Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE ALLOWABLE AMOUNTS FOR CERTAIN ORTHOTIC DEVICES ARE NOT COMPARABLE WITH PAYMENTS MADE BY SELECT NON-MEDICARE PAYERS

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October 2019
A-05-17-00033

Office of Inspector General

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Report in Brief
Date: October 2019
Report No. A-05-17-00033

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

Medicare Allowable Amounts for Certain Orthotic Devices Are Not Comparable With Payments Made by Select Non-Medicare Payers

Why OIG Did This Review

For calendar years (CYs) 2012 through 2015, Medicare allowable amounts for certain back, knee, elbow, and wrist orthotic devices increased from $631.8 million to $815.5 million. We are concerned about the relationship of these increased costs to prices per orthotic device, and specifically whether Medicare allowable amounts are comparable with payments made by select non-Medicare payers.

Our objective was to determine whether Medicare allowable amounts payments for certain orthotic devices were comparable with payments made by select non-Medicare payers.

How OIG Did This Review

Our audit covered $2.8 billion in Medicare allowable amounts for 7.9 million orthotic devices billed under 161 Healthcare Common Procedure Coding System (HCPCS) codes during CYs 2012 through 2015. We calculated a nonstatistical estimate of payment differences for the 161 HCPCS codes reviewed that was based on a comparison of Medicare allowable amounts and payments made by select non-Medicare payers. We estimated that Medicare would pay 80 percent of the payment differences and that the remaining 20 percent would be paid by the Medicare beneficiaries. We limited our analysis to orthotic devices paid under Medicare fee schedules for the 48 contiguous States and the District of Columbia.

What OIG Found

Medicare allowable amounts for certain orthotic devices are not comparable with payments made by select non-Medicare payers. For CYs 2012 through 2015, we estimated that Medicare and beneficiaries paid $341.7 million more than select non-Medicare payers on 142 HCPCS codes and $4.2 million less than select non-Medicare payers on 19 HCPCS codes. Of the net $337.5 million payment difference, we estimated that Medicare paid $270 million and Medicare beneficiaries paid $67.5 million. Generally, Medicare allowable amounts are more than select non-Medicare payer payments because CMS does not routinely evaluate pricing trends for orthotic devices or payments made by select non-Medicare payers. Instead, 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 durable medical equipment, prosthetics, orthotics, and supplies fee schedule amounts using information from the competitive bidding program, but this change did not affect the 161 orthotic device HCPCS codes reviewed for this report.

We identified 95 of the 161 codes for which the Medicare allowable amounts could be adjusted using existing legislative authority to make those amounts comparable with payments made by select non-Medicare payers. For the remaining 66 codes, CMS would be required to seek new legislative authority to make those adjustments.

What OIG Recommends and CMS Comments

We recommend that CMS (1) review the allowable amounts for 161 orthotic device HCPCS codes for which Medicare and beneficiaries paid an estimated $337.5 million more than select non-Medicare payers and adjust the allowable amounts, as appropriate, using regulations promulgated under existing legislative authority or if the allowable amounts cannot be adjusted using regulations promulgated under existing legislative authority, seek authority to align Medicare allowable amounts for these items with payments made by select non-Medicare payers; and (2) routinely review Medicare allowable amounts for new and preexisting orthotic devices to ensure that Medicare allowable amounts are in alignment with payments made by select non-Medicare payers or pricing trends.

In written comments on our draft report, CMS concurred with our recommendations and described its planned payment changes for certain orthotic devices.

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INTRODUCTION

WHY WE DID THIS REVIEW

During calendar years (CYs) 2012 through 2015, Medicare allowable amounts for certain back, knee, elbow, and wrist orthotic devices billed under 161 Healthcare Common Procedure Coding System (HCPCS) codes steadily increased from $631.8 million for 1.8 million units to $815.5 million for 2.2 million units.[1, 2] We are concerned about the relationship of these increased costs to prices per orthotic device, specifically whether Medicare allowable amounts are comparable with payments made by select non-Medicare payers. For this report, "select non-Medicare payers" refers to private insurance companies that gave us pricing data from CYs 2012 through 2015 in a format that was comparable to the Medicare fee schedules.[3]

OBJECTIVE

Our objective was to determine whether the Medicare allowable amounts for certain orthotic devices were comparable with payments made by select non-Medicare payers.

BACKGROUND

The Medicare Program

The Medicare program provides health insurance for people aged 65 years or 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 (DMEPOS).[4] Medicare beneficiaries are responsible for certain out-of-pocket costs, such as deductibles and coinsurance, for both Part A and Part B services.

[1] In requesting information from select non-Medicare payers and extracting applicable Medicare data, we determined that data from CYs 2012 through 2015 were the most complete and readily available. Medicare payments for orthotic devices billed under the 161 HCPCS codes were $901.8 million in CY 2016 for 2.4 million units and $1 billion in CY 2017 for 2.5 million units.

[2] The allowable amounts referenced in this report consist of the Medicare payment and any coinsurance and deductible requirements that are the beneficiary's responsibility.

[3] We sent letters to 58 private insurance companies that provided coverage in the 48 contiguous States and the District of Columbia. We obtained pricing data from 13 private insurance companies that were comparable to the Medicare fee schedule payments for certain orthotic devices billed under 161 HCPCS codes. The 13 private insurance companies provided coverage in 24 States and the District of Columbia.

[4] The Social Security Act (the Act) §§ 1832(a) and 1861(s)(6), (s)(8), and (s)(9).

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 orthotic devices. Each DME MAC processes claims for two jurisdictions, which are composed of 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.

Payment Methodology for Orthotic Devices

Orthotic devices are eligible for Part B coverage, and Federal law[5] requires the use of a fee schedule to determine payment. CMS established and implemented the DMEPOS fee schedules in 1989 and has adjusted them yearly in accordance with provisions in the Act. For CYs 2012 through 2015, CMS established the Medicare allowable amounts for the 161 orthotic device HCPCS codes covered in this audit by updating the prior year's DMEPOS fee schedule amount using an annual economic adjustment factor (such as an adjusted consumer price index).[6] In 2016, CMS was required to adjust certain DMEPOS fee schedule amounts using information from the competitive bidding program,[7] but this change did not affect the 161 orthotic device HCPCS codes reviewed for this report.

When processing orthotic device claims, the DME MACs determine the allowable amount, which is the lower of the actual charge for the item or the applicable fee schedule amount. In most instances, the fee schedule amount for the billed HCPCS code is the allowable amount. Once the allowable amount is determined, the beneficiary's unmet deductible is subtracted from the allowable amount. Typically, Medicare's responsibility is 80 percent and the beneficiary's responsibility is 20 percent of the allowable amount.[8]

Orthotic Device Definition and Billing Code Categories

Orthotic devices are rigid and semirigid devices used for supporting a weak or deformed body part or restricting or eliminating motion in a diseased or injured part of the body. For this report, these orthotic devices were billed using HCPCS codes that the OIG categorized into four main billing categories: "off-the-shelf" (OTS), "custom fitted" (prefabricated), "custom fabricated" (custom), or "other accessory." The "other accessory" billing category represents orthotic devices that are additions or ancillary devices used with OTS, prefabricated, or custom

[5] The Act § 1834(h).

[6] The Act §§ 1834(h)(2)(B)(ii) and (h)(4)(A)(xi).

[7] 42 CFR § 414.210(g).

[8] Claims with service dates on or after April 1, 2013, are subject to a mandatory 2-percent "sequestration" payment reduction until further notice. The DME MACs must consider this sequestration reduction in determining what Medicare pays and **not** the Medicare allowable amounts. The beneficiary's payment for deductibles and coinsurance are not affected by the payment reduction.

orthotic devices. The definitions for HCPCS codes billed as "other accessory" do not indicate whether the item should be billed as an OTS, prefabricated, or custom orthotic device. Table 1 shows the primary requirements in determining whether an item is billed as an OTS, prefabricated, or custom orthotic device.

Table 1: Coding Requirements by Orthotic Device Billing Category

Requirement	OTS	Prefabricated	Custom
Prefabricated Item	X	X	
Minimal Self-Adjustment[9]	X		
Substantial Modification Needed[10]		X	
Individually Made for Beneficiary			X
Expertise of a Certified Orthotist or Equivalent		X	X
Access to Followup Treatment		X	X
Training and Instructions on Use of the Device		X	X

CMS's Authority To Adjust Medicare Allowable Amounts

Currently, CMS has the authority under Federal regulations to adjust Medicare allowable amounts for orthotic device HCPCS codes if certain requirements are met under either of two methodologies. The two methodologies are: (1) the inherent reasonableness process and (2) the competitive bidding program.

Inherent Reasonableness Process

Under CMS's inherent reasonableness regulations, if CMS determines that the standard rules for calculating payment amounts will result in grossly deficient or excessive payment amounts for particular items, such as the orthotic devices selected for this audit, CMS can establish a special payment limit that is realistic and equitable for those items. The payment limit can be either a specific dollar amount or it can be based on a special method to be used in determining the payment amount. For a payment amount to be considered grossly deficient or excessive, it must be determined that an overall payment adjustment of 15 percent or more is necessary to produce a realistic and equitable payment amount.[11] In identifying grossly deficient or excessive payments and establishing payment amounts that are realistic and equitable, CMS needs to use valid and reliable data that meet Federal guidelines to the extent applicable. Before adopting a payment limit for a category of items or services under this authority, CMS

[9] 42 CFR § 414.402.

[10] Substantial modifications are changes made to an item that achieve an individualized fit for the beneficiary and require the expertise of a certified orthotist or an individual who has equivalent specialized training in the provision of orthotics, such as a physician, a treating practitioner, an occupational therapist, or a physical therapist, in compliance with all applicable Federal and State licensure and regulatory requirements.

[11] 42 CFR §§ 405.502(g)(1)(ii), (g)(1)(iii), and (g)(1)(v).

must publish proposed and final notices in the *Federal Register*. The notices must provide the requirements and circumstances, if any, under which a DME MAC may grant an exception to the payment limit.[12] Additional requirements must be met if a payment limit established under this authority would cause a payment adjustment that is greater than 15 percent of the payment amount within a year.[13] CMS last used its inherent reasonableness process in 1995 to lower the payment amounts for standard home blood glucose monitors.[14]

Competitive Bidding Program

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)[15] included a requirement for CMS to phase in a Medicare competitive bidding program under which current prices for certain DMEPOS items would not be determined by a fee schedule. The Act lists OTS orthotics as one of the categories of items subject to competitive bidding.[16] However, the Act authorized CMS to phase in the competitive bidding program first for items and services that have the highest cost or highest volume or that the Secretary of Health and Human Services determines have the highest savings potential.[17]

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)[18] 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. OTS orthotics were not included in the Round 1 Rebid or Round 2, which CMS implemented in July 2013. In 2014, CMS identified orthotic devices that qualify as OTS devices by specific HCPCS codes.[19] Although OTS orthotics are on the list of

[12] 42 CFR § 405.502(g)(3)(i).

[13] 42 CFR §§ 405.502(g)(1)(vi) and (h).

[14] 60 Fed. Reg. 3405, 3409 (Jan. 17, 1995).

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

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

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

[18] P.L. No. 110-275 § 154(a)(1).

[19] Of the 161 HCPCS codes covered by this audit, CMS classified 50 of them as qualifying as OTS devices subject to competitive bidding. Of these 50 codes, 26 were preexisting codes billed as prefabricated devices and reclassified as OTS devices in 2014. The remaining 24 codes were new and added to the Medicare fee schedules in 2014. For reporting purposes, we considered the 26 codes reclassified in 2014 as being billed for OTS devices for all 4 years of our audit period.

categories subject to competitive bidding, the program has not yet been implemented for OTS orthotics.[20]

HOW WE CONDUCTED THIS REVIEW

Our audit covered $2.8 billion in Medicare allowable amounts for 7.9 million orthotic devices billed under 161 HCPCS codes during CYs 2012 through 2015. The orthotic devices were billed under 50 OTS codes, 49 prefabricated codes, 48 custom codes, and 14 other accessory codes. We obtained pricing data from CYs 2012 through 2015 that were comparable to the Medicare fee schedules that select non-Medicare payers voluntarily provided.[21] For each HCPCS code and CY, we calculated a nonstatistical estimate of payment differences that was based on a comparison of Medicare allowable amounts and payments made by select non-Medicare payers. The Medicare allowable amounts and select non-Medicare payer payments included any coinsurance and deductibles requirements that are the beneficiaries' responsibility. We estimated that Medicare would pay 80 percent of the payment differences and the remaining 20 percent would be the Medicare beneficiaries' responsibility. We analyzed the payment differences for each HCPCS code and CY to identify certain orthotic device Medicare payment amounts that CMS could adjust under current authorities to ensure Medicare payments were comparable with payments made by select non-Medicare payers.

We limited our analysis to orthotic devices paid for under Medicare fee schedules for the 48 contiguous States and the District of Columbia. We did not determine whether the billed orthotic devices 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.

Appendix A contains the details of our audit scope and methodology, Appendix B contains the Federal regulations related to Medicare payments for orthotic devices, Appendix C contains our mathematical calculation methodology of payment differences, Appendix D contains the total estimated payment differences by HCPCS code for our audit period, Appendix E contains the

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

[21] We sent letters to 58 private insurance companies that provided coverage in the 48 contiguous States and the District of Columbia. In response to those 58 letters, we received 26 voluntary responses and 32 insurance companies did not respond. Of the 26 voluntary responses, only 13 private insurance companies provided pricing data from CYs 2012 through 2015 for certain orthotic devices billed under 161 HCPCS code that were comparable to Medicare fee schedules. These 13 private insurance companies provided coverage in 24 States and the District of Columbia.

comparative payments calculated by HCPCS code and CY, and Appendix F contains our analysis of estimated payment differences by CY.

FINDINGS

Medicare allowable amounts for certain orthotic devices are not comparable with payments made by select non-Medicare payers. For CYs 2012 through 2015, we estimated that Medicare and beneficiaries paid $341.7 million more than select non-Medicare payers on 142 HCPCS codes and $4.2 million less than select non-Medicare payers on 19 HCPCS codes. Of the net $337.5 million[22] in estimated payment differences, we calculated that Medicare paid $270 million and Medicare beneficiaries paid $67.5 million.

Of the 161 HCPCS codes we reviewed, we identified 95 codes for which the Medicare allowed amounts could be adjusted using existing legislative authority to make those amounts comparable with payments made by select non-Medicare payers. For the remaining 66 codes, CMS would be required to seek new legislative authority to make those adjustments.

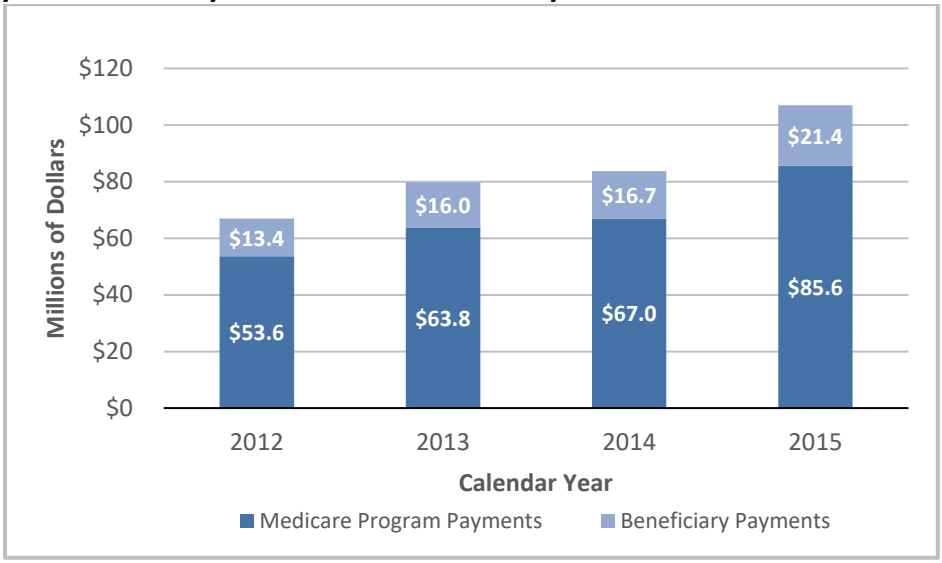
MEDICARE ALLOWABLE AMOUNTS FOR CERTAIN ORTHOTIC DEVICES ARE NOT COMPARABLE WITH PAYMENTS MADE BY SELECT NON-MEDICARE PAYERS

Medicare allowable amounts for certain orthotic devices are not comparable with payments made by select non-Medicare payers. For CYs 2012 through 2015, we estimated that Medicare and beneficiaries paid $341.7 million more than select non-Medicare payers on 142 HCPCS codes and paid $4.2 million less than select non-Medicare payers on 19 HCPCS codes. Of the net $337.5 million in Medicare payment differences for certain orthotic devices, we estimated that Medicare paid $270 million and Medicare beneficiaries paid $67.5 million. The net $337.5 million ($341.7 million minus $4.2 million) payment difference estimate is based on the assumption that Medicare payments for certain orthotic devices should have been comparable to the select non-Medicare payer payments shown in Appendix E.

The figure on the next page shows the estimated annual Medicare and beneficiary payments that exceeded payments made by select non-Medicare payers for certain orthotic devices during CYs 2012 through CY 2015.

[22] The net estimated payment differences totaling $337,547,542 are summarized by HCPCS codes in Appendix D.

Figure: Estimated Annual Medicare Program and Beneficiary Payments That Exceeded Payments Made by Select Non-Medicare Payers for Certain Orthotic Devices



Medicare and beneficiaries paid more than select non-Medicare payers for certain orthotic devices because CMS does not routinely evaluate pricing trends for orthotic devices or payments made by select non-Medicare payers for the same devices. CMS uses mandated fee schedule amounts that were adjusted using a general economic update factor that is applied annually in accordance with the Act. However, the general economic factors in the Act are not specific to any type of DME, including orthotic devices, or orthotic-device pricing trends by select non-Medicare payer.

Of the 161 HCPCS codes reviewed, we identified 95 codes for which the Medicare allowable amounts could be adjusted using existing legislative authority and 66 codes that would require CMS to seek new legislative authority to establish allowable amounts that are comparable to payments made by select non-Medicare payers. Using existing legislative authority and assuming that CMS established annual rates comparable to the amounts paid by select non-Medicare payers (see Appendix E), we determined that approximately two-thirds of the net $337.5 million in estimated payment differences for CYs 2012 through 2015 could have been avoided (see Appendix F).

CONCLUSION

A strategic goal for CMS is to improve Medicare services and to make them affordable.[23] Medicare fee schedules for orthotic devices are based on historical data updated annually using general economic factors, such as an adjusted consumer price index, as prescribed in the Act. Over time, Medicare payment amounts may not be comparable with payments made by select non-Medicare payers or pricing trends. CMS, under its existing authority, can adjust Medicare allowable amounts for orthotic devices using its inherent reasonableness and competitive bidding processes. We identified net Medicare and beneficiary payment differences totaling $337.5 million for CYs 2012 through 2015 and encourage CMS to consider these audit results and the impact of adjusting the Medicare fee schedules.

RECOMMENDATIONS

We recommend that the Centers for Medicare & Medicaid Services:

- review Medicare allowable amounts for 161 orthotic device HCPCS codes for which Medicare and beneficiaries paid an estimated $337,547,542 more than select non-Medicare payers and:
    - adjust the allowable amounts, as appropriate, using regulations promulgated under existing legislative authority, or
    - if the allowable amounts cannot be adjusted using regulations promulgated under existing legislative authority, seek legislative authority to align Medicare allowable amounts for these items with payments made by select non-Medicare payers; and
- routinely review Medicare allowable amounts for new and preexisting orthotic devices to ensure that Medicare allowable amounts are in alignment with payments made by select non-Medicare payers or pricing trends.

CMS COMMENTS

In written comments on our draft report, CMS concurred with our recommendations and described its planned payment changes for certain orthotic devices. CMS's comments are included in their entirety as Appendix G.

For the first recommendation, CMS indicated that select OTS back and knee braces have been included in Round 2021 of the DMEPOS competitive bidding program, which is scheduled to

[23] 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 and accessed on October 11, 2018.

take effect January 1, 2021. CMS will consider whether to phase in additional OTS orthotic devices in future rounds of this program. CMS does not have authority to set payments for custom orthotics under the DMEPOS competitive bidding program. However, CMS will review OIG's list of orthotic device HCPCS codes and related findings and take this recommendation into consideration when determining its next steps.

For the second recommendation, CMS stated that current regulations do not grant CMS authority to base fee schedule amounts for orthotics on payments made by select non-Medicare payers or pricing trends, but it will consider whether to recommend this proposal for inclusion in the President's next budget. CMS will consider OIG's findings and this recommendation when considering its next steps for review of orthotic device payment amounts. In the absence of authority under current regulations, CMS will consider whether to recommend this proposal for inclusion in the President's next budget. Additionally, CMS indicated that it included a methodology for calculating new fee schedule payments for new DMEPOS items and services in its DMEPOS calendar year 2020 proposed rule.[24]

[24] 84 Fed. Reg. 38330, 38377 (Aug. 6, 2019). This rule proposes a one-time adjustment to gap-filled fee schedule amounts based on decreases in supplier or commercial prices. CMS is required by statute to establish fee schedule amounts for DMEPOS items and services based on average reasonable charges from a past period of time, generally when the market for most items was stable and competitive. Although the updates to fee schedule covered items described in the Act allow for increases to the fees schedule amounts that can address increases in the cost of furnishing items and services over time or track increases in supplier or commercial prices, there are no corresponding updates to covered items that result in decreases in fee schedule amounts when the market for a new item becomes more mature and competitive following the initial gap-filling of the fee schedule amounts.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered $2.8 billion in Medicare payments for 7.9 million select orthotic devices billed within the 48 contiguous United States and the District of Columbia during CYs 2012 through 2015. Providers billed these selected orthotic devices under 161 HCPCS codes. We extracted the related Medicare payments from CMS's 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 billed orthotic devices were medically necessary.

We did not perform a detailed review of CMS's internal control structure or its process for establishing DMEPOS fee schedule amounts. We limited our review to understanding the basis for the DMEPOS fee schedule rates established for the 161 selected orthotic device HCPCS codes and our comparative analysis of the Medicare allowable amounts 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 allowable amounts published by HCPCS codes and 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 orthotic devices;

- verified with CMS officials the process for monitoring and establishing the Medicare fee schedule payments applicable to the 161 orthotic device HCPCS codes selected;

- selected 161 orthotic device HCPCS codes that related to simple back, knee, elbow, and wrist braces;

- arranged the 161 selected orthotic device HCPCS codes into 4 categories—OTS, prefabricated, custom, and other accessory—using published HCPCS code definitions in effect for CYs 2012 through 2015;

- obtained summary lines of service claims data for the 161 selected orthotic devices from CMS's NCH file of orthotic devices billed under 161 select HCPCS codes with beginning service dates between January 1, 2012, and December 31, 2015, having a Medicare payment amount greater than $0, and having a State code related to the 48 contiguous United States and the District of Columbia;

- obtained non-Medicare pricing data for CYs 2012 through 2015 from information voluntarily provided by select non-Medicare payers that provided coverage in the 48 contiguous United States and the District of Columbia (Appendix C);

- determined a non-Medicare payment for each of the 161 selected orthotic device HCPCS codes by calculating the rate for each code that was greater than 75 percent of rates received from select non-Medicare payers (Appendix C);

- compared Medicare allowable amounts with calculated non-Medicare payments for each of the 161 selected orthotic device HCPCS codes for CYs 2012 through 2015 to identify differences in payment amounts;

- estimated differences between Medicare allowable amounts and payments made by select non-Medicare payers;

- identified potential Medicare savings that CMS could achieve using available authorities to make Medicare allowable amounts comparable with payments made by select non-Medicare payers;

- identified potential Medicare savings associated with payment differences for which CMS currently has no authority to align Medicare allowable amounts with payments made by select non-Medicare payers;

- determined the Medicare and beneficiary portions of the Medicare payment differences by calculating 80 percent and 20 percent of the estimated Medicare payment differences, respectively; 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)(I), an individual covered by Part B is entitled to have payment made to him or her on his or her behalf for prosthetic devices and orthotics and prosthetics (described in § 1834(h)(4) of the Act) that are furnished by a provider of services or by others under arrangements made by a provider of services.

Section 1861(s) of the Act defines "medical and other health services" as any of the following items or services:

> (6) durable medical equipment; . . . (8) prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens; (9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition; . . . .

Section 1834(h) of the Act identifies the payment methodology for "prosthetic devices and orthotics and prosthetics" that are eligible for Part B coverage and require the use of a fee schedule payment methodology. Specifically, payments for prosthetic devices and orthotics and prosthetics are generally made in a lump-sum amount for the purchase of the item in an amount equal to 80 percent of the payment basis that is the lesser of (1) the actual charge for the item or (2) the amount recognized under section 1834(h)(2) as the purchase price for the item (the Act §§ 1834(h)(1)(A) and (h)(1)(B)). In 1994 and subsequent years, the amount recognized under section 1834(h)(2) is the regional purchase price computed under section 1834(h)(2)(B) for that year (the Act § 1834(h)(2)(C)(iv)).

Section 1834(h)(2)(B) of the Act identifies how regional purchase prices should be computed from 1992 and for each subsequent year and includes DMEPOS Fee Schedules for the United States and the District of Columbia from 1992 and each subsequent year. After 1992, the computed regional purchase prices were computed by increasing the prior year regional purchase price by an "applicable percentage increase" as defined in section 1834(h)(4).

Section 1834(h)(4)(A)(xi) of the Act defines the "applicable percentage increases" for 2011 and each subsequent year as:

> (I) the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year, reduced by—
>
> (II) the productivity adjustment described in Section 1866(b)(3)(B)(xi)(II).
>
> The application of subparagraph (A)(xi)(II) may result in the applicable percentage increase under subparagraph (A) being less than 0.0 for a year and may result in payment rates under this subsection for the year being less than such payment rates for the preceding year.

Section 1847(a) of the Act enabled the Secretary of Health and Human Services to establish and implement competitive acquisition programs. These programs are being phased in for select items and services as identified in section 1847(a)(2). CMS has authority to establish a competitive acquisition program for OTS orthotics. These OTS orthotics are items in which payment would otherwise be made under section 1834(h) of the Act.

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 shall 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

For purposes of the Competitive Bidding Program for certain DMEPOS, Federal regulations (42 CFR § 414.402) define OTS orthotics and minimal self-adjustment as:

> (4) Off-the-shelf orthotics, which are orthotics described in Section 1861(s)(9) of the Act that require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling or customizing to fit a beneficiary.
>
> *Minimal self-adjustment* means an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board

for Orthotist/Prosthetist Certification) or an individual who has specialized training.

Federal regulations (42 CFR § 414.210(g)) established 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.

Federal regulations (42 CFR § 405.502) established criteria for determining reasonable charges as follows:

> (a) *Criteria*. The law allows for flexibility in the determination of reasonable charges to accommodate reimbursement to the various ways in which health services are furnished and charged for. The criteria for determining what charges are reasonable include:
>
> > (7) Other factors that may be found necessary and appropriate with respect to a category of service to use in judging whether the charge is inherently reasonable. This includes special reasonable charge limits (which may be either upper or lower limits) established by CMS or a carrier if it determines that the standard rules for calculating reasonable charges set forth in this subpart result in the grossly deficient or excessive charges. The determination of these limits is described in 42 CFR 405.502(g) and (h) . . . .

Federal regulations (42 CFR § 405.502(g)) provide guidance in determining payment amounts for a "category of items or services" in special circumstances. A "category of items or services" may consist of a single item or service or any number of items or services. Specifically, within 42 CFR § 405.502(g), a determination has to be made as to whether the payment amount is grossly excessive or deficient to pursue a special payment amount or adjustment. This determination is explained respectively in paragraphs (g)(1)(ii) and (g)(1)(iii), which state:

> CMS or a carrier may determine that the standard rules for calculating payment amounts set forth in this subpart for a category of items or services identified in section 1861(s) of the Act . . . will result in grossly deficient or excessive amounts. A payment amount will not be considered grossly excessive or deficient if it is determined that an overall payment adjustment of less than 15 percent is necessary to produce a realistic and equitable payment amount . . . .
>
> If CMS or the carrier determines that the standard rules for calculating payment amounts for a category of items or services will result in grossly deficient or excessive amounts, CMS, or the carrier, may establish special payment limits that are realistic and equitable for a category of items or services. If CMS makes a

> determination, it is considered a national determination. A carrier determination is one made by a carrier or intermediary or groups of carriers or intermediaries even if the determination applies to payment in all States . . . .

Subsequent general rules that CMS must follow in determining whether a payment amount is grossly excessive or deficient and establishing an appropriate payment amount are explained in 42 CFR §§ 405.502(g)(1)(iv) through (g)(5).

Federal regulations (42 CFR § 405.502(h)) provide guidance for CMS in establishing a payment adjustment greater than 15 percent of the amount for a category of items or services within a year. This guidance is in addition to CMS applying the general rules under 42 CFR §§ 405.502(g)(1) through (g)(5).

APPENDIX C: MATHEMATICAL CALCULATION METHODOLOGY OF PAYMENT DIFFERENCES

For 161 selected orthotic device HCPCS codes, we compared the amounts paid by Medicare with the amounts paid by 13 select non-Medicare payers. We performed this comparison to determine whether Medicare allowable amounts were comparable with the pricing data received from the 13 non-Medicare payers who responded to our survey.

We extracted Medicare allowable amounts from the CMS NCH file. We identified private insurance company pricing data using fee schedule data obtained from the 13 companies that responded to our voluntary survey. We performed analytic testing to ensure that these companies covered a reasonably wide range of States, including those States with high Medicare reimbursements.

We determined a non-Medicare payer payment for each of the 161 selected orthotic device HCPC codes by calculating a payment for each code that was greater than 75 percent of the surveyed non-Medicare payer payments received (the 75th percentile).[25] This approach results in a higher non-Medicare payment than would be obtained using the average or median and, as a result, is more conservative for the purpose of calculating differences with the Medicare allowable amounts. Like the Medicare allowable amounts, our calculated select non-Medicare payer payments included any applicable beneficiary payments, such as coinsurance and deductibles.

We calculated the annual payment differences for each HCPCS code by taking the difference between the Medicare allowable amount and the select non-Medicare payer payments, multiplied by the number of Medicare units. A Medicare beneficiary is typically responsible for a coinsurance payment of 20 percent of the allowed amount (i.e., the fee schedule rate), plus any unmet Part B deductible. Accordingly, our estimated Medicare payment differences were calculated at 80 percent of the calculated annual total payment differences by HCPCS code, and the remaining 20 percent represented annual beneficiary payment differences. Our estimated payment differences do not account for any unmet deductibles that would be applied in determining final Medicare payments. See Appendix D for a 4-year summary of estimated payment differences calculated by HCPCS code.

[25] The specific calculation was performed using the "PERCENTILE.INC" function in Excel.

The following example shows the basic mathematical calculation steps in determining payment differences by HCPCS code and calendar year:

HCPCS code L1830—knee orthosis, immobilizer

(1)	2014 Medicare units billed under L1830	26,322
(2)	2014 Medicare payments for L1830	$2,274,914*
(3)	2014 calculated 75th percentile select non-Medicare payment for L1830	$73.67†
(4)	2014 Medicare payments for L1830 (from Line 2)	$2,274,914
(5)	2014 calculated select non-Medicare payer payments (Line 1 × Line 3)	$1,939,142
(6)	2014 calculated payment difference for L1830 (Line 4 minus Line 5)	$335,772
(7)	2014 calculated Medicare program payment differences for L1830 (80 percent of Line 6)	$268,618
(8)	2014 calculated beneficiary payment differences for L1830 (20 percent of Line 6)	$67,154

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

† This non-Medicare payer payment of $73.67 represents the 75th percentile payment as calculated using the "PERCENTILE.INC" function in Excel on the 26 fee schedule payments obtained from select non-Medicare payers for HCPCS code L1830.

APPENDIX D: TOTAL RESULTS BY HCPCS CODE

Table 2: Total Results by HCPCS Code

Table Legend

Column 1: The OIG generic billing type for the HCPCS codes that the OIG reviewed.

Column 2: Orthotic device HCPCS codes that the OIG reviewed.

Columns 3 through 6: Summary of the annual comparison results for CYs 2012 through 2015 that were done in accordance with Appendix C. The estimated payment differences column represents the differences between the OIG's calculation of Medicare allowable amounts and non-Medicare payments. These estimated payment differences represent Medicare allowable amounts that were not comparable with payments made by select non-Medicare payers.

c. 1	c.2	c.3	c.4	c.5	c.6
Orthotic Device Type	HCPCS Code	Medicare Units	Medicare Allowable Amounts	Calculated Non-Medicare Payments	Estimated Payment Differences
OTS	L1833	215,548	162,871,370	123,254,657	39,616,713
OTS	L0650	136,192	159,503,808	150,756,069	8,747,739
OTS	L3908	1,028,739	61,526,653	53,019,859	8,506,794
OTS	L1902	370,427	32,668,498	25,736,847	6,931,651
OTS	L0648	123,857	119,590,413	113,828,299	5,762,114
OTS	L3670	276,286	30,691,802	25,808,674	4,883,128
OTS	K0901	29,873	28,329,482	24,123,347	4,206,135
OTS	L4361	135,393	35,882,923	33,311,747	2,571,176
OTS	L3809	80,273	17,651,899	15,649,179	2,002,720
OTS	L1906	106,611	12,657,670	10,816,907	1,840,763
OTS	L0642	82,826	31,931,017	30,288,403	1,642,614
OTS	L4350	136,912	11,905,820	10,565,332	1,340,488
OTS	L1830	106,133	9,125,894	7,837,250	1,288,644
OTS	L0174	50,073	12,866,413	11,729,479	1,136,934
OTS	L1812	37,250	4,353,563	3,493,191	860,372
OTS	K0902	9,412	7,866,990	7,227,779	639,211
OTS	L3650	99,189	5,578,809	4,958,600	620,209
OTS	L3660	68,883	6,319,666	5,752,003	567,663
OTS	L3916	2,660	1,659,711	1,157,477	502,234
OTS	L0172	31,114	3,961,325	3,569,467	391,858
OTS	L4397	17,632	2,931,925	2,634,802	297,123
OTS	L0457	5,328	4,998,010	4,764,641	233,369
OTS	L3710	4,664	705,535	504,933	200,602
OTS	L0120	70,138	1,771,816	1,578,217	193,599
OTS	L0621	12,260	1,157,372	978,602	178,770
OTS	L4387	28,526	4,189,738	4,071,801	117,937
OTS	L3762	12,546	1,130,306	1,035,634	94,672
OTS	L3924	21,742	1,705,440	1,616,451	88,989

c. 1	c.2	c.3	c.4	c.5	c.6
Orthotic Device Type	HCPCS Code	Medicare Units	Medicare Allowable Amounts	Calculated Non-Medicare Payments	Estimated Payment Differences
OTS	L1850	1,853	529,016	443,629	85,387
OTS	L0628	15,278	1,165,122	1,079,809	85,313
OTS	L3675	8,213	1,214,536	1,143,595	70,941
OTS	L0450	2,690	468,079	400,521	67,558
OTS	L0625	26,764	1,337,761	1,279,961	57,800
OTS	L3912	4,866	447,776	394,824	52,952
OTS	L3925	12,973	615,092	564,061	51,031
OTS	L4370	2,037	365,487	337,339	28,148
OTS	L3927	9,765	292,752	266,259	26,493
OTS	L0160	1,565	241,923	219,937	21,986
OTS	L0651	263	310,286	288,343	21,943
OTS	L1836	612	84,610	67,767	16,843
OTS	L4398	1,550	118,658	103,724	14,934
OTS	L0641	5,702	419,944	407,864	12,080
OTS	L0643	974	145,977	135,360	10,617
OTS	L0649	266	71,613	65,621	5,992
OTS	L0455	142	45,878	42,798	3,080
OTS	L1848	4	3,176	2,083	1,093
OTS	L3918	313	28,762	27,925	837
OTS	L0467	28	10,421	9,671	750
OTS	L0469	11	5,071	4,515	556
OTS	L3930	183	12,323	12,576	(253)
Prefabricated	L1832	245,478	169,750,903	134,526,304	35,224,599
Prefabricated	L0637	246,924	291,013,171	248,401,298	42,611,873
Custom	L1940	106,503	59,469,073	46,577,941	12,891,132
Custom	L1960	82,073	51,776,558	41,699,740	10,076,818
Custom	L1970	116,246	89,328,595	75,687,401	13,641,194
Prefabricated	L1932	66,905	63,385,590	53,174,415	10,211,175
Prefabricated	L1971	98,402	48,092,302	39,677,969	8,414,333
Custom	L1844	20,170	34,193,983	28,732,462	5,461,522
Prefabricated	L1810	172,544	20,399,987	15,297,538	5,102,449
Other Accessory	L2397	201,376	27,309,066	22,197,296	5,111,770
Prefabricated	L3760	45,791	21,379,488	17,925,667	3,453,821
Other Accessory	L2280	28,332	14,460,625	11,144,343	3,316,282
Prefabricated	L1831	22,538	8,643,354	5,657,339	2,986,015
Custom	L1990	24,506	12,009,702	9,250,455	2,759,247
Custom	L1846	23,758	27,611,713	23,584,100	4,027,613
Custom	L1945	5,090	6,097,516	4,266,798	1,830,718
Prefabricated	L4396	180,922	30,227,339	25,757,193	4,470,146
Custom	L1907	6,241	3,996,361	3,278,996	717,365
Custom	L3740	1,266	1,551,359	1,161,150	390,209
Custom	L1950	2,442	2,098,710	1,738,078	360,632
Other Accessory	L3995	12,604	679,852	390,411	289,441
Custom	L3901	321	680,865	416,996	263,869
Custom	L1980	1,762	764,622	599,549	165,073
Custom	L1904	1,607	809,908	658,110	151,798

c. 1	c.2	c.3	c.4	c.5	c.6
Orthotic Device Type	HCPCS Code	Medicare Units	Medicare Allowable Amounts	Calculated Non-Medicare Payments	Estimated Payment Differences
Custom	L3720	1,054	723,693	606,059	117,634
Custom	L3730	1,068	1,010,683	842,370	168,313
Other Accessory	L0150	5,892	640,342	536,665	103,677
Prefabricated	L1910	295	102,150	70,285	31,865
Custom	L1834	155	127,811	108,164	19,647
Custom	L1840	89	88,411	74,338	14,073
Prefabricated	L1847	24	21,236	11,293	9,943
Custom	L1900	452	121,994	113,490	8,504
Custom	L1860	14	17,153	12,989	4,164
Prefabricated	L0468	313	142,765	125,185	17,580
Prefabricated	L0466	348	127,638	111,018	16,620
Other Accessory	L4392	134	3,664	2,832	832
Custom	L0622	269	51,602	59,093	(7,491)
Other Accessory	L0170	486	250,646	275,199	(24,553)
Prefabricated	L3981	176	118,980	141,576	(22,596)
Custom	L3674	417	340,377	391,090	(50,713)
Custom	L3702	8,851	1,871,436	1,985,014	(113,578)
Prefabricated	L3931	8,713	1,203,136	1,375,689	(172,553)
Custom	L0220	2,322	149,379	251,892	(102,513)
Custom	L3764	511	207,228	336,647	(129,419)
Custom	L3671	1,778	705,989	1,244,316	(538,327)
Prefabricated	L0631	310,373	294,459,896	277,135,115	17,324,781
Prefabricated	L4360	558,023	143,179,318	133,430,184	9,749,134
Prefabricated	L1845	68,430	58,093,426	51,027,093	7,066,333
Prefabricated	L1843	99,329	88,079,753	81,079,243	7,000,510
Prefabricated	L0627	195,722	73,849,662	69,374,318	4,475,344
Prefabricated	L3807	291,758	59,585,706	55,973,349	3,612,357
Prefabricated	L1820	238,289	31,831,493	28,667,431	3,164,062
Other Accessory	L2275	134,246	18,668,661	15,998,770	2,669,891
Prefabricated	L1951	24,398	21,451,471	19,099,644	2,351,827
Custom	L3906	48,237	17,376,572	15,310,208	2,066,364
Prefabricated	L4386	192,694	27,707,551	25,926,156	1,781,395
Prefabricated	L0456	23,139	21,308,301	19,922,288	1,386,013
Custom	L4631	9,826	14,766,576	13,545,484	1,221,092
Prefabricated	L0464	10,059	14,055,195	12,943,058	1,112,137
Prefabricated	L1930	54,336	12,829,764	11,851,122	978,642
Prefabricated	L0472	20,798	8,321,060	7,405,845	915,215
Prefabricated	L3923	108,167	8,069,357	7,585,796	483,561
Prefabricated	L0460	6,537	6,106,947	5,667,650	439,297
Custom	L3913	63,418	14,086,294	13,654,447	431,847
Prefabricated	L0639	2,586	3,032,967	2,682,911	350,056
Prefabricated	L3984	23,830	7,393,778	7,050,606	343,172
Custom	L0486	8,422	15,097,298	14,809,301	287,997
Custom	L3900	1,731	2,199,395	1,923,237	276,158
Other Accessory	L0180	11,065	4,096,088	3,845,047	251,041
Other Accessory	L2795	16,449	1,449,680	1,257,326	192,354

c. 1	c.2	c.3	c.4	c.5	c.6
Orthotic Device Type	**HCPCS Code**	**Medicare Units**	**Medicare Allowable Amounts**	**Calculated Non-Medicare Payments**	**Estimated Payment Differences**
Prefabricated	L0630	14,070	2,081,784	1,934,845	146,939
Prefabricated	L0626	35,294	2,530,213	2,385,454	144,759
Custom	L0636	777	1,124,463	985,385	139,078
Custom	L3766	1,233	1,462,391	1,340,397	121,994
Prefabricated	L0462	1,554	1,779,282	1,677,900	101,382
Prefabricated	L3980	15,931	4,678,217	4,589,479	88,738
Prefabricated	L0458	902	749,201	689,503	59,698
Prefabricated	L0635	604	578,893	521,711	57,182
Prefabricated	L0633	3,239	851,926	799,581	52,345
Prefabricated	L3982	15,567	5,225,349	5,173,110	52,239
Custom	L0484	882	1,487,017	1,438,264	48,753
Custom	L0638	1,588	1,949,323	1,915,213	34,110
Prefabricated	L0454	1,415	452,898	421,679	31,219
Other Accessory	L0200	1,184	607,687	577,824	29,863
Prefabricated	L0470	321	199,804	180,110	19,694
Prefabricated	L3917	2,808	245,720	227,807	17,913
Other Accessory	L0190	597	286,255	268,653	17,602
Custom	L0480	487	697,353	680,781	16,572
Custom	L1920	571	188,177	174,874	13,303
Prefabricated	L0113	754	200,827	188,041	12,786
Other Accessory	L0130	658	105,822	94,145	11,677
Prefabricated	L0491	292	203,323	192,858	10,465
Prefabricated	L0488	148	137,761	128,179	9,582
Custom	L3921	3,034	761,454	757,960	3,494
Custom	L3765	399	410,756	407,341	3,415
Prefabricated	L0492	62	28,876	26,622	2,254
Other Accessory	L0140	3,235	182,333	180,707	1,626
Prefabricated	L3915	3,158	1,279,466	1,277,927	1,539
Custom	L3919	8,419	1,802,663	1,802,228	435
Custom	L0112	60	73,425	73,079	346
Prefabricated	L0490	61	15,423	15,118	305
Other Accessory	L4394	1	16	15	1
Custom	L0640	1,538	1,473,250	1,474,026	(776)
Prefabricated	L3929	6,189	379,815	409,463	(29,648)
Custom	L0482	2,739	4,150,486	4,192,116	(41,630)
Custom	L3935	2,652	418,333	468,343	(50,010)
Custom	L3763	6,483	3,721,518	3,803,818	(82,300)
Custom	L3905	1,802	1,304,456	1,428,535	(124,079)
Custom	L3806	5,397	1,932,029	2,097,415	(165,386)
Custom	L3933	37,797	6,229,798	6,447,034	(217,236)
Custom	L3808	76,434	21,180,698	23,484,484	(2,303,786)
TOTAL		**7,925,899**	**$2,817,489,776**	**$2,479,942,235**	**$337,547,542**

APPENDIX E: CALCULATED COMPARATIVE ALLOWABLE AMOUNTS BY HCPCS CODE AND CALENDAR YEAR

We calculated the annual Medicare allowable amount in the table below by HCPCS code for CYs 2012 through 2015 by using data from CMS's NCH file, as explained in Appendix A. We calculated the annual payments made by non-Medicare payers by using pricing data obtained from private insurance companies by HCPCS code and calendar year, as explained in Appendix C.

Table 3: Calculated Comparative Allowable Amounts by HCPCS Code and Calendar Year

TABLE LEGEND

Medicare allowable amount billed for an OTS orthotic devices that could be adjusted through competitive bidding, as authorized in the Act (bold and shaded in the table below).

Medicare allowable amount that could be adjusted using the inherent reasonableness process. Specifically, the Medicare allowable amounts considered to be grossly deficient or excessive payment amounts as explained in Footnote 26 of Appendix F (bold only in the table below).

Medicare allowable amount that are not in bold or shaded did not qualify for adjustment using current legislative authority and CMS would need to seek such authority to align with payments made by select non-Medicare payers.

HCPCS Code	2012 Medicare Allowable Amount	2012 Non-Medicare Payments	2013 Medicare Allowable Amount	2013 Non-Medicare Payments	2014 Medicare Allowable Amount	2014 Non-Medicare Payments	2015 Medicare Allowable Amount	2015 Non-Medicare Payments
L1833	N/A	N/A	N/A	N/A	**705.84**	571.82	**786.87**	571.82
L0650	N/A	N/A	N/A	N/A	**1,159.38**	1,098.17	**1,176.03**	1,110.55
L3908	**58.87**	50.91	**59.72**	51.19	**60.06**	51.57	**60.57**	52.47
L1902	**93.96**	69.14	**90.15**	69.12	**84.67**	69.12	**84.71**	70.43
L0648	N/A	N/A	N/A	N/A	**959.30**	919.03	**971.22**	919.03
L3670	***109.49***	92.38	**109.90**	92.23	**111.40**	93.60	**113.00**	95.01
K0901	N/A	N/A	N/A	N/A	**845.48**	763.00	**958.61**	811.98
L4361	N/A	N/A	N/A	N/A	**262.55**	244.15	**266.16**	246.90
L3809	N/A	N/A	N/A	N/A	**214.50**	193.93	**223.18**	195.57
L1906	**112.44**	101.71	**114.55**	100.86	**118.08**	101.11	**129.78**	102.04
L0642	N/A	N/A	N/A	N/A	**383.90**	365.36	**387.96**	366.18
L4350	**85.32**	76.55	**86.33**	76.86	**87.40**	77.11	**88.73**	78.14
L1830	**84.33**	73.76	**85.42**	73.12	**86.43**	73.67	**87.59**	74.73
L0174	**251.51**	232.48	**256.25**	233.65	**258.65**	233.65	**261.71**	237.29
L1812	N/A	N/A	N/A	N/A	**116.38**	93.91	**117.09**	93.72
K0902	N/A	N/A	N/A	N/A	**828.58**	764.02	**837.03**	768.57
L3650	**54.88**	49.42	**55.57**	49.83	**56.66**	50.24	**57.97**	50.48
L3660	**88.47**	82.47	**90.83**	80.72	**91.66**	83.62	**93.27**	84.88
L3916	N/A	N/A	N/A	N/A	**383.51**	412.81	**630.07**	435.71

HCPCS Code	2012 Medicare Allowable Amount	2012 Non-Medicare Payments	2013 Medicare Allowable Amount	2013 Non-Medicare Payments	2014 Medicare Allowable Amount	2014 Non-Medicare Payments	2015 Medicare Allowable Amount	2015 Non-Medicare Payments
L0172	**125.90**	114.22	**126.81**	114.90	**127.54**	114.90	**129.51**	114.95
L4397	N/A	N/A	N/A	N/A	**166.72**	149.19	**166.13**	149.52
L0457	N/A	N/A	N/A	N/A	**926.75**	902.61	**942.13**	891.27
L3710	**134.17**	107.73	**146.10**	108.38	**154.95**	108.54	**165.24**	108.23
L0120	**24.68**	22.46	**25.10**	22.40	**25.45**	22.46	**25.89**	22.70
L0621	**90.87**	79.59	**94.66**	80.04	**95.27**	79.63	**95.73**	79.94
L4387	N/A	N/A	N/A	N/A	**146.57**	142.74	**147.02**	142.74
L3762	**86.55**	81.44	**89.86**	82.23	**89.95**	82.85	**92.62**	83.26
L3924	N/A	N/A	N/A	N/A	**77.24**	73.79	**79.05**	74.63
L1850	**278.48**	236.88	**288.87**	238.30	**285.14**	238.76	**290.38**	244.17
L0628	**75.69**	70.30	**76.02**	70.48	**76.65**	70.47	**77.09**	71.79
L3675	**145.83**	142.72	**147.03**	138.12	**148.69**	137.48	**150.47**	137.99
L0450	**172.21**	149.09	**173.97**	149.57	**173.12**	147.14	**177.52**	149.57
L0625	**49.05**	49.53	**49.74**	47.31	**50.18**	47.31	**51.09**	47.03
L3912	**96.42**	80.57	**91.06**	80.92	**90.63**	80.92	**88.62**	82.45
L3925	**46.59**	44.12	**47.38**	42.25	**47.59**	42.57	**48.10**	44.95
L4370	**186.22**	163.90	**173.05**	164.62	**174.51**	165.85	**181.95**	168.50
L3927	**29.08**	27.30	**29.81**	26.78	**31.14**	27.42	**29.83**	27.52
L0160	**153.77**	144.94	**153.34**	138.17	**154.21**	138.17	**157.13**	139.79
L0651	N/A	N/A	N/A	N/A	**1,197.89**	1,094.18	**1,152.56**	1,099.64
L1836	**140.50**	111.08	**133.88**	111.40	**144.70**	111.40	**134.61**	109.12
L4398	**76.30**	68.20	**77.12**	66.32	**76.06**	66.48	**76.67**	66.73
L0641	N/A	N/A	N/A	N/A	**73.02**	70.47	**73.96**	72.06
L0643	N/A	N/A	N/A	N/A	**149.07**	138.18	**150.44**	139.53
L0649	N/A	N/A	N/A	N/A	**268.50**	244.69	**269.34**	247.03
L0455	N/A	N/A	N/A	N/A	**321.79**	300.05	**323.83**	302.17
L1848	N/A	N/A	N/A	N/A	**794.09**	520.86	N/A	524.11
L3918	N/A	N/A	N/A	N/A	**89.01**	88.02	**92.83**	89.61
L0467	N/A	N/A	N/A	N/A	**381.32**	344.48	**363.05**	346.31
L0469	N/A	N/A	N/A	N/A	**433.84**	408.91	**476.46**	411.29
L3930	N/A	N/A	N/A	N/A	**68.70**	69.30	**66.34**	68.30
L1832	**688.84**	543.20	**695.04**	546.70	**686.47**	552.49	**694.49**	554.53
L0637	1,165.02	997.79	1,167.50	1,007.92	**1,193.19**	1,007.35	**1,214.15**	1,017.34
L1940	**550.08**	435.66	**554.51**	436.04	**556.72**	436.04	**571.20**	441.33
L1960	**621.37**	504.44	**628.65**	505.18	**634.42**	509.62	**641.83**	514.42
L1970	757.54	645.40	**765.30**	646.68	**769.47**	651.18	**783.75**	662.48
L1932	**933.88**	771.68	939.92	802.15	**952.58**	802.15	**962.33**	802.15
L1971	469.46	401.70	**481.52**	402.48	**499.16**	403.47	**500.66**	404.96
L1844	**1,669.62**	1,410.89	**1,673.82**	1,419.61	**1,691.01**	1,419.61	**1,743.11**	1,446.43
L1810	**115.91**	89.32	**118.63**	87.83	**118.85**	87.92	**120.71**	89.91
L2397	121.62	108.46	121.34	109.11	128.25	109.13	**144.15**	111.25

HCPCS Code	2012 Medicare Allowable Amount	2012 Non-Medicare Payments	2013 Medicare Allowable Amount	2013 Non-Medicare Payments	2014 Medicare Allowable Amount	2014 Non-Medicare Payments	2015 Medicare Allowable Amount	2015 Non-Medicare Payments
L3760	**460.88**	390.04	**467.12**	390.80	**469.31**	391.76	**470.05**	393.21
L2280	**500.09**	389.98	**507.03**	392.33	**511.77**	392.33	**525.91**	399.79
L1831	**375.21**	252.23	**373.23**	252.72	**388.46**	247.63	**405.51**	250.44
L1990	**482.22**	376.79	**489.79**	376.79	**490.61**	376.81	**500.00**	379.87
L1846	1,156.33	988.33	1,147.60	990.27	**1,165.43**	990.27	**1,179.48**	1,001.81
L1945	**1,203.32**	830.20	**1,168.66**	835.54	**1,189.27**	836.86	**1,228.49**	851.71
L4396	167.39	143.84	165.88	141.01	166.66	142.08	**168.77**	142.55
L1907	**641.70**	518.81	**638.39**	521.81	**634.98**	522.09	**645.99**	538.59
L3740	**1,427.86**	905.95	**1,124.61**	913.02	**1,087.87**	919.87	**1,106.70**	935.98
L1950	**836.75**	699.19	**846.74**	703.70	**868.17**	713.71	**876.88**	724.88
L3995	**53.07**	30.92	**53.82**	30.92	**53.07**	30.97	**55.51**	31.07
L3901	**2,552.84**	1,292.45	1,468.37	1,284.06	**1,629.56**	1,331.38	**1,553.71**	1,316.36
L1980	**425.95**	333.42	**433.05**	338.02	**440.65**	343.18	**440.30**	349.69
L1904	**513.39**	404.99	**482.73**	407.43	**503.76**	407.43	**514.63**	418.66
L3720	**706.48**	570.56	**699.85**	575.13	**686.03**	575.13	634.89	581.87
L3730	922.98	786.18	898.14	789.73	**1,007.88**	789.73	**975.61**	789.98
L0150	105.29	90.94	**108.85**	90.94	**109.47**	90.94	**110.37**	91.49
L1910	252.43	233.96	274.26	236.03	**361.40**	238.01	**422.07**	241.68
L1834	793.13	682.40	**885.72**	703.18	**833.95**	704.80	767.62	707.36
L1840	961.08	834.08	**1,002.89**	839.44	**961.49**	802.72	**1,063.56**	864.75
L1847	**893.33**	470.56	524.15	472.48	**1,058.78**	468.27	N/A	495.48
L1900	**299.03**	247.95	249.99	249.08	264.09	251.20	264.75	255.12
L1860	**1,102.24**	925.92	**1,116.00**	925.92	**1,470.82**	925.92	**1,280.48**	951.75
L0468	460.18	397.00	439.44	399.55	450.70	399.55	**481.92**	409.60
L0466	364.34	317.96	367.50	318.82	363.84	322.00	**379.82**	320.18
L4392	**26.16**	21.07	**28.47**	21.17	**29.37**	21.17	**25.81**	21.17
L0622	201.55	216.29	**188.36**	216.67	**160.60**	217.19	207.09	228.09
L0170	**481.73**	561.84	**477.72**	563.00	531.74	563.00	583.39	578.64
L3981	N/A	N/A	N/A	N/A	N/A	N/A	**676.02**	804.41
L3674	921.76	930.77	**344.21**	930.42	**451.79**	966.40	**722.08**	1,004.95
L3702	233.78	224.27	**194.87**	224.27	195.14	224.27	212.06	224.27
L3931	138.43	156.60	**133.03**	157.55	**136.96**	158.75	145.50	159.22
L0220	**61.80**	107.69	**63.68**	107.18	**62.90**	109.65	**75.65**	111.29
L3764	**413.20**	645.17	**377.94**	658.12	**397.08**	664.01	**447.10**	675.75
L3671	**403.61**	699.84	**374.58**	699.84	**408.59**	699.84	**401.06**	699.84
L0631	941.93	906.26	949.62	881.48	957.23	883.63	971.97	886.90
L4360	254.06	239.77	255.93	238.35	257.61	238.35	260.16	240.35
L1845	845.32	747.49	845.96	738.46	848.49	748.09	860.74	752.96
L1843	849.98	827.44	890.81	806.55	912.84	806.55	874.22	838.10
L0627	374.39	356.06	376.75	352.95	378.53	353.81	382.86	355.12
L3807	198.98	193.26	201.74	189.93	207.80	191.14	212.78	193.88

HCPCS Code	2012 Medicare Allowable Amount	2012 Non-Medicare Payments	2013 Medicare Allowable Amount	2013 Non-Medicare Payments	2014 Medicare Allowable Amount	2014 Non-Medicare Payments	2015 Medicare Allowable Amount	2015 Non-Medicare Payments
L1820	133.26	118.48	133.03	119.42	132.92	120.62	134.81	121.81
L2275	137.60	118.21	138.78	118.94	139.06	118.94	141.16	120.84
L1951	863.58	774.55	870.61	779.12	883.99	779.21	891.75	794.00
L3906	350.66	312.17	357.27	314.04	360.59	316.41	371.43	326.27
L4386	141.99	135.88	143.27	133.24	144.66	134.24	146.42	134.91
L0456	905.63	894.03	911.10	854.00	924.54	854.00	939.07	848.79
L4631	1,485.95	1,361.67	1,491.41	1,369.92	1,504.34	1,370.20	1,528.50	1,410.99
L0464	1,360.47	1,273.06	1,374.30	1,289.59	1,399.67	1,289.59	1,429.69	1,289.59
L1930	233.63	215.52	235.46	217.25	238.07	217.73	238.01	222.70
L0472	395.20	355.53	397.61	355.53	401.24	355.53	407.41	357.94
L3923	72.94	69.15	74.49	70.13	75.37	70.76	76.18	70.76
L0460	920.63	884.42	928.53	861.95	939.29	861.95	953.95	856.69
L3913	216.51	212.61	219.84	213.14	223.20	215.66	227.69	219.11
L0639	1,158.51	1,034.13	1,185.10	1,032.71	1,190.68	1,034.93	1,162.74	1,053.15
L3984	287.31	291.93	306.09	294.03	315.16	296.25	322.11	299.02
L0486	1,772.29	1,701.69	1,787.54	1,747.61	1,814.27	1,758.70	1,797.86	1,818.87
L3900	1,275.12	1,093.21	1,222.71	1,132.18	1,272.54	1,099.79	1,310.50	1,120.65
L0180	358.10	345.24	366.34	345.73	367.47	347.35	374.97	348.43
L2795	87.75	75.21	87.28	76.22	86.60	76.22	90.52	77.88
L0630	146.23	138.79	147.38	136.11	149.36	137.13	151.43	137.82
L0626	70.54	69.48	71.51	66.93	72.25	66.93	73.10	66.53
L0636	1,433.65	1,255.95	1,486.86	1,271.54	1,386.49	1,278.49	1,443.54	1,294.66
L3766	1,230.62	1,065.01	1,163.81	1,065.01	1,160.20	1,110.79	1,182.79	1,110.79
L0462	1,135.78	1,079.73	1,146.36	1,079.73	1,145.93	1,079.73	1,153.45	1,079.73
L3980	288.59	282.80	291.71	283.32	296.03	290.28	298.02	295.60
L0458	820.62	764.31	823.18	765.79	836.24	756.92	849.18	770.51
L0635	987.59	867.35	934.10	867.35	995.85	867.35	920.45	856.67
L0633	261.17	247.98	261.61	247.98	263.99	242.78	268.48	247.74
L3982	329.05	329.99	333.96	332.07	337.14	332.07	340.89	334.53
L0484	1,648.54	1,615.55	1,681.78	1,625.13	1,706.05	1,659.32	1,738.90	1,633.67
L0638	1,208.80	1,187.41	1,221.83	1,206.03	1,230.63	1,207.35	1,253.89	1,227.97
L0454	316.34	299.92	316.92	296.31	323.00	296.31	329.25	298.77
L0200	498.42	482.59	518.86	485.50	517.06	485.50	518.64	497.84
L0470	606.49	558.85	602.28	558.36	630.90	558.36	661.38	570.60
L3917	85.16	80.76	87.50	80.76	87.84	81.37	90.01	81.79
L0190	472.69	444.53	477.20	450.72	491.25	450.72	478.03	458.07
L0480	1,408.63	1,387.11	1,435.48	1,395.36	1,431.99	1,395.56	1,464.78	1,422.16
L1920	339.73	302.84	331.39	313.65	324.77	303.93	310.91	305.04
L0113	263.65	251.65	265.33	248.29	267.05	248.29	271.00	248.29
L0130	158.04	141.23	160.29	142.88	165.32	143.58	162.09	146.10
L0491	686.46	664.14	696.50	650.05	698.43	664.14	725.23	664.14

HCPCS Code	2012 Medicare Allowable Amount	2012 Non-Medicare Payments	2013 Medicare Allowable Amount	2013 Non-Medicare Payments	2014 Medicare Allowable Amount	2014 Non-Medicare Payments	2015 Medicare Allowable Amount	2015 Non-Medicare Payments
L0488	921.68	868.09	926.50	860.81	936.60	868.09	949.29	868.09
L3921	243.14	249.47	248.45	250.11	258.68	249.47	253.58	250.21
L3765	1,118.74	995.89	958.17	995.89	1,010.32	1,048.98	983.76	1,048.98
L0492	458.00	430.44	460.17	430.44	467.10	425.94	472.44	430.53
L0140	55.94	55.45	57.09	55.89	57.66	55.89	55.53	56.04
L3915	363.31	412.87	368.35	403.99	443.16	403.99	450.96	395.68
L3919	207.47	216.59	213.71	211.37	214.50	216.91	220.70	211.50
L0112	1,232.00	1,237.85	1,203.68	1,242.20	1,171.38	1,242.20	1,283.30	1,144.06
L0490	258.05	247.84	254.35	247.84	242.85	247.84	264.25	247.84
L4394	N/A	14.87	16.14	14.87	N/A	14.87	N/A	14.83
L0640	955.20	941.71	967.18	948.01	923.02	958.15	988.88	989.29
L3929	59.18	65.38	61.60	65.86	60.17	65.82	66.10	68.25
L0482	1,489.34	1,515.95	1,511.84	1,522.85	1,523.90	1,534.01	1,550.90	1,559.97
L3935	160.53	176.60	153.76	176.60	155.38	176.60	161.40	176.60
L3763	547.04	583.47	574.24	583.47	580.46	590.17	594.05	589.82
L3905	728.98	792.75	725.10	792.75	709.84	792.75	731.64	792.75
L3806	345.77	385.09	350.39	385.99	367.08	388.86	372.13	395.67
L3933	157.50	170.57	164.80	170.57	166.18	170.57	169.60	170.57
L3808	266.12	300.21	273.75	302.92	280.78	310.46	288.45	315.96

APPENDIX F: OIG ANALYSIS OF ESTIMATED ANNUAL PAYMENT DIFFERENCES

As shown in the figure, we estimated that Medicare and beneficiaries paid $337.5 million more than non-Medicare payers ($67 million in 2012, $79.8 million in 2013, $83.7 million in 2014, and $107 million in 2015). We analyzed the annual payment differences determined in accordance with the methodology explained in Appendix C and identified what authority CMS had to adjust the annual Medicare allowable amount to make them comparable with payments made by select non-Medicare payers. This analysis assumes that CMS would adjust the Medicare allowable amounts for certain orthotic devices to be comparable to the annual payments made by select non-Medicare payers shown in Appendix E.

We determined that CMS could have used existing legislative authority to adjust the annual Medicare allowable amounts for 95 of the 161 HCPCS codes we reviewed to make those amounts comparable with payments made by select non-Medicare payers. Of the 95 HCPCS codes, 50 were for OTS devices that were adjustable through the competitive bidding process[26] and 45 met the criteria for being grossly excessive or deficient compared to payments made by select non-Medicare payers and, as such, were adjustable through the inherent reasonableness process.[27]

[26] Medicare allowable amounts that are in bold and shaded in Appendix E are for HCPCS codes that CMS identified as OTS orthotic devices and authorized for competitive bidding.

[27] We did not consider a Medicare allowable amount for a HCPCS code to be comparable if the payment amount for that year was not at least 15 percent greater (grossly excessive) or 15 percent less (grossly deficient) than the calculated select non-Medicare payer's payment. These grossly excessive or deficient payments are the Medicare allowable amounts that are in bold only in Appendix E.

Table 4 summarizes, by CY, the number of HCPCS codes that CMS could have potentially adjusted the Medicare allowable amounts to align with payments made by select non-Medicare payers.[28]

Table 4: Potential HCPCS Code Payment Differences That CMS Could Adjust

Calendar Year	Legislate Authority	Number of HCPCS Codes	Estimated Payment Differences	Percentage of Payment Difference
2012	Competitive Bidding	26	$6,832,494	10%
2012	Inherent Reasonableness	27	$25,471,540	38%
2012	No Authority	108	$34,700,294	52%
	2012 Total		**$67,004,328**	
2013	Competitive Bidding	26	$7,213,804	9%
2013	Inherent Reasonableness	32	$31,280,913	39%
2013	No Authority	103	$41,294,575	52%
	2013 Total		**$79,789,292**	
2014	Competitive Bidding	50	$26,140,135	31%
2014	Inherent Reasonableness	37	$37,742,605	45%
2014	No Authority	74	$19,801,938	24%
	2014 Total		**$83,684,678**	
2015	Competitive Bidding	50	$55,913,871	52%
2015	Inherent Reasonableness	37	$38,037,041	36%
2015	No Authority	74	$13,118,332	12%
	2015 Total		**$107,069,244**	
4-YR	**Competitive Bidding**	**50**	**$96,100,304**	**28%**
4-YR	**Inherent Reasonableness**	**45**	**$132,532,099**	**39%**
4-YR	**No Authority**	**66**	**$108,915,139**	**33%**
	4-YR Total		**$337,547,542**	

As shown in Table 4, approximately two-thirds of the net estimated payment differences for CYs 2012 through 2015 could have been avoided.

[28] Table 4 summarizes the payment differences that we estimated by HCPCS code and CY as explained in Appendix C and the annual allowable amounts shown in Appendix E. We analyzed the differences between the Medicare allowable amounts and select non-Medicare payer's payments (Appendix E) to determine by HCPCS code and CY whether CMS had the legislative authority to adjust the annual Medicare allowable amounts. The 4-year summary of estimated payment differences by HCPCS is shown in Appendix D.

APPENDIX G: CMS COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: September 24, 2019

TO: Joanne Chiedi
Acting Inspector General
Office of Inspector General

FROM: Seema Verma
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: Medicare Allowable Amounts for Certain Orthotic Devices Are Not Comparable With Payments Made by Select Non-Medicare Payers (A-05-17-00033)

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 strives to maximize affordability and availability of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and the Medicare DMEPOS Competitive Bidding Program is consistent with this goal. 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.

Section 1834(a)(1)(F)(i) and Section 1847(a)(2)(C) of the Social Security Act authorizes Medicare to replace the fee schedule payment methodology for certain off-the-shelf orthotics furnished within competitive bidding areas with the payment amounts determined under the DMEPOS Competitive Bidding Program. As such, off-the-shelf back and knee braces have been included in Round 2021 of the DMEPOS Competitive Bidding Program which is scheduled to take effect January 1, 2021. CMS will consider whether to phase in additional off-the-shelf orthotic devices in future rounds of the program. Additionally, CMS has included a methodology for calculating fee schedule payment amounts for new DMEPOS items and services as part of the DMEPOS Calendar Year 2020 proposed rule.

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

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services review Medicare allowable amounts for 161 orthotic device HCPCS codes for which Medicare and beneficiaries paid an estimated $337,547,542 more than select non-Medicare payers and adjust the allowable amounts, as appropriate, using regulations promulgated under existing legislative authority, or, if the allowable amounts cannot be adjusted using regulations promulgated under existing legislative authority, seek legislative authority to align Medicare allowable amounts for these items with payments made by select non-Medicare payers.

CMS Response

CMS concurs with this recommendation. As stated above, off-the-shelf back and knee braces have been included in Round 2021 of the DMEPOS Competitive Bidding which is scheduled to take effect January 1, 2021. CMS will consider whether to phase in additional off-the-shelf orthotic devices in future rounds of the program.

CMS does not have the authority to set payment amounts for custom orthotics under the DMEPOS Competitive Bidding Program. CMS will review the OIG's list of orthotic device HCPCS codes and take the OIG's findings and recommendation into consideration when determining appropriate next steps.

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services routinely review Medicare allowable amounts for new and preexisting orthotic devices to ensure that Medicare allowable amounts are in alignment with payments made by select non-Medicare payers or pricing trends.

CMS Response

CMS concurs with this recommendation. Currently, the statute does not grant authority to base fee schedule amounts for orthotics on payments made by select non-Medicare payers or pricing trends. CMS will consider the OIG's findings and this recommendation when considering appropriate next steps for review of orthotic device payment amounts. In the absence of authority under current law, CMS will consider whether to recommend this proposal for inclusion in the President's next budget. Additionally, CMS has included a methodology for calculating fee schedule payment amounts for new DMEPOS items and services as part of the DMEPOS Calendar Year 2020 proposed rule.