

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE-ALLOWED CHARGES
FOR NONINVASIVE VENTILATORS
ARE SUBSTANTIALLY HIGHER
THAN PAYMENT RATES OF
SELECT
NON-MEDICARE PAYERS**

*Inquiries about this report may be addressed to the Office of Public Affairs at
Public.Affairs@oig.hhs.gov.*



Christi A. Grimm
Principal Deputy Inspector General

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Office of Inspector General

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Report in Brief

Date: September 2020
Report No. A-05-20-00008

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Audit

Medicare-allowed charges for noninvasive ventilators increased from \$279.9 million in 2016 to \$424.4 million in 2018, an increase of 52 percent. We are concerned about the relationship of these increased costs to prices per noninvasive ventilator, and specifically concerned about whether Medicare-allowed charges are comparable with payment rates of select non-Medicare payers.

Our objective was to determine whether Medicare-allowed charges for noninvasive ventilators were comparable with payment rates of select non-Medicare payers.

How OIG Did This Audit

Our audit covered \$1.1 billion in Medicare-allowed charges for approximately 1 million monthly noninvasive ventilator rental units billed under Healthcare Common Procedure Coding System (HCPCS) code E0466 during calendar years (CYs) 2016 through 2018. We calculated a nonstatistical estimate of payment differences for HCPCS code E0466 that was based on a comparison of Medicare-allowed charges and payment rates of select non-Medicare payers. Of the estimated payment differences, we calculated the 80 percent that Medicare would pay and the 20 percent that beneficiaries would pay. Our analysis included noninvasive ventilators paid under Medicare fee schedules for all 50 States, the District of Columbia, and U.S. territories.

Medicare-Allowed Charges for Noninvasive Ventilators Are Substantially Higher Than Payment Rates of Select Non-Medicare Payers

What OIG Found

For CYs 2016 through 2018, we estimated that Medicare and beneficiaries could have saved \$86.6 million if Medicare-allowed charges were comparable with payment rates of select non-Medicare payers on HCPCS code E0466. Of this payment difference, we estimated that Medicare paid \$69.3 million and Medicare beneficiaries paid \$17.3 million. Generally, Medicare-allowed charges are higher than select non-Medicare payer payment rates because the Centers for Medicare & Medicaid Services (CMS) does not routinely evaluate pricing trends for noninvasive ventilators or payment rates of select non-Medicare payers. Rather, CMS uses statutorily mandated fee schedule payments that have an economic update factor applied to them annually. In 2016, CMS was required to adjust certain fee schedule amounts for durable medical equipment, prosthetics, orthotics, and supplies using information from the competitive bidding program. But this change did not affect the noninvasive ventilator HCPCS code reviewed for this report.

What OIG Recommends and CMS Comments

We recommend that CMS review Medicare-allowed charges for noninvasive ventilators HCPCS code E0466, for which Medicare and beneficiaries could have potentially saved an estimated \$86.6 million in CYs 2016 through 2018, and add noninvasive ventilators HCPCS code E0466 to the competitive bidding program as soon as practicable.

In written comments on our draft report, CMS confirmed that it had been evaluating noninvasive ventilators for potential inclusion in the competitive bidding program. CMS also confirmed that noninvasive ventilators had initially been included in Round 2021 of the program. However, the product category was removed on April 9, 2020, because of the COVID-19 pandemic, limited access to ventilators, and other factors. CMS stated that it will consider whether to include noninvasive ventilators in future rounds of the program.

TABLE OF CONTENTS

INTRODUCTION.....	1
Why We Did This Audit.....	1
Objective.....	1
Background.....	1
The Medicare Program.....	1
Noninvasive Ventilator Definition and Billing Codes.....	2
Payment Methodology for Noninvasive Ventilators.....	2
CMS’s Authority To Adjust Medicare-Allowed Charges Under Competitive Bidding.....	3
How We Conducted This Audit.....	4
FINDING.....	5
Medicare and Beneficiaries Could Have Saved \$86.6 Million if Medicare- Allowed Charges Were Comparable With Select Non-Medicare Payers.....	5
Conclusion.....	7
RECOMMENDATIONS.....	7
CMS COMMENTS.....	7
APPENDICES	
A: Audit Scope and Methodology.....	9
B: Federal Laws and Regulations.....	11
C: Mathematical Calculation Methodology of Payment Differences.....	13
D: Total Estimated Payment Differences by Calendar Year.....	15
E: CMS Comments.....	16

INTRODUCTION

WHY WE DID THIS AUDIT

Medicare-allowed charges for noninvasive ventilators increased from \$279.9 million for 280,533 monthly rental units in 2016 to \$424.4 million for 417,335 monthly rental units in 2018, an increase of 52 percent.¹ We are concerned about the relationship of these increased Medicare costs to industry prices for noninvasive ventilators and whether the allowed charges are comparable with payment rates of select non-Medicare payers. For this report, “select non-Medicare payers” refers to private insurance companies that gave us pricing data for calendar years (CYs) 2016 through 2018 in a format that was comparable with the Medicare fee schedules.²

OBJECTIVE

Our objective was to determine whether the Medicare-allowed charges for noninvasive ventilators during CYs 2016 through 2018 were comparable with payment rates of select non-Medicare payers.

BACKGROUND

The Medicare Program

The Medicare program provides health insurance for people aged 65 and older, people with disabilities, and people with permanent kidney disease. Medicare Part A provides inpatient hospital insurance benefits and coverage of extended care services for patients after hospital discharge, and Medicare Part B provides supplementary medical insurance for medical and other health services, including durable medical equipment, prosthetics, orthotics, and supplies

¹ Total allowed charges were as of March 2019. The allowed charges referenced in this report consist of the allowed payment rate listed on the Medicare fee schedule, including any coinsurance and deductible requirements that are the beneficiary’s responsibility. CMS develops fee schedules for durable medical equipment, and this comprehensive listing of fee maximums is used to reimburse a physician, other providers, or both for covered services.

² We contacted 94 private insurance companies that provided coverage in all 50 States, the District of Columbia, and Puerto Rico. We obtained pricing data from 40 of those private insurance companies for monthly noninvasive ventilator rental units billed under Healthcare Common Procedure Coding System (HCPCS) code E0466. We used pricing data in the form of fee schedules in our comparison with Medicare fee schedules. We considered only pricing data that was not: (1) an average or median rate; (2) a percent of billed charges; (3) for purchases; or (4) for rental units funded by Medicare or Medicaid. The 40 private insurance companies provided a total of 50 responses covering 33 States, the District of Columbia, and Puerto Rico. Eight of these companies provided responses that covered more than one State or geographic area within a State.

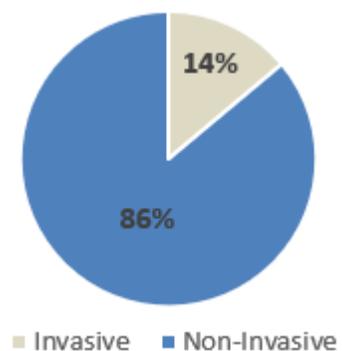
(DMEPOS).³ Medicare beneficiaries are responsible for certain out-of-pocket costs, such as deductibles and coinsurance, for both Part A and Part B services.

The Centers for Medicare & Medicaid Services (CMS) administers Medicare. Currently, CMS contracts with two durable medical equipment Medicare administrative contractors (DME MACs) to process and pay Medicare Part B claims for DMEPOS, including ventilators. Each DME MAC processes claims for two jurisdictions that comprise specific States and territories. Suppliers must submit claims to the DME MAC that services the State or territory in which a Medicare beneficiary permanently resides.

Noninvasive Ventilator Definition and Billing Codes

Ventilators are machines that supply oxygen, or a mixture of oxygen and air, and that are used in artificial respiration to control or assist breathing. Noninvasive ventilators are ventilators in which the interface, such as a mask or chest shell, does not enter the body.⁴ A ventilator is categorized as an item requiring frequent and substantial servicing to avoid risk to a beneficiary's health.⁵ Rental payments for items requiring frequent and substantial servicing are made monthly and continue until the medical necessity ends. During CYs 2016 through 2018, ventilators were billed using two HCPCS codes: one for invasive ventilators (E0465) and one for noninvasive ventilators (E0466). This audit focused solely on noninvasive ventilators because they account for 86 percent of the total \$1.2 billion Medicare spent on both types of ventilators. (See Figure 1.)

Figure 1: Total Invasive and Noninvasive Ventilator Allowed Charges During CYs 2016 through 2018



Payment Methodology for Noninvasive Ventilators

Noninvasive ventilators are eligible for Part B coverage, and Federal law generally requires the use of a fee schedule to determine payment.⁶ CMS established and implemented the DMEPOS fee schedules in 1989 and has adjusted them yearly in accordance with provisions in the Act. For CYs 2016 through 2018, CMS established the Medicare-allowed charges for the noninvasive ventilator HCPCS code by updating the prior year's DMEPOS fee schedule amount using an

³ The Social Security Act (the Act) §§ 1832(a)(1) and 1861(s)(6), (s)(8), and (s)(9).

⁴ A chest shell fits snugly to the outside of the chest. A machine creates a vacuum between the shell and the chest wall, causing the chest to expand and air to be sucked into the lungs.

⁵ 42 CFR § 414.222.

⁶ The Act § 1834(a)(1).

annual economic adjustment factor (such as an adjusted consumer price index).⁷ In 2016, CMS was required to adjust certain DMEPOS fee schedule amounts using information from the competitive bidding program,⁸ but this change did not affect the fee schedule amount for noninvasive ventilator HCPCS code E0466.

When processing noninvasive ventilator claims, DME MACs determine the allowed charge, which is the lower of the billed charge for the item or the applicable fee schedule amount. In most instances, the fee schedule amount for the billed HCPCS code is the allowed charge. Once the allowed charge is determined, the beneficiary's deductible is subtracted from the allowed charge. Typically, Medicare's responsibility is 80 percent and the beneficiary's responsibility is 20 percent of the allowed charge.⁹

CMS's Authority To Adjust Medicare-Allowed Charges Under Competitive Bidding

CMS has legislative authority to adjust Medicare-allowed charges for ventilator HCPCS codes under the competitive bidding program. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)¹⁰ directed CMS to phase in a Medicare competitive bidding program under which prices for certain DMEPOS items would not be determined by a fee schedule. The Act includes durable medical equipment (DME), including DME items requiring frequent and substantial servicing, such as ventilators, as one of the categories of items subject to competitive bidding.¹¹ However, the Act authorized CMS to first phase into the competitive bidding program those items and services that have the highest cost and highest volume, or that the Secretary of Health and Human Services (Secretary) determines have the largest savings potential.¹²

⁷ The Act § 1834(a)(3)(B)(iv).

⁸ 42 CFR § 414.210(g).

⁹ The Budget Control Act of 2011 (P.L. No. 112-25) required mandatory, across-the-board reductions in Federal spending, also known as sequestration. The American Taxpayer Relief Act of 2012 (P.L. No. 112-240) postponed sequestration for 2 months. As required by law, President Obama issued a sequestration order on March 1, 2013. As a result, claims with service dates on or after April 1, 2013, are subject to a mandatory 2-percent payment reduction. DME MACs must make this sequestration reduction when determining what Medicare pays rather than solely use the Medicare-allowed charges. The beneficiary's payment for deductibles and coinsurance are not affected by the payment reduction. The Coronavirus Aid, Relief, and Economic Security Act (P.L. No. 116-136) temporarily exempts Medicare from payment reductions under sequestration between May 1 and December 31, 2020.

¹⁰ P.L. No.108-173 § 302(b)(1), amending the Act § 1847, 42 U.S.C. § 1395w-3.

¹¹ The Act §§ 1847(a)(1)(A) and (a)(2)(A), 42 U.S.C. §§ 1395w-3(a)(1)(A) and (a)(2)(A).

¹² The Act § 1847(a)(1)(B)(ii), 42 U.S.C. § 1395w-3(a)(1)(B)(ii).

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)¹³ temporarily delayed the implementation of the DMEPOS competitive bidding program. As a result, the first round of the competitive bidding program, referred to as the “Round 1 Rebid,” did not become effective until January 1, 2011. Ventilators were not included in the Round 1 Rebid or Round 2, which CMS implemented in July 2013. Although ventilators are DME items that are subject to competitive bidding, a competitive bidding program for ventilators has not yet been implemented.¹⁴ Noninvasive ventilators were scheduled to be included in the next round of competitive bidding beginning in January 2021. As of April 2020, CMS removed noninvasive ventilators from Round 2021 of the DMEPOS Competitive Bidding Program because of the COVID-19 pandemic, the President’s exercise of the Defense Production Act, public concern regarding access to ventilators, and because the noninvasive ventilators product category was new to the DMEPOS Competitive Bidding Program.

HOW WE CONDUCTED THIS AUDIT

Our audit covered \$1.1 billion in Medicare-allowed charges for approximately 1 million monthly noninvasive ventilator rental units billed under HCPCS code E0466 during CYs 2016 through 2018. Select non-Medicare payers voluntarily provided pricing data for CYs 2016 through 2018.¹⁵ For each CY, we calculated a nonstatistical estimate of the difference between the Medicare-allowed charge and the median payment rate of select non-Medicare payers. Of the estimated payment differences, we calculated the 80 percent that Medicare would pay and the 20 percent that beneficiaries would pay. We analyzed the payment differences for E0466 in each CY to identify the noninvasive ventilator Medicare-allowed charge that CMS could adjust under the competitive bidding program to determine whether Medicare payments were comparable with payment rates of select non-Medicare payers. Our analysis included noninvasive ventilators paid for under Medicare fee schedules for all 50 States, the District of Columbia, and U.S. territories. We did not determine whether the allowed charges were for ventilators that were medically necessary.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

¹³ P.L. No. 110-275 § 154(a)(1).

¹⁴ As of January 1, 2019, CMS temporarily halted the entire DMEPOS competitive bidding program. CMS expects to resume the program after December 31, 2020.

¹⁵ We contacted 94 private insurance companies that provided coverage in all 50 States, the District of Columbia, and Puerto Rico. We received 53 voluntary responses; 41 private insurance companies did not respond. Of the 53 voluntary responses, 40 private insurance companies provided pricing data for CYs 2016 through 2018 for ventilator rental units billed under HCPCS code E0466 in a format similar to Medicare fee schedules. These 40 private insurance companies provided a total of 50 responses covering 33 States, the District of Columbia, and Puerto Rico.

Appendix A contains the details of our audit scope and methodology, Appendix B contains the Federal laws and regulations related to Medicare payments for ventilators, Appendix C contains our mathematical calculation methodology of payment differences, and Appendix D contains the total estimated payment differences by CY for our audit period.

FINDING

Medicare-allowed charges for noninvasive ventilators are not comparable with payment rates of select non-Medicare payers. Specifically, Medicare and beneficiaries paid millions of dollars more than non-Medicare payers for ventilators billed under HCPCS code E0466 during CYs 2016 through 2018. Medicare and beneficiaries paid more than select non-Medicare payers for noninvasive ventilators because CMS did not routinely evaluate pricing trends for ventilators or payment rates of select non-Medicare payers for the same devices. For the HCPCS code reviewed, we determined that the Medicare-allowed charges could be adjusted under the competitive bidding program.

MEDICARE AND BENEFICIARIES COULD HAVE SAVED \$86.6 MILLION IF MEDICARE-ALLOWED CHARGES WERE COMPARABLE WITH SELECT NON-MEDICARE PAYERS

We estimated that Medicare and beneficiaries could have saved \$86.6 million over the 3-year period if Medicare-allowed charges had been adjusted to match non-Medicare payer prices on HCPCS code E0466. We estimated that Medicare could have saved \$69.3 million of this amount and Medicare beneficiaries could have saved \$17.3 million.

We received 50 responses from 40 private insurance companies covering 33 States, the District of Columbia, and Puerto Rico. Eight of these companies provided responses that covered more than one State or geographic area within a State. Figure 2 shows the range of non-Medicare payment rates provided by the 40 companies that voluntarily responded.

Figure 2: Range of Select Non-Medicare Payment Rates for HCPCS Code E0466



Medicare fee schedule-allowed charges for E0466 were \$1,055 in 2016, \$1,063 in 2017, and \$1,074 in 2018. Pricing data voluntarily provided from select non-Medicare payers resulted in a median payment rate of \$923 in 2016 and 2017, and \$929 in 2018. Figure 3 shows the comparison of the Medicare fee schedule rates to the median non-Medicare payment rates in each year.

Figure 3: Comparison of Medicare Fee Schedule to Median Non-Medicare Payment Rates

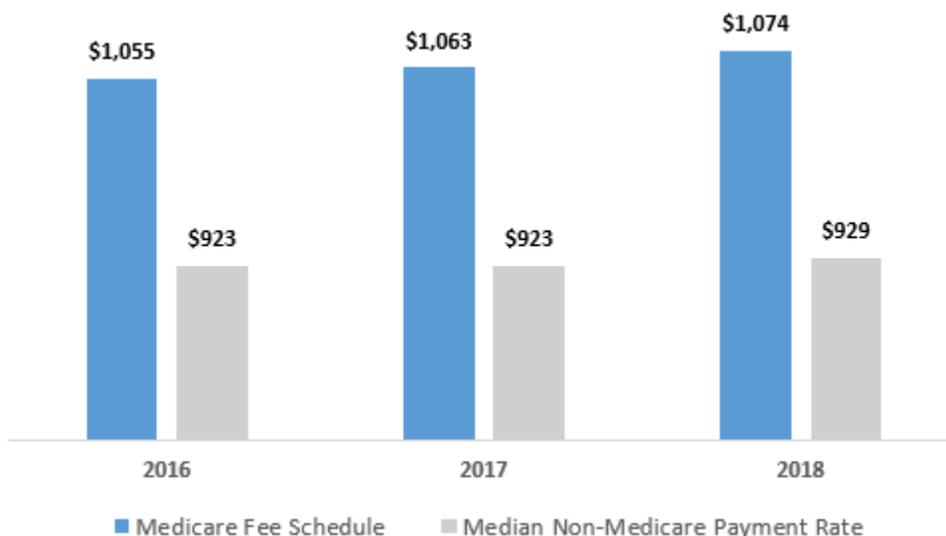
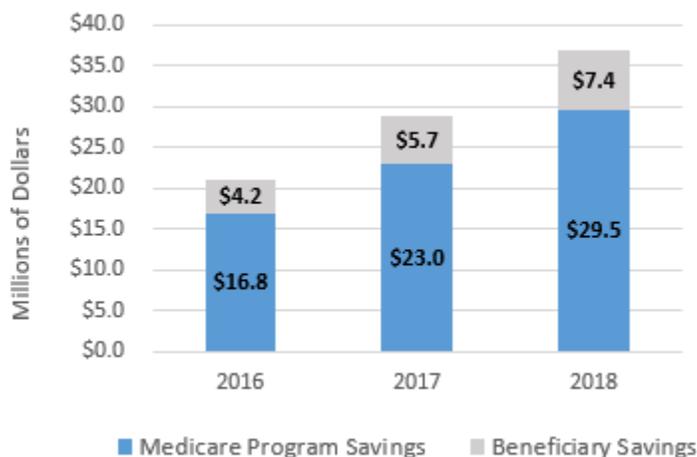


Figure 4 shows the estimated annual Medicare and beneficiary savings if Medicare-allowed charges had been comparable with payment rates of select non-Medicare payers for noninvasive ventilators during CYs 2016 through 2018.

Figure 4: Estimated Annual Medicare Program and Beneficiary Savings for Noninvasive Ventilators



Medicare and beneficiaries paid more than select non-Medicare payers for noninvasive ventilators because CMS did not routinely evaluate pricing trends for ventilators or payment

rates of select non-Medicare payers for the same devices. CMS used mandated fee schedule amounts that it adjusted by annually applying a general economic update factor as required by the Act. However, the general economic update factors in the Act are not specific to any type of DME, including noninvasive ventilators, or to trends in ventilator prices set by non-Medicare payers.

For the HCPCS code reviewed, we determined that the Medicare-allowed charges could have been adjusted using competitive bidding. Assuming that CMS established annual rates comparable to the payment rates of select non-Medicare payers, the estimated payment differences for CYs 2016 through 2018 could have been significantly reduced.

CONCLUSION

A strategic goal for CMS is to improve Medicare services and make them affordable.¹⁶ CMS bases Medicare fee schedules for noninvasive ventilators on historical data updated annually using general economic factors, such as an adjusted consumer price index, as prescribed in the Act. Over time, the difference between the fee schedule amounts and the payment rates of select non-Medicare payers may widen because the general economic adjustment factor does not account for trends in prices for noninvasive ventilators. CMS, under its existing authority, may adjust Medicare-allowed charges for noninvasive ventilators using its competitive bidding process. We identified Medicare and beneficiary payment differences totaling \$86.6 million for CYs 2016 through 2018.

RECOMMENDATIONS

We recommend that the Centers for Medicare & Medicaid Services review Medicare-allowed charges for noninvasive ventilators HCPCS code E0466, for which Medicare and beneficiaries could have potentially saved an estimated \$86,579,173 in CYs 2016 through 2018, and add noninvasive ventilators HCPCS code E0466 to the competitive bidding program as soon as practicable.

CMS COMMENTS

In written comments on our draft report, CMS confirmed that it had been evaluating noninvasive ventilators for potential inclusion in the competitive bidding program. CMS also confirmed that noninvasive ventilators had initially been included in Round 2021 of the program. However, the product category was removed on April 9, 2020, because of the COVID-19 pandemic, limited access to ventilators, and other factors. CMS stated that it will consider

¹⁶ CMS Strategic Planning Documents and Reports. Available online at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Strategic-Planning-Documents-Reports.html>. Accessed on January 28, 2020.

whether to include noninvasive ventilators in future rounds of the program. CMS's comments are included in their entirety as Appendix E.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$1.1 billion in Medicare payments for approximately 1 million monthly noninvasive ventilator rental units billed within the 50 States, the District of Columbia, and U.S. territories during CYs 2016 through 2018. Providers billed these ventilator rentals under HCPCS code E0466. We extracted the related Medicare-allowed charges from the CMS National Claims History (NCH) file. We established reasonable assurance of the authenticity and accuracy of the data obtained from the NCH file, but we did not assess the completeness of the file or whether the allowed charges were for ventilators that were medically necessary.

We did not perform a detailed review of the CMS internal control structure or its process for establishing the DMEPOS fee schedule amounts. We limited our review to understanding how CMS updated fee schedule rates for the HCPCS code E0466, and to comparing the Medicare-allowed charges with pricing data voluntarily provided by select non-Medicare payers. We did not independently verify the information provided to us by the select non-Medicare payers, but we verified that the information provided was comparable in format to the Medicare-allowed charges published according to specific geographic areas during our audit period.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and program guidance related to Medicare reimbursements for noninvasive ventilators;
- verified with CMS officials the process for monitoring and establishing the Medicare fee schedule payments applicable to the noninvasive ventilator HCPCS code reviewed;
- confirmed that the noninvasive ventilator HCPCS code E0466 was used for CYs 2016 through 2018;
- obtained summary lines of service claims data as of February 2019 for the noninvasive ventilators from the CMS NCH file billed under HCPCS code E0466 with beginning service dates between January 1, 2016, and December 31, 2018, and having a Medicare payment amount greater than \$0;
- obtained 50 non-Medicare, noninvasive ventilator rental unit prices for CYs 2016 through 2018 covering 33 States, the District of Columbia, and Puerto Rico from information voluntarily provided by 40 non-Medicare payers (Appendix C);

- calculated the median non-Medicare payment rate for noninvasive ventilator HCPCS code E0466 for CYs 2016 through 2018 (Appendix C);
- compared the Medicare-allowed charges with calculated non-Medicare payments for noninvasive ventilator HCPCS code E0466 for CYs 2016 through 2018 to estimate the differences in payment amounts;
- identified potential Medicare savings that CMS could achieve using available authorities to make Medicare-allowed charges comparable with payment rates of select non-Medicare payers;
- determined the Medicare and beneficiary portions of the Medicare payment differences by calculating 80 percent and 20 percent, respectively, of the estimated Medicare payment differences; and
- discussed the results of our review with CMS officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: FEDERAL LAWS AND REGULATIONS

SOCIAL SECURITY ACT

Section 1831 of the Act established a voluntary insurance program to provide medical insurance benefits for aged and disabled individuals who elect to enroll under the supplementary medical insurance program, commonly known as Medicare Part B.

Section 1832 of the Act outlines the benefits provided under Part B, including medical and other health services under section 1832(a)(1). Under section 1832(a)(2)(G), an individual covered by Part B is entitled to have payments made to him or her on his or her behalf for covered items (described in section 1834(a)(13)) that are furnished by a provider of services or by others under arrangements made by a provider of services.

Section 1861(S)(6) of the Act defines “medical and other health services” to include DME. Additionally, in section 1834(a)(13), the term “covered item” means DME as defined in section 1861(n), including equipment described in section 1861(m)(5). Section 1861(n) defines DME to include rented or purchased items used in a patient’s home. Section 1861(m)(5) defines covered home health services to include medical supplies and DME.

Section 1834(a)(3) of the Act identifies additional covered items as those for which there must be frequent and substantial servicing to avoid risk to the patient’s health, specifically including ventilators.

Section 1834(a)(3) of the Act identifies the payment methodology for items requiring frequent and substantial servicing eligible for Part B coverage. It also requires the use of a fee schedule payment methodology. Specifically, payments for ventilators are generally made monthly for their rental, and the amount recognized is the amount specified in subparagraph (B). For 1993 and subsequent years, the amount specified under section 1834(a)(3)(B)(iv) is the national limited payment amount for the item or device computed under subparagraph (C)(ii) for that year, defined as the amount determined for the preceding year increased by the covered item update for the subsequent year.

Section 1834(a)(14) of the Act identifies how the “covered item update” should be computed from 1991 and for each subsequent year. After 2011, the computed covered item update is the percentage increase in the consumer price index for all urban consumers for the 12-month period ending with June of the previous year reduced by the productivity adjustment as defined in section 1886(b)(3)(B)(xi)(II).

Section 1886(b)(3)(B)(xi)(II) of the Act defines “productivity adjustment” as an adjustment equal to the 10-year moving average of changes in annual economywide private nonfarm business multifactor productivity.

Section 1847(a) of the Act required that the Secretary establish and implement competitive acquisition programs for select items and services described in section 1847(a)(2), including DME for which payment would otherwise be made under section 1834(a). Therefore, CMS has the authority to establish a competitive acquisition program for ventilators requiring frequent and substantial servicing. Section 1847(a)(1)(B)(ii) allows the competitive acquisition programs to be phased in first among the items and services with the highest costs and highest volumes, or among those items and services that the Secretary determines have the largest savings potential.

LEGISLATION AUTHORIZING PAYMENT FOR DURABLE MEDICAL EQUIPMENT THROUGH COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES

Section 302(b) of the MMA amended section 1847 of the Act, stating that the Secretary must establish and implement payment of select DMEPOS items and services through a competitive acquisition program. Section 154 of the MIPPA temporarily delayed implementation of the new DMEPOS competitive acquisition program. As a result, the first round of this competitive acquisition program did not become effective until January 1, 2011.

CODE OF FEDERAL REGULATIONS

Federal regulations (42 CFR § 414.402) identify items requiring frequent and substantial servicing as specified in § 414.222(a) as eligible for inclusion in the competitive bidding program.

Federal regulations (42 CFR § 414.210(g)) establish that fee schedule amounts for certain DME items furnished on or after January 1, 2016, must be adjusted using information from competitive bidding programs. The regulation identifies several methodologies for applying competitive bidding information in adjusting fee schedule amounts.

APPENDIX C: MATHEMATICAL CALCULATION METHODOLOGY OF PAYMENT DIFFERENCES

For noninvasive ventilator HCPCS code E0466, we compared the amount paid by Medicare with the amount paid by 40 select non-Medicare payers. We performed this comparison to determine whether the Medicare-allowed charge was comparable with the pricing data received from the 40 non-Medicare payers that responded to our survey.

We extracted the Medicare-allowed charges from the CMS NCH file. We identified private insurance company pricing data using fee schedule data obtained from the 40 insurance companies that responded to our voluntary survey. We verified that these companies covered a reasonably wide range of States, including those States with high Medicare reimbursements.

We calculated the median non-Medicare payer payment rate using the non-Medicare payer payment rates received. Like the Medicare-allowed charges, the median select non-Medicare payer payment rates included any applicable beneficiary payments, such as coinsurance and deductibles.

We calculated the annual payment difference by taking the difference between the Medicare-allowed charge and the median select non-Medicare payer payment rate and multiplying that difference by the number of Medicare units provided in each year. A Medicare beneficiary is typically responsible for a coinsurance payment of 20 percent of the allowed charge (i.e., the fee schedule rate), plus any unmet Part B deductible. Accordingly, we calculated our estimated Medicare payment difference at 80 percent of the calculated annual total payment difference. The remaining 20 percent represented the annual beneficiary payment difference. Our estimated payment difference does not account for any unmet deductibles that would be applied in determining final Medicare payments.

Figure 5 on the next page shows an example of the mathematical calculation steps we used to determine the payment difference by calendar year:

Figure 5: Calculation of Payment Difference by Calendar Year

HCPCS code E0466—ventilator, noninvasive (e.g., mask, chest shell)

(1) 2018 Medicare units billed under E0466	417,335
(2) 2018 Medicare-allowed charges for E0466	\$424,419,307*
(3) 2018 calculated median select non-Medicare payment rate for E0466	\$928.60 [†]
(4) 2018 Medicare-allowed charges for E0466 (from Line 2)	\$424,419,307
(5) 2018 calculated select non-Medicare payer payments (Line 1 × Line 3)	\$387,537,281
(6) 2018 calculated payment difference for E0466 (Line 4 minus Line 5)	\$36,882,026
(7) 2018 calculated Medicare program payment differences for E0466 (80 percent of Line 6)	\$29,505,621
(8) 2018 calculated beneficiary payment differences for E0466 (20 percent of Line 6)	\$7,376,405

* Payment amounts for all steps in Figure 5 except step 3 are rounded to the nearest dollar.

[†] This non-Medicare payer payment rate of \$928.60 represents the median payment rate as calculated using the MEDIAN function in Microsoft Excel on the 50 fee schedule payment rates obtained from 40 non-Medicare payers.

APPENDIX D: TOTAL ESTIMATED PAYMENT DIFFERENCES BY CALENDAR YEAR

Table: Total Estimated Payment Differences by Calendar Year for HCPCS Code E0466

Calendar Year	Medicare Units*	Medicare-Allowed Charges*	Calculated Non-Medicare Payments*	Estimated Payment Differences*†
2016	280,533	\$279,877,914	\$258,867,436	\$21,010,477
2017	347,449	349,302,184	320,615,514	28,686,670
2018	417,335	424,419,307	387,537,281	36,882,026
TOTAL	1,045,317	\$1,053,599,405	\$967,020,231	\$86,579,173

* Summary of the annual comparison results for CYs 2016 through 2018 in accordance with Appendix C.

† This represents the differences between our calculation of Medicare-allowed charges and non-Medicare payment rates. These estimated payment differences represent Medicare-allowed charges that were not comparable with payment rates of select non-Medicare payers. Amounts in the Estimated Payment Differences column may not be exact due to rounding.

APPENDIX E: CMS COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: July 13, 2020

TO: Christi Grimm
Principal Deputy Inspector General
Office of Inspector General

FROM: Seema Verma
Administrator
Centers for Medicare & Medicaid Services

A handwritten signature in blue ink that reads "Seema Verma".

SUBJECT: Office of Inspector General (OIG) Draft Report: Medicare-Allowed Charges for Noninvasive Ventilators Are Substantially Higher Than Payment Rates of Select Non-Medicare Payers (A-05-20-00008)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report.

CMS ensures access to Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) for Medicare beneficiaries and is committed to incorporating market-based forces in our pricing methodologies whenever possible. The Medicare DMEPOS Competitive Bidding Program is consistent with these goals. The Medicare DMEPOS Competitive Bidding Program was established by the Medicare Prescription Drug Improvement and Modernization Act of 2003, and later modified by the Medicare Improvements for Patients and Providers Act of 2008, the Patient Protection and Affordable Care Act of 2010, and the Medicare Access and CHIP Reauthorization Act of 2015. Under the DMEPOS Competitive Bidding Program, DMEPOS suppliers compete to become Medicare contract suppliers by submitting bids to furnish certain items in competitive bidding areas. The statute requires that single payment amounts replace the current Medicare DMEPOS fee schedule payment amounts for competitively bid DMEPOS items and services furnished in competitive bidding areas of the country. The single payment amounts are determined by using bids submitted by DMEPOS suppliers. The DMEPOS Competitive Bidding Program has been an essential tool to help Medicare set market-based payment rates for DMEPOS items, save money for beneficiaries and taxpayers, and limit fraud and abuse in the Medicare Program. The program has saved billions of dollars since implementation while ensuring access to quality items and services.

As stated in the OIG's report, non-invasive ventilators were initially included in Round 2021 of the DMEPOS Competitive Bidding Program, which is scheduled to take effect January 2021. On April 9, 2020 the non-invasive ventilators product category was removed from this round of the program due to the novel COVID-19 pandemic, the Defense Production Act, access to ventilators, and the non-invasive ventilators product category being new to the DMEPOS Competitive Bidding Program.

The OIG's recommendations and CMS' responses are below.

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services review the Medicare-allowed charges for noninvasive ventilators HCPCS code E0466, for which Medicare and beneficiaries could have potentially saved an estimated \$86,579,173 in CYs 2016 through 2018, and add noninvasive ventilators HCPCS code E0466 to the competitive bidding program as soon as practicable.

CMS Response

CMS had been monitoring and evaluating noninvasive ventilators for potential inclusion in the DMEPOS Competitive Bidding Program during the OIG's audit period. As stated above, non-invasive ventilators were initially included in Round 2021 of the DMEPOS Competitive Bidding Program, which is scheduled to take effect January 2021. On April 9, 2020 the non-invasive ventilators product category was removed from this round of the program due to the novel COVID-19 pandemic, the Defense Production Act, access to ventilators, and the non-invasive ventilators product category being new to the DMEPOS Competitive Bidding Program. CMS will consider whether to include non-invasive ventilators in future rounds of the program.