

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**PACIFIC MEDICAL, INC.,  
RECEIVED SOME UNALLOWABLE  
MEDICARE PAYMENTS FOR  
ORTHOTIC BRACES**

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# *Office of Inspector General*

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## Report in Brief

Date: December 2018

Report No. A-09-17-03027

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



### Why OIG Did This Review

From January 1, 2015, through March 31, 2017 (audit period), Medicare paid approximately \$1.3 billion for back, knee, and ankle-foot braces (selected orthotic braces) provided to Medicare beneficiaries. Prior OIG reviews found that some suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) billed for orthotic braces that did not comply with Medicare billing requirements. During our audit period, the Centers for Medicare & Medicaid Services found that orthotic braces were among the top 20 DMEPOS items with the highest improper payment rates. After analyzing Medicare claim data, we selected for review Pacific Medical, Inc., an orthotic braces supplier in Tracy, California.

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

### How OIG Did This Review

For our audit period, Pacific Medical received approximately \$6.2 million in Medicare Part B payments for selected orthotic braces. After excluding certain claims, we reviewed a stratified random sample of 100 claims. We provided copies of Pacific Medical's supporting documentation to a medical review contractor to determine whether claims for orthotic braces met Medicare requirements.

## Pacific Medical, Inc., Received Some Unallowable Medicare Payments for Orthotic Braces

### What OIG Found

Pacific Medical did not always comply with Medicare requirements when billing for selected orthotic braces. For 89 of the 100 sampled claims, Pacific Medical complied with the requirements. However, for the remaining 11 claims, it did not comply with the requirements. Specifically, Pacific Medical billed for orthotic braces that were not medically necessary for nine claims and could not provide medical records for two claims.

These deficiencies occurred because Pacific Medical did not always obtain sufficient information from the beneficiaries' medical records to assure itself that the claims for orthotic braces met Medicare requirements. On the basis of our sample results, we estimated that Pacific Medical received at least \$247,493 in unallowable Medicare payments for orthotic braces.

### What OIG Recommends and Pacific Medical Comments

We recommend that Pacific Medical (1) refund to the durable medical equipment Medicare administrative contractors \$247,493 in estimated overpayments for orthotic braces; (2) exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule, and identify any 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.

Pacific Medical did not concur with our first recommendation but concurred with our second and third recommendations to the extent that it continues to conduct self-audits and respond to ongoing recovery audit contractor audits. Regarding our first recommendation, Pacific Medical stated that (1) the extrapolated overpayment was unreasonable and that our report failed to reference the authority to extrapolate; (2) as an accredited supplier, Pacific Medical follows the direction of referring licensed physicians in providing specific DMEPOS; and (3) it believes where it has documentation of an order and delivery, it should receive, at a minimum, reimbursement for the least costly alternative to the delivered product. Our response is that (1) Federal courts have consistently upheld extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid; (2) if the information in a beneficiary's medical record does not adequately support medical necessity, the supplier is liable for the dollar amount of the orthotic brace; and (3) our report clarifies that OIG recommendations do not represent final determinations by Medicare but are recommendations to HHS action officials.

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## INTRODUCTION

### WHY WE DID THIS REVIEW

From January 1, 2015, through March 31, 2017 (audit period), Medicare paid approximately \$1.3 billion for back, knee, and ankle-foot braces (selected orthotic braces) provided to Medicare beneficiaries. Although the Office of Inspector General (OIG) has not recently conducted reviews in this area, prior OIG reviews 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 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 claim data for our audit period, we selected several DMEPOS suppliers (suppliers) for review based on (1) Medicare Part B payments to the suppliers and (2) other risk factors, including the percentage of Medicare payments for selected orthotic braces. This report covers one of those suppliers, Pacific Medical, Inc., an orthotic braces supplier in Tracy, California.

### OBJECTIVE

Our objective was to determine whether Pacific Medical complied with Medicare requirements when billing for selected 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.<sup>1</sup> 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.<sup>2</sup> Orthotic braces are defined as

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<sup>1</sup> The Social Security Act (the Act) § 1832(a)(1) and §§ 1861(s)(5), (s)(6), (s)(8), and (s)(9).

<sup>2</sup> 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.”<sup>3</sup>

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

**Figure: Back, Knee, and Ankle-Foot Braces**



CMS contracts with two durable medical equipment Medicare administrative contractors (DME MACs) to process and pay Medicare Part B claims for DMEPOS, including orthotic braces. Each DME MAC processes claims for two of four jurisdictions (A, B, C, and D), which include specific States and territories.<sup>4</sup> 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.<sup>5</sup> 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)<sup>6</sup> for some covered orthotic braces. The LCDs outline the conditions under which DME MACs will pay suppliers for those braces.

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

<sup>4</sup> Before July 1, 2016, there were four DME MACs, each covering one jurisdiction.

<sup>5</sup> HCPCS codes are used throughout the healthcare industry to standardize coding for medical procedures, services, products, and supplies.

<sup>6</sup> 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)).

Before submitting a claim for an orthotic brace to the DME MAC, a supplier must have on file the following:<sup>7</sup>

- written documentation of a verbal order or a preliminary written order from the treating physician,
- 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,<sup>8</sup> and
- proof of delivery of the orthotic brace to the beneficiary.

A 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. If the information in the medical record does not adequately support the medical necessity of the orthotic brace, the supplier is responsible for the payment amount of the brace.<sup>9</sup>

### **Medicare Requirements for Suppliers To Identify and Return Overpayments**

OIG believes that this audit report constitutes credible information of potential overpayments. Suppliers that receive notification of these potential overpayments must (1) exercise reasonable diligence to investigate the potential overpayment, (2) quantify any overpayment amount over a 6-year lookback period, and (3) report and return any overpayments within 60 days of identifying those overpayments (60-day rule).<sup>10</sup>

### **Pacific Medical**

Pacific Medical is a distributor of DMEPOS, specializing in supplies related to orthopedic rehabilitation, arthroscopic surgery, and sports medicine. Pacific Medical is located in Tracy, California. For our audit period, Pacific Medical received \$14,859,847 in Medicare Part B payments. Approximately 42 percent of these payments were for the selected orthotic braces and the related DMEPOS accessories (e.g., various add-on components) provided to Medicare beneficiaries in all States and one territory. Table 1 on the following page shows a breakdown of the payments.

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<sup>7</sup> CMS's *Medicare Program Integrity Manual*, Pub. No. 100-08 (the Manual), chapter 5, §§ 5.2.2 and 5.8(A), (B), and (D).

<sup>8</sup> A modifier is a two-digit code that further describes the service performed, such as indicating the limb affected.

<sup>9</sup> The Manual, chapter 5, § 5.8(A).

<sup>10</sup> The Act § 1128J(d); 42 CFR part 401, subpart D; 42 CFR §§ 401.305(a)(2) and (f); and 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016).

**Table 1: Medicare Part B Payments to Pacific Medical  
for Back, Knee, and Ankle-Foot Braces<sup>11</sup> and Other DMEPOS**

Year	Payment for Back Braces	Payment for Knee Braces	Payment for Ankle-Foot Braces	Payment for Other DMEPOS	Total Payments by Year
2015	\$457,768	\$1,015,117	\$1,286,520	\$3,744,361	\$6,503,766
2016	509,400	1,095,418	1,336,437	3,978,412	6,919,667
2017 (Jan.–Mar.)	108,877	127,822	287,476	912,239	1,436,414
<b>Total</b>	<b>\$1,076,045</b>	<b>\$2,238,357</b>	<b>\$2,910,433</b>	<b>\$8,635,012</b>	<b>\$14,859,847</b>
Percentage of Total Payment	7.2%	15.1%	19.6%	58.1%	100%

**HOW WE CONDUCTED THIS REVIEW**

Pacific Medical received Medicare Part B payments of \$6,224,835 for claims that included the selected orthotic braces,<sup>12</sup> representing 25,656 paid claims with dates of service during our audit period. We excluded from our review claims less than \$100 and certain claims that had been reviewed by the recovery audit contractors (RACs)<sup>13</sup> and other review entities (such as the DME MACs). As a result, our review covered 16,190 paid claims totaling \$5,482,563. We selected a stratified random sample of 100 claims totaling \$47,772.<sup>14</sup>

Pacific Medical provided us with supporting documentation for the sampled claims. The documentation included physician orders, proof of delivery, and medical records that Pacific Medical 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.<sup>15</sup>

<sup>11</sup> The payment amounts represent the total paid amounts for the claims, which included the selected orthotic braces and the related DMEPOS accessories (e.g., various add-on components).

<sup>12</sup> We limited our review to claims that included at least 1 of the 126 HCPCS codes that suppliers used to bill for back, knee, and ankle-foot braces during our audit period.

<sup>13</sup> CMS contracts with RACs to identify improper payments of Medicare claims. RACs conduct postpayment reviews to identify improper payments and recoup any overpayments identified.

<sup>14</sup> Because one sampled claim was canceled before the start of our audit, we treated this claim and the related payment as allowable.

<sup>15</sup> 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.

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.

## **FINDINGS**

Pacific Medical did not always comply with Medicare requirements when billing for selected orthotic braces. For 89 of the 100 sampled claims, Pacific Medical complied with the requirements. However, for the remaining 11 claims, with payments totaling \$4,777, it did not comply with the requirements. Specifically, Pacific Medical:

- billed for orthotic braces that were not medically necessary for nine claims and
- could not provide medical records for two claims.

These deficiencies occurred because Pacific Medical did not always 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. On the basis of our sample results, we estimated that Pacific Medical received at least \$247,493 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 (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. If the information in the beneficiary's medical record does not 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, the supplier is responsible for the dollar amount (the Manual, chapter 5, § 5.7).

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.

## **PACIFIC MEDICAL DID NOT ALWAYS COMPLY WITH MEDICARE REQUIREMENTS WHEN BILLING FOR ORTHOTIC BRACES**

Pacific Medical billed for orthotic braces that were not medically necessary and could not provide medical records for some claims.

### **Pacific Medical Billed for Orthotic Braces That Were Not Medically Necessary**

For nine sampled claims, Pacific Medical 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 box shows an example of a medically unnecessary knee brace provided to a beneficiary.

<b>Example of a Medically Unnecessary Knee Brace</b>
Medicare paid Pacific Medical \$666 for providing a knee brace to a 71-year-old beneficiary on August 28, 2015. According to the physician order, a knee brace for HCPCS code L1845 was prescribed on August 18, 2015. The beneficiary was seen on August 11, 2015, for right knee discomfort; however, the beneficiary had no history of surgery or an identified recent injury. The physician documented an absence of instability in the knee's ligaments and that the beneficiary had only mild narrowing of the medial joint space (i.e., near the middle of the knee on the inner side). As a result, the independent medical review contractor found that the knee brace was not medically necessary.

### **Pacific Medical Could Not Provide Some Beneficiary Medical Records**

For two sampled claims, Pacific Medical billed for orthotic braces for which it could not provide medical records by the end of our fieldwork.

## **CAUSE AND EFFECT OF IMPROPER BILLING OF ORTHOTIC BRACES**

Although Pacific Medical had adequate documentation related to the physician orders and proof of delivery for the orthotic braces, it did not always obtain sufficient information from the beneficiaries' medical records to assure itself that the claims for orthotic braces met Medicare requirements. When we provided Pacific Medical with our preliminary results during the audit, Pacific Medical officials stated that "the claims were billed in error and it will be resolved with additional training and education" for most of the claims.

On the basis of our sample results, we estimated that Pacific Medical received at least \$247,493 in unallowable Medicare payments for orthotic braces.

## RECOMMENDATIONS

We recommend that Pacific Medical:

- refund to the DME MACs \$247,493 in estimated overpayments for orthotic braces (of which \$4,777 was overpayments identified in our sample);<sup>16</sup>
- exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule, and identify any 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.

### PACIFIC MEDICAL COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Pacific Medical did not concur with our first recommendation. However, Pacific Medical concurred with our second and third recommendations to the extent that it continues to conduct self-audits and respond to ongoing RAC audits. Pacific Medical stated that it returns any and all overpayments of which it becomes or is made aware. Pacific Medical's comments are included as Appendix F. We did not include Pacific Medical's attachment with claim information because it contained personally identifiable information.

After reviewing Pacific Medical's comments, we maintain that our recommendations remain valid. As stated in the report, when we provided Pacific Medical with our preliminary results, Pacific Medical acknowledged that most of the claims were billed in error.

### PACIFIC MEDICAL COMMENTS

Regarding our first recommendation, Pacific Medical had the following comments:

- Pacific Medical stated that the estimated overpayment amount is egregious based on the findings of the audit team. Pacific Medical also stated that the extrapolated

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<sup>16</sup> OIG audit recommendations do not represent final determinations by the Medicare program but are recommendations to Department of Health and Human Services (HHS) action officials. Action officials at CMS, acting through a MAC or other contractor, will determine whether a potential overpayment exists and will recoup any overpayments consistent with CMS's policies and procedures. If a disallowance is taken, a supplier has the right to appeal the determination that a payment for a claim was improper (42 CFR § 405.904(a)(2)). The Medicare Part A/B appeals process has five levels, including a contractor redetermination, a reconsideration by a Qualified Independent Contractor, and a decision by the Office of Medicare Hearings and Appeals. If a supplier exercises its right to an appeal, it does not need to return funds paid by Medicare until after the second level of appeal. An overpayment based on extrapolation is re-estimated depending on the result of the appeal.

overpayment request was unexpected and is both unreasonable and unjustified, pointing out that our report fails to reference the authority to extrapolate alleged overpayment amounts.

- Pacific Medical stated that, as an accredited DMEPOS supplier, Pacific Medical follows the direction of referring licensed physicians in providing specific DMEPOS products and services. Pacific Medical stated that it is at all times cognizant of its responsibilities and the magnitude of CMS's requirements for receiving reimbursement for products and services provided, pointing out that "we are not physicians." Pacific Medical also stated that if it fails to follow a physician's prescription and an injury occurs to a patient allegedly as a result of that failure, it is put into a position of potential legal negligence for failing to follow those orders.
- Pacific Medical stated that it believes where Pacific Medical has documentation of an order and delivery, it should receive, at a minimum, reimbursement for the least costly alternative to the product actually delivered.

## OFFICE OF INSPECTOR GENERAL RESPONSE

Our responses to Pacific Medical's comments are as follows:

- Regarding our statistical estimate, Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.<sup>17</sup> We calculated our recommended recovery amount using the lower limit of a two-sided 90-percent confidence interval. This approach is more conservative and less administratively burdensome for the supplier than a review of all of the claims in the sampling frame.<sup>18</sup> Furthermore, our use of statistical sampling by no means removes Pacific Medical's right to appeal through the normal appeals process the individual determinations on which the estimation is based.<sup>19</sup>
- Regarding Pacific Medical's comments on its responsibilities as a supplier, according to the Manual, chapter 5, section 5.8.A, a supplier should obtain as much documentation from a beneficiary's medical record as it determines necessary to assure itself that an orthotic brace meets Medicare requirements. If the information in the medical record

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<sup>17</sup> See *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84 (2d Cir. 1991); *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982); *Momentum EMS, Inc. v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 at \*26-28 (S.D. Tex. 2013), adopted by 2014 U.S. Dist. LEXIS 4474 (S.D. Tex. 2014); *Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

<sup>18</sup> See *Puerto Rico Dep't of Health*, DAB No. 2385, at 10 (2011); *Oklahoma Dep't of Human Servs.*, DAB No. 1436, at 8 (1993).

<sup>19</sup> See *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at \*34 (S.D. Tex. 2012).

does not adequately support the medical necessity of the orthotic brace, the supplier is liable for the dollar amount of the brace, unless a properly executed Advanced Beneficiary Notice of possible denial has been obtained.

- Regarding Pacific Medical's comments on receiving reimbursement for the least costly alternative, we clarified in the footnote to our first recommendation that OIG audit recommendations do not represent final determinations by the Medicare program but are recommendations to HHS action officials. Action officials at CMS, acting through a MAC or other contractor, will determine whether a potential overpayment exists and will recoup any overpayments consistent with CMS's policies and procedures. If a disallowance is taken, a supplier has the right to appeal the determination that a payment for a claim was improper (42 CFR § 405.904(a)(2)). An overpayment based on extrapolation is re-estimated depending on the result of the appeal.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

Pacific Medical received Medicare Part B payments of \$6,224,835 for claims that included the selected orthotic braces, representing 25,656 paid claims with dates of service from January 1, 2015, through March 31, 2017. We excluded from our review 9,380 claims, totaling \$691,830, for claims less than \$100; 9 claims, totaling \$12,034, that had been reviewed by the RACs; and 77 claims, totaling \$38,408, that had been reviewed by other review entities.<sup>20</sup> As a result, our review covered 16,190 claims totaling \$5,482,563. We selected a stratified random sample of 100 claims, totaling \$47,772. Because one sampled claim was canceled before the start of our audit, we treated this claim and the related payment as allowable.

Pacific Medical provided us with supporting documentation for the sampled claims. The documentation included physician orders, proof of delivery, and medical records that Pacific Medical 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. For two sampled claims, Pacific Medical could not provide medical records for the orthotic braces billed. We treated these claims and the related payments as unallowable.

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

We conducted our audit from July 2017 to September 2018, which included fieldwork performed at Pacific Medical's offices in Tracy, California.

### METHODOLOGY

To accomplish our objective, we:

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

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<sup>20</sup> 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 selected orthotic braces that Pacific Medical billed to Medicare for our audit period;<sup>21</sup>
- created a sampling frame of 16,190 claims and reviewed a stratified random sample of 100 claims (Appendix B);
- reviewed data from CMS’s Common Working File for the sampled claims to determine whether claims had been canceled or adjusted;
- obtained documentation from Pacific Medical for the orthotic braces for the sampled claims and provided the documentation to an independent medical review contractor, which determined whether the claims met Medicare requirements;
- reviewed the independent medical review contractor’s results;
- estimated the amount of the unallowable payments for selected orthotic braces billed by Pacific Medical (Appendix C); and
- discussed the results of our review with Pacific Medical 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.

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<sup>21</sup> Our review 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

### TARGET POPULATION

The target population consisted of Pacific Medical’s paid Medicare Part B claims that (1) included at least one of the selected HCPCS codes for orthotic braces and (2) had service dates during our audit period.<sup>22</sup>

### SAMPLING FRAME

We obtained claim data from CMS’s NCH file, representing 25,656 paid claims totaling \$6,224,835. We removed 9,380 claims, totaling \$691,830, for claims less than \$100; 9 claims, totaling \$12,034, that had been reviewed by the RACs; and 77 claims, totaling \$38,408, that had been reviewed by other review entities. As a result, the sampling frame consisted of 16,190 paid claims totaling \$5,482,563.

### SAMPLE UNIT

The sample unit was a claim that included one of the selected orthotic braces.

### SAMPLE DESIGN

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

**Table 2: Strata**

Stratum	Description	No. of Claims	Payment
1	Claims greater than or equal to \$100 and less than \$500	12,247	\$2,496,806
2	Claims greater than or equal to \$500	3,943	2,985,757
<b>Total</b>		<b>16,190</b>	<b>\$5,482,563</b>

### SAMPLE SIZE

We selected a total of 100 claims. We selected 50 claims from each stratum.

### SOURCE OF RANDOM NUMBERS

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

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<sup>22</sup> We limited our review to claims that included at least 1 of the 126 HCPCS codes that suppliers used to bill for back, knee, and ankle-foot braces during our audit period.

## **METHOD OF SELECTING SAMPLE ITEMS**

We consecutively numbered the sample units in each stratum. After generating random numbers for each stratum, 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 will be less than the actual overpayment total at least 95 percent of the time.

**APPENDIX C: SAMPLE RESULTS AND ESTIMATES**

**Table 3: Sample Results**

<b>Stratum</b>	<b>No. of Items in Sampling Frame</b>	<b>Value of Frame</b>	<b>Sample Size</b>	<b>Value of Sample</b>	<b>No. of Unallowable Sample Items</b>	<b>Value of Unallowable Sample Items</b>
1	12,247	\$2,496,806	50	\$10,407	4	\$698
2	3,943	2,985,757	50	37,365	7	4,079
<b>Total</b>	<b>16,190</b>	<b>\$5,482,563</b>	<b>100</b>	<b>\$47,772</b>	<b>11</b>	<b>\$4,777</b>

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

Point estimate	\$492,735
Lower limit	247,493
Upper limit	737,977

**APPENDIX D: RELATED OFFICE OF INSPECTOR GENERAL REPORTS**

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>Medicare Payments for Orthotics: Inappropriate Payments</i>	<a href="#"><u>OEI-02-99-00120</u></a>	3/2000
<i>Medicare Allowed Charges for Orthotic Body Jackets</i>	<a href="#"><u>OEI-04-97-00391</u></a>	3/2000
<i>Orthotic Procedure Code Claims Paid to Medassist-OP, Inc. by Medicare During the Period January 1, 1994 to December 31, 1996</i>	<a href="#"><u>A-02-97-01039</u></a>	11/2/1999
<i>Medicare Payments for Orthotic Body Jackets</i>	<a href="#"><u>OEI-04-97-00390</u></a>	9/1999
<i>Medicare Orthotics</i>	<a href="#"><u>OEI-02-95-00380</u></a>	10/1997
<i>Medicare Payments for Orthotic Body Jackets</i>	<a href="#"><u>OEI-04-92-01080</u></a>	6/1994

## 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.”

#### Medicare Program Integrity Manual

The Manual, chapter 5, section 5.7, outlines the requirements 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. . . .

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 requirements 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 [Advance Beneficiary Notice] of possible denial has been obtained.

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

## Local Coverage Determinations

The LCDs outline the conditions under which the DME MACs will cover back, knee, and ankle-foot braces.<sup>23</sup> (These braces are referred to in the LCDs as "orthoses.")

### *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) (L11459)*].

### *Knee Braces*

A knee orthosis with joints (L1810, L1812) or knee orthosis with condylar pads and joints with or without patellar control (L1820) are covered for ambulatory beneficiaries who have weakness or deformity of the knee and require stabilization. If [the knee orthosis] is provided but the criteria above are not met, the orthosis will be denied as not reasonable and necessary [*LCD: Knee Orthoses (L33318) (L27058)*].

A knee immobilizer without joints (L1830), or a knee orthosis with adjustable knee joints (L1832, L1833), or a knee orthosis, with an adjustable flexion and extension joint that provides both medial-lateral and rotation control (L1843, L1845, L1851, L1852), are covered if the beneficiary has had recent injury to or a surgical procedure on the knee(s). . . . Knee orthoses L1832, L1833, L1843, L1845, L1851 and L1852 are also covered for a beneficiary who 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

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<sup>23</sup> In the LCD citations that follow, the first LCD number refers to the LCD in effect for the first part of our audit period (January 1 through September 30, 2015), and the second LCD number refers to the LCD in effect for the second part of our audit period (October 1, 2015, through March 31, 2017).

if only pain or a subjective description of joint instability is documented [*LCD: Knee Orthoses (L33318) (L27058)*].

### *Ankle-Foot Braces*

Ankle-foot orthoses [L1900, L1902-L1990, L2106-L2116, L4350, L4360, L4361, L4386, L4387, L4631] . . . are covered for ambulatory beneficiaries with weakness or deformity of the foot and ankle, who: (1) require stabilization for medical reasons, and, (2) have the potential to benefit functionally. . . . If the basic coverage criteria for [ankle-foot orthoses] are not met, the orthosis will be denied as not reasonable and necessary [*LCD: Ankle-Foot/Knee-Ankle-Foot Orthosis (L33686) (L142)*].

## **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.”

### **Medicare Program Integrity Manual**

The Manual, chapter 5, sections 5.2.2 and 5.8(A), (B), and (D), detail the documentation requirements for orthotic braces:

Suppliers may dispense most items of DMEPOS based on a verbal order or preliminary written order from the treating physician. This order must include: a description of the item, the beneficiary’s name, the physician’s name and the start date of the order. Suppliers must maintain the preliminary written order or written documentation of the verbal order and this documentation must be available to the DME MACs, Zone Program Integrity Contractors (ZPICs) or other CMS review contractor upon request. If the supplier does not have an order from the treating physician before dispensing an item, the contractor shall consider the item as noncovered.

Before submitting a claim to the DME MAC the supplier must have on file a dispensing order, the detailed written order, the [Certificate of Medical Necessity] (if applicable), the [DME Information Form] (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.

## APPENDIX F: PACIFIC MEDICAL COMMENTS



December 5, 2018

Lori Ahlstrand  
Regional Inspector General  
Office of Audit Services, Region IX  
90 – 7<sup>th</sup> Street, Suite 3-650  
San Francisco, CA 94103

**Re: Pacific Medical, Inc.'s response re: Report No. A-09-17-03027**

Dear Ms. Ahlstrand:

Please allow the following to serve as Pacific Medical, Inc.'s written response to the draft report entitled *Pacific Medical, Inc. Received Some Unallowable Medicare Payments for Orthotic Braces*. Pacific Medical, Inc. expended a significant amount of time and resources in assisting and educating the OIG audit team throughout the fourteen (14) month audit process. We worked closely with the audit team providing a significant amount of education regarding Medicare billing requirements for DMEPOS as well as the processes through which DME Suppliers/Providers go to provide products and services to the Medicare patient population.

We do not concur with the first recommendation in the draft letter as the estimated overpayment amount is egregious based on the findings of the audit team. The draft report states clearly on page 6 that "Pacific Medical had adequate documentation related to the physician orders and proof of delivery for the orthotic braces." Pacific Medical is a credentialed and accredited DMEPOS supplier in good standing with both CMS and ABC. We are routinely audited by RAC contractors on random claims and go through all required accreditation processes set forth by CMS and ABC. Clearly we do not have a situation where Pacific Medical has committed any type of fraud or abuse of the Medicare payment system. The extrapolated overpayment request of \$247,493 was certainly unexpected and is both unreasonable and unjustified (the report fails to reference authority to extrapolate alleged overpayment amounts).

As an accredited DMEPOS supplier Pacific Medical follows the direction of referring licensed physicians in providing specific DMEPOS products and services. We are at all times cognizant of our responsibilities and the magnitude of requirements set forth by CMS to receive reimbursement for products and services provided. However, we are not physicians. If we fail to follow a physician's prescription and an



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injury occurs to a patient allegedly as a result of that failure, we are put in a position of potential legal negligence for failing to follow those orders. Again, we do not concur with the first recommendation in the draft letter as the estimated overpayment amount is egregious based on the findings of the audit team.

Given the above, we believe where Pacific Medical has documentation of an order and delivery, Pacific Medical should receive, at a minimum, the reimbursement for the least costly alternative to the product actually delivered. While we are still challenged by this result and the extrapolation calculation and would request terms in making any repayments, we believe it is a far more reasonable and fair outcome than the one currently proposed.

With regards to recommendations two (2) and (3), Pacific Medical concurs to the extent that it continues to conduct self audits and respond to ongoing RAC audits which are received on a continual basis. Pacific Medical returns any and all overpayments of which it becomes or is made aware.

Thank you in advance for your attention to this matter. Should you have any questions or wish to discuss in more detail, please feel free to contact me at [mweaver@pacmedical.com](mailto:mweaver@pacmedical.com) or 800 726-9180 ext 7006.

Respectfully,

Mark Weaver  
General Counsel  
Pacific Medical, Inc.