

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**CGS ADMINISTRATORS, LLC
MADE MEDICARE PART B
PAYMENTS FOR THERAPEUTIC
SHOES FURNISHED TO
BENEFICIARIES IN PUERTO RICO
THAT GENERALLY DID NOT
COMPLY WITH FEDERAL
REQUIREMENTS**

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



**James P. Edert
Regional Inspector General**

**June 2013
A-02-11-01001**

Office of Inspector General

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EXECUTIVE SUMMARY

CGS Administrators, LLC made payments for therapeutic shoes furnished to Medicare beneficiaries in Puerto Rico that generally did not comply with Federal requirements.

WHY WE DID THIS REVIEW

Medicare Part B covers durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), including therapeutic shoes for individuals with diabetes. CGS Administrators, LLC (CGS) contracts with the Centers for Medicare & Medicaid Services (CMS) to process and pay Medicare Part B claims for DMEPOS including therapeutic shoes and inserts (therapeutic shoes).

This review was performed as a result of Medicare program integrity efforts that identified suppliers who were improperly billing for therapeutic shoes furnished to beneficiaries (beneficiaries) in Puerto Rico. In addition, a prior Office of Inspector General review of DMEPOS claims determined that suppliers did not always have required documentation on file.

Our objective was to determine whether Medicare Part B claims processed and paid by CGS for therapeutic shoes furnished to beneficiaries complied with Federal requirements.

BACKGROUND

Medicare Part B provides for the coverage of DMEPOS. CMS, which administers the Medicare program, contracts with durable medical equipment Medicare administrative contractors (DME MAC) to, among other things, process and pay claims for therapeutic shoes. CGS is the DME MAC for the Commonwealth of Puerto Rico.

A physician who is treating a beneficiary's systemic diabetic condition must certify the need for therapeutic shoes to treat qualifying foot conditions and the shoes must be ordered by a podiatrist or other qualified physician. In addition, therapeutic shoe suppliers must add a KX modifier to the claims attesting that required documentation, including the signed and dated physician's order and proof of delivery, is on file. Claims submitted without the KX modifier will be denied for payment.

HOW WE CONDUCTED THIS REVIEW

During the period January 1, 2009, through June 30, 2010, CGS processed approximately \$1.5 million in Part B claims for therapeutic shoes supplied to 6,269 beneficiaries. We selected a stratified random sample of 100 beneficiaries and for each sampled beneficiary we obtained and reviewed the supporting documentation maintained by the therapeutic shoe supplier.

WHAT WE FOUND

Most Medicare Part B claims processed and paid by CGS for therapeutic shoes furnished to beneficiaries did not comply with Federal requirements. For the 100 sampled beneficiaries in our stratified random sample, CGS correctly processed and paid claims for therapeutic shoes for 38 of the sampled beneficiaries. However, for the remaining 62 sampled beneficiaries, CGS processed and paid claims for therapeutic shoes totaling \$13,906 in unallowable payments to suppliers that did not comply with Federal requirements. Specifically:

- For 43 sampled beneficiaries, physician's orders were missing or incomplete.
- For 37 sampled beneficiaries, the physician's certification for therapeutic shoes was missing or incomplete.
- For two sampled beneficiaries, the supplier did not maintain proof of delivery documentation.

The total exceeds 62 because we found more than 1 deficiency for 19 sampled beneficiaries.

On the basis of our sample results, we estimated that CGS paid \$781,751 in unallowable Medicare payments for therapeutic shoes furnished to beneficiaries during our January 1, 2009, through June 30, 2010 audit period.

Suppliers included in our sample attributed the unallowable payments to clerical errors and a lack of knowledge of applicable Medicare requirements. Moreover, CGS did not review these claims to determine if they were allowable. Rather, CGS relied on training and guidance provided to suppliers and the required the usage of the KX modifier to ensure claims complied with Federal requirements.

WHAT WE RECOMMEND

We recommend that CGS:

- recover the \$13,906 in identified overpayments;
- determine the additional amount of unallowable payments in the population, estimated to be \$767,845 (\$781,751 less \$13,906); and
- use the results of this audit in its supplier education activities.

CGS COMMENTS

In written comments on our draft report, CGS concurred with our first and third recommendations. Regarding our second recommendation, CGS stated that it would consider conducting a statistical review of claims for therapeutic shoes. CGS also stated that it was aware of vulnerabilities associated with claims for therapeutic shoes and described corrective actions that it has taken to address those vulnerabilities.

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INTRODUCTION

WHY WE DID THIS REVIEW

Medicare Part B covers durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), including therapeutic shoes for individuals with diabetes. CGS Administrators, LLC (CGS) contracts with the Centers for Medicare & Medicaid Services (CMS) to process and pay Medicare Part B claims for DMEPOS including therapeutic shoes and inserts (therapeutic shoes).¹

This review was performed as a result of Medicare program integrity efforts that identified suppliers who were improperly billing for therapeutic shoes furnished to beneficiaries (beneficiaries) in Puerto Rico. In addition, a prior Office of Inspector General review of DMEPOS claims determined that suppliers did not always have required documentation on file.²

OBJECTIVE

Our objective was to determine whether Medicare Part B claims processed and paid by CGS for therapeutic shoes furnished to beneficiaries complied with Federal requirements.

BACKGROUND

Medicare Program

Pursuant to Title XVIII of the Social Security Act (the Act), the Medicare program provides health insurance for people aged 65 and over and those who are disabled or have permanent kidney disease. CMS administers the Medicare program.

Medicare Part B Coverage of Therapeutic Shoes

Medicare Part B covers DMEPOS including therapeutic shoes for individuals with diabetes (sections 1832(a)(1) and 1861(n) of the Act). These shoes are designed to reduce the risk of skin breakdown for individuals with poor circulation which can result in calluses, ulcers, or amputation.

A physician who is treating a beneficiary's systemic diabetic condition must certify the need for therapeutic shoes to treat qualifying foot conditions.³ In addition, the shoes must be ordered by a

¹ CGS processes and pays DMEPOS claims for Puerto Rico, Alabama, Arkansas, Colorado, Florida, Georgia, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, U.S. Virgin Islands, Virginia, and West Virginia.

² *Review of Jurisdiction C Medicare Payments for Selected Durable Medical Equipment Claims With the KX Modifier for Calendar Year 2007* (A-04-09-04039, issued June 16, 2010).

³ Section 1861(s)(12) of the Act. Qualifying foot conditions include poor circulation, history of pre-ulcerative calluses, peripheral neuropathy with evidence of callus formation, history of ulceration, foot deformity, and previous amputation or partial amputation.

podiatrist or other qualified physician. The Local Coverage Determination (LCD) requires therapeutic shoe suppliers to add a KX modifier to the claims attesting that required documentation, including the signed and dated physician's order and proof of delivery documentation, is on file.⁴ Claims submitted without the KX modifier will be denied for payment.

CGS Administrators, LLC

CMS contracts with durable medical equipment Medicare administrative contractors (DME MAC) to, among other things, process and pay DMEPOS claims. CGS is the DME MAC for the Commonwealth of Puerto Rico. During the period January 1, 2009, through June 30, 2010, CGS processed and paid approximately \$1.5 million in Part B claims for therapeutic shoes furnished to beneficiaries.

HOW WE CONDUCTED THIS REVIEW

We selected a stratified random sample of 100 beneficiaries. For each sampled beneficiary, we obtained and reviewed the supporting documentation maintained by the therapeutic shoe supplier.

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

Appendix A contains the details of our audit scope and methodology, Appendix B contains details of our statistical sampling methodology, and Appendix C contains our sample results and estimates.

FINDINGS

Most Medicare Part B claims processed and paid by CGS for therapeutic shoes furnished to beneficiaries did not comply with Federal requirements. For the 100 sampled beneficiaries in our stratified random sample, CGS correctly processed and paid claims for therapeutic shoes for 38 of the sampled beneficiaries. However, for the remaining 62 sampled beneficiaries, CGS processed and paid claims for therapeutic shoes totaling \$13,906 in unallowable payments to suppliers that did not comply with Federal requirements. Specifically:

- For 43 sampled beneficiaries, physician's orders were missing or incomplete.
- For 37 sampled beneficiaries, the physician's certification for therapeutic shoes was missing or incomplete.

⁴ LCD L11525. An LCD is a decision by a Medicare administrative contractor to cover a particular item or service. LCDs must be consistent with all statutes; rulings; regulations; and national coverage, payment, and coding policies.

- For two sampled beneficiaries, the supplier did not maintain proof of delivery documentation.

The total exceeds 62 because we found more than 1 deficiency for 19 sampled beneficiaries.

On the basis of our sample results, we estimated that CGS paid \$781,751 in unallowable Medicare payments for therapeutic shoes furnished to beneficiaries during our January 1, 2009, through June 30, 2010 audit period.

Suppliers included in our sample attributed the unallowable payments to clerical errors and a lack of knowledge of applicable Medicare requirements. Moreover, CGS did not review these claims to determine if they were allowable. Rather, CGS relied on training and guidance provided to suppliers and the required the usage of the KX modifier to ensure claims complied with Federal requirements.

PHYSICIAN'S ORDER MISSING OR INCOMPLETE

The particular type of therapeutic shoes are prescribed by a podiatrist or other qualified physician (section 1861(s)(12)(B) of the Act). In addition, the physician's order must be signed and dated, kept on file by the supplier, and made available upon request (LCD L11525).

For 43 of the 100 sampled beneficiaries, suppliers submitted claims that were not supported by a physician's order. For 32 of these beneficiaries, suppliers had a physician's order on file but the order did not include required elements. Specifically, the physician's order either was not signed and dated or did not include a description of the item. For the remaining 11 beneficiaries, suppliers did not have a physician's order on file.

PHYSICIAN'S CERTIFICATION MISSING OR INCOMPLETE

A physician who is treating a Medicare beneficiary's diabetic condition must, among other things, certify under a comprehensive plan of care the beneficiary's need for therapeutic shoes to treat qualifying foot conditions (section 1861(s)(12)(A) of the Act). The supplier must obtain a completed, signed, and dated certification from the physician (LCD L11525).

For 37 of the 100 sampled beneficiaries, suppliers submitted claims that were not supported by a statement from the beneficiary's physician certifying the need for the therapeutic shoes. For 19 of these beneficiaries, suppliers had the physician's certification statement on file. However, the certification statement was either not signed and dated by the physician or did not include a description of the qualifying foot conditions being treated. For the remaining 18 beneficiaries, suppliers did not have a physician's certification statement on file.

NO PROOF OF DELIVERY

Suppliers are responsible for delivering Medicare-covered items to beneficiaries and maintaining proof of delivery documentation for 7 years.⁵

⁵ 42 CFR § 424.57(c)(12); chapter 4, section 4.26 of CMS's *Medicare Program Integrity Manual*, Pub. No. 100-08.

For 2 of the 100 sampled beneficiaries, the supplier did not maintain proof of delivery documentation to support billing for the therapeutic shoes.

RECOMMENDATIONS

We recommend that CGS:

- recover the \$13,906 in identified overpayments;
- determine the additional amount of unallowable payments in the population, estimated to be \$767,845 (\$781,751 less \$13,906); and
- use the results of this audit in its supplier education activities.

CGS COMMENTS

In written comments on our draft report, CGS concurred with our first and third recommendations. Regarding our second recommendation, CGS stated that it would consider conducting a statistical review of claims for therapeutic shoes. CGS also stated that it was aware of vulnerabilities associated with claims for therapeutic shoes and described corrective actions that it has taken to address those vulnerabilities. CGS's comments are included in their entirety as Appendix E.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our review covered 7,321 Medicare Part B claims, totaling \$1,516,309, which were processed and paid by CGS for therapeutic shoes furnished to 6,269 beneficiaries during the period January 1, 2009, through June 30, 2010.

We did not assess the overall internal control structure of CGS. Rather, we reviewed only the internal controls that pertained directly to our objective. Our review allowed us to establish reasonable assurance of the authenticity and accuracy of the data obtained from the National Claims History file for our audit period, but we did not assess the completeness of the file.

We conducted fieldwork at 52 therapeutic shoe suppliers located in Puerto Rico and 4 suppliers located in Florida.⁶ In addition, we contacted CGS officials in Nashville, Tennessee.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations and other guidance;
- interviewed CGS officials to obtain an understanding of CGS's procedures for processing Medicare therapeutic shoe claims;
- extracted from the CMS National Claims History file a sampling frame of 6,269 beneficiaries with therapeutic shoe claims that were processed and paid by CGS during the period January 1, 2009, through June 30, 2010;
- selected a stratified random sample of 100 beneficiaries from the sampling frame of 6,269 beneficiaries, and for each of the 100 sampled beneficiaries, we:
 - interviewed supplier officials to gain an understanding of their policies and procedures for submitting claims for therapeutic shoes to CGS and
 - reviewed corresponding claims documentation maintained by the supplier; and
- discussed the results of our review with CGS officials.

See Appendix B for the details of our statistical sampling methodology and Appendix C for our sample results and estimates.

⁶ For 11 sampled beneficiaries, the therapeutic shoes were furnished in Puerto Rico by suppliers with main offices located in Florida.

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

APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

POPULATION

The population consisted of beneficiaries for whom therapeutic shoe suppliers were paid by CGS during our January 1, 2009, through June 30, 2010 audit period.

SAMPLING FRAME

The sampling frame consisted of 6,269 Medicare beneficiaries for whom therapeutic shoe suppliers were paid by CGS, totaling \$1,516,309. The Medicare Part B claims were extracted from the CMS National Claims History file.

SAMPLE UNIT

The sample unit was a Medicare beneficiary for whom a therapeutic shoe supplier was paid by CGS. (One Medicare beneficiary may have had multiple therapeutic shoes claimed for reimbursement.)

SAMPLE DESIGN

We used a stratified random sample.

SAMPLE SIZE

We selected a sample of 100 Medicare beneficiaries as follows:

- Stratum 1: 60 beneficiaries with 1 claim for therapeutic shoes.
- Stratum 2: 40 beneficiaries with 2 claims for therapeutic shoes.

SOURCE OF RANDOM NUMBERS

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

METHOD OF SELECTING SAMPLE UNITS

We consecutively numbered the 6,269 Medicare beneficiaries. After generating 100 random numbers, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to calculate our estimates. We used the point estimate of the 90-percent confidence level to estimate the overpayment associated with the unallowable claims.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Sample Details and Results

Stratum	Frame Size	Value of Frame	Sample Size	Value of Sample	Number of Beneficiaries With Errors	Overpayments
1	5,316	\$1,169,091	60	\$13,397	35	\$ 6,954
2	953	\$ 347,218	40	\$13,418	27	\$ 6,952
Total	6,269	\$1,516,309	100	\$26,815	62	\$13,906

Estimated Unallowable Payments (Limits Calculated for the 90-Percent Confidence Interval)

Point Estimate	\$781,751
Lower Limit	\$654,792
Upper Limit	\$908,711

APPENDIX D: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets-Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction C</i>	<u>A-09-08-00045</u>	01/21/11
<i>Review of Medicare Claims for Home Blood-Glucose Test Strips and Lancets-Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction D</i>	<u>A-09-08-00046</u>	02/04/11
<i>Questionable Billing by Suppliers of Lower Limb Prostheses</i>	<u>OEI-02-10-00170</u>	08/17/11
<i>Claim Modifier Did Not Prevent Medicare From Paying Millions in Unallowable Claims for Selected Durable Medical Equipment</i>	<u>A-04-10-04004</u>	04/05/12

APPENDIX E: CGS COMMENTS

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May 3, 2013

James P. Edert
Regional Inspector General for Audit Services
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RE: CGS Response to draft OIG Report entitled *CGS Administrators, LLC Made Medicare Part B Payments for Therapeutic Shoes Furnished to Beneficiaries in Puerto Rico that Generally Did Not Comply with Federal Requirements (A-02-11-01001)*

Dear Mr. Edert,

CGS Administrators, LLC, the Durable Medical Equipment Medicare Administrative Contractor for Jurisdiction C, appreciates the opportunity to comment on the Office of Inspector General's draft report entitled *CGS Administrators, LLC Made Medicare Part B Payments for Therapeutic Shoes Furnished to Beneficiaries in Puerto Rico that Generally Did Not Comply with Federal Requirements*. In addition to requesting comments on the report, you ask that CGS state concurrent or nonconcurrency with each of the three recommendations in the report.

The OIG makes three (3) recommendations in its report. Those recommendations are:

1. Recover the overpayment identified in the report as \$13,906.00.
2. Determine the additional amount of unallowable payments in the population, estimated to be \$767,845.00.
3. Use the results of this audit in its supplier educational activities.

CGS concurs with two of the three recommendations in the report. CGS will recoup the overpayment identified and will use the information from the audit in its supplier educational activities. For Recommendation 2 CGS will consider, based on data analysis, the inclusion of the option to conduct a Statistical Sampling with Overpayment Estimation (SSOE) for the Therapeutic Shoes policy group in its next Medical Review Strategy.

CGS Administrators, LLC has for several years included in its annual Medical Review Strategy the policy group and specific codes from the Therapeutic Shoes for Persons with Diabetes (TSD) Local Coverage Determination. In addition, CGS has engaged in numerous additional

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DME Medicare Administrative Contractor for the Centers for Medicare & Medicaid Services



activities to educate suppliers specifically about TSD and more generally about the use of the KX modifier. Our comments on the report, detailed below, highlight those activities.

Comments

1. CGS notes in the “Background” section of A-02-11-01001 that the report states that suppliers are required to keep specific documentation on file. This is not correct. It must only be available upon request. In the Documentation Section, the TSD LCD states:

KX AND GY MODIFIERS:

Suppliers must add a KX modifier to codes for shoes, inserts, and modification only if criteria 1-5 in the Non-Medical Necessity Coverage and Payment Rules section of the related Policy Article have been met. This documentation must be available upon request. The Statement of Certifying Physician form is not sufficient to meet this requirement.

This is a critical point to note and one that is often misunderstood by auditing entities. The definition of the KX modifier is unique to each LCD. For example, use of the KX modifier in the context of diabetic testing strip claims indicates that the beneficiary is using insulin. To emphasize this important distinction to the supplier community, CGS routinely conducts both in-person seminars and online education in the form of webinars for Medicare documentation and the use of the KX modifier (see below). In addition, CGS created an educational video on the KX modifier featuring the Jurisdiction C Medical Director. The video illustrates how the KX modifier definition varies between LCDs and the importance of using this modifier correctly. The website page evidencing the webinar is enclosed as **Exhibit A**.

2. CMS requires contractors to prioritize actions and workload and justify those decisions in an annual Medical Review Strategy.¹ CGS conducts ongoing surveillance of claims data and routinely monitors the types of errors associated with Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) claims. One metric used to prioritize actions is how much the Medicare program disburses to suppliers for DMEPOS items. In 2012, the Medicare program had \$108M in allowed charges for the Therapeutic shoes policy group in Jurisdiction C, ranking #15 of all DMEPOS policy groups. For comparison, oxygen allowed charges in 2012 totaled \$806M and glucose

¹ *Program Integrity Manual* (Internet-Only Manual, Publ. 100-8, Chapter 3, Section 3.2.1 - Setting Priorities and Targeting Reviews).

monitor testing supplies totaled \$652M.² These are the top 2 policy groups in allowed charges for the benefits administered by the DME MACs and the two policy groups with the highest Comprehensive Error Rate Testing (CERT) program errors. Consequently, CGS prioritizes the TSD policy group at a level commensurate with the policy group's positioning and error profile within the entire DMEPOS benefits administered by CGS.

3. For the specific issues identified in A-02-11-01001 (i.e., no order on file, no proof of delivery, no physician certification), there is no automated ability for contractors to adjudicate claims based on the presence (or lack of) this information. Examination of supporting claim documentation through prepayment review is the only method for preventing these types of claim errors. CGS is not funded to conduct 100% prepayment review of therapeutic shoe claims; consequently, CGS is unable to eliminate entirely the types of claim errors noted in the OIG report.

In order to improve the effectiveness of the KX modifier through additional claim review, CGS provided CMS with a Rough Order of Magnitude (ROM) proposal in 2010. In the proposal, CGS suggested implementing prepayment documentation edits for four policy groups based on prior OIG reports noting high error rates for the DMEPOS items. CMS elected to reject the ROM proposal; however, additional funding for partial implementation of the prepayment activities was approved at a later date (see below).

4. CGS does recognize that therapeutic shoes have a history of improper payments and, as noted above, has included the TSD policy group in multiple MR Strategies over the past decade. As a result of this knowledge and expertise, CGS included this policy group in its proposal for DMEPOS items to target with the additional funds provided by CMS noted in #3 above. In 2012 CMS provided CGS with additional Medical Review funding. As part of that funding increase, CGS added resources to increase therapeutic shoe claim editing. This edit continues today. Results of this edit to date in 2013 (First Quarter 2013):

Diabetic Shoes	JAN-13	FEB-13	MAR-13
# Claims Reviewed	175	233	185
# Claims Denied	131	197	156
Denial %	75%	85%	84%

So far in 2013, these edits have resulted in \$158,373.83 in denied claims.

5. Finally, CGS has conducted extensive education regarding the TSD policy and use of the KX modifier. The following information reflects CGS' educational outreach specifically

² Both Oxygen Equipment and Glucose Monitor Supplies have been the topic of numerous OIG reports.

related to Therapeutic Shoes coverage, coding and documentation requirements (including the KX modifier) in Puerto Rico and Miami, FL. Miami is included in these numbers because of the frequent travel of suppliers between Miami and Puerto Rico:

<u>Web-based Education:</u>	2011 – 11 (2 Spanish)
2013 – 2 (1 Spanish) to date	2010 – 14 (1 Spanish)
2012 – 12 (2 Spanish)	2009 – 7

<u>In-Person Seminars:</u>	2011 – Puerto Rico (May/Sept)
2012 – Miami (April)	2010 – Miami (February)
2012 – Puerto Rico (June/Sept/Nov)	2010 – Puerto Rico (August)
2011 – Miami (April/Oct)	

In summary, CGS Administrators, LLC is fully aware of the vulnerabilities outlined in draft report A-02-11-01001 and, as demonstrated above, has taken aggressive and extensive steps to address those vulnerabilities. Should you have any additional questions, please feel to contact Larry Kennedy at 615.782.4607 or Larry.Kennedy@cgsadmin.com.

Sincerely,



John F. Kimball