

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**KELLEY MEDICAL
EQUIPMENT AND SUPPLY, LLC,
RECEIVED UNALLOWABLE
MEDICARE PAYMENTS FOR
ORTHOTIC BRACES**

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Office of Inspector General

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Report in Brief

Date: January 2019

Report No. A-09-17-03030

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. During our audit period, the Centers for Medicare & Medicaid Services found that orthotic braces were among the top 20 items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) with the highest improper payment rates. Prior OIG reviews found that some DMEPOS suppliers billed for orthotic braces that did not comply with Medicare billing requirements. After analyzing Medicare claim data, we selected for review Kelley Medical Equipment and Supply, LLC (Kelley Medical), an orthotic braces supplier in Durant, Oklahoma.

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

How OIG Did This Review

For our audit period, Kelley Medical received almost \$6.7 million in Medicare Part B payments for selected orthotic braces provided to 7,189 Medicare beneficiaries. After excluding certain claims, we grouped the remaining claims by beneficiary and reviewed a stratified random sample of 100 beneficiaries. We provided copies of Kelley Medical's supporting documentation to a medical review contractor to determine whether claims for orthotic braces met Medicare requirements.

Kelley Medical Equipment and Supply, LLC, Received Unallowable Medicare Payments for Orthotic Braces

What OIG Found

Kelley Medical did not always comply with Medicare requirements when billing for selected orthotic braces. For 24 of the 100 sampled beneficiaries, Kelley Medical complied with the requirements. However, for the remaining 76 beneficiaries, it did not comply with the requirements. Specifically, Kelley Medical billed for orthotic braces that were not medically necessary for 67 beneficiaries and could not provide medical records for 9 beneficiaries.

These deficiencies occurred because Kelley 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 Kelley Medical received at least \$4 million in unallowable Medicare payments for orthotic braces.

What OIG Recommends and Kelley Medical Comments

We recommend that Kelley Medical (1) refund to the durable medical equipment Medicare administrative contractors \$4 million 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.

Kelley Medical disputed our findings and recommendations. Regarding our first recommendation, Kelley Medical disputed that it received Medicare overpayments for orthotic braces and stated that it obtained appropriate documentation at all times, HHS's regulations are unequally applied and have no rational basis, and the extrapolated results are flawed. Regarding our second recommendation, Kelley Medical disputed that it was "in violation of any overpayment." Regarding our third recommendation, Kelley Medical disputed that it had failed to meet its obligations for the reasons given in its response to our first recommendation.

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

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INTRODUCTION

WHY WE DID THIS 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, Kelley Medical Equipment and Supply, LLC (Kelley Medical), an orthotic braces supplier in Durant, Oklahoma.¹

OBJECTIVE

Our objective was to determine whether Kelley 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.² To be paid by Medicare, a service or an item must be reasonable and necessary for the diagnosis or treatment of illness or injury

¹ We issued a report covering another supplier in California: *Pacific Medical, Inc., Received Some Unallowable Medicare Payments for Orthotic Braces (A-09-17-03027)*, issued December 31, 2018.

² The Social Security Act (the Act) § 1832(a)(1) and §§ 1861(s)(5), (s)(6), (s)(8), and (s)(9).

or to improve the functioning of a malformed body member.³ Orthotic braces are defined as “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.”⁴

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.⁵ 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.⁶ 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)⁷ for some covered orthotic braces. The LCDs outline the conditions under which DME MACs will pay suppliers for those braces.

³ The Act § 1862(a)(1)(A).

⁴ CMS's *Medicare Benefit Policy Manual*, Pub. No. 100-02, chapter 15, § 130.

⁵ Before July 1, 2016, there were four DME MACs, each covering one jurisdiction.

⁶ HCPCS codes are used throughout the healthcare industry to standardize coding for medical procedures, services, products, and supplies.

⁷ 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:⁸

- 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,⁹ 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.¹⁰

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).¹¹

Kelley Medical Equipment and Supply

Kelley Medical is a family owned and operated supplier in Durant, Oklahoma. For our audit period, Kelley Medical received \$6,731,911 in Medicare Part B payments. Approximately 99 percent of these payments were for orthotic braces, primarily back and knee braces, provided to 7,189 Medicare beneficiaries in all States and territories, except Alaska. Table 1 on the following page shows a breakdown of the payments.

⁸ CMS's *Medicare Program Integrity Manual*, Pub. No. 100-08 (the Manual), chapter 5, §§ 5.2.2 and 5.8(A), (B), and (D).

⁹ A modifier is a two-digit code that further describes the service performed, such as indicating the limb affected.

¹⁰ The Manual, chapter 5, § 5.8(A).

¹¹ 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 Kelley Medical
for Back and Knee Braces and Other DMEPOS**

Year	Payment for Back Braces	Payment for Knee Braces	Payment for Other DMEPOS	Total Payments by Year
2015	\$1,299,832	\$1,234,060	\$40,898	\$2,574,790
2016	1,669,897	1,658,209	24,499	3,352,605
2017 (Jan.–Mar.)	375,265	422,818	6,433	804,516
Total	\$3,344,994	\$3,315,087	\$71,830*	\$6,731,911
Percentage of Total Payment	49.7%	49.2%	1.1%	100%
* Includes ankle-foot braces.				

HOW WE CONDUCTED THIS REVIEW

Kelley Medical received Medicare Part B payments of \$6,674,764 for selected orthotic braces¹² provided to 7,189 Medicare beneficiaries, representing 8,684 paid claims with dates of service during our audit period. We excluded from our review certain claims that had been reviewed by the recovery audit contractors (RACs)¹³ and other review entities (such as the DME MACs). We then grouped the claims by beneficiary. As a result, our review covered 7,067 beneficiaries, representing 8,508 paid claims totaling \$6,530,929. We selected a stratified random sample of 100 beneficiaries¹⁴ and reviewed 135 claims, totaling \$103,718, that were associated with the sampled beneficiaries.¹⁵

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

¹² 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.

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

¹⁴ The sample unit was a beneficiary, not a claim, because some beneficiaries in the sampling frame had two claims for orthotic braces.

¹⁵ Of the 135 claims, 2 were canceled before the start of our audit. We treated these two claims and the related payments as allowable.

independent medical review contractor to determine whether the claims for orthotic braces met Medicare requirements.¹⁶

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

Kelley Medical did not always comply with Medicare requirements when billing for selected orthotic braces. For 24 of the 100 sampled beneficiaries, Kelley Medical complied with the requirements. However, for the remaining 76 beneficiaries, with payments totaling \$76,964, it did not comply with the requirements. Specifically, Kelley Medical:

- billed for orthotic braces that were not medically necessary for 67 beneficiaries and
- could not provide medical records for 9 beneficiaries.

These deficiencies occurred because Kelley 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 Kelley Medical received at least \$4,079,308 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).

¹⁶ 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.

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.

KELLEY MEDICAL DID NOT ALWAYS COMPLY WITH MEDICARE REQUIREMENTS WHEN BILLING FOR ORTHOTIC BRACES

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

Kelley Medical Billed for Orthotic Braces That Were Not Medically Necessary

For 67 sampled beneficiaries, Kelley 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 are examples of medically unnecessary back and knee braces provided to beneficiaries.

Example of Medically Unnecessary Back and Knee Braces for the Same Beneficiary

Medicare paid Kelley Medical \$1,282 for providing a back brace and a left knee brace to a 60-year-old beneficiary. According to the physician order dated September 21, 2016, the back brace was prescribed for low back pain, and the knee brace was prescribed for arthritis of the knee. However, the medical record showed that there was no history or mention of recent injury to or surgery on the beneficiary’s spine or knee, and there was no mention of deformity, weakness, or complaints of pain with motion or mobility affecting the spine. The physician notes described the beneficiary’s posture while standing and walking as normal, despite weakness of the right side of the body, and there was no mention of a back or knee brace. Rather, according to the medical records, the beneficiary saw the physician multiple times from August 6, 2015, through June 13, 2016, to obtain necessary documentation for dental work and to have followups for blood work to monitor diabetes and hypertension. As a result, the independent medical review contractor found that the back and knee braces were not medically necessary.

Example of a Medically Unnecessary Back Brace

Medicare paid Kelley Medical \$754 for providing a back brace to a 62-year-old beneficiary. According to the physician order dated March 7, 2017, the brace was prescribed for lower back pain. However, the medical records did not indicate a complaint of back pain, and there was no mention of a back brace. Rather, according to the medical records, the beneficiary saw his physician on March 2, 2017, for relief of persistent cough and chest congestion. As a result, the independent medical review contractor found that the back brace was not medically necessary.

Example of a Medically Unnecessary Knee Brace

Medicare paid Kelley Medical \$515 for providing a knee brace to a 77-year-old beneficiary. According to the physician order dated November 2, 2016, the brace was prescribed for arthritis of the knee. However, the medical record showed that the beneficiary made no complaint of knee pain or instability when walking, and there was no history of a recent surgery or injury and no mention of a knee brace. Rather, according to the medical records, the beneficiary saw the physician twice: once on August 22, 2016, to manage her digestive disorder and again on September 16, 2016, to establish care. As a result, the independent medical review contractor found that the knee brace was not medically necessary.

Kelley Medical Could Not Provide Some Beneficiary Medical Records

For nine sampled beneficiaries, Kelley Medical billed for orthotic braces for which it could not provide medical records by the end of our fieldwork. Kelley Medical officials stated that they planned to refund the Medicare payments for those braces.

CAUSE AND EFFECT OF IMPROPER BILLING OF ORTHOTIC BRACES

Although Kelley 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. The independent medical review contractor's evaluation of 67 of the 100 sampled beneficiaries' medical records found that the medical records did not contain sufficient information related to each beneficiary's medical condition to substantiate the necessity for the type and quantity of items ordered. Kelley Medical officials stated that they "considered a Detailed Written Order signed by the ordering physician sufficient documentation to support the dispensing of the device based upon a valid prescription. Kelley Medical asserts that the totality of the information in the medical records will support medical necessity of the brace."

On the basis of our sample results, we estimated that Kelley Medical received at least \$4,079,308 in unallowable Medicare payments for orthotic braces.

RECOMMENDATIONS

We recommend that Kelley Medical:

- refund to the DME MACs \$4,079,308 in estimated overpayments for orthotic braces (of which \$76,964 was overpayments identified in our sample);¹⁷
- 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.

KELLEY MEDICAL COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Kelley Medical disputed our findings and recommendations. A summary of Kelley Medical's comments and our responses follow. Kelley Medical's comments are included in their entirety as Appendix F.

After reviewing Kelley Medical's comments, we maintain that our findings and recommendations remain valid. The independent medical review contractor found that the information in the beneficiaries' medical records did not support the medical necessity of the orthotic braces.

MEDICAL REVIEW OF BENEFICIARY MEDICAL RECORDS

Kelley Medical Comments

In its introductory comments, Kelley Medical stated that our draft report did not provide any detail as to why the vast majority of the claims were found medically unnecessary. Kelley

¹⁷ 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 provider 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 provider 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.

Medical also stated that the independent medical review contractor that determined which claims were medically necessary reviewed only an artificially limited collection of each beneficiary's medical records; namely, medical records from the treating physician only. Kelley Medical commented that medical records, however, may reside with any number of providers of which Kelley Medical is unaware. Kelley Medical stated that it believes a review of each beneficiary's full medical records, as well as context from the treating physician, would show that every claim was medically necessary.

Office of Inspector General Response

The independent medical review contractor found that the information in the beneficiaries' medical records did not support the medical necessity of the orthotic braces. Kelley Medical provided medical records from the treating physicians that signed the physician orders for the orthotic braces and did not indicate that it needed additional time or that there might have been additional medical records to consider. We gave Kelley Medical the opportunity to provide documentation during our fieldwork from August to October 2017. In addition, OIG audit recommendations do not represent final determinations by the Medicare program but are recommendations to HHS action officials. Action officials at CMS, acting through a MAC or another contractor, can review any additional information that Kelley Medical would like to provide and will determine whether a potential overpayment exists and will recoup any overpayments consistent with CMS's policies and procedures. If a disallowance is taken, a provider has the right to appeal the determination that a payment for a claim was improper (42 CFR § 405.904(a)(2)).

FIRST RECOMMENDATION

Regarding our first recommendation, Kelley Medical disputed that it received \$4,079,308 in Medicare overpayments for orthotic braces and stated that (1) it obtained appropriate documentation at all times, (2) HHS's regulations are unequally applied and have no rational basis, and (3) the extrapolated results are flawed.

Documentation

Kelley Medical Comments

Kelley stated that it obtained all required documentation before dispensing any DMEPOS item or billing Medicare for it. Kelley Medical also stated that for every claim in our sample, it followed the Medicare billing requirements to the letter. Kelley Medical stated that it did not generally obtain the beneficiary's medical records before submitting a claim but that section 5.7 of the Manual does not require this: "The documentation in the patient's medical record does not have to be routinely sent to the supplier . . ." Kelley Medical said that it relied on a prescription signed by the treating physician, as well as the physician's signed certification that a DMEPOS item was medically necessary.

Office of Inspector General Response

The Manual, chapter 5, section 5.8(A), states that a supplier should obtain as much documentation from the 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 does not adequately support the medical necessity of the orthotic brace, the supplier is responsible for the payment amount of the brace. The Manual, chapter 5, section 5.7, states that neither a physician's order nor a Certificate of Medical Necessity (CMN) nor a DME Information Form (DIF) nor a supplier-prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier. Section 5.7 also states that 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.

HHS Regulations

Kelley Medical Comments

Kelley Medical stated that the DMEPOS regulations impose an unfair burden on suppliers—one that no other supplier faces throughout the healthcare system—and that suppliers are expected to act as unlicensed healthcare providers and second-guess the professional judgment of doctors to prevent the payment of medically unnecessary claims. Kelley Medical also stated that HHS imposes liability on suppliers for physicians' actions, both when a physician writes a medically unnecessary prescription and when a prescription is medically necessary but insufficiently documented as determined by an independent reviewer. Kelley Medical said that suppliers, though, have no control over physicians' actions in either scenario and no practical way to alter their behavior. In addition, Kelley Medical stated that the Manual does not require physicians to provide medical records to a supplier before the supplier can dispense a DMEPOS item. Kelley Medical stated that, as a consequence, its experience is that physicians categorically refuse to provide medical records to suppliers except in response to an audit or a similar investigation.

Office of Inspector General Response

According to section 1862(a)(1)(A) of the Act, no payment may be made under Medicare Part A or Part B for any expenses incurred for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Although the supplier is not required to maintain all documentation, according to the Manual, chapter 5, § 5.8(A), a supplier should 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 liable for the dollar amount of the brace, unless a properly executed Advanced Beneficiary Notice (ABN) of possible denial

has been obtained. In that case, the beneficiary would be responsible for the dollar amount. The independent medical review contractor found that the information in the beneficiaries' medical records did not support the medical necessity of the orthotic braces, and Kelley Medical did not provide ABNs for any of the claims submitted.

Extrapolated Results

Kelley Medical Comments

Kelley Medical stated that it believes that the extrapolated results are flawed because they rely on incomplete data. Kelley Medical also stated that our audit did not allow for sufficient time to gather the records necessary to defend an audit and said that it was given 30 days to obtain records from 100 patients residing in 49 different States. Kelley Medical said that this put it in the position of being unable to review, analyze, and follow up with other providers to try to obtain additional records. Kelley Medical stated that to utilize such results from the flawed audit to extrapolate to the entire list of all beneficiaries is unfair and unconscionable.

Office of Inspector General Response

We maintain that our estimated overpayment remains valid because of our responses to Kelley Medical's comments on the medical review of beneficiary medical records. Kelley Medical provided medical records from the treating physicians that signed the physician orders for the orthotic braces and did not indicate that it needed additional time or that there might have been additional medical records to consider. We gave Kelley Medical the opportunity to provide documentation during our fieldwork from August to October 2017. In addition, OIG audit recommendations do not represent final determinations by the Medicare program but are recommendations to HHS action officials.

SECOND AND THIRD RECOMMENDATIONS

Kelley Medical Comments

Regarding our second recommendation, Kelley Medical stated that it agrees that the wording of our recommendation correctly states the supplier's obligation under CMS's 60-day rule but disputed that it was "in violation of any overpayment" for the reasons it gave in the response to our first recommendation.

Regarding our third recommendation, Kelley Medical stated that it agrees that obtaining as much information from beneficiary medical records as it determines necessary to assure itself that claims for orthotic braces meet Medicare requirements correctly states the supplier's obligation under the Manual, but it disputed that it had failed to meet its obligations for the reasons given in its response to our first recommendation.

Office of Inspector General Response

We maintain that our second and third recommendations remain valid because of our responses to Kelley Medical's comments on the first recommendation.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Kelley Medical received Medicare Part B payments of \$6,674,764 for selected orthotic braces provided to 7,189 Medicare beneficiaries, representing 8,684 paid claims with dates of service from January 1, 2015, through March 31, 2017. We excluded from our review 3 claims, totaling \$2,681, that had been reviewed by the RACs and 173 claims, totaling \$141,154, that had been reviewed by other review entities.¹⁸ We then grouped the claims by beneficiary and created a sampling frame of 7,067 beneficiaries, representing 8,508 claims totaling \$6,530,929. We selected a stratified random sample of 100 beneficiaries and reviewed 135 claims, totaling \$103,718, that were associated with the sampled beneficiaries. For two sampled beneficiaries, two claims were canceled before the start of our audit. We treated these two claims and the related payments as allowable.

Kelley Medical provided us with supporting documentation for the sampled beneficiaries. The documentation included physician orders, proof of delivery, and medical records that Kelley 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 9 sampled beneficiaries, representing 12 claims, Kelley 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 Kelley 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 August 2018, which included fieldwork performed at Kelley Medical's offices in Durant, Oklahoma.

METHODOLOGY

To accomplish our objective, we:

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

¹⁸ 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 Kelley Medical billed to Medicare for our audit period;¹⁹
- created a sampling frame of 7,067 beneficiaries and reviewed a stratified random sample of 100 beneficiaries (Appendix B);
- reviewed data from CMS’s Common Working File for the sampled beneficiaries’ claims to determine whether claims had been canceled or adjusted;
- obtained documentation from Kelley Medical for the orthotic braces for the sampled beneficiaries and provided the documentation to an independent medical review contractor, which determined whether the claims met Medicare requirements;
- reviewed the independent medical review contractor’s results;
- estimated the amount of the unallowable payments for selected orthotic braces billed by Kelley Medical (Appendix C); and
- discussed the results of our review with Kelley 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.

¹⁹ 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 Kelley 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 the audit period.²⁰

SAMPLING FRAME

We obtained claim data from CMS’s NCH file, representing 8,684 paid claims totaling \$6,674,764. We removed 3 claims, totaling \$2,681, that had been reviewed by the RACs and removed 173 claims, totaling \$141,154, that had been reviewed by other review entities. We then grouped the claims by beneficiary. As a result, the sampling frame consisted of 7,067 beneficiaries, representing 8,508 paid claims totaling \$6,530,929.

SAMPLE UNIT

The sample unit was a beneficiary.²¹ We reviewed the claims associated with each beneficiary.

SAMPLE DESIGN

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

Table 2: Strata

Stratum	Description	No. of Beneficiaries	No. of Claims	Payment
1	Beneficiaries with one Medicare claim	5,631	5,631	\$4,263,196
2	Beneficiaries with two Medicare claims	1,436	2,877	2,267,733
Total		7,067	8,508	\$6,530,929

SAMPLE SIZE

We selected a total of 100 beneficiaries, consisting of 65 beneficiaries from stratum 1 and 35 beneficiaries from stratum 2.

²⁰ 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.

²¹ The sample unit was a beneficiary, not a claim, because some beneficiaries in the sampling frame had two claims for orthotic braces.

SOURCE OF RANDOM NUMBERS

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

METHOD OF SELECTING SAMPLE ITEMS

We consecutively numbered the sample units in each stratum. After generating 65 random numbers for stratum 1 and 35 random numbers for stratum 2, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

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

Stratum	No. of Items in Sampling Frame	Value of Frame	Sample Size	Value of Sample	No. of Unallowable Sample Items	Value of Unallowable Sample Items
1	5,631	\$4,263,196	65	\$49,869	41	\$30,878
2	1,436	2,267,733	35	53,849	35	46,086
Total	7,067	\$6,530,929	100	\$103,718	76	\$76,964

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

Point estimate	\$4,565,793
Lower limit	4,079,308
Upper limit	5,052,277

APPENDIX D: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Pacific Medical, Inc., Received Some Unallowable Medicare Payments for Orthotic Braces</i>	<u>A-09-17-03027</u>	12/2018
<i>Medicare Payments for Orthotics Inappropriate Payments</i>	<u>OEI-02-99-00120</u>	3/2000
<i>Medicare Allowed Charges for Orthotic Body Jackets</i>	<u>OEI-04-97-00391</u>	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>	<u>A-02-97-01039</u>	11/2/1999
<i>Medicare Payments for Orthotic Body Jackets</i>	<u>OEI-04-97-00390</u>	9/1999
<i>Medicare Orthotics</i>	<u>OEI-02-95-00380</u>	10/1997
<i>Medicare Payments for Orthotic Body Jackets</i>	<u>OEI-04-92-01080</u>	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. . . .

Neither a physician’s order nor a CMN nor a DIF nor a supplier prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier. . . .

The documentation in the [beneficiary’s] medical record does not have to be routinely sent to the supplier or to the DME MACs, DME PSCs [program safeguard contractors], or ZPICs [zone program integrity contractors]. However, the DME MACs, DME PSCs, or ZPICs may request this information in selected cases. If [they] do not receive the information when requested or if the information in the [beneficiary’s] medical record does not adequately support the medical necessity for the item, then on assigned claims the supplier is liable for the dollar amount involved

The Manual, chapter 5, section 5.8.A, provides additional 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.²² (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 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.,

²² 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).

varus/valgus instability, anterior/posterior Drawer test). Claims for [these knee orthoses] will be denied as not reasonable and necessary when the beneficiary does not meet the above criteria for coverage. For example, they will be denied if only pain or a subjective description of joint instability is documented [*LCD: Knee Orthoses (L33318) (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 CMN (if applicable), the DIF (if applicable), information from the treating physician concerning the [beneficiary’s] diagnosis, and any information required for the use of specific

modifiers or attestation statements as defined in certain DME MAC policies. Documentation must be maintained in the supplier's files for seven (7) years from date of service. . . .

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

APPENDIX F: KELLEY MEDICAL COMMENTS



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December 6, 2018

Via Federal Express

Lori A. Ahlstrand
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Office of Audit Services, Region IX
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And

Via Email

Lorrali Herrera—Lorrali.Herrera@oig.hhs.gov

Re: *Kelley Medical Equipment and Supply, LLC's, response to Draft Report A-09-17-03030*

Dear Ms. Ahlstrand and Ms. Herrera:

Kelley Medical Equipment and Supply, LLC (“Kelley Medical”), has fully reviewed Draft Report Number A-09-17-03030 (“Draft Report”), entitled *Kelley Medical Equipment and Supply, LLC, Received Unallowable Medicare Payments for Orthotic Braces*.

While Kelley Medical has endeavored to respond to the Draft Report’s findings, the Draft Report does not provide any detail as to why the vast majority of the claims were found medically unnecessary. Further, the independent medical review contractor that determined which claims were medically necessary only reviewed an artificially-limited collection of each beneficiary’s medical records—namely medical records from the treating physician only. Medical records, however, may reside with any number of providers of which Kelley Medical is unaware. The limited scope of the independent medical review contractor’s examination, as well as Kelley

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Medical's ignorance of the basis for its subjective determination of medical non-necessity for all but three of the 76 disallowed claims, prevents Kelley Medical from responding to the Draft Report in a fully-informed manner. Nevertheless, Kelley Medical believes that a review of each beneficiary's full medical records, as well as context from the treating physician would show that every claim was medically necessary. Despite the significant limitations it faces in doing so, Kelley Medical provides the following response:

I. Kelley Medical's Specific Response to the Draft Report's Recommendations

In response to the specific recommendations, Kelley Medical states as follows:

A.

Recommendation: [Kelley Medical should] refund the DME MACs \$4,079,308 in estimated overpayments for orthotic braces (of which \$76,964 was overpayments identified in our sample):

For the reasons stated below, Kelley Medical disputes that it received \$4,079,308 in Medicare overpayments for orthotic braces.

1. Kelley Medical Obtained Appropriate Documentation At All Times

The Draft Report premises its recommendations on finding that "Kelley Medical did not always comply with Medicare requirements when billing" Draft Report at pg. 5. In every case, however, Kelley Medical obtained all required documentation before dispensing any DMEPOS item or billing Medicare for it.

The Medicare requirements for billing are contained in Section Five of the Medicare Program Integrity Manual ("MPIM.") Prior to submitting a claim for an orthotic brace, a supplier must have

[A] dispensing order, the detailed written order, the CMN (if applicable), the DIF (if applicable), information from the treating physician concerning the patient's diagnosis, and any information required for the use of specific modifiers or attestation statements as defined in certain DME MAC policies.

DPIM § 5.8.

For every claim in the reviewed sample, Kelley Medical followed these regulations to the letter. Before it dispensed or billed for a DMEPOS item, it obtained the required documentation. Kelley Medical even went a step beyond the DPIM requirements and requested that physicians submit a signed certification attesting that the prescribed item was, in the physician's trained and expert opinion, medically necessary. During the time period at issue in this audit, Kelley Medical also sent a letter to prescribing physicians informing them of what information CMS required for the patient's medical record in order for the prescription to be medically necessary.

Kelley Medical did not generally obtain the beneficiary's medical records before submitting a claim, but the MPIM specifically does not require this. *See* MPIM § 5.7 (“The documentation in the patient’s medical record does not have to be routinely sent to the supplier”) To ensure that it was appropriately dispensing DMEPOS items, however, Kelley Medical had two options. It could either obtain and review all of a proposed beneficiary’s medical records upon receiving a prescription before it dispensed an item, or it could rely upon the medical training and expertise of the physician, as well as the physician’s professional incentive to not prescribe medically-unnecessary items. Kelley Medical chose the latter, but even if it had wanted to obtain the beneficiary’s medical records first, it would have been nearly impossible to do so because they may be held by parties other than the prescribing physician that are unknown to Kelley Medical. Thus, in dispensing a DMEPOS item, Kelley Medical relied upon a prescription signed by the treating physician, as well the physician’s signed certification that the DMEPOS item was medically necessary.

2. The HHS’s Regulations Are Unequally Applied And Have No Rational Basis

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

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

Doctors treat patients. They have the opportunity to speak with them and ask questions about their ailments and medical history. As trained and licensed medical professionals, they are also in the best position to determine whether a patient needs a prescription for a DMEPOS item.

Despite the physicians’ much greater knowledge and access to the patient, the MPIM requires DMEPOS suppliers like Kelley Medical to undertake a second-level review for every claim and second-guess a physician’s determination that a prescription for a DMEPOS item is medically necessary. This is not something that Kelley Medical’s management is trained to do. They are not health care providers. They have not gone to medical school, done a residency, or taken any licensing examinations. They simply own a business that serves to effectuate the treatment directions of trained medical providers.

Requiring suppliers to second-guess the medical judgment of trained physicians with a full patient history will not make the Medicare system better nor will it do anything to prevent a

physician from writing medically-unnecessary prescriptions. Instead, if a supplier second-guesses a prescription, the only effect will be that the physician simply places the order with a supplier that does not question her medical judgment. OIG thus expects Kelley Medical to choose between going out of business by questioning physicians' medical judgment or incurring the wrath of OIG for failing to do so.

Even if suppliers could reasonably ensure the medical necessity of every DMEPOS prescription without going out of business, doing so is not feasible. Suppliers do not have easy or quick access to the relevant medical records.

The MPIM does not require physicians to provide medical records to a DMEPOS supplier before the supplier can dispense a DMEPOS item. As a consequence, it is Kelley Medical's experience that physicians categorically refuse to provide medical records to suppliers except in response to an audit or similar investigation.

Complicating things further, most physicians do not store their records on-site. Instead, they store them off-site with third-party vendors. These third-party vendors, however, require that all records requests come directly from a physician. The records vendors refuse to entertain any requests from a supplier like Kelley Medical. Thus, in most cases, in order to access a patient's medical records before dispensing an orthotic, Kelley Medical would have to have the treating physician request them from a third-party vendor, the very same physician that refuses to provide medical records on a regular basis.

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

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

This is not the case with Kelley Medical. It may not rely on the physician's training, expertise, and judgment that a prescription is medically necessary. Rather its non-medically licensed management is required to decide whether the doctor's determination of medical necessity is correct. There is no rational basis for such unequal treatment.

3. The extrapolation results are flawed

Kelley Medical believes that the extrapolated results are flawed because the results rely upon incomplete data. The OIG audit did not allow Kelley Medical sufficient time to gather the records necessary to defend an audit. The normal time provided to Kelley Medical to respond to a Medicare audit or any other contractor audit is 45 days. Even more importantly, a typical Medicare or contractor audit involves only one patient. Thus, in the typical case Kelley Medical has time to gather the records, review the records and potentially contact other providers identified in the review of such records. This allows sufficient time to also track down any missing records. However, in this audit, Kelley Medical was given 30 days to obtain the records from 100 patients (who were residing in 49 different states). This put Kelley Medical in the position of being unable to review, analyze, and follow up with other providers to try to obtain additional records. Once the OIG had the records from Kelley Medical, multiple months were spent in analyzing the records.

To utilize such results from the flawed audit to extrapolate to the entire list of all beneficiaries is unfair and unconscionable.

B.

Recommendation: Kelley Medical [should] 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:

Kelley Medical agrees that this correctly states the supplier's obligation under CMS rules, but disputes that it is in violation of any overpayment for the reasons stated above in the response for Paragraph A.

C.

Recommendation: [Kelley Medical should] obtain as much information from beneficiary medical records as it determines necessary to assure itself that claims for orthotic braces meet Medicare requirements.

Kelley Medical agrees that this correctly states the supplier's obligation under the MPIM, but disputes that it has failed to meet its obligations for the reasons stated above in the response for Paragraph A.

LETTER TO MS. AHLSTRAND AND MS. HERRERA
December 6, 2018
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Very truly yours,
/s/
Ken Stone

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