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Medicare Remains Vulnerable to Fraud, Waste, and Abuse Related to Off-the-Shelf Orthotic Braces, Which May Result in Improper Payments and Impact the Health of Enrollees

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PORTFOLIO HIGHLIGHTS

Providers ordered braces for enrollees for whom there was no history of a treating relationship.

New suppliers were located in geographic areas with known Medicare fraud.

Medicare paid more than private payers for OTS braces.

Suppliers used prohibited solicitation to contact enrollees.

Why OIG Prepared This Portfolio

From calendar years (CYs) 2014 through 2020, Medicare paid approximately $5.3 billion for orthotic braces provided to Medicare enrollees. The Centers for Medicare & Medicaid Services (CMS) found that orthotic braces were consistently among the top 20 durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items with the highest improper payment rates.[1] Adequate CMS oversight is critical in ensuring that Medicare enrollees continue to have access to and receive medically necessary braces.

Prior Office of Inspector General (OIG) audits, evaluations, and investigations identified vulnerabilities related to orthotic braces including: (1) questionable supplier billing patterns, (2) limited or no provider involvement with enrollees, (3) improper payments made for braces that were not medically necessary or were not documented, (4) Medicare allowable amounts for orthotic braces that were higher than payments made by private payers, (5) inappropriate telemarketing practices, and (6) fraud related to off-the-shelf (OTS) braces.[2] CMS's implementation of procedure codes for OTS braces in CY 2014 could have provided an incentive for DMEPOS suppliers (suppliers) to bill those codes because the payment rates for OTS braces were the same as the rates for custom-fitted braces but the supplier requirements for OTS braces were less stringent. In addition, Medicare payments for OTS braces accounted for more payments than for custom-fitted braces after CY 2014. Therefore, for this portfolio we analyzed Medicare claims data for OTS braces from CYs 2018 through 2020 and reviewed the results of prior OIG work specific to OTS braces. For this 3-year period, more than 90 percent of suppliers billed for OTS braces, for which Medicare paid nearly $1.9 billion (almost 70 percent of all payments for orthotic braces). Enrollees were responsible for $484.6 million in coinsurance for those braces.

Issues Identified in This Portfolio

Based on our review of the vulnerabilities identified in OIG's prior work and our analysis of Medicare claims data, we identified issues related to CMS's oversight of OTS braces. These issues continue to

put Medicare and its enrollees at risk and demonstrate the need for CMS to strengthen its oversight related to supplier billing requirements, ordering provider requirements, supplier enrollment and monitoring, Medicare allowable amounts for OTS braces, telemarketing to Medicare enrollees, and fraud related to OTS braces. If not addressed, these issues could result in improper payments, potential enrollee harm, and Medicare paying more than non-Medicare payers, such as private insurance companies, for OTS braces.

What Action Is Needed and CMS Comments

To reduce the risk of fraud, waste, and abuse related to OTS braces and to protect the health of Medicare enrollees, we recommend that CMS strengthen its oversight of Medicare billing for OTS braces by: (1) taking steps to prevent payments for claims for replacement OTS braces billed without required modifiers;[3] (2) identifying providers who ordered OTS braces for enrollees with whom they had no treating relationships, and use that information to determine whether to provide additional education to or take administrative or legal action against the ordering providers or associated suppliers; (3) analyzing supplier billing patterns to determine whether to conduct additional prepayment or postpayment reviews of suppliers; (4) ensuring that Medicare allowable amounts are reasonably comparable with payments made by non-Medicare payers; (5) educating suppliers and enrollees on telemarketing practices for OTS braces; and (6) using predictive data analysis and information from other Federal agencies and from State agencies to identify emerging fraud schemes related to OTS braces, and using CMS's authority to prevent further losses to the Medicare program.

The full text of our recommendations is shown in the "Recommendations" section of this portfolio.

CMS did not state whether it concurred with our recommendations but described its efforts to reduce and prevent improper payments related to OTS braces.

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Background

Medicare Program

The Medicare program provides health insurance coverage to people aged 65 years and older, people with disabilities, and people with end-stage renal disease. The Centers for Medicare & Medicaid Services (CMS) administers the program. Medicare Part B provides medical insurance for medical and other health services and supplies. Medicare Part B covers durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), including orthotic braces.[4]

Orthotic Braces

Orthotic braces are rigid and semirigid devices used to support a weak or deformed body part or to restrict or eliminate motion in a diseased or injured body part (e.g., neck, back, arm, or leg). There are three types of orthotic braces: off-the-shelf (OTS), custom-fitted, and custom-fabricated (Figure 1).

Figure 1: Types of Orthotic Braces

Off-the-Shelf	Custom-Fitted	Custom-Fabricated
• Prefabricated • Minimal self-adjustment can be done by enrollee, caretaker, or DMEPOS supplier*	• Prefabricated • Requires more than minimal self-adjustment by a certified orthotist or equivalent	• Individually fabricated for enrollee • Requires substantial modification by a certified orthotist or equivalent†

* A DMEPOS supplier is an entity or individual, including a physician or a Medicare Part A provider, that sells or rents Medicare Part B-covered items to Medicare enrollees and meets quality standards.

† An orthotist is a health care professional (certified by the American Board for Certification in Orthotics and Prosthetics, Inc., or by the Board for Orthotist/Prosthetist Certification) who works under a doctor's orders to fit and adapt braces or create custom-designed braces.

Requirements for DMEPOS Suppliers of Orthotic Braces

CMS requires DMEPOS suppliers (suppliers) to obtain accreditation to enroll in Medicare and to comply with CMS's DMEPOS quality standards in order to keep Medicare billing privileges.[5, 6] Suppliers of OTS braces are not subject to the same requirements as suppliers of custom-fitted braces or custom-fabricated braces. Figure 2 compares supplier requirements.

Figure 2: Requirements for Suppliers of Orthotic Braces

Suppliers of Off-the-Shelf Braces	Suppliers of Custom-Fitted or Custom-Fabricated Braces
• Not required to be licensed or certified • Not required to modify, adjust, or repair braces • May ship braces directly to enrollees without the need to custom-fit braces	• Must be licensed or certified • Must maintain a facility to modify, adjust, and repair braces • May not ship braces before custom-fitting braces to enrollees

Medicare Coverage of Orthotic Braces

To be covered by Medicare, an orthotic brace must be reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member.[7] Medicare will also pay to replace an orthotic brace based on the item's reasonable useful lifetime (RUL). An RUL, which is generally 5 years, is the period after which a Medicare payment may be made for replacing an item.[8] However, replacement during an RUL may be covered if the item is lost, stolen, or irreparably damaged, or if the enrollee's medical condition has changed such that the current item no longer meets the enrollee's needs. When billing for a replacement brace, a supplier adds a modifier to a claim to indicate that the RUL exception requirements have been met.[9] Medicare does not cover replacements needed because of irreparable wear due to day-to-day use during the RUL.

Medicare Part B reimburses suppliers for orthotic braces based on a fee schedule; a reimbursement amount is generally 80 percent of the reasonable charges.[10] An enrollee is responsible for the remaining 20 percent of the charges (referred to as "coinsurance").[11]

When submitting claims for orthotic braces, suppliers use Healthcare Common Procedure Coding System codes (procedure codes).[12] A supplier must include on a claim the name and National Provider Identifier (NPI) number of the provider who treated the enrollee and ordered the orthotic brace (ordering provider).[13, 14] A supplier should also obtain as much documentation from the enrollee's medical record as it determines necessary to assure itself that the orthotic brace meets Medicare requirements.

Who Can Order Orthotic Braces

Ordering providers include physicians, dentists, podiatrists, optometrists, physician assistants, clinical nurse specialists, nurse practitioners, psychologists, midwives, and clinical social workers.

CMS Oversight of Medicare, Including Orthotic Braces

To ensure the integrity of the Medicare program, CMS oversight includes programs to prevent improper payments and protect the Medicare Trust Fund. One example is CMS's Center for Program Integrity, whose mission is to detect and combat fraud, waste, and abuse in Medicare. The Center's functions include: (1) building systems and managing programs to enroll providers in Medicare; (2) using predictive data analytics, such as market saturation and utilization mapping tools, to identify and seek to prevent fraud, waste, and abuse; and (3) overseeing medical reviews and audits to safeguard Medicare from fraud, waste, and abuse.[15] CMS also works with other agencies (i.e., the Department of Justice, the Department of Health and Human Services Office of Inspector General (OIG), and State law enforcement agencies) to combat fraud, waste, and abuse.

In addition, CMS relies on contractors to assist in oversight of Medicare Part B, including oversight of billing of and payment for orthotic braces. These contractors include National Provider Enrollment (NPE) contractors, durable medical equipment Medicare Administrative Contractors (DME MACs), the Supplemental Medical Review Contractor (SMRC), Recovery Audit Contractors (RACs), Unified Program Integrity Contractors (UPICs), and Comprehensive Error Rate Testing (CERT) contractors. Appendix B summarizes these contractors' roles and responsibilities.

Adequate CMS oversight of suppliers and ordering providers as well as CMS's use of its authority to adjust Medicare allowable amounts for OTS braces are critical in preventing fraud, waste, and abuse related to OTS braces and protecting Medicare and its enrollees from paying for medically unnecessary, unallowable, or even harmful braces. Adequate CMS oversight is also critical in ensuring that Medicare enrollees continue to have access to and receive medically necessary braces.

Prior Office of Inspector General Work Identifying Vulnerabilities Related to Orthotic Braces

OIG identified vulnerabilities related to orthotic braces starting in 1997. OIG's first evaluation of orthotic braces found that: (1) suppliers were more likely than orthotists to supply medically unnecessary braces to enrollees and (2) orthotic braces that did not have fitting requirements (i.e., OTS braces) were more likely to be medically unnecessary and more likely to be provided by suppliers.[16] The evaluation also found that orthotic braces provided in southeastern States were more likely to be medically unnecessary. A followup evaluation issued in 2000 found that inappropriate Medicare reimbursement for orthotic braces continued at significant levels, and found a lack of ordering provider involvement in enrollee use of orthotic braces (e.g., lack of followup, no plan of care, and no instructions on how a brace should be used).[17] In a companion report, CMS carriers (a type of contractor preceding the Medicare Administrative Contractors (MACs)) stated that more instruction and education for suppliers and providers would solve incorrect coding and medical necessity problems.[18]

Subsequent OIG work focused on OTS braces following the growth in Medicare payments after CMS implemented new procedure codes for OTS braces in calendar years (CYs) 2014 and 2015. (See the following section, “Implementation of Procedure Codes for Off-the-Shelf Braces.”) That OIG work was as follows:

- From CYs 2018 through 2020, OIG issued five audit reports covering individual suppliers that identified improper payment rates averaging 71 percent and estimated overpayments of almost $16.7 million for OTS braces that were not medically necessary or were not documented in enrollee medical records.[19]

- In CY 2019, another audit report estimated that Medicare and its enrollees paid $337.5 million more than non-Medicare payers, such as private insurance companies, for orthotic braces because Medicare allowable amounts were not reasonably comparable with payments made by select non-Medicare payers for 161 procedure codes.[20, 21] Of these codes, 50 were for OTS braces, which accounted for $96 million of the $337.5 million.

- In CY 2019, OIG, in cooperation with its law enforcement partners, announced the investigation Operation Brace Yourself, which dismantled one of the largest health care fraud schemes in terms of the amount billed to Medicare. This scheme caused estimated losses to Medicare of more than $1.2 billion for medically unnecessary OTS braces. The investigation resulted in administrative action by CMS against more than 130 suppliers, and Federal and State charges against 24 defendants associated with 5 telemedicine companies, dozens of suppliers, and 3 licensed medical professionals.[22] As of November 2023, there had been 299 charging documents issued as a result of Operation Brace Yourself.

Appendix C contains a list of prior OIG reports on orthotic devices, including braces. Appendix D contains details of the Operation Brace Yourself fraud scheme.

Implementation of Procedure Codes for Off-the-Shelf Braces

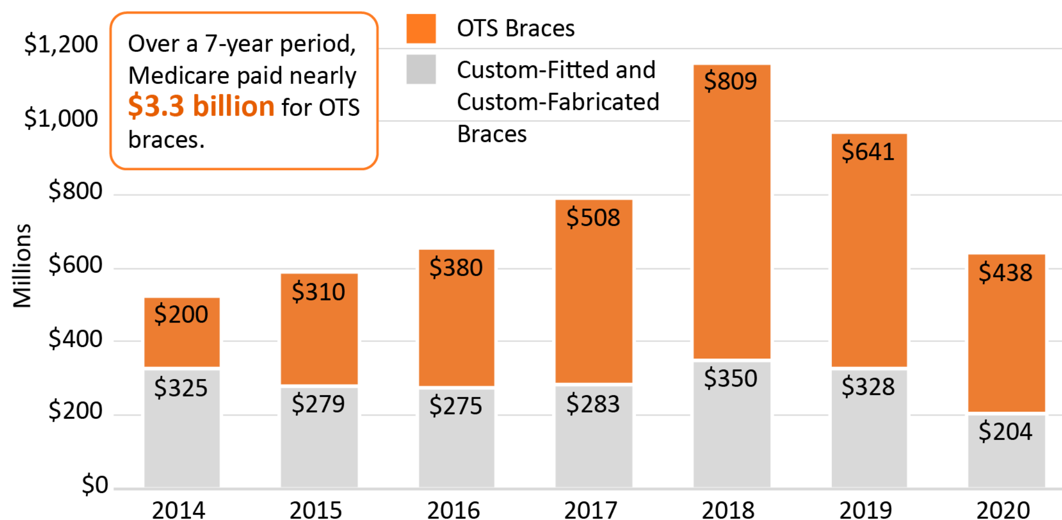
As part of its procedure code updating in CYs 2014 and 2015, CMS created 55 new procedure codes for OTS braces, 23 of which had corresponding procedure codes for custom-fitted versions of the same braces.[23] The 23 procedure codes for OTS braces were paid at the same amounts as the procedure codes for custom-fitted braces, but suppliers that billed for OTS braces were not subject to the same licensing, facility, and shipping requirements as suppliers that billed for custom-fitted braces. (See Figure 2 for supplier requirements.) Because the requirements for supplying OTS braces were less stringent, this difference could have provided an incentive for suppliers to bill for OTS braces.

Rapid Shift in Supplier Billing From Custom-Fitted to Off-the-Shelf Braces

In June 2018, a Medicare Payment Advisory Commission (MEDPAC) report to Congress found that suppliers rapidly shifted to billing for OTS braces in the 3 years following CMS's procedure code changes in CY 2014. According to the report, suppliers had an incentive to bill for OTS braces because the payments for these braces were the same as for custom-fitted braces but were not subject to additional quality standards. (MEDPAC, *Issues in Medicare's Medical Device Payment Policies*, June 2018)

From CYs 2014 through 2020, Medicare paid approximately $5.3 billion for orthotic braces, including $3.3 billion for OTS braces.[24] After CMS implemented the new procedure codes, Medicare payments for OTS braces grew rapidly after CY 2014 and peaked in CY 2018 at $809 million. Medicare payments for OTS braces began to decrease after CY 2018, which coincided with Operation Brace Yourself. (See Figure 3 for the Medicare payments by type of orthotic brace from CYs 2014 through 202.)

Figure 3: Medicare Payments by Type of Orthotic Brace for CYs 2014 Through 2020



This portfolio focuses on the vulnerabilities identified in OIG's prior work related to OTS braces and our analysis of Medicare payments for OTS braces from CYs 2018 through 2020.

ISSUES RELATED TO CMS OVERSIGHT OF OFF-THE-SHELF BRACES

Prior OIG audits, evaluations, and investigations identified vulnerabilities related to orthotic braces, including questionable supplier billing patterns, limited provider involvement with enrollees, Medicare allowable amounts for orthotic braces that were higher than payments made by non-Medicare payers, inappropriate telemarketing practices, and fraud related to OTS braces. For this portfolio, we analyzed Medicare claims data for OTS braces from CYs 2018 through 2020 and reviewed the results of prior OIG work specific to OTS braces. We did this because: (1) CMS's implementation of procedure codes for OTS braces in CY 2014 could have provided an incentive for suppliers to bill those codes and (2) Medicare payments for OTS braces accounted for more payments than for custom-fitted braces after 2014. (Appendix A describes our objective, scope, and methodology.)

For CYs 2018 through 2020, more than 90 percent of suppliers that provided orthotic braces billed for OTS braces that were provided to nearly 3.5 million enrollees. Medicare paid nearly $1.9 billion for OTS braces (almost 70 percent of all payments for orthotic braces), and enrollees were responsible for $484.6 million in coinsurance.

Based on our review of OIG's prior work and our analysis of Medicare claims data, we identified the following issues related to CMS's oversight of OTS braces:

- Medicare paid for potentially unallowable replacement OTS braces that did not meet RUL requirements.
- Medicare paid for OTS braces that were ordered by providers who did not have treating relationships with enrollees.
- The majority of new suppliers were located in geographic areas known to have high levels of Medicare fraud and furnished OTS braces ordered by providers who did not have treating relationships with enrollees.
- CMS has not fully used its authority to adjust Medicare allowable amounts for OTS braces to be reasonably comparable with payments made by select non-Medicare payers.

- Medicare paid for OTS braces that were marketed to enrollees by telemarketers using prohibited direct solicitation.

- Payments to suppliers for fraudulently billed OTS braces have cost Medicare millions of dollars.

These issues could result in improper payments, potential harm to enrollees (both financial harm and lower quality of care), and Medicare paying more for OTS braces than non-Medicare payers, such as private insurance companies.

Medicare Paid for Potentially Unallowable Replacement Off-the-Shelf Braces That Did Not Meet Reasonable Useful Lifetime Requirements

Medicare generally does not pay to replace an orthotic brace with the same or a similar orthotic brace (i.e., a replacement brace) within its RUL (after which Medicare payment can be made for replacing an item) unless the brace was lost, stolen, or irreparably damaged, or the enrollee's medical condition changed such that the brace no longer meets the enrollee's needs.[25] A supplier adds a modifier to a claim to indicate that a brace met RUL requirements.[26] DME MACs provide options to a supplier on how to verify that a replacement brace met RUL requirements. A supplier can verify by asking an enrollee about the item and accessing the DME MAC's online portal, which allows a supplier to check whether the enrollee received the same or a similar brace within the RUL.

If an enrollee receives a medically unnecessary orthotic brace, Medicare may later decline to pay for a brace that is needed because Medicare already covered the same or a similar brace within its RUL.

Although Medicare required suppliers to add modifiers to claims to show that orthotic braces met RUL requirements, our analysis of claims data for CYs 2018 through 2020 showed that more than half of all suppliers that submitted claims for replacement OTS braces did not use the required modifiers for replacing OTS braces that were the same as or similar to braces previously provided to enrollees within the braces' RULs.[27] As a result, Medicare paid suppliers $66.4 million for those potentially unallowable replacement OTS braces.[28]

Medicare Paid for Off-the-Shelf Braces That Were Ordered by Providers Who Did Not Have Treating Relationships With Enrollees

Ordering providers play a key role in Medicare utilization of OTS braces (i.e., the number of braces purchased per enrollee). Ordering providers are responsible for determining whether an orthotic brace is medically necessary to treat an enrollee's medical condition. For OTS braces, Medicare requires that a supplier has a written order from the ordering provider documenting the need for the brace and that the supplier includes the name and NPI number of the ordering provider on the claim submitted to the DME MAC. In addition, Medicare requires that the

enrollee's medical records demonstrate not only that the brace is reasonable and necessary but that the documentation is timely. Documentation is considered timely when an enrollee's medical records are dated within the preceding 6 or 12 months from the order date, depending on the brace.[29]

In 2019, Operation Brace Yourself found that suppliers paid kickbacks and bribes to physicians who ordered medically unnecessary OTS braces. Often, the physicians ordered braces without communicating with the enrollees.

Our analysis of claims data for CYs 2018 through 2020 showed that Medicare paid more than $1 billion for OTS braces ordered by providers who did not have treating relationships with enrollees.[30] We determined that a provider did not have a treating relationship with an enrollee if there was not a Medicare claim from that provider for the enrollee within 12 months before or on the date that the supplier billed Medicare (date of service) for an orthotic brace that the provider ordered for the enrollee. Of the approximately 279,000 providers who ordered OTS braces, almost 52,000 (nearly 19 percent) ordered braces for more than 750,000 enrollees with whom they had no treating relationships.

For CYs 2018 through 2020, Medicare paid more than

$1 billion

for OTS braces ordered by providers who did not have treating relationships with the enrollees.

For example, one of those providers—a diagnostic radiologist in California—ordered the third-highest number of OTS braces in the Nation and accounted for the third-highest total payments to suppliers for OTS braces. Although this provider ordered braces for just over 1 year during the period CYs 2018 through 2020, the provider ordered approximately 20,500 OTS braces, including replacement braces during their RULs, for approximately 8,600 enrollees in 44 States and 1 Territory; the provider did not have a treating relationship with any of the enrollees. This ordering pattern represented an average of 51 braces ordered for an average of 21 enrollees per day. Medicare paid 162 suppliers nearly $13 million for braces ordered by this provider, and enrollees were responsible for $3.3 million in coinsurance. Of the 162 suppliers, 15 were part of the fraud scheme uncovered by Operation Brace Yourself and accounted for $1.7 million in Medicare payments for OTS braces.

Suppliers are responsible for improper payments for medically unnecessary braces because they bill Medicare and are paid for braces supplied to enrollees, but ordering providers are responsible for determining medical necessity. It is unlikely that an ordering provider can determine whether a brace is medically necessary if the provider has no treating relationship with an enrollee. Therefore, the $1 billion that Medicare paid for braces ordered by providers who had no treating relationships with enrollees was potentially unallowable.

The Majority of New Suppliers Were Located in Geographic Areas Known To Have High Levels of Medicare Fraud and Furnished Off-the-Shelf Braces Ordered by Providers Who Did Not Have Treating Relationships With Enrollees

A supplier must obtain accreditation to enroll in Medicare and must comply with CMS's DMEPOS quality standards to keep its Medicare billing privileges. CMS designates each prospective supplier as high risk, which triggers additional screening requirements such as the requirement for NPE contractors to conduct background and criminal history checks of individuals who maintain 5 percent or greater ownership interest in the supplier.[31] In addition, all suppliers are assigned a fraud-level indicator, which shows a supplier's potential for fraud or abuse and is updated annually.[32] CMS may impose a temporary moratorium on enrolling new Medicare suppliers if CMS determines that there is significant potential for fraud, waste, or abuse with respect to a particular provider or supplier type (e.g., home health agencies), geographic area, or both.[33] As of the issuance date of this portfolio, CMS had not imposed a temporary moratorium on suppliers of OTS braces.

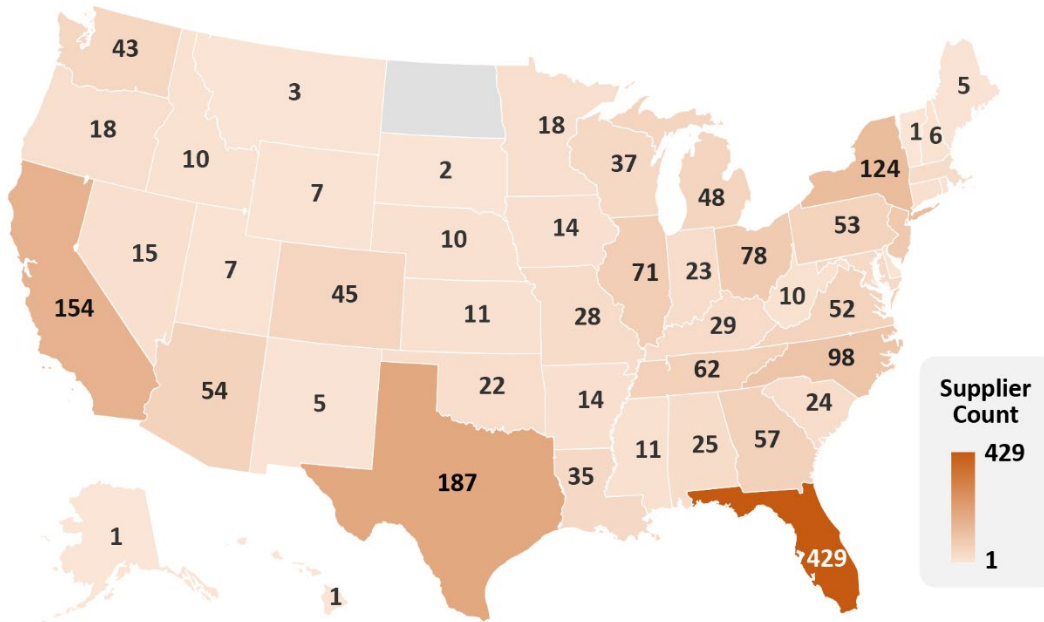
The fraud scheme uncovered during Operation Brace Yourself included new suppliers that provided OTS braces.[34] In addition, according to one CMS contractor, suppliers that bill for OTS braces have been a concern for some time and, because of "limited regulations and licensure requirements, suppliers have found a niche for billing OTS braces." Another CMS contractor recommended placing a moratorium on new suppliers because there has been an "abundance" of suppliers, especially suppliers of OTS braces.

Our analysis of claims data for CYs 2018 through 2020 showed that Medicare paid new suppliers almost $431 million for OTS braces. Of the 2,120 new suppliers, 75 percent were located in 23 States with geographic areas known to have high levels of Medicare fraud.[35] In addition, approximately $395 million (92 percent of the total payments) was paid for OTS braces ordered by providers who did not have treating relationships with the enrollees.

For CYs 2018 through 2020, new suppliers accounted for **23%** of payments for OTS braces and **11%** of enrollees who received OTS braces.

Florida and Texas had the largest number of new suppliers, followed by California and New York, all of which are known to have high levels of Medicare fraud. See Figure 4 for a map showing the number of new suppliers for CYs 2018 through 2020 by State.

Figure 4: Florida and Texas Had the Largest Number of New Suppliers for CYs 2018 Through 2020



For example, in June 2018 one new supplier in New York started billing Medicare for orthotic braces, primarily OTS braces. Medicare paid the supplier more than $9.2 million ($6.1 million in CY 2018 and $3.1 million in CY 2019) for OTS braces provided to almost 8,000 enrollees in all 50 States and 1 Territory. Of those payments (including payments for replacement braces within the RULs), 97 percent were for OTS braces ordered by providers who did not have treating relationships with the enrollees. The supplier did not bill Medicare for orthotic braces in CY 2020.

Because most payments to new suppliers (primarily located in geographic areas known to have high levels of Medicare fraud) from CYs 2018 through 2020 were associated with ordering providers who did not have treating relationships with the enrollees, Medicare paid $395 million for potentially unallowable OTS braces.

CMS Has Not Fully Used Its Authority To Adjust Medicare Allowable Amounts for Off-the-Shelf Braces To Be Reasonably Comparable With Payments Made by Select Non-Medicare Payers

CMS has the authority to adjust Medicare allowable amounts for orthotic braces if certain requirements are met under the inherent reasonableness process and the DMEPOS Competitive Bidding Program.[36, 37] One OIG audit found that Medicare allowable amounts were not reasonably comparable with payments made by select non-Medicare payers, such as private insurance companies.[38] The audit estimated that for CYs 2012 through 2015 Medicare and enrollees paid $337.5 million more than non-Medicare payers for orthotic braces because Medicare allowable amounts were higher than amounts paid by non-Medicare payers for 161 procedure codes. Of these procedure codes, 50 were for OTS braces, accounting for $96 million of the $337.5 million. We recommended that CMS adjust the allowable amounts as appropriate for future cost savings to Medicare and enrollees. CMS agreed with our recommendations and partially implemented them by including select OTS back and knee braces in the DMEPOS Competitive Bidding Program, which adjusted the Medicare allowable amounts for those items.

OTS back and knee braces were competitively bid for the first time in Round 2021 of the DMEPOS Competitive Bidding Program, with expected savings to Medicare of $600 million.

Although CMS added 22 of the 50 procedure codes for OTS braces (15 back brace codes and 7 knee brace codes) to the DMEPOS Competitive Bidding Program, the remaining 28 procedure codes continued to be paid based on the Medicare fee schedule.[39] Those 28 procedure codes accounted for more than $381 million in payments (20 percent of total Medicare payments for OTS braces for CYs 2018 through 2020).

Medicare Paid for Off-the-Shelf Braces That Were Marketed to Enrollees by Telemarketers Using Prohibited Direct Solicitation

Medicare prohibits suppliers or other parties on a supplier's behalf (e.g., telemarketers) from directly soliciting Medicare enrollees (e.g., through cold calls).[40, 41] In addition, payment is prohibited to a supplier that knowingly submits a claim generated pursuant to a prohibited direct solicitation.[42] If a supplier knowingly submitted a claim generated by a prohibited solicitation, both the supplier and the telemarketer are potentially liable for criminal, civil, or administrative penalties for causing the filing of a false claim.[43]

Although CMS provided guidance to suppliers on telemarketing and prohibited direct solicitation, Operation Brace Yourself found that suppliers billed for medically unnecessary OTS braces provided to enrollees who were contacted through prohibited direct solicitation by

telemarketers, which resulted in more than $1.2 billion in losses to Medicare.[44] (See Appendix D for details of this fraud scheme.)

Payments to Suppliers for Fraudulently Billed Off-the-Shelf Braces Have Cost Medicare Millions of Dollars

CMS works with Federal and State agencies to combat fraud, waste, and abuse. Fraud related to OTS braces has received national attention. In addition to CMS and OIG, other agencies and organizations—including the Department of Justice, the Federal Trade Commission, and the Better Business Bureau—have issued alerts warning the public about scams related to orthotic braces. National and local news organizations have also reported on consumers receiving unwanted orthotic braces in the mail, being tricked into providing their Medicare information, and being told that they qualify for free braces paid for by Medicare.

As demonstrated by Operation Brace Yourself, payments to suppliers for fraudulently billed OTS braces have cost Medicare millions of dollars.[45] In addition, medically unnecessary OTS braces provided to enrollees through fraud schemes may not address enrollee medical issues or may worsen enrollee medical conditions.

CONCLUSION

CMS's CERT program found that orthotic braces were consistently among the top 20 DMEPOS items with the highest improper payment rates from CYs 2014 through 2020. In addition, OIG has identified vulnerabilities related to orthotic braces since 1997. In CY 2014, CMS created new procedure codes for suppliers to use when billing for OTS braces, and Medicare payments for those codes grew rapidly. Payment rates for the new codes for OTS braces were the same as rates for codes for custom-fitted braces but were not subject to additional supplier requirements, which could have provided an incentive for suppliers to bill for OTS braces. In CY 2020, OTS braces accounted for almost 70 percent of Medicare payments for all orthotic braces.

Our review of prior OIG work and our analysis of Medicare claims data for OTS braces from CYs 2018 through 2020 found the following issues related to CMS oversight of OTS braces, which could result in improper payments and enrollee harm: (1) Medicare paid for potentially unallowable replacement OTS braces that did not meet RUL requirements, (2) Medicare paid for OTS braces that were ordered by providers who did not have treating relationships with enrollees, (3) the majority of new suppliers were located in geographic areas known to have high levels of Medicare fraud and furnished OTS braces ordered by providers who did not have treating relationships with enrollees, (4) CMS has not fully used its authority to adjust Medicare allowable amounts for OTS braces to be reasonably comparable with payments made by select non-Medicare payers, (5) Medicare paid for braces that were marketed to enrollees by telemarketers using prohibited direct solicitation, and (6) payments to suppliers for fraudulently billed OTS braces have cost Medicare millions of dollars.

Adequate CMS oversight of suppliers and ordering providers as well as CMS's use of its authority to adjust Medicare allowable amounts for OTS braces are critical in preventing fraud, waste, and abuse related to OTS braces and protecting Medicare and its enrollees from paying for medically unnecessary, unallowable, or even harmful braces. Adequate CMS oversight is also critical in ensuring that Medicare enrollees continue to have access to and receive medically necessary braces.

RECOMMENDATIONS

To reduce the risk of fraud, waste, and abuse related to OTS braces and to protect the health of Medicare enrollees by ensuring that suppliers provide medically necessary OTS braces, we recommend that the Centers for Medicare & Medicaid Services:

- determine why claims that did not have the required modifiers were paid for replacement OTS braces, and take steps to prevent payments for such claims;
- identify providers who ordered OTS braces for enrollees with whom they had no treating relationships and use that information to determine whether to provide additional education to—or take administrative or legal action against—the ordering providers or associated suppliers;
- analyze supplier billing patterns and use that information to determine whether to:
    - conduct additional prepayment or postpayment reviews of suppliers or
    - impose a temporary moratorium on enrolling new suppliers of OTS braces if CMS determines that there is significant potential for fraud, waste, or abuse;
- review Medicare allowable amounts for OTS braces that are not currently in the DMEPOS Competitive Bidding Program to ensure that Medicare payments for OTS braces are reasonably comparable with payments made by non-Medicare payers, and determine whether to include any of those procedure codes for braces in future rounds of competitive bidding;
- educate suppliers and enrollees on telemarketing practices for OTS braces, specifically on not using direct solicitation of enrollees, and consider revoking billing privileges of suppliers that engage in prohibited solicitation practices; and
- use predictive data analysis and information from other Federal agencies and from State agencies to identify emerging fraud schemes related to OTS braces, and use CMS's authority to prevent further losses to the Medicare program.

CMS Comments and Office of Inspector General Response

In written comments on our draft report, CMS did not state whether it concurred with our recommendations but described its efforts to reduce and prevent improper payments related to OTS braces. The following sections summarize CMS's comments on the recommendations and our responses. CMS's comments are included in their entirety as Appendix E.

First Recommendation: Prevent Payment for Claims for Replacement Off-the-Shelf Braces Without the Required Modifiers

CMS Comments

CMS stated that it concluded that the claims for replacement OTS braces without the required modifiers were paid in error because of a claims processing problem that the DME MACs identified and fixed in 2021. CMS also stated that it will continue to monitor and enhance the claims processing system to ensure that claims are paid appropriately. CMS suggested that, given these efforts, we close this recommendation as implemented.

OIG Response

We confirmed that CMS fixed the claims processing system, which includes modifier edit logic that addresses our recommendation. Therefore, we consider this recommendation implemented.

Second Recommendation: Take Action Against Providers Who Ordered Off-the-Shelf Braces for Enrollees With Whom They Had No Treating Relationships

CMS Comments

CMS stated that, given the Medicare requirement that the treating physician be the one who orders the DMEPOS item, CMS would expect that there would be a medical record to support that the enrollee was evaluated by the treating physician and that the item was medically reasonable and necessary. CMS also stated that it uses a robust program integrity strategy to reduce and prevent improper payments, and takes action deemed appropriate based on the findings of its program integrity activities.

OIG Response

We acknowledge that CMS's program integrity strategy (e.g., the requirement for a supplier to receive prior authorization before delivering an item and the requirement for a face-to-face encounter with a practitioner as a condition of payment), which was implemented after our audit period, may prevent improper payment for certain orthotic braces. However, because of the significance of the issues identified in this portfolio, we maintain that CMS should specifically identify providers who ordered OTS braces for enrollees with whom they had no treating relationships and take appropriate action.

Third Recommendation: Analyze Supplier Billing Patterns and Use That Information To Determine Whether To Conduct Reviews of Suppliers or Impose a Temporary Moratorium

CMS Comments

CMS stated that it uses a robust program integrity strategy to reduce and prevent improper payments. CMS stated that the strategy includes using automated system edits and conducting prepayment and postpayment reviews. CMS suggested that, given these efforts, we close this recommendation as implemented. CMS did not specifically address our recommendation to analyze supplier billing patterns to determine whether to impose a temporary moratorium on enrolling new suppliers.

OIG Response

We acknowledge CMS's program integrity strategy (e.g., conducting prepayment and postpayment reviews) related to suppliers. However, because of the significance of the issues identified in this portfolio, we maintain that CMS should analyze supplier billing patterns and determine whether to impose a temporary moratorium on enrolling new suppliers, specifically those suppliers located in geographic areas known to have high levels of Medicare fraud. Until CMS takes action to address our recommendation, we will consider this recommendation unimplemented.

Fourth Recommendation: Review Medicare Allowable Amounts for Off-the-Shelf Braces That Are Not in the DMEPOS Competitive Bidding Program To Ensure That Medicare Payments Are Reasonably Comparable With Non-Medicare Payers

CMS Comments

CMS stated that it intends to implement necessary changes to the DMEPOS Competitive Bidding Program to establish sustainable prices; save money for Medicare enrollees and taxpayers; help limit fraud, waste, and abuse in the Medicare program; and ensure enrollee access to quality items and services. CMS also stated that it will take our recommendation into consideration as it proceeds with implementing future rounds of competitive bidding.

OIG Response

We acknowledge CMS's efforts to reduce Medicare costs while ensuring access to quality items and services for enrollees through its DMEPOS Competitive Bidding Program. After CMS takes action to review Medicare allowable amounts for procedure codes for OTS braces that are not currently in the DMEPOS Competitive Bidding Program and determines whether to include any of those procedure codes in future rounds of competitive bidding, we will consider this recommendation implemented.

Fifth Recommendation: Educate Suppliers and Enrollees on Telemarketing Practices for Off-the-Shelf Braces and Consider Revoking Billing Privileges of Suppliers That Engage in Prohibited Solicitation Practices

CMS Comments

CMS described its ability to revoke billing privileges of suppliers that engage in prohibited solicitation and stated that it has provided guidance to suppliers on telemarketing. CMS stated that it will continue to educate suppliers on the DMEPOS Supplier Standards and will take action against suppliers that do not meet the standards in accordance with Federal regulations. In addition, CMS described its ongoing efforts to use social media and other means to educate enrollees on telemarketing practices. CMS suggested that, given these efforts, we close this recommendation as implemented.

OIG Response

We appreciate CMS's continued efforts to educate suppliers and enrollees on telemarking practices related to OTS braces. We also acknowledge CMS's actions taken (e.g., implementing payment suspensions and revoking suppliers' billing privileges) during Operation Brace Yourself

and CMS's efforts to continue these actions against suppliers that do not meet the DMEPOS Supplier Standards. Therefore, we consider this recommendation implemented.

Sixth Recommendation: Identify and Prevent Emerging Fraud Schemes Related to Off-the-Shelf Braces To Prevent Further Losses to Medicare

CMS Comments

CMS described its program integrity strategy to reduce and prevent Medicare improper payments, including using predictive analytic technologies to identify and prevent the payment of fraudulent claims. CMS stated that it coordinates closely with other partners to meet its program integrity objectives and will continue to partner with others to aggressively investigate fraud, waste, and abuse and take actions to protect enrollees and prevent losses to Medicare. CMS suggested that, given these efforts, we close this recommendation as implemented.

OIG Response

We acknowledge CMS's program integrity strategy and its coordinated efforts with its Federal, State, and local partners to identify national fraud trends and program vulnerabilities. However, these efforts do not specifically target OTS braces. Because of the significance of the issues identified in this portfolio and because OTS braces continue to be at risk for fraud, we maintain that CMS should identify and prevent emerging fraud schemes related to OTS braces. Until CMS takes additional action to address our recommendation, we will consider this recommendation unimplemented.

Appendix A: Objective, Scope, and Methodology

Objective

Our objective was to review vulnerabilities identified in OIG's prior work related to OTS braces and analyze Medicare payments for OTS braces from CYs 2018 through 2020 to identify issues with CMS's oversight of OTS braces.

Scope

Our portfolio covered paid Medicare Part B claims data from CYs 2018 through 2020 for orthotic braces, with payments totaling approximately $2.8 billion.

We obtained an understanding of CMS's oversight activities for OTS braces that were relevant to our objective.

We conducted our audit from September 2021 to January 2024.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- reviewed prior OIG work to identify vulnerabilities related to OTS braces (i.e., issues found in audits, evaluations, and investigations from 1997 through 2020);
- obtained paid Medicare Part B claims data from CMS's Integrated Data Repository;
- analyzed claims data to identify:
    - replacement braces within the RUL of a same or similar brace;
    - OTS braces ordered by providers who did not have treating relationships with enrollees;
    - Medicare payments to new suppliers for OTS braces, and to determine whether new suppliers were located in geographic areas known to have high levels of Medicare fraud; and

- Medicare payments for procedure codes for OTS braces that were not part of the DMEPOS Competitive Bidding Program; and

- discussed the results of our audit 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.

The OIG work referenced throughout this portfolio was conducted in accordance with the Quality Standards for Inspection and Evaluation issued by the Council of the Inspectors General on Integrity and Efficiency, Generally Accepted Government Auditing Standards issued by the Government Accountability Office, and investigative and legal professional standards, as applicable.

Appendix B: CMS Contractors' Roles and Responsibilities

National Provider Enrollment Contractors

NPE contractors process all enrollment applications for suppliers.[46] Each newly enrolling supplier is designated as high risk, which requires the supplier to submit fingerprints for a national background and criminal history check for all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the supplier.[47] NPE contractors also analyze the potential for fraud among all enrolled suppliers, and assign a fraud-level indicator that factors in a supplier's experience with payers other than Medicare, prior Medicare experience, geographic area, the fraud potential of products and services that the supplier provides, site visit results, inventory, and supplier accreditation. NPE contractors update the fraud-level indicator annually and share this information with other CMS contractors.

Durable Medical Equipment Medicare Administrative Contractors

CMS contracts with two DME MACs to process and pay Medicare Part B claims for DMEPOS. Each DME MAC makes coverage decisions for services provided within its jurisdiction.[48] In addition, DME MACs respond to supplier inquiries; educate suppliers about billing requirements; handle redetermination requests for first-stage appeals of denied claims; implement automated, service-specific prepayment claim processing system edits; and conduct targeted, provider-specific, and service-specific prepayment and postpayment medical record reviews as well as Targeted Probe and Educate reviews.[49, 50] DME MACs coordinate with UPICs on medical reviews and refer suppliers to UPICs when fraud is suspected. DME MACs also coordinate and communicate with RACs to obtain information on identified vulnerabilities, which DME MACs use to analyze data to identify actual or potential claim payment errors and corrective actions, including payment suspensions, penalties, and claim reviews.

The Supplier Medical Review Contractor

The SMRC conducts nationwide medical reviews of Medicare Part A, Part B, and DMEPOS claims to help lower improper payment rates and protect the Medicare Trust Fund.[51] These medical reviews focus on vulnerabilities identified by CMS data analysis, the CERT program, professional organizations, and Federal oversight agencies, such as OIG and the Government Accountability Office. The SMRC notifies suppliers of review findings and makes recommendations to DME MACs for provider outreach and education. The SMRC also refers suppliers to UPICs.

Recovery Audit Contractors

RACs review Medicare claims on a postpayment basis. RACs detect and correct past improper payments so that CMS and MACs can implement actions to prevent future improper payments. CMS contracts with one RAC to review DMEPOS claims. An RAC shares identified vulnerabilities with DME MACs to use in analyzing claims data and developing possible corrective actions.

Unified Program Integrity Contractors

UPICs perform fraud, waste, and abuse detection, deterrence, and prevention activities related to Medicare claims, including claims for orthotic braces. The primary goal of a UPIC is to identify cases of suspected fraud, waste, and abuse. UPICs refer suppliers and providers to law enforcement and identify the need for administrative actions, such as payment suspensions, civil monetary penalties, and revocations of license and billing privileges. When appropriate, UPICs may request that DME MACs install prepayment edits.

Comprehensive Error Rate Testing Contractors

CERT contractors review a stratified random sample of claims and calculate the fee-for-service improper payment rate annually. MACs, including DME MACs, use the CERT improper payment rates primarily to identify where to target improper payment prevention efforts.

Appendix C: Prior Office of Inspector General Reports

Report Title	Report Number	Date Issued
Visionquest Industries, Inc.: Audit of Medicare Payments for Orthotic Braces	A-09-19-03010	8/10/2020
Desoto Home Health Care, Inc.: Audit of Medicare Payments for Orthotic Braces	A-09-19-03021	8/6/2020
Freedom Orthotics, Inc.: Audit of Medicare Payments for Orthotic Braces	A-09-19-03012	7/6/2020
Medicare Allowable Amounts for Certain Orthotic Devices Are Not Comparable With Payments Made by Select Non-Medicare Payers	A-05-17-00033	10/30/2019
Kelley Medical Equipment and Supply, LLC, Received Unallowable Medicare Payments for Orthotic Braces	A-09-17-03030	1/17/2019
Pacific Medical, Inc., Received Some Unallowable Medicare Payments for Orthotic Braces	A-09-17-03027	12/31/2018
Medicare Payments for Orthotics, Inappropriate Payments	OEI-02-99-00120	March 2000
Medicare Allowed Charges for Orthotic Body Jackets	OEI-04-97-00391	March 2000
Orthotic Procedure Code Claims Paid to Medassist-OP, Inc. by Medicare During the Period January 1, 1994 to December 31, 1996	A-02-97-01039	11/2/1999
Medicare Payments for Orthotic Body Jackets	OEI-04-97-00390	September 1999
Medicare Orthotics	OEI-02-95-00380	October 1997

Appendix D: Fraud Scheme Uncovered by Operation Brace Yourself

The conspirator starts the scheme. The conspirator owns a call center that pays for marketing, resulting in enrollees contacting the call center where telemarketers offer "free or low-cost" orthotic braces. The conspirator may purchase Medicare enrollees' contact information. Telemarketers illegally make unsolicited calls to enrollees directly.

The call center confirms that an enrollee is covered by Medicare and obtains specific medical information from the enrollee. The call center's telemarketers attempt to have the enrollee agree to receive more braces than the enrollee initially requested. The call center transfers enrollee contact information and medical notes to a telemedicine company and pays the telemedicine company for a provider consultation.

The ordering provider and the telemedicine company keep the scheme running. Often, the provider orders an orthotic brace without communicating with the enrollee. When a provider does speak with an enrollee, the brace is generally not prescribed in compliance with Medicare regulations or standard medical guidelines. The telemedicine company then submits the order for the brace to the call center.

The call center collects orthotic brace orders and sells them to the supplier.

The supplier sends the orthotic braces to enrollees. The supplier bills Medicare for the braces. The supplier receives $500 to $900 per brace from Medicare and pays the conspirator a kickback of almost $300 per prescribed brace.

Appendix E: CMS Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: March 11, 2024

TO: Juliet T. Hodgkins
Principal Deputy Inspector General
Office of Inspector General

FROM: Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Portfolio: Medicare Remains Vulnerable to Fraud, Waste, and Abuse Related to Off-the-Shelf Orthotic Braces, Which May Result in Improper Payments and Impact the Health of Enrollees (A-09-21-03019)

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 recognizes the importance of continuing to provide Medicare beneficiaries with access to medically necessary services and, at the same time, working to protect the Medicare Trust Funds from improper payments. CMS uses a robust program integrity strategy to reduce and prevent Medicare improper payments, including automated system edits within the claims processing system, and conducting prepayment and post-payment reviews. As part of this strategy, CMS recovers identified overpayments in accordance with agency policies and procedures.

CMS coordinates closely with a variety of other partners to meet its program integrity objectives, including but not limited to the Department of Health and Human Services OIG, the Department of Justice (DOJ), State law enforcement officials, including those from the state Medicaid Fraud Control Units (MFCUs), and other federal, state, and local agencies. As noted in OIG's report, Operation Brace Yourself was announced in 2019. In April 2019, CMS implemented administrative actions as part of Operation Brace Yourself, a joint effort with OIG and DOJ to target fraudulent Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers. As part of this effort, CMS implemented payment suspensions on 130 DMEPOS suppliers totaling $74 million as of August 2019. Additionally, CMS implemented more than 300 revocations. CMS implemented payment suspensions on an additional seven DMEPOS suppliers subsequent to those initial actions. Forty suppliers under payment suspension voluntarily withdrew from the Medicare program and 45 suppliers were revoked from Medicare since that activity.

Orthotics is the term used to describe the devices covered under the Medicare Part B benefit for leg, arm, back, and neck braces in accordance with section 1861(s)(9) of the Social Security Act. The terms "orthotics" and "braces" are interchangeable for Medicare purposes.

The OIG's audit period ranged from calendar year 2018 through 2020. Since that time, CMS has taken a number of actions related to orthotics, including off-the-shelf orthotics that are braces. For example, beginning in 2022 CMS began requiring prior authorization for five orthoses HCPCS codes as a condition of payment.[1] Under prior authorization, the supplier submits the prior authorization request and receives the decision before the services are rendered. CMS utilizes the prior authorization program for certain DMEPOS items that are frequently subject to unnecessary utilization. In 2023, CMS announced that ten additional orthoses would require a face-to-face encounter and written order prior to delivery as a condition of payment.[2] For all items requiring a face-to-face encounter, a practitioner visit is required within six months preceding the order. The encounter must be used to gather information associated with diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered. As per the requirements at 42 CFR 424.516(f)(2)(i), a supplier must maintain the written order and the supporting documentation provided by the treating practitioner and make them available to CMS and its contractors upon request. Review contractors assess compliance with the face-to-face encounter and written order prior to delivery requirements to help reduce unnecessary utilization.

Additionally, CMS strives to maximize affordability and availability of DMEPOS items and services. The Medicare DMEPOS Competitive Bidding Program is consistent with this goal. 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 sustainable payment rates for DMEPOS items, save money for beneficiaries and taxpayers, and limit fraud, waste, and abuse in the Medicare Program. When competitive bidding contracts were in place for all previously bid items, including a national mail-order program, the DMEPOS Competitive Bidding Program saved approximately $2 billion annually.

Off-the-shelf back and knee braces were included in Round 2021 of the DMEPOS Competitive Bidding Program, which was in effect January 1, 2021 through December 31, 2023. As such, Medicare payment amounts for off-the-shelf back and knee braces furnished within competitive bidding areas were based on bids submitted under the DMEPOS Competitive Bidding Program, in accordance with Section 1834(a)(1)(F)(i) and Section 1847(a)(2)(C) of the Social Security Act.

Before a competitive bidding contract is offered to a supplier, CMS determines whether a supplier is properly licensed and accredited for each competition in which it bids and meets specific competitive bidding program financial standards. Medicare's accreditation and financial standards are intended to ensure that contract suppliers provide high quality items and services and are viable entities that can meet beneficiaries' needs for the duration of the contract period.

Contract suppliers are monitored to ensure they comply with the contract terms and conduct business in a manner that meets the Medicare Supplier Standards and the CMS Quality Standards

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[1] The HCPCS requiring prior authorization include spinal orthoses (L0648, L0650) and knee orthoses (L1832, L1833, L1851).

[2] A full list of DMEPOS items added to the requires face-to-face encounter and written order prior to delivery list is available online at: https://www.cms.gov/files/document/required-face-face-encounter-and-written-order-prior-delivery-list.pdf

to be accredited. CMS's monitoring program includes routine analysis of supplier performance indicators, claims data monitoring, Medicare enrollment data, and a formal complaint monitoring system. In addition, extensive education is provided to ensure suppliers, beneficiaries, providers, and referral agents understand the rules that govern the DMEPOS Competitive Bidding Program. If CMS is made aware of issues of suppliers not meeting competitive bidding program rules, CMS investigates the situation and takes action in accordance with regulations.

Further, CMS has taken action to prevent improper Medicare payments by educating health care providers and suppliers on proper billing. CMS educates health care providers and suppliers on Medicare billing through various channels including the Medicare Learning Network (MLN), weekly electronic newsletters, and quarterly compliance newsletters. For example, CMS maintains an MLN Fact Sheet on DMEPOS Accreditation which includes information on the supplier standards.[3] Supplier Standard 11 states that DMEPOS suppliers "must agree not to contact a beneficiary by telephone when supplying a Medicare-covered item" unless certain exceptions are met.

CMS also educates enrollees through our social media channels, email, and paid outreach campaigns reminding individuals of fraud-related activities and how to report them. For example, CMS has published a booklet titled "Protecting Yourself & Medicare from Fraud."[4] Additionally, Medicare.gov includes information on reporting Medicare fraud and abuse.[5] CMS has also used social media to educate Medicare beneficiaries specifically about orthotic brace scams, including what to do if a beneficiary receives a call offering free medical items in exchange for the beneficiaries Medicare number.

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

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services determine why claims that did not have the required modifiers were paid for replacement OTS braces, and take steps to prevent payments for such claims.

CMS Response

After researching the claims provided by the OIG, CMS concluded that the modifier edit logic was working correctly, but the claims were paid in error due to a separate claims processing problem previously identified by the Medicare Administrative Contractors in August of 2021. The Medicare Administrative Contractors updated their editing to fix the problem at that time. Therefore, no claims processing updates are needed at this time to implement the recommendation. CMS and the Medicare Administrative Contractors will continue to monitor and enhance the claims processing system to help ensure that claims are paid appropriately.

Given the efforts CMS highlights above, we suggest OIG close this recommendation as implemented.

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[3] MLN Fact Sheet DMEPOS Accreditation (December 2022) available at: https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/dmepos_basics_factsheet_icn905710.pdf

[4] This booklet is available online at: https://www.medicare.gov/publications/10111-protecting-yourself-and-medicare.pdf.

[5] Please see Medicare.gov for more information: https://www.medicare.gov/basics/reporting-medicare-fraud-and-abuse.

OIG Recommendation
The OIG recommends that the Centers for Medicare & Medicaid Services identify providers who ordered OTS braces for enrollees with whom they had no treating relationships and use that information to determine whether to provide additional education to, or take administrative action against, the ordering providers or associated suppliers.

CMS Response
Given the Medicare requirement that the treating physician be the one who orders the DMEPOS item, CMS would expect that there would be a medical record to support that the patient was evaluated and the item was medically reasonable and necessary to support the treating physician requirement.

As stated above, CMS uses a robust program integrity strategy to reduce and prevent Medicare improper payments, including automated system edits within the claims processing system, and conducting prepayment and post-payment reviews. CMS takes action deemed appropriate based on the findings of program integrity activities.

OIG Recommendation
The OIG recommends that the Centers for Medicare & Medicaid Services analyze supplier billing patterns and use that information to determine whether to 1) conduct additional prepayment or post-payment reviews of suppliers or 2) impose a temporary moratorium on enrolling new suppliers.

CMS Response
As stated above, CMS uses a robust program integrity strategy to reduce and prevent Medicare improper payments, including automated system edits within the claims processing system, and conducting prepayment and post-payment reviews. CMS takes action deemed appropriate based on the findings of program integrity activities.

Given the efforts CMS highlights above, we suggest OIG close this recommendation as implemented.

OIG Recommendation
The OIG recommends that the Centers for Medicare & Medicaid Services review Medicare allowable amounts for OTS braces that are not currently in the DMEPOS Competitive Bidding Program to ensure that Medicare payments for OTS braces are reasonably comparable with payments made by non-Medicare payers, and determine whether to include any of those procedure codes for braces in future rounds of competitive bidding.

CMS Response
Off-the-shelf back and knee braces were included in Round 2021 of the DMEPOS Competitive Bidding Program which was in effect January 1, 2021, through December 31, 2023. Due to a lag in claim submission and timely filing requirements, CMS has not yet finalized the actual savings of Round 2021. However, we expect actual savings to be in line with the $600 million we estimated at the beginning of Round 2021.

As of January 1, 2024, there is a temporary gap period for the DMEPOS Competitive Bidding Program. CMS will start bidding for the next round of the DMEPOS Competitive Bidding Program after rulemaking. We intend to implement necessary changes to the DMEPOS Competitive Bidding Program to establish sustainable prices, save money for Medicare patients

and taxpayers, help limit fraud, waste, and abuse in the Medicare Program, and ensure patient access to quality items and services. Product categories for the next round of competitive bidding have not yet been announced. CMS will take OIG's recommendation into consideration as we proceed with implementation of future rounds of competitive bidding.

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services educate suppliers and enrollees on telemarketing practices for OTS braces, specifically on not using direct solicitation of enrollees, and consider revoking billing privileges of suppliers that engage in prohibited solicitation practices.

CMS Response

Supplier Standard 11 states that DMEPOS suppliers, "must agree not to contact a beneficiary by telephone when supplying a Medicare-covered item unless certain exceptions are met."[6] This supplier standard is part of the DMEPOS Site Visit checks. CMS is able to revoke billing privileges of suppliers that engage in prohibited solicitation using 42 CFR 424.535(a)(1) and 42 CFR 424.535(a)(23). Additionally, if CMS receives a report or complaint of solicitations, we work with the DMEPOS Accreditation Organizations and the National Provider Enrollment Contractors to thoroughly investigate the supplier in question. Any complaints where evidence is found may lead to revocation of Medicare billing privileges. As stated in the OIG's report, CMS has provided guidance to suppliers on telemarketing and prohibited direct solicitation. CMS will continue to educate suppliers on the DMEPOS Supplier Standards, and will take action against suppliers that do not meet the standards in accordance with the regulations.

CMS also educates enrollees through our social media channels, email, and paid outreach campaigns reminding individuals of fraud-related activities and how to report them. For example, CMS has published a booklet titled "Protecting Yourself & Medicare from Fraud."[7] Medicare.gov includes information on reporting Medicare fraud and abuse.[8] CMS has also used social media to educate Medicare beneficiaries specifically about orthotic brace scams, including what to do if a beneficiary receives a call offering free medical items in exchange for the beneficiary's Medicare number. CMS will continue to educate Medicare beneficiaries about fraud-related activities and how to report them.

Given the efforts CMS highlights above, we suggest OIG close this recommendation as implemented.

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services use predictive data analysis and information from other Federal agencies and from State agencies to identify emerging fraud schemes related to OTS braces, and use CMS's authority to prevent further losses to the Medicare program.

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[6] For additional information regarding the supplier standards is available at: https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-424/subpart-D/section-424.57#p-424.57(c)

[7] This booklet is available online at: https://www.medicare.gov/publications/10111-protecting-yourself-and-medicare.pdf.

[8] Please see Medicare.gov for more information: https://www.medicare.gov/basics/reporting-medicare-fraud-and-abuse.

CMS Response

As stated above, CMS uses a robust program integrity strategy to reduce and prevent Medicare improper payments, including leveraging the Fraud Prevention System (FPS). FPS utilizes predictive analytic technologies to identify and prevent the payment of fraudulent claims in the Medicare Fee-for-Service Program. FPS was developed in response to the Small Business Jobs Act of 2010 which mandated the use of predictive modeling and other analytic technologies, such as models and edits, to prevent potential fraud, wase, and abuse. Additionally, CMS coordinates closely with a variety of other partners to meet its program integrity objectives, including but not limited to the Department of Health and Human Services OIG, the DOJ, State law enforcement officials, including those from the state MFCUs, and other federal, state, and local agencies. For example, CMS participates in the Major Case Coordination initiative, which provides an opportunity for Medicare and Medicaid policy experts, law enforcement officials, clinicians, and fraud investigators to collaborate before, during, and after the development of fraud leads. This level of collaboration has contributed to several successful coordinated law enforcement actions and helped CMS to better identify national fraud trends and program vulnerabilities. CMS will continue to partner with others as we aggressively investigate fraud, waste and abuse, take action to protect patients and, critical health care resources and prevent losses to the Medicare Trust Fund.

Given the efforts CMS highlights above, we suggest OIG close this recommendation as implemented.

Endnotes

[1] CMS's Comprehensive Error Rate Testing (CERT) program measures the improper Medicare fee-for-service payment rate annually. CERT reports for CYs 2013 through 2020 are available online at https://www.cms.gov/data-research/monitoring-programs/improper-payment-measurement-programs/comprehensive-error-rate-testing-cert/cert-reports. Accessed on May 27, 2022.

[2] The Medicare allowable amount consists of the Medicare payment and any coinsurance and deductible that were the enrollee's responsibility.

[3] A modifier is a two-digit code on a claim that provides additional information or changes the description of a service to improve accuracy or specificity (e.g., to specify a right limb or a left limb).

[4] Social Security Act (the Act) § 1832(a)(1) and §§ 1861(s)(5), (s)(6), (s)(8), and (s)(9).

[5] Quality standards are organized into two sections: (1) Supplier Business Service Requirements, which focus on administration, financial management, human resources management, consumer services, performance management, product safety, and information management; and (2) Supplier Product-Specific Service Requirements, which focus on intake and assessment, delivery and setup, patient or caregiver training and instruction, and followup.

[6] The Medicare Improvements for Patients and Providers Act of 2008, P.L. No. 110-275, section 154(b)(1), amended section 1834(a)(20)(F)(ii) of the Act, exempting certain eligible professionals and other persons from accreditation, such as orthotists.

[7] The Act § 1862(a)(1)(A).

[8] 42 CFR § 414.210(f). The RUL for certain knee orthoses (i.e., orthotic braces) may be less than 5 years depending on the Healthcare Common Procedure Coding System code for the orthosis. The specific RULs are listed in CMS's "Policy Article A52465: Knee Orthoses."

[9] CMS, "Transmittal 1993, Change Request 6945," July 1, 2010. Available online at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1993CP.pdf. Accessed on June 9, 2023.

[10] 42 CFR § 414.210.

[11] Medicare enrollees may also have supplemental insurance to cover their coinsurance. Details available online at https://www.cms.gov/Medicare/Health-Plans/Medigap. Accessed on Nov. 8, 2022.

[12] Procedure codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

[13] The NPI number is a unique identification number for covered health care providers that must be used in administrative and financial transactions.

[14] To qualify as an ordering provider, a provider must: (1) have an individual NPI number, (2) be enrolled in Medicare in either an "approved" or "opt-out" status, and (3) be of an eligible specialty type.

[15] Predictive analytics is the use of historical data to make predictions about future outcomes. CMS's predictive analytics system analyzes Medicare fee-for-service claims to detect potentially fraudulent activity. Market saturation refers to the density of providers of a particular service within a defined geographic area relative to the number of enrollees receiving that service in the area. Utilization mapping tools include interactive maps and datasets that show national, State, and county-level provider services and utilization data for selected health service areas.

[16] OIG, *Medicare Orthotics* (OEI-02-95-00380), October 1997.

[17] OIG, *Medicare Payments for Orthotics, Inappropriate Payments* (OEI-02-99-00120), March 2000.

[18] OIG, *Medicare Payments for Orthotics, Carrier Perspectives* (OEI-02-99-00121), March 2000.

[19] The following are OIG reports: *Pacific Medical, Inc., Received Some Unallowable Medicare Payments for Orthotic Braces* (A-09-17-03027), Dec. 31, 2018; *Kelley Medical Equipment and Supply, LLC, Received Unallowable Medicare Payments for Orthotic Braces* (A-09-17-03030), Jan. 17, 2019; *Freedom Orthotics, Inc.: Audit of Medicare Payments for Orthotic Braces* (A-09-19-03012), July 6, 2020; *Desoto Home Health Care, Inc.: Audit of Medicare Payments for Orthotic Braces* (A-09-19-03021), Aug. 6, 2020; and *Visionquest Industries, Inc.: Audit of Medicare Payments for Orthotic Braces* (A-09-19-03010), Aug. 10, 2020.

[20] OIG, *Medicare Allowable Amounts for Certain Orthotic Devices Are Not Comparable With Payments Made by Select Non-Medicare Payers* (A-05-17-00033), Oct. 30, 2019.

[21] For CYs 2012 through 2015, we estimated that Medicare and enrollees paid $341.7 million more than select non-Medicare payers for 142 procedure codes and $4.2 million less than select non-Medicare payers for 19 procedure codes.

[22] OIG, "Nationwide Brace Scam." Available online at https://oig.hhs.gov/newsroom/media-materials/nationwide-brace-scam/.

[23] CMS created additional procedure codes for OTS braces after the updates in CYs 2014 and 2015. Specifically, in January 2017 CMS created two new codes for OTS knee braces, and in January 2018 CMS created a new code for OTS elbow braces.

[24] There are so-called other accessory procedure codes (e.g., a code for a suspension sleeve for a knee brace) that are billed in addition to the codes for orthotic braces. The payment amounts in our portfolio do not include other accessory procedure codes.

[25] The Act § 1862(a)(1)(A); 42 CFR § 414.210(f).

[26] See endnote 9.

[27] Details available online at https://med.noridianmedicare.com/web/jddme/topics/same-or-similar and https://www.cgsmedicare.com/jb/pubs/pdf/chpt5.pdf. Accessed on Mar. 13, 2023, and Oct. 27, 2023.

[28] We excluded claim lines that did not specify a right or left modifier. We also excluded claim lines if both the right and left modifiers were billed with a unit quantity other than 2.

[29] Local Coverage Article A55426: Standard Documentation Requirements for All Claims Submitted to DME MACs.

[30] We did not determine whether providers had opted out of billing Medicare or had compromised NPI numbers. We also did not determine whether enrollees' Medicare beneficiary identifier numbers were compromised. CMS's *Medicare Program Integrity Manual*, Pub. No. 100-08, chapter 4, section 4.7.2, defines a "compromised number" as a provider, supplier, or beneficiary number that has been stolen and used by unauthorized entities or individuals to bill Medicare.

[31] 42 CFR §§ 424.518(c)(1) and (2).

[32] NPE contractors use four fraud-level indicators: (1) low risk (e.g., a national drug store chain), (2) limited risk (e.g., a prosthetist in a low fraud area), (3) medium risk (e.g., a midsize general medical supplier in a high fraud area), and (4) high risk (e.g., a very small-space diabetic supplier with low inventory in a high fraud area whose owner has previously had a Chapter 7 bankruptcy). CMS, *Medicare Program Integrity Manual,* Pub. No. 100-08, chapter 10, § 10.2.5.2.

[33] 42 CFR § 424.570.

[34] We defined "new supplier" as any supplier that from CYs 2018 through 2020: (1) obtained an NPI number, (2) enrolled in Medicare, and (3) received Medicare payments for orthotic braces.

[35] To identify areas known to have high levels of Medicare fraud, we used the same areas that OIG's Medicare Fraud Strike Force used. (The 23 States included the District of Columbia.) Details available online at https://oig.hhs.gov/fraud/strike-force/.

[36] The DMEPOS Competitive Bidding Program replaced the traditional Medicare fee schedule payment methodology for select DMEPOS items through a competitive bidding process. Under this process, suppliers that operate in a particular area are required to submit bids for select items, and CMS uses those bids to establish a single payment amount. The intent of competitive bidding is to improve the effectiveness of the Medicare methodology for setting DMEPOS payment amounts and to reduce Medicare cost and enrollee coinsurance while ensuring access to quality items and services.

[37] See endnote 2.

[38] See endnote 20.

[39] CMS added one back brace to the DMEPOS Competitive Bidding Program, which was not part of our audit.

[40] Section 1834(a)(17) of the Act and *Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards* (Jan. 9, 2018), Appendix C, prohibit suppliers from making unsolicited telephone calls to Medicare enrollees regarding the furnishing of a covered item, except in three specific situations: (1) the enrollee has given written permission to the supplier to make contact by phone, (2) the contact is regarding a covered item that the supplier has already furnished to the enrollee, or (3) the supplier has furnished at least one covered item to the enrollee during the preceding 15 months.

[41] Direct solicitation means direct contact—which includes but is not limited to telephone, computer, email, instant messaging, or in-person contact—by a DMEPOS supplier or its agents with a Medicare enrollee without the enrollee's consent for the purpose of marketing the DMEPOS supplier's health care products or services, or both.

[42] The Act §§ 1834(a)(17)(A) and (B).

[43] OIG, "Special Fraud Alert, Telemarketing by Durable Medical Equipment Suppliers." Available online at https://oig.hhs.gov/documents/special-fraud-alerts/868/fraudalert_telemarketing.pdf.

[44] CMS, "Telemarketing Frequently Asked Questions." Available online at https://www.cms.gov/medicare/provider-enrollment-and-certification/medicareprovidersupenroll/downloads/dmepostelemarketingfaqs.pdf. Accessed on Mar. 21, 2023.

[45] As of Mar. 16, 2023, suppliers of orthotic braces continued to be convicted of Medicare fraud. For example, see the press release "Texas Man Sentenced for $2 Million Medicare Fraud." Available online at https://www.justice.gov/usao-edva/pr/texas-man-sentenced-2-million-medicare-fraud. Accessed on Mar. 21, 2023.

[46] Effective Nov. 7, 2022, NPE contractors replaced the existing contractor, National Supplier Clearinghouse.

[47] 42 CFR § 424.518.

[48] A MAC makes a coverage decision (also referred to as a "local coverage determination") on whether a particular service or item is reasonable and necessary and therefore covered by Medicare within the specific jurisdiction that the MAC oversees.

[49] Automated prepayment edits prevent payment for noncovered, incorrectly coded, or inappropriately billed services.

[50] During a Targeted Probe and Educate review, a DME MAC reviews up to 3 rounds of 20 to 40 claims from a supplier and provides individualized education to the supplier based on the review. If the supplier's compliance improves, there is at least a 12-month period before another review may start. If there is no improvement after three rounds, the DME MAC sends the supplier's information to CMS for further action, such as a 100-percent prepayment review, extrapolation, or referral to a RAC. Details available online at https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medicare-ffs-compliance-programs/medical-review/targeted-probe-and-educatetpe. Accessed on Dec. 13, 2022.

[51] Medical reviews identify errors through a claims analysis or a medical record review, or both. Contractors use this information to help ensure that they make proper Medicare payments (and recover any improper payments if claims were already paid).