

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**ROUND 2 COMPETITIVE
BIDDING FOR CPAP/RAD:
DISRUPTED ACCESS UNLIKELY
FOR DEVICES, INCONCLUSIVE
FOR SUPPLIES**



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Why OIG Did This Review

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established the Competitive Bidding Program for durable medical equipment (DME). The program replaces a fee schedule with a competitive bidding process to set Medicare reimbursement amounts in certain areas. The Centers for Medicare & Medicaid Services' (CMS) analysis found that the program is saving money without compromising beneficiary health outcomes. Round 2 was a significant expansion of the program to more geographic areas.

In a letter to OIG, Members of Congress expressed concerns about the program's effect on access to DME and requested that OIG study this issue.

How OIG Did This Review

We used Medicare claims to identify two populations of beneficiaries for whom Medicare paid claims before Round 2 of the Competitive Bidding Program began in 2013. The first population included those with paid claims for CPAP/RAD devices; the second, those with paid claims for CPAP/RAD supplies. Using discontinued payments after Round 2 began as a proxy for disrupted access within each population, we compared the rates of discontinued payments in areas that were part of the program and areas that were not. In addition, we drew samples of beneficiaries for whom device payments stopped and for whom supply payments stopped. We then surveyed the physicians who had ordered devices or supplies for these beneficiaries. In cases in which physicians reported a continued beneficiary need, we surveyed those beneficiaries to learn about their experiences after Round 2 began. Our survey results are not projectable but provide some context for a sample of beneficiaries.

Round 2 Competitive Bidding for CPAP/RAD: Disrupted Access Unlikely

What OIG Found

Nearly all beneficiaries who in 2013 started using what we refer to in this report as CPAP/RAD devices—i.e., continuous positive airway pressure (CPAP) devices or respiratory assist devices (RADs)—appeared to have continued access to them after Round 2 of the Competitive Bidding Program for durable medical equipment began in July 2013. Medicare payments for devices continued for at least 96 percent of these beneficiaries after Round 2 began.

Our surveys provided some anecdotal context for a sample of beneficiaries for whom payments for devices stopped. For example, their physicians told us that the beneficiaries still needed the devices, and beneficiaries generally reported continuing to use them.

We also found that Medicare payments for supplies stopped for 46 percent of beneficiaries in Round 2 competitive bidding areas (CBAs) compared to 33 percent in areas that were not CBAs (which we refer to as non-CBAs). In 2012, the year before Round 2 began, 35 percent of beneficiaries who had a paid claim for CPAP/RAD supplies in the first half of the year did not have a paid claim in the second half of the year.

Our surveys provided some limited insights for a sample of beneficiaries without continued supply payments. For example, their physicians told us that the beneficiaries still needed the devices after Round 2 began. However, only half of responding beneficiaries reported needing supplies and nearly all of those beneficiaries reported getting needed supplies.

What OIG Concludes

Round 2 of the Competitive Bidding Program did not appear to disrupt beneficiary access to CPAP/RAD devices. Our finding is consistent with CMS's conclusion that the program is not compromising beneficiary health outcomes. Our analysis is less conclusive regarding whether the program disrupted beneficiary access to CPAP/RAD supplies. We saw a bigger decline in claims for supplies in Round 2 CBAs than in non-CBAs. The decline may or may not indicate disruptions in receiving needed supplies. For example, the decline may indicate that the program reduced the provision of unnecessary supplies, as CMS determined to be the case with Round 1 of the program.

Key Takeaway

Round 2 of the Competitive Bidding Program does not appear to have disrupted access to CPAP/RAD devices, but whether it disrupted access to CPAP/RAD supplies is unclear. Nearly all beneficiaries who started using their devices in 2013 appeared to still have access to them after Round 2 began. We saw a bigger decline in claims for supplies in Round 2 CBAs than in non-CBAs after Round 2 began. This may or may not mean that beneficiaries experienced disruptions in access to supplies; e.g., the Competitive Bidding Program may have reduced provision of unnecessary supplies. In fact, CMS analysis of Round 1 of the program found that beneficiaries who stopped receiving supplies after Round 1 began often had more than enough supplies on hand.

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OBJECTIVE

To determine whether Round 2 of the Competitive Bidding Program (CBP) appeared to disrupt beneficiary access to continuous positive airway pressure (CPAP) devices, respiratory assist devices (RADs), and related supplies.

BACKGROUND

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established the CBP as one of several efforts aimed at combating fraud, waste, and abuse.¹ For selected categories of durable medical equipment (DME), this program replaces a fee-schedule payment methodology with a competitive bidding process in certain areas of the country. The goals of the program are to improve the methodology for setting DME payment amounts, thereby creating cost savings for Medicare and its beneficiaries while maintaining beneficiary access to quality items and services. The Centers for Medicare & Medicaid Services (CMS) reports that the CBP is a success; however, Congress and other stakeholders have raised concerns about the program's impact on beneficiary access to DME.

According to CMS, the CBP is saving money for Medicare and its beneficiaries without compromising access to DME. CMS reports that the CBP has saved more than \$4 billion.² It also reports that the CBP has had no negative impact on beneficiary health outcomes.³ CMS conducts real-time data analysis to monitor the health status of beneficiaries served by the CBP; as of the end of September 2016, CMS had not observed any negative changes in beneficiary health outcomes.⁴ For this analysis, CMS monitors health outcomes such as deaths, hospitalizations, and emergency room visits, as well as average number of days spent hospitalized, among other data.

¹ Medicare Prescription Drug, Improvement, and Modernization Act of 2003. P.L. No. 108-173 § 302(b).

² CMS, *Providing Quality, Affordable Durable Medical Equipment for Beneficiaries*. Accessed at <https://wayback.archive-it.org/2744/20161207130006/https://blog.cms.gov/2016/05/17/providing-quality-affordable-durable-medical-equipment-for-beneficiaries/> on April 26, 2017.

³ Ibid.

⁴ CMS, *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program—Health Status Monitoring: Summary of Findings thru the Third Quarter of 2016*. Accessed at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Downloads/DME-Summary-of-Findings.pdf> on April 24, 2017.

In a July 2014 letter to the Office of Inspector General (OIG), 138 Members of Congress expressed concerns about the CBP's effect on Medicare beneficiary access to DME. The letter suggested that noncompliance of contracted suppliers in the CBP is affecting the quality and choice of DME available to beneficiaries and requested that OIG study the effect of the CBP on access to DME.

Overview of Competitive Bidding

Under the CBP, DME suppliers compete to contract with Medicare to supply selected DME items within specific geographic areas known as Competitive Bidding Areas (CBAs). CMS and its Competitive Bidding Implementation Contractor evaluate suppliers' bids based on the bid amount and several other criteria, including the supplier's eligibility and financial stability.⁵

Pursuant to the Medicare Modernization Act, CMS established bidding in rounds, which CMS must recompetete at least once every 3 years.⁶ Each round involves certain DME product categories and CBAs. Each product category includes related products that treats a similar medical condition. Product categories include both equipment and the separately billable supplies such as masks and tubing. In January 2016, CMS began using pricing data from the CBP to set reimbursement rates for DME in areas of the country not subject to the CBP. (In this report, we refer to areas not subject to the CBP as "non-CBAs.") See Table 1 below for details on the rounds of the CBP.

⁵ CMS, *DMEPOS Competitive Bidding – Home*. Accessed at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/index.html?redirect=/dmeuposcompetitivebid/> on May 5, 2015.

⁶ Social Security Act, § 1847(b)(3)(B); 42 U.S.C. § 1395w-3(b)(3)(B); 42 CFR § 414.422(b).

Table 1: CBP Round Effective Dates, CBAs, and Product Categories

CBP Round	Effective Dates	CBAs	Product Categories*
Round 1	<p>Round 1 Rebid:⁷ Jan. 1, 2011 – Dec. 31, 2013</p> <p>Round 1 Recompete:⁸ Jan. 1, 2014 – Dec. 31, 2016</p> <p>Round 1 2017: Jan. 1, 2017 – Dec. 31, 2018</p>	<p>9 to 13 CBAs – For the Round 1 Rebid and Round 1 Recompete, 9 CBAs covering the largest metropolitan statistical areas by population that did not span multiple Medicare Administrative Contractor Jurisdictions,⁹ but not including New York City, Los Angeles, and Chicago. For Round 1 2017, to prevent multi-State CBAs, CMS split 3 of the original 9 CBAs into multiple CBAs, for a total of 13 CBAs.</p>	<p><u>All Effective Dates:</u> Oxygen; CPAP/RAD devices and supplies; enteral nutrition; standard power wheelchairs; scooters; walkers; hospital beds</p> <p><u>Some Effective Dates:</u> Complex rehabilitative wheelchairs, standard manual wheelchairs, support surfaces, mail-order diabetic supplies, commode chairs, patient lifts, seat lifts, transcutaneous electrical nerve stimulation, external infusion pumps, nebulizers, negative pressure wound therapy pumps</p>
Round 2	<p>July 1, 2013 – June 30, 2016</p> <p>Recompete: July 1, 2016 – December 31, 2018</p>	<p>100 to 117 CBAs – For Round 2, 100 CBAs, covering the next 91 largest metropolitan statistical areas and including New York City, Los Angeles, and Chicago, with each subdivided into multiple CBAs. For the Round 2 Recompete, 117 CBAs to prevent multi-State CBAs.</p>	<p>Oxygen, CPAP/RAD, enteral nutrition, standard wheelchairs, walkers, hospital beds, support surfaces, negative pressure wound therapy pumps</p>
National Mail Order Program	<p>July 1, 2013 – June 30, 2016</p> <p>Recompete: July 1, 2016 – December 31, 2018</p>	<p>1 CBA – All parts of the United States, including the 50 States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa.</p>	<p>Diabetic testing supplies</p>

*Some product categories were renamed and combined from one contract cycle to the next.

Suppliers not awarded a contract under the CBP may continue renting the items to beneficiaries in CBAs to whom they were renting at the time the CBP was implemented. Those suppliers may also provide related supplies to the beneficiaries to whom they are renting equipment. These

⁷ Round 1 was implemented in 2008 and discontinued two weeks later by the passage of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). As required by MIPPA, the supplier competition was held again in 2009 and referred to as the Round 1 Rebid.

⁸ The Round 1 Rebid included contracts for mail-order diabetic testing supplies, but those contracts ended in December 2012, and bidding for diabetic testing supplies moved to the National Mail Order Program. CMS, *Round 1 Rebid Mail-Order Diabetic Supply Contracts Ending on December 31, 2012*. Accessed at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Downloads/2012-12-14-DMEPOS.pdf> on January 12, 2017.

⁹ CMS, *General Overview of the Final Rule for Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies*, April 10, 2007. Accessed at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Downloads/DMEPOSRegSumm.pdf> on May 5, 2015.

noncontract suppliers are called grandfathered suppliers and must agree to meet certain conditions, including accepting assignment of Medicare payment as payment in full.¹⁰ Grandfathering may support continuity of access to DME when an area transitions to the CBP.

Medicare Coverage of CPAP and RAD Devices and Supplies

To be covered by Medicare, an item or service must be reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body part.¹¹ Medicare considers CPAP devices to be reasonable and necessary for beneficiaries diagnosed with obstructive sleep apnea.¹² Medicare considers RADs to be reasonable and necessary for beneficiaries with non-life-threatening conditions that require only intermittent and relatively short durations of respiratory support, such as restrictive thoracic disorders or severe chronic obstructive pulmonary disease.¹³

Medicare pays for CPAP devices and RADs (which we refer to collectively in this report as CPAP/RAD devices) through monthly rental payments. Payments for the devices may last up to 13 months, after which the beneficiary may continue using the equipment.¹⁴ For continued coverage of a CPAP/RAD device beyond the first 3 months, a beneficiary

¹⁰ CMS, *The Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program: Grandfathering Requirements for Non-Contract Suppliers* (ICN 900923). Accessed at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/DME_Grandfathering_Factsheet_ICN900923.pdf on October 25, 2016.

¹¹ Social Security Act § 1862(a)(1)(A), 42 U.S.C. § 1395y(a)(1)(A).

¹² CMS, *Medicare National Coverage Determination Manual*, Pub. No. 100-03, ch. 1, pt. 4, § 240.4, p. 92. See also *Local Coverage Determination (LCD): Positive Airway Pressure Devices for the Treatment of Obstructive Sleep Apnea (L33718)* for DME MAC Jurisdictions A, B, C, and D. Accessed at <https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx> on November 2, 2016. Prior to October 1, 2015, the DME MACs had separate but identical LCDs for PAPs (i.e., LCDs L11528, L27230, L11518, and L171 for DME MAC Jurisdictions A, B, C, and D, respectively), online at http://localcoverage.cms.gov/mcd_archive/overview.aspx?from2=overview.aspx&.

¹³ *Local Coverage Determination (LCD): Respiratory Assist Devices (L33800)* for DME MAC Jurisdictions A, B, C, and D. Accessed at <https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx> on July 22, 2016. Prior to October 1, 2015, the DME MACs had separate but identical LCDs for RADs (i.e., LCDs L11504, L27228, L5023, and L11493 for DME MAC Jurisdictions A, B, C, and D, respectively), online at http://localcoverage.cms.gov/mcd_archive/.

¹⁴ 42 CFR § 414.229.

must be reevaluated to ensure that he or she is using and benefiting from the device.^{15, 16}

Medicare also pays for the related supplies necessary to use the devices. It makes these payments separately from device rental payments and continues making them as long as medically necessary.¹⁷

CPAP/RAD supplies range from disposable masks and airhoses that need to be replaced as frequently as every 30 days to more durable items like chinstraps and headgear that last for months.¹⁸ Supplies may need to be replaced less frequently, depending on how beneficiaries use and care for them. In fact, Medicare instructs suppliers to send replacement supplies only after they have contacted beneficiaries to ensure they need them.¹⁹

Program Integrity Concerns with CPAP/RAD

Medicare's Comprehensive Error Rate Testing (CERT) program has long found high error rates in DME, including CPAP/RAD supplies. In 2012, the year before Round 2 of the CBP started, the CERT found a 66-percent error rate in DME and a 56-percent error rate in CPAP/RAD supplies.²⁰ In addition, when CMS noticed a drop in claims for CPAP/RAD supplies after it implemented Round 1 of the CBP, it called a sample of beneficiaries and learned that in nearly every case, the beneficiary reported having more than enough supplies on hand, often many months' worth.²¹ This may indicate that suppliers were sending unneeded replacement supplies to beneficiaries despite Medicare's requirement for suppliers to send them only when beneficiaries needed them.

¹⁵ LCDs L33718 and L33800.

¹⁶ CMS, *Durable Medical Equipment Center*. Accessed at <https://www.cms.gov/Center/Provider-Type/Durable-Medical-Equipment-DME-Center.html> on February 13, 2017.

¹⁷ LCDs L33718 and L33800.

¹⁸ *Ibid.*

¹⁹ CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 5, § 5.2.8, p. 7. Accessed at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c05.pdf> on October 26, 2016.

²⁰ CMS, *Medicare Fee-For-Service 2012 Improper Payments Report*, pp. 31, 35. Accessed at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/Downloads/Medicare-Fee-for-Service-2012-Improper-Payments-Report.pdf> on November 2, 2016.

²¹ CMS, *Competitive Bidding Update—One Year Implementation Update, April 17, 2012*. Accessed at <https://www.cms.gov/medicare/medicare-fee-for-service-payment/dmeposcompetitivebid/downloads/competitive-bidding-update-one-year-implementation.pdf> on October 26, 2016.

Related OIG Work

OIG has a long history of identifying fraud, waste, and abuse in the provision of DME devices and supplies. For example, a 2013 OIG report found that Medicare inappropriately paid claims for \$6 million worth of diabetes test strips.²² Additionally, since passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, OIG has opened more than 2,000 investigative cases involving DME suppliers. Recently, OIG investigations have contributed to several Department of Justice fraud cases against suppliers of CPAP/RAD devices.^{23, 24, 25, 26}

In April 2014, an OIG audit found that CMS generally met requirements in the first round of the CBP.²⁷ However, because of inconsistency in following its procedures, CMS awarded Round 1 contracts to a small number of suppliers that did not meet program requirements. OIG is also auditing the process that CMS used to conduct competitive bidding and to make pricing determinations for certain categories of DME under Rounds 1 and 2 of the CBP. OIG has released three memorandum reports evaluating the market share of different types of diabetes test strips.^{28, 29, 30}

²² OIG, *Inappropriate and Questionable Medicare Billing for Diabetes Test Strips*, OEI-04-11-00330, August 2013.

²³ U.S. Department of Justice, *Hendersonville Physician Indicted on Federal Kickback Charges*, June 2016. Accessed at <https://www.justice.gov/usao-mdtn/pr/hendersonville-physician-indicted-federal-kickback-charges> on February 16, 2017.

²⁴ U.S. Department of Justice, *Connecticut Medical Equipment Company Pays \$600,000 to Settle False Claims Act Allegations*, January 2016. Accessed at <https://www.justice.gov/usao-ct/pr/connecticut-medical-equipment-company-pays-600000-settle-false-claims-act-allegations-0> on February 16, 2017.

²⁵ U.S. Department of Justice, *Respironics to Pay \$34.8 Million for Allegedly Causing False Claims to Medicare, Medicaid and Tricare Related to the Sale of Masks Designed to Treat Sleep Apnea*, March 2016. Accessed at <https://www.justice.gov/opa/pr/respironics-pay-348-million-allegedly-causing-false-claims-medicare-medicare-and-tricare> on February 16, 2017.

²⁶ U.S. Department of Justice, *Bay Sleep Clinic and Related Entities Agree To Pay the United States \$2.6 Million To Settle False Claims Act Allegations*, December 2016. Accessed at <https://www.justice.gov/usao-ndca/pr/bay-sleep-clinic-and-related-entities-agree-pay-united-states-26-million-settle-false> on February 16, 2017.

²⁷ OIG, *CMS Generally Met Requirements in the DME Competitive Bidding Round 1 Rebid Program*, A-05-12-00067, April 2014.

²⁸ OIG, *Memorandum Report: Medicare Market Shares of Mail Order Diabetes Test Strips from July-September 2013*, OEI-04-13-00680, June 2014.

²⁹ OIG, *Memorandum Report: Medicare Market Shares of Mail Order Diabetes Test Strips Immediately Prior to the National Mail Order Program*, OEI-04-13-00681, June 2014.

³⁰ OIG, *Memorandum Report: Medicare Market Shares of Mail Order Diabetes Test Strips 3-6 Months After the Start of the National Mail Order Program*, OEI-04-13-00682, November 2014.

This study is the first in a series and concerns CPAP/RAD devices and supplies, which in 2013 made up 33 percent of paid claims in Round 2 of the CBP. Forthcoming studies in this series will examine how the 2013 launch of Round 2 of the CBP has affected beneficiary access to oxygen and to enteral nutrition, respectively.

METHODOLOGY

This inspection considers two different populations of Medicare beneficiaries over two different time spans to determine whether Round 2 of the CBP appeared to disrupt access to CPAP/RAD devices and supplies. The first population includes beneficiaries using CPAP/RAD devices and covers the 6 months before and the 6 months after Round 2 contracts became effective on July 1, 2013. The second population includes beneficiaries using CPAP/RAD supplies and covers the same two 6-month periods. For ease of presentation in this report, we refer to July 1, 2013—the date Round 2 contracts went into effect—as the date that Round 2 began.

We used Medicare claims data to identify our populations. Both populations include beneficiaries who resided in Round 2 CBAs and non-CBAs, which enabled us to make comparisons to look for evidence of potential disruptions in access.

Beneficiaries With Claims for CPAP/RAD Devices: Beneficiaries in our first population, which includes beneficiaries using CPAP/RAD devices, met both of the criteria below:

- They started using CPAP/RAD devices in the first half of calendar year 2013, before Round 2 began. Choosing beneficiaries who were new to CPAP/RAD eliminated the chance that any interruption in Medicare payments for CPAP/RAD rental was because beneficiaries had reached the 13-month limit on payments, at which point the beneficiaries own the devices.
- They had five or more paid claims for CPAP/RAD devices in the first half of 2013. This ensured that our focus was on beneficiaries with demonstrated compliance beyond 90 days and decreased the chance that any interruption in Medicare payments for CPAP/RAD devices would be due to beneficiary noncompliance.

Beneficiaries With Claims for CPAP/RAD Supplies: Our second population includes beneficiaries for whom there was at least one claim for CPAP/RAD supplies in the first half of 2013.

Using Medicare claims data, we determined the extent to which beneficiaries in our populations appeared to have their access to

CPAP/RAD devices and/or supplies disrupted by Round 2 of the CBP. Specifically, we used the absence of paid claims for beneficiaries in each population after Round 2 began as a marker of potential disruption in access. We calculated the percentages of beneficiaries in each population for whom Medicare payments stopped and compared them between beneficiaries residing in Round 2 CBAs and non-CBAs.

To learn more about the experience of beneficiaries with a potential disruption in access after Round 2 began, we selected samples of beneficiaries in our populations for whom Medicare payments stopped. We stratified the samples by whether the beneficiaries resided in Round 2 CBAs or non-CBAs. To determine whether the sampled beneficiaries continued to need the items after Round 2 began, we surveyed separately the physicians who ordered their CPAP/RAD devices and the physicians who ordered their CPAP/RAD supplies. Each physician we surveyed ordered devices or supplies for one of our sampled beneficiaries. When a physician told us that the beneficiary had a continued need for the items and Medicare records indicated that the beneficiary was still living in 2016, we considered that beneficiary to be eligible for our survey, which asked beneficiaries to describe their experiences after Round 2 began. Tables 2 and 3 provide details on these samples and surveys.

Table 2: Surveys Regarding CPAP/RAD Devices

	Round 2 CBAs	Non-CBAs	Total
Total Physicians in Sample	150	150	300
Physicians Surveyed¹	144	145	289
Physicians Responding With Usable Data²	106	116	222
Physician Response Rate	71%	77%	74%
Beneficiaries Eligible for Survey	70	78	148
Beneficiaries Responding With Usable Data	27	31	58
Beneficiary Response Rate	39%	40%	39%

Source: OIG analysis of physician and beneficiary responses to survey, 2016.

¹ We did not survey a physician if the beneficiary was deceased when bidding began, if the physician was under investigation, or if the physician was no longer in business.

² In some cases, physicians cooperated by responding to our survey, but their responses included no usable information.

Table 3: Surveys Regarding CPAP/RAD Supplies

	Round 2 CBAs	Non-CBAs	Total
Total Physicians in Sample	150	150	300
Physicians Surveyed¹	147	143	290
Physicians Responding With Usable Data²	96	97	193
Physician Response Rate	64%	65%	64%
Beneficiaries Eligible for Survey	69	72	141
Beneficiaries Responding With Usable Data	38	24	62
Beneficiary Response Rate	55%	33%	44%

Source: OIG analysis of physician and beneficiary responses to survey, 2016.

¹ We did not survey a physician if the beneficiary was deceased when bidding began, if the physician was under investigation, or if the physician was no longer in business.

² In some cases, physicians cooperated by responding to our survey, but their responses included no usable information.

Limitations

This review has two limitations. First, discontinuation of claims or disproportionately lower rates of continued claims for supplies in Round 2 CBAs may or may not indicate disruption of or impediment to access to supplies. Such discontinuation or lower rates may be caused by factors that did not disrupt access to supplies. For example, if some beneficiaries had received more supplies than they needed prior to Round 2 of the CBP, they could have had fewer claims after Round 2 yet still have accessed all needed supplies.

Secondly, our survey response rate was too low to project the results to all beneficiaries for whom claims did not continue. Therefore, we present our survey responses as testimonial evidence to provide insights into these individual beneficiaries' experiences in accessing CPAP/RAD devices and supplies. We did not independently verify responses from physicians and beneficiaries, nor did we conduct a medical review of beneficiaries' medical need for these devices or supplies. See Appendix A for a detailed description of our methodology.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

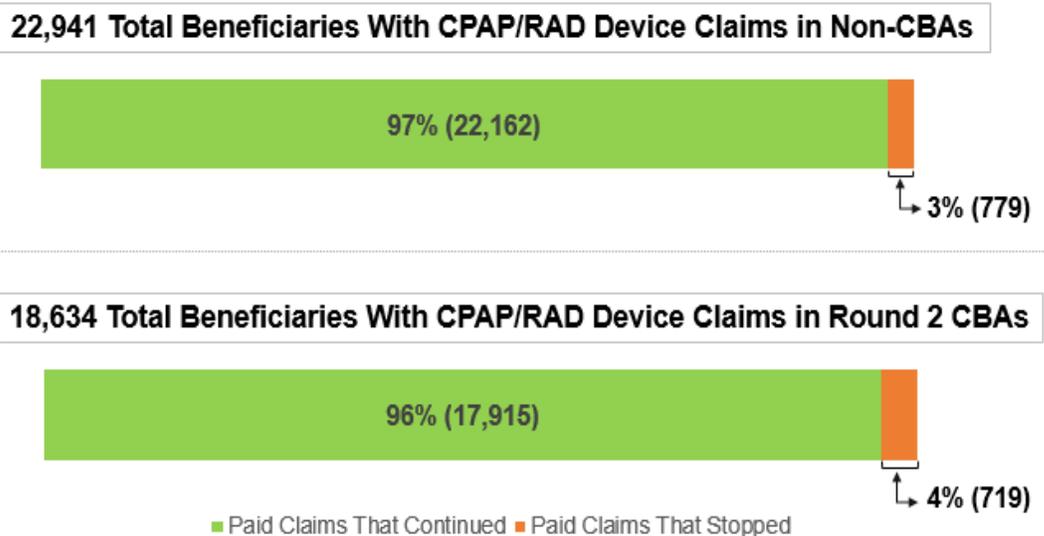
Nearly all beneficiaries who started using CPAP/RAD devices in 2013 appeared to have continued access to them after Round 2 began

In the first half of 2013, 41,575 beneficiaries started using CPAP/RAD devices in Round 2 CBAs and non-CBAs. These beneficiaries had claims that indicated Medicare paid for the devices for at least 5 months, suggesting that the beneficiaries had met the Medicare criteria for continued coverage beyond 3 months by the time Round 2 started on July 1, 2013.

Medicare payments continued for over 95 percent of beneficiaries in both Round 2 CBAs and non-CBAs

After CMS awarded Round 2 contracts and competitive bidding began, 96 percent of beneficiaries in Round 2 CBAs and 97 percent in non-CBAs had one or more paid claims for monthly rental of CPAP/RAD devices. Furthermore, Medicare paid three or more claims for nearly all of these beneficiaries, which suggests that beneficiaries continued to possess CPAP/RAD devices both in Round 2 CBAs and non-CBAs months after bidding began. Continued payment suggests continued access. See Figure 1 for additional detail on the number and percentage of beneficiaries with continued or stopped paid claims for devices.

Figure 1: Numbers and Percentages of Beneficiaries for Whom Paid Claims for CPAP/RAD Devices Continued or Stopped After Round 2 Began



Source: OIG analysis of Medicare claims data, 2016.

In addition, Medicare claims suggest that nearly all of these beneficiaries likely continued to possess devices without interruption, indicating continued access. In the first half of 2013, suppliers billed Medicare every 31 days, on average, for a beneficiary's CPAP/RAD rental. Fewer than 2 percent of beneficiaries with continuing payments in both Round 2 CBAs and non-CBAs went longer than 31 days between their last claim before bidding started and their first claim after bidding started. This suggests that beneficiaries with continued Medicare payments overwhelmingly kept their CPAP/RAD devices without interruption after bidding began. CMS's grandfathering policy may have supported continued access; however, we did not determine whether these beneficiaries switched suppliers and received a new device or continued on with a grandfathered supplier.

In their survey responses, physicians told us that beneficiaries without continued payments still had a prescribed need for the devices, and beneficiaries reported continued use of the devices

Our surveys provide some insights, albeit limited, to the experiences of these beneficiaries for whom payments stopped after Round 2 began—an indicator of a potential disruption in access. For example, the physicians who responded to our survey generally reported that beneficiaries for whom they ordered CPAP/RAD devices still had a prescribed need for them after bidding began. This was the case both in Round 2 CBAs and non-CBAs. In responding to our key question on beneficiaries' prescribed need for devices, 80 of 87 physicians in Round 2 CBAs who provided usable data reported that the beneficiaries for whom they ordered devices still had a prescribed need for those devices. This compares to 97 of 100 physicians in non-CBAs who responded with usable data.

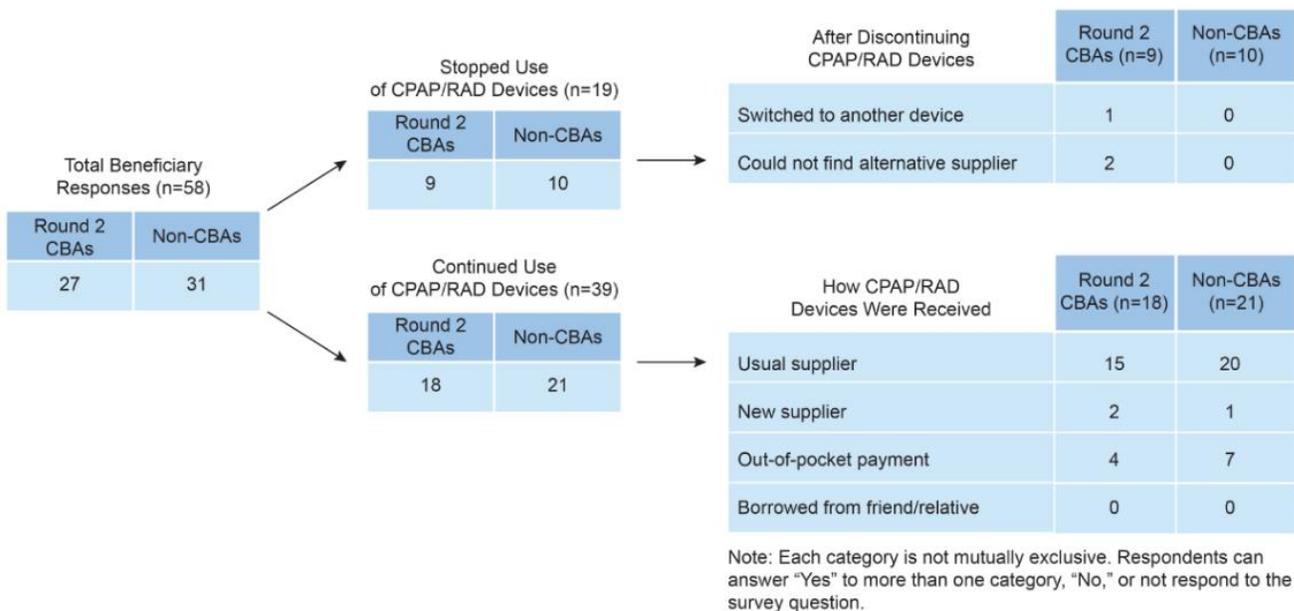
Our survey also provided limited insights to alternatives to CPAP/RAD devices. For example, physicians rarely reported prescribing alternative devices, such as oral appliances, for beneficiaries who had a continued prescribed need for CPAP/RAD devices. According to our survey, responding physicians prescribed alternative devices to 3 beneficiaries in Round 2 CBAs and to 10 beneficiaries in non-CBAs.

Finally, responding beneficiaries provided some insights on their experiences with CPAP/RAD devices. For example, the majority of these beneficiaries reported continued use of CPAP/RAD devices, even though Medicare stopped paying for the devices. Specifically, 18 of 27 responding beneficiaries from Round 2 CBAs and 21 of 31 responding beneficiaries from non-CBAs reported continued use of CPAP/RAD devices. Seven of these beneficiaries in non-CBAs reported paying out of pocket compared to four beneficiaries in Round 2 CBAs who said they

paid out of pocket. Having to pay out of pocket could limit access to needed items.

Also, of the nine beneficiaries in Round 2 CBAs who reported that they stopped using their CPAP/RAD devices, two reported doing so because they could not find a supplier. In comparison, 10 beneficiaries in non-CBAs reported that they stopped using their CPAP/RAD devices, but none cited inability to find a supplier as a reason for doing so. See Figure 2 for additional detail on survey responses from beneficiaries.

Figure 2: Survey Responses From a Subset of Beneficiaries for Whom Paid Claims for CPAP/RAD Devices Stopped



Source: OIG analysis of beneficiary responses to survey, 2016.

Claims for CPAP/RAD supplies declined more in Round 2 CBAs than in non-CBAs

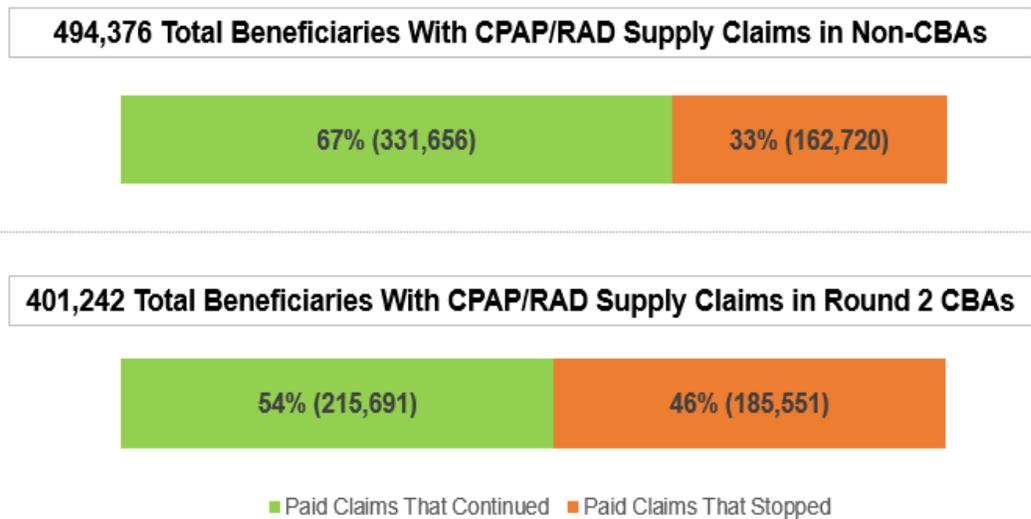
In the first half of 2013, 895,618 beneficiaries had one or more claims for CPAP/RAD supplies in Round 2 CBAs and non-CBAs. These beneficiaries may or may not have needed to replace their CPAP/RAD supplies in the second half of 2013.

After Round 2 began, the rate at which Medicare payments for CPAP/RAD supplies stopped was 13 percent higher in Round 2 CBAs than in non-CBAs

Forty-six percent of beneficiaries in Round 2 CBAs who had one or more paid claims for CPAP/RAD supplies in the first half of 2013 had no paid claims in the second half of the year, compared to 33 percent in non-CBAs. The percentage of beneficiaries with no paid claims in non-CBAs is in line with the claim patterns for the year before Round 2

began—in 2012, 35 percent of beneficiaries who had a paid claim for CPAP/RAD supplies in the first half of the year did not have a paid claim in the second half of the year. The higher percentage of beneficiaries without claims in Round 2 CBAs may suggest a potential disruption in access to CPAP/RAD supplies. However, it may also indicate that the CBP reduced the provision of unnecessary replacement supplies to beneficiaries. This decline in claims for supplies is also consistent with CMS’s statements during interviews that the CBP reduced the provision of unnecessary replacement supplies to beneficiaries. See Figure 3 for additional detail on the number and percentage of beneficiaries with continued or stopped paid claims for supplies.

Figure 3: Numbers and Percentages of Beneficiaries for Whom Paid Claims for CPAP/RAD Supplies Continued or Stopped After Round 2 Began



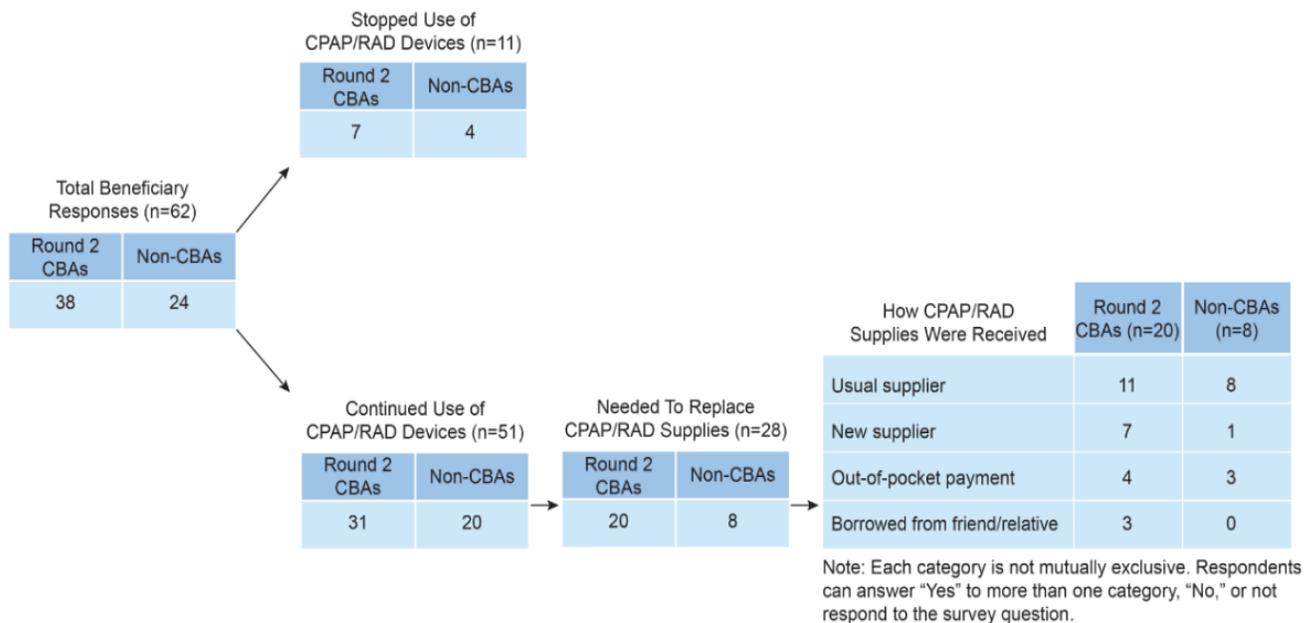
Source: OIG analysis of Medicare claims data, 2016.

In their survey responses, physicians told us that beneficiaries still had a prescribed need for supplies, and beneficiaries reported getting supplies when they needed them

We surveyed physicians and beneficiaries to gain some insight to the experience of beneficiaries for whom Medicare payments for CPAP/RAD supplies stopped after Round 2 began. For example, responding physicians who provided usable data largely told us that the beneficiary we asked about continued to have a prescribed need for them after Round 2 began. In responding to our key question on beneficiaries’ prescribed need for supplies, 77 of 80 physicians in Round 2 CBAs who provided usable data reported that the beneficiary for whom they ordered supplies still had a prescribed need for supplies after Round 2 began, compared to 80 of 85 physicians in non-CBAs.

Beneficiaries who responded to our survey provided insight to their experience. About half of beneficiaries who responded to our survey reported needing to replace supplies in the 6 months after Round 2 began. Nearly all of these beneficiaries reported getting supplies when they needed them. Three of 8 beneficiaries in non-CBAs who reported needing supplies reported paying out of pocket for them, compared to 4 of 20 beneficiaries needing supplies in Round 2 CBAs. See Figure 4 for additional detail on survey responses from beneficiaries.

Figure 4: Survey Responses From a Subset of Beneficiaries for Whom Paid Claims for CPAP/RAD Supplies Stopped



Source: OIG analysis of beneficiary responses to survey, 2016.

CONCLUSION

This study is the first in a series aimed at determining whether the CBP, which transformed how Medicare provides and pays for DME, has disrupted access to DME. In this study we examined CPAP/RAD devices and supplies, which together accounted for a third of paid Medicare claims under Round 2 of the CBP in 2013, the year we examined. CPAP/RAD devices and supplies are important for the millions of Medicare beneficiaries with conditions requiring respiratory support.

According to our claims analysis, Round 2 of the CBP does not appear to have disrupted beneficiary access to CPAP/RAD devices. This finding is consistent with CMS's conclusion that the CBP is not compromising beneficiary health outcomes.

Our analysis is less conclusive regarding whether the CBP disrupted beneficiary access to supplies associated with CPAP/RAD. We saw a bigger decline in claims for supplies in Round 2 CBAs than non-CBAs. The decline may or may not suggest disruptions in receiving needed supplies, as it may instead indicate that—similar to what CMS analysis found after Round 1 of the CBP, and as stated by CMS—Round 2 of the CBP reduced the provision of unnecessary supplies.

Forthcoming OIG studies will examine how the CBP affected beneficiary access to oxygen and enteral nutrition under Round 2 of the CBP. Through these evaluations and other efforts, OIG will continue to monitor DME in Medicare.

APPENDIX A

Detailed Methodology

Scope

This inspection considers two different populations of Medicare beneficiaries over two different time spans to determine the effect of Round 2 of the CBP on access to CPAP/RAD devices and supplies. The first population includes beneficiaries using CPAP/RAD devices and covers the 6 months before and the 6 months after Round 2 contracts became effective on July 1, 2013. The second population includes beneficiaries using CPAP/RAD supplies and covers the same two 6-month periods. For ease of presentation in this report, we refer to July 1, 2013, as the date that Round 2 began.

We used Medicare claims data to identify our populations. Both populations include beneficiaries who resided in Round 2 CBAs and non-CBAs, which enabled us to make comparisons to look for evidence of potential disruptions in access.

Beneficiaries With Claims for Devices: Beneficiaries in our first population, which includes beneficiaries using CPAP/RAD devices, met both of the criteria below:

- They started using CPAP/RAD devices in the first half of calendar year 2013, before Round 2 began. Choosing beneficiaries who were new to CPAP/RAD eliminated the chance that any interruption in Medicare payments for CPAP/RAD rental was because beneficiaries had reached the 13-month limit on payments, at which point the beneficiaries own the devices.
- They had five or more paid claims for CPAP/RAD devices in the first half of 2013. This ensured that our focus was on beneficiaries with demonstrated compliance beyond 90 days and decreased the chance that any interruption in Medicare payments for CPAP/RAD devices would be due to beneficiary noncompliance.

Combined, these criteria enabled us to focus our analysis on beneficiaries who generally could be expected to continue using and having Medicare payments for devices for several months after Round 2 began.

Beneficiaries With Claims for Supplies: Our second population includes beneficiaries for whom there was at least one claim for CPAP/RAD supplies in the first half of 2013.

Data Sources

Our data sources for this evaluation were Medicare claims and administrative data and survey responses we collected from samples of beneficiaries and the physicians who ordered their DME. We used the continuation of paid claims as a marker for continued access after Round 2 began. We surveyed physicians and beneficiaries to learn about the experience of beneficiaries for whom Medicare stopped paying for devices and supplies after Round 2 began. Because we did not receive sufficiently high response rates to our surveys, we did not project the survey responses we received to our populations of beneficiaries.

Identification of Beneficiaries Using Devices and Supplies

We identified beneficiaries who used CPAP/RAD devices and supplies in 2013 using data from Medicare's National Claims History File and CMS's Competitive Bidding Implementation Contractor.

We first created files of claims for CPAP/RAD devices and supplies. To do so, we downloaded a list of Healthcare Common Procedure Coding System (HCPCS) codes for CPAP/RAD devices and supplies subject to bidding from the Competitive Bidding Implementation Contractor's website. We then used these HCPCS codes to extract paid claims for CPAP/RAD devices and supplies from Medicare's National Claims History File. We created one claim file for 2012 and another for 2013. Next, we matched ZIP Codes from Medicare's Competitive Bidding Implementation Contractor to the beneficiary ZIP Code on the claim to identify each claim as being for a beneficiary in a Round 2 CBA, Round 1 CBA, or non-CBA.

To identify beneficiaries using devices, we used our claims files to select beneficiaries who were new users of CPAP/RAD with established compliance with the therapy. Specifically, we selected all beneficiaries in Round 2 CBAs and non-CBAs for whom there were no paid claims for devices in 2012 and at least five paid claims for devices in the first half of 2013. This identified 41,575 beneficiaries.

To identify beneficiaries using CPAP/RAD supplies, we used our 2013 claims file to select all beneficiaries for whom there was at least one paid claim for supplies from January through June 2013. This identified 895,618 beneficiaries. We used this criterion because CPAP/RAD supplies comprise a wide range of items, some of which may need to be replaced once a month and others every several months. See Tables A-1 and A-2 for additional detail on beneficiary selection criteria.

Table A-1: Selection Criteria for Sample of Beneficiaries Using CPAP/RAD Devices

Characteristics of Device-Using Beneficiaries in Sample	Beneficiaries in Round 2 CBAs	Beneficiaries in Non-CBAs	Total
<p><u>HCPCS: With RR Modifier:</u> E0470–E0472: Respiratory Assist Device E0601: Continuous Airway Pressure Device</p> <p><u>Payment History</u> No paid claims in 2012 At least 5 paid claims Jan.-June 2013</p>	18,634	22,941	41,575

Source: OIG analysis of Medicare claims data, 2016.

Table A-2: Selection Criteria for Sample of Beneficiaries Using CPAP/RAD Supplies

Characteristics of Supply-Using Beneficiaries in Sample	Beneficiaries in Round 2 CBAs	Beneficiaries in Non-CBAs	Total
<p><u>HCPCS:</u> A4604: Tubing With Heating Element A7027–A7029: Combination Oral/Nasal Mask, etc. A7030–A7033: Full Face Mask, etc. A7034–A7039: Nasal Interface, etc. A7044–A7045: Oral Interface, Exhalation Port A7046: Water Chamber for Humidifier</p> <p><u>Payment History</u> At least 1 paid claim Jan.-June 2013</p>	401,242	494,376	895,618

Source: OIG analysis of Medicare claims data, 2016

Identification of Populations of Beneficiaries for Whom Medicare Payments Stopped

Next, for each group of beneficiaries we identified, we identified the population of those for whom there were no paid Medicare claims after Round 2 began. For CPAP/RAD devices, we identified 1,498 beneficiaries for whom there were claims for CPAP/RAD devices from January 1 through June 30, 2013, only. We did the same for the supplies, identifying 348,271 beneficiaries for whom there were claims for supplies in the first half of 2013 only. See Tables A-3 and A-4 for additional detail on beneficiary claims data.

Table A-3: Beneficiaries With Paid Claims for CPAP/RAD Devices

Status of Beneficiaries Who Used CPAP/RAD Devices Before Round 2 Began	Beneficiaries in Round 2 CBAs	Beneficiaries in Non-CBAs	Total
Medicare payments stopped after Round 2 began (device population)	719	779	1,498
Medicare payments continued after Round 2 began	17,915	22,162	40,077

Source: OIG analysis of Medicare claims data, 2016.

Table A-4: Beneficiaries With Paid Claims for CPAP/RAD Supplies

Status of Beneficiaries Who Used CPAP/RAD Supplies Before Round 2 Began	Beneficiaries in Round 2 CBAs	Beneficiaries in Non-CBAs	Total
Medicare payments stopped after Round 2 began (supply population)	185,551	162,720	348,271
Medicare payments continued after Round 2 began	215,691	331,656	547,347

Source: OIG analysis of Medicare claims data, 2016.

Sample Selection

From each population of beneficiaries for whom Medicare payments stopped after Round 2 began, we drew a statistical sample of 300 beneficiaries. We stratified the samples by whether the beneficiaries were in Round 2 CBAs or non-CBAs. See Table A-5 for a description of beneficiary sample sizes.

Table A-5: Samples of Beneficiaries Using CPAP/RAD Devices and Supplies

Type of Beneficiary	Beneficiaries in Round 2 CBAs	Beneficiaries in Non-CBAs	Total
Beneficiaries using CPAP/RAD devices	150	150	300
Beneficiaries using CPAP/RAD supplies	150	150	300
Total	300	300	600

Source: OIG analysis of Medicare claims data, 2016.

Physician Survey

To determine whether beneficiaries in our samples still had a prescribed need for devices or supplies, we surveyed the physicians who were the ordering physician on the beneficiaries' final CPAP/RAD claims and who were still living. We sent similar but different surveys for devices and supplies. The surveys asked physicians if the beneficiary for whom they ordered devices or supplies had a prescribed need for them during the period from July 1 through December 31, 2013. In the surveys, we also asked physicians if they prescribed alternate DME to replace CPAP/RAD devices, such as a home ventilator or oral appliance.

We made at least three attempts to reach physicians with our survey. We sent the surveys using a trackable delivery service and accepted survey responses by mail and by fax to a secure fax server. We received responses from 501 of the 579 physicians we surveyed. In 352 of those responses, physicians were able to answer our key question as to whether or not the beneficiary still needed devices or supplies after bidding began. In 289 of these responses, physicians told us that the beneficiary had a prescribed need for CPAP/RAD devices or supplies after Round 2 began. See Tables A-6 and A-7 for information on physician survey sampling and responses.

Table A-6: Results From Survey of Physicians for Beneficiaries Using CPAP/RAD Devices

Characteristics of Physicians	Round 2 CBAs	Non-CBAs	Total
A) Total Physicians in Sample	150	150	300
B) Physicians Surveyed¹	144	145	289
C) Physicians Responding with Usable Data²	106	116	222
D) Physicians Answering Key Question	87	100	187
Physician Response Rate (Row C/Row A)	71%	77%	74%

Source: OIG analysis of data from survey of physicians, 2016.

¹We did not survey a physician if the beneficiary was deceased when bidding began, if the physician was under investigation, or if the physician was no longer in business.

²In some cases, physicians cooperated by responding to our survey, but their responses included no usable information.

Table A-7: Results from Survey of Physicians for Beneficiaries Using CPAP/RAD Supplies

Characteristics of Physicians	Round 2 CBAs	Non-CBAs	Total
A) Total Physicians in Sample	150	150	300
B) Physicians Surveyed¹	147	143	290
C) Physicians Responding With Usable Data²	96	97	193
D) Physicians Answering Key Question	80	85	165
Physician Response Rate (Row C/Row A)	64%	65%	64%

Source: OIG analysis of data from survey of physicians, 2016.

¹We did not survey a physician if the beneficiary was deceased when bidding began, if the physician was under investigation, or if the physician was no longer in business.

²In some cases, physicians cooperated by responding to our survey, but their responses included no usable information.

Beneficiary Survey

To learn about beneficiaries' experiences in the 6 months immediately after Medicare stopped paying for their CPAP/RAD devices or supplies, we sent a brief survey to beneficiaries. Specifically, we surveyed the beneficiaries who were still living and whose physicians told us in the physician survey that they had a prescribed need for devices or supplies

after Round 2 began. We sent similar but different surveys for devices and supplies. In the surveys, we asked beneficiaries if they continued to use CPAP/RAD devices/supplies after Round 2 began and, if so, how they managed given that Medicare did not pay for their devices/supplies.

We made at least three attempts to reach beneficiaries with our survey. We used a trackable delivery service to send the surveys to beneficiaries and provided them with postage-paid business reply mail envelopes for returning the surveys directly to the Office of Inspector General. We received responses from 124 of the 289 beneficiaries we surveyed. We did not survey beneficiaries when Medicare records indicated that they were no longer living. See Tables A-8 and A-9 for information on beneficiary survey eligibility and responses.

Table A-8: Response Rates for Survey of Beneficiaries Using CPAP/RAD Devices

Status of Beneficiaries	Beneficiaries in Round 2 CBAs	Beneficiaries in Non-CBAs	Total
Beneficiaries Eligible for Survey	70	78	148
Beneficiaries Responding With Usable Data	27	31	58
Beneficiary Response Rate	39%	40%	39%

Source: OIG analysis of survey data, 2016.

Table A-9: Response Rates for Survey of Beneficiaries Using CPAP/RAD Supplies

Status of Beneficiaries	Beneficiaries in Round 2 CBAs	Beneficiaries in Non-CBAs	Total
Beneficiaries Eligible for Survey	69	72	141
Beneficiaries Responding With Usable Data	38	24	62
Beneficiary Response Rate	55%	33%	44%

Source: OIG analysis of survey data, 2016.

Data Analysis

All-Beneficiary Analysis Using Medicare Claims

We analyzed claims data to determine the extent to which beneficiaries experienced a potential disruption in access to devices or supplies. To do so, we calculated the percentage of device-using beneficiaries for whom there were no paid claims for devices after Round 2 began and the

percentage of supply-using beneficiaries for whom there were no paid claims for supplies after Round 2 began. We used these percentages as the basis of our lead findings for devices and supplies.

We analyzed claims data to determine two aspects of Medicare payments for device-using beneficiaries for whom there were continued payments after bidding began. First, we counted the number of paid claims for devices for these beneficiaries after Round 2 began to determine whether payments had continued for a sustained period. Second, we checked whether these beneficiaries experienced an interruption in payments immediately after Round 2 began. To do so, we calculated the days between the last paid claim for a device before Round 2 began and the first paid claim after Round 2 began. We then determined the percentage of beneficiaries for whom this span was greater than 31 days, which was the average, median, and mode number of days between claims for three of the four CPAP/RAD devices subject to bidding and was the median and mode number of days for the fourth device.

We also analyzed claims data to determine the Medicare payments for our sample of supply-using beneficiaries in the 6 months before Round 2 began. Specifically, we determined the average number of supply claims that beneficiaries had and the number of unique types of supplies they received.

Tabulation of Physician and Beneficiary Survey Responses

We counted responses to our physician survey to determine the number of responding physicians who told us that beneficiaries in our samples still needed devices or supplies after Round 2 began. Our denominator of responses for this analysis considered the responses in which physicians were able to tell us whether or not the beneficiary still needed devices or supplies after Round 2 began—i.e., we did not include “cannot determine” responses.

We also counted survey responses to determine the extent to which responding physicians reported that they prescribed alternate DME to beneficiaries in our samples.

We counted responses to our survey of device-using beneficiaries to determine the extent to which beneficiaries reported that they continued to use CPAP/RAD devices in the 6 months after Round 2 began. For beneficiaries who reported continued use, we counted how many reported that they continued to use the device from their existing supplier, found a new supplier, paid out of pocket, or borrowed a device from a friend. When beneficiaries reported stopping use of CPAP/RAD, we counted how

many reported stopping because they could not find a supplier or they had switched to an alternative device.

We counted responses to our survey of supply-using beneficiaries to determine the extent to which beneficiaries reported that they continued to use CPAP/RAD supplies in the 6 months after Round 2 began, and, if so, whether they needed any supplies during that time. For beneficiaries who reported that they did need supplies during that time, we counted how many reported that they got supplies from their existing supplier, found a new supplier, paid out of pocket, or borrowed a device from a friend.

Limitations

This review has two limitations. First, discontinuation of claims or disproportionately lower rates of continued claims for supplies in Round 2 CBAs may indicate disrupted or impeded access to supplies. Such discontinuation or lower rates may be caused by factors that did not disrupt access to supplies. For example, if some beneficiaries had received more supplies than they needed prior to Round 2 of the CBP, they could have had fewer claims after Round 2 yet still have accessed all needed supplies.

Secondly, our survey response rate was too low to project the results to all beneficiaries for whom claims did not continue. Therefore, we present our survey responses as testimonial evidence to provide insights into these individual beneficiaries' experiences in accessing CPAP/RAD devices and supplies. We did not independently verify responses from physicians and beneficiaries, nor did we conduct a medical review of beneficiaries' medical need for these devices or supplies.

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