United States Government Accountability Office

Report to Congressional Requesters

September 2016

MEDICARE

CMS's Round 2 Durable Medical Equipment and National Mail-order Diabetes Testing Supplies Competitive Bidding Programs

Accessible Version

GAO-16-570

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GAO Highlights

Highlights of GAO-16-570, a report to congressional requesters

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, such as wheelchairs and oxygen, in phases, or rounds. Round 1 started in 2008, and round 2 and the national mail-order program started in 2013. CMS estimated that the first 2 years of round 2 and the national mail-order program saved Medicare approximately $3.6 billion. GAO has reported on several prior CBP rounds.

GAO was asked to continue to review the implementation of the CBP. In this report, GAO examines the extent to which round 2 and the national mail-order program have affected (1) utilization of CBP-covered DME items, and (2) beneficiaries' access to DME items. This report also (3) describes the number and market shares of the round 2 and mail-order program suppliers.

To examine the effect of CBP on utilization, GAO used Medicare DME claims data from 2012 and 2014—the year before and the year after implementation of round 2—to compare the number of beneficiaries who received CBP-covered DME items. To examine the effect of CBP on beneficiary access, GAO reviewed information about CMS's efforts to monitor the effects of the CBP, and interviewed selected Medicare beneficiary organizations and state hospital associations. To describe the supplier markets, GAO analyzed 2014 Medicare claims data, the latest year with complete available data when GAO began this engagement.

View GAO-16-570. For more information, contact Kathleen M. King at (202) 512-7114 or kingk@gao.gov.

What GAO Found

The number of beneficiaries receiving durable medical equipment (DME) items covered under the competitive bidding program (CBP) generally decreased after implementation of two CBP phases that began July 1, 2013—round 2 and the national mail-order program for diabetes testing supplies. Under the CBP, (administered by the Centers for Medicare & Medicaid Services (CMS)), only competitively selected contract suppliers can furnish certain DME items at competitively determined prices to beneficiaries in designated competitive bidding areas. From the year before (2012) to the year after (2014) implementation, the number of beneficiaries receiving covered items in round 2 areas decreased 17 percent, compared with a 6 percent decrease for beneficiaries in non-CBP areas. The number of beneficiaries that received diabetes testing supplies through the national mail-order program also decreased 39 percent between 2012 and 2014, with a corresponding 13 percent increase in the number of beneficiaries receiving these items through retail outlets. CMS officials stated that CBP has helped limit fraud and abuse and may have curbed unnecessary utilization of some CBP-covered items in competitive bidding areas.

CMS reports that available evidence from the agency's monitoring efforts indicates that the implementation of round 2 and the national mail-order program have had no widespread effects on beneficiary access. In particular, CMS has reported that its health status monitoring tool has not detected any changes in health measures attributable to the CBP, and the results of its 2014 post-CBP beneficiary satisfaction surveys remained positive. In addition, the number of CBP inquiries and complaints generally decreased throughout the first 2 years of round 2 and the national mail-order program. CMS officials told GAO that CMS took measures to ensure that contract suppliers met their contract obligations, such as investigating complaints using secret shopping calls, and terminating contracts of suppliers that remained noncompliant after receiving targeted education. However, some beneficiary advocacy groups and state hospital associations reported specific access issues, such as difficulty locating contract suppliers that will furnish certain items and delays in delivery of DME items.

Round 2 and the national mail-order program included 801 separate competitive bidding area and product category competitions. Most of these competitions had at least five active contract suppliers in 2014. However, 11 percent of the competitions had three or fewer active contract suppliers and 1 percent had just one active contract supplier. In addition, while multiple suppliers had substantial shares of the market for most competitions, in some competitions a single supplier had a majority. For example, in 6 percent of the competitions, one contract supplier had at least 90 percent of the market. Conversely, 11 percent of contract suppliers did not furnish any CBP-covered items for any competitions in their contract. CMS officials told GAO that CMS monitors these suppliers to help ensure that they are meeting their contractual obligations, such as being willing to service all beneficiaries in their areas and to furnish the same items to Medicare beneficiaries that they make available to other customers.

The Department of Health and Human Services provided technical comments on a draft of this report, which were incorporated as appropriate.

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Abbreviations

CBP	competitive bidding program
CMS	Centers for Medicare & Medicaid Services
CPAP	continuous positive airway pressure
DME	durable medical equipment
FFS	fee-for-service
HCPCS	Healthcare Common Procedure Coding System
HHS	Department of Health and Human Services
MIPPA	Medicare Improvements for Patients and Providers Act of 2008
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003

NPWT	negative pressure wound therapy

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September 15, 2016

The Honorable Kevin Brady
Chairman
Committee on Ways and Means
House of Representatives

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

Medicare, a federal health insurance program administered by the Centers for Medicare & Medicaid Services (CMS), within the Department of Health and Human Services (HHS), spent $6.7 billion in 2015 on fee-for-service (FFS) payments for durable medical equipment (DME), including prosthetics, orthotics, and related supplies for beneficiaries.[1] Most Medicare beneficiaries enroll in Medicare Part B, which helps pay for DME items, such as oxygen, wheelchairs, hospital beds, and walkers, if they are medically necessary and prescribed by a physician. Medicare beneficiaries typically obtain DME items from suppliers, who then submit claims for payment to Medicare on behalf of beneficiaries.

[1]The amount that Medicare paid for DME in 2015 is for Medicare Part B FFS payments and does not include Medicare Advantage. In addition, it does not include the additional 20 percent coinsurance that beneficiaries are responsible for paying to suppliers or any additional payments that beneficiaries may have made to suppliers that do not accept assignment. Suppliers who accept assignment must accept the Medicare-approved payment amount and may not charge beneficiaries more than any unmet deductible and 20 percent coinsurance. For this report, the term DME item refers to durable medical equipment, prosthetics, orthotics, and supplies. Durable medical equipment 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, enteral nutrition, 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.

Historically, Medicare paid for DME items by using a fee schedule generally based on what suppliers charged for the items and services during the 1980s, and these amounts were increased annually. However, both we and the HHS Office of Inspector General reported that Medicare and its beneficiaries sometimes paid higher than market rates for various DME items, and there were long-standing concerns about the high rates of improper payments related to DME.[2] To achieve savings and address improper payment concerns, Congress, through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), directed that CMS change the way it pays for DME and other items by implementing a competitive bidding program (CBP).[3] The CBP changed a long-standing policy that any qualified provider could enroll in Medicare and furnish DME items to instead having CMS conduct a competitive process to select suppliers eligible to provide certain DME product categories to Medicare beneficiaries in designated competitive bidding areas.[4] The CBP also based DME payments on competitive bids, rather than on the fee schedule. DME suppliers that win competitions, called contract suppliers, are awarded contracts based on their bid amounts and are paid at the competitively determined payments for CBP-covered DME items.[5] These payments, referred to as single payment amounts, are

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

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

[4]A product category is a group of related items used to treat a similar medical condition. A competitive bidding area is either a metropolitan statistical area or a part thereof. The CBP does not apply to beneficiaries enrolled in Medicare Advantage plans, which are operated by private companies. These beneficiaries obtain DME items through their Medicare Advantage plans.

[5]Competitions are held for each combination of a single product category and competitive bidding area.

calculated for each DME item included in the CBP and must be equal to or lower than Medicare's traditional FFS payments for the same items.[6]

CMS and its competitive bidding implementation contractor, Palmetto GBA, have implemented the CBP in several phases—referred to as CBP rounds or programs. The first phase, round 1, initially included 10 competitive bidding areas, but following the termination of round 1, it was subsequently rebid in 9 of the 10 same areas.[7] Round 2 began July 1, 2013, and expanded the CBP to an additional 100 competitive bidding areas for 8 product categories. At the same time, CMS also began another phase of the CBP, called the national mail-order program, which included diabetes testing supplies received through mail-order. CMS also announced that it will implement additional phases of the CBP in 2016 and 2017. In addition, beginning January 1, 2016, as required by law, CMS began using CBP rates to adjust FFS payments in areas where CBP had not been implemented.[8]

According to CMS, the competitive bidding process has produced savings through lower payment rates and has decreased unnecessary utilization. Specifically, CMS estimated that the first 2 years of round 2 and the national mail-order program (July 1, 2013-June 30, 2015) saved Medicare approximately $3.6 billion. CMS reported that round 2 single payment amounts were, on average, 45 percent less than Medicare's current FFS payments, and the national mail-order program payments for diabetes

[6]FFS payments are adjusted for each state, reflecting the geographic price differences that are subject to national floor and ceiling payment limits.

[7]Beginning in 2007, CMS conducted the first phase of competitive bidding, referred to as CBP round 1, in 10 competitive bidding areas for 10 product categories and awarded contracts to suppliers that were effective July 1, 2008. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) terminated the contracts awarded during CBP round 1 on July 15, 2008, and required CMS to repeat the competition, referred to as the round 1 rebid. Pub. L. No. 110-275, § 154(a)(1), 122 Stat. 2494, 2560-63 (2008) (codified, as amended, at 42. U.S.C. § 1395w-3). In 2009, CMS began the CBP round 1 rebid process and awarded contracts in 9 of the same competitive bidding areas for most of the same items included in round 1. In anticipation of the expiration of the round 1 rebid contracts, in 2012 CMS held a new competition for CBP contracts for the same 9 competitive bidding areas as the round 1 rebid, referred to as the round 1 recompete, which included 6 product categories.

[8]On December 28, 2015, the Patient Access and Medicare Protection Act delayed for 1 year the application of adjusted fee schedule rates based on CBP rates in non-CBP areas for wheelchair accessories furnished in connection with group 3 complex rehabilitative power wheelchairs.

testing supplies were, on average, 72 percent less than the FFS payments at the time the programs began. In addition to these savings, CMS has also reported that CBP has helped limit fraud and abuse and may have curbed unnecessary utilization of some CBP-covered items in competitive bidding areas. For example, CMS reported that by bringing Medicare payments for DME items more in line with the prices paid by others, CBP-covered items are a less profitable target area for suppliers involved with fraudulent billing practices. However, some stakeholder groups have raised concerns that the lower payment rates and smaller number of suppliers in CBP have disrupted beneficiary access to quality DME items, and may have led to increased adverse health outcomes.

We previously reported that the CBP round 1 rebid was generally implemented successfully, but that it was important to continue monitoring CBP to determine effects that CBP may have on Medicare beneficiaries and DME suppliers as CMS expands the program into additional areas and product categories.[9] You asked us to continue monitoring the CBP by examining the possible effects of round 2 and the national mail-order program on beneficiaries and DME suppliers. In this report, we examine

- changes in utilization of CBP-covered DME items after the implementation of round 2 and the national mail-order program,
- the extent to which round 2 and the national mail-order program may have affected Medicare beneficiaries' access to covered DME items, and
- the number and market share of contract suppliers in round 2 and national mail-order program competitions.

To examine changes in utilization of DME items after the implementation of round 2 and the national mail-order program, we used Medicare claims data and other CMS data to calculate the percentage change in the number of beneficiaries receiving CBP-covered items and in the number of items received in 2012 and 2014—the years before and after

[9]GAO, *Medicare: Second Year Update for CMS's Durable Medical Equipment Competitive Bidding Program Round 1 Rebid,* GAO-14-156 (Washington, D.C.: Mar. 7, 2014) and GAO, *Medicare: Review of the First Year of CMS's Durable Medical Equipment Competitive Bidding Program's Round 1 Rebid,* GAO-12-693 (Washington, D.C.: May 9, 2012). For a full list of related products, see the Related GAO Products page.

implementation.[10] For the round 2 analysis, we examined changes in beneficiary utilization and how these changes varied for items across each of the 8 product categories—which included a total of 202 Healthcare Common Procedure Coding System (HCPCS) codes—and 100 areas.[11] We also compared these changes in utilization to those for items and areas not included in round 2—non-CBP items and areas.[12] For the national mail-order program analysis, we examined changes in beneficiary utilization for all 8 HCPCS codes included in the program, and whether beneficiaries received the items through mail order or a retail location.

To examine the extent to which round 2 and the national mail-order program may have affected Medicare beneficiary access to covered DME items, we analyzed CMS data from the first 2 years of implementation, July 2013 through June 2015, including both CBP inquiry data from the 1-800-MEDICARE beneficiary help line and CBP complaint data. We also examined CMS's health status monitoring tool that tracks health measures in both CBP and non-CBP areas as well as pre- and post-CBP round 2 and national mail-order program beneficiary satisfaction survey results. We interviewed CMS and CBP contractor officials, and CMS's Competitive Acquisition Ombudsman. In addition, we also interviewed five beneficiary advocacy groups representing Medicare beneficiaries that may have specific conditions requiring DME items, such as diabetes and disabilities requiring wheelchairs.[13] Specifically, we asked about their experiences with CBP round 2 and the national mail-order program and the extent to which their members had reported issues related to access and choice of DME items. We also contacted four state hospital

[10]We used 2014 Medicare claims data because it was the latest year with complete available data when we began this engagement.

[11]Suppliers use HCPCS codes to submit claims for Medicare payments. HCPCS codes identify a category of like items, for example, walkers, which 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.

[12]The non-CBP comparisons excluded items and areas covered under the round 1 rebid or round 1 recompete.

[13]We spoke with individuals representing the American Association of Diabetes Educators, the American Diabetes Association, the Center for Medicare Advocacy, the Medicare Rights Center, and the United Spinal Association.

associations from states with several competitive bidding areas.[14] These associations provided us contact information to speak with stakeholders such as referral agents, discharge planners, case managers, and other staff who assist CBP-covered beneficiaries in obtaining DME items. In response to concerns raised by some stakeholders we contacted, we also reviewed the national average length of stay in hospitals for beneficiaries who underwent a hip or knee replacement.[15] We selected hip or knee replacements because beneficiaries would likely need DME items following this surgery and because CMS reported it was the most frequently occurring FFS discharge code in the year that round 2 was implemented. We reviewed the length of stay for those beneficiaries who both did and did not receive a DME item between one day before and after the date of discharge from the hospital in 2014 as compared to 2012 in both CBP and non-CBP areas.

To examine the number and market shares of contract suppliers in round 2 and national mail-order program competitions, we used 2014 Medicare claims data, the latest year with complete available data when we began this engagement, and a list of contract suppliers from CMS.[16] We defined a contract supplier as active in a given market during 2014 if it furnished at least one item in that competition and defined a contract supplier's market share as its Medicare allowed charges in a competition as a percentage of the total charges in that competition across all suppliers (including non-contract suppliers).[17] For each competition, we calculated

[14]We spoke with individuals representing the California Hospital Association, the Florida Hospital Association, the Healthcare Association of New York State, and the Illinois Hospital Association.

[15]We identified beneficiaries who underwent a hip or knee replacement as those with a claim for diagnosis related group 470, which is defined as a major joint replacement or reattachment of lower extremity without major complication or comorbidity.

[16]There were 801 such competitions: eight product categories in 100 round 2 areas, plus the national competition for diabetes testing supplies. In general, a contract supplier enters into a single contract with CMS for the relevant CBP round, which covers all of the competitions that were awarded to and accepted by the contract supplier.

[17]We defined a contract supplier by using the unique contract number assigned by CMS to each distinct bidding supplier to ensure that we captured all Medicare total allowed charges submitted by a contract supplier that may have been doing business in several locations under different registered names or national provider identifier numbers. However, some claims could not be uniquely matched to a single contract supplier; charges for these claims were included in the total charges for a competition but were not assigned to a contract supplier.

the market share of the top contract supplier, which is a measure of the extent to which the market is competitive. We also examined the extent to which this measure varied by product category. Additionally, we calculated each contract supplier's market shares across all competitions included in its contract, as well as the number of suppliers that did not furnish any items in one or more of the competitions included in their contract.

We assessed the reliability of Medicare claims data, which we obtained from CMS's 100 Percent Standard Analytic Files, by reviewing existing information about the data and the systems that produced them, performing appropriate electronic data checks, and interviewing CMS officials. To assess the reliability of the data we received from CMS and Palmetto GBA, we reviewed relevant documentation, performed electronic data checks, and interviewed CMS officials. We determined that these data were sufficiently reliable for the purposes of this report.

We conducted this performance audit from June 2015 to September 2016 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

CBP Contract Supplier Bidding and Award Process

CMS and Palmetto GBA administer and implement the CBP and its bidding phases. In each CBP bidding phase, suppliers that want to participate in the CBP may submit a bid in one or more product categories in one or more designated competitive bidding areas. To be offered a CBP contract, suppliers must be qualified, meaning they have met general Medicare enrollment and quality standards as well as CBP's financial and applicable licensing standards; be eligible to bill Medicare

for DME items; have a DME surety bond; and be accredited and licensed.[18]

After CMS and Palmetto GBA review qualified suppliers' bids, the bids are ordered by lowest to highest price, and CMS then makes offers to all those needed to meet or exceed CMS's estimated beneficiary demand who submitted the lowest prices.[19] If a bidding supplier accepts an offer to furnish a specific product category in a specific competitive bidding area, it must agree to furnish all of the items included in the product category to all eligible Medicare beneficiaries residing in the competitive bidding area at the applicable single payment amounts. Because the single payment amount is the median of the winning bid price offers for each DME item in a product category for each competitive bidding area, the payment can be less or more than a particular winning supplier's actual bid for an item. Furthermore, because each competitive bidding area and product category combination is a separate competition, the same DME item may have a different single payment amount in each area. For example, the round 2 single payment amounts for a new foam rubber mattress ranged between $111.38 in the Palm Bay and Deltona, Florida, competitive bidding areas to $178.62 in the Honolulu, Hawaii, competitive bidding area. Contracts are generally awarded for 3 years and can include one or many competitions. While generally only contract suppliers that accepted a contract for a given product category and competitive bidding area are eligible to furnish those items, there are circumstances in which suppliers not awarded a CBP contract—referred to as non-contract suppliers—may be grandfathered to continue to furnish some CBP-covered items to

[18]For 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).

[19]For detailed information on how bids are ordered, see GAO, *Medicare: Bidding Results from CMS's Durable Medical Equipment Competitive Bidding Program*, GAO-15-63 (Washington, D.C.: Nov. 7, 2014).

certain beneficiaries for a limited time.[20] In addition, physicians, treating practitioners, and hospitals can furnish walkers, folding manual wheelchairs, or external infusion pumps to their own patients as part of their professional services or during hospital admission or discharge without a CBP contract.

When offering contracts, CMS takes steps that it believes will ensure beneficiary access and choice. For example, CMS's goal is to award at least five contracts for each product category and competitive bidding area competition.[21] To help meet this goal, CMS caps the estimated projected capacity of any single supplier at 20 percent of the total projected beneficiary demand for each product category, in each competitive bidding area, regardless of the capacity estimated by the supplier in its bid submission.[22] CMS also tries to ensure that small suppliers are awarded CBP contracts by setting a target that 30 percent

[20]Grandfathered suppliers are suppliers that were not awarded a CBP contract but chose to continue to furnish certain CBP-covered rental items, such as hospital beds or walkers, or oxygen and oxygen equipment, to beneficiaries who were their customers when the CBP round began, 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 generally can no longer provide the CBP-covered items and services to the beneficiary. The exception is grandfathered oxygen suppliers: if they furnish oxygen supplies for 36 months, they must continue to furnish the equipment for any period of medical need during the remainder of remaining reasonable useful lifetime of the equipment.

[21]If there are fewer than five suppliers with qualified bids, CMS must award contracts to at least two suppliers if the suppliers have sufficient capacity to satisfy beneficiary demand in the product category in the competitive bidding area. If there are not at least two eligible qualified suppliers to satisfy beneficiary demand in each product category and competitive bidding area competition, CMS considers that competition to be nonviable.

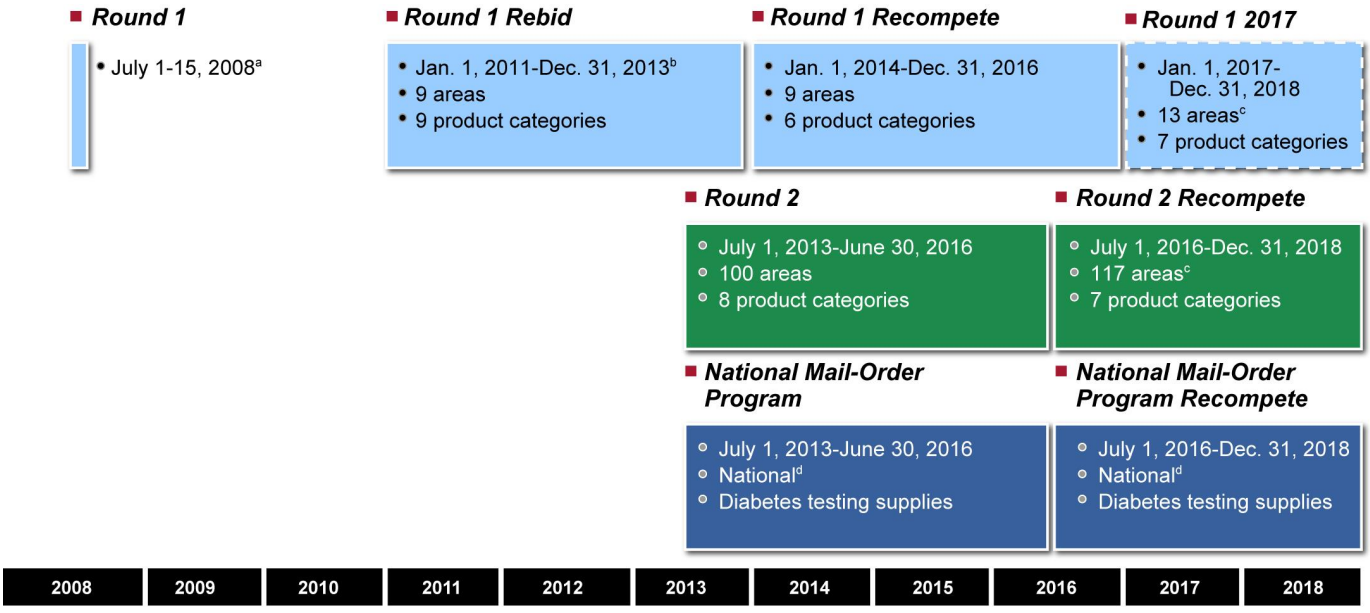
[22]Although CMS caps a supplier's projected capacity to 20 percent, if awarded a CBP contract, suppliers may furnish more than 20 percent of the beneficiary demand in a product category and competitive bidding area competition because CMS does not limit the number of items a supplier can furnish. According to CMS officials, a supplier may furnish less than 20 percent of the beneficiary demand in a product category and competitive bidding area competition because contract suppliers are not guaranteed a minimum amount of business. Contract suppliers will compete among themselves for Medicare beneficiaries' business on factors such as quality and customer service.

of the qualified suppliers awarded a contract in each product category and competitive bidding area competition are small.[23]

Phase-In of the CBP

CMS is required by the MMA to conduct a new CBP phase at least once every 3 years, and begins the bid submission and award process for the new contracts before the current contracts expire. Beginning with the first round of CBP in 2008, CMS and Palmetto GBA have continued to phase-in CBP through additional rounds and programs. (See fig. 1 for a timeline summarizing the phase-in of the CBP and app. II for additional information about the CBP phases.)

Figure 1: Phase-In of the Durable Medical Equipment (DME) Competitive Bidding Program (CBP)



Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-16-570

[a]The Medicare Improvements for Patients and Providers Act of 2008 was enacted on July 15, 2008. This legislation stopped round 1 contracts 2 weeks after they became effective, terminated single

[23]For CBP, CMS defined a small supplier as one that generates gross revenue of $3.5 million or less in annual receipts, including both Medicare and non-Medicare revenue. In instances when the small supplier target is not initially met, CMS may award contracts to additional suppliers after CMS has determined the number of suppliers needed to meet or exceed CMS's estimated beneficiary demand.

payment amounts, and required the Centers for Medicare & Medicaid Services (CMS) to repeat the competition in 2009. Pub. L. No. 110-275 § 154(a)(1), 122 Stat. 2494, 2560-63 (2008) (codified, as amended, at 42 U.S.C. § 1395w-3).

[b]The round 1 rebid included a mail-order diabetes testing supplies product category, but unlike the other product categories for which contracts were awarded for a period of 3 years, the mail-order product category had a 2-year contract period (January 1, 2011, through December 31, 2012). Beginning July 1, 2013, the national mail-order program began with contracts awarded for a 3-year period (July 1, 2013, through June 30, 2016).

[c]CMS redefined areas for both the round 1 2017 and the round 2 recompete so that each round covers the same areas that were included in earlier related rounds, but each competitive bidding area is only in one state.

[d]The national mail-order program and national mail-order program recompete include all parts of the United States, including all 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa.

Number of Contract Suppliers and Product Categories in Round 2

As of October 2015, there were 822 round 2 contract suppliers—520 of which were small suppliers—to furnish DME items and services in eight product categories and 100 competitive bidding areas.[24] (See table 1 for a list of round 2 product categories and app. I for a list of the 100 competitive bidding areas.) Contracts were effective beginning July 1, 2013, and expired June 30, 2016.

[24]CMS awarded round 2 contracts to a total of 822 suppliers. On April 9, 2013, CMS announced that 799 suppliers were awarded round 2 contracts. However, according to CMS officials, between April 9, 2013, and July 1, 2013, several contract offers were rejected, and CMS offered an additional 19 contracts to meet beneficiary demand and/or the small supplier target. After July 1, 2013, CMS officials told us they offered an additional 3 contracts to suppliers that were found to have had bids disqualified incorrectly, and 1 contract was separated into 2 separate contracts, which resulted in 1 additional contract.

Table 1: Number of Items Included in Each of the Eight Round 2 Competitive Bidding Program Product Categories

Product category	Covered HCPCS[a]
Standard (power and manual) wheelchairs, scooters, and related accessories	101
Hospital beds and related accessories	26
Continuous positive airway pressure (CPAP) devices, respiratory assist devices, and related supplies and accessories	23
Enteral nutrients, equipment, and supplies	17
Walkers and related accessories	14
Oxygen supplies and equipment	13
Support surfaces (group 2 mattresses and overlays)	5
Negative pressure wound therapy (NPWT) pumps and related supplies and accessories[b]	3
Total	**202**

Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-16-570

[a]Suppliers 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 items, for example, walkers, but can encompass a broad range of items that serve the same general purpose but vary in price and characteristics.

[b]NPWT pumps apply controlled negative or subatmospheric pressure to treat ulcers or wounds that have not responded to traditional wound treatment methods.

National Mail-Order Program Contract Suppliers and Covered Items

There were 19 national mail-order contract suppliers as of October 2015—6 of which were small suppliers—to furnish the eight mail-order diabetes testing supply HCPCS codes included in the national mail-order program.[25] Contracts were effective beginning July 1, 2013, and expired June 30, 2016. The program operates in the 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa, and includes the same eight mail-order diabetes testing supply HCPCS codes as the round 1 rebid. For this round and future national mail-order program rounds, a supplier's diabetes testing supply bid must demonstrate that the supplier's bid would cover at least 50 percent, by

[25]CMS awarded national mail-order contracts to a total of 19 suppliers. On April 9, 2013, CMS announced that 18 suppliers were awarded national mail-order contracts. According to CMS officials, between April 9, 2013, and July 1, 2013, CMS offered an additional 2 contracts in order to meet beneficiary demand, 1 of which was accepted. Seven of the 19 national mail-order program contract suppliers are also round 2 contract suppliers; therefore, there is a total of 834 contract suppliers in the two CBP phases that began July 1, 2013.

sales volume, of all types of diabetes test strips on the market. Medicare payments for items included in the national mail-order program are the same regardless of whether they are furnished via mail order or by retail, though out-of-pocket costs for beneficiaries may be higher when they receive these supplies through retail outlets.[26]

Sources for CBP-Related Beneficiary 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, questions, or complaints.

- **Medicare Supplier Directory**. To locate a CBP contract supplier, beneficiaries can use the CMS online supplier directory tool on CMS's Medicare website. The Medicare Supplier Directory contains the 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 to CMS each quarter regarding the specific brands of items they plan to furnish in the upcoming quarter, and CMS uses this information to update the supplier directory tool.

- **1-800-MEDICARE inquiries**. CMS directs beneficiaries to call its 1-800-MEDICARE beneficiary help line for assistance with CBP-related questions. Customer service representatives are trained to assist CBP beneficiaries and use several scripts to respond to questions and assist beneficiaries in locating contract suppliers. If a beneficiary's inquiry cannot be addressed by the customer service representatives,

[26]During the round 1 rebid, items covered under the mail-order diabetes testing supplies product category were paid at single payment amounts if delivered by mail, but were paid at the traditional FFS payments if purchased at retail outlets. However, the American Taxpayer Relief Act of 2012 stipulated that diabetes testing supplies included in the national mail-order program be paid at the single payment amounts, regardless of whether they are furnished by mail order or non-mail-order. Pub. L. No. 112-240, § 636, 126 Stat. 2313, 2356 (2013). National mail-order contract suppliers must accept assignment, which means that they must accept the Medicare-approved single payment amount and are not allowed to charge beneficiaries more than any unmet deductible and 20 percent coinsurance. Retail stores can choose to either accept or not accept assignment. If they do not accept, they may charge an amount that is higher than any unmet deductible and 20 percent coinsurance, although according to CMS, this is rare. CMS encourages beneficiaries seeking items from retail stores to first ask whether the stores accept assignment.

the inquiry is forwarded to an advanced-level customer service representative, who researches and responds to the beneficiary's inquiry.

- **Palmetto GBA and CMS regional offices**. Palmetto GBA provides CBP-related information and updates through its website and works with CMS regional office staff to monitor CBP activities and provide educational outreach.

- **Competitive Acquisition Ombudsman**. The Competitive Acquisition Ombudsman 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.

CMS's CBP-related Monitoring Activities

CMS has implemented several activities to monitor whether beneficiary access or satisfaction have been affected by the implementation of CBP and to ensure that contract suppliers are meeting their contract obligations.

- **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 customer service representative and are elevated to another entity, such as Palmetto GBA, CMS's regional offices, or the Competitive Acquisition Ombudsman for resolution.

- **Secret shopping calls**. According to CMS officials, CMS utilizes shopping calls, in which Palmetto GBA representatives pose as referral agents or family members acting on behalf of beneficiaries and call contract suppliers to request items, such as specific diabetes testing supplies, to determine whether the suppliers offer the supplies covered under their contracts. Some calls are conducted on a random basis and are intended to reach contract suppliers from across all product categories and competitive bidding areas, while others are directed at particular suppliers. According to CMS officials, the agency uses both random and targeted calls to monitor contract suppliers that have not billed for items included in their contracts over a period of time. In addition, CMS officials said that a third type of secret shopping call, focused calls, is used to investigate specific complaints and verify contract supplier compliance with contract requirements after any necessary education to the supplier(s) is provided.

According to CMS, if contract suppliers remain noncompliant following education, the agency will start the contract termination process.

- **Beneficiary satisfaction surveys**. CMS conducted both pre- and post-round 2 and national mail-order program surveys to measure beneficiary satisfaction with CBP. The round 2 pre-implementation survey was conducted January 3 through March 18, 2013, and the post-implementation survey was conducted from March 5 through April 10, 2014. The national mail-order program pre-implementation survey was conducted April 10 through April 24, 2013, and the post-implementation survey was conducted April 17 through April 27, 2014.
- **Health Status Monitoring Tool**. CMS analyzes Medicare claims data to monitor health measures, including encounters with the health care system (such as hospitalizations, emergency room visits, and physician visits) and one outcome (death) for beneficiaries in both CBP-covered areas and non-CBP areas for both round 2 and the national mail-order program. CMS posts quarterly reports on its website to show historical and regional trends in health measures for specific groups of beneficiaries.

Number of Beneficiaries Receiving CBP-covered Items Generally Decreased after Implementation of Round 2 and the National Mail-Order Program

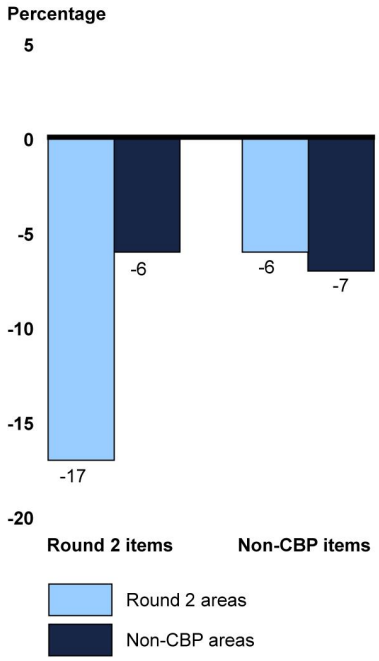
The number of beneficiaries receiving DME items covered under CBP round 2 generally decreased after the implementation of round 2, and these utilization decreases generally were larger than the decreases for items or areas that were not included in CBP. The number of beneficiaries receiving diabetes testing supplies covered under the national mail-order program also generally decreased after the implementation of the program, although there was an increase in the utilization of some items through retail outlets.

Number of Beneficiaries Receiving CBP-Covered Items Generally Decreased after Implementation of Round 2,

with Larger Decreases Than Those for Items and Areas Not in CBP

The number of beneficiaries receiving at least one DME item included in CBP round 2 decreased after the implementation of round 2, and these decreases were larger than those for items or areas that were not included in CBP. That is, the decrease was largest among items and areas for which CMS established competitively set rates beginning in July 2013. Specifically, the percentage decrease in the number of beneficiaries receiving at least one round 2 DME item between 2012 and 2014 was 17 percent. In contrast, the decreases in utilization were 6 to 7 percent for the same items in non-CBP areas and for non-CBP items. (See fig. 2.)

Figure 2: Percentage Change from 2012 to 2014 in Number of Beneficiaries Receiving Durable Medical Equipment (DME) Items, by Whether Item or Area Was Included in Competitive Bidding Program (CBP) Round 2



Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-16-570

Numerous factors could have contributed to the decrease in the number of beneficiaries receiving DME, and the decreases do not necessarily indicate that beneficiaries did not receive needed DME. Some stakeholders have expressed concern that lower payment rates and a smaller number of suppliers may have caused some beneficiaries to not

receive needed DME. However, CMS stated that CBP has helped limit fraud and abuse and may have curbed unnecessary utilization of some CBP-covered items in competitive bidding areas.[27] Additionally, in recent years CMS began implementing several broader antifraud efforts that were not limited to CBP-covered items or areas, such as taking additional steps to identify aberrant or suspicious billing patterns among all Medicare FFS claims before making payments, and implementing new safeguards to better screen existing and new Medicare suppliers.[28]

Looking at each of the eight product categories individually, the number of beneficiaries receiving covered items generally decreased after implementation of round 2, and these decreases were generally larger than those for the same items in non-CBP areas. Specifically, utilization of seven of the eight round 2 product categories decreased between 2012 and 2014, with decreases that were larger than in non-CBP areas for six of these seven categories. While there was substantial variation in the magnitude of the decrease in beneficiaries receiving these items, the percentage decreases in the number of beneficiaries receiving items and in the number of items received were generally similar, indicating that the average number of items beneficiaries received was relatively constant. Continuous positive airway pressure (CPAP) was the only product category for which the number of beneficiaries receiving items increased between 2012 and 2014, as well as the category with the largest

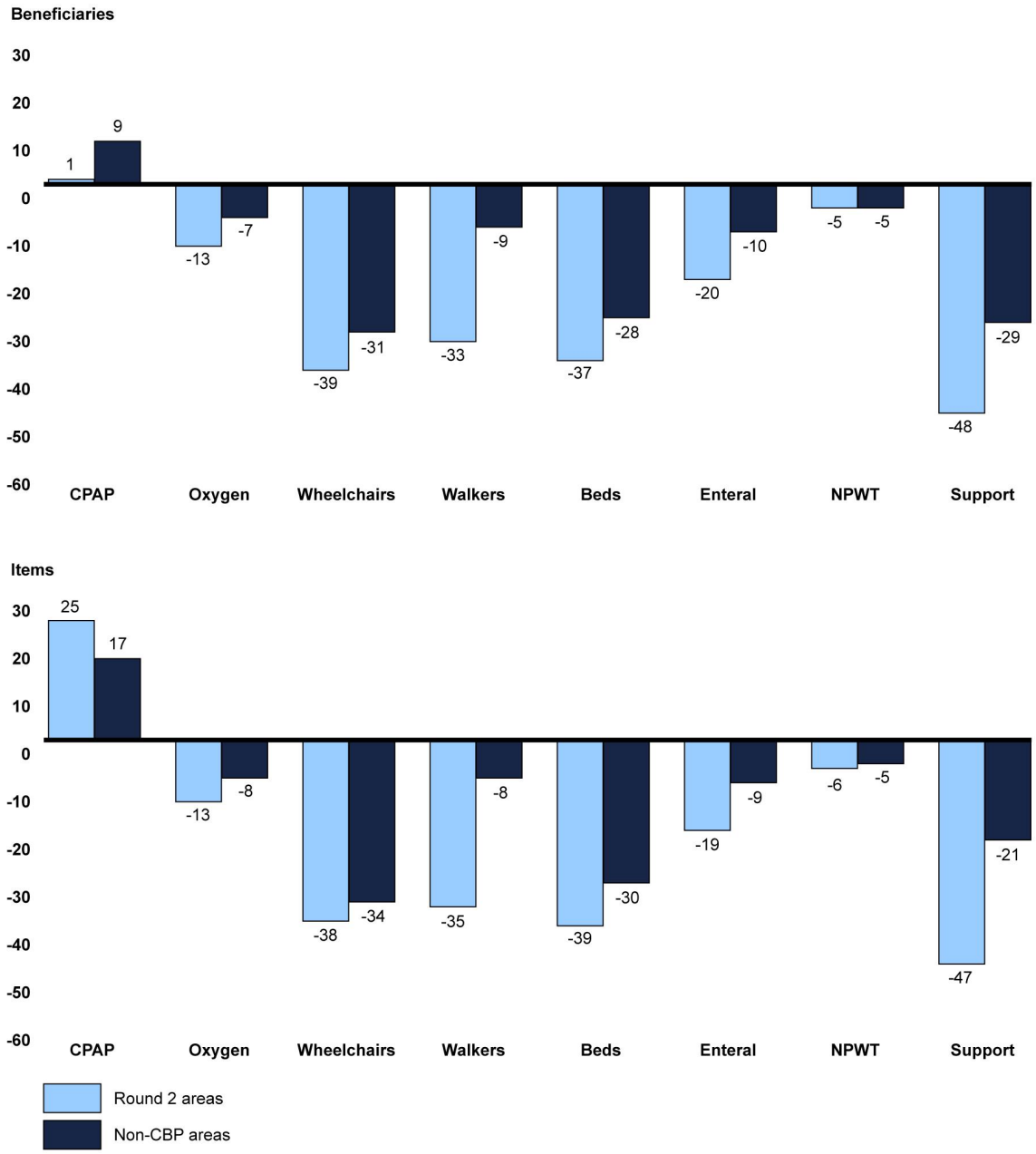
[27]CMS defines "unnecessary utilization" as the furnishing of items that do not comply with one or more of Medicare's coverage, coding, and payment rules, as applicable. Under Section 1834(a)(15) of the Social Security Act, the Secretary of Health and Human Services has the authority to develop and periodically update a list of DME items that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization and to develop a prior authorization process for these items. On December 30, 2015, CMS issued a final rule that included a list of 135 DME items that were identified as being frequently subject to unnecessary utilization and developed a prior authorization process for these items that began February 29, 2016. Several of the items on the list are included in a CBP round. 80 Fed. Reg. 81,674 (Dec. 30, 2015).

[28]According to CMS, between 2011 and May 2016 CMS deactivated billing privileges for more than 543,100 providers and suppliers that did not meet Medicare requirements and revoked the enrollment and billing privileges of an additional 34,800 providers and suppliers.

difference between the percentage change in beneficiaries and in items.[29] (See fig. 3.)

[29]According to CMS, the agency reviews both the usage of CPAP devices and related accessories as part of its health status monitoring. CMS also identified an increase in the usage of CPAP items in all areas, but did not analyze reasons for the increase in utilization.

Figure 3: Percentage Change from 2012 to 2014 in Number of Beneficiaries Receiving Competitive Bidding Program (CBP) Round 2 Durable Medical Equipment (DME) Items and in Number of Items Received



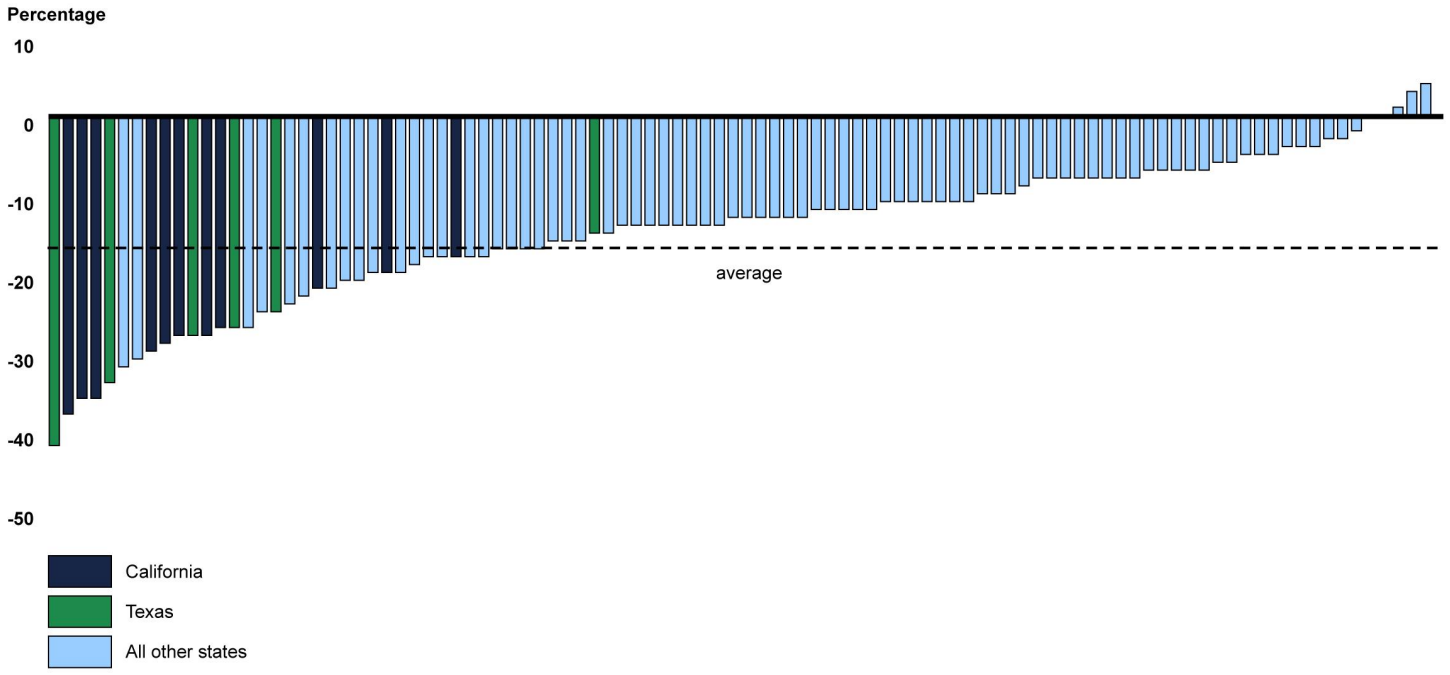
Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-16-570

Note: The eight round 2 product categories are listed in order of the number of beneficiaries receiving these supplies in round 2 areas during 2012, which ranged from about 570,000 beneficiaries receiving continuous positive airway pressure (CPAP) items to fewer than 20,000 receiving support

surface items. The percentage changes for negative pressure wound therapy (NPWT) and wheelchairs include the utilization of accessories that may have been used with items not covered under round 2, as CMS data did not include the modifiers needed to identify the type of item the accessory was used with in non-CBP areas. Enteral refers to enteral nutrients, equipment, and supplies, which are used to provide food through a tube placed in the stomach or small intestine.

Similarly, almost all round 2 areas experienced a decrease in the number of beneficiaries receiving CBP round 2 items after the implementation of round 2, though the magnitude of the decrease varied. Specifically, 95 of the 100 round 2 areas experienced a decrease between 2012 and 2014 in the number of beneficiaries receiving CBP round 2 items, ranging from 2 to 42 percent. Of the 15 areas with the largest percentage decreases in the number of beneficiaries receiving these items, 12 were in California and Texas. Nine of these 12 areas also had the largest relative decreases in the number of beneficiaries receiving round 2 items compared with the number receiving non-CBP-covered DME items. CMS officials told us that the relatively large decreases in California and Texas attributed to the implementation of CBP round 2 were likely because these states historically had high rates of potential fraud and abuse. (See fig. 4.)

Figure 4: Percentage Change from 2012 to 2014 in Number of Beneficiaries Receiving Competitive Bidding Program (CBP) Durable Medical Equipment (DME) Round 2 Items, by Round 2 Area



Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-16-570

Note: The CBP round 2 areas with the largest percentage decrease in the number of beneficiaries receiving round 2 items were McAllen-Edinburg-Mission, TX (-42 percent) and Bakersfield-Delano,

CA (-38 percent). The areas with the largest percentage increase were Wichita, KS (4 percent) and Palm Bay-Melbourne-Titusville, FL (3 percent).

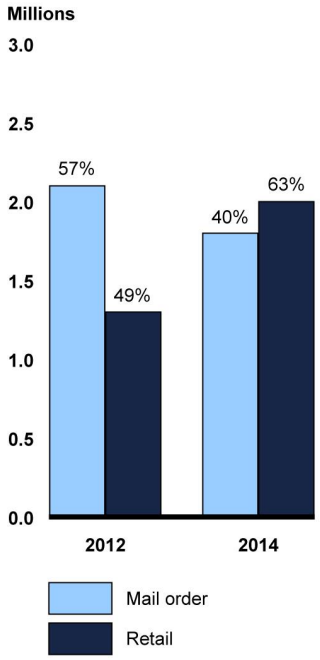
Number of Beneficiaries Receiving National Mail-Order Program Items Generally Decreased after Implementation, Though Utilization Increased for Some Items Acquired through Retail Outlets

The total number of beneficiaries receiving at least one diabetes testing supply item covered under the national mail-order program decreased after implementation of the program, although there was an increase in the number of beneficiaries receiving some of these items through retail outlets. Specifically, there was an overall 12 percent decrease between 2012 and 2014 in the number of beneficiaries receiving at least one diabetes testing supply item through any acquisition method. However, during the same time period there was a 39 percent decrease in the number of beneficiaries receiving these items through mail order and a 13 percent increase in the number of beneficiaries receiving these items through retail outlets such as stores or pharmacies. The net result was a switch from a majority of beneficiaries (57 percent) receiving these supplies through mail order in 2012 to a majority receiving supplies through retail in 2014 (63 percent).[30] (See fig. 5.) These utilization results were driven by changes in the two most commonly received items covered under the national mail-order program: diabetes test strips and lancets.[31] For the other six covered diabetes testing supplies, the number of beneficiaries receiving these items through retail outlets decreased.

[30]When analyzing beneficiaries' acquisition of diabetes testing supplies between 2012 and 2014, we found that some beneficiaries who received them in 2012 no longer received them in 2014, and this percentage was similar for both mail order and retail outlets. For the remaining beneficiaries who received strips in 2012 only through mail order, about 19 percent switched to receiving strips only through retail in 2014. Conversely, only 6 percent of beneficiaries switched from retail to mail order.

[31]For both strips and lancets, beneficiaries who received these items through mail order received 1.5 to 2 times more items than those who received them through retail outlets. CMS officials told us they have not compared the usage of mail-order test strips versus retail test strips, but that CMS's previous analysis indicated that beneficiaries commonly receive automated refills of mail-order test strips and regularly had overlapping claims for mail-order test strips.

Figure 5: Number and Percentage of Beneficiaries Receiving Diabetes Testing Supplies Covered under the National Mail-Order Program in 2012 and 2014, by Acquisition Method



Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-16-570

Note: The percentages of beneficiaries receiving diabetes testing supplies through mail order and through retail sum to over 100 percent as some beneficiaries received supplies through both methods during a single year.

Although CMS officials said that they could not speculate about reasons for this switch, a diabetes advocacy group we interviewed speculated that beneficiaries may have decided to switch to retail because they had difficulty finding contract suppliers that would provide the specific brand of

test strips they requested.[32] The use of retail outlets could result in higher out-of-pocket payments for beneficiaries because unlike mail-order contract suppliers, retail outlets are not required to accept assignment for diabetes testing supplies covered under the national mail-order program.

CMS Reports That Available Evidence Indicates No Widespread Effects of Round 2 and the National Mail-Order Program on Beneficiary Access

Based on its monitoring of health measures, CMS reported that the implementation of the CBP has not resulted in widespread beneficiary access issues. The number of round 2 and national mail-order program inquiries and complaints to 1-800-MEDICARE generally decreased throughout the first 2 years of the programs' implementation. CMS told us that it investigates complaints using secret shopping calls and that its post-implementation beneficiary satisfaction surveys remained positive. Nevertheless, several stakeholder groups we interviewed reported specific concerns such as delays in delivery of CBP-covered DME items and beneficiaries having difficulty locating a contract supplier.

[32]The CBP includes a special beneficiary safeguard intended to ensure that beneficiaries have access to specific brands or modes of delivery of competitively bid items when needed to avoid an adverse medical outcome. This process is sometimes referred to as the physician authorization process. Under the physician authorization process, when a physician or treating practitioner prescribes a particular brand or mode of delivery for a beneficiary to avoid an adverse medical outcome, the contract supplier must, as a term of its contract, ensure that the beneficiary receives the needed item. When submitting bids to participate in the national mail-order program, suppliers must demonstrate that their bids cover at least 50 percent, by volume, of all types of diabetes testing strips on the market (referred to as the "50 percent rule"). This may include brands that bidding suppliers intend to furnish only on a limited basis in order to comply with the physician authorization process. In these cases, although the supplier does not intend to furnish a significant quantity of these brands, the brands would still be counted in determining whether the supplier is in compliance with the 50 percent rule. Federal regulations generally prohibit contract suppliers of diabetes testing supplies from influencing or incentivizing beneficiaries to switch their current glucose monitor and testing supplies brand to another brand. See 42 C.F.R. § 422(e)(3) (2015).

CMS's Health Status Monitoring Indicates the CBP Has Not Affected Health Measures

CMS reported that its health status monitoring tool showed similar trends in health measures in both CBP and non-CBP areas, both before and after the implementation of round 2. CMS has reported no changes in health measures attributable to the implementation of any CBP round since the agency began monitoring measures in 2011, which CMS officials told us is an indication that the CBP has not caused widespread problems with beneficiary access. Officials told us that CMS investigated aberrant trends in health measures identified by the monitoring tool and concluded that all such trends were the result of issues unrelated to CBP. For example, CMS officials told us that they investigated an increased mortality rate in one competitive bidding area and concluded it was due to an influenza outbreak. Similarly, they found that other issues resulted from changes in DME policy not specific to CBP, such as new requirements regarding prior authorization for wheelchairs.

CMS's health status monitoring tool uses Medicare claims data to track seven health measures—deaths, hospitalizations, emergency room visits, physician visits, admissions to skilled nursing facilities, average number of days spent hospitalized in a month, and average number of days in a skilled nursing facility in a month. CMS monitors these health measures for three groups of Medicare FFS beneficiaries residing in both CBP and non-CBP areas: (1) all beneficiaries enrolled in FFS, (2) beneficiaries likely to use one of the competitively bid products on the basis of related health conditions, and (3) beneficiaries for whom Medicare has paid a claim for one of the competitively bid products. CMS's tool considers historical and regional trends in health status to monitor health measures in all CBP and non-CBP areas. CMS publishes aggregated results for four U.S. geographic regions quarterly on its website.[33] CMS uses the tool to review Medicare claims data on a bi-weekly basis. According to a monitoring tool user guide that CMS provided us, the tool uses a statistical scoring algorithm to identify potential changes in health measures in every competition. The goal of the scoring algorithm is to

[33]See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Monitoring.html for more information about CMS's health status monitoring tool (accessed on May 20, 2016).

identify persistent aberrant trends in health measures in individual competitive bidding area and product category competitions that are not mirrored in other regions. These aberrant trends can then be investigated further, through steps such as beneficiary and supplier outreach and contract compliance reviews.[34]

Based on our analysis, CMS's methodologies and scoring algorithm used to evaluate health measure trends among CBP areas appear to be sound. However, we did not examine individual investigations that CMS conducted to assess aberrant changes in trends in particular competitive bidding areas and product categories and whether these trends could be attributed to CBP.

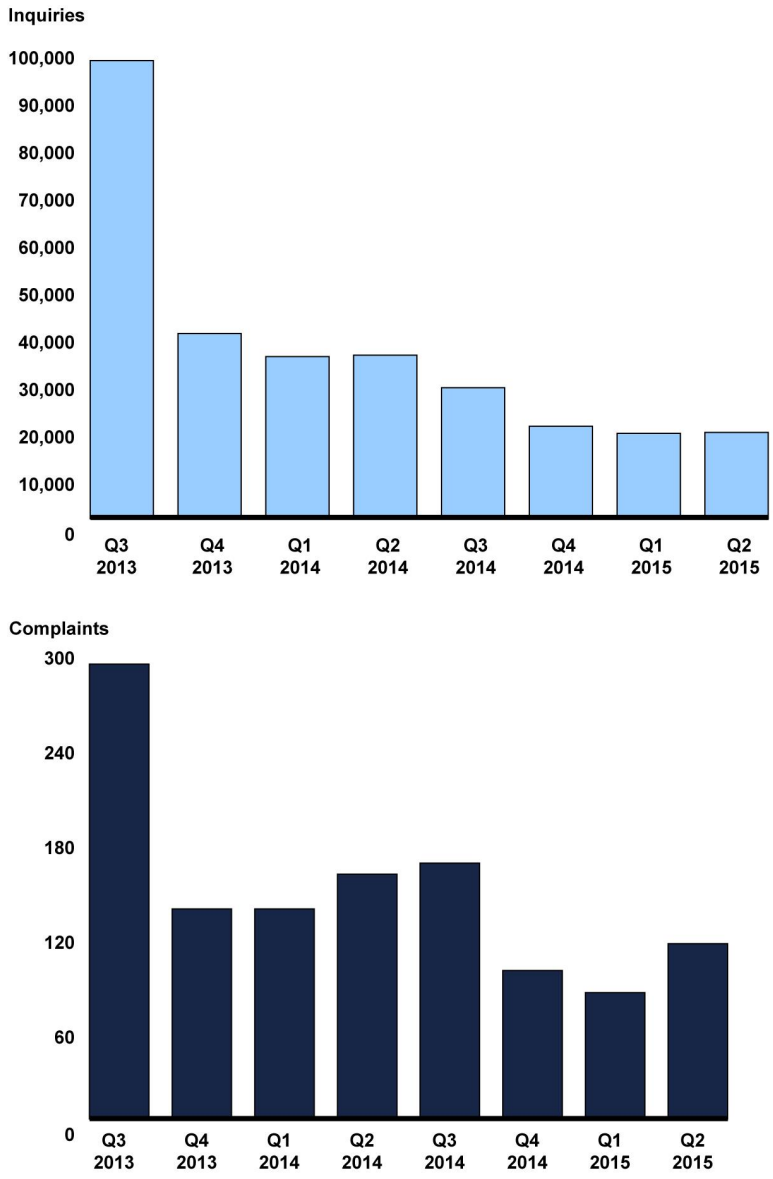
Number of Round 2 and National Mail-Order Program Inquiries and Complaints to 1-800-MEDICARE Generally Decreased throughout the First 2 Years

The number of inquiries and complaints to 1-800-MEDICARE regarding CBP round 2 or the national mail-order program represented less than 1 percent of all calls to 1-800-MEDICARE, and inquiries and complaints generally decreased throughout the programs' first 2 years of implementation. During the first quarter of implementation (July 1, 2013, to September 30, 2013), 1-800-MEDICARE received almost 100,000 inquiries—including almost 300 complaints—related to CBP round 2 or the national mail-order program. However, the number of inquiries and complaints dropped sharply during the second quarter of implementation,

[34]To calculate a competitive bidding area's score for a given health measure and population, the tool first calculates the rate of the health measure in the competitive bidding area over a 2-month period and compares that to the rate in the prior 2 months. The algorithm then compares this competitive bidding area rate change to the corresponding rate change among all round 2 areas in the same region, and calculates the difference between the two rate changes. Last, CMS compares this difference-in-difference to the historical distribution of the same measure prior to the implementation of round 2, and calculates the number of standard deviations away from the historical average and the current difference-in-difference. By default, the tool flags all scores for current trends that are more than three standard deviations away from the historical trends. However, CMS staff can set different score thresholds and can change the scoring window to identify shorter- and longer-term trends. CMS recognizes that there are limitations with this algorithm. For example, the monitoring tool user guide notes that, because the tool uses contiguous months of data, seasonal trends could lead to temporarily high scores, and because processing of Medicare claims has a lag time, the scoring algorithm excludes the two most recent months of the study window.

and then generally continued to decrease slowly or remained relatively consistent over subsequent quarters. (See fig. 6.)

Figure 6: Number of Round 2 and National Mail-Order Program Inquiries and Complaints to 1-800-MEDICARE during First 2 Years of Implementation



Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-16-570

Notes: Each bar represents one quarter of the corresponding calendar year. For example, Q3 2013 refers to July 1, 2013, to September 30, 2013, which was the first quarter of implementation for round 2 and the national mail-order program.

The Centers for Medicare & Medicaid Services (CMS) classifies all Competitive Bidding Program (CBP) calls to 1-800-MEDICARE as CBP inquiries. CMS defines a CBP complaint as a CBP inquiry that cannot be resolved by any 1-800-MEDICARE customer service representative and is sent to another entity, such as Palmetto GBA, for resolution.

After implementation of the CBP, CMS began to track CBP-related inquiries to 1-800-MEDICARE and to classify them as either general CBP inquiries, such as requests for general information, or assistance determining whether a beneficiary resided in a competitive bidding area and whether the inquiries were about a specific product category. The highest number of general CBP inquiries occurred in the first quarter after implementation—61,457—which decreased to 8,741 by the last quarter of the 2-year period. The number of category-specific inquiries for each product category generally decreased from the first quarter to the last quarter. The mail-order diabetes testing supplies product category had the highest number of specific inquiries during the first quarter—15,953—which fell to 1,610 inquiries in the last quarter. The standard wheelchairs product category had the next-highest number of inquiries during the first quarter—6,438—which fell to 2,967 inquiries in the last quarter.

The total number of complaints was small compared to the total number of inquiries. However, the number of complaints may not fully capture the number of people who expressed problems or dissatisfaction with the CBP program, because CMS defines a complaint as an inquiry to 1-800-MEDICARE that needs to be referred to an outside entity for resolution, such as Palmetto GBA. The 1,156 complaints recorded in the first 2 years occurred across multiple round 2 product categories, rather than being concentrated in a few specific categories. The complaints varied, but included complaints that contract suppliers refused to serve beneficiaries residing in their competitive bidding areas or had provided poor customer service, that beneficiaries had experienced delays in receiving DME or had received the wrong DME, and that beneficiaries had difficulty obtaining specific brands and models of DME items that had been prescribed by their physicians.[35] For example, Palmetto GBA received several complaints indicating that contract suppliers refused to provide the U-Step walker, a specific brand of walker, furnished under a specific

[35]Under 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 that 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.

HCPCS code.[36] According to CMS, U-Step walkers are infrequently prescribed, and Palmetto GBA worked with beneficiaries on a case-by-case basis to obtain them from contract suppliers. CMS told us that in every instance in which Palmetto GBA intervened, Palmetto GBA was able to locate a contract supplier to provide the item for each beneficiary with a prescription for the U-Step walker.[37]

CMS Investigates CBP Complaints Using Secret Shopping Calls, and Terminates Contracts of Suppliers That Remain Noncompliant after Targeted Education

CMS officials told us that the agency monitors contract suppliers to ensure that they are complying with the terms of their contracts, such as servicing all beneficiaries that reside in their competitive bidding areas and furnishing the same items to Medicare beneficiaries that they make available to other customers. Officials told us that when CMS receives complaints regarding contract suppliers' noncompliance with contract terms, CMS may contact the supplier and/or beneficiary to obtain information necessary for investigation and may also work with other CMS contractors or deploy secret shopper calls, if deemed appropriate to do so. CMS told us that the reason for the secret shopping call helps the agency determine the strategy chosen—that is, whether it is appropriate to conduct the secret shopping calls with one or multiple supplier locations, or with multiple contract suppliers for particular competitive bidding areas or product category competitions. According to CMS, Palmetto GBA may conduct dozens or hundreds of focused secret shopping calls to investigate a single complaint to thoroughly investigate an allegation or verify contract supplier compliance. CMS told us that

[36]The specific HCPCS 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.

[37]We previously reported that Palmetto GBA received several complaints about HCPCS code E0147 during the second year of the round 1 rebid. Some complainants reported that contract suppliers would not provide the specific walker brand and model prescribed by beneficiaries' physicians because it is expensive and the CBP single payment amount was lower than the cost of the item. See GAO-14-156. Although E0147 is included in the upcoming round 1 2017 (with contracts effective beginning January 1, 2017), on March 15, 2016, CMS announced that it had excluded E0147 from the round 2 recompete (with contracts effective beginning July 1, 2016).

during secret shopping calls, Palmetto GBA representatives may pose as referral agents on behalf of beneficiaries and request items, such as specific diabetes testing supplies from contract suppliers, to determine whether the suppliers offer the supplies they claim to furnish.[38] According to CMS, if those calls find that the contract supplier refused to provide DME items according to the terms of its CBP contract, Palmetto GBA describes the results of the call to the supplier's representative and sends an educational letter reiterating contract obligations. Officials said that for a contract supplier who remains noncompliant, CMS sends a letter terminating the supplier's CBP contract, and suppliers can submit a corrective action plan, accept the termination, or request a hearing.

According to CMS, between July 2013 and June 2015, Palmetto GBA made a total of 3,953 focused secret shopping calls related to round 2 complaints and a total of 254 focused secret shopping calls related to the national mail-order program. CMS officials told us that as a result of those secret shopping calls, the agency issued 43 termination notices to contract suppliers during this time frame. Of those, 37 contract suppliers came into compliance and 6 suppliers' contracts were terminated.

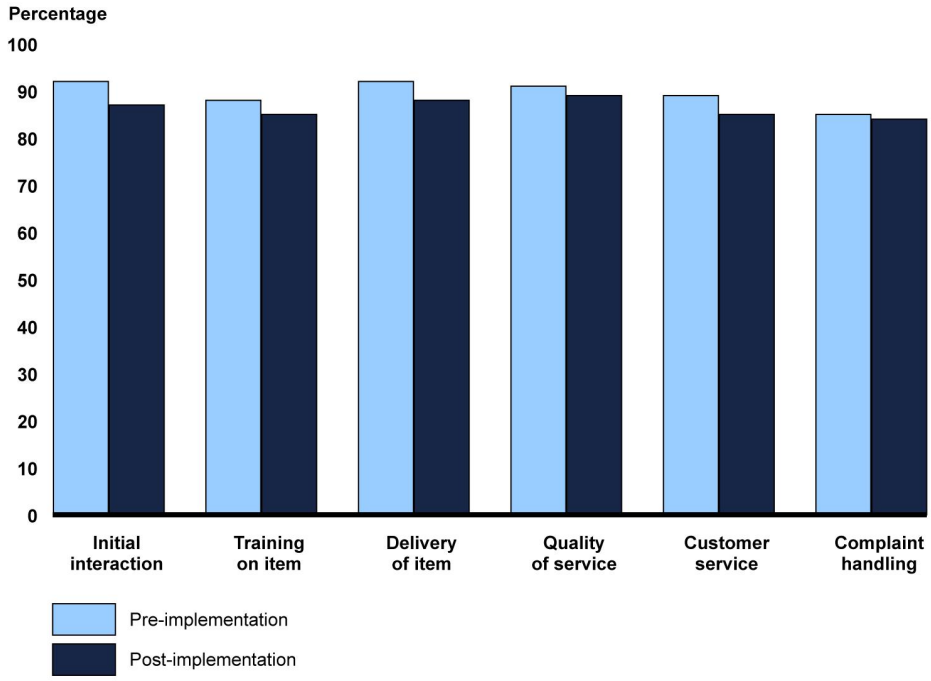
CMS's Post-Implementation Beneficiary Satisfaction Survey Results Remained Positive

CMS reported that its pre- and post-CBP implementation beneficiary satisfaction surveys found that the majority of respondents rated their experiences positively in both time periods. For both the pre- and post-implementation surveys, CMS obtained telephone responses from a random sample of approximately 400 beneficiaries in each of the 100 competitive bidding areas who received at least one CBP-covered DME item. The surveys asked beneficiaries to record their satisfaction ratings on a five-point scale for six questions: the beneficiary's initial interaction with DME suppliers, the training received regarding the DME item, the delivery of the DME item, the quality of the item provided by the supplier, the customer service provided by the supplier, and the supplier's overall

[38]Contract suppliers are required to submit a Form C each quarter that describes information about items they plan to furnish for each competition included in 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 directory tool on the Medicare website is updated with Form C product information within 30 days after the Form C submission deadline.

complaint handling. In both the pre- and post-implementation surveys, a majority of the beneficiaries who responded to each of the six questions rated their experiences as either “good” or “very good,” although there were slightly fewer positive responses in the post-implementation survey. The percentage of positive responses after implementation decreased for each question, ranging between 85 and 92 percent for pre-implementation questions, and between 84 and 89 percent for the same questions post-implementation. (See fig. 7.)

Figure 7: Competitive Bidding Program Round 2 Pre- and Post-Implementation Beneficiary Satisfaction Survey Results

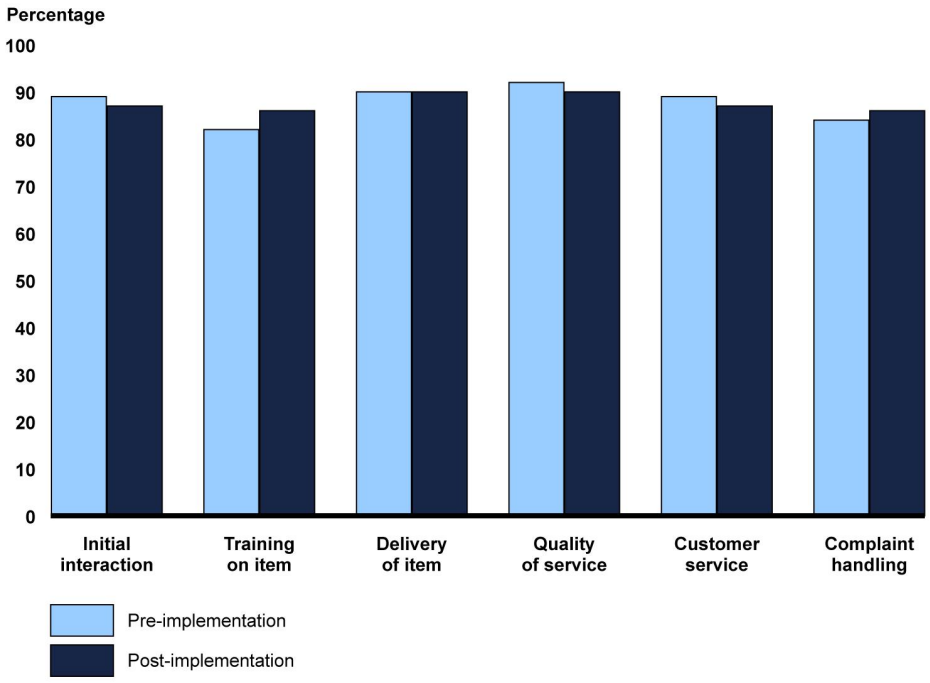


Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-16-570

CMS also conducted pre- and post-implementation surveys for the national mail-order program using the same methodology. Those surveys also found that post-implementation satisfaction levels remained high. CMS obtained responses from a random sample of 2,086 beneficiaries for the 2013 pre-implementation survey and 2,000 for the 2014 post-implementation survey. For each of the six questions in both surveys, results indicated that between 82 and 92 percent of beneficiaries surveyed rated their experiences as either “good” or “very good,” although

the exact percentage decreased slightly for some questions and increased slightly for others. (See fig. 8.)

Figure 8: National Mail-Order Program Pre- and Post-Implementation Beneficiary Satisfaction Survey Results



Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-16-570

As we reported previously, CMS's survey design has some limitations.[39] For example, the survey design did not capture responses from beneficiaries who may have needed, but did not obtain, DME during the period. That is, if a beneficiary did not receive a DME item, the beneficiary's response regarding his or her potential access issue to the DME item would not be included in the survey. Additionally, the distribution of beneficiaries who received items across the different product categories could have changed between the pre- and post-implementation surveys, and the results were not analyzed separately by product category.

[39]See GAO-12-693.

Some Stakeholders Reported Specific Beneficiary Access Concerns

The stakeholders we interviewed reported varied experiences with CBP and the national mail-order program. Some stakeholders reported that they had no beneficiary access issues following the implementation of round 2 and the national mail-order program and others reported numerous beneficiary access concerns. In general, stakeholders from one of the five beneficiary advocacy groups and one of four state hospital associations (California, Florida, Illinois, and New York) reported no or very few specific concerns with CBP beneficiary access. However, stakeholders from four beneficiary advocacy groups reported that their members experienced several access issues with the implementation of CBP round 2 and the national mail-order program. These issues included delays in delivery of CBP-covered DME items, such as walkers, and trouble locating contract suppliers to provide specific DME items, such as liquid oxygen and specific brands of diabetes testing strips, or to repair wheelchairs. In addition, discharge planners and other stakeholders from three state hospital associations reported that beneficiaries also experienced delays in delivery of CBP-covered items, such as walkers and wheelchairs, and had difficulty locating contract suppliers to provide oxygen or service DME items when the beneficiaries were visiting in a competitive bidding area but resided elsewhere.

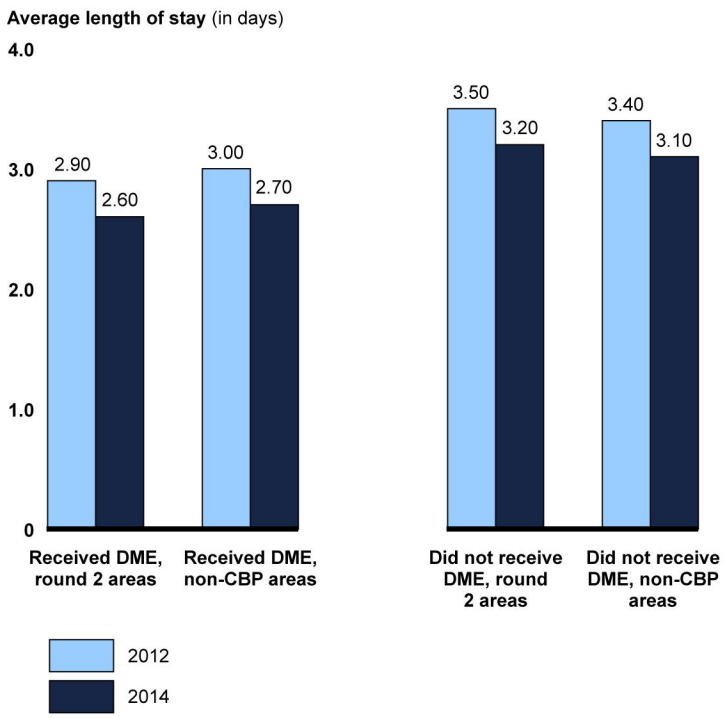
Discharge planners and referral agents from the Florida and California hospital associations told us that the delays in delivery of needed DME resulted in an increase in the length of hospital stays for some beneficiaries. For example, individuals we spoke with from the Florida Hospital Association told us that prior to CBP, DME suppliers typically delivered DME within 24 hours of the request, 7 days a week. However, since CBP round 2 was implemented, contract suppliers in Florida's competitive bidding areas no longer delivered on weekends and also delivered only during certain hours Monday through Friday. The planners and agents from the Florida Hospital Association told us that delays in delivery can extend the length of beneficiaries' hospital stays when the DME is necessary prior to discharge, such as DME for orthopedic-related injuries. In some cases, they told us that the hospital loans or provides certain DME, such as walkers, in order to discharge beneficiaries on time.

As previously described, CMS's health status monitoring tool did not indicate changes in the average length of hospital stays resulting from the implementation of CBP.[40] We conducted a limited analysis to compare the length of hospital stays in 2012 (pre-CBP) and 2014 (post-CBP) for beneficiaries who had a hip or knee replacement, both nationally and in California and Florida.[41] We found that the average length of stay was slightly lower in 2014 than in 2012, both for the two selected states and nationally. This was true for both beneficiaries who received DME within a day of discharge and those who did not, within as well as outside competitive bidding areas. (See fig. 9.) This limited analysis did not indicate an increase in the average length of stay among beneficiaries as a result of the implementation of CBP, although we did not expand our analysis to determine if results were consistent across other reasons for hospitalization.

[40]CMS also told us that it conducted analyses on length of hospital stays in response to statements by representatives from a state hospital association that delays in delivery of DME have resulted in longer hospital stays. CMS reported that the average length of hospital stay for specific groups of beneficiaries was the same pre- and post-CBP. According to CMS, the base study population for these investigations included all beneficiaries enrolled in Medicare Parts A and B in any month from January 2013 through 2015 who were living in a round 2 competitive bidding area or a non-CBP area in the state in the same month. In particular, CMS officials told us they focused on beneficiaries with conditions related to the need for mobility products, including wheelchairs, walkers, and hospital beds, and also examined length of stay by diagnosis related group. Officials said they also analyzed the population of beneficiaries that utilized one of these products within 3 weeks (21 days) of being discharged from a hospital.

[41]We analyzed hip or knee replacements because beneficiaries would likely need DME following this surgery, and we chose Florida and California because representatives from the Florida and California Hospital Associations reported that delays in receiving DME have resulted in longer hospital stays. We did not conduct similar analyses for other orthopedic procedures.

Figure 9: Average Length of Hospital Stay in 2012 and 2014 among Beneficiaries Who Had a Hip or Knee Replacement



Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-16-570

Note: Medicare beneficiaries received durable medical equipment (DME) in both competitive bidding areas included in the competitive bidding program (CBP) and non-CBP areas.

Most Competitions Had Several Active Contract Suppliers, Although Some Competitions Had a Single Active Supplier or a Single Supplier with a Large Market Share

Most round 2 and national mail-order program competitions had at least five active contract suppliers in 2014, but other competitions had just one or a few active suppliers. In addition, some competitions had a single contract supplier that accounted for the majority of the market share. Eleven percent of contract suppliers were inactive during 2014 in all the competitions in which they were awarded and accepted a contract, and about half of contract suppliers were inactive in at least one of the competitions in their contract. CMS told us that it monitors the contract supplier market and has its contractor conduct secret shopping calls of

inactive suppliers on a quarterly basis to confirm that the suppliers are not in breach of their contracts.

Most Round 2 and National Mail-Order Program Competitions Had Several Active Contract Suppliers in 2014, but Others Had Just One or a Few Active Suppliers

A large majority of the possible 801 individual competitions in which a contract supplier could be awarded a contract had at least five contract suppliers that were active in 2014, which we defined as having furnished at least one covered item during 2014 in at least one of the competitive bidding areas and product category competitions in which they were awarded and accepted a contract.[42] We found that 84 percent of the competitions had at least five active contract suppliers; however, 11 percent of competitions had three or fewer active suppliers and 1 percent had just one active supplier. (See table 2.) During the bid evaluation and contract award processes, CMS tries to ensure beneficiary access and choice by awarding contracts to at least five contract suppliers in each competition. To ensure that there is sufficient capacity to satisfy beneficiary demand, CMS considers a competition with only one qualified supplier to be nonviable.[43] According to CMS officials, once contracts are awarded, contract suppliers are required to furnish items and services upon request, but are not otherwise required to furnish a certain amount of DME items as part of their contract obligations.

[42]The total 801 individual competitions includes eight round 2 product categories in each of 100 round 2 competitive bidding areas, and the single national competition for mail-order diabetes testing supplies.

[43]If a competition is declared nonviable, the DME items in the product category in that competitive bidding area would continue to be paid according to the Medicare DME fee schedule and all Medicare-enrolled DME suppliers would continue to be allowed to submit claims for those DME items in that competitive bidding area. All competitions were found to be viable for CBP round 2.

Table 2: Number and Percentage of Round 2 and National Mail-Order Program Competitions, by Number of Active Contract Suppliers in 2014

Number of active contract suppliers	Competitions		
	Number	Percentage	Cumulative percentage
21+	54	7	7
16-20	106	13	20
11-15	200	25	45
6-10	269	34	79
5	46	6	84
4	40	5	89
3	54	7	96
2	24	3	99
1	8	1	100

Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-16-570

Note: A contract supplier was defined as active in a competition during 2014 if the supplier furnished at least one covered item.

The number of active contract suppliers across the 800 round 2 competitions varied substantially by product category. The round 2 product category with the largest number of active contract suppliers was oxygen, in which 352 suppliers accounted for over $362 million in charges during 2014. Furthermore, the majority (86) of the 100 competitions for the oxygen product category had at least 11 active suppliers. In contrast, the product category with the fewest active contract suppliers was negative pressure wound therapy (NPWT), with 60 suppliers that accounted for over $48 million in charges. Over half (69) of the 100 competitions for NPWT had 4 or fewer active contract suppliers and 4 had a single active supplier. For the national mail-order program, all 19 contract suppliers were active in 2014.

Some Competitions Had a Single Supplier with a Large Market Share

While multiple suppliers had substantial shares of the market for most competitions, in some competitions a single supplier had a majority. In 72 percent of the 801 competitions, no contract supplier had more than half of the market. However, in 14 percent (113) of the competitions, a single contract supplier had at least three quarters of the market, and in 6 percent (48) of the competitions, one contract supplier had 90 percent or more of the market. (See table 3.)

Table 3: Number and Percentage of Round 2 and National Mail-Order Program Competitions, by Top Contract Supplier's Market Share in 2014

Market share of top contract supplier	Competitions		
	Number	Percentage	Cumulative percentage
< 10%	3	0	0
10% to 24%	176	22	22
25% to 49%	398	50	72
50% to 74%	111	14	86
75% to 89%	65	8	94
90% to 100%	48	6	100
Total	**801**	**100**	

Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-16-570

Market concentration varied substantially by product category. The round 2 product category with the least market concentration was wheelchairs, for which the top contract supplier had less than 25 percent of the market in 43 of the 100 total competitions. One reason for this was the relatively high market share of non-contract suppliers, as physicians and hospitals are allowed to provide folding manual wheelchairs to their patients directly in certain circumstances. In addition, other suppliers chose to be grandfathered and continued furnishing capped rental wheelchairs to beneficiaries who were their customers when CBP round 2 began.[44] For example, we found that non-contract suppliers had at least 25 percent of the market share in 56 of the 100 total wheelchair competitions. In contrast, the product category with the largest market concentration was NPWT, for which the top contract supplier had at least 90 percent of the market in 47 of the 100 competitions. NPWT was also the only round 2 product category for which non-contract suppliers accounted for less than 10 percent of market share in all 100 competitions.

In addition, some contract suppliers had a substantial proportion of the total round 2 and national mail-order program market—which was over $1 billion in 2014—as well as even higher market share for individual product categories. For example, the contract supplier with the highest market

[44]Capped rental DME items have a limited time period during which they can be rented and paid for by Medicare. Once the relevant rental periods expire or a beneficiary decides to select a contract supplier, the grandfathered supplier generally can no longer provide the CBP-covered items and services to the beneficiary.

share based on charges for CBP-covered items, Lincare, had $157 million in charges, or 13 percent of the round 2 and mail-order program market in 2014. It also had 25 percent of the oxygen market and the highest market share in three other product categories (CPAP, hospital beds, and walkers). Arriva, the contract supplier with the second highest overall market share, had $85 million in charges, or 7 percent of total 2014 charges. However, these charges were for mail-order diabetes testing supplies only; Arriva had 50 percent of the $170 million national mail-order program market.[45] Apria, the contract supplier with the third highest overall market share, had $68 million in charges, or 6 percent of the total market, and accounted for over 10 percent of the CPAP and oxygen markets. KCI, with the fourth highest market share, was only active in the NPWT category, and had $42 million in charges during 2014, which accounted for 86 percent of the NPWT market.

Eleven Percent of Suppliers Were Inactive in All Competitions in their Contracts, and Others Were Inactive in at Least One Competition or Barely Active

Eleven percent of contract suppliers (94 of 834) were inactive during 2014 in all of the competitions in their contract—that is, they did not furnish any CBP-covered items during 2014 in any of the competitive bidding areas and product categories in which they were awarded and accepted a contract. The completely inactive suppliers varied in their categories, areas, and duration of participation in CBP. The 94 completely inactive suppliers' contracts included over half of all competitions (446 of 801), and spanned all 8 round 2 product categories and 99 of the 100 round 2 areas.[46] In addition, about half of the 94 completely inactive contract suppliers stopped participating in CBP prior to the end of 2014—19 were terminated by CMS and 23 closed or otherwise voluntarily withdrew from the CBP.[47] However, the majority of completely inactive contract suppliers

[45]The retail market for diabetes testing supplies was an additional $149 million in 2014.

[46]Completely inactive suppliers' contracts included 95 of the 100 competitions for enteral nutrients, and over 80 of the competitions for oxygen, and CPAP. None of the completely inactive suppliers' contracts included the national mail-order program.

[47]In general, a contract supplier enters into a single contract with CMS for each CBP round, which covers all of competitions awarded to and accepted by the contract supplier. Accordingly, if the contract is terminated or a supplier voluntarily withdraws, the contract supplier can no longer participate in CBP as individual competitions cannot be severed from the CBP contract.

had higher composite bids than other contract suppliers. Specifically, 82 of the 94 completely inactive contract suppliers' bids (estimates of the price at which they could profitably provide those items) were above the median bid of all suppliers in the same competition, on average, and for 56 of the contract suppliers this difference was more than 10 percent. In addition, 61 of the 94 completely inactive contract suppliers were designated as small bidders by CMS, and 59 had only one or two competitions in their contract.

In 2014, an additional 39 percent of contract suppliers (324 suppliers) were inactive in at least one of the competitions in their contract, and 3 percent (28) had less than $1,000 in total Medicare charges for CBP-covered items. These partially inactive suppliers included contract suppliers that were very active in other markets. For example, Lincare, the supplier with the largest overall market share, was inactive in 144 of the 689 competitions in its contract. Similar to the completely inactive suppliers, the 28 barely active contract suppliers' contracts spanned all eight round 2 product categories and 96 of the 100 round 2 areas, and 24 of the 28 barely active contract suppliers bid above the median bid, on average.

CMS Monitors CBP Competitions, Including Making Secret Shopping Calls to Inactive Suppliers

To help ensure beneficiary access and choice, CMS officials said that CMS monitors all competitions, but applies greater focus to those where there is just one or a few active contract suppliers and assesses whether there is a need for CMS to award subsequent contract offers to existing contract suppliers.[48] CMS officials told us that the agency does not believe that having competitions with just one or a few active contract suppliers has decreased beneficiary access and choice because its routine monitoring of beneficiary access has not identified access issues. CMS also told us that the agency monitors suppliers that are inactive by having Palmetto GBA conduct secret shopping calls quarterly. According

[48]According to CMS, two suppliers that received initial contract offers to furnish hospital bed product category items on January 30, 2013, in the Honolulu, Hawaii, competitive bidding area were offered subsequent offers on March 25, 2014, to furnish standard wheelchair items in the same area. CMS stated that these offers were made in response to referral agents' complaints about time differences and distances associated with contract suppliers located on the mainland.

to CMS, most of the secret shopping calls to contract suppliers that were inactive resulted in finding that the suppliers were not in breach of contract, and in some instances, they reported that they had not received requests from beneficiaries or referral agents for CBP-covered items. However, CMS reported that Palmetto GBA found that eight inactive contract suppliers were in breach of their contracts because they were not providing items that had been requested. Of those, three contract suppliers were brought into compliance and the other five contract suppliers' contracts were terminated. In addition, CMS officials told us that the agency also works with the Competitive Acquisition Ombudsman and uses local competitive bidding liaisons to provide an on-the-ground physical presence and investigate and address any potential issues.

Agency Comments

We provided a draft of this product to HHS for comment. HHS provided technical comments, which were incorporated as appropriate.

As agreed with your offices, 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 staffs have any questions about this report, please contact me at (202) 512-7114 or kingk@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix III.

Kathleen M. King
Director, Health Care

Appendix I: The 100 Competitive Bidding Areas Included in the Centers for Medicare & Medicaid Services' Competitive Bidding Program Round 2

Table 4: The 100 Competitive Bidding Areas and Regions Included in the Centers for Medicare & Medicaid Services' Competitive Bidding Program Round 2

	Competitive bidding area	State
Midwest	Akron, OH	Ohio
	Central-Chicago Metro area	Illinois
	Columbus, OH	Ohio
	Dayton, OH	Ohio
	Detroit-Warren-Livonia, MI	Michigan
	Flint, MI	Michigan
	Grand Rapids-Wyoming, MI	Michigan
	Huntington-Ashland, WV-KY-OH	Kentucky
	Indiana-Chicago Metro area	Indiana
	Indianapolis-Carmel, IN	Indiana
	Milwaukee-Waukesha-West Allis, WI	Wisconsin
	Minneapolis-St. Paul-Bloomington, MN-WI	Minnesota
	Northern-Chicago Metro area	Illinois
	Omaha-Council Bluffs, NE-IA	Iowa
	South-West-Chicago-Metro area	Illinois
	St. Louis, MO-IL	Illinois
	Toledo, OH	Ohio
	Wichita, KS	Kansas
	Youngstown-Warren-Boardman, OH-PA	Ohio
Northeast	Albany-Schenectady-Troy, NY	New York
	Allentown-Bethlehem-Easton, PA-NJ	New Jersey
	Boston-Cambridge-Quincy, MA-NH	Massachusetts
	Bridgeport-Stamford-Norwalk, CT	Connecticut
	Bronx-Manhattan NY	New York

	Competitive bidding area	State
	Buffalo-Niagara Falls, NY	New York
	Hartford-West Hartford-East Hartford, CT	Connecticut
	New Haven-Milford, CT	Connecticut
	Nassau-Brooklyn-Queens-Richmond County Metro area	New York
	North East NY Metro area	New York
	Northern NJ Metro area	New Jersey
	Philadelphia-Camden-Wilmington, PA-NJ-DE-MD	Delaware
	Poughkeepsie-Newburgh-Middletown, NY	New York
	Providence-New Bedford-Fall River, RI-MA	Massachusetts
	Rochester, NY	New York
	Scranton-Wilkes-Barre, PA	Pennsylvania
	Southern NY Metro area	New Jersey
	Springfield, MA	Massachusetts
	Suffolk County	New York
	Syracuse, NY	New York
	Worcester, MA	Massachusetts
South	Asheville, NC	North Carolina
	Atlanta-Sandy Springs-Marietta, GA	Georgia
	Augusta-Richmond County, GA-SC	Georgia
	Austin-Round Rock-San Marcos, TX	Texas
	Baltimore-Towson, MD	Maryland
	Baton Rouge, LA	Louisiana
	Beaumont-Port Arthur, TX	Texas
	Birmingham-Hoover, AL	Alabama
	Cape Coral-Fort Myers, FL	Florida
	Charleston-North Charleston-Summerville, SC	South Carolina
	Chattanooga, TN-GA	Georgia
	Columbia, SC	South Carolina
	Deltona-Daytona Beach-Ormond Beach, FL	Florida
	El Paso, TX	Texas
	Greensboro-High Point, NC	North Carolina
	Greenville-Mauldin-Easley, SC	South Carolina
	Houston-Sugar Land-Baytown, TX	Texas
	Jackson, MS	Mississippi
	Jacksonville, FL	Florida
	Knoxville, TN	Tennessee
	Lakeland-Winter Haven, FL	Florida

	Competitive bidding area	State
	Little Rock-North Little Rock-Conway, AR	Arkansas
	Louisville-Jefferson County, KY-IN	Indiana
	McAllen-Edinburg-Mission, TX	Texas
	Memphis, TN-MS-AR	Arkansas
	Nashville-Davidson-Murfreesboro-Franklin, TN	Tennessee
	New Orleans-Metairie-Kenner, LA	Louisiana
	North Port-Bradenton-Sarasota, FL	Florida
	Ocala, FL	Florida
	Oklahoma City, OK	Oklahoma
	Palm Bay-Melbourne-Titusville, FL	Florida
	Raleigh-Cary, NC	North Carolina
	Richmond, VA	Virginia
	San Antonio-New Braunfels, TX	Texas
	Tampa-St. Petersburg-Clearwater, FL	Florida
	Tulsa, OK	Oklahoma
	Virginia Beach-Norfolk-Newport News, VA-NC	North Carolina
	Washington-Arlington-Alexandria, DC-VA-MD-WV	District of Columbia
West	Albuquerque, NM	New Mexico
	Bakersfield-Delano, CA	California
	Boise City-Nampa, ID	Idaho
	Colorado Springs, CO	Colorado
	Denver-Aurora-Broomfield, CO	Colorado
	Fresno, CA	California
	Honolulu, HI	Hawaii
	Las Vegas-Paradise, NV	Nevada
	Los Angeles County	California
	Orange County	California
	Oxnard-Thousand Oaks-Ventura, CA	California
	Phoenix-Mesa-Glendale, AZ	Arizona
	Portland-Vancouver-Hillsboro, OR-WA	Oregon
	Sacramento-Arden-Arcade-Roseville, CA	California
	Salt Lake City, UT	Utah
	San Diego-Carlsbad-San Marcos, CA	California
	San Francisco-Oakland-Fremont, CA	California
	San Jose-Sunnyvale-Santa Clara, CA	California
	Seattle-Tacoma-Bellevue, WA	Washington
	Stockton, CA	California

Competitive bidding area	State
Tucson, AZ	Arizona
Visalia-Porterville, CA	California

Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-16-570

Note: Regions listed in the table are determined by the corresponding metropolitan statistical area. These are areas, designated by the Office of Management and Budget, that include major cities and the suburban areas surrounding them. By law, round 2 was required to be conducted in designated metropolitan statistical areas. On January 8, 2008, the Centers for Medicare & Medicaid Services (CMS) announced 70 metropolitan statistical areas for round 2. Under the Patient Protection and Affordable Care Act, CMS was required to designate an additional 21 areas for round 2, resulting in a total of 91 areas. 42 U.S.C. § 1395w-3(a)(1)(D)(ii). The round 2 competitive bidding areas are defined by specific ZIP codes related to a metropolitan statistical area, and they may be the same size as, larger than, or smaller than the related metropolitan statistical area, depending on a variety of considerations. The competitive bidding area is the area wherein only contract suppliers may furnish competitively bid items to beneficiaries unless an exception is permitted by law. Metropolitan statistical areas with populations over 8 million may be subdivided into multiple competitive bidding areas. Most round 2 metropolitan statistical areas have only one competitive bidding area. However, the three largest metropolitan statistical areas (Chicago, Los Angeles, and New York) are subdivided into multiple competitive bidding areas, so there are a total of 100 competitive bidding areas.

Appendix II: Description of the Centers for Medicare & Medicaid Services' Phase-In of the Competitive Bidding Program

Since the durable medical equipment (DME) competitive bidding program (CBP) was implemented in 2008, the Centers for Medicare & Medicaid Services (CMS) has phased in several additional CBP rounds and programs.

CBP Rounds in the Original Competitive Bidding Areas

Round 1. CMS awarded contracts to 329 contract suppliers—208 of which were designated by CMS as small suppliers—to furnish DME items and services in 10 product categories in 10 competitive bidding areas.[1] According to CMS, the round 1 competitive bidding areas were selected, in part, because they may have had prior instances of unnecessary DME utilization. Contracts were intended to be effective for a 3-year period, July 1, 2008, through June 30, 2011; however, round 1 was stopped on July 15, 2008, through the enactment of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).[2] Among other provisions,

[1]The 10 product categories were oxygen supplies and equipment; standard power wheelchairs, scooters, and related accessories; complex rehabilitative power wheelchairs and related accessories; mail-order diabetes testing supplies; enteral nutrients, equipment, and supplies; continuous positive airway pressure devices, and respiratory assist devices, and related supplies and accessories; hospital beds and related accessories; negative pressure wound therapy pumps and related supplies and accessories; walkers and related accessories; and support surfaces (limited to group 2 mattresses and overlays—pressure-reducing support surfaces for persons with or at high risk for pressure ulcers—in the Miami and San Juan competitive bidding areas only). The round 1 competitive bidding areas were Charlotte (Charlotte-Gastonia-Concord, North Carolina, and South Carolina); Cincinnati (Cincinnati-Middletown, Ohio, Kentucky, and Indiana); Cleveland (Cleveland-Elyria-Mentor, Ohio); Dallas (Dallas-Fort Worth-Arlington, Texas); Kansas City (Kansas City, Missouri, and Kansas); Miami (Miami-Fort Lauderdale-Miami Beach, Florida); Orlando (Orlando-Kissimmee, Florida); Pittsburgh (Pittsburgh, Pennsylvania); Riverside (Riverside-San Bernardino-Ontario, California); and San Juan (San Juan-Caguas-Guaynabo, Puerto Rico).

[2]Pub. L. No. 110-275, § 154(a)(1), 122 Stat. 2494, 2560-63 (2008) (codified, as amended, at 42 U.S.C. § 1395w-3).

MIPPA terminated the contracts already awarded by CMS to suppliers in round 1 and required CMS to repeat the competition for round 1—referred to as the CBP round 1 rebid.

Round 1 rebid. CMS awarded contracts to 356 contract suppliers—219 of which were small suppliers—to furnish DME items and services in nine product categories in nine competitive bidding areas.[3] Contracts were effective January 1, 2011, and expired after 3 years on December 31, 2013, except for the contracts for the mail-order diabetes testing supplies product category, which expired on December 31, 2012.

Round 1 recompete. CMS awarded contracts to 282 contract suppliers—163 of which were small suppliers—to furnish DME items and services in six product categories and nine competitive bidding areas.[4] The recompete contracts were effective January 1, 2014, and expire December 31, 2016.

Round 1 2017. Round 1 2017 will include seven product categories, with the same items as were bid in the round 1 recompete except for the external infusion pumps and supplies product category, which is not included in round 1 2017. Round 1 2017 will be implemented in the same 9 competitive bidding areas as the round 1 rebid and round 1 recompete, but because competitive bidding areas that included more than one state have been redefined so that there are no longer any multistate areas, the total number of competitive bidding areas is 13. These contracts become effective January 1, 2017, and expire December 31, 2018.

CBP Rounds Included in the Expanded Competitive Bidding Areas

Round 2 and national mail-order program. CMS awarded contracts to 822 contract suppliers—520 of which were small suppliers—to furnish DME items and services in eight product categories and 100 competitive

[3]The round 1 rebid competitive bidding areas were the same as the round 1 competitive bidding areas, except that the San Juan (San Juan-Caguas-Guaynabo, Puerto Rico) area was excluded. The product categories were also the same, except that the negative pressure wound therapy product category was excluded and the complex rehabilitative power wheelchairs and related accessories product category was limited to group 2 wheelchairs because MIPPA excluded from competitive bidding group 3 complex rehabilitative power wheelchairs and wheelchair accessories when furnished with them.

[4]The round 1 recompete's six product categories differ from the round 1 rebid categories by adding infusion pumps and negative pressure wound therapy (NPWT) pumps, deleting complex wheelchairs, and creating a new category that includes home equipment, such as hospital beds and commode chairs. The nine competitive bidding areas are the same as those included in the round 1 rebid.

bidding areas.[5] CMS also awarded 19 contracts—6 of which were to small suppliers—to furnish mail-order diabetes testing supplies included in the national mail-order program. The round 2 and national mail-order program contracts were effective July 1, 2013, and expired June 30, 2016.

Round 2 recompete and national mail-order program recompete. According to CMS officials, the agency awarded contracts to 586 contract suppliers—334 of which were small suppliers—to furnish DME items for seven product categories with most of the same items bid in other rounds, although CMS grouped certain items into different product categories. Round 2 recompete will be implemented in the same 100 competitive bidding areas as round 2, but because competitive bidding areas that included more than one state have been redefined so that there are no longer any multistate areas, the total number of competitive bidding areas is 117. CMS officials told us that the agency also awarded contracts to 9 contract suppliers—2 of which were small suppliers—to furnish the same diabetes testing supplies in the same areas that were included in the first national mail-order program. The round 2 recompete and national mail-order program recompete contracts were effective July 1, 2016, and expire December 31, 2018.

[5]The round 2 product categories are: (1) oxygen supplies and equipment; (2) standard (power and manual) wheelchairs, scooters, and related accessories; (3) enteral nutrients, equipment and supplies; (4) continuous positive airway pressure devices, respiratory assist devices, and related supplies and accessories; (5) hospital beds and related accessories; (6) walkers and related accessories; (7) support surfaces (group 2 mattresses and overlays); and (8) NPWT pumps and related supplies and accessories.

Appendix III: 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, Martin T. Gahart, Assistant Director; Michelle Paluga, Analyst-in-Charge; Todd Anderson; Alison Binkowski; Elizabeth T. Morrison; and Emily Wilson made key contributions to this report.

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