

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**FREEDOM ORTHOTICS, INC.:
AUDIT OF MEDICARE PAYMENTS
FOR ORTHOTIC BRACES**

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Office of Inspector General

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Report in Brief

Date: July 2020

Report No. A-09-19-03012

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



Why OIG Did This Audit

From July 1, 2016, through December 31, 2018 (audit period), Medicare paid approximately \$4 billion for orthotic braces provided to Medicare beneficiaries. Prior OIG audits found that some suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) billed for orthotic braces that did not comply with Medicare requirements. During our audit period, the Centers for Medicare & Medicaid Services found that orthotic braces were among the top 20 DMEPOS items with the highest improper payment rates. After analyzing Medicare claim data, we selected for audit Freedom Orthotics, Inc. (Freedom), an orthotic braces supplier in Dunedin, Florida.

Our objective was to determine whether Freedom complied with Medicare requirements when billing for orthotic braces.

How OIG Did This Audit

For our audit period, Freedom received approximately \$7.7 million in Medicare Part B payments for orthotic braces provided to 5,254 Medicare beneficiaries. After excluding certain claims, we grouped the remaining claims by beneficiary, selected a stratified random sample of 100 beneficiaries, and reviewed 247 claims associated with the sampled beneficiaries. We provided copies of Freedom's supporting documentation to an independent medical review contractor to determine whether the claims met Medicare requirements.

Freedom Orthotics, Inc.: Audit of Medicare Payments for Orthotic Braces

What OIG Found

Freedom did not comply with Medicare requirements when billing for orthotic braces. For all 100 sampled beneficiaries, with payments totaling \$165,306, Freedom billed for orthotic braces that were not medically necessary.

These deficiencies occurred because Freedom did not obtain sufficient information from the beneficiaries' medical records to assure itself that the claims for orthotic braces met Medicare requirements for medical necessity. On the basis of our sample results, we estimated that Freedom received at least \$6.9 million in unallowable Medicare payments for orthotic braces.

What OIG Recommends and Freedom Comments

We recommend that Freedom (1) refund to the durable medical equipment Medicare administrative contractors \$6.9 million in estimated overpayments for orthotic braces; (2) based upon the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made in accordance with this recommendation; and (3) obtain as much information from beneficiary medical records as it determines necessary to assure itself that claims for orthotic braces meet Medicare requirements for medical necessity.

Freedom stated that it disagreed with our entire review and our finding. Freedom also stated that it disagreed with each of our recommendations and will assert its rights for an appeal. Freedom stated that it disagreed with "the alleged overpayment amount" and further stated that it believes it has obtained sufficient information from the beneficiary medical records to determine medical necessity.

We maintain that our finding and recommendations remain valid. If the information in a beneficiary's medical record does not adequately support medical necessity, the supplier is liable for the payment amount of the orthotic brace. In addition, our report clarifies that OIG recommendations do not represent final determinations by Medicare but are recommendations to HHS action officials.

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INTRODUCTION

WHY WE DID THIS AUDIT

From July 1, 2016, through December 31, 2018 (audit period), Medicare paid approximately \$4 billion for orthotic braces provided to Medicare beneficiaries. Prior Office of Inspector General (OIG) audits and evaluations in this area found that some suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) billed for orthotic braces that did not comply with Medicare requirements and that orthotic braces were vulnerable to fraud, waste, and abuse. (Appendix D lists related OIG reports.) During our audit period, the Centers for Medicare & Medicaid Services' (CMS's) Comprehensive Error Rate Testing (CERT) program, which measures improper Medicare fee-for-service payments, found that orthotic braces were among the top 20 DMEPOS items with the highest improper payment rates.

After analyzing Medicare claims data for our audit period, we selected several DMEPOS suppliers (suppliers) for audit based on (1) Medicare Part B payments to the suppliers and (2) other risk factors, including the percentage of Medicare payments for orthotic braces. This report covers one of those suppliers, Freedom Orthotics, Inc. (Freedom), an orthotic braces supplier in Dunedin, Florida.

OBJECTIVE

Our objective was to determine whether Freedom complied with Medicare requirements when billing for orthotic braces.

BACKGROUND

The Medicare Program

The Medicare program provides health insurance coverage to people aged 65 and over, people with disabilities, and people with end-stage renal disease. CMS administers the program. Medicare Part B provides supplementary medical insurance for medical and other health services.

Medicare Coverage of Orthotic Braces

Medicare Part B covers DMEPOS, including orthotic braces.¹ To be paid by Medicare, a service or an item must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.² Orthotic braces are defined as

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

² The Act § 1862(a)(1)(A).

“rigid and semi-rigid devices which are used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.”³

The figure shows examples of knee, back, and ankle-foot braces.

Figure: Knee, Back, and Ankle-Foot Braces



CMS contracts with two durable medical equipment Medicare administrative contractors (DME MACs) to process and pay Medicare Part B claims for DMEPOS, including orthotic braces. Each DME MAC processes claims for two of four jurisdictions (A, B, C, and D), which include specific States and territories. Suppliers must submit claims to the DME MAC that serves the State or territory in which a Medicare beneficiary permanently resides.

When submitting claims to DME MACs for orthotic braces, suppliers use Healthcare Common Procedure Coding System (HCPCS) codes.⁴ Under Medicare Part B, the MACs reimburse suppliers for orthotic braces based on a fee schedule.

Medicare Requirements for Suppliers Billing for Orthotic Braces

The DME MACs develop local coverage determinations (LCDs)⁵ for some covered orthotic braces. The LCDs outline the conditions under which DME MACs will pay suppliers for those braces.

³ CMS's *Medicare Benefit Policy Manual*, Pub. No. 100-02, chapter 15, § 130.

⁴ HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

⁵ An LCD is a decision by a Medicare contractor, such as a DME MAC, whether to cover a particular item or service on a contractor-wide basis in accordance with section 1862(a)(1)(A) of the Act (the Act § 1869(f)(2)(B)).

DME MACs list certain documentation that they expect a supplier to have on file before the supplier submits a claim for an orthotic brace, including:⁶

- written documentation of a verbal order or a preliminary written order from the treating physician (if applicable),
- a detailed written order from the treating physician,
- information from the treating physician concerning the beneficiary's diagnosis,
- any information required for the use of specific modifiers,⁷ and
- proof of delivery of the orthotic brace to the beneficiary.

The supplier should also obtain as much documentation from the beneficiary's medical record as it determines necessary to assure itself that the orthotic brace meets Medicare requirements.

Medicare Requirements for Suppliers To Identify and Return Overpayments

OIG believes that this audit report constitutes credible information of potential overpayments. Upon receiving credible information of potential overpayments, suppliers must exercise reasonable diligence to identify overpayments (i.e., determine receipt of and quantify any overpayments) during a 6-year lookback period. Suppliers must report and return any identified overpayments by the later of (1) 60 days after identifying those overpayments or (2) the date that any corresponding cost report is due (if applicable). This is known as the 60-day rule.⁸

The 6-year lookback period is not limited by OIG's audit period or restrictions on the Government's ability to reopen claims or cost reports. To report and return overpayments under the 60-day rule, suppliers can request the reopening of initial claims determinations, submit amended cost reports, or use any other appropriate reporting process.⁹

⁶ CMS's *Medicare Program Integrity Manual*, Pub. No. 100-08, chapter 5, §§ 5.2.2; Local Coverage Article (LCA): Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426). The documentation standards contained within LCA A55426 were originally found within each individual DME MAC LCD as they applied to that particular LCD. However, such information was removed from all DME MAC LCDs and moved to the LCA effective January 1, 2017. Although these standards are not a basis for a denial of payment, we looked at whether the supplier complied with these standards; however, we did not have any findings based on these standards.

⁷ A modifier is a two-digit code that further describes the service performed, such as indicating the limb affected.

⁸ The Act § 1128J(d); 42 CFR §§ 401.301–401.305; 81 Fed. Reg. 7654 (Feb. 12, 2016).

⁹ 42 CFR §§ 401.305(d), 405.980(c)(4), and 413.24(f); CMS, *Provider Reimbursement Manual*—Part 1, Pub. No. 15-1, § 2931.2; 81 Fed. Reg. at 7670.

Freedom Orthotics, Inc.

Freedom is a supplier in Dunedin, Florida. For our audit period, Freedom received approximately \$7.7 million in Medicare Part B payments.

All of these payments were for orthotic braces and related DMEPOS accessories provided to 5,254 Medicare beneficiaries in all States and territories, except North Dakota. Table 1 shows a breakdown of the payments.

**Table 1: Medicare Part B Payments to Freedom
for Knee, Back, and Other Braces***

Year	Payment for Knee Braces	Payment for Back Braces	Payment for Other Braces	Total Payments by Year
2016 (Jul.-Dec.)	\$18,454	\$22,795	\$20,548	\$61,797
2017	983,573	1,176,837	903,017	3,063,427
2018	2,260,471	1,197,776	1,086,588	4,544,835
Total	\$3,262,498†	\$2,397,408	\$2,010,153	\$7,670,059
Percentage of Total Payment	42.5%	31.3%	26.2%	100%
* Other braces consist of ankle-foot, elbow, neck, shoulder-elbow-wrist, and wrist braces.				
† Includes payments for related DMEPOS accessories (i.e., suspension sleeves for knee braces).				

HOW WE CONDUCTED THIS AUDIT

Freedom received Medicare Part B payments of \$7,670,059 for orthotic braces provided to 5,254 Medicare beneficiaries, representing 11,285 paid claims with dates of service during our audit period. We excluded from our audit certain claims that had been reviewed by the recovery audit contractors (RACs)¹⁰ and other review entities (such as the DME MACs). We then grouped the remaining claims by beneficiary. As a result, our audit covered 5,242 beneficiaries, representing 11,237 paid claims totaling \$7,633,945. We selected a stratified random sample of 100 beneficiaries and reviewed 247 claims, totaling \$165,306, that were associated with the sampled beneficiaries.

Freedom provided us with supporting documentation for the sampled beneficiaries. The documentation included physician orders, proof of delivery, and medical records that Freedom

¹⁰ CMS contracts with RACs to identify improper payments of Medicare claims. RACs conduct postpayment reviews to identify improper payments and recoup any overpayments identified.

obtained from the treating physicians. We provided copies of the documentation to an independent medical review contractor to determine whether the claims for orthotic braces met Medicare requirements.¹¹

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 describes our audit scope and methodology, Appendix B describes our statistical sampling methodology, and Appendix C contains our sample results and estimates.

FINDING

Freedom did not comply with Medicare requirements when billing for orthotic braces. For all 100 sampled beneficiaries, with payments totaling \$165,306, Freedom billed for orthotic braces that were not medically necessary.

These deficiencies occurred because Freedom did not obtain sufficient information from the beneficiaries' medical records to assure itself that the claims submitted to the DME MAC for orthotic braces met Medicare requirements for medical necessity. On the basis of our sample results, we estimated that Freedom received at least \$6.9 million¹² in unallowable Medicare payments for orthotic braces.

MEDICARE REQUIREMENTS

To be paid by Medicare, an item or a service must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (Social Security Act (the Act) § 1862(a)(1)(A)). Medicare pays for an orthotic brace if it is medically necessary and supported by the beneficiary's medical record.

Payment must not be made to a supplier for an item or a service unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (the Act § 1833(e)).

Appendix E contains details on the Medicare requirements related to orthotic braces.

¹¹ The independent medical review contractor's staff included, but was not limited to, physicians and certified medical professionals. In addition, the contractor had quality assurance procedures to ensure that all medical review determinations made by its staff were factually accurate, complete, and concise.

¹² Without rounding, the amount is \$6,987,413.

FREEDOM BILLED FOR ORTHOTIC BRACES THAT WERE NOT MEDICALLY NECESSARY

For all 100 sampled beneficiaries, Freedom billed for orthotic braces that were not medically necessary. Specifically, the independent medical review contractor found that the information in the beneficiaries' medical records did not support the medical necessity of the orthotic braces.

The following are examples of medically unnecessary braces provided to beneficiaries.

Example of Medically Unnecessary Back and Bilateral Ankle-Foot Braces for the Same Beneficiary

Medicare paid Freedom \$995 for providing a back brace and bilateral ankle-foot braces to a 59-year-old beneficiary on November 21, 2017. According to the physician's order, dated November 20, 2017, the back brace (HCPCS L0650) was prescribed for low back pain, and the ankle-foot braces (HCPCS L1906) were prescribed for ligament sprains. The beneficiary's medical records for the back brace, dated October 31, 2017, did not indicate that restricting mobility would improve pain; the records also did not indicate (1) weak or deformed spinal muscles or (2) recent injury to or surgery on the spine. The beneficiary's medical records for the ankle-foot braces, dated February 22, 2017, and March 22, 2017, indicated that there was a right ankle fracture. However, subsequent medical records dated between September 18 and November 28, 2017, did not support weakness or deformity of the foot or ankle. In addition, the medical records did not indicate that the beneficiary needed an ankle-foot brace for stabilization or had the potential to benefit functionally from the brace. There was no mention of weakness or deformity of the left ankle. As a result, the independent medical review contractor found that the back and ankle-foot braces were not medically necessary.

Example of a Medically Unnecessary Knee Brace

Medicare paid Freedom \$753 for providing a knee brace to a 43-year-old beneficiary on April 26, 2018. According to the physician's order, dated April 24, 2018, the knee brace (HCPCS L1851) was prescribed for osteoarthritis of the left knee. However, the beneficiary's medical records dated September 6, 2017, showed that the beneficiary's chief complaint was right knee osteoarthritis. The beneficiary's ambulatory status was not clear in the documentation, and there was no mention of recent injury to or surgery on the left knee. Furthermore, there was no physical examination documented in the medical records describing knee instability or joint laxity (freedom of movement in a joint). Knee instability must be documented by examination of the beneficiary and an objective description of joint laxity. As a result, the independent medical review contractor found that the knee brace was not medically necessary.

CAUSE AND EFFECT OF IMPROPER BILLING OF ORTHOTIC BRACES

Although Freedom had adequate documentation related to the physician orders and proof of delivery for the orthotic braces, it did not obtain sufficient information from the beneficiaries' medical records to assure itself that the claims for orthotic braces met Medicare requirements for medical necessity. The independent medical review contractor's evaluation of the 100 sampled beneficiaries' medical records found that the medical records did not contain sufficient information related to the medical necessity of each of the items ordered.

On the basis of our sample results, we estimated that Freedom received at least \$6.9 million in unallowable Medicare payments for orthotic braces.

RECOMMENDATIONS

We recommend that Freedom Orthotics, Inc.:

- refund to the DME MACs \$6,987,413 in estimated overpayments for orthotic braces;¹³
- based upon the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule¹⁴ and identify any of those returned overpayments as having been made in accordance with this recommendation; and
- obtain as much information from beneficiary medical records as it determines necessary to assure itself that claims for orthotic braces meet Medicare requirements for medical necessity.

¹³ OIG audit recommendations do not represent final determinations by Medicare. CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures. Providers have the right to appeal those determinations and should familiarize themselves with the rules pertaining to when overpayments must be returned or are subject to offset while an appeal is pending. The Medicare Part A and Part B appeals process has five levels (42 CFR § 405.904(a)(2)), and if a provider exercises its right to an appeal, the provider does not need to return overpayments until after the second level of appeal. Potential overpayments identified in OIG reports that are based on extrapolation may be re-estimated depending on CMS determinations and the outcome of appeals.

¹⁴ This recommendation does not apply to any overpayments that are both within our sampling frame (i.e., the population from which we selected our statistical sample) and refunded based upon the extrapolated overpayment amount. Those overpayments are already covered in the previous recommendation.

FREEDOM COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Freedom stated that it disagreed with our entire review and our finding. Freedom also stated that it disagreed with each of our recommendations and will assert its rights for an appeal. A summary of Freedom's comments and our responses follow. Freedom's comments are included in their entirety as Appendix F.

After reviewing Freedom's comments, we maintain that our finding and recommendations remain valid. The independent medical review contractor found that the information in the beneficiaries' medical records (such as evidence of weakness or deformity of a body part) did not support the medical necessity of the orthotic braces.

DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATIONS

Freedom Comments

Freedom stated that the DMEPOS regulations impose an unfair burden on suppliers, one that no other supplier faces throughout the health care system. Freedom stated that suppliers are expected to act as unlicensed health care providers and to second-guess the professional judgment of doctors to prevent the payment of medically unnecessary claims stemming from medically unnecessary prescriptions.

Freedom stated that the Department of Health and Human Services (HHS) imposes liability on suppliers for physicians' actions, both when a physician writes a medically unnecessary prescription and when a prescription is medically necessary but insufficiently documented as determined by an independent medical reviewer. Freedom said that suppliers have no control over physicians' actions in either scenario.

Freedom stated that the *Medicare Program Integrity Manual* (the Manual) requires DMEPOS suppliers like Freedom to undertake a second-level review for every claim and second-guess a physician's determination that a prescription for a DMEPOS item is medically necessary. Freedom also stated that "[t]he concept that a DMEPOS [supplier] cannot make a medical diagnosis nor determine medical necessity is abundantly clear in statutes and rules associated with these programs." Freedom then stated that even if suppliers could reasonably ensure the medical necessity of every DMEPOS prescription, doing so is not feasible. Freedom stated that suppliers do not have easy or quick access to the relevant medical records.

In addition, Freedom stated that the Manual does not require physicians to provide medical records to a supplier before the supplier can dispense a DMEPOS item. Freedom stated that, as a consequence, it is Freedom's experience that physicians in many cases refuse to provide medical records to suppliers except in response to an audit.

Office of Inspector General Response

According to section 1862(a)(1)(A) of the Act, no payment may be made under Medicare Part A or Part B for any expenses incurred for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Further, section 1833(e) of the Act precludes payment to any provider or supplier unless “there has been furnished such information as may be necessary in order to determine the amounts due such provider.” The relevant LCDs state that it is expected that the beneficiary’s medical records, which include the treating physicians’ office records, hospital records, records from other health care professionals, and test reports, will reflect the need for the care provided. This documentation must be available upon request. The independent medical review contractor found that the information in the beneficiaries’ medical records did not support the medical necessity of the orthotic braces.

MEDICAL REVIEW OF BENEFICIARY MEDICAL RECORDS FOR TWO SAMPLED BENEFICIARIES

Freedom Comments

Freedom provided detailed comments on the medical review determinations for two sampled beneficiaries. Freedom discussed two specific examples of wrist and ankle braces that the independent medical review contractor found were medically unnecessary, which Freedom stated were from our draft report. For both examples, Freedom disagreed with the medical review determinations.

Office of Inspector General Response

The two examples cited by Freedom were not discussed in our report, but the beneficiaries were included in our sample. The independent medical review contractor found that the information in the beneficiaries’ medical records did not support the medical necessity of the orthotic braces. In addition, OIG audit recommendations do not represent final determinations by the Medicare program but are recommendations to HHS action officials. Action officials at CMS, acting through a MAC or another contractor, can review information that Freedom would like to provide and will determine whether a potential overpayment exists and will recoup any overpayments consistent with CMS’s policies and procedures. If a disallowance is taken, a provider has the right to appeal the determination that a payment for a claim was improper (42 CFR § 405.904(a)(2)).

FREEDOM’S RESPONSE TO OUR FINDING AND RECOMMENDATIONS

Freedom Comments

Freedom stated that it disagreed with our finding and stated that it intends to appeal the finding and the requests for overpayment. Freedom also stated that it disagreed with “the alleged overpayment amount and believes that any extrapolation off of the claims reviewed is

inaccurate and would be significantly and substantially modified after the review process.” Freedom further stated that it believes it has obtained sufficient information from the beneficiary medical records to determine medical necessity. In closing, Freedom stated that “with regard to each recommendation of the OIG, Freedom disagrees with such recommendation” and will assert its rights for an appeal because it “disagrees with the application of the requirements as they have been applied by the OIG reviews in this matter.”

Office of Inspector General Response

We maintain that our finding and recommendations remain valid. If the information in a beneficiary’s medical record does not adequately support medical necessity, the supplier is liable for the payment amount of the orthotic brace. Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.¹⁵ In addition, our report clarifies that OIG recommendations do not represent final determinations by Medicare but are recommendations to HHS action officials.

¹⁵ See *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84 (2d Cir. 1991); *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982); *Momentum EMS, Inc. v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 at *26-28 (S.D. Tex. 2013), adopted by 2014 U.S. Dist. LEXIS 4474 (S.D. Tex. 2014); *Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Freedom received Medicare Part B payments of \$7,670,059 for orthotic braces provided to 5,254 Medicare beneficiaries, representing 11,285 paid claims with dates of service from July 1, 2016, through December 31, 2018. We excluded from our audit 6 claims, totaling \$4,470, that had been reviewed by the RACs and 42 claims, totaling \$31,644, that had been reviewed by other review entities.¹⁶ We then grouped the remaining claims by beneficiary and created a sampling frame of 5,242 beneficiaries, representing 11,237 claims totaling \$7,633,945. We selected a stratified random sample of 100 beneficiaries and reviewed 247 claims, totaling \$165,306, that were associated with the sampled beneficiaries.

Freedom provided us with supporting documentation for the sampled beneficiaries. The documentation included physician orders, proof of delivery, and medical records that Freedom obtained from the treating physicians. We provided copies of the documentation to an independent medical review contractor to determine whether the claims for orthotic braces met Medicare requirements.

We did not audit Freedom's overall internal control structure. Rather, we limited our audit of internal controls to those that were significant to our objective.

We conducted our audit from April 2019 to January 2020, which included fieldwork performed at Freedom's offices in Dunedin, Florida.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- reviewed Freedom's policies and procedures for billing claims for orthotic braces;
- interviewed Freedom's officials to obtain an understanding of Freedom's procedures for (1) providing orthotic braces to beneficiaries, (2) maintaining documentation for billed orthotic braces, and (3) billing Medicare for orthotic braces;

¹⁶ CMS created a RAC data warehouse to track information about claims reviewed by the RACs. Other review entities used this data warehouse to identify claims they had previously reviewed so that the claims could be excluded from RAC reviews. DMEPOS review entities include DME MACs, OIG, and law enforcement entities.

- obtained from CMS’s National Claims History (NCH) file the paid Medicare Part B claims for orthotic braces that Freedom billed to Medicare for our audit period;¹⁷
- created a sampling frame of 5,242 beneficiaries and reviewed a stratified random sample of 100 beneficiaries (Appendix B);
- reviewed data from CMS’s Common Working File for the sampled beneficiaries’ claims to determine whether claims had been canceled or adjusted;
- obtained documentation from Freedom for the orthotic braces for the sampled beneficiaries and provided the documentation to an independent medical review contractor, which determined whether the claims met Medicare requirements;
- reviewed and summarized the independent medical review contractor’s results;
- estimated the amount of the unallowable payments for orthotic braces billed by Freedom (Appendix C); and
- discussed the results of our audit with Freedom 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.

¹⁷ Our audit allowed us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS’s NCH file, but we did not assess the completeness of the file.

APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

We obtained paid Medicare Part B claim data for Freedom that included at least one of the HCPCS codes for orthotic braces and had service dates during our audit period, representing 11,285 paid claims totaling \$7,670,059. We removed 6 claims, totaling \$4,470, that had been reviewed by the RACs and removed 42 claims, totaling \$31,644, that had been reviewed by other review entities. We then grouped the remaining claims by beneficiary. As a result, the sampling frame consisted of 5,242 beneficiaries, representing 11,237 paid claims totaling \$7,633,945.

SAMPLE UNIT

The sample unit was a beneficiary. We reviewed the claims associated with each beneficiary.

SAMPLE DESIGN

We used a stratified random sample, consisting of two strata (Table 2).

Table 2: Strata

Stratum	Description	No. of Beneficiaries	No. of Claims	Payment
1	Beneficiaries with multiple Medicare claims	3,224	9,219	\$6,221,283
2	Beneficiaries with one Medicare claim	2,018	2,018	1,412,662
Total		5,242	11,237	\$7,633,945

SAMPLE SIZE

We selected a total of 100 beneficiaries, consisting of 80 beneficiaries from stratum 1 and 20 beneficiaries from stratum 2.

SOURCE OF RANDOM NUMBERS

We generated the random numbers with the OIG, Office of Audit Services (OAS), statistical software.

METHOD OF SELECTING SAMPLE ITEMS

We consecutively numbered the sample units in each stratum. After generating 80 random numbers for stratum 1 and 20 random numbers for stratum 2, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to estimate the amount of unallowable payments. To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Table 3: Sample Results

Stratum	No. of Items in Sampling Frame	Value of Frame	Sample Size	Value of Sample	No. of Unallowable Sample Items	Value of Unallowable Sample Items
1	3,224	\$6,221,283	80	\$152,576	80	\$152,576
2	2,018	1,412,662	20	12,730	20	12,730
Total	5,242	\$7,633,945	100	\$165,306	100	\$165,306

**Table 4: Estimated Value of Unallowable Payments
(Limits Calculated for a 90-Percent Confidence Interval)**

Point estimate	\$7,433,265
Lower limit	6,987,413
Upper limit¹⁸	7,633,945

¹⁸The upper limit, calculated using the OIG/OAS statistical software, for the total overpayment amount was \$7,879,116. We adjusted this estimate downward to reflect the known value of the sampling frame.

APPENDIX D: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Kelley Medical Equipment and Supply, LLC, Received Unallowable Medicare Payments for Orthotic Braces</i>	<u>A-09-17-03030</u>	1/17/2019
<i>Pacific Medical, Inc., Received Some Unallowable Medicare Payments for Orthotic Braces</i>	<u>A-09-17-03027</u>	12/31/2018
<i>Medicare Payments for Orthotics Inappropriate Payments</i>	<u>OEI-02-99-00120</u>	March 2000
<i>Medicare Allowed Charges for Orthotic Body Jackets</i>	<u>OEI-04-97-00391</u>	March 2000
<i>Orthotic Procedure Code Claims Paid to Medassist-OP, Inc. by Medicare During the Period January 1, 1994 to December 31, 1996</i>	<u>A-02-97-01039</u>	11/2/1999
<i>Medicare Payments for Orthotic Body Jackets</i>	<u>OEI-04-97-00390</u>	September 1999
<i>Medicare Orthotics</i>	<u>OEI-02-95-00380</u>	October 1997
<i>Medicare Payments for Orthotic Body Jackets</i>	<u>OEI-04-92-01080</u>	June 1994

APPENDIX E: MEDICARE REQUIREMENTS RELATED TO ORTHOTIC BRACES

MEDICAL NECESSITY REQUIREMENTS

Social Security Act

The Act, section 1862(a)(1)(A), states: “. . . no payment may be made under part A or part B for any expenses incurred for items or services—(1)(A) which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

Local Coverage Determinations

The LCDs outline the conditions under which the DME MACs will cover knee, back, and ankle-foot braces. (These braces are referred to in the LCDs as “orthoses.”)

Knee Braces

A knee immobilizer without joints (L1830), or a knee orthosis with adjustable knee joints (L1832, L1833), or a knee orthosis, with an adjustable flexion and extension joint that provides both medial-lateral and rotation control (L1843, L1845, L1851, L1852), are covered if the beneficiary (1) has had recent injury to or a surgical procedure on the knee(s). . . . Knee orthoses L1832, L1833, L1843, L1845, L1851 and L1852 are also covered for a beneficiary who (2) is ambulatory and has knee instability due to a condition specified in the [diagnosis] codes that Support Medical Necessity Knee instability must be documented by examination of the beneficiary and objective description of joint laxity (e.g., varus/valgus instability, anterior/posterior Drawer test). Claims for [these knee orthoses] will be denied as not reasonable and necessary when the beneficiary does not meet the above criteria for coverage. For example, they will be denied if only pain or a subjective description of joint instability is documented [*LCD: Knee Orthoses (L33318)*].

Back Braces

A [back] orthosis ([HCPCS codes] L0450 - L0651) is covered when it is ordered for one of the following indications: (1) to reduce pain by restricting mobility of the trunk; or (2) to facilitate healing following an injury to the [back] or related soft tissue; or (3) to facilitate healing following a surgical procedure on the [back] or related soft tissue; or (4) to otherwise support weak [back] muscles and/or a deformed [back]. If a [back] orthosis is provided and the coverage criteria are not met, the item will be denied as not medically necessary [*LCD: Spinal Orthoses: TLSO and LSO (L33790)*].

Ankle-Foot Braces

Ankle-foot orthoses [L1900, L1902-L1990, L2106-L2116, L4350, L4360, L4361, L4386, L4387, L4631] . . . are covered for ambulatory beneficiaries with weakness or deformity of the foot and ankle, who: (1) require stabilization for medical reasons, and, (2) have the potential to benefit functionally. . . . If the basic coverage criteria for [ankle-foot orthoses] are not met, the orthosis will be denied as not reasonable and necessary [*LCD: Ankle-Foot/Knee-Ankle-Foot Orthosis (L33686)*].

DOCUMENTATION REQUIREMENTS

Social Security Act

The Act, section 1833(e), states: “No payment shall be made to any [supplier] of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such [supplier] or other person under this part for the period with respect to which the amounts are being paid or for any prior period.”

CMS GUIDANCE¹⁹

Medicare Program Integrity Manual

The Manual²⁰ (chapter 3, §§ 3.3.3 and 3.6.2.2) outlines guidance for determining what is reasonable and necessary, in the absence of policies.

Section 3.3.3 of the Manual states: “The MACs . . . have the discretion to review claims, in the absence of policies, whether a NCD [national coverage determination], coverage provision in an interpretive Medicare manual, or LCD exists for that service.”

Section 3.6.2.2 of the Manual states the following:

CMS issues national coverage determinations (NCDs) that specify whether certain items, services, procedures or technologies are reasonable and necessary under §1862(a) (1) (A) of the Act. In the absence of an NCD, Medicare contractors are responsible for determining whether services are reasonable and necessary. If no local coverage determination (LCD) exists for a particular item

¹⁹ All Manual provisions were used strictly as guidance. We did not have any findings based on the guidance found within the Manual.

²⁰ The CMS Online Manual System is used by CMS program components, partners, contractors, and State survey agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives.

or service, the MACs . . . shall consider an item or service to be reasonable and necessary if the item or service meets the following criteria:

- It is safe and effective;
- It is not experimental or investigational; and
- It is appropriate, including the duration and frequency in terms of whether the service or item is:
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the beneficiary's condition or to improve the function of a malformed body member;
 - Furnished in a setting appropriate to the beneficiary's medical needs and condition;
 - Ordered and furnished by qualified personnel; and,
 - One that meets, but does not exceed, the beneficiary's medical need.

The Manual, chapter 5, section 5.7, outlines guidance for documenting medical necessity:

For any DMEPOS item to be covered by Medicare, the [beneficiary's] medical record must contain sufficient documentation of the [beneficiary's] medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the [beneficiary's] diagnosis and other pertinent information including, but not limited to, duration of the [beneficiary's] condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc. . . .

Neither a physician's order nor a CMN [Certificate of Medical Necessity] nor a DIF [DME Information Form] nor a supplier prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier. . . .

The documentation in the [beneficiary's] medical record does not have to be routinely sent to the supplier or to the DME MACs, DME PSCs [program safeguard contractors], or ZPICs [zone program integrity contractors]. However, the DME MACs, DME PSCs, or ZPICs may request this information in selected cases. If [they] do not receive the information when requested or if the information in the [beneficiary's] medical record does not adequately support

the medical necessity for the item, then on assigned claims the supplier is liable for the dollar amount involved

The Manual, chapter 5, section 5.8.A, provides additional guidance for documenting medical necessity:

The supplier should also obtain as much documentation from the [beneficiary's] medical record as they determine they need to assure themselves that coverage criteria for an item have been met. If the information in the [beneficiary's] medical record does not adequately support the medical necessity for the item, the supplier is liable for the dollar amount involved unless a properly executed ABN of possible denial has been obtained.

Documentation must be maintained in the supplier's files for seven (7) years from date of service.

The Manual (chapter 5, §§ 5.2.2 and 5.8(A), (B), and (D))²¹ details the documentation guidance for orthotic braces:

Suppliers may dispense most items of DMEPOS based on a verbal order or preliminary written order from the treating physician.

Before submitting a claim to the DME MAC the supplier must have on file a dispensing order, the detailed written order, the CMN (if applicable), the DIF (if applicable), information from the treating physician concerning the [beneficiary's] diagnosis, and any information required for the use of specific modifiers or attestation statements as defined in certain DME MAC policies. Documentation must be maintained in the supplier's files for seven (7) years from date of service.

Proof of delivery documentation must be available to the DME MAC, Recovery Auditor, CERT and ZPIC on request. All items that do not have appropriate proof of delivery from the supplier will be denied and overpayments will be requested.

²¹ The Manual, chapter 5, section 5.8, was updated during our audit period under Rev. 750, effective November 20, 2017. Subsection 5.8(D) was removed, but similar language is included in 5.8(B): "In certain instances, compliance with proof of delivery may be required as a condition of payment, and must be available to the DME MAC, RAC, SMRC [supplemental medical review contractor], CERT, and ZPIC/UPIC [unified program integrity contractor] on request. For such items, if the supplier does not have appropriate proof of delivery documentation within the prescribed timeframes, associated claims will be denied and overpayments recouped."

APPENDIX F: FREEDOM COMMENTS



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May 14, 2020

Via Federal Express

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Via Email

Lorrari Herrera— Lorrari.Herrera@oig.hhs.gov

RE: Report No.: A-09-19-03012 Freedom Orthotics, Inc.'s response to draft report

Dear Ms. Ahlstrand and Ms. Herrera:

Please accept the following as the response to the draft report number A – 09 – 19 – 03012 directed to Freedom Orthotics, Inc.

Freedom Orthotics, Inc. ("Freedom") is a supplier of durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS"). Although it is located in Florida, it does business across the United States based upon contacts with patients requesting orthotic braces for problems they have been suffering from and for which a medical diagnosis was obtained.

Freedom does not refer patients to physicians. The patients primarily go to their own treating physician in their locale. As a result, the audit which occurred involved 100 different patients with 100 different physicians. Interestingly enough, the reviewer or reviewers who performed the audit on behalf of the OIG found that 100 different physicians with 100 different patients all completely failed to properly document the diagnosis for which each of the 100 separate physicians certified by their signature that the information contained in the physician's written order is true and correct and that the medical records support the medical need for the items prescribed. Each physician further attested that the information is true, accurate and complete to the best of their knowledge and that they understand that any falsification, omission or concealment of material fact could subject them to administrative, civil or criminal liability. The physician written order specifies what orthotic brace they are ordering as well as specifies the basis for why such brace is being ordered and actually references the medical necessity on the order. Thus, the reviewer or reviewers for the OIG are essentially stating that 100 different physicians on 100 different patients did not properly document the medical need or the specific language that the reviewers wanted to see in order to approve such payments.

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The HHS's Regulations Are Unequally Applied and Have No Rational Basis

The DMEPOS regulations impose an unfair burden on suppliers, one that no other supplier faces throughout the health care system. They are expected to act as unlicensed health care providers and second-guess the professional judgment of doctors to prevent the payment of medically-unnecessary claims stemming from medically-unnecessary prescriptions. But DMEPOS suppliers like Freedom are in no position to affect how licensed physicians practice medicine. The DMEPOS regulations (as interpreted by the OIG) puts suppliers in the untenable position of having to decide whether to lose their customers or face the government's chargebacks.

Specifically, HHS imposes liability on suppliers for physicians' actions—both when a physician writes a medically-unnecessary prescription and when a prescription is medically necessary but insufficiently documented as determined by an independent reviewer. Suppliers, though, have no control over physicians' actions in either scenario.

Doctors treat patients. They have the opportunity to speak with them and ask questions about their ailments and medical history. As trained and licensed medical professionals, they are also in the best position to determine whether a patient needs a prescription for a DMEPOS item. Despite the physicians' much greater knowledge and access to the patient, the Medicare Program Integrity Manual ("MPIM") requires DMEPOS suppliers like Freedom to undertake a second-level review for every claim and second-guess a physician's determination that a prescription for a DMEPOS item is medically necessary. This is not something that Freedom's management is trained to do. They are not health care providers. They have not gone to medical school, done a residency, or taken any licensing examinations. They simply own a business that serves to effectuate the treatment directions of trained medical providers.

Requiring suppliers to second-guess the medical judgment of trained physicians with a full patient history will not make the Medicare system better nor will it do anything to prevent a physician from writing medically-unnecessary prescriptions. Instead, if a supplier second-guesses a prescription, the only effect will be that the physician simply places the order with a supplier that does not question her medical judgment.

Even if suppliers could reasonably ensure the medical necessity of every DMEPOS prescription, doing so is not feasible. Suppliers do not have easy or quick access to the relevant medical records.

The MPIM does not require physicians to provide medical records to a DMEPOS supplier before the supplier can dispense a DMEPOS item. As a consequence, it is Freedom's experience that physicians in many cases refuse to provide medical records to suppliers except in response to an audit.

Complicating things further, most physicians do not store their records on-site. Instead, they store them off-site with third-party vendors. These third-party vendors, however, require that

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all records requests come directly from a physician. The records vendors are either very slow to respond or refuse to entertain any requests from a supplier like Freedom. Thus, in most cases, in order to access a patient's medical records before dispensing an orthotic, Freedom would have to have the treating physician request them from a third-party vendor, the very same physician that refuses to provide medical records on a regular basis.

Even if a physician will make a request to its third-party records vendor, the vendors do not instantly provide the necessary records. In most cases, records requests are responded to after about 30 days. Between the time it takes to get a physician to submit a request and the time for the records vendor to respond to the request, it would take Freedom, at best, about a months to obtain a patient's medical records. This is far too long for patients and physicians. It is simply unfeasible to obtain a beneficiary's medical records beyond the signed prescription and signed physician certification in order to confirm that the prescription written by a trained physician is medically necessary.

The concept that a DMEPOS cannot make a medical diagnosis nor determine medical necessity is abundantly clear in statutes and rules associated with these programs. However, the DMEPOS provider is still supposed to be liable and responsible for licensed physicians from around the country who make a medical diagnosis and prescribe orthotic braces and certify that there is medical necessity for such device and are willing to sign their name to a physician order certifying the medical necessity and diagnosis code for such orthotic brace. However the DMEPOS provider such as Freedom is then somehow held responsible for reimbursing the government when the records which providers almost rarely provide with the prescription form (even though requested to provide with the prescription form) are ultimately judged to be insufficient.

The MPIM regulations are unreasonable because they impose a different standard on DMEPOS suppliers than on any other supplier. A physician ordinarily jeopardizes his or her medical license by writing a medically-unnecessary prescription. The physician's incentive to not lose his or her livelihood is usually a sufficient basis for allowing almost every medical supplier to fill a physician's prescription without having to second-guess the physician's medical judgment. For instance, when a pharmacist receives a prescription from a doctor, the pharmacist, despite having extensive specialized training, does not have to determine whether the prescribed medicine is appropriate. Instead, he or she may rely on the doctor's determination of medical necessity, as evidenced by the prescription, without facing penalties and fines.

Can you imagine how our healthcare system would completely fall apart if pharmacists were to be held to a standard equaling that of the DMEPOS provider? A pharmacist is a licensed and trained medical professional who can rely upon a physician's order without having to obtain backup documentation and then scour that documentation to ascertain whether or not the prescription is necessary for the patient when the doctor has ordered such medication for the patient. This is unequal treatment and no rational basis exists for how Freedom and other DMEPOS providers are treated.

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Examples

Patient 3

The OIG draft report gives examples from two patients, one of whom is patient 3 from the sample. The draft report only addresses the issue of a medically unnecessary knee brace. It does not go into the issue of the denial of the right and left wrist orthotic braces which were ordered by the same physician on April 24, 2018. The right and left wrist orthotic braces were also denied on the basis that they were not medically necessary.

The draft report does give a fairly accurate Narrative Statement relating to the patients records. However, the reviewer fails to discuss the history indicating that the patient had numbness and pain in both hands up to mid forearm and showed diminished handgrip strength bilaterally in an April 2017 examination. Testing for neurologic issues was undertaken following that visit. However, the patient returned in July 2017 and again in November of 2017. The November 22, 2017 visit was primarily focused on bilateral wrist pain. Obviously, this pain was likely a continuation of the pain which was well-known to the physician from the April 2017 visit. Although the exam did not document the continued weakness in hand-strength in the November 2017 exam, it also did not note that the patient had recovered strength. Since the doctor was already aware of the decreased handgrip strength from the April 2017 visit, it would be presumed to still be weak. The physician then specifically stated that the plan was for the physician to order wrist brace under the "Bilateral wrist pain-Primary" heading for the Plan. This was accomplished 5 months later with the April 24, 2018 prescription filled by Freedom. However, the reviewer denied on the basis that the patient had no weakness (among other observations). This is inaccurate in that clearly the physician had documented that the patient did have weakness in both wrists and planned and specifically ordered a prescription for bilateral wrist braces. Further, the physician documented in the chart on November 22, 2017 the same bilateral wrist pain code on the physician order for the wrist braces in April of 2018. Although the physician may not have used all of the magic words that the reviewer wanted, it is clear that the physician felt there was a problem with the patient's wrists and wanted to try the braces for treatment to alleviate the pain or weakness. Thus, the reviewer's analysis is flawed and the prescription should not have been denied.

Patient 74

This patient was prescribed orthotic devices for both the left and right ankles. The reviewer determined that the documentation does not reveal objective evidence of right or left foot/ankle instability. However, there is no specified test for such instability in any LCD relied upon by the reviewer. Instead, the reviewer decides that the treating physician did not have a valid medical reason for prescribing braces for a patient weighing 358 pounds (up from 336 pounds 10 months earlier) who was described on the day of the prescription (August 10, 2018) as having a "limping gait, moderate tender bilateral knees, ankles, limited range of motion..." The patient also described localized bilateral ankle pain. The treating physician had a new diagnosis of unspecified sprain of both the left and right foot (not present at last visit). The treating physician stated that the plan was

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to provide patient with “Ankles brace with foot heel stabilizer”. The reviewer felt this description of medical necessity was insufficient for a non-physician DMEPOS to rely upon a physician order for the ankle braces. The DMEPOS provider must rely upon the physician to make a medical diagnosis and provide objective information that the provider believes justifies the need for the braces. The above seems to meet that requirement.

Response

Freedom disagrees with the entire review and findings of the OIG and intends on asserting its right to appeal such findings and requests for overpayment. As such Freedom disagrees with the alleged overpayment amount and believes that any extrapolation off of the claims reviewed is inaccurate and would be significantly and substantially modified after the review process. As stated above, it is incomprehensible that out of 100 different physicians who wrote prescriptions for their own patients that each and every one of them failed to provide adequate medical necessity in the records before ordering a medical device for their own patient. There is no relationship between Freedom and any of these physicians and no control that Freedom would have over any of these physicians as to how they document their medical records and/or how they prescribe care to their patients.

Freedom believes that it has obtained sufficient information from the beneficiary medical records to determine medical necessity as demonstrated by 100 different physicians providing documentation which they believe meets the standard of care for prescribing a medical device for their patient. If the reviewer or reviewers believe that there is a 100% failure rate then it seems unlikely that any orthotic brace that is prescribed by any doctor in the country will meet the standard of these reviewers.

As such, with regard to each recommendation of the OIG, Freedom disagrees with such recommendation and will assert its rights for an appeal because it disagrees with the application of the requirements as they have been applied by the OIG reviewers in this matter.

Thank you.

Sincerely,



Ken C. Stone

KCS/ld