

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**LOWER LIMB PROSTHETICS CLAIMS
PAID TO PREMIER PROSTHETICS
AND ORTHOTICS WERE NOT ALWAYS
SUPPORTED BY ADEQUATE
DOCUMENTATION**

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



Patrick J. Cogley
Regional Inspector General

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A-07-12-05026

Office of Inspector General

<https://oig.hhs.gov/>

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EXECUTIVE SUMMARY

BACKGROUND

Pursuant to sections 1832(a)(1), 1861(s)(6), (s)(8), and (s)(9), and 1861(n) of the Social Security Act, Medicare Part B provides for the coverage of durable medical equipment (DME), prosthetics, orthotics, and supplies (DMEPOS). The Centers for Medicare & Medicaid Services (CMS) contracts with four DME Medicare administrative contractors (DME MAC) to process and pay Medicare Part B claims.

When submitting claims to DME MACs, suppliers use Healthcare Common Procedure Coding System (HCPCS) codes as well as modifiers that indicate left or right limb and a functional level. Each claim can include multiple HCPCS codes, each of which represents a different component of the lower limb prosthetic provided by the supplier. A lower limb prosthetic is an artificial replacement for any or all parts of the leg and provides an individual who has an amputated limb with the opportunity to perform functional tasks, particularly walking, which may not be possible without the device.

DME MACs develop local coverage determinations (LCD) for some covered DMEPOS items. LCDs describe the circumstances for Medicare coverage for lower limb prosthetics and outline the conditions under which DME MACs will cover those devices. LCDs require that some lower limb prosthetics have minimum functional levels to be covered by Medicare.

To be paid for a Medicare DMEPOS claim, the supplier must have on file: (1) written documentation of a verbal order/preliminary written order, (2) a detailed written order, (3) proof of delivery, (4) a beneficiary authorization, (5) information from the treating physician concerning the patient's diagnosis, and (6) any information required for the use of specific modifiers or attestation statements as defined in certain DME policies.

A DMEPOS supplier should also obtain as much documentation from the patient's medical record as it requires to ensure that the coverage criterion for an item has been met. If the information in the patient's medical record does not adequately support the medical necessity for the item, the supplier is liable for the dollar amount involved.

This review was completed as followup work to the Office of Inspector General, Office of Evaluation and Inspections, review, *Questionable Billing by Suppliers of Lower Limb Prostheses*, issued in August 2011.

Premier Prosthetics and Orthotics (Premier), based in Creve Coeur, Missouri, supplies lower limb prosthetics.

OBJECTIVE

Our objective was to determine whether Premier's paid claims for lower limb prosthetics were supported in accordance with Medicare DMEPOS documentation requirements.

SUMMARY OF FINDINGS

Premier's paid claims for lower limb prosthetics were not always supported in accordance with Medicare DMEPOS documentation requirements. Of the 100 sampled claims totaling \$864,139 in payments, 57 claims were supported in accordance with Medicare DMEPOS documentation requirements. However, the remaining 43 claims were either not supported or were only partially supported in accordance with Medicare DMEPOS documentation requirements. Specifically, we identified the following deficiencies (two claims had more than one error):

- For 35 claims, Premier did not have documentation from the patients' medical records supporting the medical necessity of the items for which it had submitted the claims.
- For one claim, Premier did not obtain a verbal or preliminary written order from a physician before delivering the item and submitting the claim.
- For four claims, Premier did not obtain properly completed written orders from physicians before submitting the claims.
- For three claims, Premier did not have documentation showing that it obtained authorization from the beneficiaries before submitting the claims.
- For two claims, Premier's documentation did not support the minimum functional level, as required by the LCD, of the prosthetics for which it had submitted claims.

Premier submitted unsupported claims because it lacked adequate internal controls to ensure that it collected and maintained the required documentation. As a result of these errors, Premier received payments totaling \$115,558 for the 43 sampled claims that were not supported in accordance with Medicare DMEPOS documentation requirements.

Based on the results of our sample, we estimated that unsupported claims for lower limb prosthetics paid to Premier resulted in overpayments totaling \$284,023 during the period January 1, 2010, through December 31, 2011.

RECOMMENDATIONS

We recommend that Premier:

- refund \$284,023 to the Federal Government for unallowable lower limb prosthetic claims and
- strengthen internal controls by developing and implementing policies and procedures to help ensure that it collects and maintains the required documentation.

AUDITEE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Premier agreed that the claims we had identified as findings had documentation deficiencies, but did not agree that the deficiencies reached a level that would require Premier to refund the \$284,023 to the Federal Government for unallowable claims. Regarding our second recommendation, Premier said that it had instituted internal controls and process improvements.

After reviewing Premier's comments, we note that the provisions of CMS's *Medicare Program Integrity Manual*, the *Jurisdiction D Durable Medical Equipment Supplier Manual*, and the LCD for lower limb prosthetics are very specific as to the requirements that must be met for these types of claims to be allowable, and we therefore maintain that the recommendation to refund the unallowable claims remains valid.

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INTRODUCTION

BACKGROUND

Medicare Coverage of Durable Medical Equipment

Pursuant to Title XVIII of the Social Security Act (the Act), the Medicare program provides health insurance for people aged 65 and over, people with disabilities, and people with permanent kidney disease. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program.

Pursuant to sections 1832(a)(1), 1861(s)(6), (s)(8), and (s)(9), and 1861(n) of the Act, Medicare Part B provides for the coverage of durable medical equipment (DME), prosthetics, orthotics, and supplies (DMEPOS). Section 1862(a)(1)(A) of the Act requires that, to be paid by Medicare, a service or an item be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

As a result of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, enacted December 8, 2003, CMS contracted with four DME Medicare administrative contractors (DME MAC) to process and pay Medicare Part B claims for DMEPOS. When submitting claims to DME MACs, suppliers use Healthcare Common Procedure Coding System (HCPCS) codes¹ as well as modifiers that indicate left or right limb and a functional level.² Each claim can include multiple HCPCS codes, each of which represents a different component of the lower limb prosthetic provided by the supplier. A lower limb prosthetic is an artificial replacement for any or all parts of the leg and provides an individual who has an amputated limb with the opportunity to perform functional tasks, particularly walking, which may not be possible without the device.

DME MACs develop local coverage determinations (LCD) for some covered DMEPOS items. LCDs describe the circumstances for Medicare coverage for lower limb prosthetics and outline the conditions under which DME MACs will cover those devices. LCDs require that some lower limb prosthetics have minimum functional levels to be covered by Medicare.

This review was completed as followup work to an Office of Inspector General, Office of Evaluation and Inspections, review.³

¹ HCPCS codes are used throughout the health care industry as a standardized coding system for describing and identifying health care equipment and supplies in health care transactions.

² Lower limb prosthetic functional levels are submitted in terms of K-levels. Functional levels range from a K0 (the patient does not have the ability or potential to ambulate or transfer safely with or without assistance, and a prosthetic does not enhance his/her quality of life or mobility) through a K4 (the patient has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills and that exhibits high impact, stress, or energy levels; this level is typical of the prosthetic demands of the child, active adult, or athlete). Potential functional ability is based on the reasonable expectations of the prosthetist and treating physician.

³ *Questionable Billing by Suppliers of Lower Limb Prostheses* (OEI-02-10-00170), issued August 2011.

Medicare Durable Medical Equipment Documentation Requirements

Pursuant to the *Jurisdiction D DME MAC Supplier Manual*, before submitting a claim to the DME MAC, the supplier must have on file: (1) written documentation of a verbal order/preliminary written order, (2) a detailed written order, (3) proof of delivery, (4) a beneficiary authorization, (5) information from the treating physician concerning the patient's diagnosis, and (6) any information required for the use of specific modifiers or attestation statements as defined in certain DME policies.

A DMEPOS supplier should also obtain as much documentation from the patient's medical record as it requires to ensure that the coverage criterion for an item has been met. If the information in the patient's medical record does not adequately support the medical necessity for the item, the supplier is liable for the dollar amount involved.

Premier Prosthetics and Orthotics

Premier Prosthetics and Orthotics (Premier) based in Creve Coeur, Missouri, supplies lower limb prosthetics.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Premier's paid claims for lower limb prosthetics were supported in accordance with Medicare DMEPOS documentation requirements.

Scope

We reviewed a total of \$2,958,124 in DMEPOS claims that Premier submitted for lower limb prosthetics and that DME MACs paid during the period January 1, 2010, through December 31, 2011.

Our review focused on whether Premier met Medicare documentation requirements for lower limb prosthetics. We did not conduct a medical review to determine whether the services were medically necessary. However, we communicated with Noridian Administrative Services, LLC (Noridian),⁴ about the allowability of certain HCPCS codes and the LCD for the lower limb prosthetics.

We did not review Premier's overall internal control structure. We limited our review of internal controls to those related to our audit objective.

⁴ Noridian is the DME MAC for Medicare DME Jurisdiction D. Ninety percent of the claims submitted by Premier were processed and paid by Noridian, and the other 10 percent were processed and paid by National Government Services, the DME MAC for Medicare DME Jurisdiction B.

We conducted our fieldwork in March 2012 at Premier's office in Creve Coeur, Missouri.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and DME MAC guidance;
- reviewed Premier's policies and procedures for submitting claims for lower limb prosthetics;
- interviewed staff at Premier to gain an understanding of its process for billing DMEPOS claims for lower limb prosthetics;
- discussed with staff at Noridian the allowability of lower limb prosthetic claims that contained HCPCS codes L5964 (addition, endoskeletal system, above knee, flexible protective outer surface covering system) and L7368 (lithium ion battery charger);
- obtained electronic paid claims data for Premier during the period January 1, 2010, through December 31, 2011;
- selected a stratified random sample of 100 paid claims from the 368 paid claims during the period January 1, 2010, through December 31, 2011;
- obtained and reviewed the supporting documentation for each claim that we sampled to determine the allowability of the claim; and
- discussed the results of our review with Premier officials on May 21, 2012.

See Appendix A for our sample design and methodology and Appendix B for our sample results and estimates.

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 objective.

FINDINGS AND RECOMMENDATIONS

Premier's paid claims for lower limb prosthetics were not always supported in accordance with Medicare DMEPOS documentation requirements. Of the 100 sampled claims totaling \$864,139 in payments, 57 claims were supported in accordance with Medicare DMEPOS documentation requirements. However, the remaining 43 claims were either not supported or were only partially supported in accordance with Medicare DMEPOS documentation requirements. Specifically, we identified the following deficiencies (two claims had more than one error):

- For 35 claims, Premier did not have documentation from the patients' medical records supporting the medical necessity of the items for which it had submitted the claims.
- For one claim, Premier did not obtain a verbal or preliminary written order from a physician before delivering the item and submitting the claim.
- For four claims, Premier did not obtain properly completed written orders from physicians before submitting the claims.
- For three claims, Premier did not have documentation showing that it obtained authorization from the beneficiaries before submitting the claims.
- For two claims, Premier's documentation did not support the minimum functional level, as required by the LCD, of the prosthetics for which it had submitted claims.

Premier submitted unsupported claims because it lacked adequate internal controls to ensure that it collected and maintained the required documentation. As a result of these errors, Premier received payments totaling \$115,558 for the 43 sampled claims that were not supported in accordance with Medicare DMEPOS documentation requirements.

Based on the results of our sample, we estimated that unsupported claims for lower limb prosthetics paid to Premier resulted in overpayments totaling \$284,023 during the period January 1, 2010, through December 31, 2011.

MEDICARE DOCUMENTATION REQUIREMENTS NOT MET

Necessity of Claim Items Not Substantiated by Medical Records

Chapter 5, section 5.7, of CMS's *Medicare Program Integrity Manual*, Pub. No. 100-08 (the manual), states:

For any DMEPOS item to be covered by Medicare, the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered ... if the information in the patient'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.

Further, Chapter 5, section 5.8, of the manual provides that "The supplier should ... obtain as much documentation from the patient's medical record as they determine they need to assure themselves that coverage criteria for an item have been met."

For 35 of the 100 claims that we sampled, Premier did not have documentation from the patients' medical records supporting the medical necessity of the items for which it had submitted the claims. Specifically:

- For 24 claims, Premier submitted claims using HCPCS code L5964 (addition, endoskeletal system, above knee, flexible protective outer surface covering system). This code is for an upgraded outer protective cover for a prosthetic. Premier's documentation did not contain support from either the ordering physicians or Premier itself that the beneficiaries had a specific need for an upgraded protective cover.
- For seven claims, Premier submitted claims using HCPCS code L7368 (lithium ion battery charger). This code is for a replacement charger for a prosthetic that contains electronic components. However, for each of these claims Premier also billed for a different HCPCS code for a prosthetic that included a battery charger. Accordingly, an additional bill for a replacement battery charger was not allowable unless supported by documentation substantiating its necessity. Premier's documentation did not contain support for the necessity of a replacement charger.
- For two claims, Premier did not maintain sufficient documentation of the patients' medical condition to substantiate the necessity for the items ordered. We requested, but did not receive, medical records from the treating physicians' offices that would support the medical necessity of these two claims.
- For two claims, Premier did not maintain sufficient documentation to substantiate the necessity for the items ordered. The HCPCS codes for these items were not included on the physicians' detailed written orders, and those items were therefore not authorized by the physicians.

Physician's Verbal or Preliminary Written Order Not Obtained Prior to Dispensing

Chapter 5, section 5.2.1, of the manual requires that the DME supplier obtain an order from the treating physician before dispensing an item(s) of DMEPOS to a beneficiary. Chapter 5, section 5.2.2, of the manual states that the "[s]upplier may dispense most items of DMEPOS based on a verbal order or preliminary written order from the treating physician.... If the supplier does not have an order from the treating physician before dispensing an item, the item is noncovered."

For 1 of the 100 claims that we sampled, Premier did not obtain a verbal or preliminary written order from the physician before delivering the item to the beneficiary.

No Detailed Written Order Prior to Claim Submission

Chapter 5, section 5.2.3, of the manual provides that a "supplier must have a detailed written order prior to submitting a claim.... [T]he treating physician must ... personally sign and date the order ... if the supplier does not have an order that has been both signed and dated by the

treating physician before billing the Medicare program, the item will be denied as not reasonable and necessary.”

For 4 of the 100 claims that we sampled, Premier did not obtain properly completed detailed written orders from physicians before submitting the claims. For three of the claims, Premier did not receive properly completed detailed written orders from the physicians. For one claim, Premier did not obtain a written order that was both signed and dated by the ordering physician.

Beneficiary Authorization Not on File

Chapter 3, of the *Jurisdiction D Durable Medical Equipment Supplier Manual* requires that “[b]efore submitting a claim to the DME MAC, the supplier must have on file ... [b]eneficiary authorization....”

For 3 of the 100 claims that we sampled, Premier did not have documentation on file showing that it obtained authorization from the beneficiaries before billing Medicare for the lower limb prosthetics.

Documentation Did Not Support Minimum Functional Level of Claimed Items

From the LCD (L11453) for lower limb prosthetics:

- A flex-walk system or equal (HCPCS code L5981) is covered for beneficiaries whose functional level is K3 or above.
- A fluid, pneumatic, or electronic knee (HCPCS codes L5814 and L5848) is covered for beneficiaries whose functional level is K3 or above.

For 2 of the 100 claims that we sampled, Premier’s documentation did not support the minimum functional level, as required by this LCD, of the prosthetics for which it had submitted claims. Specifically, Premier was paid for lower limb prosthetic claims that it had submitted using HCPCS codes (L5981, L5848 and L5814) that required a minimal functional level of K3. However, Premier’s documentation supported a functional level that was below the minimum allowable for Medicare coverage. These two claims were unallowable because the physicians’ orders indicated that the functional level of the beneficiaries was a level K2 (see footnote 2).

INADEQUATE INTERNAL CONTROLS

Premier submitted unsupported claims because it lacked adequate internal controls to ensure that it collected and maintained the required documentation. Specifically, Premier did not have policies and procedures in place to ensure that it collected and maintained all required documentation for lower limb prosthetics claims and that it billed only for properly supported HCPCS codes.

OVERPAYMENTS FOR UNSUPPORTED CLAIMS

Of the 100 claims in our sample, 43 did not comply with the Medicare DMEPOS requirements. Based on the results of our sample, we estimated that unsupported claims for lower limb prosthetics paid to Premier resulted in overpayments totaling \$284,023 during the period January 1, 2010, through December 31, 2011.

RECOMMENDATIONS

We recommend that Premier:

- refund \$284,023 to the Federal Government for unallowable lower limb prosthetic claims and
- strengthen internal controls by developing and implementing policies and procedures to help ensure that it collects and maintains the required documentation.

AUDITEE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Premier agreed that the claims we had identified as findings had documentation deficiencies, but did not agree that the deficiencies reached a level that would require Premier to refund the \$284,023 to the Federal Government for unallowable claims. Regarding our second recommendation, Premier said that it had instituted internal controls and process improvements. A summary of Premier's comments and our responses follows.

Premier's comments appear in their entirety as Appendix C.

After reviewing Premier's comments, we note that the provisions of the manual, the *Jurisdiction D Durable Medical Equipment Supplier Manual*, and the LCD for lower limb prosthetics are very specific as to the requirements that must be met for these types of claims to be allowable, and we therefore maintain that the recommendation to refund the unallowable claims remains valid.

Necessity of Claim Items Not Substantiated by Medical Records

Auditee Comments

For the 24 claims that Premier submitted using HCPCS code L5964, Premier agreed that its files did not contain specific support from the ordering physician or Premier relating to a specific need for an upgraded protective cover. Premier added that this lack of documentation should not have been interpreted as support that the flexible protective outer surface covering was unnecessary. Premier also said that because the protective cover (HCPCS code L5707) and the flexible protective outer surface (L5964) are intended to work in conjunction to provide protection, separate medical necessity is not required and all claims relating to this combination should be paid.

For the seven claims that Premier submitted using HCPCS code L7368, Premier concurred that the files related to these claims did not contain support for the necessity of a replacement charger. Premier added, though, that the charger is necessary for the prosthetic to function. Premier also said that before January 2012, CMS's description of this HCPCS code was for a lithium battery charger; in January 2012, CMS added the word "replacement" to this description. Premier said that because the prosthetic in question (a microprocessor knee) did not come with a charger, and because Premier was in compliance with the law when written, all claims should be paid.

For the two claims for which Premier did not maintain sufficient documentation of the patients' medical condition to substantiate the necessity for the items ordered, Premier agreed with the finding. For one claim, Premier said that it obtained detailed prescriptions but did not verify that the patient had been seen in the last 12 months by a treating physician. For the other claim, Premier stated that extenuating circumstances prevented the patient from going to the physician's office. Premier added that both patients had their prostheses.

For the two claims for which Premier did not maintain sufficient documentation to substantiate the necessity for the items ordered, Premier concurred with the finding. However, Premier stated that in each instance it delivered a K3 (more expensive) prosthetic foot but billed Medicare for a K2 foot (see footnote 2).

Office of Inspector General Response

We maintain that all of our findings involving unsubstantiated claim items are valid and note that Premier agreed with all of the documentation deficiencies. The manual is very specific in stating that for any DMEPOS item to be covered by Medicare, the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered. The manual adds that if the information in the patient's medical record does not adequately support the medical necessity for the item, then on assigned claims the supplier—that is, Premier—is liable for the dollar amount involved.

The documentation maintained by Premier was not sufficient to substantiate the claims that included HCPCS codes L5964 (flexible protective outer surface) and L7368 (lithium ion battery charger). Specific documentation must exist in the medical files for these HCPCS codes to be allowable.

Although Premier stated in its comments that the protective cover (HCPCS code L5707) and the flexible protective outer surface (HCPCS code L5964) are intended to work in conjunction, none of the claims we reviewed that contained HCPCS code L5964 also contained HCPCS code L5707.

Further, the change to the description of HCPCS code L7368 in January 2012 was a clarification and was not intended to be seen as a change in the definition or purpose of that code as it applied to the lithium ion battery charger. Before the January 2012 clarification, HCPCS codes L7368 and L7367 were intended for replacement

components; in fact, the description for HCPCS code L7367 before the January 2012 clarification was “Lithium ion battery, replacement.”

Physician’s Verbal or Preliminary Written Order Not Obtained Prior to Dispensing

Auditee Comments

For the one claim for which Premier did not obtain a verbal or preliminary written order from the physician before delivering the item to the beneficiary, Premier agreed with the finding but said that it received the detailed prescription 1 day after delivery of the item. Premier added that the prosthetic was delivered and that the patient continued to use the device, and stated that for these reasons and because all other documentation was in order, there should be no financial penalty associated with this claim.

Office of Inspector General Response

We maintain that our finding is valid because Premier did not obtain a verbal or preliminary written order from the physician before delivering the item to the beneficiary. Accordingly, for this claim Premier did not meet the standards set forth in the manual.

No Detailed Written Order Prior to Claim Submission

Auditee Comments

For the four claims for which Premier did not obtain properly completed detailed written orders from physicians before submitting the claims, Premier concurred with the findings but provided additional information explaining why one prescription was not dated, another was not signed, and two others were not received until after the prosthetics had been delivered to the beneficiaries.

Office of Inspector General Response

We maintain that our finding is valid because in all four cases Premier did not obtain properly completed detailed written orders from physicians before submitting the claims. For a claim to be reasonable and necessary, the manual clearly states that the supplier must have a properly completed written order before submitting the claim. Accordingly, for this claim Premier did not meet the standards set forth in the manual.

Beneficiary Authorization Not on File

Auditee Comments

For the three claims for which Premier did not have documentation on file showing that it obtained authorization from the beneficiaries before billing Medicare for the lower limb

prosthetics, Premier concurred that the authorizations were not in place but described the errors as clerical in nature and added that in each case the patient received and was using the prosthetic.

Office of Inspector General Response

We maintain that our finding is valid because Premier did not have documentation on file, as required by the *Jurisdiction D Durable Medical Equipment Supplier Manual*, showing that it obtained authorization from the beneficiaries before billing Medicare for the lower limb prosthetics.

Documentation Did Not Support Minimum Functional Level of Claimed Items

Auditee Comments

For the two claims for which Premier's documentation did not support the minimum functional level, Premier concurred but provided additional information. Premier described the error in the case of the first claim as clerical in nature and asserted that the appropriate refund should be the difference between the cost of a prosthetic foot with a K3 functional level and the cost of one with a K2 functional level. For the second claim, Premier stated that because of the patient's weight, its only alternative was to supply a prosthetic knee with a K3 functional level.

Office of Inspector General Response

We maintain that our finding is valid because in both cases Premier's documentation did not support the minimum functional level as required by the LCD. Further, the manual specifically states that for a claim to be reasonable and necessary, the supplier must have a properly completed order prior to delivery. Because both of these requirements state that the documentation must support the functional level (K3) of the prosthetics for which Premier claimed reimbursement, and because in both cases the physician's orders indicated that the beneficiaries had a functional level of only K2, Premier's claim was not allowable. Moreover, the relevant criteria make no allowance for calculation and refunds of the kind of differences in amounts that Premier suggested.

APPENDIXES

APPENDIX A: SAMPLING METHODOLOGY

POPULATION

The population consists of Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) claims paid to Premier Prosthetics and Orthotics (Premier) during the period January 1, 2010, through December 31, 2011.

SAMPLING FRAME

The sampling frame contained 368 paid claims with a payment amount greater than \$1,000 totaling \$2,958,124 for the period January 1, 2010, through December 31, 2011.

SAMPLE UNIT

The sampling unit is a paid Premier Medicare DMEPOS claim.

SAMPLE DESIGN

We used a stratified random sample.

Stratum 1 – \$1,000 to \$39,999.99: 366 paid claims

Stratum 2 – \$40,000 and more: 2 paid claims

SAMPLE SIZE

We selected a sample of 100 units (paid claims).

Stratum 1 – 98 paid claims

Stratum 2 – 2 paid claims

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE ITEMS

We consecutively numbered the sample units for Stratum 1. After generating 98 random numbers for Stratum 1, we selected the corresponding frame items. We selected both claims in Stratum 2.

ESTIMATION METHODOLOGY

We used the OAS statistical software to estimate the amount of overpayments.

APPENDIX B: SAMPLE RESULTS AND ESTIMATES

Sample Results

Stratum	Frame Size	Value of Frame	Sample Size	Value of Sample	Number of Unallowable Services	Value of Unallowable Services
1	366	\$2,873,970	98	\$779,985	41	\$113,637
2	2	\$84,154	2	\$84,154	2	\$1,921
Total	368	\$2,958,124	100	\$864,139	43	\$115,558

Estimated Value of Unallowable Services
(Limits Calculated for a 90-Percent Confidence Interval)

Point estimate	\$426,320
Lower limit	\$284,023
Upper limit	\$568,617

APPENDIX C: AUDITEE COMMENTS



November 5, 2012

Patrick J. Cogley
Regional Inspection General for Audit Services
601 East 12th Street, Room 0429
Kansas City, MO 64106

RE: Response to Report No. A-07-12-05026

Dear Mr. Cogley:

We have received the draft copy of the above-referenced report and have spent a significant amount of time reviewing the report and its findings. We appreciate not only the time that your agency has spent in reviewing the audit findings, but also appreciate the professionalism with which our company has been treated throughout. As the owners of a small growing business, we take great pride in not only the services we provide to our patients, but our reputation in this community. As such, we approached the audit and have now approached the result of the audit with the highest amount of seriousness and attention to detail as possible. Indeed, as we will more fully set forth in this response even before the results of the audit had been presented to us in the draft form, we had already instituted significant internal controls and changes to our process which we believe will eliminate any possibility of these findings being repeated. Before we begin a detailed response to the draft audit findings, we believe that some history of Premier Prosthetics and Orthotics ("PPO") would be helpful.

The founders and owners of PPO are Greg Doerr and Manny Rivera. Greg and Manny both graduated from the Prosthetic-Orthotic Center at the Feinburg Medical School at Northwestern University. Prior to founding PPO, they worked at a combined three prosthetic and orthotic businesses in the St. Louis area and have a combined 35 years of experience in prosthetic and orthotics. While PPO is a "new" practice, the reality is over these 35 years of experience, Greg and Manny had developed a significant network of trusted referral sources allowing them to "hit the ground running" when they opened PPO. As a result instead of being a start-up business struggling to find new customers, PPO was able to quickly establish itself as an orthotic and prosthetic supplier in the St. Louis area.

In starting their own practice, Greg and Manny used many of the same or similar methods and practices which they had successfully used at their prior employers. With that as a backdrop, PPO responds as follows to the specific claims set forth in the draft report.

633 Emerson Road – Suite 10 – St. Louis, MO 63141
Ph: 314-262-8900 – fax: 314-743-3575
www.premierpando.com

The draft report indicates:

For 24 claims, Premier submitted claims using HCPCS code L5964 (addition, endo skeletal system, above knee, flexible protective outer surface covering system). This code is for an upgraded outer protective cover for a prosthetic. Premier's documentation did not contain support from the ordering physician or Premier itself that the beneficiaries had a specific need for an upgraded protective cover.

PPO agrees that its records for Sample Nos. 6, 8, 13, 20, 28, 33, 35, 41, 44, 47, 50, 54, 58, 62, 63, 68, 71, 78, 83, 88, 91, 92, 98 and 99 did not contain specific support from the ordering physician or PPO relating to a specific need for an upgraded protective cover. This lack of documentation should not be interpreted as support that the flexible protective outer surface covering (L5964) is unnecessary. Indeed, based on PPO's history as set forth above, the flexible protective outer surface covering is necessary when used in conjunction with the protective cover (L5707) for a number of reasons. As an initial matter, the protective cover (L5707) is designed to provide protection for the underlying prosthetic. The protective cover is relatively inexpensive in comparison with the prosthetic and by having the protective cover installed, protection for the dramatically more expensive prosthetic is provided. However, the protective cover is porous foam that cannot be easily cleaned or disinfected. Indeed, this foam and the very protection it provides causes it soak up moisture, dirt and germs. The flexible protective outer surface covering however, is non-porous and therefore not only protects the protective cover from the moisture, dirt and germs, but further protects the prosthesis from moisture. Additionally the protective outer covering can be cleaned with soap and water and disinfected if required. When the two devices are used concurrently, the prosthetic has protection – allowing a longer usable life and therefore reducing the expense of having to purchase a replacement prosthetics.

In Greg and Manny's long-standing experience in the prosthetic field, they had never seen Medicare question the use of the flexible protective outer surface covering (L5964) in any circumstance. Because the protective cover (L5707) and flexible protective outer surface (L5964) are intended to work in conjunction to provide protection for the underlying prosthesis, the absence of separate medical necessity is not required and all claims relating to same should be paid.

The draft report further indicates:

For seven claims, Premier submitted claims using HCPCS code L7368 (lithium ion battery charger). This code is for a replacement charger for a prosthetic that contains electronic components. However, for each of these claims, Premier also billed for a different HCPCS code for a prosthetic that included the battery charger. Accordingly, an additional bill for replacement battery charger was not allowable unless supported by documentation substantiating its necessity. PPO's documentation did not contain support for the necessity of a replacement charger.

The above seven claims are found in Sample Nos. 12, 25, 56, 82, 83, 99 and 100. PPO concurs that the files related to those sample numbers do not contain support for the necessity of a replacement charger. However, PPO believes that its documentation properly supports the charge as written.

Prior to January 2012, the Medicare description for HCPCS code L7368 was for a lithium battery charger. In January 2012, Medicare added the word replacement to this HCPCS code. The prosthetic in question, a microprocessor knee, is supplied and billed with a separate prosthetic knee, but does not come with a charger. In other words, a battery charger is necessary for the prosthetic to function, but one is not included. Without the supplied and billed charger, the prosthetic cannot function. Accordingly, while PPO agrees that its documentation does not support the new Medicare regulations it does not agree that the documentations warrant or merit a disallowance of the charges in the above-referenced sample numbers. PPO has discussed this issue and the January 2012 change in the law with its supplier who is working toward a resolution with Medicare. Because PPO was in compliance with the law when written, it believes all claims should be paid.

The report further goes on to state:

For two claims Premier did not maintain sufficient documentation of the patients' medical condition to substantiate the necessity for the items ordered. We requested, but did not receive, medical records from the treating physicians' office that would support the medical necessity of these two claims.

In response PPO agrees with the findings from Sample Nos. 4 and 34. In Sample No. 4 the patient called the original amputation surgeon indicating that they were in need of a new prosthesis because the prosthesis no longer functioned. That physician referred their patient to PPO. In this referral we were able to obtain detailed prescriptions and other paperwork. However, we failed to verify that the patient had been seen in the last 12 months by the treating physician. Sample No. 34 presented an extenuating circumstance that the patient was a severe chronic alcoholic who had a high risk of further injury in the absence of a new prosthesis. Due to the unique situation of this patient, he was unable to make it into the office. PPO acknowledges that its actions in Sample No. 34 did not necessarily comply with Medicare requirements. However, it made decisions in the best interest of the patient. While the documentation may not be present, both patients have their prosthesis and disallowance of the entire claim appears to be an inappropriately harsh punishment. When the client's needs have been appropriately met, PPO's failures in these two cases do not support disallowance of the entire claim.

The report further goes on to state:

For two claims, Premier did not maintain sufficient documentation to substantiate the necessity for the items ordered. The HCPCS codes for these items were not included on the physician's detailed written orders, and those items were therefore not authorized by the physician.

PPO concurs with the findings from Sample Nos. 29 and 52. In each instance PPO delivered prosthetic feet that were of a K3 (higher activity level) but billed Medicare for K2 (lower activity level). In reaching a determination to reject this claim, some background is necessary. A K2 foot, because it is designed for a lower activity level is less robust than a K3 foot, which is designed for a higher activity level. The K3 foot is more expensive due to its construction. The patient received a K3 (more expensive) foot. Medicare was billed for a K2 foot. Disallowance of these claims fails to take into consideration all of the information available and unnecessarily punishes PPO for a simple clerical error.

The report further goes on to say:

For one claim Premier did not obtain a verbal or preliminary written order from a physician before delivering the item and submitting the claim.

PPO agrees with the findings of the report in Sample No. 65. The detailed prescription was received one day after delivery. However, the prosthetic was delivered and the patient continues to use the device. Disallowance of the entire amount is an overly harsh resolution. Indeed, given that the patient is using the device and all other documentation is in order, there should be no penalty. In past, Medicare audits which Greg and Manny are aware this level of perfection was not required. As more fully set forth herein the revised claims review process will prevent such an error from occurring in the future.

The report further goes on to say:

For four of the claims that we sampled, Premier did not obtain properly completed detailed written orders from a physician before submitting the claims. For three of the claims, Premier did not receive properly completed detailed written orders from the physicians. For one claim, Premier did not obtain a written order that was both signed and dated by the ordering physician.

PPO concurs with the findings from Sample Nos. 15, 16, 30 and 49. However, for each there are explanations which PPO believes should be taken into consideration in the final version of the report. In Sample No. 16, PPO received the signed prescription from the surgeon, however, the surgeon failed to date that prescription. Additional documentation in the file namely the fax header showing the date of receipt supports that the prescription was prepared by the physician at that time. Disallowance of a claim based on the mistake of a physician, not PPO, is an overly harsh resolution. In Sample No. 30, PPO was given a verbal order to begin construction of the prosthesis. In addition the physician from the patient's nursing home signed to have the patient start physical therapy with the prosthesis. Following these orders, the physician left for vacation and was not reachable by the time the prosthesis was ready for delivery to sign the detailed written order. Given the patient was obviously in need of the prosthesis and had already begun therapy for same, a disallowance of the entire claim is an overly harsh resolution. In Sample Nos. 15 and 49, the audit revealed that detailed written prescriptions were not received by PPO until after the time of delivery. The samples indicate a mistake as PPO did not realize that the detailed prescriptions were missing at the time of delivery. The prosthesis, as delivered, confirmed to the preliminary and detailed prescription and it cannot be ignored that the patient has the prosthesis and is using it. Separate from the overly

very harsh nature of disallowance, as more fully set forth herein, PPO believes that mistakes of this type will no longer occur given the revised claims process that has been put into place.

The report further goes on to say:

For three of the 100 claims that we sampled, Premier did not have documentation on file showing that it obtained authorization from the beneficiaries before billing Medicare for the lower limb prosthetics.

These three claims are presented in Sample Nos. 36, 66 and 69. As a result of PPO's independent review of these samples, PPO does concur that authorization was not in place. The failure to have the signed authorizations in the file is one of a clerical error and was primarily due to the patients being seen outside of PPO's office and the signed authorizations not being properly scanned into the patient's file at PPO. However, what PPO believes this report should include and what should be taken into consideration in the finalization of this report is that for each instance the patient received the prosthesis as prescribed and is using the prosthesis. It seems inequitable for the entire claims to be denied. As set forth above, in Greg and Manny's experience, audits of prosthetic companies in the past did not require this level of perfection for claim allowance. In addition, the internal controls instituted will avoid any such problem in the future.

The report further goes on to say:

For two of the claims, Premier's documentation did not support the minimum functional level as required by the LCD, of the prosthetics for which it had submitted.

This issue involves Sample Nos. 4 and 34. PPO concurs that Sample Nos. 4 and 34 did not contain the appropriate documentation to support function level. Sample No. 4 was simply a clerical error which based on PPO's refined claims submission process should not occur in the future. As the script required a K2 foot and K2 foot was provided, PPO believes the appropriate remedy is a refund of the difference between a K3 and K2 foot, not disallowance of the entire claim.

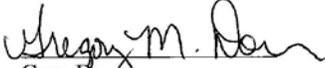
In Sample No. 34, however, further explanation is necessary. While the patient exhibited a K2 level, that patient weighed in excess of 350 pounds. K2 level prosthetic knee rated for a patient over 350 pounds was not available (as far as PPO is aware, no such knee exists). As a result, the only alternative was to provide the patient with a K3 level prosthetic knee. Until this billing issue can be cleared up with Medicare PPO will simply refuse to provide transfemoral amputees who weigh over 350 pounds with prosthesis. Based on PPO's participation in its industry, this is a common issue, with no resolution available.

As indicated above PPO has considered this audit a very serious matter. It is disappointed that there have been any errors in its processing of claims as it prides itself in being a well-run and efficient company. In response PPO has worked with a Six Sigma Black Belt to develop and implement a Six Sigma measurement based strategy to focus on process improvement and variation reduction. This process uses the Six Sigma methodology known as

the DMAIC process (define, measure, analyze, improve, control) which is an improvement system for existing processes falling below specification and looking for incremental improvement. PPO would be proud to present this process and the resulting process map to the auditors. All PPO staff has been trained and has been given ownership of the process through each step. It is believed by PPO that this process will eliminate the mistakes found above. In addition PPO has assigned an individual with the daily task of reviewing the Medicare website to catch any changes or revisions in Medicare policy immediately. Through the Six Sigma process PPO determined that its office manager position needed to be upgraded and hiring has occurred to reflect that need.

In summary PPO, while disturbed by the findings in the draft report, freely acknowledges that its processes did not provide perfect compliance with the law, it is disappointed, but as indicated, perfection had not previously been required. However, in acknowledging this PPO has taken significant steps to ensure that such mistakes do not occur in the future. PPO believes that disallowing all of the above claims for the simple errors recounted above is an unnecessarily harsh resolution and would request that the punishment for the above mistakes be more appropriate and in line with the level of the actual mistake.

Sincerely,


Greg Doett


Manny Rivera