84 percent in the second quarter of 2011. (See fig. 20.) In the Riverside competitive bidding area, The Scooter Store's highest individual percentage of all Medicare total allowed charges was about 72 percent in the fourth quarter of 2012. (See fig. 21.)

⁵⁸Besides The Scooter Store, there was a range of between 7 and 27 other contract suppliers in each of the nine competitive bidding areas for the standard power wheelchair product category.

Figure 20: Contract Supplier with the Highest Percentage of Medicare Total Allowed Charges for 20 Round 1 Rebid Standard Power Wheelchair Product Category Codes, Miami Competitive Bidding Area, 2011 and 2012



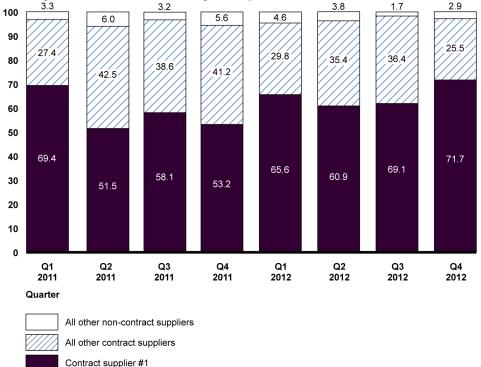
Percentage of all Medicare total allowed charges each quarter

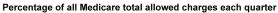
Source: GAO analysis of CMS data.

Contract supplier #1

Note: The figure includes the contract supplier with the highest percentage of Medicare total allowed charges for 20 rebid-covered standard power wheelchair product category codes across all 8 quarters of 2011 and 2012. For the "all other contract suppliers" group, we combined the other 15 contract suppliers' individual percentages of Medicare total allowed charges for the codes. For the "all other non-contract suppliers" individual percentages of Medicare total suppliers' individual percentages of Medicare total allowed charges for the codes.

Figure 21: Contract Supplier with the Highest Percentage of Medicare Total Allowed Charges for 20 Round 1 Rebid Standard Power Wheelchair Product Category Codes, Riverside Competitive Bidding Area, 2011 and 2012





Source: GAO analysis of CMS data.

Note: The figure includes the contract supplier with the highest percentage of Medicare total allowed charges for 20 rebid-covered standard power wheelchair product category codes across all 8 quarters of 2011 and 2012. For the "all other contract suppliers" group, we combined the other 27 contract suppliers' individual percentages of Medicare total allowed charges for the codes. For the "all other non-contract suppliers" individual percentages of Medicare total allowed charges of Medicare total allowed charges for the codes.

Round 1 Rebid's Top Standard Power Wheelchair Contract Supplier in 2011 and 2012 Was Terminated in 2013

In September 2013, CMS issued a termination notice, with an effective date of October 26, 2013, for The Scooter Store's CBP round 1 rebid contract in all competitive bidding areas. Prior to issuing the termination notice, CMS removed all references to both The Scooter Store and its Alliance Seating & Mobility Division from all CBP round 1 rebid contract supplier lists on its website in March 2013. A CMS official told us that the

removal occurred because of compliance issues identified with The Scooter Store's round 1 rebid contract and that CMS began initiating the contract termination process at that time.⁵⁹ According to CMS, it carefully scrutinizes CBP bidders to ensure that only qualified suppliers are selected to participate in the program; however, The Scooter Store had been the subject of allegations of fraud prior to being awarded a contract in both CBP's round 1 and round 1 rebid. Specifically, in 2007, The Scooter Store entered into a civil settlement agreement with the U.S. Government to resolve several lawsuits and agreed to pay \$4 million and relinguish its right to receive reimbursement for pending Medicare claims.⁶⁰ In one of the lawsuits, the Government alleged that the company violated the civil False Claims Act and defrauded the United States by, among other things, enticing some beneficiaries to obtain power scooters covered by Medicare and Medicaid and then supplying more costly power wheelchairs that beneficiaries did not want, did not need, or could not use.

Although too soon to determine the full effects, The Scooter Store's 2013 termination as a contract supplier could potentially result in access issues for beneficiaries residing in the CBP round 1 rebid competitive bidding areas. For example, one round 1 rebid contract supplier we interviewed told us that her company received calls from some of The Scooter Store's beneficiaries seeking wheelchair repairs. However, this contract supplier and two others told us that some contract suppliers are reluctant or unwilling to repair a wheelchair that they did not originally provide because if the contract suppliers did the repairs, and CMS later determined that The Scooter Store had furnished a wheelchair that did not meet documentation requirements, CMS could recover payments made to the repairing contract suppliers.

⁵⁹In February 2013, it was publicly reported that The Scooter Store was under investigation by the HHS Office of Inspector General, the Federal Bureau of Investigation, and the Texas Attorney General. The Scooter Store declared bankruptcy in April 2013.

⁶⁰These pending Medicare claims totaled more than \$43 million, but CMS estimated that the actual payments The Scooter Store would have received was approximately \$13 million.

Few Contract Suppliers Left the Competitive Bidding Program in its First Two Years

In CBP's First Two Years, About 8 Percent of Contract Suppliers Had Contracts Terminated or Voluntarily Withdrew From Medicare In the round 1 rebid's second year, a few contract suppliers—8 percent had their contracts terminated by CMS or voluntarily withdrew from Medicare, and some had an ownership change. Contract suppliers continued to use subcontractors to provide certain services to beneficiaries in the round 1 rebid competitive bidding areas, but no new agreements were disclosed in 2012. The number of grandfathered suppliers decreased in 2012 to the point that CMS discontinued its monitoring as rental agreements expired.

By the end of the CBP's second year, 27 of the original 356 contract suppliers—about 8 percent—had been terminated by CMS or had voluntarily withdrawn from Medicare, according to CMS data. Eleven contract suppliers were terminated—4 in 2012 and 7 in 2011. Nine terminated suppliers were small suppliers as defined for CBP. One terminated supplier was not experienced in one of its competitive bidding areas; all were experienced in their product categories. The 11 terminated contract suppliers had a total of 22 round 1 rebid product category and competitive bidding area combinations. (See table 1.) The oxygen product category and the Miami competitive bidding area were the most affected.

Table 1: Total Number of Round 1 Rebid Product Categories and Competitive Bidding Areas Affected by the 11 Terminated Contract Suppliers, 2011 and 2012

Product category		Competitive bidding area	
Oxygen	6	Miami	9
Standard wheelchairs	5	Orlando	4
Complex wheelchairs	3	Kansas City	3
CPAP/RAD ^a	2	Riverside	3
Enteral	2	Cincinnati	1
Walkers	2	Dallas	1
Hospital beds	1	Pittsburgh	1
Support surfaces	1	Charlotte	0
Mail-order diabetic testing supplies	0	Cleveland	0
Total	22	Total	22

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data.

^aCPAP/RAD are continuous positive airway pressure devices and respiratory assist devices, and related supplies and accessories used to treat sleep apnea for example.

Note: In general, a contract supplier enters into a single contract with CMS for the relevant competitive bidding program (CBP) round, which covers all the product category and competitive bidding area combinations awarded to and accepted by the contract supplier. The number of product category and competitive bidding area combinations within each contract supplier's contract can vary. Accordingly, for this analysis, we counted the number of product categories and competitive bidding areas individually that were affected by CMS's termination of 11 contract suppliers.

Sixteen contract suppliers withdrew voluntarily from Medicare, 7 in 2012 and 9 in 2011. Of these 16 withdrawn suppliers, 13 were small suppliers. Two suppliers that withdrew had no experience in 1 of their product categories; and all 16 were experienced in their competitive bidding areas. The 16 suppliers that withdrew had a total of 37 round 1 rebid product category and competitive bidding area combinations. (See table 2.) The oxygen product category and the Miami competitive bidding area were the most affected.

Table 2: Total Number of Round 1 Rebid Product Categories and CompetitiveBidding Areas Affected by the 16 Contract Suppliers that Voluntarily Withdrew fromMedicare, 2011 and 2012

Product category		Competitive bidding area	
Oxygen	14	Miami	16
Standard wheelchairs	6	Riverside	6
Enteral	4	Kansas City	5
CPAP/RAD ^a	3	Orlando	5
Complex wheelchairs	3	Charlotte	3
Hospital beds	3	Dallas	2
Walkers	3	Cincinnati	0
Support surfaces	1	Cleveland	0
Mail-order diabetic testing supplies	0	Pittsburgh	0
Total	37	Total	37

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data.

^aCPAP/RAD are continuous positive airway pressure devices and respiratory assist devices, and related supplies and accessories used to treat sleep apnea for example.

Note: In general, a contract supplier enters into a single contract with CMS for the relevant competitive bidding program (CBP) round, which covers all the product category and competitive bidding area combinations awarded to and accepted by the contract supplier. The number of product category and competitive bidding area combinations within each contract supplier's contract can vary. Accordingly, for this analysis, we counted the number of product categories and competitive bidding areas individually that were affected by the 16 contract suppliers that voluntarily withdrew from Medicare.

Twelve Contract Supplier Ownership Changes Occurred in CBP's First Two Years During the round 1 rebid's first two years, 12 of the original 356 round 1 rebid contract suppliers—3 percent—had a change in ownership. (See table 3.) For 11 of the 12 changes, CMS awarded the round 1 rebid contracts to the acquiring entity as the entity assumed the obligations under these contracts. In 2012, the only ownership change involved a contract supplier that purchased another contract supplier, but did not assume the purchased supplier's CBP contracts. In this ownership change, the purchasing contract supplier already had CBP contracts in

the same competitive bidding areas for the same product categories, and began serving the purchased contract supplier's Medicare beneficiaries including its grandfathered beneficiaries.

Supplier ownership change transaction	Which supplier assumes the involved round 1 rebid contract	Ownership changes
Contract supplier purchases another contract supplier	CMS allows the purchasing contract supplier to assume the purchased contract supplier's contract or contracts	7 [°]
Non-contract supplier purchases a contract supplier	CMS allows the purchasing non-contract supplier to assume the purchased contract supplier's contract or contracts (non- contract supplier becomes contract supplier)	5
Total		12
	Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data.	
	Note: During the period after CMS announced the round 1 rebid single pay 2010, until the round 1 rebid began January 1, 2011, CMS also approved ti (1) two contract supplier purchases of other contract suppliers, and (2) one purchase of a contract supplier.	hese ownership changes:
	^a In one transaction, the purchasing contract supplier did not assume the purchasing contract because it already had a rebid contract for the same product competitive bidding areas.	
Contract Suppliers Did Not Enter Into New	While contract suppliers have continued to use subcor assist them in furnishing items to CBP-covered benefic	
Subcontracting Agreements, and Grandfathered Suppliers Continued to Decrease	officials told us no contract suppliers disclosed any new agreements in 2012 or during the first three months of 2013, CMS data indicated that 116 distinct contract su least one subcontracting agreement; in total, there wer involving 228 distinct subcontractor suppliers. Forty-se the 116 contract suppliers had one subcontract agreer contract suppliers had multiple subcontracts, including supplier with 50 agreements. Eight of the 116 contract subcontract agreements that ended in 2011, 2012, or each subc	2013. As of April ppliers have had at re 730 agreements even percent (55) of nent. The other 61 one contract suppliers had

Table 3: Twelve Ownership Changes Involving Round 1 Rebid Contact Suppliers, 2011 and 2012

⁶¹A subcontractor supplier may perform three services: (1) purchase inventory and fill orders, fabricate or fit items from its own inventory or contract with other companies to purchase items necessary to fill an order, (2) deliver CBP-covered items to beneficiaries, and (3) repair rented equipment. The contract supplier involved is responsible for billing Medicare for any CBP-covered items and services furnished by the subcontractor supplier.

CMS officials also told us that the number of grandfathered suppliers had so diminished that the agency was no longer monitoring them after the second quarter 2012. As we previously reported,⁶² the number of grandfathered suppliers had declined steadily during the rebid's first year (2011); in December 2011, 22 percent (575 of 2,594) of the grandfathered suppliers were still billing Medicare for CBP-covered beneficiaries they had at the end of December 2010, the year before the CBP began.⁶³

The Number of Suppliers and Their Medicare Allowed Charges Generally Decreased More in Competitive Bidding Areas than in Comparator Areas

Comparing the third guarters of 2010, before the rebid began, and 2012, the rebid's second year, both the number of suppliers and their Medicare allowed charges generally decreased more in the competitive bidding areas than in the comparator areas.⁶⁴ (See app. I.) The number of suppliers with Medicare allowed charge amounts of \$2,500 or more per quarter decreased an average of 27 percent in the competitive bidding areas, and 5 percent in the comparator areas. (See table 4.) All nine competitive bidding areas and six of the nine comparator areas experienced decreases in those supplier numbers. The Miami competitive bidding area experienced the greatest change in suppliers-decreasing by 227 suppliers—a 32 percent change. The number of large suppliers, which we define as having guarterly allowed Medicare charges of \$100,000 or more, decreased an average of 18 percent in the competitive bidding areas, while there was essentially no change in the average number of large suppliers in the comparator areas. All nine competitive bidding areas and three of the nine comparator areas had decreases in these large suppliers. The Cincinnati competitive bidding area had the greatest percentage decrease in suppliers at this level-32 percent.

⁶²See GAO-12-693.

⁶³As we previously reported in GAO-12-693, when CBP's round 1 rebid began January 1, 2011, there were 1,364 grandfathered suppliers, or 58 percent of the 2,363 suppliers that had billed for beneficiaries with CBP-covered items that they had been serving as of December 31, 2010.

⁶⁴Because suppliers can have Medicare allowed charges in more than one area, some suppliers were counted more than once in our analysis.

 Table 4: Percentage Decreases in Number of Suppliers by Medicare Allowed Charge Amounts Comparing Round 1 Rebid

 Competitive Bidding Areas and Their Comparator Areas, Third Quarter 2010 to Third Quarter 2012

Medicare allowed charges comparing third quarter 2010 to third quarter 2012	Round 1 rebid areas	Average percentage decrease in number of suppliers	Highest percentage decrease in number of suppliers	Lowest percentage decrease in suppliers
Suppliers with charges of \$2,500 or more ^a	Competitive bidding areas	27%	32% (Miami)	19% (Cincinnati)
	Comparator areas	5	11 (Houston, Tampa)	6 (San Diego)
Suppliers with charges of \$100,000 or more ^a	Competitive bidding areas	; 18	32 (Cincinnati)	4 (Charlotte, Kansas City)
	Comparator areas	0%	17% (San Diego)	4% (Oklahoma City)

Source: GAO analysis of Medicare claims data.

^aThere are duplicate suppliers included in the number of supplier totals. For example, the same supplier may have submitted Medicare charges in more than one competitive bidding area or comparator area; the supplier is counted in each area in which it had a Medicare allowed charge.

The total Medicare allowed charges for the same time period also decreased for all nine competitive bidding areas and all nine comparator areas. (See app. II.) The average decrease for the competitive bidding areas was 28 percent, and 7 percent for the comparator areas. (See table 5.) There were three competitive bidding areas with the highest total charge decrease of 32 percent, including for example, the Cincinnati area's charges that decreased about \$4.2 million from third quarter 2010 (\$12.9 million) to third quarter 2012 (\$8.7 million). The Orlando competitive bidding area had the lowest percentage decrease change— 22 percent—a decrease in total charge of about \$3.3 million. Among the comparator areas, the highest total charge decrease was San Diego— 15 percent—a decrease of about \$2 million (from \$13.7 million to \$11.6 million), while Virginia Beach had the lowest decrease— 0.1 percent—or \$17,077 (from \$12,603,542 to \$12,586,465).

 Table 5: Percentage Decrease in Total Medicare Allowed Charges Comparing Round 1 Rebid Competitive Bidding Areas and

 Their Comparator Areas, Third Quarter 2010 to Third Quarter 2012

	٦	Fotal Medicare Allowed Charges	
Round 1 rebid areas	Average percentage decrease	Highest percentage decrease	Lowest percentage decrease
Competitive bidding areas	28%	32% (Cincinnati, Miami, Riverside)	22% (Orlando)
Comparator areas	7%	15% (San Diego)	.1% (Virginia Beach)

Source: GAO analysis of Medicare claims data.

Concluding Observations	The CBP round 1 rebid's savings for both the Medicare program and the rebid-covered beneficiaries continued in the second year, with CMS reporting total savings of more than \$400 million in the rebid's first two years due to its lower payments, decreased utilization, and lower beneficiary coinsurance. In the rebid's second year, beneficiary utilization of CBP-covered DME items continued to decrease—more in the rebid's competitive bidding areas than the comparator areas. CMS's monitoring activities, however, did not indicate beneficiary access issues. As we reported in 2012, we do not assume that all pre-CBP utilization was appropriate, and CBP may be continuing to reduce unnecessary utilization. CMS's fraud prevention efforts may also be affecting DME utilization.
	Continued monitoring of CBP experience is important to determine the full effects it may have on Medicare beneficiaries and DME suppliers. It will be important to determine whether the DME utilization trends in the round 1 rebid's first two years are similar to those in CBP's other rounds. With the CBP's 3-year round 1 rebid complete, the CBP's 2013 round 2 expansion into an additional 100 competitive bidding areas, the 2013 implementation of the national mail-order diabetic testing supplies program, and the 2013 selection of the new contract suppliers in the original nine areas for the next 3-year contracts beginning in 2014, significant new data will soon be available to further assess the impact of the program.
Agency Comments and Our Evaluation	HHS reviewed a draft of this report and provided written comments which are reprinted in appendix III. HHS also provided technical comments, which we incorporated as appropriate. In its general comments, HHS stated that CMS will continue monitoring the CBP to ensure Medicare beneficiaries are not adversely affected by the program, including

continuing to use its real-time claims monitoring system. The monitoring activities are important as the CBP has expanded to include 100 additional competitive bidding areas and a national mail-order program for diabetic testing supplies. HHS also 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 IV.

Kathlen M. Kny

Kathleen M. King Director, Health Care

Appendix I: Number of Suppliers in the Round 1 Rebid Competitive Bidding Areas and Their Comparator Areas; 2010 and 2012

	Number of suppliers with \$2,500 or more in Medicare allowed charges per quarter					Numbei Mec	of suppli	iers with \$100,00 wed charges pe	0 or more in r quarter
cc	ound 1 rebid ompetitive bidding area id its comparator area	Third quarter 2010	Third quarter 2012	Difference between third quarter 2010 and third quarter 2012	Percentage change in number of suppliers	Third quarter 2010	Third quarter 2012	Difference between third quarter 2010 and third quarter 2012	Percentage change in number of suppliers
1	Charlotte	301	218	83 fewer	28% decrease	28	27	1 fewer	4% decrease
	Virginia Beach comparator	236	239	3 more	1 increase	29	29	Same	0 no change
2	Cincinnati	284	230	54 fewer	19 decrease	34	23	11 fewer	32 decrease
	Indianapolis comparator	337	349	12 more	4 increase	23	20	3 fewer	13 decrease
3	Cleveland	292	202	90 fewer	31 decrease	32	28	4 fewer	13 decrease
	Columbus comparator	269	279	10 more	4 increase	19	21	2 more	11 increase
4	Dallas	551	404	147 fewer	27 decrease	86	67	19 fewer	22 decrease
	Houston comparator	523	465	58 fewer	11 decrease	60	66	6 more	10 increase
5	Kansas City	251	182	69 fewer	27 decrease	24	23	1 fewer	4 decrease
	Oklahoma City comparator	266	248	18 fewer	7 decrease	27	26	1 fewer	4 decrease
6	Miami	700	473	227 fewer	32 decrease	74	57	17 fewer	23 decrease
	Tampa comparator	457	405	52 fewer	11 decrease	44	46	2 more	5 increase
7	Orlando	316	229	87 fewer	28 decrease	30	29	1 fewer	3 decrease
	Jacksonville comparator	287	268	19 fewer	7 decrease	28	30	2 more	7 increase
8	Pittsburgh	222	168	54 fewer	24 decrease	28	20	8 fewer	29 decrease
	Detroit comparator	637	584	53 fewer	8 decrease	79	80	1 more	1 increase

				liers with \$2,500 wed charges pe		Number of suppliers with \$100,000 or more in Medicare allowed charges per quarter			
Round 1 rebid competitive bidding area and its comparator area		Third quarter 2010	Third quarter 2012		Percentage change in number of suppliers	Third quarter 2010	Third quarter 2012	Difference between third quarter 2010 and third quarter 2012	Percentage change in number of suppliers
9	Riverside	414	286	128 fewer	31 decrease	35	24	11 fewer	31 decrease
	San Diego comparator	289	271	18 fewer	6% decrease	35	29	6 fewer	17% decrease

Source: GAO analysis of Medicare claims data.

Notes: For this analysis, we compared the number of suppliers with Medicare allowed charges in the 18 areas using the allowed charge data for the third quarter 2010—the most recent quarter before the round 1 rebid contract suppliers were announced in November 2010, and for the third quarter 2012 in the round 1 rebid's second year. The suppliers included had at least one allowed charge for a beneficiary residing in any of the 9 round 1 rebid areas and their 9 comparator areas for any Medicare DMEPOS fee-for-service Healthcare Common Procedure Coding System (HCPCS) codes, excluding the prosthetic and orthotic codes as this category generally represents more individualized items needing to be fitted to a beneficiary, and including the parenteral—intravenous nutrition—codes.

Appendix II: Medicare Allowed Charges for Round 1 Rebid Competitive Bidding Areas and Their Comparator Areas; 2010 and 2012

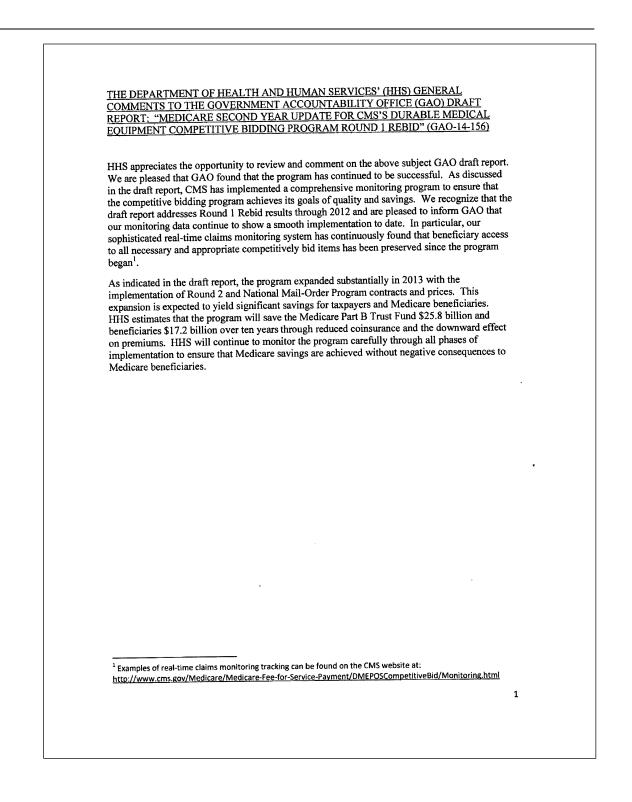
	und 1 rebid competitive bidding as and their comparator areas	Third quarter 2010	Third quarter 2012	Decreases from third quarter 2010 compared to third quarter 2012	Percentage decreases from third quarter 2010 compared to third quarter 2012
1	Charlotte	\$15,148,336	\$11,373,360	\$3,774,976	25%
	Virginia Beach comparator	12,603,542	12,586,465	17,077	.1
2	Cincinnati	12,899,494	8,714,392	4,185,102	32
	Indianapolis comparator	13,625,894	12,714,630	911,264	7
3	Cleveland	16,429,149	12,186,145	4,243,004	26
	Columbus comparator	10,021,862	9,845,307	176,555	2
4	Dallas	38,387,712	28,002,782	10,384,930	27
	Houston comparator	27,728,595	26,370,487	1,358,108	5
5	Kansas City	13,851,306	10,648,079	3,203,227	23
	Oklahoma City comparator	11,239,073	10,280,836	958,237	9
6	Miami	35,765,663	24,399,299	11,366,364	32
	Tampa comparator	21,147,496	19,582,931	1,564,565	7
7	Orlando	15,202,738	11,868,894	3,333,844	22
	Jacksonville comparator	12,278,514	11,482,182	796,332	6
8	Pittsburgh	11,305, 345	7,973,134	3,332,211	29
	Detroit comparator	41,510,133	37,106,154	4,403,979	11
9	Riverside	18,332,526	12,412,464	5,920,062	32
	San Diego comparator	\$13,756,963	\$11,686,078	\$2,070,885	15%

Source: GAO analysis of Medicare claims data.

Notes: For this analysis, we compared the number of suppliers with Medicare allowed charges in the 18 areas using the allowed charge data for the third quarter 2010—the most recent quarter before the round 1 rebid contract suppliers were announced in November 2010, and for the third quarter 2012 in the round 1 rebid's second year. The suppliers included had at least one allowed charge for a beneficiary residing in any of the 9 round 1 rebid areas and their 9 comparator areas for any Medicare DMEPOS fee-for-service Healthcare Common Procedure Coding System (HCPCS) codes, excluding the prosthetic and orthotic codes as this category generally represents more individualized items needing to be fitted to a beneficiary, and including the parenteral—intravenous nutrition—codes.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES	OFFICE OF THE SECRETARY
2	Assistant Secretary for Legislation Washington, DC 20201
FEB 2 0 2014	
hleen King ector, Health Care	
Government Accountability Office G Street NW	
shington, DC 20548	
r Ms. King: ached are comments on the U.S. Government Accour edicare: Second Year Update for CMS's Durable M gram Round 1 Rebid" (GAO-14-156).	ntability Office's (GAO) report entitled, edical Equipment Competitive Bidding
Department appreciates the opportunity to review the	his report prior to publication.
Sincerely,	
U JIII K. ESU	uca Secretary for Legislation
achment	



Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact	Kathleen M. King, (202) 512-7114 or kingk@gao.gov
Staff Acknowledgments	In addition to the contact named above, key contributors to this report were Martin T. Gahart, Assistant Director; Yesook Merrill, Assistant Director; Todd Anderson; Dan Lee; Drew Long; Michelle Paluga; Hemi Tewarson; and Opal Winebrenner.

Related GAO Products

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.

Medicare: The First Year of the Durable Medical Equipment Competitive Bidding Program Round 1 Rebid. GAO-12-733T. Washington, D.C.: May 9, 2012.

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

Medicare: CMS Has Addressed Some Implementation Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program for the Round 1 Rebid. GAO-10-1057T. Washington, D.C.: Sept. 15, 2010.

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.

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

Medicare: Competitive Bidding for Medical Equipment and Supplies Could Reduce Program Payments, but Adequate Oversight Is Critical. GAO-08-767T. Washington, D.C.: May 6, 2008.

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

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

Medicare Durable Medical Equipment: Class III Devices Do Not Warrant a Distinct Annual Payment Update. GAO-06-62. Washington, D.C.: March 1, 2006.

Medicare: More Effective Screening and Stronger Enrollment Standards Needed for Medical Equipment Suppliers. GAO-05-656. Washington, D.C.: Sept. 22, 2005. *Medicare: CMS's Program Safeguards Did Not Deter Growth in Spending for Power Wheelchairs.* GAO-05-43. Washington, D.C.: Nov. 17, 2004.

Medicare: Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies. GAO-04-765. Washington, D.C.: Sept. 7, 2004.

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

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