

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**DESOTO HOME HEALTH CARE, INC.:
AUDIT OF MEDICARE PAYMENTS
FOR ORTHOTIC BRACES**

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



**Amy J. Frontz
Deputy Inspector General
for Audit Services**

**August 2020
A-09-19-03021**

Office of Inspector General

<https://oig.hhs.gov>

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These audits help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at <https://oig.hhs.gov>

Section 8M of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG website.

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

Report in Brief

Date: August 2020

Report No. A-09-19-03021

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 and evaluations 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 claims data, we selected for audit Desoto Home Health Care, Inc. (Desoto), an orthotic braces supplier in Wauchula, Florida.

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

How OIG Did This Audit

For our audit period, Desoto received approximately \$3.2 million in Medicare Part B payments for orthotic braces provided to 2,659 Medicare beneficiaries. After excluding certain claims, we grouped the remaining claims by beneficiary, selected a stratified random sample of 100 beneficiaries, and reviewed 183 claims associated with the sampled beneficiaries. We provided copies of Desoto's supporting documentation to an independent medical review contractor to determine whether the claims met Medicare requirements.

Desoto Home Health Care, Inc.: Audit of Medicare Payments for Orthotic Braces

What OIG Found

Desoto did not comply with Medicare requirements when billing for orthotic braces. For all 100 sampled beneficiaries, with payments totaling \$143,714, Desoto billed for orthotic braces that were not medically necessary.

These deficiencies occurred because Desoto 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 Desoto received at least \$2.8 million in unallowable Medicare payments for orthotic braces.

What OIG Recommends and Desoto Comments

We recommend that Desoto: (1) refund to the durable medical equipment Medicare administrative contractors \$2.8 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.

Desoto stated that our recommendation of a refund was not appropriate and that it may decide to appeal. Desoto did not address our other two recommendations. Desoto stated that our findings were not accurately reflective of the data gathered during the audit process. It also stated that the audit team preliminarily concluded that 38 sampled beneficiaries did have sufficient documentation to support medical necessity and stated that our independent medical review contractor later reversed these determinations. Desoto stated that it worked only with a beneficiary's primary care doctor and furnished products to the beneficiary under that doctor's medical supervision.

We maintain that our finding and recommendations remain valid. During the audit process, we obtained Desoto's documentation for the sampled beneficiaries. We did not make any preliminary conclusions but rather provided the documentation to an independent medical review contractor, which determined whether the orthotic braces were medically necessary. The contractor found that the information in the beneficiaries' medical records did not support medical necessity. In addition, OIG audit recommendations do not represent final determinations by the Medicare program.

TABLE OF CONTENTS

INTRODUCTION..... 1

 Why We Did This Audit..... 1

 Objective..... 1

 Background..... 1

 The Medicare Program..... 1

 Medicare Coverage of Orthotic Braces..... 1

 Medicare Requirements for Suppliers Billing for Orthotic Braces..... 2

 Medicare Requirements for Suppliers To Identify and Return Overpayments..... 3

 Desoto Home Health Care, Inc. 4

 How We Conducted This Audit..... 4

FINDING..... 5

 Medicare Requirements..... 5

 Desoto Billed for Orthotic Braces That Were Not Medically Necessary..... 6

 Cause and Effect of Improper Billing of Orthotic Braces..... 7

RECOMMENDATIONS..... 7

DESOTO COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE..... 8

 Findings for Sampled Beneficiaries..... 8

 Supporting Documentation From Beneficiaries’ Medical Records..... 9

 Appeals Process..... 10

APPENDICES

 A: Audit Scope and Methodology..... 11

 B: Statistical Sampling Methodology..... 13

 C: Sample Results and Estimates..... 15

 D: Related Office of Inspector General Reports..... 16

E: Medicare Requirements Related to Orthotic Braces.....	17
F: Desoto Comments.....	21

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, Desoto Home Health Care, Inc. (Desoto), an orthotic braces supplier in Wauchula, Florida.

OBJECTIVE

Our objective was to determine whether Desoto 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 The 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 and back braces.

Figure: Knee and Back 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 (the Manual), 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.

Desoto Home Health Care, Inc.

Desoto is a supplier in Wauchula, Florida. For our audit period, Desoto received approximately \$3.3 million in Medicare Part B payments.

Approximately 98 percent of the total Medicare Part B payments, or \$3,212,604, was for orthotic braces and related DMEPOS accessories provided to 2,659 Medicare beneficiaries in 39 States. Table 1 shows a breakdown of the payments.

**Table 1: Medicare Part B Payments to Desoto
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.)	\$2,200	\$7,224	\$5,163	\$14,587
2017	438,614	495,836	455,857	1,390,307
2018	642,163	465,468	700,079	1,807,710
Total	\$1,082,977†	\$968,528	\$1,161,099	\$3,212,604
Percentage of Total Payment	34%	30%	36%	100%
* Other braces consist of various shoulder and wrist braces.				
† Includes payments for related DMEPOS accessories (i.e., suspension sleeves for knee braces).				

HOW WE CONDUCTED THIS AUDIT

Desoto received Medicare Part B payments of \$3,212,604 for orthotic braces provided to 2,659 Medicare beneficiaries, representing 4,116 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 2,644 beneficiaries, representing 4,067 paid claims totaling \$3,175,278. We selected a stratified random sample of 100 beneficiaries and reviewed 183 claims, totaling \$143,714, that were associated with the sampled beneficiaries.

Desoto provided us with supporting documentation for the sampled beneficiaries. The documentation included physician orders, proof of delivery, and medical records that Desoto obtained from the treating physicians. We provided copies of the documentation to an

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.

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

Desoto did not comply with Medicare requirements when billing for orthotic braces. For all 100 sampled beneficiaries, with payments totaling \$143,714, Desoto billed for orthotic braces that were not medically necessary.

These deficiencies occurred because Desoto 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 Desoto received at least \$2.8 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 \$2,878,544.

DESOTO BILLED FOR ORTHOTIC BRACES THAT WERE NOT MEDICALLY NECESSARY

For all 100 sampled beneficiaries, Desoto 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, Shoulder, and Knee Braces for the Same Beneficiary

Medicare paid Desoto \$2,441 for providing a back brace on July 18, 2018, and a right shoulder brace and right knee brace with pad and sleeve on July 20, 2018, to a 61-year-old beneficiary. According to the physician's orders, the back brace was prescribed for low back pain on July 15, 2018, the shoulder brace was prescribed for arthritis on July 17, 2018, and the knee brace with pad and sleeve was prescribed for osteoarthritis on July 18, 2018. The beneficiary's medical records showed that there was one visit to the doctor on April 25, 2018. The visit documentation was focused on evaluation of an abnormal electrocardiogram and recurrent shortness of breath with exertion. There was no documentation regarding the back, shoulder, or knee.

Regarding the back, there was no documentation that the doctor had performed a spinal examination or that the beneficiary had complained of low back pain. The medical records did not document weak spinal muscles or a deformed spine. In addition, the medical records did not document any recent injury to or surgical procedure on the back.

Regarding the shoulder, there was no documentation that the doctor had performed a shoulder examination or that the beneficiary had arthritis in the shoulder or had complained of pain. The medical records did not show evidence of shoulder instability or abnormalities. The documentation did not support that the right shoulder brace was furnished to diagnose or treat the beneficiary's condition or to improve the function of a malformed body member. In addition, the medical records did not document any recent injury to or surgical procedure on the shoulder.

Regarding the knee, there was no documentation that the doctor had performed a knee examination or that the beneficiary had knee instability or joint laxity or osteoarthritis in the knee. There was also no documentation that the beneficiary had complained of knee pain. In addition, the beneficiary's ambulatory status was not clear in the medical records, and the medical records did not document any recent injury to or surgical procedure on the knee.

As a result, the independent medical review contractor found that the back, shoulder, and knee braces were not medically necessary.

Example of Medically Unnecessary Back Brace

Medicare paid Desoto \$929 for providing a back brace to a 65-year-old beneficiary on July 6, 2018. According to the physician's order, dated July 3, 2018, the back brace was prescribed for low back pain and degeneration of the spine.

The beneficiary's medical records dated June 4, 2018, stated that the beneficiary was seen to establish care and to refill medication. A general physical examination was negative for back pain, gait problems, and joint swelling. A neurological exam revealed normal strength and reflexes. The beneficiary did not complain of back pain, and the medical records did not document that there was a focused spinal examination. In addition, the medical records did not document any recent injury to or surgical procedure on the back. As a result, the independent medical review contractor found that the back brace was not medically necessary.

CAUSE AND EFFECT OF IMPROPER BILLING OF ORTHOTIC BRACES

Although Desoto 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. Instead, Desoto relied on the signed physician orders to certify medical necessity of the braces. 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 Desoto received at least \$2.8 million in unallowable Medicare payments for orthotic braces.

RECOMMENDATIONS

We recommend that Desoto Home Health Care, Inc.:

- refund to the DME MACs \$2,878,544 in estimated overpayments for orthotic braces;¹³

¹³ OIG audit recommendations do not represent final determinations by the Medicare program but are recommendations to Department of Health and Human Services action officials. CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures. Suppliers 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 supplier exercises its right to an appeal, the supplier 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.

- 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.

DESOTO COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Desoto stated that our recommendation of a refund was not appropriate and that it may decide to appeal. Desoto did not address our other two recommendations. A summary of Desoto’s comments and our responses follow. Desoto’s comments are included in their entirety as Appendix F.

After reviewing Desoto’s comments, we maintain that our finding and recommendations remain valid. The independent medical review contractor found that there was no information in the beneficiaries’ medical records (such as evidence of weakness or deformity of a body part) to support the medical necessity of the orthotic braces.

FINDINGS FOR SAMPLED BENEFICIARIES

Desoto Comments

Desoto stated that our findings were not accurately reflective of the data gathered during the audit process. Desoto stated that the audit team preliminarily concluded on a spreadsheet that 38 of the sampled beneficiaries audited did have sufficient documentation to support medical necessity and stated that these determinations were later reversed by “the independent audit review team” (i.e., our independent medical review contractor). Desoto also questioned the objectivity of the independent medical review contractor. Specifically, Desoto asked whether the contractor had “been audited for producing results that are not influenced by race, gender, sexual orientation or any other subjective factor that would taint the process thereby making it unfair and biased.”

Office of Inspector General Response

During the audit process, we obtained documentation from Desoto for the orthotic braces for the sampled beneficiaries, including detailed written orders from the treating physicians, medical information from the treating physicians concerning the beneficiaries’ diagnoses, proof

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.

of delivery of the orthotic braces to the beneficiaries, and billing information for the braces. We provided Desoto with a spreadsheet that summarized each of the documents received; however, we did not make any preliminary conclusions on the medical necessity of the orthotic braces. As we explained to Desoto throughout the audit process, we provided the documentation to an independent medical review contractor, which determined whether the orthotic braces were medically necessary. Two clinicians review all claims that need a medical necessity determination before giving them to OIG. Second-level reviews are conducted by the medical director or a physician with appropriate qualifications and experience. All reviewers are required to be free of any conflict of interest. Therefore, we maintain that our findings and recommendations are valid.

SUPPORTING DOCUMENTATION FROM BENEFICIARIES' MEDICAL RECORDS

Desoto Comments

Desoto stated that it provided documentation from beneficiaries' records or that was received from beneficiaries' primary care doctors. Desoto said that it worked only with a beneficiary's primary care doctor and made it mandatory that the doctor sign two attestation statements declaring the beneficiary's medical need for the product as well as the availability of supporting documentation in the beneficiary's medical history. Desoto stated that, therefore, the company furnished the products under the medical supervision of the beneficiary's primary care doctor and that it "produced 100 out of 100 prescriptions requested in the audit sample." Desoto also stated it was able to "secure 91 out of 100 detailed medical history notes." In addition, Desoto stated that it "produced 100 out of 100 official proof of delivery documents."

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.

APPEALS PROCESS

Desoto Comments

Desoto stated that it may decide to have this audit reviewed by the second-level appeal process and requested a timeline for the appeal process.

Office of Inspector General Response

As pointed out in our report, OIG audit recommendations do not represent final determinations by Medicare but are recommendations to Department of Health and Human Services action officials. CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures. Suppliers 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 supplier exercises its right to an appeal, the supplier 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.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Desoto received Medicare Part B payments of \$3,212,604 for orthotic braces provided to 2,659 Medicare beneficiaries, representing 4,116 paid claims with dates of service from July 1, 2016, through December 31, 2018. We excluded from our audit 49 claims, totaling \$37,326, that had been reviewed by either the RACs or other review entities.¹⁵ We then grouped the remaining claims by beneficiary and created a sampling frame of 2,644 beneficiaries, representing 4,067 claims totaling \$3,175,278. We selected a stratified random sample of 100 beneficiaries and reviewed 183 claims, totaling \$143,714, that were associated with the sampled beneficiaries.

Desoto provided us with supporting documentation for the sampled beneficiaries. The documentation included physician orders, proof of delivery, and medical records that Desoto 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 Desoto'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 April 2020, which included fieldwork performed at Desoto's offices in Wauchula, Florida.

METHODOLOGY

To accomplish our objective, we:

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

¹⁵ 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 Desoto billed to Medicare for our audit period;¹⁶
- created a sampling frame of 2,644 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 Desoto 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 Desoto (Appendix C); and
- discussed the results of our audit with Desoto 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.

¹⁶ 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 claims data for Desoto that included at least 1 of the HCPCS codes for orthotic braces and had service dates during our audit period, representing 4,116 paid claims totaling \$3,212,604. We removed 49 claims, totaling \$37,326, that had been reviewed by either the RACs or other review entities. We then grouped the remaining claims by beneficiary. As a result, the sampling frame consisted of 2,644 beneficiaries, representing 4,067 paid claims totaling \$3,175,278.

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	990	2,413	\$1,899,749
2	Beneficiaries with one Medicare claim	1,654	1,654	1,275,529
Total		2,644	4,067	\$3,175,278

SAMPLE SIZE

We selected a total of 100 beneficiaries, consisting of 60 beneficiaries from stratum 1 and 40 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 60 random numbers for stratum 1 and 40 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	990	\$1,899,749	60	\$115,536	60	\$115,536
2	1,654	1,275,529	40	28,178	40	28,178
Total	2,644	\$3,175,278	100	\$143,714	100	\$143,714

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

Point estimate	\$3,071,507
Lower limit	2,878,544
Upper limit ¹⁷	3,175,278

¹⁷ The upper limit, calculated using the OIG/OAS statistical software, for the total overpayment amount was \$3,264,471. 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>Freedom Orthotics, Inc.: Audit of Medicare Payments for Orthotic Braces</i>	<u>A-09-19-03012</u>	7/6/2020
<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 and back braces. (These braces are referred to in the LCDs as “orthoses.”)

Knee Braces

A knee orthosis with joints (L1810 . . .) . . . [is] covered for ambulatory beneficiaries who have a weakness or deformity of the knee and require stabilization, 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 (L1845, L1851), are covered if the beneficiary (1) has had recent injury to or a surgical procedure on the knee(s). . . . Knee orthoses L1832, L1833, L1845, and L1851 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)*].

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 GUIDANCE¹⁸

Medicare Program Integrity Manual

The Manual¹⁹ (chapter 3, §§ 3.3.3 and 3.6.2.2) outlines the 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 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:

¹⁸ All Manual provisions were used strictly as guidance. We did not have any findings based on the guidance found within the Manual.

¹⁹ 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.

- 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 the 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))²⁰ 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.

²⁰ 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: DESOTO COMMENTS

Re: Desoto Home Health Care Audit Response
Report Number A-09-19-03021

To: Office of Audit Services, Region IX,
90-7th Street Suite 3-650
San Francisco, CA 94103

The OIG Audit report findings are not accurately reflective of the data gathered during the audit process. Documented on a spreadsheet of the interpretation of each of the medical history notes it was preliminarily concluded by the audit team that 38 of the 100 patients audited did have sufficient documentation to support the medical necessity. These 38 patients were flagged green to indicate sufficient detail existed in the medical history.

The final report from May 8, 2020 states that all 38 of these patient's preliminary conclusions were overturned by the independent audit review team. Furthermore, the report places 100% of the emphasis on the historical medical documentation. DHHC was able to secure medical history documents on 94 out of 100 patients and again from their primary care doctor. The Audit report omits the many relevant steps that DHHC took to ensure that medical necessity requirements were maintained and by doing this the report takes on a subjective and biased tone.

DHHC took pride and confidence in the fact that they only worked with the patient's primary care doctor and made it mandatory that the doctor sign 2 attestation statements declaring that he/she their patient's medical need for the product as well as availability of supporting documentation in the patient's medical history. Therefore, the company furnished the products under the medical supervision of the PCP of the patient which should, at minimum, be included in the report and sincerely should be a major contributing factor in this audit.

Desoto Home Health Care provided the following documentation from our patient records or were received from the patient's primary care doctor:

1. DHHC, Inc. shipped all product to the patient's home address via **FedEX with signature required**. DHHC produced 100 out of 100 official **proof of delivery** documents which show patient's home as the destination along with patient's signature confirming delivery.
2. DHHC, Inc. worked with the patient's primary care doctor only to obtain physician consent via a signed Rx and the company was produced 100 out of 100 prescriptions requested in the audit sample. There are 2 attestation statements on the prescription for which the signing physician is certifying.
 - a. Attestation statement #1 is located before the doctor signature box and outlines the basic medical necessity requirements for the specific orthotic device being authorized by the clinician.
 - i. An example of the exact wording is below for the lumbar sacral orthoses; **"I attest that my patient requires the device listed above for one or more of the following medical necessity reasons."**
 - ✓ **To Help facilitate healing after a recent injury**
 - ✓ **Surgical procedure to the knee**
 - ✓ **To improve instability and laxity of a joint (i.e.,varus/valgus instability, anterior/posterior drawer test)**
 - b. Attestation statement #2 is placed directly above the signature provided by the patient's doctor. This statement of attestation reads; **"My Signature certifies that the prescribed product is medically necessary and that the medical records reflect this need."**
 - i. The authorizing physician for the patient signed the Rx declaring the following
 1. Certifying that the product is medically necessary
 2. Certifying that he/she has medical records that reflect this need
3. DHHC obtained signed prescriptions with medical necessity attestation on board from the patient's primary care physician. The company was able to secure 91 out of 100 detailed medical history notes, therefore, DHHC maintains that the medical necessity requirements were available upon request, which is similar how hospitals and other institutional care providers use attestations. **The company furnished the products to the patients**

based on the patient's physician attestation and signature. DHHC, would not and did not ever furnish a device without a signed RX from the patient's PCP or patient signature proof of delivery with the shipper.

In summary, DHHC, Inc maintains that the recommendations made by the Audit team to refund nearly \$3 million dollars is not appropriate and not a fair recommendation based on the objective findings. Therefore, the company is asking for consideration as described in the list below:

DHHC is asking for the following:

- 1) The report should include the process described above to be more objective. The report is written in a biased manner by omitting salient facts that reveal the company making efforts to operate in good faith. Several segments of the report are written in an inflammatory manner, which is made evident by the word choices and omission of detail in favor of the DHHC.
- 2) A copy of the rationale for overturning the preliminary findings on 38 patients who were determined to have met the medical necessity requirements. Why were these reviewed and approved and later reversed by the independent audit team? What is the name of the independent audit team and has this company been audited for producing results that are not influenced by race, gender, sexual orientation or any other subjective factor that would taint the process thereby making it unfair and biased?
- 3) DHHC may decide to have this reviewed by 2nd Level Appeal process. Please provide timeline info for this in writing.

Written by
Former Owner of Desoto Home Health Care Inc