American Orthotic & Prosthetic Association

Overview of O&P RAC Audit/Pre-payment Audit Problem

Background

Actions of the Medicare Contractors Is So Severely Constricting Cash Flow in Small O&P Businesses (Annual Total Sales Roughly $1 Million) As Major Force Prompting Closings of these businesses and trigger fewer choices/providers to patients and a significant consolidation in field

1. HHS OIG generated a report which was premised on very significant misunderstanding of the patient care delivery model, and recommended inaccurate and unrealistic actions.
2. CMS accepted most of the major findings of the OIG report without correction or rebuttal.
3. That said, CMS' Office of Program Integrity has determined that whatever is going on with O&P care and documentation, there is generally an absence of indicators of fraud (contrary to the premise of the OIG report)
4. Medicare contractors exacerbated the problem by 'announcing' new standards without reference to the APA and without the benefit of any rulemaking
5. Audit contractors have applied the newly announced standards retrospectively as to claims where the provider could have not knowledge of the standard at the time services rendered.
6. OIG's gross misunderstandings of the care model, faulty conclusions drawn fro those inaccuracies, and contractor false assumptions of fraud have triggered a second wave of massive pre-payment audits designed to stimulate diminution in the applicable standard of amputee care. These pre-payment audits (in Jurisdiction B approaching 100% of prosthetic claims) have made the cash-flow problems for small O&P businesses dramatically worse.
7. O&P practitioners and patients have become Medicare's surrogates and collateral damage because neither has the leverage to compel physicians to provide the greater documentation that CMS demands and physicians are unwilling to give.
8. CMS contractors appear to operate without rules, supervision or coordination.
9. When CMS contractors do secure substantial caches of additional physician documentation it is misused as rat:ionale for detached audit personnel who have never seen the amputee patient, generally without either credentials or experience in orthotics or prosthetics, to countermand the prescription and care orders of the physician who has the responsibility for the overall clinical care of the patient.

(Over Please)

Recommendation

Communicate your concerns as a Member of Congress: (1) by signing onto the joint, bipartisan Congressional letter to Secretary Sebelius and CMS Administrator Tavenner; and/or (2) by communicating directly in a letter to CMS Administrator Tavenner and follow-up discussions with top CMS staff, that patients with limb loss or limb impairment may be getting shortchanged in the type of device they receive or experience delayed treatment when overzealous CMS contract auditors cite misunderstood documentation errors as basis for claim denials. The audits are designed to uncover fraud and abuse and not to foster "gotcha" denials adversely affecting patient care.

DRAFT Letter

Dear Administrator Tavenner,

I am writing to express my concerns about significant changes made to documentation requirements for the coverage of prostheses in the Medicare program. These policy changes stem from the August 2011 Department of Health and Human Services Office of the Inspector General report, "Questionable Billing by Suppliers of Lower Limb Prostheses" (OE1-02-00170). These changes are adversely impacting the ability of the supplier community to provide the appropropriate prosthetic limbs to Medicare beneficiaries.

A direct result of this report has been a significant increase for physician documentation which is often difficult to obtain. One DME audit contractor recently reported a lower limb prostheses claim denial rate of 86.6 percent with 96 percent of these denials attributed to insufficient physician documentation. The supplier community believes that many of these claims denials are erroneous and the physician documentation is adequate and identical to documentation submitted prior to the OIG report. They maintain that the only thing that has changed is CMS contractors having announced without any rulemaking a new, excessive and unattainable requirements for documents from physicians.

Suppliers must rely on physicians to comply with these additional documentation requirements, but they are facing increased physician frustration over these additional requirements and, in many instances, physicians are refusing to comply with these requirements. The increase in claims being denied because of physician documentation issues adversely affects the ability of suppliers to provide prostheses and ultimately this can compromise the quality of care afforded to Medicare beneficiaries.

While I support efforts to ensure that only appropriate claims are paid and to investigate all instances of fraud and abuse, I am concerned that the emphasis CMS and its contractors are placing on additional physician documentation could hinder access to care. I request that you take steps to work with the supplier community to ensure that these program integrity efforts go through the right rulemaking channels and do not impede the providing these vital services to Medicare beneficiaries.

For more information contact the American Orthotic & Prosthetic

Association (AOPA) at (571) 431-0876 or www.AOPAnet.org

Department of Health & Human Services

OFFICE OF INSPECTOR GENERAL

QUESTIONABLE BILLING BY SUPPLIERS OF LOWER LIMB PROSTHESES

Daniel R. Levinson
Inspector General

August 2011
OEI-02-10-00170

EXECUTIVE SUMMARY

OBJECTIVES

1. To identify payments for lower limb prostheses in 2009 that did not meet certain Medicare requirements.
2. To identify Medicare payments for lower limb prostheses in 2009 for beneficiaries with no claims from their referring physicians.
3. To identify suppliers of lower limb prostheses that had questionable billing in 2009.
4. To describe the program safeguards in place in 2009 and the first half of 2010 to prevent inappropriate payments for lower limb prostheses.

BACKGROUND

Medicare covers lower limb prostheses under its Part B Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) benefit. Between 2005 and 2009, Medicare spending for lower limb prostheses increased 27 percent, from $517 million to $655 million, while the number of Medicare beneficiaries receiving lower limb prostheses decreased by 2.5 percent, from almost 76,000 to about 74,000.

Lower limb prostheses are designed to replace, as much as possible, the function of a missing limb. A prosthesis joins the beneficiary's residual limb at one of several sites, such as the hip, above or below the knee, the ankle, or the foot. Medicare requires that a supplier have an order from a physician before providing prostheses to the beneficiary. This physician is known as the referring physician. After receiving the order, the supplier fits the beneficiary with the most appropriate prostheses. Medicare also requires that suppliers follow local coverage determination policies, which provide guidelines for determining the beneficiary's potential functional level and specify how suppliers must submit claims for certain types and combinations of prostheses.

The Centers for Medicare & Medicaid Services (CMS) contracts with Durable Medical Equipment (DME) Medicare Administrative Contractors (MAC) to process and pay claims for lower limb prostheses. These contractors also apply processing edits and conduct data analysis that may lead to medical reviews. In addition, CMS

contracts with Zone Program Integrity Contractors (ZPIC) and DME Program Safeguard Contractors (DME PSC) to conduct analyses for aberrant billing and to investigate allegations of fraud.

We based this study on an analysis of Medicare Part B claims for lower limb prostheses from 2009 and an analysis of Part A and B claims from 2004 to 2009 for beneficiaries who received lower limb prostheses in 2009. We also interviewed CMS contractors.

FINDINGS

In 2009, Medicare inappropriately paid $43 million for lower limb prostheses that did not meet certain requirements; these payments could have been prevented by using claims processing edits. These payments were for claims that did not meet the requirements specified in the local coverage determination. The $43 million is based solely on an analysis of claims data and does not include payments that a medical record review may find to be unreasonable or unnecessary. Most of these payments were made to suppliers that incorrectly billed for prostheses for both the right and left limbs using two claims, rather than one. Billing in this manner allows these suppliers to appear to be billing for only one limb when in fact they are billing for both limbs. In other cases, the claims did not include any information about the beneficiaries' potential functional level when it was required, or the claims were for prostheses that were not medically necessary given the beneficiaries' potential functional level.

Medicare paid an additional $61 million for beneficiaries with no claims from their referring physicians. These beneficiaries had no Medicare Part A or Part B claims that included their referring physicians during the last 5 years, meaning they did not have an office visit with or receive any other services from their referring physicians during this time. Billing for prostheses when the beneficiary had no claims from the referring physician raises questions about whether the physician ever evaluated the beneficiary and whether these devices were medically necessary.

In 2009, 267 suppliers of lower limb prostheses had questionable billing. In 2009, 136 suppliers frequently submitted claims that did not meet certain Medicare requirements or were for beneficiaries with no claims from their referring physicians. An additional 131 suppliers

had other questionable billing, such as billing for a high percentage of beneficiaries with no history of an amputation or missing limb.

Medicare contractors conducted varying degrees of program safeguard activities related to lower limb prostheses. The four DME MACs had varying claims processing edits in place, but none had edits for all requirements. In addition, none of the DME MACs conducted medical reviews, and not all conducted data analyses or provided education related to lower limb prostheses. All five ZPICs and DME PSCs conducted data analyses and opened investigations related to lower limb prostheses.

RECOMMENDATIONS

We recommend that CMS:

Implement additional claims processing edits to prevent inappropriate payments. CMS should instruct the four DME MACs to implement claims processing edits based on all of the local coverage determination requirements.

Strengthen monitoring of billing for lower limb prostheses. CMS should instruct the DME MACs, ZPICs, and DME PSCs to monitor billing for lower limb prostheses using the measures discussed in this report. CMS should develop thresholds for these measures and instruct its contractors to conduct additional reviews of suppliers that exceed the thresholds.

Implement requirements for a face-to-face encounter to establish the beneficiary's need for prostheses. We recommend that CMS implement requirements that the referring physician document that a face-to-face encounter occurred. This would help ensure that lower limb prostheses provided to beneficiaries are medically necessary.

Revise the requirements in the local coverage determination. CMS should work with the DME MACs to clarify several aspects of the local coverage determination. First, CMS should clarify the definitions of beneficiaries' functional levels. Second, CMS should revise the local coverage determination or take other steps to require that licensed/certified medical professionals, such as physical therapists, evaluate beneficiaries to determine their potential functional levels. Finally, CMS should consider denying as medically unnecessary certain combinations of prostheses.

Enhance screening for currently enrolled suppliers of lower limb prostheses. Federal regulations place new DMEPOS suppliers at the high-risk level and currently enrolled DMEPOS suppliers at the moderate-risk level. CMS should consider placing current suppliers of lower limb prostheses at the high-risk level, thus subjecting them to the more rigorous screening procedures.

Take appropriate action on suppliers with questionable billing. In a separate memorandum, we will refer the suppliers that we identified to CMS for appropriate action.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with five of the six recommendations. In response to our first recommendation, to implement additional claims processing edits, CMS concurred and stated it would instruct the DME MACs to implement consistent claims processing edits based on local coverage determination requirements.

In response to our second recommendation, to strengthen monitoring of billing for lower limb prostheses, CMS concurred and stated it would issue guidance to the DME MACs and instruct them to consider the measures used in this report as supplemental criteria for detecting high-risk suppliers.

In response to our third recommendation, to implement requirements for a face-to-face encounter to establish the beneficiary's need for prostheses, CMS concurred and stated it is exploring its current authorities to implement such requirements. CMS also stated that it would issue an educational article to further explain policy requirements for lower limb prostheses to providers and suppliers.

In response to our fourth recommendation, to revise the local coverage determination, CMS concurred and stated it would review the definitions for the functional levels and develop refinements as appropriate. CMS also stated it would consider adapting an algorithm to guide determination of the functional status of the beneficiary. CMS did not explicitly comment on our recommendation to consider requiring that an objective party determine the functional level. We ask CMS to consider this approach because it would further ensure

that beneficiaries receive only prostheses appropriate for their functional levels.

In response to our fifth recommendation, to enhance screening for currently enrolled suppliers of lower limb prostheses, CMS did not concur and stated that it has in place sufficient tools that allow for increased scrutiny of existing DMEPOS suppliers. CMS noted that if an existing supplier meets one of several triggering events, that supplier automatically is elevated to the high-risk level. Based on this report and the findings of other Office of Inspector General reports on DMEPOS, we maintain that all current suppliers of lower limb prostheses should be placed at the high-risk level.

In response to our sixth recommendation, to take appropriate action on the suppliers with questionable billing, CMS concurred and stated it would share our information with the DME MACs and the Recovery Auditors. Recovery Auditors review Medicare claims on a postpayment basis to identify inappropriate payments.

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INTRODUCTION

OBJECTIVES

1. To identify payments for lower limb prostheses in 2009 that did not meet certain Medicare requirements.
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BACKGROUND

Medicare covers lower limb prostheses under its Part B Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) benefit. Between 2005 and 2009, Medicare expenditures for lower limb prostheses increased 27 percent, from $517 million to $655 million, while the number of Medicare beneficiaries receiving lower limb prostheses decreased by 2.5 percent, from almost 76,000 to about 74,000.[1] In 2009, lower limb prostheses represented 81 percent of Medicare Part B payments for all prostheses.

Recently, in a number of cases, suppliers fraudulently billed for lower limb prostheses. For example, one supplier was convicted of health care fraud after billing Medicare nearly $1 million for prostheses that were not medically necessary.[2] In another case, a husband and wife were indicted on charges of billing Medicare $1.5 million for prostheses and other items for deceased beneficiaries as well as for beneficiaries who had never been evaluated by their referring physicians.[3]

[1] Office of Inspector General (OIG) analysis of Part B claims data from the Centers for Medicare & Medicaid Services' (CMS) National Claims History File for 2005 and 2009.

[2] Melissa Correa Velazquez, *El Vocero,* "Lluvia de fraudes al Medicare," July 28, 2010. Accessed at http://www.vocero.com/noticias/ley-y-orden/9412-lluvia-de-fraudes-al-medicare.html on September 26, 2010. The information is no longer available online.

[3] Department of Justice (DOJ) and the Department of Health and Human Services (HHS), *Maria and Armando Montiel Charged in a 469 Count Indictment for Medicare Fraud,* August 11, 2010. Accessed at http://www.stopmedicarefraud.gov/HEATnews/puertorico.html on August 10, 2011.

Further, during initial discussions about this study, staff at CMS raised a number of concerns about lower limb prostheses. They were concerned that suppliers were providing higher priced prostheses when lower priced ones were more appropriate, noting that these practices result in inappropriate Medicare payments.

This evaluation was conducted as part of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which focuses on reducing health care fraud through innovative data analysis and enhanced cooperation between DOJ, OIG, and CMS.[4]

Lower Limb Prostheses

Lower limb prostheses are designed to replace, as much as possible, the function of a missing limb. A beneficiary typically requires lower limb prostheses after amputation because of complications from a disease, such as diabetes. Other beneficiaries need prostheses because they were born without one or both lower limbs. A prosthesis joins the beneficiary's residual limb at one of several sites, such as the hip, above or below the knee, the ankle, or the foot.[5]

Prostheses can be temporary or definitive. Temporary prostheses are used when the amputated limb is still maturing. Once the residual limb has matured, the supplier fits the beneficiary with definitive prostheses. Definitive prostheses are meant for prolonged use and are typically replaced every 3 to 5 years. They are also typically more expensive than temporary prostheses.

Prostheses are further divided into base prostheses and additions. A supplier will typically fit a beneficiary with a base prosthesis and then enhance the base prosthesis with several additions. For example, a base prosthesis for a beneficiary with an above-the-knee amputation typically consists of a foot, an ankle, a shin, a knee, and a socket that interfaces with the residual limb. The additions include enhancements to the base prosthesis, such as a more sophisticated socket or knee or an insert or suspension system for the socket.

Medicare pays suppliers for prostheses according to a national fee schedule. Medicare payments for a given prosthesis vary across States; however, they cannot be higher than the ceiling price or lower

[4] DOJ and HHS, *HEAT Task Force Success,* Accessed at http://www.stopmedicarefraud.gov/heatsuccess/index.html on January 11, 2010.

[5] For the purpose of this report, we refer to each of these sites as a site of amputation.

than the floor price set by CMS. In 2009, over one-quarter of the $655 million that Medicare spent on lower limb prostheses was for sockets ($167 million), followed by inserts or suspension systems ($113 million) and base prostheses ($107 million). See Appendix A for 2009 Medicare spending for each type of lower limb prostheses.

Medicare Requirements for Lower Limb Prostheses

Provisions of the Social Security Act (the Act) govern Medicare payment for all items or services, including lower limb prostheses. The Act states that Medicare will cover only services and items considered reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body part.[6]

In addition, Medicare requires that a supplier have an order from a physician before providing prostheses to the beneficiary.[7] This physician is known as the referring physician. Upon receiving the order, the supplier consults with the referring physician as needed to confirm the order and to recommend any necessary changes and evaluates the beneficiary.[8] The supplier fits the beneficiary with the most appropriate prostheses. The supplier then determines the group of codes that best describes the prostheses provided, choosing from 178 Healthcare Common Procedure Coding System (HCPCS) codes that are specific to lower limb prostheses.[9] In this report, we refer to each HCPCS code as a prosthesis.

Further, local coverage determination policies provide additional Medicare requirements for lower limb prostheses. These policies, consistent with policies for other DMEPOS, are identical across the country.[10] The local coverage determination specifies how suppliers

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[6] The Act § 1862(a)(1)(A), 42 U.S.C. § 1395y(a)(1)(A).

[7] CMS, *Medicare Program Integrity Manual (PIM)*, Pub. No. 100-08, ch.5, § 5.2.1 (as of Rev. 242; effective 03-01-08). A new physician order is required when there is a change in the order, when an item needs to be replaced, and when there is a change in the supplier. CMS, *Medicare PIM*, Pub. No. 100-08, ch.5, § 5.2.4 (as of Rev. 242; effective 03-01-08).

[8] CMS, *DMEPOS Quality Standards*, October 2008.

[9] HCPCS is a standardized coding system maintained by CMS to ensure uniform billing. The 178 HCPCS codes for lower limb prostheses include all defined codes from L5000 to L5999.

[10] CMS, *Medicare PIM*, Pub. No. 100-08, ch.13, § 13.1.4. The four identical local coverage determinations are entitled *Local Coverage Determination for Lower Limb Prostheses*. In addition, four identical policy articles on lower limb prostheses provide additional requirements. For the purposes of this report, we refer to all eight documents as "the local coverage determination." We used the version of the local coverage determination that was in effect in 2009.

must submit claims for certain types and combinations of prostheses. In particular, it states that each claim must include a modifier to indicate whether the prosthesis is for the right or left limb. When a supplier provides a prosthesis for each limb on the same date, the supplier must submit only one claim and include both the right and left modifiers on the claim.[11]

The local coverage determination also has guidelines for determining the beneficiary's potential functional level. Specifically, it states that a beneficiary is placed at one of five potential functional levels based on the reasonable expectations of the supplier and the referring physician. When determining the potential functional level, suppliers must take into account the beneficiary's history, current condition, and desire to walk. The supplier then uses a modifier on the claim to indicate the beneficiary's potential functional level (K0 to K4). Prostheses are not considered medically necessary if the beneficiary has the lowest potential functional level (K0), which indicates that he or she does not have the ability or the potential to walk. In addition, for some prostheses, the local coverage determination specifies the minimum potential functional level that the beneficiary must have for the prosthesis to be considered medically necessary.

Further, the local coverage determination limits the number of certain prostheses that can be billed on a claim. If the number of units of these prostheses exceeds the limit, the additional items will be denied as not medically necessary. The local coverage determination also considers certain combinations of prostheses to be medically unnecessary. For example, certain sockets are not allowed for use with temporary base prostheses. Finally, the local coverage determination states that HCPCS L5990, a specific type of foot addition, will be denied as not medically necessary.[12]

In addition, CMS recently established new screening procedures for provider enrollment. Screening may include, for example, licensure and criminal background checks. CMS created three levels of screening—limited, moderate, and high—based on the risk of fraud,

[11] Typically, a supplier bills for a set of prostheses on one claim, listing each prosthesis as a separate line item on that claim. For the purposes of this report, we refer to claim line items as claims.

[12] While not covered by Medicare, this HCPCS code may be covered by other health care insurers.

waste, and abuse.[13] New DMEPOS suppliers were placed at the high-risk level, while currently enrolled DMEPOS suppliers were placed at the moderate-risk level.[14]

Lastly, recent legislation established a face-to-face encounter requirement for certain DMEPOS.[15] For specified DMEPOS that require a written order prior to delivery, the referring physician must document that a physician, physician assistant, nurse practitioner, or clinical nurse specialist has had a face-to-face encounter with the beneficiary before writing the order for the item.[16]

Claims Processing and Program Safeguard Activities

CMS contracts with four DME Medicare Administrative Contractors (MAC) to process and pay claims in different areas of the country. In addition to developing local coverage determinations, the DME MACs apply processing edits to reject, deny, or suspend claims. If the DME MAC rejects a claim, the supplier may resubmit it after making the necessary corrections. If the DME MAC suspends a claim, it reviews the medical records to determine whether the claim should be paid. DME MACs may also conduct medical reviews of claims based on proactive data analysis to prevent improper payments or to collect overpayments. In addition, they conduct outreach and education to suppliers.

CMS also contracts with Zone Program Integrity Contractors (ZPIC) and DME Program Safeguard Contractors (PSC) to identify fraud and abuse in their jurisdictions. These contractors conduct data analysis to check for aberrant billing and to investigate allegations of fraud and abuse. They may refer claims to DME MACs to collect overpayments or to law enforcement for further investigation. CMS is transitioning the role of the PSCs to the ZPICs.

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[13] 76 Fed. Reg. 5862, 5867 (Feb. 2, 2011).

[14] 42 CFR § 424.518 (b)(1)(x) and (c)(1)(ii), effective March 25, 2011.

[15] In addition to establishing the new requirement for DMEPOS, section 6407(c) of the Patient Protection and Affordable Care Act (ACA), P.L. 111-148, authorized CMS to apply the face-to-face encounter requirement to other Medicare items and services based on a decision that it would reduce the risk of waste, fraud, or abuse.

[16] Section 6407(b) of the ACA, amending 1834(a)(11)(B) of the Act. CMS can specify that the requirements at 1834(a)(11)(B) for a written order before delivery and for a face-to-face encounter apply to any durable medical equipment (DME) (see section 1834(a)(13) of the Act) or any orthotics or prosthetics (see sections 1834(h)(3) and (h)(4)(C) of the Act). As of May 2011, CMS had not applied the face-to-face requirement to lower limb prostheses.

METHODOLOGY

We based this study on: (1) an analysis of all paid Part B claims for lower limb prostheses from 2009; (2) an analysis of paid Part A and Part B claims[17] from 2004 to 2009 for beneficiaries who received lower limb prostheses in 2009; and (3) structured interviews with staff from the following CMS contractors: the DME MACs, ZPICs, and DME PSCs.

Using CMS's National Claims History File, we identified all paid Part B claims for lower limb prostheses (HCPCS codes L5000 to L5999) for 2009.[18] For beneficiaries who had a prosthesis claim in 2009, we identified all of their paid Part A and Part B claims during the 5 years prior to their first prosthesis claim in 2009.[19] We used the beneficiary's Health Insurance Claim Number to link these Part A and Part B claims to the 2009 prostheses claims.

Identification of Medicare Payments for Lower Limb Prostheses That Did Not Meet Certain Requirements or Were for Beneficiaries With No Claims From Their Referring Physicians

We first analyzed the claims data to determine the number of claims that did not meet the requirements specified in the local coverage determination and the total Medicare payments for these claims. We considered a paid claim to not meet these requirements if the supplier (1) did not indicate whether the prosthesis was for the right or left limb, (2) billed for a prosthesis for both limbs on the same date using two claims,[20] (3) did not meet potential functional level requirements,[21] (4) billed for a higher number of units of a prosthesis than allowed on a claim, (5) billed for combinations of prostheses that were not allowed, or (6) billed for prostheses that were not covered.

[17] Note that we did not include DME claims.

[18] We included all claims from the 50 States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, American Samoa, and Guam.

[19] For the purposes of this report, we refer to the 5 years prior to the beneficiary's first prosthesis claim in 2009 as "the last 5 years."

[20] The supplier should bill for prostheses for both limbs on the same claim, using a right and a left modifier.

[21] In this report, we did not verify whether the potential functional level assigned to the beneficiary was appropriate. We did verify: (1) whether the supplier indicated the beneficiary's potential functional level on each claim and (2) whether the prostheses were medically necessary for the potential functional level indicated on the claim.

Next, we analyzed the claims data to determine the number of claims for beneficiaries with no claims from their referring physicians during the last 5 years and the Medicare payments for these claims. Using the National Provider Identifier and Unique Physician Identification Number on the prostheses claims, we identified each beneficiary's referring physician. We then used these physician identifiers to determine whether the referring physician was included on any of the beneficiary's Part A and Part B claims, which would indicate that the beneficiary had an office visit or received other services from the referring physician. If a beneficiary had more than one referring physician in 2009, we determined whether the beneficiary had a Part A or Part B claim with any of the referring physicians.

Identification of Suppliers That Had Questionable Billing

Medicare paid 4,575 suppliers for lower limb prostheses in 2009. To identify the suppliers that had questionable billing, we based our analyses on suppliers that had at least 10 beneficiaries and that were paid at least $100,000 for lower limb prostheses in 2009. These included 1,632 of the 4,575 suppliers and accounted for 92 percent of the $655 million billed for lower limb prostheses.

For each supplier, we first determined the percentage of its claims that did not meet Medicare requirements specified in the local coverage determination. If that percentage was greater than the 75th percentile plus two times the interquartile range, we considered the supplier to have an unusually high percentage of claims that did not meet these requirements.[22] We conducted a similar analysis to identify suppliers that had an unusually high percentage of claims for beneficiaries with no claims from their referring physicians during the last 5 years.

Next, we identified suppliers of lower limb prostheses that had other questionable billing. We developed seven measures based on the results of past OIG analyses and fraud investigations related to lower limb prostheses, as well as input from CMS staff and contractors. As above, we considered a supplier to be unusually high on a measure if it was greater than the 75th percentile plus two times the interquartile range. The seven measures include:

[22] This is a standard method for identifying members of a population with unusually high values on a statistic compared to the rest of the population. See J.W. Tukey, *Exploratory Data Analysis*, Addison-Wesley, 1977.

- The percentage of beneficiaries that suppliers have in common. We based this measure on the number of each supplier's beneficiaries who also received lower limb prostheses from another supplier.
- The percentage of beneficiaries who had no Part A or Part B history related to an amputation during the last 5 years. We based this measure on the number of each supplier's beneficiaries who did not have a Part A or Part B claim that included a diagnosis code associated with a missing lower limb or a procedure code associated with a lower limb amputation or prosthesis fitting.
- The percentage of beneficiaries with unusual combinations of prostheses. We considered two prostheses billed on the same date for the same limb to be unusual if they were both definitive base prostheses or were for different sites of amputation. While certain prostheses may be provided more than once for the same limb on the same date, definitive base prostheses should be provided only once. Also, if a supplier routinely provides prostheses for different sites of amputation—such as below the knee and above the knee—for the same limb, that is a cause for concern.[23]
- The percentage of beneficiaries who received prostheses for both limbs. Nationwide, 15 percent of Medicare beneficiaries who had lower limb prostheses in 2009 received prostheses for both limbs.[24]
- The percentage of beneficiaries who received prostheses for above-the-knee amputations. On average, the payment per beneficiary for prostheses for above-the-knee amputations is more than twice the payment for below-the-knee amputations.[25]
- High average payment per beneficiary for above-the-knee prostheses.[26] We based this measure on the total payment for

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[23] For this analysis, we included prostheses that were appropriate for only one site of amputation, such as a below-the-knee socket. Of the 181 lower limb prostheses, about 100 are appropriate for one site of amputation, while the remaining prostheses are appropriate for multiple sites.

[24] OIG analysis of prostheses claims data from the National Claims History File for 2009.

[25] Prostheses for above-the-knee and below-the-knee amputations accounted for 88 percent of all Medicare spending on lower limb prostheses. Prostheses for other sites accounted for the remaining 12 percent of total spending. OIG analysis of prostheses claims data from the National Claims History File for 2009.

[26] To determine the average payment per beneficiary, we included prostheses that are appropriate for one site of amputation or for multiple sites. If a prosthesis was appropriate for multiple sites, we identified the site based on other prostheses provided on the same date for the same limb.

above-the-knee prostheses divided by the number of each supplier's beneficiaries who received these prostheses. For this analysis, we included suppliers that provided above-the-knee prostheses to at least 10 beneficiaries. Additionally, because the price for a given prosthesis varies by State, we used CMS floor prices so that we could compare suppliers across States.

- High average payment per beneficiary for below-the-knee prostheses. We based this measure on the total payment for below-the-knee prostheses divided by the number of each supplier's beneficiaries who received these prostheses. As we did in the above analysis, we included suppliers that provided below-the-knee prostheses to at least 10 beneficiaries. We also used CMS floor prices so that we could compare suppliers across States.

Next, we compared the characteristics of the suppliers that had questionable billing to those of other suppliers. Specifically, for both groups of suppliers, we calculated the percentage of suppliers that were independently owned, rather than owned by a chain, and the percentage of suppliers in each State.[27] We identified the States in which the percentage of suppliers that had questionable billing was at least twice as high as the percentage of other suppliers.

Identification of Program Safeguards To Prevent Inappropriate Payments for Lower Limb Prostheses

We conducted structured telephone interviews with staff from the four DME MACs, the three ZPICs, and the two DME PSCs. We discussed the program safeguard activities they conducted from January 2009 to August 2010.[28]

We asked the DME MACs about their claims processing edits and any medical reviews and analyses they conducted, as well as any education they provided about billing for lower limb prostheses. We then asked the ZPICs and DME PSCs about any data analyses and investigations they conducted regarding suppliers of lower limb prostheses. We completed these interviews between August and September 2010.

[27] We used data from the National Supplier Clearinghouse to identify the State where the supplier practiced and determine whether the supplier was independently owned or owned by a chain.

[28] Eight of these contractors were able to discuss the safeguard activities they conducted since January 2009. The ninth contractor began operations in January 2010 and was able to discuss its activities since that time.

In addition, we reviewed documentation from all of the contractors. Specifically, we requested and reviewed documentation related to their claims processing edits, data analyses, investigations, and any education they provided.

Limitations

The findings in this report are based on analysis of claims data; we did not conduct a medical review of any claims to determine the medical necessity of the prostheses. In addition, the measures included in our analysis are not intended to be a comprehensive set of measures for identifying questionable billing.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

In 2009, Medicare inappropriately paid $43 million for lower limb prostheses that did not meet certain requirements; these payments could have been prevented by using claims processing edits

Of the $655 million that Medicare paid for lower limb prostheses in 2009, $43 million was for claims that did not meet the requirements specified in the local coverage determination. These payments—for 32,260 claims for 9,265 beneficiaries—could have been prevented if claims processing edits had been in place.[29] The $43 million is based solely on an analysis of claims data and does not include payments that a medical record review may find to be unreasonable or unnecessary.

As shown in Table 1, Medicare paid $20.1 million to suppliers that incorrectly billed for a prosthesis for both the right and left limbs on the same date using two claims, rather than one claim. Billing on different claims enables suppliers to appear to be billing for only one limb, when, in fact, they are billing for both limbs.

Table 1: Inappropriate Medicare Payments for Lower Limb Prostheses, 2009

	Inappropriate Payment Amount	Percentage of All Paid Claims
Billed for a prosthesis for each limb on the same date using two claims, rather than one claim	$20.1 million	3.3%
Did not meet potential functional level requirements	$17.8 million	1.0%
Did not indicate whether the prosthesis was for the left or right limb	$2.7 million	0.4%
Billed for combinations of prostheses that were not allowed	$1.6 million	0.4%
Billed for a higher number of units of prostheses than allowed	$0.9 million	0.1%
Billed for prostheses that were not covered	$0.4 million	< 0.1%
Total*	**$42.6 million**	**5.2%**

* The figures in the last two columns do not sum to the total because a claim may have failed to meet multiple requirements.

Source: OIG analysis of Part B prostheses claims, 2010.

[29] This amount may not be the total cost savings to the Medicare program. In some cases, when a claims processing edit rejects a claim, the supplier may resubmit the claim after making the necessary corrections.

Medicare paid another $17.8 million for claims that did not meet potential functional level requirements. As noted, beneficiaries have one of five potential functional levels, depending on their health status and desire to walk. In most cases, the claims did not include any information about the beneficiaries' potential functional level when it was required. In other cases, Medicare paid for prostheses that were not medically necessary given the potential functional level of the beneficiaries as indicated on the claims. For example, some suppliers billed for a knee addition that was designed for the highest potential functional level, even though the beneficiary had a lower potential functional level.

Further, Medicare inappropriately paid $2.7 million for claims that did not indicate whether the prostheses were for the right or left limb. It also paid $1.6 million for combinations of prostheses that were not allowed. Most commonly, Medicare inappropriately paid for a definitive socket in combination with a temporary base prosthesis. Lastly, Medicare paid over $1 million for a higher number of units of certain prostheses than was allowed and for prostheses that were not covered by the program.

Medicare paid an additional $61 million for beneficiaries with no claims from their referring physicians

In addition to the $43 million that did not meet certain Medicare requirements, another $61 million was for beneficiaries with no claims from their referring physicians. Specifically, these beneficiaries had no Medicare Part A or Part B claims that included their referring physicians during the last 5 years, indicating they did not have an office visit or receive any other services from their referring physicians during this time. These payments were for 55,274 claims for 7,066 beneficiaries.

Medicare requires the beneficiary's referring physician to write an order specifying the beneficiary's need for prostheses. Billing for prostheses when the beneficiary had no claims from the referring physician raises questions about whether the physician ever evaluated the beneficiary and whether these devices were medically necessary.

In 2009, 267 suppliers of lower limb prostheses had questionable billing

In 2009, 136 suppliers frequently submitted claims that did not meet certain Medicare requirements or were for beneficiaries with no claims from their referring physicians. An additional 131 suppliers had other questionable billing, such as billing for a high percentage of beneficiaries with no history of an amputation or missing limb or a high percentage of beneficiaries with unusual combinations of prostheses.

These 267 suppliers differed from other suppliers of lower limb prostheses. For example, two-thirds of these suppliers were independently owned, rather than owned by a chain, compared to 41 percent of other suppliers. In addition, these suppliers were at least twice as likely as other suppliers to be in Alabama, Mississippi, Puerto Rico, or Wyoming.

In 2009, 136 suppliers frequently submitted claims that did not meet certain Medicare requirements or were for beneficiaries with no claims from their referring physicians

These 136 suppliers accounted for $22 million of the payments in 2009 that did not meet certain Medicare requirements or were for beneficiaries with no claims from their referring physicians. One supplier alone accounted for $2.5 million of these payments. As shown in Table 2, 114 suppliers frequently submitted claims that did not meet Medicare requirements specified in the local coverage determination. Between 16 and 89 percent of their claims did not meet these Medicare requirements, whereas half of all suppliers had 2 percent or less of claims that did not meet these requirements. In addition, 33 suppliers frequently submitted claims for beneficiaries with no claims from their referring physicians during the last 5 years. Between 32 and 100 percent of these suppliers' claims were for beneficiaries with no claims from their referring physicians.

Table 2: Suppliers That Frequently Submitted Claims That Did Not Meet Certain Medicare Requirements or Were for Beneficiaries With No Claims From Their Referring Physicians, 2009

	Median Among All Suppliers	Suppliers With Unusually High Values*	
		Range of Percentages	Number of Suppliers
Percentage of claims that did not meet certain Medicare requirements	2 percent	16 to 89 percent	114
Percentage of claims for beneficiaries with no claims from their referring physicians	8 percent	32 to 100 percent	33
Total**			**136**

* We considered a supplier's percentage to be unusually high if it was greater than the 75th percentile plus two times the interquartile range.

** The figures do not sum to the total because 11 suppliers frequently submitted both types of claims.

Source: OIG analysis of Part B prostheses claims, 2010.

An additional 131 suppliers had other questionable billing

One hundred thirty-one suppliers had unusually high values for at least one of the seven other measures we reviewed. In addition, 34 of the suppliers that frequently submitted claims that did not meet certain Medicare requirements or were for beneficiaries with no claims from their referring physicians also had unusually high values for at least 1 of the 7 measures listed in Table 3.

As shown in Table 3, 56 suppliers routinely had beneficiaries in common with other suppliers. These suppliers had between 23 and 92 percent of their beneficiaries in common with other suppliers, whereas half of all suppliers had 4 percent or less of their beneficiaries in common with other suppliers. In addition, 13 suppliers frequently had beneficiaries with no history of an amputation or missing limb during the last 5 years. At least 65 percent of the beneficiaries of these suppliers had no amputation or missing limb history, whereas half of all suppliers had no history of an amputation or missing limb for 28 percent or less of their beneficiaries.

Further, 68 suppliers frequently billed for unusual combinations of prostheses. Specifically, these suppliers frequently billed for two prostheses on the same date for the same limb that were either (1) both definitive base prostheses or (2) prostheses for different sites of amputation. Most commonly, these suppliers billed for a

below-the-knee definitive base prosthesis (L5301) in combination with a socket that is appropriate for an ankle amputation (L5632).

Table 3: Suppliers With Other Questionable Billing, 2009

	Median Among All Suppliers	Suppliers With Unusually High Values*	
		Range of Values	Number of Suppliers
Percentage of beneficiaries that suppliers have in common	4%	23 to 92%	56
Percentage of beneficiaries with no history of an amputation or missing limb	28%	65 to 95%	13
Percentage of beneficiaries with unusual combinations of prostheses	3%	18 to 89%	68
Percentage of beneficiaries who received prostheses for both limbs	13%	36 to 77%	13
Percentage of beneficiaries who received prostheses for above-the-knee amputations	16%	45 to 92%	16
Average payment per beneficiary for above-the-knee prostheses	$14,695	$29,798 to $40,070	4
Average payment per beneficiary for below-the-knee prostheses	$6,128	$12,166 to $17,348	10
Total**			**165**

This table includes the 36 suppliers that also frequently submitted claims that did not meet certain Medicare requirements or were for beneficiaries with no claims from their referring physicians.

* We considered a supplier's value to be unusually high if it was greater than the 75th percentile plus two times the interquartile range.

** The figures do not sum to the total because a supplier may have unusually high values for more than one measure.

Source: OIG analysis of Part B prostheses claims, 2010.

Further, as shown in Table 3, many suppliers had an unusually high percentage of beneficiaries who received prostheses for both limbs or for above-the-knee amputations. Finally, a number of suppliers had unusually high average payments per beneficiary for either above-the-knee prostheses or for below-the-knee prostheses. These suppliers commonly billed for significantly more prostheses—or for more complex prostheses—for each beneficiary, compared to other suppliers.

Medicare contractors conducted varying degrees of program safeguard activities related to lower limb prostheses

The four DME MACs had varying claims processing edits in place for lower limb prostheses; however, none had edits in place for all of the requirements specified in the local coverage determination. These edits might have prevented the $43 million that Medicare inappropriately paid in 2009 for lower limb prostheses that did not meet these requirements.

Additionally, between January 2009 and August 2010, none of the four DME MACs conducted medical reviews and not all conducted data analyses or provided education that was specific to lower limb prostheses. In contrast, during the same period, all five ZPICs and DME PSCs conducted data analyses and opened a number of investigations related to lower limb prostheses.

The four DME MACs had varying claims processing edits in place, but none had edits for all requirements

The DME MACs most commonly had edits in place that checked for whether the prosthesis was for the right or left limb and whether the beneficiary had the required potential functional level. Additionally, two contractors had implemented edits related to the different combinations of prostheses that were not allowed, and two had edits for prostheses that were not covered. None of the four contractors had edits to check for billing for a prosthesis for each limb on the same date on different claims or for billing for a higher number of prostheses than allowed. Interestingly, the contractor that had the most edits in place had not implemented them until June 2010.

None of the DME MACs conducted medical reviews, and not all had conducted data analyses or provided education related to lower limb prostheses

None of the four DME MACs conducted medical reviews of lower limb prostheses between January 2009 and August 2010. Staff at the DME MACs noted that medical reviews of prostheses claims were very difficult and required specialized knowledge because of the complicated components that needed to be reviewed. Staff also commonly noted that assessing the beneficiary's potential functional level was difficult because the local coverage determination did not clearly define the five different levels. Staff reported that the vague definitions made it difficult to determine whether the more complex prostheses allowed for higher potential functional levels were medically necessary.

In addition, only two of the DME MACs conducted analyses on lower limb prostheses claims. One contractor looked for inappropriate combinations of prostheses and unusually high use of certain prostheses. The other contractor looked for prostheses that were not medically necessary based on the beneficiaries' potential functional levels indicated on the claims.

Finally, three of the four DME MACs provided education to suppliers regarding coverage or billing instructions for lower limb prostheses. This usually consisted of presentations to suppliers or general information that the contractors posted on their Web sites.

All ZPICs and DME PSCs conducted data analyses and opened investigations related to lower limb prostheses

All five ZPICs and DME PSCs reported conducting data analyses related to lower limb prostheses between January 2009 and August 2010. Specifically, four of the five contractors looked at replacement frequencies. Two looked at trends involving the beneficiaries' potential functional levels indicated on the claims. One checked for medical histories consistent with an amputation. In addition, four contractors conducted analyses to identify high utilization or billing spikes among suppliers of lower limb prostheses.

All five ZPICs and DME PSCs reported opening investigations based on their analyses, referrals, or beneficiary complaints. In total, they reported opening 19 investigations that were specific to lower limb prostheses. The issues typically investigated included suppliers' providing prostheses that were not needed by the beneficiary or suppliers' billing for, but not providing, prostheses. According to the contractors, the investigations have had differing results. For example, three contractors referred three suppliers to law enforcement. However, another closed two cases because it could not substantiate that the beneficiaries did not need the more complex prostheses that are allowed for higher potential functional levels.

RECOMMENDATIONS

Our findings show a number of problems with Medicare payments for lower limb prostheses. In 2009, Medicare inappropriately paid $43 million for lower limb prostheses that did not meet certain Medicare requirements. These payments could have been prevented by using claims processing edits. Medicare also paid an additional $61 million for beneficiaries with no claims from their referring physicians. Further, we found that 267 suppliers of lower limb prostheses had questionable billing. These included, for example, suppliers that frequently billed for beneficiaries who had no history of an amputation or missing limb or for unusual combinations of prostheses. Lastly, we found that the DME MACs had varying claims processing edits in place for lower limb prostheses; however, none had edits in place for all of the requirements specified in the local coverage determination. We recommend that CMS:

Implement additional claims processing edits to prevent inappropriate payments

CMS should instruct the DME MACs to implement claims processing edits based on all of the local coverage determination requirements. These edits should check: whether the right or left limb is indicated on the claim, how a prosthesis for each limb on the same date is billed, potential functional level requirements, the number of units allowed for certain prostheses, inappropriate combinations of prostheses, and noncovered prostheses.

Strengthen monitoring of billing for lower limb prostheses

CMS should instruct the DME MACs, ZPICs, and DME PSCs to use the measures discussed in this report to periodically profile suppliers of lower limb prostheses and focus resources on those that are most likely to present a risk to the program. Specifically, the contractors should determine for each supplier: (1) the percentage of claims that did not meet certain Medicare requirements, (2) the percentage of claims for beneficiaries with no claims from their referring physicians, (3) the percentage of beneficiaries who had no Part A or Part B history related to an amputation, (4) the percentage of beneficiaries who received unusual combinations of prostheses, (5) the percentage of beneficiaries that suppliers have in common, (6) the percentage of beneficiaries who received prostheses for both lower limbs, (7) the percentage of beneficiaries who received prostheses for above-the-knee amputations, (8) the average payment per beneficiary for above-the-

knee prostheses, and (9) the average payment per beneficiary for below-the-knee prostheses. CMS should develop thresholds for these measures and instruct its contractors to conduct additional reviews of suppliers that exceed the thresholds.

The contractors should use this information to target their efforts to more effectively prevent inappropriate payments and identify fraud or abuse. Contractors could conduct medical reviews of a sample of claims from suppliers that exceed the thresholds on the above measures and use their findings to recover inappropriate payments, place certain suppliers on prepayment review, and initiate fraud investigations.

Implement requirements for a face-to-face encounter to establish the beneficiary's need for prostheses

We recommend that CMS use its authority to implement requirements that the referring physician document that a face-to-face encounter occurred. This would help ensure that lower limb prostheses provided to Medicare beneficiaries are medically necessary.

Revise the requirements in the local coverage determination

We recognize that the DME MACs have an initiative to revise the local coverage determination for lower limb prostheses. CMS should work with the DME MACs to clarify several aspects of the local coverage determination.

First, CMS should clarify the definitions of beneficiaries' potential functional levels. In particular, CMS should set an expectation for when the beneficiary should achieve the level of walking ability indicated by his or her potential functional level. After creating improved definitions, CMS should consider specifying the range of potential functional levels that are appropriate for each prosthesis. These changes would help ensure that prostheses are matched to beneficiaries' needs and that CMS contractors can assess the medical necessity of these devices.

Second, CMS should revise the local coverage determination or take other steps to require that licensed/certified medical professionals, such as physical therapists, evaluate beneficiaries to determine their potential functional levels. To further ensure an objective determination of the beneficiary's functional level, CMS should require that this person not be financially affiliated with the supplier. The evaluation should include a written report that provides detailed information supporting the determined functional level, and the report

should be made available to CMS upon request. While Medicare would need to cover this additional service, the cost would be offset by ensuring that beneficiaries receive only prostheses appropriate for their functional levels.

Lastly, CMS should consider revising the local coverage determination to deny as medically unnecessary certain combinations of prostheses, such as more than one definitive base prosthesis or prostheses for different sites of amputation billed for the same limb on the same date.

Enhance screening for currently enrolled suppliers of lower limb prostheses

Federal regulations place new DMEPOS suppliers at the high-risk level and currently enrolled DMEPOS suppliers at the moderate-risk level. Given the high costs of prostheses and the high rates of questionable billing, CMS should consider placing current suppliers of lower limb prostheses at the high-risk level, thus subjecting them to the more rigorous screening procedures.

Take appropriate action on suppliers with questionable billing

In a separate memorandum, we will refer the suppliers that we identified to CMS for appropriate action.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with five of the six recommendations. In response to our first recommendation, to implement additional claims processing edits, CMS concurred and stated it would instruct the DME MACs to implement consistent claims processing edits based on local coverage determination requirements.

In response to our second recommendation, to strengthen monitoring of billing for lower limb prostheses, CMS concurred and stated it would issue guidance to the DME MACs and instruct them to consider the measures used in this report as supplemental criteria for detecting high-risk suppliers.

In response to our third recommendation, to implement requirements for a face-to-face encounter to establish a beneficiary's need for prostheses, CMS concurred and stated it is exploring its current authorities to implement such requirements. CMS also stated that it would issue an educational article to further explain policy requirements for lower limb prostheses and to providers and suppliers.

In response to our fourth recommendation, to revise the local coverage determination, CMS concurred and stated it would review the definitions for the functional levels and develop refinements as appropriate. CMS also stated it would consider adapting an algorithm to guide determination of the functional status of the beneficiary. CMS did not explicitly comment on our recommendation to consider requiring that an objective party determine the functional level. We ask CMS to consider this approach because it would further ensure that beneficiaries receive only prostheses appropriate for their functional levels.

In response to our fifth recommendation, to enhance screening for currently enrolled suppliers of lower limb prostheses, CMS did not concur and stated that it has in place sufficient tools that allow for increased scrutiny of existing DMEPOS suppliers. CMS noted that if an existing supplier meets one of several triggering events, that supplier automatically is elevated to the high-risk level. Based on this report and the findings of other OIG reports on DMEPOS, we maintain that all current suppliers of lower limb prostheses should be placed at the high-risk level.

In response to our sixth recommendation, to take appropriate action on the suppliers with questionable billing, CMS concurred and stated it would share our information with the DME MACs and the Recovery Auditors. Recovery Auditors review Medicare claims on a postpayment basis to identify inappropriate payments.

For the full text of CMS's comments, see Appendix B.

APPENDIX A

Medicare Payments for Lower Limb Prostheses, by Type, 2009		
Type of Lower Limb Prostheses	**Total Medicare Payments (millions)**	**Average Medicare Payments per Prosthesis**
Base	$107	$1,935
Addition prostheses		
Socket	$167	$684
Insert or suspension system	$113	$508
Knee	$92	$3,020
Foot	$87	$2,370
Other	$79	$542
Ankle	$10	$659
Total*	**$655**	

* The figures in this column do not sum to the total because of rounding.

Source: Office of Inspector General analysis of Part B prostheses claims, 2010.

APPENDIX ~ B

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JUN 2 4 2011

TO: Daniel R. Levinson
Inspector General

FROM: Donald M. Berwick, M.D. /S/
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Questionable Billing by Suppliers of Lower Limb Prostheses" (OEI-02-10-00170)

Thank you for the opportunity to review and comment on the OIG draft report titled, "Questionable Billing by Suppliers of Lower Limb Prostheses." The Centers for Medicare & Medicaid Services (CMS) appreciates the time and resources OIG has invested to determine the extent to which Medicare improperly paid claims for lower limb prostheses.

Lower limb prostheses are covered by Medicare to replace, as much as possible, the function of a missing limb. Local coverage determinations for lower limb prostheses further explain how claims must be submitted and what is covered as reasonable and necessary.

Through data analysis and structured interviews with Medicare contractors, OIG concluded that in 2009: 1) Medicare inappropriately paid $43 million for lower limb prostheses; 2) Medicare paid for prostheses despite the fact the beneficiaries had no claims from their referring physicians; 3) 267 suppliers of lower limb prostheses had questionable billing; and 4) Medicare contractors conducted program safeguard activities related to lower limb prostheses to varying degrees.

The CMS will work to improve our oversight of lower limb prostheses in the future and move forward in establishing the necessary changes. OIG made the following recommendations.

OIG Recommendation 1

Implement additional claims processing edits to prevent inappropriate payments.

CMS Response

The CMS concurs and will instruct the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) to implement consistent claims processing edits based on local coverage determination requirements.

OIG Recommendation 2

Strengthen monitoring of billing for lower limb prostheses.

CMS Response

The CMS concurs. CMS will issue guidance to the DME MACs and inform them of these findings. We will instruct the DME MACs that they should consider the OIG measures used in this report as supplemental criteria for detecting high risk suppliers. We will encourage the DME MACs to consider developing thresholds for these measures while prioritizing their workload.

OIG Recommendation 3

Implement requirements for a face-to-face encounter to establish the beneficiary's need for prostheses.

CMS Response

The CMS concurs that face-to-face encounters are important. Although section 6407(b) of the Affordable Care Act (ACA) gives the authority to implement a face-to-face documentation requirement for certain DME, the definition of DME under this section does not include prosthetics. However, we are exploring using the section 6407(c) authority to address improper billing and payment for lower limb prosthetics. Section(c) gives the Secretary the authority to apply the face-to-face requirement "…to other items and services for which payment is provided under Title XVIII of the Social Security Act." In the meantime, CMS is in the process of implementing Section 6407(b) on certain items of durable medical equipment.

The CMS will issue an educational article to further explain policy requirements for lower limb prostheses to the provider and supplier community.

OIG Recommendation 4

Revise the requirements in the local coverage determination.

CMS Response

The CMS concurs. With the DME MACs, CMS will: 1) review the alignment between the current K code definitions and the current clinical evidence base and develop refinements as appropriate; and 2) consider adapting the algorithmic model presented in the Mobility Assistive Equipment National Coverage Determination (NCD) to guide determination of the functional status of the amputee patient and thus his/her best "fit" for a prosthesis.

OIG Recommendation 5

Enhance screening for currently enrolled suppliers of lower limb prostheses. Federal regulations place new DMEPOS suppliers at the high risk level and currently enrolled DMEPOS suppliers at the moderate risk level. CMS should consider placing current suppliers of lower limb prostheses into the high risk level, thus subjecting them to the more rigorous screening procedures.

CMS Response

The CMS non-concurs. CMS believes we now have in place sufficient tools that allow for increased scrutiny of existing DMEPOS suppliers – particularly new authorities provided to us under the Affordable Care Act in 2010. CMS-6028-FC, Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers, issued on February 2, 2011 implements the screening, suspension and moratoria provisions in the Affordable Care Act.

Although CMS has new authorities, CMS acknowledges that the vast majority of existing providers and suppliers are honest. CMS can impose a payment suspension against an existing provider or supplier in cases where it has been determined, after consulting with OIG and, as appropriate, the Department of Justice, that there is a credible allegation of fraud against the provider or supplier. Furthermore, in the event an existing DMEPOS supplier meets one of the triggering events described in 42 C.F.R. § 424.518(c)(3), that supplier automatically is elevated to the "high" category of risk such that persons with a direct or indirect ownership interest of 5 percent or greater in the supplier would be subject to fingerprinting and criminal background check requirements.

Accordingly, while CMS understands the concern that OIG has expressed regarding existing DMEPOS suppliers, CMS believes current authorities will allow us the flexibility to combat fraud, waste, and abuse among existing DMEPOS suppliers as effectively as if such suppliers were initially categorized as "high" risk via the methodology described in 42 C.F.R. § 424.518.

OIG Recommendation 6

Take appropriate action on the suppliers with questionable billing.

CMS Response

The CMS concurs. Upon receipt of the files from OIG, CMS will share any additional supplier and claims information with the Durable Medical Equipment Medicare Administrative Contractors (MACs). The CMS requests the OIG furnish the data necessary (Medicare contractor numbers, provider numbers, claims information including the paid date, HIC numbers, etc.). In addition, CMS requests that Medicare contractor-specific data be written to separate CD-ROMs or sent to a secure portal to better facilitate the transfer of information to the appropriate contractors. We will instruct the contractors to consider taking the appropriate

actions on the suppliers identified in this report and the additional claim information when prioritizing their Medicare review strategies or other interventions.

The Recovery Auditors review Medicare Fee-For-Service claims on a post payment basis and are tasked with identifying overpayments and underpayments. CMS has approved all Recovery Auditors to conduct complex review on DME. While CMS does not mandate areas for review, we will share this information with them and encourage them to consider these findings as they decide what claims to review.

The CMS appreciates the OIG's efforts and insight on this report. CMS looks forward to continually working with OIG on issues related to waste, fraud and abuse in the Medicare program.

ACKNOWLEDGMENTS

This report was prepared under the direction of Jodi Nudelman, Regional Inspector General for Evaluation and Inspections in the New York regional office, and Meridith Seife, Deputy Regional Inspector General.

Judy Bartlett and Judy Kellis served as the team leaders for this study. Other principal Office of Evaluation and Inspections staff from the New York regional office who contributed to the report include Christine Moundas, Shanti Nandiwada, and Rachel Siman; other central office staff who contributed include Robert Gibbons, Scott Manley, and Berivan Demir Neubert.

Office of Inspector General

http://oig.hhs.gov

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Important Message from the . . . **DME Medicare Administrative Contracto for the Centers for Medicare & Medicaid Servic**

August 11, 2011

Dear Physician – Documentation of Artificial Limbs

Dear Physician,

The Durable Medical Equipment Medical Administrative Contractors (DME MAC) have jurisdiction for processing claims from prosthetists for artificial limbs. In the event of an audit, the Medicare contractor may request medical records to demonstrate that the prosthetic arm or leg was reasonable and necessary. Since the prosthetist is a supplier, the prosthetist's records must be corroborated by the information in your patient's medical record. It is the treating physician's records, not the prosthetist's, which are used to justify payment.

The patient's functional capabilities are crucial to establishing the medical necessity for a prosthetic device. Many prosthetic components are restricted to specific functional levels; therefore, it is critical that physicians thoroughly document the functional capabilities of their patients, both before and after amputation. Clinical assessments of a patient's rehabilitation potential must be based on the following classification levels:

> **Level 0:** Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.
>
> **Level 1:** Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
>
> **Level 2:** Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.
>
> **Level 3:** Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
>
> **Level 4:** Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

The records must document the patient's current functional capabilities and his/her expected functional potential, including an explanation for the difference. Note that it is recognized, within the functional classification hierarchy, that bilateral amputees often cannot be strictly bound by functional level classifications.

The physician's assessment of a patient's physical and cognitive capabilities typically includes:

- History of the present condition(s) and past medical history that is relevant to functional deficits
- Symptoms limiting ambulation or dexterity
- Diagnoses causing these symptoms
- Other co-morbidities relating to ambulatory problems or impacting the use of a new prosthesis
- What ambulatory assistance (cane, walker, wheelchair, caregiver) is currently used (either in addition to the prosthesis or prior to amputation)
- Description of activities of daily living and how impacted by deficit(s)
- Physical examination that is relevant to functional deficits

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- Weight and height, including any recent weight loss/gain
- Cardiopulmonary examination
- Musculoskeletal examination
    - Arm and leg strength and range of motion
- Neurological examination
    - Gait
    - Balance and coordination

The assessment points above are not all-inclusive and physicians should tailor their history and examination to the individual patient's condition, clearly describing the pre and post-amputation capabilities of the patient. The history should paint a picture of your patient's functional abilities and limitations on a typical day. It should contain as much objective data as possible. The physical examination should be focused on the body systems that are responsible for the patient's ambulatory or upper extremity difficulties or impact on the patient's functional ability.

Note that when physicians are unable to provide the requested documentation to the supplier, the suppliers receive denials for the items billed which could result in your patient being financially responsible for all or part of the charges for the items/service received. If a supplier contacts your office to request additional clinical documentation, please partner with the supplier to establish what clinical records are needed to support that the service/item you ordered is medically necessary.

Section 1842(p)(4) of the Social Security Act mandates that:

> [i]n case of an item or service...ordered by a physician or a practitioner...but furnished by another entity, if the Secretary (or fiscal agent of the Secretary) requires the entity furnishing the item or service to provide diagnostic or other medical information in order for payment to be made to the entity, the physician or practitioner shall provide that information to the entity at the time that the item or service is ordered by the physician or practitioner.

Providing medical records to the supplier is not a violation of the HIPAA Privacy Rule. Thank you for your cooperation in future documentation requests.

Sincerely,

Paul J. Hughes, MD
Medical Director, DME MAC Jurisdiction A
NHIC, Corp.

Stacey V. Brennan, MD, FAAFP
Medical Director, DME MAC Jurisdiction B
National Government Services

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Medical Director, DME MAC Jurisdiction D
Noridian Administrative Services

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

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Congress of the United States
Washington, DC 20515

April 15, 2013

The Honorable Kathleen Sebelius
Secretary, US Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

CC: Marilyn Tavenner, Acting Administrator, Centers for Medicare and Medicaid Services

Dear Secretary Sebelius,

We are writing because of our concern that efforts to reduce fraud and abuse in Medicare claims for prosthetics may be harming access to care for the most vulnerable Medicare beneficiaries.

We strongly support efforts to combat fraudulent payments. According the GAO, for Fiscal Year 2011, the estimated improper payments within Medicare cost approximately $65 billion. Finding and stopping these fraudulent payments is a critical task, however, we are seriously concerned about the unintended consequences of current efforts that may reduce patient access to care and harm upstanding small businesses. It has been brought to our attention that audits conducted by the Centers for Medicare and Medicaid Services (CMS) contractors concerning claims for prosthetics are jeopardizing the economic viability of these critical health care providers.

As we see it there are two issues. The first is challenges to physician documentation for prosthetics. Auditors are now using a standard that CMS contractors, without the benefit of any rulemaking processes, generated in an August 2011 "Dear Physician" letter that is based on a flawed 2011 Office of Inspector General Report. Second, according to the industry, the number and scope of audits are continuing to increase dramatically. Furthermore, these claims are being appealed, with some adverse decisions by CMS contractor auditors being overturned at the administrative law judge (ALJ) level.

Consequently, CMS's current policies are resulting in contractor audits challenging legitimate payments for prosthetic care to the degree that these critical health providers are facing terminal cash flow deficiencies. In addition to jeopardizing the jobs and economic growth added by providers of orthotic and prosthetic devices and services, many of which are small businesses, the inability of these providers to serve patients, including vulnerable Medicare beneficiaries, creates an unnecessary barrier to access.

The American Orthotic and Prosthetic Association (AOPA), representing facilities that provide orthotic and prosthetic services, recently completed a survey of its members' encounters with such audits. The survey found that 77 percent of AOPA's facilities have been subject to one or more recovery audit contractor (RAC) audits relating to physician documentation, with many facilities having been subjected to more than 20 such audits in the 11 months preceding the survey. At the facility level, these and other similar audits have led to many small businesses being stretched to their breaking points financially, hindering economic growth and costing

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precious jobs. Taken collectively, the strain on the industry undermines critical patient access to orthotic and prosthetic services.

It is imperative that we find a way to develop policies that allow CMS to eliminate true fraud and abuse, while not slowing payment to providers so significantly that they cannot function. We believe it is possible to strike a reasonable balance that would ensure effective scrutiny and protection of taxpayer dollars while still preserving the viability of crucial orthotic and prosthetic specialists.

We understand it is not CMS' intent to harm these facilities. CMS leadership has also acknowledged significant deficiencies with the physician documentation standard (from the "Dear Physician" letter) that CMS contractors apply, frequently retroactively, to claims from before that standard was articulated. However, given that this has been the effect of anti-fraud activities, we respectfully request clarification on a few areas of concern for orthotic and prosthetic suppliers. Please respond to the following questions in writing.

- What specifically is CMS' policy to ensure that anti-fraud activities, while necessarily rigorous, do not place undue and/or counterproductive burdens on providers?
- Does CMS believe that implementing regulations pursuant to the Benefits Improvement Protection Act of 2000 (BIPA), Transmittal 656, or other measures, including legislation, could aid in ensuring that only licensed and/or accredited providers be eligible for Medicare reimbursement, thereby reducing instances of fraud and the need for overly burdensome "pay and chase" activities?
- Given the growing number and scope of audits, and the confusion over standards that providers are subject to, are there interim steps CMS could take to maintain program integrity while not restricting provider cash flow so severely?
- In some instances, after delivery of an orthotic or prosthetic device, auditors may disagree with a single line-item amongst an otherwise wholly appropriate course of treatment, resulting in a provider's payment being entirely withheld. Would it be possible for CMS to withhold reimbursement for the specific codes or components of an artificial limb that CMS' auditors believe is inappropriate, instead of denying payment for the entire limb or service?
- Can you provide information documenting the rate at which ALJ decisions ultimately result in auditor payment denials being reversed, both in number and as a percentage of total appeals, also noting at what stage of appeal the final decision was made?

If you have any questions, please do not hesitate to contact Kalina Bakalov in the office Representative Tammy Duckworth at 202-225-3711, or Megan Spindel in the office of Representative Brett Guthrie at 202-225-3501.

Sincerely,

Tammy Duckworth

Tammy Duckworth (IL-08)
MEMBER OF CONGRESS

Brett Guthrie

Brett Guthrie (KY-02)
MEMBER OF CONGRESS

Aaron Schock (IL-18)
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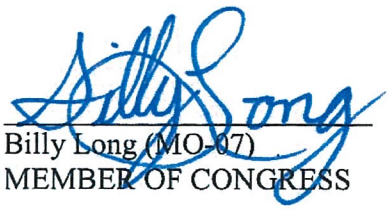

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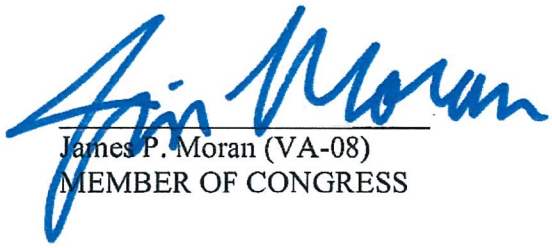

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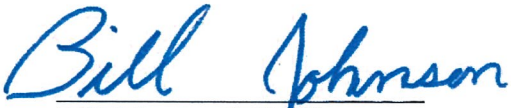

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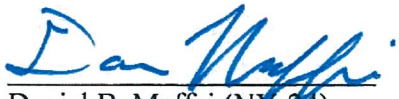

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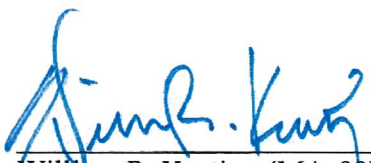

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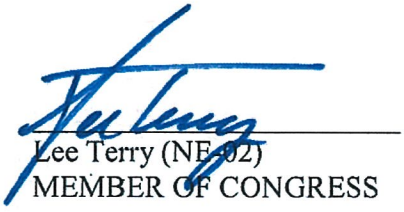

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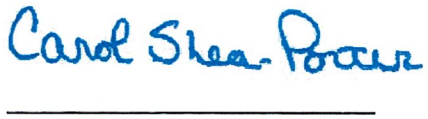

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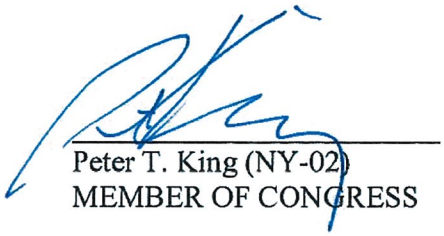

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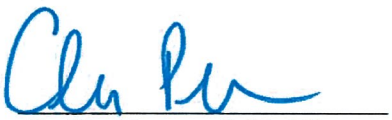

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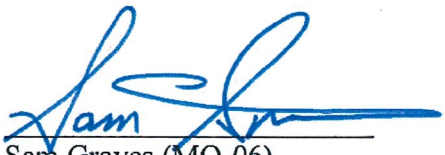

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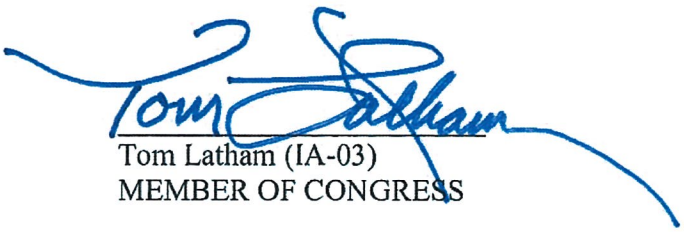

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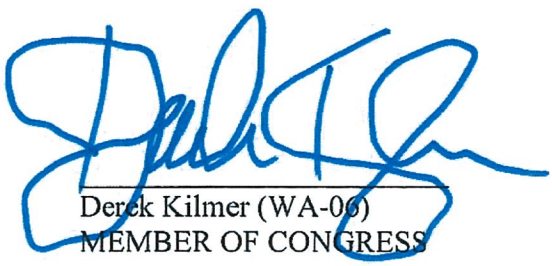

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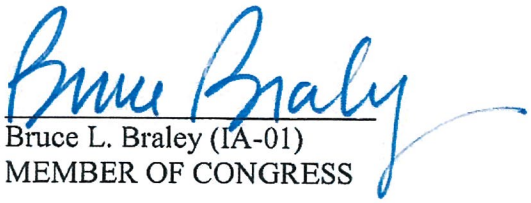

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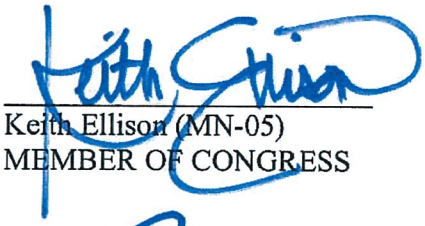

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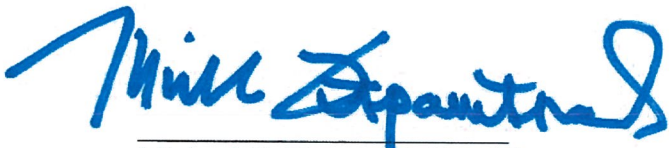

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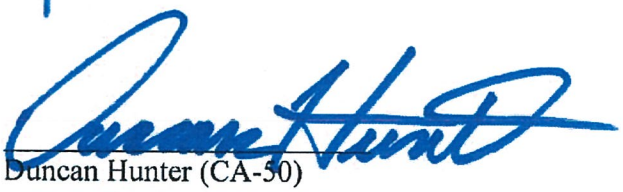

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MEMBER OF CONGRESS

Avalere Analysis of Utilization and Medicare Spending on Prosthetic Feet, Prosthetic Foot Systems, and Additions to Prosthetic Feet

		2005		2006		2007		2008		2009		2010	
HCPCS	Description	Total Medicare Allowed Services	Total Medicare Spending	Total Medicare Allowed Services	Total Medicare Spending	Total Medicare Allowed Services	Total Medicare Spending	Allowed Services	Total Allowed Amount	Allowed Services	Total Allowed Amount	Allowed Services	Total Allowed Amount
L5970	External keel SACH foot	1,332	$230,487	910	$161,621	760	$140,317	655	$125,204	572	$114,591	629	$125,755
L5971	All lower extremity prosthesis, solid ankle cushion heel (SACH) foot, replacement only	.	.	249	$45,410	201	$36,262	152	$29,157	142	$28,885	137	$27,330
L5972	Flexible keel foot	7,512	$2,386,425	7,697	$2,451,507	7,422	$2,474,973	6,806	$2,332,552	6,130	$2,206,386	6,680	$2,402,820
L5973	Microprocessor controlled ankle/foot	.	.	.	.	.	.	.	.	.	.	200	$3,054,545
L5974	Single axis ankle/foot	3,455	$740,882	2,893	$612,905	2,455	$544,255	2,124	$488,783	1,904	$465,480	1,626	$389,411
L5975	All lower extremity prosthesis, combination single axis ankle and flexible keel foot	1,461	$548,060	1,455	$549,991	1,278	$501,588	1,298	$522,341	1,165	$489,762	1,013	$426,672
L5976	Energy storing foot	4,650	$2,318,417	4,471	$2,198,700	4,003	$2,061,498	3,451	$1,822,648	2,730	$1,532,207	2,291	$1,286,647
L5978	Multiaxial ankle/foot	1,451	$383,978	1,151	$303,970	1,038	$287,367	868	$245,481	607	$180,153	603	$178,540
L5979	Dynamic response/ multi-axial ankle	4,648	$9,200,348	4,321	$8,538,659	3,791	$7,826,860	3,347	$7,080,843	2,612	$5,806,106	2,243	$4,970,747
L5980	Flex foot system	4,793	$15,348,173	5,490	$17,527,659	5,770	$19,078,864	5,837	$20,059,862	5,366	$19,321,894	5,248	$18,967,559
L5981	Flex-walk system	7,265	$18,400,959	7,664	$19,438,283	8,946	$23,593,582	9,704	$26,236,841	11,427	$32,392,719	11,345	$32,163,083
L5987	Shank foot vertical loading pylon	1,636	$9,370,825	2,086	$11,966,931	2,608	$15,605,547	3,222	$19,830,154	3,694	$23,905,219	4,626	$29,943,555
L5990	Addition to lower extremity prosthesis, user adjustable heel height	446	$645,609	293	$425,357	167	$250,213	192	$300,339	215	$352,726	142	$233,046
	TOTAL	38,649	$59,574,163	38,680	$64,220,993	38,439	$72,401,326	37,656	$79,074,205	36,564	$86,796,128	36,783	$94,169,710

Source: Avalere analysis of the Physician/Supplier Procedure Summary Master File
http://www.cms.gov/NonIdentifiableDataFiles/06_PhysicianSupplierProcedureSummaryMasterFile.asp#TopOfPage

Avalere | © Avalere Health LLC

OIG, DME MACs, CERT Reports Relating to Claims for Orthotics and Prosthetics: Where There is Smoke, Is There Really Fire?

Starting on August 28, 2011 with the Report from the HHS Office of the Inspector General, several reports and or complaints have surfaced relating to Medicare claims documentation filed by orthotics and prosthetics providers. The best way to get a sense of these critiques and their value is to look at some of the specific assertions:

Comments from OIG "Questionable Billing by Suppliers of Lower Limb Prostheses"

"In 2009, Medicare inappropriately paid $43 million for lower limb prostheses that did not meet certain requirements....Most of these payments were made to suppliers that incorrectly billed for prostheses for both the right and left limbs using two claims, rather than one. Billing in this manner allows these suppliers to appear to be billing for only one limb when in fact they are billing for both limbs."

AOPA Response. This analysis seems to miss the fact that there are a significant number of bilateral amputees, who have lost both left and right limbs, and the long-standing policy for the claims for these patients is that their prosthetic claims can legitimately be reported as both limbs in a single claim or separate claims for the right and left limbs respectively. OIG's lack of familiarity with the field showed when they labeled this practice as claim splitting. By definition, a bilateral amputee may receive two separate prosthetic devices and each is, in fact, a separate service. It is well within the regulation and an appropriate claims submission policy to submit two separate claims on the same date of service for bilateral amputees. The fact that bilateral lower limb prostheses are billed on separate claims—or on more than one claim form—does not, by itself, point to any questionable or fraudulent billing practices.

"Medicare paid an additional $61 million for beneficiaries with no claims from their referring physicians. These beneficiaries had no Medicare Part A or Part B claims that included their referring physicians during the last 5 years, meaning they did not have an office visit with or receive any other services from their referring physicians during this time. Billing for prostheses when the beneficiary had no claims from the referring physician raises questions about whether the physician ever evaluated the beneficiary and whether these devices were medically necessary."

AOPA Response. OIG's assertions demonstrate they do not understand how care is delivered to amputees. But it says volumes about the tug-of-war CMS and OIG are engaged in to use patients and providers as surrogates to try to wrangle more extensive documentation from physicians. Yet, CMS refuses to compensate physicians anything for the additional documentation they are demanding. A few keys facts that OIG seems to misunderstand:

- In their medical training, most physicians do not learn specifics about the mechanics. engineering, operation and repair of prosthetic devices;
- Typically, the referring physician for a patient's first prosthesis will be the surgeon who performed the amputation—this referring physician is very unlikely to have an ongoing role in the patient's care, hence it would be very unusual for the patient to have a regular visit with this "referring physician."
- The physician's prescription, unsupported by proof of a face-to-face visit is, sufficient alone to prompt the delivery of Class I narcotics to a patient. In the case of prosthetics, under the long-standing care model, a second layer of physician documentation has been provided in addition to the physician's prescription which includes the physician's prescription (which includes the physician's assessment of the patient's "K" level— which is the physician's best estimate of the patient's expected level of recovery. The initial prescription is taken to the prosthetist who generates a "detailed order" of precisely how and with what components the device will be fabricated, which goes back to the prescribing physician for signature. Given the facts of physician training underscored in the first bullet, the physician could not have done this by

themself. Yet, OIG and CMS contractors are now saying this detailed order is not to be trusted because it was prepared with the technical assistance of the O&P provider. Now, in addition to the two official orders signed by the physician, CMS/OIG seek to impose a third documentation layer, evidence in the physician's notes of a face-to-face patient examination with very specific recitation of why the prothesis needs to be replaced in order for the patient to be able to walk.

- Patients who have had amputations and wear prosthetic devices have ongoing health care needs, and are likely to have a primary care physician like everyone else. Some may have a physical medicine and rehabilitation physician or an orthopedic specialist; the majority of amputees do not have a physician whose primary focus is their mobility needs. Routinely, if there is a problem with their prosthesis, the patient goes to the prosthetist, knowing that the prosthetist is the one who can repair the device and get them walking again.

"The four DME MACs had varying claims processing edits in place, but none had edits for all requirements."

AOPA Response. The reaction to this assertion has been to prompt DME MACs into zero tolerance "deny" mode. The DME MACs generated a "Dear Physician" letter, which again makes the patients and providers their heavies, the enforcers and enlisting this help under threat of claims denial to extract more and more unpaid documentation from physicians.

In addition to the above, the "questionable billing" report is seriously flawed because CMS and the OIG looked at the totality of suppliers and didn't make any distinction between qualified and unqualified suppliers. Many of the problems they found would be from those unqualified suppliers. Failure to segregate claims by the qualifications of the supplier has contributed to the OIG's negative findings in its report, and caused the OIG to unfairly characterize the billing practices of legitimate and qualified providers of O&P services as "questionable."

Comments from OIG "Program Integrity Problems with Newly Enrolled Medicare Equipment Suppliers"

"Although NSC conducted post enrollment site visits within the timeframes required by CMS, several suppliers in our sample had already received significant Medicare payments before the first site visit."

AOPA Response. The OIG has identified some shortcomings by NSC, a Medicare contractor. This may be a CMS/contractor process that needs to be rectified, but it is not, ipso facto, fraudulent.

"Four percent of high- and medium-risk suppliers omitted information regarding criminal histories or adverse legal actions from their applications."

AOPA Response. Again, CMS and its contractors should be looking to see that required information is fully provided.

"Thirteen percent of high- and medium-risk suppliers and 4 percent of low/limited risk suppliers omitted ownership or management information from their Medicare enrollment applications."

AOPA Response. Once again, it is legitimate for Medicare and its contractors to require that enrollment forms be completed with answers to all questions, but this does not equate to fraudulent efforts by providers.

This study highlights the flaws in the system whereby the supplier enrollment process assures that that qualified suppliers are appropriately vetted, yet on the payment side there is only a claim level edit that validates that the supplier is properly enrolled and that there is no claim edit examining appropriateness or qualifications of the supplier to the service billed.

Finally, we note that this report is not specific to orthotics and prosthetics, but relates to all of DMEPOS, and further *reflects the state of activities over two years ago.* The report states: "We selected a stratified random sample of DMEPOS suppliers that enrolled in Medicare for the first time between October 1 and December 31, 2008.....We examined multiple data sources regarding the sampled suppliers, covering the period from the date of their Medicare enrollment through December 31, 2009."

NHIC, Corp, A DME MAC Jurisdiction A Contractor: Result of Widespread Prepayment Probe for Lower Limb Prostheses

"(C)odes billed with a K3 functional level modified and components/additions provided....For the remaining 86 claims, 10 claims were allowed and 76 were denied resulting in a claim denial rate of 88%...an overall Charge Denial Rate of 86.6%.

AOPA Response. This report demonstrates some of the downstream consequences of the OIG's report. The flaws of the OIG report have been taken by DME MACs and other CMS contractors as if they were correct. These contractors have now initiated a "crack down" on the legitimate billing practices of honest O&P professionals. Contractors have adopted a zero tolerance policy. It appears that the CERT and OIG processes are basically using a black and white financial control model to look at health care claims. In essence they are treating health care claims as financial documents where by in an audit any single individual exception negates the entire transaction. Perfection is not the normal standard for payment of a health care claim, but clearly, as to O&P claims; frightened contractors have taken the cue—if the claim is not perfect, reject it.

"96% of the denied claims were missing the clinical documentation to corroborate the prosthetist's records and support medical necessity."

AOPA Response. Thus at a claim level O&P providers are seeing a lack of adequate physician documentation as a fatal claim transaction flaw because the Program Integrity Manual says that medical necessity resides there. Likewise, is the prohibition on using "clinical inference" to adjudicate a claim. Inference is not an acceptable path in financial audit and analysis.

For example, prohibition on clinical inference has been interpreted to mean that the fact that the patient has a Medicare claim for an amputation, and has received a prosthesis previously, it cannot be assumed the patient is an amputee unless that is documented in the physician's notes. Claims staffs caution that they will not process for payment a claim to an O&P provider unless the provider has secured a signature of the physician sufficiently legible that all letters in the doctor's full name can be identified.

This approach by these Medicare contractors is reactionary. Their regular and appropriate claims processing practices have been questioned, so they have shifted into a "deny" mode that does not serve Medicare, its beneficiaries or its providers well.

Conclusion

There is fraud and abuse across DMEPOS. Problems in DME are significantly worse than in O&P, but there is undoubtedly significant fraud in orthotics and prosthetics. Unfortunately, the measures underscored in the reports referenced above by the OIG and Medicare contractors don't understand the problem very well, and the steps they are taking will not rectify the fraud and abuse that does exist in orthotics and prosthetics. These measures deny claims, and deny amputees patient access to the care promised to Medicare beneficiaries. There is, however, a powerful vehicle that would attack this O&P fraud—**enactment of the Medicare Orthotics and Prosthetics Improvements Act, H.R. 1958 has been estimated to save Medicare between $100 to $230 million per year!**

UGH!!!!! Believe me, I am only the messenger so please do not shoot me! While some of the stuff above is not really documented in the policies; I can assure you that Medicare is using the "gray areas" of the policies to deny claims. All of the info above is coming directly from denials that we are having to appeal, and too often, coming as a surprise to all! I will just share a few of the recent denials (understand these may not be yours but could be one of our other clients) that we have had to appeal and you can judge for yourselves...

1. Dispensing order that was obtained prior to delivery and filed but unreadable. Audit received. Practice asked to contact physician office for a more legible copy of the document. Document received via fax. The date that the script was signed is supported by clinical notes and the signature date is well before delivery. Across the top, of course, it shows when the fax was sent. Claim denied due to date that the document was received. Claim still in appeals.
2. Item dispensed that is not on the PDAC. Currently, there is no policy that I can find that "requires" PDAC approval on every device. There is a requirement on diabetic shoe and insert policy but not on all (yet). Claim denied for not having PDAC verification of device. Claim still in appeal status.
3. The new AFO/KAFO policy was just actually published a couple of weeks ago on the DMERC websites. However, it became effective January 1, 2014. We have had 3 denials from Medicare replacement policies related to the new requirements for either a Cro Walker or Static AFO (months before the policy was actually put on the website for providers to make the appropriate changes to meet the policy requirements).
4. Claim for spinal brace. All of the Medical records clearly show the necessity for a spinal brace, including X-Rays and MRI's. However, because the physician did not specifically state that he ordered a spinal brace at the in-person visit, the claim denied. They could not find anything in the records that were wrong EXCEPT that the physician did not notate the order. Claim denied and is currently in appeal.
5. Dispensing order received and patient was not seen by the physician prior to the date written. Patient was told by the practice to get an in-person evaluation with their physician. Clinical notes

were obtained as a result of that in-person visit, however, a new dispensing (written) order was not obtained. Device was delivered but the detailed written order was still pending. Claim was not billed until the detailed written order was received, however, because the physician did not see the patient prior to writing the order, the written order was considered null and void. Since the device was delivered without having a valid order on file (the written order is not valid and the detailed was received prior to delivery), the claim was denied. This claim is still in appeal.
6. Physician that actually wrote the dispensing order (written order) is not the same as the physician that signed the detailed written order (actually, the PA signed the dispensing and the physician over the PA signed the detailed). Claim denied. The claim is in appeal.
7. Last but not least.... Physician sent 2 of 7 pages of clinical notes from an in-person visit. The two pages that were on file clearly support the need for the ordered device and do state that the device was ordered. Since the pages received clearly stated page 2 of 7 and page 3 of 7, the DMERC inappropriately assumes that we (the practice) removed the other pages because they contradicted the necessity for the device and denied the claim. The actual fact in this case is that the patient is HIV positive (which is a protected health class) and neither the patient nor the physician is required to give the records as it relates to the HIV status to anyone that is not directly impacted by that part of the record. But again, the claim is denied and either way it was necessary to appeal.

Do ya'll see where I am going with this..... The audits are getting much uglier than they were. They are looking at records that we have not even seen or know exist to make determinations about a patient's functional levels. They are looking at dates that faxes are received to state that they were not on file prior to delivery, etc. They are looking to see if a device was ordered before the patient actually had an in-person evaluation.....

So, for my final thoughts, there is no way to forecast where and how some of the newer denials will come through. In other words, I do not have a magic wand that will forewarn me where the next punch will come from. The DMERCs are constantly looking for new (and actually creative) ways to pick holes in existing policies to recoup your funds.

While we will still continue to attempt to close those gaps, sometimes we are caught with our mouths

Tom Fise

From: Tom Fise
Sent: Tuesday, July 01, 2014 10:07 AM

, Thanks for passing this along. Some of the things you have noted were new to me, and some were things of which I am aware. There is no doubt that the contractors' behavior on what is an appropriate basis to deny Medicare payment is pernicious. I was commiserating with a colleague from one of the medical societies yesterday that what has changed in the Medicare world in the past five years is that the agency used to sometimes reach outrageous conclusions about denying or reducing payments, but they were always able to articulate some semblance of a comprehensible rationale for their actions. Now, any semblance of rational or fairness has been jettisoned. Medicare has negligible care for its providers, and only the slightest scintilla of added concern for Medicare beneficiaries—it is ALL and ONLY about the money, and if the contractors can find even the flimsiest, or even ludricous assertion as the basis for denying a claim, that claim is essentially ALWAYS denied.

Take-Aways from Email from AOPA Member:

1. CMS appears to have no process or scientific backing for policies like OTS, AKO/KAFO, pre-fab vs. custom fitted.
2. CMS/contractors have no authorization for applying new policies retroactively, with stated effective dates that pre-date the date the policy was either issued, or even first thought of.
3. There is NO face-to-face physician visit requirement for O&P (though there is for DME)—contractors confuse the two, so seem to be demanding evidence of a face-to-face that has never been mandated.
4. There is NO universal PDAC verification requirement, so having one cannot be a prerequisite for getting paid.
5. A RAC audit denial is not a final agency decision until ALJ appeal process, yet CMS is trying to collect under surety bonds for claims that are pending appeals (and placing the bond-holders at risk of going out of business).

PALMETTO
Prosthetics & Orthotics, Inc.

451 West Cheves Street
Florence, South Carolina 29501
(843) 673-9222

Hello Tom,

We received this blanket letter from a local MD's office.
This attitude is representative of a lot of the physicians' offices in South Carolina.

I do not blame this group at all. It is becoming increasingly more difficult to provide "medically necessary" services to our patient's.
Also, their suggestion on having patient's bring the paperwork with them to the appointment was frowned upon by Medicare. We tried it; CMS called and stated that it was the responsibility of the facility to get the documentation.
Hopefully, this will be a productive arrow in your quiver.
Let me know what I can do to further help our plight.

PS. That was not our patient with the LSO.

John L Moyd

John Moyd

Family Physicians

January 23, 2012

TO: Medical Supply Businesses, Diabetic Supplies, Mobility Devices and Wheelchairs, All Orthopedic Devices including Lumbosacral Supports, Urological Supplies including Erecto-vac.

Dear Sirs:

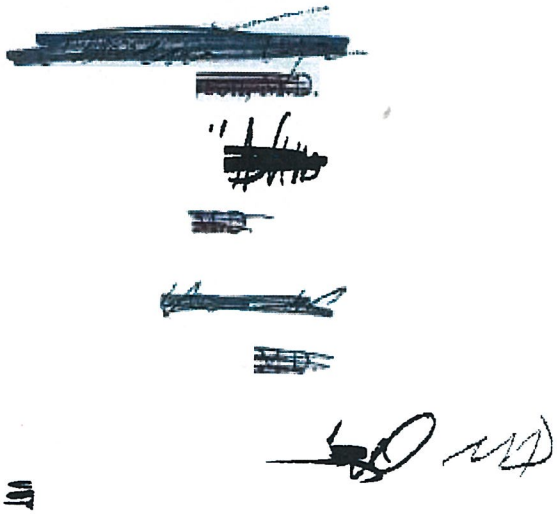
This is to inform you that beginning immediately we will trash all forms regarding any of the above items.

Your paperwork is requiring an inordinate amount of staff time and physician time to handle the "mail". We are receiving not just dozens, but hundreds of forms on the same person. One patient you are sending lumbosacral orthotic request for I would estimate we have received three-hundred pieces of paper spread out over the last year; same applies to another patient regarding diabetic supplies.

We suggest sending your forms to the patients to bring with them to their appointment.

Again, any further forms received will be trashed immediately on receipt by the office staff.

Sincerely,



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

MAR - 6 2014

The Honorable Dave Camp
Chairman
Committee on Ways and Means
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Thank you for your letter about the Centers for Medicare & Medicaid Services' (CMS) efforts to ensure that only qualified orthotic and prosthetic professionals are providing devices and services to Medicare beneficiaries. CMS is committed to protecting the health of all Americans and to aggressively combating fraud, waste, and abuse in federal health care programs. CMS takes very seriously your concerns regarding potential program vulnerabilities and risks to beneficiaries.

You asked about the status of the regulations required by the Medicare, Medicaid, and State Children's Health Insurance Program Benefits Improvement and Portability Act of 2000 (BIPA). This law requires that no payment be made for an item of custom-fabricated orthotics or for an item of prosthetics unless the item is furnished by a qualified practitioner and fabricated by a qualified practitioner or a qualified supplier at a facility that meets criteria the Secretary determines appropriate. CMS is currently developing a notice of proposed rulemaking and anticipates that it will be published this calendar year.

The statute also directs the Secretary to engage in negotiated rulemaking with interested parties to define the parameters of the requirements. CMS established a Committee on Special Payment Provisions for Prosthetics and Certain Custom Fabricated Orthotics in October 2002. The Committee met nine times from October 2002 to July 2003. Although the Committee failed to reach consensus, the Committee did concur on certain recommendations. Since that time, we have been seeking ways to pursue many of these recommendations and to achieve a consensus on these important issues.

While CMS has not yet implemented certain provisions of BIPA through rulemaking, CMS has taken significant steps to limit who can be paid for prosthetics and custom fabricated orthotics. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires all DMEPOS suppliers, including those furnishing orthotics and prosthetics, to become accredited and requires the Secretary to designate independent accreditation organizations in order to evaluate suppliers for compliance with quality standards that are required to be met in order to be accredited. The Medicare Improvements for Patients and Providers Act of 2008, set a deadline of September 30, 2009, for all suppliers to become accredited.

The CMS published final rules implementing the MMA requirements for accreditation organizations on August 18, 2006 (71 FR 48354). These rules specified the criteria that all approved accreditation organizations must meet. In December 2006, we approved 11 accreditation organizations, which are now 10 accreditation organizations because two merged. These accreditation requirements are an important part of our efforts to assure that only qualified providers and suppliers are able to provide and bill for services and supplies.

Another critical tool in CMS's oversight of DMEPOS payment is the surety bond requirement, which was included in the Balanced Budget Act of 1997 (P.L. 105-33) and was implemented in a January 2009 final rule. This required new DMEPOS suppliers to have obtained a surety bond by May 4, 2009, and enrolled suppliers by October 2, 2009. Based upon these new accreditation and surety bond requirements, 10,533 DMEPOS suppliers were revoked between October 2009 and December 2009.[1] In addition to those revoked, approximately 1,500 more suppliers voluntarily terminated their enrollment between September 2009 and December 2009, likely to avoid facing revocation actions until they could procure a surety bond or obtain accreditation. Additionally, CMS has collected approximately $1.6 million in DMEPOS supplier overpayments from sureties between February 2012 and March 2013. During this same time period, CMS recouped an additional $18.5 million directly from DMEPOS suppliers immediately after their debts were referred for payment. Evidence indicates that despite these reductions in DMEPOS supplier enrollment, beneficiaries continue to have access to the DMEPOS they need.

To conduct oversight of DMEPOS suppliers, CMS uses the National Supplier Clearinghouse (NSC), a contractor responsible for processing all DMEPOS enrollments. On a quarterly basis, the NSC determines which states require orthotic and prosthetic professionals to be licensed or certified in order to furnish orthotics or prosthetics. When a state has enacted a new licensure law, CMS implements an edit that immediately limits payment only to those suppliers that have listed a specialty of orthotics and prosthetics on their enrollment applications. Then the NSC determines whether all orthotic and prosthetic suppliers in the affected state have the newly required licenses or certifications.

Currently there are 14 states for which the edits are in place and all suppliers have been reviewed for current compliance. We are in the process of implementing edits in two additional states, North Dakota and Iowa, and we will be stopping payments if, after the applicable notification period, suppliers are not properly licensed or do not comply with the NSC's documentation request. The notification period gives suppliers a reasonable timeframe to comply with the change in state law while ensuring beneficiary access to services.

Thank you for your interest in CMS's ongoing efforts to ensure that only qualified and legitimate providers and suppliers can provide health care items and services to Medicare beneficiaries, and

[1] Due to the large number of last minute filings, 2,803 of those revocations were subsequently overturned as suppliers were able to demonstrate compliance with both requirements.

I look forward to working with you on these issues going forward. I will also provide this response to Chairman Kevin Brady.

Sincerely,

Marilyn Tavenner

Marilyn Tavenner

DAVE CAMP, MICHIGAN,
CHAIRMAN

SAM JOHNSON, TEXAS
KEVIN BRADY, TEXAS
PAUL RYAN, WISCONSIN
DEVIN NUNES, CALIFORNIA
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JENNIFER SAFAVIAN,
STAFF DIRECTOR

Congress of the United States
U.S. House of Representatives
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DANNY K. DAVIS, ILLINOIS
LINDA SÁNCHEZ, CALIFORNIA

JANICE MAYS,
MINORITY CHIEF COUNSEL

February 12, 2014

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Dear Ms. Tavenner:

We write today to bring to your attention a matter that we believe is negatively impacting the Medicare program. Specifically, we are concerned about the ability of the Centers for Medicare & Medicaid Services (CMS) to ensure that only qualified orthotic and prosthetic (O&P) professionals are providing O&P devices and services to Medicare beneficiaries in accordance with existing Medicare requirements, including those that support the Durable Medical Equipment (DME) Competitive Bidding Program.

Payments to unqualified providers undermine the integrity of the Medicare program. Such payments drain the Medicare trust fund and expose Medicare beneficiaries to poor quality care. The Medicare, Medicaid and SCHIP Benefits Improvement and Portability Act of 2000 (BIPA) took the prudent step of establishing, as a condition for Medicare reimbursement, a requirement that providers of O&P devices and services possess either an applicable license to provide O&P services, or an equivalent level of accreditation. We are concerned that these requirements have not been appropriately enforced by CMS and that other program integrity efforts have not been adequately implemented.

An October 2012 report issued by the Department of Health and Human Services Office of the Inspector General documents that CMS had not promulgated relegations related to BIPA payment requirements for O&P devices and services. In addition, CMS has been slow in instructing Durable Medical Equipment Medicare Administrative Contractors (DME MACs) to update their claims processing systems to prevent payments to unlicensed providers. Five states have enacted O&P licensure laws since 2006, yet CMS only required DME MACs to implement the new claims edits needed to prevent improper payments in these states in August 2013. While we appreciate that CMS has implemented these edits, the time lapse is concerning.

We therefore respectfully request a report concerning the status of O&P device and service regulation and oversight of the impact on claims reimbursement, particularly in those five states affected by Change Request 8390. In addition, as more states add licensure laws and requirements, we ask that CMS inform us on how the agency plans on ensuring that Durable Medical Equipment Medicare Administrative Contractors are updated on a timely basis.

We believe all Medicare beneficiaries deserve access to quality providers, and that by not enforcing the measures to ensure only certified O&P providers receive payment, CMS is missing a valuable opportunity to reduce fraud and improve patient outcomes and experience. We appreciate your continued efforts to improve the integrity of the Medicare Program and look forward to your timely response.

Sincerely,

DAVE CAMP
Chairman

KEVIN BRADY
Chairman
Subcommittee on Health

United States Senate

WASHINGTON, DC 20510

February 5, 2014

Marilyn Tavenner
Administrator
Center for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Dear Administrator Tavenner,

We write today to bring to your attention a matter that we believe is negatively impacting the Medicare program. Specifically, we are concerned about the ability of the Centers for Medicare & Medicaid Services (CMS) to ensure that only qualified orthotic and prosthetic (O&P) professionals are providing O&P devices and services to Medicare beneficiaries in accordance with existing Medicare requirements, including those that support the Durable Medical Equipment (DME) Competitive Bidding Program.

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Sincerely,

Ron Wyden
United States Senator

Debbie Stabenow
United States Senator

Medicare Payments for O&P Services by Provider Type

The orthotic and prosthetic (O&P) community is interested in deterring fraudulent providers from providing orthotic or prosthetic care to Medicare beneficiaries. The community believes that one way to eliminate fraud would be for the Centers for Medicare & Medicaid Services (CMS) to enforce existing policy that unlicensed providers cannot receive payment for providing orthotic and prosthetic services to Medicare beneficiaries within a licensure state. The policy was passed by Congress as part of the Benefits Improvement and Protection Act of 2000 (BIPA Section 427) and mandated that within one year of enactment custom fabricated orthotics and all prosthetics must be provided by "qualified practitioners" and "qualified suppliers." Transmittal 656, effective October 1, 2005, further mandated that CMS should only pay for O&P services for Medicare beneficiaries from practitioners and suppliers that meet state O&P licensure laws. However, no steps were taken to enforce either of these provisions. Fourteen states have enacted an O&P licensure statute; therefore, despite current practice, only certified personnel are authorized to provide O&P services to Medicare beneficiaries in those states.

To demonstrate the need for effective enforcement of the policy, the O&P community was interested in quantifying the proportion of services provided in O&P licensure states by unlicensed providers. A "60 Minutes" segment that aired on October 25, 2009 highlighted extensive fraudulent payments to unlicensed providers in Florida, which is an O&P licensure state. There was a desire to secure data as to whether such Medicare payment to unlicensed providers has been curtailed, or has continued, largely unabated.

The American Orthotic and Prosthetic Association (AOPA) commissioned Dobson DaVanzo & Associates, LLC (Dobson | DaVanzo) to analyze Medicare claims data from 2007 through 2011 to determine the extent to which Medicare is reimbursing non-certified O&P personnel in states with a licensure statute for selected O&P services. The analyses conducted by Dobson | DaVanzo was then compared to prior analyses of claims data conducted on behalf of AOPA from 2001 through 2006. This memo summarizes the findings and trends of the data analyses from 2007 to 2011 and compares them to the trends from 2001 to 2006.

Identifying Provider Certification Status through Medicare Claims

Prior to receipt of a Medicare provider number to administer O&P services to Medicare patients, providers are required to self-designate into one of the following personnel categories: O&P Personnel (certified orthotists and/or prosthetists), medical supply facility with certified O&P professional, hospital, pharmacy, physician, occupational or physical therapist, and medical supply facility without a certified O&P professional on its staff. After the provider receives a Medicare provider number, the category designation is generally not tracked by CMS for accuracy. This category designation is reported on every claim submitted to Medicare for reimbursement and included in the publicly available Medicare claims data in the provider specialty field.

While certification is not an absolute indicator that a provider is licensed, there is a strong correlation in licensure states between being certified and being licensed. That is, it is reasonable to expect that in states with licensure, there would be a higher proportion of practitioners with certifications than compared to states without licensure. Since a personnel category is designated for the entire billing entity (e.g., medical practice or supply company), one would also expect that the composition of the personnel might

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change within the entity over time. For example, a medical supply company identified to have no certified O&P professional may hire certified O&P personnel at a later time, without changing their CMS category designation. Despite the fact that the classification of the entity may change in practice, for the purpose of this analysis, we assume that the self-designated category reflects the true composition of the personnel providing the service.

Trends in Health Care Utilization by Certified and Non-Certified O&P Personnel

In order to determine the extent to which Medicare is reimbursing non-certified O&P personnel in states with O&P licensure statute, we conducted a DME claims analysis using the 5 percent sample limited data set (LDS) of Medicare beneficiaries from 2007 through 2011. For a subset of O&P services[1] we compared the allowed services reimbursed by Medicare by provider designation for three of the states with licensure – Florida, Illinois, and Texas – and overall across all three states.

Exhibit 1 presents the results of our analysis across the three states. Across all five years (2007-2011) and both orthotic and prosthetic service categories, in the aggregate, about one-third (32.3 percent) of Medicare allowed services were billed by certified O&P personnel. The remainder – 67.7 percent – was billed by other providers such as physicians and medical supply companies without certified O&P personnel.[2] Most states that have O&P licensure exempt physicians and therapists from those licensure requirements, which places particular emphasis on the subcategory of medical supply facilities that reported in their Medicare registration that they have no certified O&P personnel.

Orthotic base codes, comprising off-the-shelf, custom fitted high and low orthotics, and custom fabricated and fitted orthotics, are billed by certified O&P personnel for 31.6 percent of allowed charges. Prosthetic base codes are billed by certified O&P personnel for 84.1 percent of all allowed charges.

Exhibit 1: Percent of Allowed Services for O&P Services Billed by Certified O&P and Other Personnel (2007-2011)

O&P Service	Total Allowed Services (2007-2011)	Percent of Allowed Services Billed by Certified O&P Personnel (2007-2011)	Percent of Allowed Services Billed by Other Personnel (2007-2011)
All Orthotic Base Codes	3,574,020	31.6%	68.4%
Off the Shelf Orthotic	428,380	27.1%	72.9%
Custom-Fitted Low Orthotic	425,600	30.7%	69.3%
Custom-Fitted High Orthotic	2,114,520	31.0%	69.0%
Custom Fabricated & Fitted Orthotic	605,520	37.6%	62.4%
Prosthetic Base Codes	49,980	84.1%	15.9%
Total	**3,624,000**	**32.3%**	**67.7%**

Source: Dobson | DaVanzo analysis of DME services for 5% sample of Medicare beneficiaries (2007-2011), extrapolated to universe of Medicare beneficiaries.

In most service categories, the proportion of allowed services billed by certified O&P personnel have decreased over time, as other providers (non-certified O&P personnel) have increased their billing. This

[1] Services of interest include orthotic and prosthetic base, custom fabricated and fitted orthotic base, custom fitted high and low orthotic base, and off the shelf orthotic base codes.

[2] Since physicians are exempt from licensure requirements, we estimate that 63.8 percent of O&P services were provided by either certified O&P personnel or physicians. Therefore, about 36.2 percent of services across all categories were provided by other non-certified personnel from 2008 through 2011.

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trend suggests that reimbursement to non-certified O&P personnel has been allowed since the passage of BIPA and Transmittal 656. Furthermore, any actions by CMS to prohibit or reduce reimbursement to these non-certified providers have been unsuccessful.

In comparing the trends in health care utilization prepared on behalf of AOPA for 2001 through 2006 to the results above for 2007-2011, similar trends were observed, in that immediately following passage of BIPA and release of Transmittal 656, the proportion of allowed services billed by non-certified O&P personnel did not significantly decrease.

The percent of allowed services billed by certified O&P and other personnel by state and year is presented in the attached analyses.

Conclusions

The data from 2001 to 2006, and from 2007 to 2011, show that there has not been any significant change by CMS to eliminate payments to unlicensed providers in O&P licensure states. Specifically, no reduction in the proportion of payments to non-certified O&P personnel has been evidenced since 2009. In fact, the data show an increase in the proportion of Medicare payments to non-certified personnel in licensure states. Our analytic results are consistent with the results of a third party independent survey that confirmed that non-certified providers are continuing to provide O&P services to Medicare beneficiaries as recently as in 2013. If any CMS enforcement to eliminate payments to unlicensed providers in O&P licensure states has occurred, it does not appear to have to been effective.

If CMS was to actively enforce that unlicensed providers cannot receive payment for providing O&P services to Medicare beneficiaries within a licensure state, Medicare savings could be realized. Under such enforcement of limiting payments to providers with proven licensure and standards of training and experience, payments to unqualified providers would be eliminated. As the "60-Minute" special suggested, allowing non-certified personnel to provide these services, especially in states with licensure, could lead to fraud and abuse in O&P services, as well as expose patients who received these services to inappropriate or substandard care. Therefore, shifting payments to only certified providers could result in better care for beneficiaries and lower Medicare payments.

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All States

Base Code Summary by Supplier Classification - 2007-2011

Orthotic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	
Certified O&P Personnel	899,120	28%	28%
Medical Supply without O&P	906,000	29%	72%
Other	33,640	1%	
Pharmacy	277,320	9%	
Physician	1,048,980	33%	
Grand Total	**3,165,060**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	963,800	28%	28%
Medical Supply without O&P	936,520	28%	72%
Other	46,820	1%	
Pharmacy	307,700	9%	
Physician	1,144,160	34%	
Grand Total	**3,399,000**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	980,040	28%	28%
Medical Supply without O&P	879,120	25%	72%
Other	56,020	2%	
Pharmacy	314,820	9%	
Physician	1,245,640	36%	
Grand Total	**3,475,640**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	959,080	27%	27%
Medical Supply without O&P	836,720	24%	73%
Other	73,760	2%	
Pharmacy	330,220	9%	
Physician	1,345,780	38%	
Grand Total	**3,545,560**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	874,360	26%	26%
Medical Supply	807,320	24%	74%
Other	79,860	2%	
Pharmacy	299,600	9%	
Physician	1,333,880	39%	
Grand Total	**3,395,020**	**100%**	

All States

Base Code Summary by Supplier Classification - 2007-2011

Prosthetic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	
Certified O&P Personnel	46,460	89%	89%
Medical Supply without O&P	2,260	4%	11%
Other	420	1%	
Pharmacy	260	0%	
Physician	2,840	5%	
Grand Total	**52,240**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	43,200	85%	85%
Medical Supply without O&P	3,720	7%	15%
Other	420	1%	
Pharmacy	340	1%	
Physician	3,340	7%	
Grand Total	**51,020**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	44,760	86%	86%
Medical Supply without O&P	2,080	4%	14%
Other	320	1%	
Pharmacy	700	1%	
Physician	3,980	8%	
Grand Total	**51,840**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	44,540	86%	86%
Medical Supply without O&P	2,100	4%	14%
Other	420	1%	
Pharmacy	560	1%	
Physician	4,100	8%	
Grand Total	**51,720**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	39,960	85%	85%
Medical Supply	1,960	4%	15%
Other	500	1%	
Pharmacy	420	1%	
Physician	4,040	9%	
Grand Total	**46,880**	**100%**	

All States

Base Code Summary by Supplier Classification - 2007-2011

Custom Fabricated & Fitted Orthotic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	
Certified O&P Personnel	222,620	43%	43%
Medical Supply without O&P	98,140	19%	57%
Other	7,880	2%	
Pharmacy	29,840	6%	
Physician	160,300	31%	
Grand Total	**518,780**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	233,180	40%	40%
Medical Supply without O&P	106,220	18%	60%
Other	17,960	3%	
Pharmacy	41,400	7%	
Physician	191,080	32%	
Grand Total	**589,840**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	239,480	38%	38%
Medical Supply without O&P	109,520	17%	62%
Other	21,660	3%	
Pharmacy	44,040	7%	
Physician	217,960	34%	
Grand Total	**632,660**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	239,100	36%	36%
Medical Supply without O&P	105,040	16%	64%
Other	26,800	4%	
Pharmacy	46,700	7%	
Physician	237,880	36%	
Grand Total	**655,520**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	217,100	37%	37%
Medical Supply	76,600	13%	63%
Other	26,740	5%	
Pharmacy	40,020	7%	
Physician	227,260	39%	
Grand Total	**587,720**	**100%**	

All States

Base Code Summary by Supplier Classification - 2007-2011

Custom Fitted High Orthotic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	
Certified O&P Personnel	438,020	26%	26%
Medical Supply without O&P	511,760	31%	74%
Other	11,420	1%	
Pharmacy	157,020	9%	
Physician	541,280	33%	
Grand Total	**1,659,500**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	477,560	27%	27%
Medical Supply without O&P	544,560	30%	73%
Other	15,000	1%	
Pharmacy	177,320	10%	
Physician	587,280	33%	
Grand Total	**1,801,720**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	508,640	26%	26%
Medical Supply without O&P	544,100	28%	74%
Other	22,220	1%	
Pharmacy	199,320	10%	
Physician	669,820	34%	
Grand Total	**1,944,100**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	499,260	25%	25%
Medical Supply without O&P	522,060	26%	75%
Other	34,520	2%	
Pharmacy	214,500	11%	
Physician	712,680	36%	
Grand Total	**1,983,020**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	436,700	23%	23%
Medical Supply	510,980	27%	77%
Other	39,260	2%	
Pharmacy	200,980	11%	
Physician	679,820	36%	
Grand Total	**1,867,740**	**100%**	

All States

Base Code Summary by Supplier Classification - 2007-2011

Custom Fitted Low Orthotic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	
Certified O&P Personnel	119,540	28%	28%
Medical Supply without O&P	129,740	30%	72%
Other	6,160	1%	
Pharmacy	28,400	7%	
Physician	148,860	34%	
Grand Total	**432,700**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	122,880	27%	27%
Medical Supply without O&P	130,040	29%	73%
Other	5,760	1%	
Pharmacy	27,260	6%	
Physician	161,900	36%	
Grand Total	**447,840**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	119,140	28%	28%
Medical Supply without O&P	100,840	24%	72%
Other	5,040	1%	
Pharmacy	22,560	5%	
Physician	171,040	41%	
Grand Total	**418,620**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	121,120	27%	27%
Medical Supply without O&P	96,860	22%	73%
Other	4,960	1%	
Pharmacy	20,520	5%	
Physician	203,460	46%	
Grand Total	**446,920**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	125,360	26%	26%
Medical Supply	104,520	22%	74%
Other	5,860	1%	
Pharmacy	19,280	4%	
Physician	222,740	47%	
Grand Total	**477,760**	**100%**	

All States

Base Code Summary by Supplier Classification - 2007-2011

Off the Shelf Orthotic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	
Certified O&P Personnel	118,940	21%	21%
Medical Supply without O&P	166,360	30%	79%
Other	8,180	1%	
Pharmacy	62,060	11%	
Physician	198,540	36%	
Grand Total	**554,080**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	130,180	23%	23%
Medical Supply without O&P	155,700	28%	77%
Other	8,100	1%	
Pharmacy	61,720	11%	
Physician	203,900	36%	
Grand Total	**559,600**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	112,780	23%	23%
Medical Supply without O&P	124,660	26%	77%
Other	7,100	1%	
Pharmacy	48,900	10%	
Physician	186,820	39%	
Grand Total	**480,260**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	99,600	22%	22%
Medical Supply without O&P	112,760	25%	78%
Other	7,480	2%	
Pharmacy	48,500	11%	
Physician	191,760	42%	
Grand Total	**460,100**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	95,200	21%	21%
Medical Supply	115,220	25%	79%
Other	8,000	2%	
Pharmacy	39,320	9%	
Physician	204,060	44%	
Grand Total	**461,800**	**100%**	

Florida

Base Code Summary by Supplier Classification - 2007-2011

Orthotic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	
Certified O&P Personnel	81,380	31%	31%
Medical Supply without O&P	40,260	15%	69%
Other	6,900	3%	
Pharmacy	16,140	6%	
Physician	115,980	44%	
Grand Total	**260,660**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	83,080	29%	29%
Medical Supply without O&P	50,720	18%	71%
Other	8,180	3%	
Pharmacy	19,700	7%	
Physician	122,440	43%	
Grand Total	**284,120**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	95,900	30%	30%
Medical Supply without O&P	58,540	18%	70%
Other	7,540	2%	
Pharmacy	20,180	6%	
Physician	136,020	43%	
Grand Total	**318,180**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	97,180	30%	30%
Medical Supply without O&P	59,120	18%	70%
Other	10,260	3%	
Pharmacy	16,100	5%	
Physician	144,680	44%	
Grand Total	**327,340**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	87,600	29%	29%
Medical Supply	53,060	18%	71%
Other	7,080	2%	
Pharmacy	17,340	6%	
Physician	136,560	45%	
Grand Total	**301,640**	**100%**	

Florida

Base Code Summary by Supplier Classification - 2007-2011

Prosthetic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	
Certified O&P Personnel	3,300	92%	92%
other	280	8%	8%
Grand Total	**3,580**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	2,820	84%	84%
Other	520	16%	16%
Grand Total	**3,340**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	2,940	80%	80%
Other	720	20%	20%
Grand Total	**3,660**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	2,900	82%	82%
Physician	620	18%	18%
Grand Total	**3,520**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	2,360	89%	89%
Physician	300	11%	11%
Grand Total	**2,660**	**100%**	

Florida

Base Code Summary by Supplier Classification - 2007-2011

Custom Fabricated & Fitted Orthotic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	
Certified O&P Personnel	20,820	40%	40%
Medical Supply without O&P	6,080	12%	60%
Other	800	2%	
Pharmacy	4,100	8%	
Physician	20,700	39%	
Grand Total	**52,500**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	18,580	32%	32%
Medical Supply without O&P	9,140	16%	68%
Other	1,840	3%	
Pharmacy	6,860	12%	
Physician	22,220	38%	
Grand Total	**58,640**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	19,440	31%	31%
Medical Supply without O&P	9,540	15%	69%
Other	2,000	3%	
Pharmacy	6,240	10%	
Physician	26,440	42%	
Grand Total	**63,660**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	20,620	34%	34%
Medical Supply without O&P	6,940	12%	66%
Other	1,840	3%	
Pharmacy	2,940	5%	
Physician	27,820	46%	
Grand Total	**60,160**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	19,920	40%	40%
Medical Supply	1,180	2%	60%
Other	2,120	4%	
Pharmacy	1,020	2%	
Physician	25,020	51%	
Grand Total	**49,260**	**100%**	

Florida

Base Code Summary by Supplier Classification - 2007-2011

Custom Fitted High Orthotic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	
Certified O&P Personnel	46,380	30%	30%
Medical Supply without O&P	27,240	18%	70%
Other	1,440	1%	
Pharmacy	12,040	8%	
Physician	65,160	43%	
Grand Total	**152,260**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	49,640	30%	30%
Medical Supply without O&P	33,060	20%	70%
Other	2,260	1%	
Pharmacy	12,840	8%	
Physician	68,960	41%	
Grand Total	**166,760**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	58,340	30%	30%
Medical Supply without O&P	40,680	21%	70%
Other	2,000	1%	
Pharmacy	13,940	7%	
Physician	76,640	40%	
Grand Total	**191,600**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	59,740	29%	29%
Medical Supply without O&P	45,940	23%	31%
Other	2,740	1%	
Pharmacy	13,160	6%	
Physician	81,380	40%	
Grand Total	**202,960**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	51,140	27%	27%
Medical Supply	45,980	25%	73%
Other	4,300	2%	
Pharmacy	12,480	7%	
Physician	73,500	39%	
Grand Total	**187,400**	**100%**	

Florida

Base Code Summary by Supplier Classification - 2007-2011

Custom Fitted Low Orthotic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	
Certified O&P Personnel	8,080	29%	29%
Medical Supply without O&P	3,260	12%	71%
Other	1,560	6%	
Physician	14,640	53%	
Grand Total	**27,540**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	8,840	30%	30%
Medical Supply without O&P	4,280	14%	70%
Other	1,380	5%	
Physician	15,380	51%	
Grand Total	**29,880**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	11,980	34%	34%
Medical Supply without O&P	4,420	13%	66%
Other	1,080	3%	
Physician	17,680	50%	
Grand Total	**35,160**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	11,160	31%	31%
Medical Supply without O&P	3,200	9%	69%
Other	1,340	4%	
Physician	20,200	56%	
Grand Total	**35,900**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	10,580	28%	28%
Medical Supply	3,300	9%	72%
Other	360	1%	
Pharmacy	1,500	4%	
Physician	21,800	58%	
Grand Total	**37,540**	**100%**	

Florida

Base Code Summary by Supplier Classification - 2007-2011

Off the Shelf Orthotic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	
Certified O&P Personnel	6,100	22%	22%
Medical Supply without O&P	3,680	13%	78%
Other	3,100	11%	
Physician	15,480	55%	
Grand Total	**28,360**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	6,020	21%	21%
Medical Supply without O&P	4,240	15%	79%
Other	2,700	9%	
Physician	15,880	55%	
Grand Total	**28,840**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	6,140	22%	22%
Medical Supply without O&P	3,900	14%	78%
Other	2,460	9%	
Physician	15,260	55%	
Grand Total	**27,760**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	5,660	20%	20%
Medical Supply without O&P	3,040	11%	80%
Other	4,340	15%	
Physician	15,280	54%	
Grand Total	**28,320**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	5,960	22%	22%
Medical Supply	2,600	9%	78%
Other	300	1%	
Pharmacy	2,340	9%	
Physician	16,240	59%	
Grand Total	**27,440**	**100%**	

Texas

Base Code Summary by Supplier Classification - 2007-2011

Orthotic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	
Certified O&P Personnel	104,460	38%	38%
Medical Supply without O&P	84,020	31%	62%
Other	5,080	2%	
Pharmacy	22,520	8%	
Physician	57,580	21%	
Grand Total	**273,660**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	116,220	39%	39%
Medical Supply without O&P	87,140	29%	61%
Other	5,920	2%	
Pharmacy	23,960	8%	
Physician	63,340	21%	
Grand Total	**296,580**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	107,140	39%	39%
Medical Supply without O&P	64,080	23%	61%
Other	6,920	3%	
Pharmacy	25,120	9%	
Physician	70,920	26%	
Grand Total	**274,180**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	92,920	35%	35%
Medical Supply without O&P	53,640	20%	65%
Other	9,660	4%	
Pharmacy	27,680	10%	
Physician	79,840	30%	
Grand Total	**263,740**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	74,200	30%	30%
Medical Supply	53,340	22%	70%
Other	11,700	5%	
Pharmacy	24,000	10%	
Physician	80,880	33%	
Grand Total	**244,120**	**100%**	

Texas

Base Code Summary by Supplier Classification - 2007-2011

Prosthetic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	
Certified O&P Personnel	3,820	83%	83%
Other	380	8%	17%
Physician	400	9%	
Grand Total	**4,600**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	3,260	81%	81%
Other	380	9%	9%
Physician	380	9%	
Grand Total	**4,020**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	4,300	81%	81%
Other	580	11%	19%
Physician	420	8%	
Grand Total	**5,300**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	3,980	82%	82%
Other	340	7%	18%
Physician	520	11%	
Grand Total	**4,840**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	3,660	82%	82%
Physician	500	11%	18%
Other	320	7%	
Grand Total	**4,480**	**100%**	

Texas

Base Code Summary by Supplier Classification - 2007-2011

Custom Fabricated & Fitted Orthotic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	
Certified O&P Personnel	15,520	43%	43%
Medical Supply without O&P	5,500	15%	57%
Other	520	1%	
Pharmacy	6,580	18%	
Physician	7,960	22%	
Grand Total	**36,080**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	15,900	40%	40%
Medical Supply without O&P	6,620	17%	60%
Other	1,180	3%	
Pharmacy	6,980	18%	
Physician	9,080	23%	
Grand Total	**39,760**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	16,260	39%	39%
Medical Supply without O&P	5,500	13%	61%
Other	1,600	4%	
Pharmacy	6,760	16%	
Physician	12,020	29%	
Grand Total	**42,140**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	15,080	34%	34%
Medical Supply without O&P	5,240	12%	66%
Other	2,460	5%	
Pharmacy	8,360	19%	
Physician	13,800	31%	
Grand Total	**44,940**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	12,800	31%	31%
Medical Supply	5,660	14%	69%
Other	2,800	7%	
Pharmacy	6,220	15%	
Physician	13,220	32%	
Grand Total	**40,700**	**100%**	

Texas

Base Code Summary by Supplier Classification - 2007-2011

Custom Fitted High Orthotic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	
Certified O&P Personnel	67,280	41%	41%
Medical Supply without O&P	50,320	30%	59%
Other	480	0%	
Pharmacy	15,940	10%	
Physician	31,200	19%	
Grand Total	**165,220**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	72,900	41%	41%
Medical Supply without O&P	52,660	30%	59%
Other	420	0%	
Pharmacy	16,980	10%	
Physician	34,000	19%	
Grand Total	**176,960**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	65,740	39%	39%
Medical Supply without O&P	42,040	25%	61%
Other	2,080	1%	
Pharmacy	18,360	11%	
Physician	38,440	23%	
Grand Total	**166,660**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	57,780	37%	37%
Medical Supply without O&P	35,120	22%	63%
Other	4,360	3%	
Pharmacy	19,320	12%	
Physician	41,140	26%	
Grand Total	**157,720**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	41,360	29%	29%
Medical Supply	33,320	24%	71%
Other	7,360	5%	
Pharmacy	16,140	11%	
Physician	42,420	30%	
Grand Total	**140,600**	**100%**	

Texas

Base Code Summary by Supplier Classification - 2007-2011

Custom Fiited Low Orthotic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	
Certified O&P Personnel	13,420	32%	32%
Medical Supply without O&P	18,420	45%	68%
Other	820	2%	
Physician	8,640	21%	
Grand Total	**41,300**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	12,040	30%	30%
Medical Supply without O&P	17,220	43%	70%
Other	860	2%	
Physician	9,720	24%	
Grand Total	**39,840**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	8,240	29%	29%
Medical Supply without O&P	8,820	31%	71%
Other	480	2%	
Physician	10,820	38%	
Grand Total	**28,360**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	9,180	29%	29%
Medical Supply without O&P	7,260	23%	71%
Other	840	3%	
Physician	14,320	45%	
Grand Total	**31,600**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	12,980	35%	35%
Medical Supply	8,320	23%	65%
Other	760	2%	
Physician	14,600	40%	
Grand Total	**36,660**	**100%**	

Texas

Base Code Summary by Supplier Classification - 2007-2011

Off the Shelf Orthotic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	
Certified O&P Personnel	8,240	27%	27%
Medical Supply without O&P	9,780	31%	73%
Other	3,260	10%	
Physician	9,780	31%	
Grand Total	**31,060**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	15,380	38%	38%
Medical Supply without O&P	10,640	27%	62%
Other	3,460	9%	
Physician	10,540	26%	
Grand Total	**40,020**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	16,900	46%	46%
Medical Supply without O&P	7,720	21%	54%
Other	2,760	7%	
Physician	9,640	26%	
Grand Total	**37,020**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	10,880	37%	37%
Medical Supply without O&P	6,020	20%	63%
Other	2,000	7%	
Physician	10,580	36%	
Grand Total	**29,480**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	7,060	27%	27%
Medical Supply	6,040	23%	73%
Other	1,380	5%	
Pharmacy	1,040	4%	
Physician	10,640	41%	
Grand Total	**26,160**	**100%**	

Illinois

Base Code Summary by Supplier Classification - 2007-2011

Orthotic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	
Certified O&P Personnel	35,400	27%	27%
Medical Supply without O&P	42,300	32%	73%
Other	4,440	3%	
Pharmacy	3,700	3%	
Physician	46,340	35%	
Grand Total	**132,180**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	37,020	26%	26%
Medical Supply without O&P	40,200	28%	74%
Other	5,020	4%	
Pharmacy	5,240	4%	
Physician	53,800	38%	
Grand Total	**141,280**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	38,420	25%	25%
Medical Supply without O&P	44,080	29%	75%
Other	5,320	3%	
Pharmacy	7,320	5%	
Physician	58,020	38%	
Grand Total	**153,160**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	41,600	27%	27%
Medical Supply without O&P	37,280	24%	73%
Other	6,040	4%	
Pharmacy	7,700	5%	
Physician	61,240	40%	
Grand Total	**153,860**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	36,940	25%	25%
Medical Supply	38,660	26%	75%
Other	1,720	1%	
Pharmacy	10,340	7%	
Physician	61,660	41%	
Grand Total	**149,320**	**100%**	

Illinois

Base Code Summary by Supplier Classification - 2007-2011

Prosthetic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	
Certified O&P Personnel	2,080	85%	80%
Other	380	15%	20%
Grand Total	**2,460**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	1,540	100%	100%
Other	0	0%	0%
Grand Total	**1,540**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	1,520	84%	84%
Other	280	16%	16%
Grand Total	**1,800**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	1,800	86%	86%
Other	300	14%	14%
Grand Total	**2,100**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	1,740	86%	86%
Other	280	14%	14%
Grand Total	**2,020**	**100%**	

Illinois

Base Code Summary by Supplier Classification - 2007-2011

Custom Fabricated & Fitted Orthotic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	49%
Certified O&P Personnel	8,940	49%	51%
Medical Supply without O&P	1,600	9%	
Other	720	4%	
Physician	6,880	38%	
Grand Total	**18,140**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	9,420	44%	44%
Medical Supply without O&P	2,340	11%	56%
Other	660	3%	
Physician	9,040	42%	
Grand Total	**21,460**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	10,340	41%	41%
Medical Supply without O&P	3,440	14%	59%
Other	880	3%	
Physician	10,640	42%	
Grand Total	**25,300**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	12,100	46%	46%
Medical Supply without O&P	1,920	7%	54%
Other	1,860	7%	
Physician	10,660	40%	
Grand Total	**26,540**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	11,860	45%	45%
Medical Supply	2,600	10%	55%
Other	460	2%	
Pharmacy	520	2%	
Physician	10,800	41%	
Grand Total	**26,240**	**100%**	

Illinois

Base Code Summary by Supplier Classification - 2007-2011

Custom Fitted High Orthotic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	
Certified O&P Personnel	14,700	22%	22%
Medical Supply without O&P	23,520	35%	78%
Other	400	1%	
Pharmacy	3,700	6%	
Physician	24,940	37%	
Grand Total	**67,260**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	16,540	22%	22%
Medical Supply without O&P	25,540	33%	78%
Other	340	0%	
Pharmacy	5,240	7%	
Physician	28,780	38%	
Grand Total	**76,440**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	17,580	20%	20%
Medical Supply without O&P	30,760	35%	80%
Other	480	1%	
Pharmacy	7,320	8%	
Physician	31,600	36%	
Grand Total	**87,740**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	19,720	22%	22%
Medical Supply without O&P	28,360	32%	78%
Other	660	1%	
Pharmacy	7,700	9%	
Physician	33,520	37%	
Grand Total	**89,960**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	16,560	19%	19%
Medical Supply	28,980	34%	81%
Other	720	1%	
Pharmacy	7,820	9%	
Physician	30,900	36%	
Grand Total	**84,980**	**100%**	

Illinois

Base Code Summary by Supplier Classification - 2007-2011

Custom Fitted Low Orthotic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	
Certified O&P Personnel	5,700	32%	32%
Medical Supply without O&P	5,400	30%	68%
Other	1,340	8%	
Physician	5,300	30%	
Grand Total	**17,740**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	5,240	32%	32%
Medical Supply without O&P	4,040	25%	68%
Other	1,160	7%	
Physician	5,860	36%	
Grand Total	**16,300**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	4,680	29%	29%
Medical Supply without O&P	3,460	21%	71%
Other	1,180	7%	
Physician	6,800	42%	
Grand Total	**16,120**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	4,680	30%	30%
Medical Supply without O&P	2,560	16%	70%
Other	900	6%	
Physician	7,680	49%	
Grand Total	**15,820**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	3,780	24%	24%
Medical Supply	2,360	15%	76%
Other	260	2%	
Pharmacy	540	3%	
Physician	8,900	56%	
Grand Total	**15,840**	**100%**	

Illinois

Base Code Summary by Supplier Classification - 2007-2011

Off the Shelf Orthotic Base Code Allowed Services

Provider Sub-Category	2007 Allowed Services	Percent of Total	
Certified O&P Personnel	6,060	21%	21%
Medical Supply without O&P	11,780	41%	79%
Other	1,980	7%	
Physician	9,220	32%	
Grand Total	**29,040**	**100%**	

Provider Sub-Category	2008 Allowed Services	Percent of Total	
Certified O&P Personnel	5,820	21%	21%
Medical Supply without O&P	8,280	31%	79%
Other	2,860	11%	
Physician	10,120	37%	
Grand Total	**27,080**	**100%**	

Provider Sub-Category	2009 Allowed Services	Percent of Total	
Certified O&P Personnel	5,820	24%	24%
Medical Supply without O&P	6,420	27%	76%
Other	2,780	12%	
Physician	8,980	37%	
Grand Total	**24,000**	**100%**	

Provider Sub-Category	2010 Allowed Services	Percent of Total	
Certified O&P Personnel	5,100	24%	24%
Medical Supply without O&P	4,440	21%	76%
Other	2,620	12%	
Physician	9,380	44%	
Grand Total	**21,540**	**100%**	

Provider Sub-Category	2011 Allowed Services	Percent of Total	
Certified O&P Personnel	4,740	21%	21%
Medical Supply	4,720	21%	79%
Other	280	1%	
Pharmacy	1,460	7%	
Physician	11,060	50%	
Grand Total	**22,260**	**100%**	

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Medicare Provider Mystery Shop for AOPA

AOPA wished to gather information on a number of companies that it believed had received payments for services that should only be performed by licensed O/P professionals, but didn't appear to have licensed O/P staff.

AOPA contacted MSG Research & Consulting to better determine what was going on. MSG put an executive interviewer on this project, who called into the companies as a prospective customer. Incidentally, the interviewer was already knowledgeable about the subject as his wife is a stroke survivor. AOPA & MSG invented a few cover stories for the interviewer, but the most common explanation he used was thus:

> "My wife recently had a stroke and her doctor is saying that she needs a custom orthotic to help her walk. Do you make custom orthotics? {**if yes**} – Ok, I think in order for our insurance to cover it, we need to have it made by a licensed Orthotist. Do you have one on staff? {**if yes**} – so who should I speak with then – the Orthotist? What's his/her name?"

Most practices denied having a licensed O/P when asked.

	Claimed to Have Lic. O/P	**Denied Having Lic. O/P**	**Not Reached**
Ohio	4	10	2
Florida	6	21	7
Texas	1	21	6

The summary table represents how the company responded when asked if it had a *licensed O/P on staff* – additionally, MSG encountered instances where respondents wished to specify beyond a "yes" or a "no" to explain

whether or not they were actually making custom orthotics/prosthetics with a licensed O/P.

Examples of situations that came up were:

> We have a floating O/P person that visits multiple locations/only comes in for fittings.
>
> We mail in orders/fit for shoes only/send information to a doctor.
>
> We're a medical supply company.
>
> We work with a pedorthist.

MSG noted each case in which a qualifying remark like this was made and sent to AOPA. Based on the statements made by employees of the medical supply facilities that we contacted — and subject to ambivalence a few expressed — it appears that 83% of these facilities (registered as Medicare providers and eligible for payment) do not have a licensed orthotic and/or prosthetic professional on their staff, despite the fact that the facility is located in a state that has a mandatory orthotic and prosthetic licensure statute.

Company Name	DBA Name	Address	Address 2	State
PLUS MEDICAL LLC	KIN CARE HOME MEDICAL & MOBILITY	9060 KIMBERLY BLVD	UNITS 28/29	FL
MDK VENTURES L.L.C	MEDICAL DEPARTMENT STORE	8595 COLLEGE PKWY	STE 170	FL
SUPERIOR MEDICAL EQUIPMENT PLUS LLC	SUPERIOR MEDICAL EQUIPMENT PLUS LLC	821 CLEARWATER LARGO RD N		FL
MEDICAL SUPPLY PLUS INC	MEDICAL SUPPLY PLUS INC	4143 SW 74TH CT	STE 100	FL
SUPERIOR HEALTHCARE SUPPLY L.L.C	SUPERIOR HEALTHCARE SUPPLY LLC	333 W 41ST ST	STE 722	FL
BROWNING'S PHARMACY AND HEALTH CARE, IN	BROWNINGS PHARMACY AND HEALTH CARE	4207 VINELAND RD	STE M1	FL
GRAHAM SEGO CORPORATION	SEGO'S HOME MED EQUIP	180 SAUSALITO BLVD		FL
BYRAM HEALTHCARE CENTERS, INC	BYRAM HEALTHCARE CENTERS INC	4900 CREEKSIDE DRIVE	SUITE M	FL
ONE SOURCE MEDICAL GROUP, LLC	ONE SOUCE MEDICAL GROUP LLC	13505 ICOT BLVD	STE 209	FL
GRAHAM SEGO CORPORATION	SEGOS HOME MEDICAL EQUIPMENT	355 CITRUS TOWER BLVD	STE 102	FL
MED-CARE PHARMACY	MED-CARE PHARMACY INC.	1052 SOUTH POWERLINE ROAD		FL
G & E LIMITED INC	G & E LIMITED INC	14535 S MILITARY TRL	STE C	FL
FOOTWAY	PETER'S SHOES	6131 C LAKE WORTH RD		FL
A M RENTAL MEDICAL EQUIPMENT CORP	AM RENTAL MEDICAL EQUIP INC	1770 W 40TH ST	UNIT 2	FL
MON ORTHOPEDIC, INC.	MON ORTHOPEDIC INC	517 E 25TH ST		FL
CATCH A FALLING ARCH, INC	FOOT SOLUTIONS	10500 ULMERTON RD	STE 240	FL
BROWNING'S PHARMACY AND HEALTH CARE, IN	BROWNINGS PHARMACY AND HEALTH CARE	141 E HIBISCUS BLVD		FL
ARDY MEDICAL SUPPLY	ARDY MEDICAL SUPPLY CORP	10465 SW 40TH ST		FL
MDK VENTURES L.L.C	MEDICAL DEPARTMENT STORE	4265 TAMIAMI TRL E		FL
UNITY RESPIRATORY AND DIABETIC INC	UNITY RESPIRATORY AND DIABETIC INC	3616 TAMIAMI TRIAL	UNIT 1	FL
MDK VENTURES L.L.C	MEDICAL DEPARTMENT STORE	3672 WEBBER ST		FL
LISSMART MEDICAL SUPPLY, INC	LISSMART MEDICAL SUPPLY INC	6712 HANLEY RD		FL
GRAHAM SEGO CORPORATION	SEGO'S HOME MEDICAL EQUIPMENT	1225 GARDEN ST		FL
MDK VENTURES L.L.C	MEDICAL DEPARTMENT STORE	1180 JACARANDA BLVD		FL
GARDENS DRUGS, INC	GARDENS DRUGS #2	2100 45TH ST #B1	STE B1	FL
EQUILIBRIUM MEDICAL SUPPLY INC	EQUILIBRIUM MEDICAL SUPPLY INC	2100 E HALLANDALE BEACH BLVD	STE 301	FL
ALDO SURGICAL & HOSPITAL SUPPLY, INC.	ALDO SURGICAL & HOSPITAL SUPPLY IN	8074 NW 103RD ST	SUITE 21	FL
PAIN CONTROL PRODUCTS MEDICAL INC.	PAIN CONTROL PRODUCTS MEDICAL INC	510 DOUGLAS AVE	SUITE 1043	FL
PRO MEDICAL EAST	PROMEDICAL EAST LLC	3551N FEDERAL HWY A		FL
AITIMA MEDICAL EQUIPMENT INC	AITIMA MEDICAL EQUIPMENT INC	275 FONTAINEBLEAU BLVD	STE 166	FL
LUPER CORP	40 ST PHARMACY	9258 SW 40TH ST		FL
R & J MEDICAL SALES, INC.	R & J MEDICAL SALES INC	2646 SW MAPP RD	STE 305	FL
DIABETIC CARE NETWORK, INC.	DIABETIC CARE NETWORK INC	3260 NW 23RD AVE 800		FL
GARDENS DRUGS, INC	GARDENS DRUGS #2	2100 45TH ST #B1	STE B1	FL

City	Zip	Phone	Orthoses: Custom Fabricated	Has Licensed O/P	Name of L O/P	O or P	Notes
BOCA RATON	33434	(561)477-2507	true	YES	Greg	O	
FORT MYERS	33919	(239)482-6111	true	YES	Deanna Sutton	O	works out of Port Charlotte office
LARGO	33770	(727)584-5500	true	YES	Roy	Both	
MIAMI	33155	(305)262-4200	true	YES	Dan Reid	Both	been there 15 years
MIAMI BEACH	33140	(305)538-7820	true	YES	Eric	Both	
ORLANDO	32811	(407)650-9585	true	YES		Both	
CASSELBERRY	32707	(407)260-6002	true	NO			O comes from Titusville evry 5 fittings
CLEARWATER	33760	(727)540-0221	true	NO			
CLEARWATER	33760	(866)834-7473	true	NO			
CLERMONT	34711	(352)242-9004	true	NO			
DEERFIELD BEACH	33442	(954)354-0530	true	NO			mail order only
DELRAY BEACH	33484	(561)496-3399	true	NO			
GREENACRES	33463	(866)366-8929	true	NO			use orthopedist for shoe fitting
HIALEAH	33012	(305)557-2830	true	NO			
HIALEAH	33013	(305)835-8600	true	NO			
LARGO	33771	(727)585-4200	true	NO			pedoritist
MELBOURNE	32901	(321)725-6320	true	NO			has Pedorothist [not in dictionary]
MIAMI	33165	(305)551-5018	true	NO			medical suppy only/no doctors
PORT CHARLOTTE	33980	(941)743-6644	true	NO			
PORT CHARLOTTE	33952	(941)235-1840	true	NO			equipment only
SARASOTA	34232	(941)923-7556	true	NO			has orthotic fitter - not DR.
TAMPA	33634	(813)882-0596	true	NO			
TITUSVILLE	32796	(321)268-0179	true	NO			
VENICE	34292	(941)497-2273	true	NO			durable medical eqipment
WEST PALM BEACH	33407	(561)841-1801	true	NO			
HALLANDALE BEACH	33009	(954)455-2190	true	NO			
HIALEAH GARDENS	33016	(305)557-2835	true	NO			
ALTAMONTE SPRINGS	32714	(407)301-6493	true	n/a			
BOCA RATON	33431	(855)444-6337	true	n/a			
MIAMI	33172	(305)229-1778	true	n/a			
MIAMI	33165	(305)554-0438	true	n/a			
PALM CITY	34990	(866)215-5576	true	n/a			
POMPANO BEACH	33069	(954)427-9510	true	n/a			
WEST PALM BEACH	33407	(561)841-1801	true	n/a			duplicate listing

Company Name	Address	Address 2	City	State	Zip	Phone	
PA ARTIFICIAL LIMB & BRACE, CO., INC.	4859 N RIDGE RD W		ASHTABULA	OH	44004	(440)969-1144	OR01
NATIONAL REHAB EQUIPMENT, INC	4630 RICHMOND RD	SUITE 270	CLEVELAND	OH	44128	(800)451-6510	OR01
ARTHUR W GUILFORD III INC.	13515 BROOKPARK RD		CLEVELAND	OH	44142	(216)362-1350	OR01
ADVANCED ANATOMICAL DESIGN LLC	300 S STATE ST		GIRARD	OH	44420	(330)288-0027	OR01
KLEINS ORTHOPEDIC AND MEDICAL EQUIPMENT INC	ONE PARK WEST BLVD	STE 140	AKRON	OH	44320	(330)865-9000	OR01
HUBER MEDICAL LLC	8051 MARKET ST	STE 2	BOARDMAN	OH	44512	(330)629-9500	OR01
MEDIC HOME HEALTH CARE, LLC	701 BETA DR	STE 7	CLEVELAND	OH	44143	(440)449-7727	OR01
HASTINGS HOME HEALTH CENTER, INC.	15210 INDUSTRIAL PKWY		CLEVELAND	OH	44135	(216)898-3300	OR01
SPORTOPEDICS MEDICAL SHOPPE INC.	1222 S PATTERSON BLVD	SUITE #130	DAYTON	OH	45402	(937)461-2663	OR01
DASCO-UNION HOSPITAL HOME MEDICAL EQUIPMENT	101 HOSPITAL DR	STE B	DOVER	OH	44622	(330)602-2400	OR01
HUBER MEDICAL LLC	16761 SAINT CLAIR AVE		EAST LIVERPOOL	OH	43920	(330)382-1112	OR01
HUBER MEDICAL LLC	10 EAST LIBERTY STREET		HUBBARD	OH	44425	(330)534-7873	OR01
DASCO-ALLIANCE, LTD.	270 E STATE ST	STE 130	ALLIANCE	OH	44601	(330)829-0565	OR01
ERIE ENTERPRISES INC	4502 LEWIS AVE		TOLEDO	OH	43612	(419)476-4322	OR01
MARQUIS HEALTHCARE, INC.	4051 WHIPPLE AVE NW	STE A	CANTON	OH	44718	(800)860-8856	OR01
VILLAGE SQUARE INC.	1412 1/2 SCOTT ST		NAPOLEON	OH	43545	(419)599-2200	OR01

	Has Licensed O/P	Name of L O/P	O or P	Notes
Orthoses: Custom Fabricated	Yes/No	Chris Cummings	both	owner
Orthoses: Custom Fabricated	YES	Mike or Joe	O	
Orthoses: Custom Fabricated	YES		both	refused to give names of O/P
Orthoses: Custom Fabricated	YES	Craig Svader [P]	Both	
Orthoses: Custom Fabricated	NO			
Orthoses: Custom Fabricated	NO			
Orthoses: Custom Fabricated	NO			
Orthoses: Custom Fabricated	NO			medical supplies only
Orthoses: Custom Fabricated	NO			Podiatrist only
Orthoses: Custom Fabricated	NO			
Orthoses: Custom Fabricated	NO			medical supply only
Orthoses: Custom Fabricated	NO			
Orthoses: Custom Fabricated	NO			
Orthoses: Custom Fabricated	NO			
Orthoses: Custom Fabricated	n/a			
Orthoses: Custom Fabricated	n/a			

Company Name	DBA Name	Address
MONARCH MEDICAL & REHAB SUPPLY INC	MONARCH MEDICAL & REHAB SUPPLY INC	1961 S MAIN ST
BRILLIANT MEDICAL BOUTIQUE LLC	BRILLIANT! MEDICAL BOUTIQUE	1630 W RANDOL MILL RD
ADVANCE MEDICAL SERVICES	ADVANCE MEDICAL SERVICES	6448E HIGHWAY 290 B102
SPECIALIZED PHARMACY SERVICES INC	SPECIALIZED PHARM SRVS INC	7645 PHELAN BLVD
CLEBURNE DRUG INC	CLEBURNE DRUG	501 N RIDGEWAY DR
ALL STAR OXYGEN AND HOME MEDICAL EQUIPMENT LLC	ALL STAR OXYGEN AND HOME MEDICAL EQ	3341 TOWERWOOD DR
BYRAM HEALTHCARE CENTERS, INC	BYRAM HEALTHCARE	1625W MOCKINGBIRD LN 308
ONE SOURCE MEDICAL SOLUTIONS, INC.	ONE SOURCE MEDICAL SOLUTIONS, INC.	11333 N. CENTRAL EXPRESSWAY
TOTAL CARE DME & SUPPLIES, LLC	TOTAL CARE DME AND SUPLIES LLC	4650 S HAMPTON RD
MARQUEZ MEDICAL SUPPLY	MARQUEZ MEDICAL SUPPLY	1580 GEORGE DIETER DR
PRECISION DRUGS	EVERGREEN PHARMACY	9180 BELLAIRE BLVD
CORAZON DEL VALLE DME LLC	CORAZON DEL VALLE DME LLC	219 N EAST ST
MAGNOLIA PHARMACY INC	MAGNOLIA PHARMACY INC	18230 FM 1488 RD
DEL VALLE MEDICAL SUPPLY, L.L.C.	DEL VALLE MEDICAL SUPPLY LLC	1510W DOVE AVE
BREATH E-Z HEALTH CARE	BREATH EZ HEALTH CARE	400 SE 1ST STREET
EXPRESS DME & SUPPLY, INC	EXPRESS DME & SUPPLY INC	802 E EXPRESSWAY 83
ALTA WELLNESS LLC	FOOT SOLUTIONS	1201 N LOOP 1604 W
ORTHO PLUS, INC.	ORTHO PLUS INC	7823 FORTUNE DR
SAN ANTONIO MEDICAL SUPPLIES LLC	SAN ANTONIO MEDICAL SUPPLIES	1500 FREDERICKSBURG ROAD
BRILLIANT MEDICAL BOUTIQUE LLC	BRILLIANT MEDICAL BOUTIQUE	925 SANTA FE DR
BETTER LIVING MEDICAL SUPPLY AND EQUIPMENT INC.	BETTER LIVING MEDICAL SUPPLY & EQUI	2625 OLD DENTON ROAD
OSCAR SAN MIGUEL JR MED-PRO	MED-PRO	404 EAST 3RD STREET
KOHLER HOMECARE PHARMACY INC	WEBB-KOHLER PHARMACY HME AND SUPPLY	2204 PARK SPRINGS BLVD
BREATH E-Z HEALTH CARE	BREATH EZ HEALTH CARE	801 E WALKER ST
FOOTWEAR CONSULTANTS, INC	FOOTWEAR CONSULTANTS INC	6363 FOREST PARK RD
MIRIAM'S DME, LLC	LILLIAN'S DME	2323 N ED CAREY DR
ZION DURABLE MEDICAL EQUIPMENT, LLC	ZION DURABLE MEDICAL EQUIPMENT LLC	401 JAMES RICHARD CLOSNER DR
MIRACLE MEDICAL EQUIPMENT & SUPPLIES OF SOUTH TEXAS LLC	MIRACLE MEDICAL EQUIPMENT AND SUPPL	502 E EXPRESSWAY 83

Address 2	City	State	Zip	Phone	Has Licensed O/P	me of L O	O or P	Notes
STE 300	KELLER	TX	76248	(817)753-6337	YES	would nc	O	can fit braces and such
	ARLINGT	TX	76012	(817)804-0611	NO			store
	AUSTIN	TX	78723	(512)371-8876	NO			store
	BEAUMO	TX	77706	(409)832-8750	NO			
	CLEBURN	TX	76033	(817)645-2415	NO			Dr. Chambers sends orders over
STE 201	DALLAS	TX	75234	(972)484-7827	NO			
	DALLAS	TX	75235	(214)638-1056	NO			
SUITE 101	DALLAS	TX	75423	(214)421-7000	NO			can do work with Pedorotist
STE 104	DALLAS	TX	75232	(214)330-4300	NO			only provide diabetic shoes
STE 305	EL PASO	TX	79936	(915)858-6513	NO			have Pedorotist
SUITE A	HOUSTO	TX	77036	(713)541-1234	NO			medical supply store only
	LA FERIA	TX	78559	(956)797-3730	NO			
STE 100	MAGNOL	TX	77354	(281)356-9089	NO			
	MCALLEN	TX	78504	(956)627-3338	NO			
	MINERAL	TX	76067	(940)325-1112	NO			none local
STE D	PHARR	TX	78577	(956)781-4004	NO			picks diabetic shoes and send orders to the doctor
STE 117	SAN ANT	TX	78258	(210)493-3338	NO			operates under Pedorotist
	SAN ANT	TX	78250	(210)541-8568	NO			
SUITE B	SAN ANT	TX	78201	(210)737-7267	NO			medical supply company only
STE 100	WEATHE	TX	76086	(817)594-5868	NO			
SUITE 452	CARROL	TX	75007	(972)820-8700	NO			
	DEL RIO	TX	78840	(830)313-8093	NO			
	ARLINGT	TX	76013	(817)861-4631	n/a			
	BRECKEN	TX	76424	(254)559-9201	n/a			
STE 215B	DALLAS	TX	75235	(214)357-3535	n/a			
STE 7	HARLING	TX	78550	(956)440-1600	n/a			
UNIT A BOX 10	LA FERIA	TX	78559	(956)797-9999	n/a			
STE E	WESLAC	TX	78596	(956)696-9596	n/a			

Competitive Bidding

- When Congress authorized competitive bidding, it constructed an important fence around O&P
  a. Authority limited to off-the-shelf orthotics only
  b. Defined OTS as a device that could be used with "minimal self-adjustment"

From the authorizing statute, 42 U.S.C. section 1395w-3(a)(2)(C)

Competitive Bidding

- "An adjustment that the beneficiary, caretaker of the beneficiary, or supplier of the device can perform and does not require the service of a certified orthotist"

As 'Minimal self-adjustment' was interpreted by CMS when it published 42 C.F.R. section 414.402 (adopted at 72 Fed. Reg. 17992, April 10, 2007)

American Orthotic & Prosthetic Association

April 2, 2014

Laurence Wilson, Director Chronic Care Policy Group
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid
7500 Security Boulevard
Baltimore, MD 21244

Dear Mr. Wilson,

The American Orthotic and Prosthetic Association (AOPA) would like to express its concern regarding the recently released second iteration of a correct coding bulletin by each of the four the DME MACs entitled, "Definitions Used for Off–the-Shelf versus Custom Fitted Prefabricated Orthotics (Braces)." AOPA's concerns rest in three areas: (1) the bulletin continues to ignore the clear meaning of the federal statute, 42 U.S.C. section 1395w-3(a)(2)(C) which defines with impeccable clarity the clear line of demarcation between off-the-shelf orthotics and custom fitted orthotics; namely, if and only if the device can be used by the patient with minimal self-adjustment can the device be treated by CMS and its contractors as off-the-shelf without violating the federal law; (2) the resulting introduction of the new term "substantial modification", which has absolutely no foundation in the statute, as well as the resulting and distinct publications/statement purporting to define language documentation criteria in respect to the Local Coverage Determination for AFOs/KAFOs, Knee orthoses, and Spinal orthoses effective for claims with a date of service on or after January 1, 2014 (more than three months prior to the publication of the bulletin and revised policy); and (3) the continued failure of CMS and its contractors to appropriately recognize the requirements of Section 427 of BIPA 2000, in this case by the failure to recognize orthotic fitters as qualified providers that meet the statutory requirement of certification/accreditation.

Last week, AOPA took the opportunity to address some of these issues in our response to CMS' ANPRM relating to the future of competitive bidding. At the time we prepared those comments the second iteration of the policy bulletin had not been published by the DME MACs; however, we had noted the same flaws in the initial DME MAC statements on this matter, announced on February 28, 2014 and quickly withdrawn on March 7, 2014. Because the second iteration of the policy bulletin simply re-states and perpetuates the errors first stated in the February 28th statement, our comments challenging those positions that AOPA stated in its ANPRM comments remain accurate, timely and germane to this second iteration.

It is noteworthy and important that the DME MAC bulletins completely avoids any recitation of the applicable law--42 U.S.C. section 1395w-3(a)(2)(C) is nowhere cited by CMS' contractors. The statement references 42 CFR section 414.402 as

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if that were the statute! Of course, there would be no authority for CMS or its contractors to make any statements about off-the-shelf orthotics had authority to do so not first been granted to the agency in 42 U.S.C. section 1395w-3(a)(2)(C) and related sections in that same statute. The first question which needs to be asked by CMS and its contractors as they consider an action should be: ***where, if at all, is CMS given statutory authority to undertake this activity, and in what way does the statutory authority define and constrain the agency's actions?***

Here are the most pertinent sentences which AOPA has previously presented in its comments on the very serious shortcomings of the DME MAC policy bulletins.

II. AOPA Remains Concerned About the Expanded Definition of the term "Minimal Self Adjustment" Used to Define Off the Shelf Orthoses

AOPA, once again, would like to express its continued concern regarding the use of the expanded regulatory definition of the term "minimal self adjustment" as the basis for the inclusion of a total of 55 HCPCS codes in the category of off the shelf orthoses. The statutory definition of an off the shelf orthosis contained in section 1847(a)(2)(C) of the Social Security Act defines off the shelf orthoses as those:

> ***which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual.***

CMS expanded the definition of the term "minimal self adjustment" in C.F.R. 414.402 as follows:

> ***Minimal self-adjustment means an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training.***

AOPA has repeatedly voiced its concern regarding the expanded regulatory definition of the term "minimal self adjustment" and the subsequent use of the regulatory definition to classify 55 HCPCS codes as OTS, 23 of which represent HCPCS codes that were "exploded" into custom fitted and OTS codes used to describe the same device, differentiated by the process used in ensuring a proper fit for the patient. Efforts to date have included multiple pieces of correspondence with CMS officials, the CMS Administrator, as well as the Secretary of Health and Human Services.

AOPA believes that the expanded regulatory definition of minimal self adjustment goes beyond the intent of the statute in defining OTS orthoses subject to competitive bidding. The use of this expanded definition has resulted in the classification of many orthotic HCPCS codes as off the shelf items that in reality require some level of professional care to avoid potential harm to Medicare beneficiaries. The subsequent explosion of 23 HCPCS codes that represent items that are sometimes delivered OTS and sometimes delivered with proper fitting and training by a certified or trained individual has only

created more questions and confusion regarding documentation requirements for claim payment.

This confusion has been further escalated by the February 28, 2014 joint release and subsequent March 7, 2014 retraction of a policy bulletin on OTS orthoses by the four DME MAC contractors. While only published for a short time before its retraction, several statements in the policy bulletin reinforced AOPA's concern regarding the correct use of both off the shelf orthosis and custom fitted orthosis codes when submitting claims to Medicare contractors. An example of this ambiguity is contained in the discussion regarding the definition of custom fitted orthoses. The policy bulletin included a statement that custom fitted orthoses require ***substantial modification*** *for fitting at the time of delivery. The bulletin further defines substantial modification as "changes made to achieve an individualized fit of the item that requires the expertise of a qualified practitioner i.e., the item must be trimmed, bent, molded (with or without heat), or otherwise modified resulting in alterations beyond minimal self adjustment." While the bulletin attempts to clearly define the term substantial modification, it actually creates confusion among the supplier community when trying to decide if modifications they have made to assure a proper fit of the orthosis will meet the threshold of "substantial" modification. This will lead to increased exposure to audit activity and may contribute to unnecessary claim denials due to different interpretations of the term substantial. The policy bulletin also indicates that providers must provide the product that is specified by the ordering physician, i.e. type of orthosis and method of fitting and/or fabrication (OTS, custom fitted or custom fabricated). AOPA believes that in most cases, the ordering physician is relying on the specific expertise of the orthotist to determine, through direct evaluation, if the patient requires an OTS or custom fitted orthosis and therefore cannot pre-determine the exact method of fabrication and fitting that will be required. While the policy bulletin was retracted on March 7, 2014, AOPA expects a revised version of the bulletin to be published in the near future and remains concerned that DME MAC attempts at clarification may actually lead to additional confusion among suppliers.*

AOPA strongly believes that competitive bidding authority, as designated by the statute, should be limited to only those OTS orthoses that may be provided with the need for minimal self adjustment, specifically provided by the patient.

It should be noted that the DME MAC narrative limiting the decision on the type of device to the physician *only* would create access to care and delay of care problems for Medicare beneficiaries.

CMS needs to instruct its contractors that the word "substantial modification" used as a requirement for coding a device under the HCPCS codes that are now defined as custom fitted is completely without authority, is in error, and must be withdrawn. 'Custom fitted' devices are the next level up the chain of orthotic device complexity after 'off-the-shelf.' The statute makes a clear definition of "off-the-shelf" as noted above stating that this term applies only to orthotics that can be used by the patient "with minimal self-adjustment." This text not only defines 'off-the-shelf,' but it also defines custom fitted—a custom fitted device, by simple reading of the statute is a device which requires the smallest increment of clinical services by the licensed/certified orthotist (or other party specifically deemed as qualified by the statute) greater than "minimal self-adjustment." By interspersing the term

'substantial modification' which is completely alien to, and without any foundation whatsoever in the statute, CMS, via its contractors compounds the violation of the statute. The term 'substantial modification' would necessarily infer that there is some ground between "minimal self-adjustment" and "substantial modification." But, of course there is none—any device which cannot be used by the patient with 'minimal self-adjustment," falls inexorably, at least, into the next adjacent level of complexity, i.e. custom fitted—there is no place in between, and so the term "substantial modification" must be removed from any consideration as contrary to the statute, confusing and unreasonable and inappropriate.

The DME MACs have gone even further in their error as they have sought to make the inappropriate, unsupported and illegal definitions this statement postulates for "minimal self-adjustment" the basis for guidance on documentation and other coding requirements relating to distinguishing OTS from custom AFOs/KAFOs. AOPA has stated previously in a 2012 communication to the DME MAC medical directors that we believe that the addition of language of this type represents a substantive change to existing medical policy and is therefore subject to appropriate notice and rulemaking provisions of the Administrative Procedure Act. The simple addition of this language as part of an LCD revision did not provide stakeholders, including AOPA members as well as physicians, the opportunity to provide comments on the potential impact this statement represents to both Medicare beneficiaries and providers.

AOPA contends that the publication of this policy change as part of a unilateral revision to the local coverage determination did not provide the public or physician community with adequate notification or opportunity to provide comment regarding this substantive policy change. This, in turn, has contributed to the unusually high claim denial rate for AFOs that was reported by the Jurisdiction D DME MAC. In addition to the publication of the revised policy bulletin on the proper coding of OTS versus custom fitted orthoses, the DME MACs simultaneously published revisions to the LCDs and Policy Articles for AFOs/KAFOs, Knee orthoses, and Spinal orthoses that incorporated the provisions of the policy bulletin into the actual medical policies. These policies are being applied retroactively for claims with a date of service on or after January 1, 2014. AOPA believes that the DME MACs do not have the authority to make claim decisions using policies that were not published at the time the service was delivered.

Congress has set the standard that, "No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing . . . the eligibility of individuals, entities, or organizations to furnish . . . services or benefits . . . shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1)." There has been no such regulation promulgated to support this change.

Further, the statute says that orthoses for a Medicare patient must be "reasonable and necessary." CMS might maintain that concrete standards for determining

whether an orthosis is "reasonable and necessary" are set forth in the MPIM and LCDs—none of which was promulgated by regulation. In taking such action the government faces an unpleasant choice—either it set or it changed the standard without going through the required rulemaking. In either case, the absence of appropriate procedure under the Administrative Procedure and Medicare Acts renders the July 2012 (if not the entire LCD) void and in violation of the Congressional statute.

Finally, the DME MAC policy bulletins seem to take cognizance of the certification/accreditation requirements of Section 427 of BIPA 2000 when it states:

> "...requires the expertise of a certified orthotist or an individual who has equivalent specialized training in the provision of orthotics such as a physician, treating practitioner, an occupational therapist, or physical therapist in compliance with all applicable Federal and State licensure and regulatory requirements. A certified orthotist is defined as an individual who is certified by the American Board for Certification in Orthotics and Prosthetics, Inc., or by the Board for Orthotist/Prosthetist Certification.

We do not agree with the context in which this reference appears because it comes up in the context of "substantial modification," and further because it misreads another statute both by ignoring the possibility that an individual could be certified by another entity which meets the statute's requirements by evaluating certification/accreditation candidates to a standard substantially equivalent to that applied by either ABC or BOC, and by omitting the adjective 'qualified' which appears before the terms physical therapist and occupational therapist in the statute, but has been dropped entirely in this publication..

But much more importantly, the DME MAC policy bulletins and subsequent LCD revisions further miss the mark by failing to indicate that an orthotic fitter is also subject to these same requirements, and must demonstrate certification/accreditation in accordance with section 427 of BIPA 2000, on precisely the same terms as the licensed/certified orthotist.

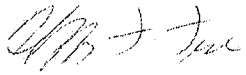
One closing note is that a second two-part action of CMS and its contractors, such as the DME MACs, is both the failure to recognize that changes to the standard by which provider submissions of requests for payment via coding MUST be established via an Administrative Procedure Act validated notice and comment rulemaking which allows the opportunity for participation and input from all stakeholders—including providers and patients. Further, policy criteria, such as those for whether a device falls within the descriptor of a HCPCS code, and whether a therapeutic intervention is deemed effective and/or appropriate for payment MUST be supported by scientific basis. AOPA has already provided previously, in our comments on the CMS draft OTS list extensive comments on errors by CMS, and in other communications, the errors of its contractors in not providing even the minimal scintilla of scientific rational, or references to support what are undeniably scientific/medical/clinical decisions about efficacy and appropriateness of specific treatments for specific orthotic patients. The policy in

the DME/MAC policy bulletins join these others, like the publication on the OTS list itself, in falling well short under both of these standards. There is nothing in the Medicare statute which authorizes either CMS or its contractors to establish payment polices ab initio and without sound scientific basis and procedural integrity under APA. Moreover, Congress delegated decisions on 'coverage' of devices to CMS, and it delegated findings of the efficacy of devices to FDA. When PDAC (perhaps with input from the DME MACs) assigns a code to a device in conjunction with the HCPCS process, they have properly addressed coverage; it goes beyond the authority of CMS or its contractors when either venture beyond coverage to attempt to abrogate authority which Congress never granted to CMS as to efficacy determinations

In conclusion, AOPA believes that CMS has no choice but to withdraw this DME MAC policy bulletin and the resulting and counterpart LCD revisions, and maintain them with no effect, pending initiating a full rulemaking which complies with the 3 statutory failings of this one—namely a rulemaking under the APA notice and comment process that complies BOTH with 42 U.S.C. section 1395w-3(a)(2)(C) AND with Section 427 of BIPA 2000.

If I can be of any assistance, please feel free to contact me at tfise@aopanet.org or via telephone at (571)431-0802.

Respectfully submitted,



Thomas F. Fise
Executive Director

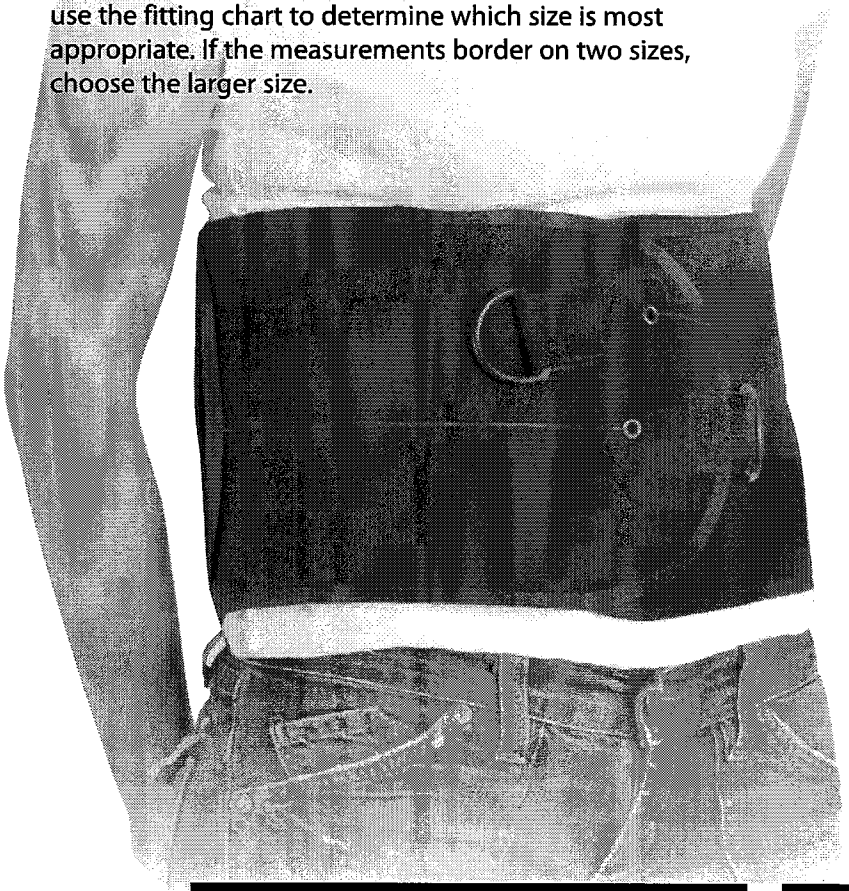
cc: Marilyn Tavenner, CMS Administrator
AOPA Board of Directors

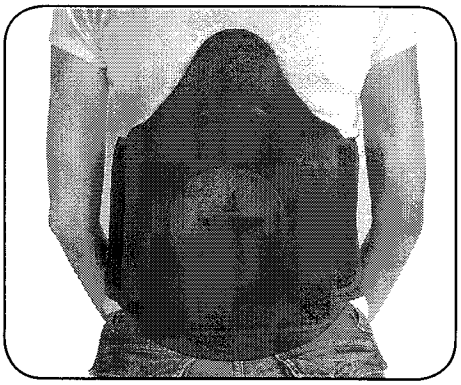
Split Code Set--- L0631 (custom fit)/L0648 (OTS)

California® Laguna™ Spinal Brace

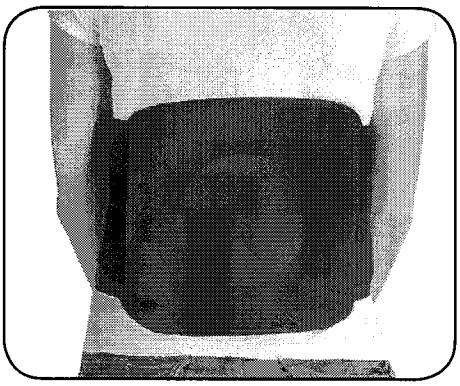
PRACTITIONER INSTRUCTIONS

Measure the body around the waist and hips and use the fitting chart to determine which size is most appropriate. If the measurements border on two sizes, choose the larger size.





631 & 637 Posterior Panels



627 Posterior Panel

À LA CARTE COMPONENTS

Laguna Builds	Fits Waists	Belt	Anterior Panel	631 Posterior Panel	637 Posterior Panel
626	26"–66"	XB7800			
627	26"–66"	XB7800	XB10		
631	26"–36"	XB7800	XB10	XB04	
631	36"–46"	XB7800	XB10	XB05	
631	46"–66"	XB7800	XB10	XB06	
637	26"–36"	XB7800	XB10		XB07
637	36"–46"	XB7800	XB10		XB08
637	46"–66"	XB7800	XB10		XB09

COMPLETE ORTHOSIS

Laguna 626	Laguna 627	Laguna 631	Laguna 637
XB7800			
	XB7803		
		XB7804	
		XB7805	
		XB7806	
			XB7807
			XB7808
			XB7809

SHELL

Posterior Height
9"
9"
14"
15½"
16½"
12"
14½"
15½"

California®
SOFT SPINAL SYSTEM

ORTHOMERICA®

CE EC REP

Emergo Europe
Molenstraat 15, 2513 BH, The Hague, The Netherlands
Phone +31-70-345-8570 | Fax +31-70-346-7299

6333 N Orange Blossom Trail
Orlando FL 32810
800-446-6770
orthomerica.com

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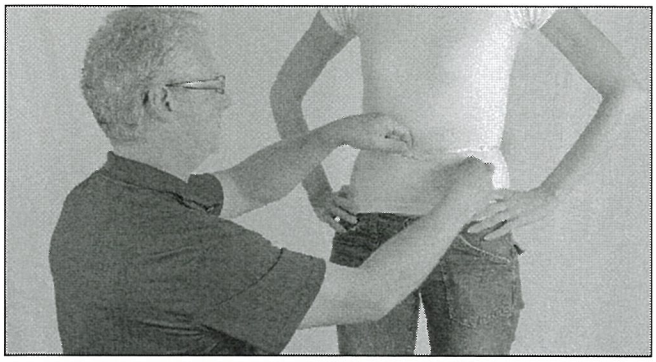
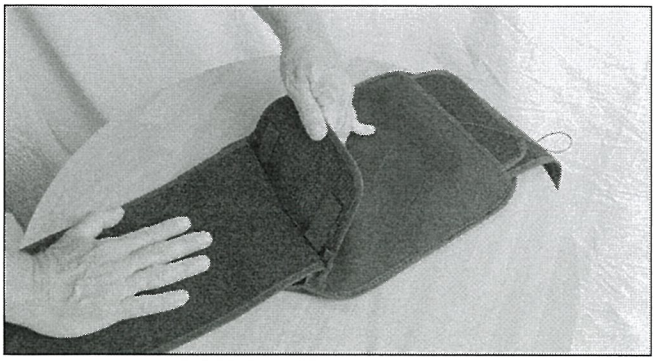
PRACTITIONER INSTRUCTIONS (CONTINUED)

The California® Laguna™ Spinal Brace comes with a one-size-fits-most belt that may require trimming.

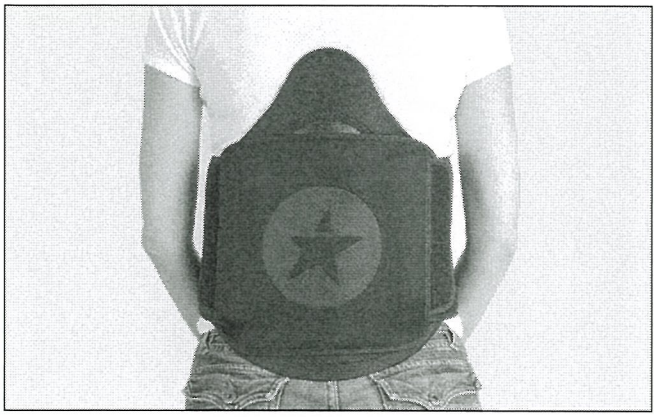
Measure patient at hip crest. Remove belt panels. Trim both sides of the belt at corresponding measurements printed on the panels.



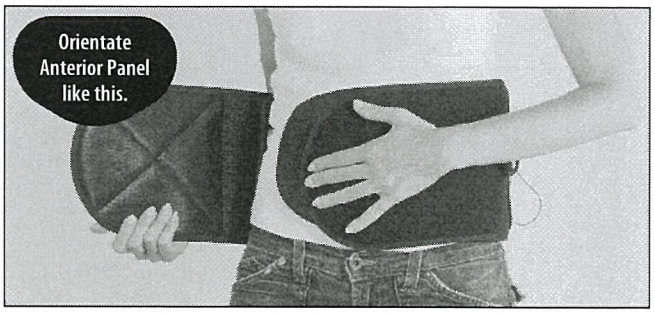
Attach the Velcro tabbed ends to each side of the belt.



Peel open the right side of the compression orthosis where it attaches to the anterior component and center the posterior component on the patient's back.



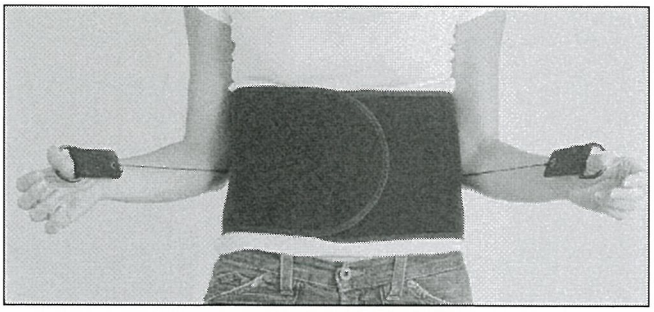
Position the anterior component on the patient's body.



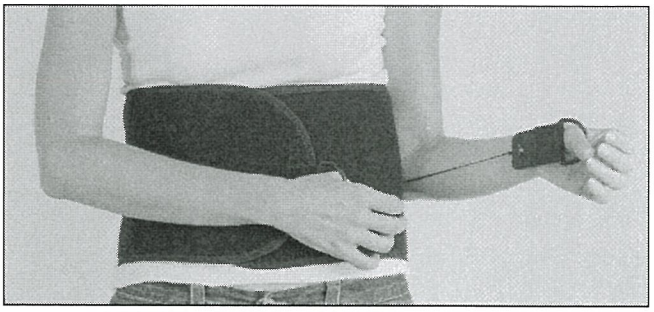
Refasten the right side of the orthosis, but do not pull it tightly at this point.

Peel open the left side of the compression orthosis and reattach it in a position that allows the anterior component to be centered.

Pull the compression pull-tabs forward to provide the desired amount of compression.



The pull-tab should be easy for the patient to reach and should be fastened to the anterior component or the Velcro® near the opposite side hip.



If the compression pull-tab is too long, cut the strings to the desired length, tie a new knot to join it to the pull tab.

Care Instructions

The foam lining inside the front and back panels can be wiped clean with mild soap and water applied with a damp cloth. Wipe the foam thoroughly with a clean, damp cloth to remove all soap residue and dirt. Allow the orthosis to air dry. **Do not machine wash or put the orthosis in a clothes dryer.**

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OTS Code---L1850

A24700, A24701
Hinged Swedish Knee Cage
Installation and User Guide

25542-001 REV F

INTRODUCTION
The Trulife Hinged Swedish Knee Cage is a "3-point pressure" knee brace based on the original Swedish Knee Cage, designed to limit genu recurvatum. The hinge allows the longer uprights to fold back and not protrude while seated.

Product Code	Size	Circumference at 4" above the knee
A24700	Small	11"–15"
A24701	Regular	15"–21"

INSTALLATION AND USE
Note: The Hinged Swedish Knee Cage should be fit on a seated patient with the knee bent at 90°.

1. Orient the knee cage so that the longer uprights are situated proximally.
2. Loosen all of the straps.
3. Apply the knee cage as proximally as the metal calf band will allow comfortably at 90°.
4. Align the proximal uprights to the center of the thigh.
5. Tighten the distal anterior thigh strap.
6. Tighten the distal anterior shin strap until the distal upright is centered on lower leg.
7. Tighten the proximal posterior thigh strap until the proximal upright is centered on the thigh.
8. Tighten the proximal anterior thigh strap.
9. Tighten the distal posterior calf strap.

Adjustments:
The proceeding should provide a lock-out at 10–15° of flexion. If less flexion is required, proceed with a combination of the following as needed:

- Loosen the posterior knee strap by repositioning the two panhead attachment screws anteriorly (1 position anteriorly allows approximately 5° more extension).
- Loosen the anterior distal shin strap to align the distal upright posterior to the center of lower leg.
- Loosen the anterior distal thigh strap.

QUESTIONS
Contact Customer Service in the U.S. at 888-878-1238, or fax 888-878-1237
Contact Customer Service in Canada at 800-267-2812, or fax 613-392-4139
If calling from outside the U.S. or Canada, contact Customer Service at 360-697-5656, or fax 360-697-6843
Visit Trulife online at www.trulife.com

LIMITED WARRANTY
Trulife warrants that the Hinged Swedish Knee Cage will be free from defects in material and workmanship for ninety (90) days from the date of installation.

This warranty will not apply if the product has been damaged by misuse, abuse, neglect, improper care, failure to follow instructions, abnormal wear and tear, or in the event that the Hinged Swedish Knee Cage has been modified/repaired by persons unauthorized by Trulife.

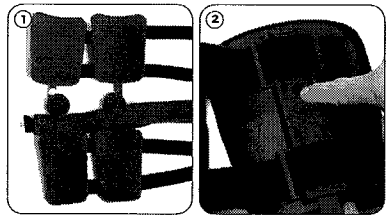
If a defect in material or workmanship is found during the warranty period, Trulife will, at Trulife's option, either repair or replace the product. If it is not possible to repair or replace the product, Trulife will be limited to refunding the purchase price.

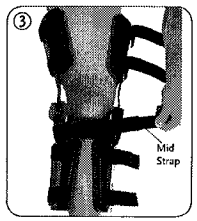
Trulife will not be liable under any legal theory for any direct, indirect, special, incidental or consequential damages arising from the use of or inability to use this product.

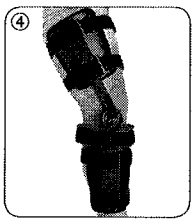
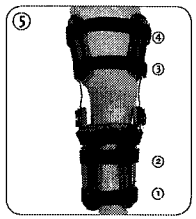
The application instructions/fitting guidelines for this Trulife product are for the use of and by certified, qualified orthopedic professionals only. Patients are not to attempt to apply or adjust any brace unless expressly instructed to do so by the orthopaedic professional responsible for the prescription and/or initial fitting of the orthosis. All questions should be referred to the orthopaedic professional and not to the manufacturer. The manufacturer warrants only that the enclosed orthosis has been inspected for quality and can be effective for certain indications, but final decisions and ongoing monitoring must be made by the orthopaedic professional(s) prescribing and/or fitting the orthosis to determine its effectiveness for an individual patient. Patient compliance is an integral part of the entire orthotic protocol and must be adhered to in order to avoid potential problems and to maximize the effectiveness of the prescribed treatment.

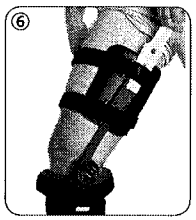
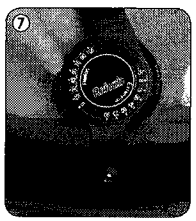
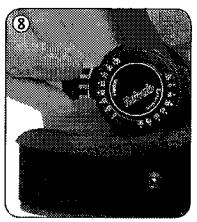
As a condition of the sale of any Trulife product, the orthosis is restricted to a "Single Patient Use Only" by the originally fitted patient in order to protect the care provider and the patient against potentially adverse consequences of infectious disease transmission, material instability in adapting to the configuration of the original user and/or decrease in orthotic therapy. Any express or implied warranties are voided if the orthosis is attempted to be reused. Additionally, a license of right to use under any relevant patents pertaining to the orthosis is terminated with the cessation of use by the original patient. As with all Trulife products, this orthosis must be prescribed and applied by a qualified orthopaedic professional to determine it meets the needs of the particular patient and accomplishes the desired results.

Split Code Set---L1832(Custom Fitted)/L1833 (OTS)





ENGLISH

CAUTION
This product is to be used only under the supervision of a licensed health care professional. Care must be taken to follow the advice of the healt care professional when using this or any medical device.

ADJUST THE BRACE LENGTH
1 Each pair of shells, (2 upper and 2 lower), must be set to the same position (**Figure 1**). Failure to do so could cause hinge malalignment and brace slippage.
2 Depress button on each shell and slide shell to required length (**Figure 2**).

APPLY THE BRACE
3 Undo mid-strap and place brace under patient´s leg (**Figure 3**). Attain correct hinge position by adjusting the mid-strap and pad.
4 Hinges are centered halfway between the front and back of the knee (**Figure 4**).
5 Hinges and shells are parallel (**Figure 5**)
6 Pass strap throug the d-ring and fasten the hook tap end back onto the strap to secure (**Figure 3**).
7 The mid-strap should be tightened as firmly as possible without restricting circulation. Adjust stap length through hinge arm d-rings
Correct Brace Position.

ADJUST THE SHELL STRAP LENGTH
8 Align calf shells so hinges are parallel to tibia. Secure strap 1 (**Figure 5**). Pull strap tight, pass strap through d-ring and fasten the hook tab end back onto the strap.
9 Align thigh shells so hinges are parallel with the femur
10 Secure straps 2,3, and 4 (**Figure 5**) using same procedure.
11 When desired strap length is achieved remove hook cover on shell and mid-strap (**Figure 6**). Press strap against hook to secure.
12 After straps are secured, check brace position again and adjust if necessary. Leave straps fastened at hook contact along shells. The brace is now properly sized for the patient. Future application and correct positioning can be done easily by fastening straps along the front of the brace position.

RANGE OF MOTION
13 Push and set to desired extension position (**Figure 7**)
14 Push and set to desired flexion position (**Figure 7**).
15 After Range of Motion is set push Range Of Motion Spring Locks into place (**Figure 8**).
16 Make adjustments to both hinges.
NOTE: Range of Motion Lock is not to be used in the 105 degree

CARE AND MAINTENANCE
Liners may be hand washed with cold water. Hang to dry.

WARRANTY
Ossur post operative bracing product are disposable, limited use devices not intended for long term use. We warrant our products against defects in material and workmanship in the following manner; 30 days for skin contact parts (foam and straps) and 90 days for shells and hinges. Since we cannot control the manner in which such devices are fit, applied, adjusted or used, this warrany does not apply to products which have been neglected, abused, incorrectly applied or incorrectly fit. There are no warranties, either expressed or implied, other than those listed above.

DEUTSCH

WARNHINWEIS
Dieses Produkt darf nur unter Aufsicht eines zugelassenen Arztes verwendet werden. Der Rat des Arztes muss sorgfältig befolgt werden, wenn Sie dieses oder ein anderes medizinisches Gerät benutzen.

ORTHESENLÄNGE ANPASSEN
1. Jedes Paar Schalen (2 obere und 2 untere) muss in der gleichen Position eingestellt sein (**Abbildung 1**). Sind die Schalen nicht gleich eingestellt, kann dies zu einer Gelenkfehlausrichtung und zu einem Verrutschen der Orthese führen.
2. Drücken Sie den Knopf auf jeder Schale und schieben Sie die Schale auf die gewünschte Länge (**Abbildung 2**).

ORTHESE ANLEGEN
3. Lösen Sie den Mittelriemen und platzieren Sie die Orthese unter dem Bein des Patienten (**Abbildung 3**). Die richtige Gelenkausrichtung erhalten Sie, indem Sie den Mittelriemen und das Polster anpassen.
4. Die Gelenke sind auf der Hälfte zwischen Vorder- und Rückseite des Knies zentriert (**Abbildung 4**).
5. Gelenke und Schalen sind parallel zueinander (**Abbildung 5**).
6. Führen Sie den Riemen durch den D-Ring und befestigen Sie das hintere Ende der Hakenschlaufe auf dem Riemen, um ihn festzuziehen (**Abbildung 3**).
7. Der Mittelriemen sollte so fest wie möglich angezogen werden, ohne die Durchblutung abzuklemmen. Passen Sie die Riemenlänge durch die D-Ringe des Gelenkarms an. Korrigieren Sie, wenn nötig die, Position der Orthese.

SCHALENRIEMENLÄNGE ANPASSEN
8. Richten Sie die Wadenschalen so aus, dass sich die Gelenke parallel zur Wade befinden. Ziehen Sie den Riemen 1 fest (**Abbildung 5**). Führen Sie ihn durch den D-Ring und befestigen Sie das Hakenschlaufenende wieder auf dem Riemen.
9. Richten Sie die Oberschenkelschalen so aus, dass die Gelenke parallel zum Oberschenkelknochen sind.
10. Befestigen Sie die Riemen 2,3 und 4 (**Abbildung 5**) auf die gleiche Art und Weise.
11. Wenn die gewünschte Riemenlänge erreicht ist, entfernen Sie die Hakenabdeckung auf der Schale und den Mittelriemen (**Abbildung 6**). Drücken Sie den Riemen gegen den Haken, um ihn zu sichern.
12. Wenn Sie die Riemen befestigt haben, überprüfen Sie erneut die Position der Orthese und korrigieren Sie sie ggf. Die Riemen sollten an den Hakenkontakten entlang der Schalen befestigt bleiben. Die Orthese ist jetzt richtig für den Patienten eingestellt. Zukünftige Anwendung und die korrekte Positionierung können ganz einfach vorgenommen werden, indem die Riemen entlang der Vorderseite der Orthese angezogen werden.

BEWEGUNGSSPIELRAUM
13. Schieben Sie und stellen Sie die gewünschte Extensionsposition ein (**Abbildung 7**).
14. Schieben Sie und stellen Sie die gewünschte Beugungsposition ein (**Abbildung 7**).
15. Wenn der Bewegungsspielraum eingestellt wurde, drücken Sie die Federschlösser des Bewegungsspielraums zurück (**Abbildung 8**).
16. Passen Sie beide Gelenke an.
HINWEIS: Das Schloss des Bewegungsspielraums darf nicht im Winkel von 105 Grad verwendet werden.

REINIGUNG UND PFLEGE
Die Polster können mit kaltem Wasser von Hand gewaschen werden. Zum Trocknen aufhängen.

GARANTIE
Die postoperativen Orthesenprodukte von Össur sind Hilfsmittel mit eingeschränkter Nutzungsdauer, die nicht für den langfristigen Gebrauch gedacht sind. Unsere Produkte besitzen die folgende Garantie gegen Material- und Verarbeitungsfehler; 30 Tage für Teile, die Kontakt mit der Haut haben (Schaumstoff und Riemen) und 90 Tage für Schalen und Gelenke. Da wir nicht die Art und Weise kontrollieren können, wie die Hilfsmittel angepasst, angelegt, eingestellt oder verwendet werden, gilt diese Garantie nicht für Produkte, die vernachlässigt, zweckentfremdet, falsch angelegt oder nicht richtig angepasst wurden. Andere Garantien, ausdrückliche oder implizierte, als die oben angegebenen werden nicht gewährt.

FRANCAIS

PRÉCAUTIONS
Ce produit ne doit être utilisé que sous la supervision d'un professionnel de santé agréé. Il convient de respecter les conseils du professionnel de santé lors de l'utilisation de ce dispositif médical ou de tout autre dispositif.

AJUSTEZ LA LONGUEUR DE L'ORTHÈSE
1 Chaque paire de coques (2 supérieures et 2 inférieures) doit être réglée à la même position (**Figure 1**). Un non-respect de cette indication risque de provoquer un mésalignement non alignement de la charnière et de faire glisser l'orthèse.
2 Appuyez sur le bouton situé sur chaque coque et faites glisser la coque jusqu'à obtenir la longueur souhaitée (**Figure 2**).

POSEZ L'ORTHÈSE
3 Défaites la sangle centrale et placez l'orthèse sous la jambe du patient (**Figure 3**). Pour obtenir une position correcte de la charnière, ajustez la sangle centrale et le rembourrage.
4 Les charnières sont centrées à mi-hauteur entre l'avant et l'arrière du genou (**Figure 4**).
5 Les charnières et les coques sont parallèles (**Figure 5**)
6 Faites passer la sangle dans l'anneau en D et repassez l'extrémité contenant le crochet de fixation sur la sangle pour la fixer (**Figure 3**).
7 La sangle centrale doit être serrée autant que possible sans entraver la circulation. Ajustez la longueur de la sangle grâce aux anneaux en D du bras d'articulation. Corrigez la position de l'orthèse.

AJUSTEZ LA LONGUEUR DE LA SANGLE DE LA COQUE
8 Alignez la coque de mollet de façon à ce que les charnières soient parallèles au tibia. Fixez la sangle 1 (**Figure 5**). Tirez fermement sur la sangle, faites-la passer dans l'anneau en D et redoublez le filet d'implantation du crochet sur la sangle pour le fixer.
9 Alignez les coques de cuisse de façon à ce que les charnières soient parallèles au fémur.
10 Fixez les sangles 2, 3, et 4 (**Figure 5**) en suivant la même procédure.
11 Lorsque vous avez obtenu la longueur de sangle souhaitée, retirez la couverture de crochet de la coque et le milieu de la sangle (**Figure 6**). Appuyez la sangle contre le crochet pour fixer.
12 Une fois que les sangles sont en place, vérifiez à nouveau la position de l'orthèse et ajustez si nécessaire. Laissez les sangles fixées au point de contact entre les crochets et les coques. L'orthèse est maintenant correctement réglée à la taille du patient. Lors d'applications futures et pour obtenir un positionnement correct en toute simplicité, fixez les sangles le long de l'avant de l'orthèse.

AMPLITUDE ARTICULAIRE
13 Appuyez et réglez pour obtenir la position d'extension voulue (**Figure 7**).
14 Appuyez et réglez pour obtenir la position de flexion voulue (**Figure 7**).
15 Une fois l'amplitude articulaire réglée, appuyez sur les verrous à ressort de l'amplitude articulaire pour les bloquer (**Figure 8**).
16 Ajustez les deux charnières.
REMARQUE: Le verrou de l'amplitude articulaire ne doit pas être utilisé à 105 degrés.

MAINTENANCE ET ENTRETIEN
Les manchons peuvent être lavés à la main à l'eau froide. Suspendez-les pour les faire sécher.

GARANTIE
Les produits orthétiques postopératoires Ossur sont des appareils jetables d'usage limité. Ils ne sont pas destinés à une utilisation à long terme. Nous garantissons nos produits contre les défauts matériels et les vices de fabrication de la façon suivante : pendant 30 jours pour pièces en contact avec la peau (mousse et sangles) et 90 jours pour les coques et les charnières. Dans la mesure où ne nous ne pouvons contrôler la façon dont ces appareils sont posés, appliqués, ajustés ou utilisés, cette garantie ne s'applique pas aux produits endommagés à l'issue de négligence, d'emploi abusif, d'application ou de pose incorrectes. Il n'existe aucune autre garantie, qu'elle soit exprimée ou implicite, à part les garanties énumérées ci-dessus.

ESPAÑOL

PRECAUCIONES
Este producto debe utilizarse únicamente bajo la supervisión de un profesional sanitario autorizado. Se debe tener la precaución de seguir la recomendación del profesional sanitario al utilizar éste o cualquier dispositivo médico.

AJUSTE LA LONGITUD DE LA ABRAZADERA
1 Cada par de piezas del armazón, (2 superiores y 2 inferiores), se debe colocar en la misma posición (**Figura 1**). El no hacerlo puede ocasionar un mal alineamiento del goznе y deslizamiento de la abrazadera.
2 Presione el botón en cada pieza del armazón y deslice la pieza hasta la longitud requerida (**Figura 2**).

COLOQUE LA ABRAZADERA
3 Desabroche la correa media y sitúe la abrazadera bajo la pierna del paciente (**Figura 3**). Llegue hasta la posición correcta del goznе ajustando la correa media y la almohadilla.
4 Los goznes se centran a mitad del recorrido entre la parte frontal y trasera de la rodilla (**Figura 4**).
5 Los goznes y las piezas del armazón son paralelos (**Figura 5**)
6 Pase la correa a través del anillo en d y apriete el extremo de la llave de gancho de nuevo sobre la correa para asegurarla (**Figura 3**).
7 La correa media debe estar apretada tan firmemente como sea posible sin impedir la circulación. Ajuste la longitud de la correa a través de los anillos en d del brazo de la bisagra Corrija la posición de la abrazadera.

AJUSTE LA LONGITUD DE LA CORREA DEL ARMAZÓN
8 Alinee las piezas del armazón de la pantorrilla de modo que los goznes estén paralelos a la tibia. Asegure la correa 1 (**Figura 5**). Tense la correa, pase la correa a través del anillo en d y apriete el extremo de la llave de gancho de nuevo sobre la correa.
9 Alinee las piezas del armazón del muslo de modo que los goznes estén paralelos al fémur.
10 Asegure las correas 2, 3, y 4 (**Figura 5**) utilizando el mismo procedimiento.
11 Cuando logre la longitud deseada de la correa retire la cubierta del gancho sobre la pieza del armazón y la correa media (**Figura 6**). Presione la correa sobre el gancho para asegurarla.
12 Después de haber asegurado las correas, compruebe la posición de la abrazadera de nuevo y ajústela si es necesario. Deje las correas apretadas en contacto con el gancho a lo largo de las piezas del armazón. El tamaño de la abrazadera esta ahora ajustado adecuadamente para el paciente. Se pueden realizar fácilmente futuras aplicaciones y posicionamientos correctos apretando las correas a lo largo de la parte frontal de la posición de la abrazadera.

RANGO DE MOVIMIENTO
13 Pulse y establezca la posición de extensión deseada (**Figura 7**).
14 Pulse y establezca la posición de flexión deseada (**Figura 7**).
15 Después de haber establecido el rango de movimiento coloque en su lugar los cierres de resorte de rango del movimiento (**Figura 8**).
16 Realice ajustes en ambos goznes.
NOTA: El cierre de rango de movimiento no se utiliza en el ángulo de 105 grados

CUIDADOS Y MANTENIMIENTO
Los encajes se pueden lavar a mano con agua fría. Cuélguelo para secar.

GARANTÍA
Los productos postoperatorios de abrazadera de Ossur son dispositivos desechables, de uso limitado no previstos para un uso a largo plazo. Garantizamos nuestros productos frente a defectos materiales y de mano de obra del siguiente modo; 30 días para las piezas en contacto con la piel (espuma y correas) y 90 días para las piezas del armazón y goznes. Puesto que no podemos controlar el modo en el que dichos dispositivos se colocan, aplican, ajustan o utilizan, esta garantía no afecta a productos que han sido descuidados, maltratados, aplicados incorrectamente o ajustados incorrectamente. No existen otras garantías, explícitas o implícitas, distintas a las citadas más arriba.

ITALIANO

PRECAUZIONI D'IMPIEGO
Questo prodotto è destinato a essere usato esclusivamente dietro controllo di un medico professionista. Quando si usa questo o un altro dispositivo medico, occorre prestare attenzione e seguire i consigli del medico.

RECOLARE LA LUNGHEZZA DEL SOSTEGNO
1 Ciascun paio di conchiglie (2 superiori e 2 inferiori), deve essere impostato alla stessa posizione (**Figura 1**). La mancata osservanza di tale precauzione potrebbe provocare il disallineamento della cerniera e lo scivolamento del sostegno.
2 Premere il pulsante posto su ciascuna delle conchiglie e far scivolare la conchiglia alla lunghezza richiesta (**Figura 2**).

APPLICARE IL SOSTEGNO
3 Slacciare la cinghia mediana e collocare il sostegno sotto la gamba del paziente (**Figura 3**). Regolare la cinghia mediana e il cuscinetto in modo da ottenere la posizione corretta della cerniera.
4 Le cerniere si centrano sulla mezzeria tra la parte anteriore e quella posteriore del ginocchio (**Figura 4**).
5 Cerniere e conchiglie sono parallele (**Figura 5**).
6 Far passare la cinghia attraverso l'anello a D e fissare il retro dell'estremità del foro del gancio sulla cinghia per fissarla (**Figura 3**).
7 Occorre fissare la cinghia mediana il più saldamente possibile senza tuttavia limitare la circolazione. Regolare la lunghezza della cinghia attraverso gli anelli a D della cerniera Correggere la posizione del sostegno.

REGOLARE LA LUNGHEZZA DELLA CINGHIA DELLA CONCHIGLIA
8 Allineare le conchiglie del polpaccio in modo che le cerniere siano parallele alla tibia. Fissare la cinghia 1 (**Figura 5**). Tirare la cinghia, farla passare attraverso l'anello a D e fissare il retro dell'estremità del foro del gancio sulla cinghia.
9 Allineare le conchiglie della coscia in modo che le cerniere siano parallele al femore.
10 Fissare le cinghie 2, 3 e 4 (**Figura 5**) usando la stessa procedura.
11 Dopo aver ottenuto la lunghezza della cinghia desiderata, togliere la copertura del gancio sulla conchiglia e sulla cinghia mediana (**Figura 6**). Premere la cinghia contro il gancio per fissarla.
12 Dopo aver fissato le cinghie, controllare nuovamente la posizione del sostegno e, se occorre, regolarla. Lasciare le cinghie fissate al contatto dei ganci lungo le conchiglie. A questo punto, il sostegno è correttamente dimensionato per il paziente. È possibile realizzare facilmente l'applicazione e il corretto posizionamento futuri fissando le cinghie lungo la parte anteriore della posizione del sostegno.

INTERVALLO DI MOVIMENTO
13 Spingere e impostare alla posizione di estensione desiderata (**Figura 7**).
14 Spingere e impostare alla posizione di flessione desiderata (**Figura 7**).
15 Dopo aver impostato l'intervallo di movimento, spingere in sede i dispositivi di bloccaggio della molla dell'intervallo di movimento (**Figura 8**).
16 Apportare le regolazioni del caso a entrambe le cerniere.
NOTA: Non bisogna usare il dispositivo di bloccaggio impostandolo sul grado 105

CONSERVAZIONE E MANUTENZIONE
I rivestimenti devono essere lavati a mano con acqua fredda. Lasciare asciugare all'aria.

GARANZIA
I dispositivi di sostegno postintervento Ossur sono monouso, destinati a un uso limitato e non a lungo termine. Garantiamo i nostri prodotti da difetti nei materiali e nella lavorazione come segue: 30 giorni per le parti a contatto con la pelle (spugna e cinghie) e 90 giorni per le conchiglie e le cerniere. Dato che non abbiamo il controllo sul modo in cui tali dispositivi sono indossati, applicati, regolati o usati, questa garanzia non vale per i prodotti che siano stati trascurati, usati, applicati o indossati in modo improprio. Oltre alle garanzie descritte in precedenza, non vi sono altre garanzie esplicite o implicite.

NORSK

FORSIKTIG
Dette produktet skal kun brukes under tilsyn av lege. Det er viktig å følge legens råd når man bruker dette eller andre medisinske apparater.

JUSTER SKINNELENGDEN
1. Hvert skallpar (2 øvre og 2 nedre) må settes i samme posisjon (**Figur 1**). Gjør man ikke dette, kan hengselet forskyve seg og skinnen kan skli.
2. Trykk ned knappen på hvert skall og skyv skallet til ønsket lengde (**Figur 2**).

SETT PÅ SKINNEN
3. Ta vekk midtremmen og sett skinnen under pasientens ben (**Figur 3**). Oppnå riktig hengseleposisjon ved å justere midtremmen og puten.
4. Hengslene er sentrert halvveis mellom forsiden og baksiden av kneet (**Figur 4**).
5. Hengsler og skall er parallelle (**Figur 5**).
6. Dra remmen gjennom d-ringen og fest enden av kroken tilbake på remmen for å sikre den (**Figur 3**).
7. Midtremmen burde festes så stramt som mulig uten å begrense sirkulasjonen. Juster remlengden gjennom hengselarmede d-ringer Riktig skinneposisjon.

JUSTER SKALLREMLENGDEN
8. Rett tykklæggskallene så hengslene står parallelt med tibia. Sikre rem 1 (**Figur 5**). Stram remmen, dra remmen gjennom d-ringen og fest kroken på remmen igjen.
9. Rett lårskallene så hengslene står parallelt med lårbenet.
10. Sikre rem 2, 3 og 4 (**Figur 5**) ved å bruke samme prosedyre.
11. Når du har riktig remlengde kan du fjerne krokdekslet på skallet og midtremmen (**Figur 6**). Trykk remmen mot kroken for å sikre.
12. Sjekk skinneposisjonen igjen og juster hvis nødvendig etter at remmene er sikret. Hold remmene festet til krokkontaktene langs skallene. Skinnen har nå riktig størrelse for pasienten. Senere påføring og riktig plassering kan gjøres lett ved å feste remmene langs forsiden av skinneposisjonen.

BEVEGELSESUTSLAG
13. Trykk og sett i ønsket ekstensjonsposisjon (**Figur 7**).
14. Trykk og sett i ønsket fleksjonsposisjon (**Figur 7**).
15. Etter bevegelsesutslaget er stilt inn, trykk bevegelsesutslag springlåsene på plass (**Figur 8**).
16. Utfør justeringer på begge hengslene
MERK: Bevegelsesutslagslåsen skal ikke brukes i 105 grader

STELL OG VEDLIKEHOLD
Linjer kan håndvaskes med kaldt vann. Henges opp til tørk.

GARANTI
Ossur postoperative skinneprodukter er kastbare, begrenset bruk apparater er ikke ment for langsiktig bruk. Vi garanterer våre produkter mot defekter materiale og utførelse på følgende måte; 30 dager for hudkontakt deler (skum og remmer) og 90 dager for skall og hengsler. Da vi ikke kan kontrollere hvordan apparater passer, påføres, justeres eller brukes, gjelder ikke denne garantien produkter som har blitt neglisjert, misbrukt, feilaktig anvendt eller feil passform. Det er ingen andre garantier, verken uttrykt eller underforstått, enn de som er listet ovenfor.

DANSK

OBS!
Dette produkt må kun anvendes af en kvalificeret læge. Man bør omhyggeligt følge lægens råd, når man anvender dette eller eshvert andet medicinsk udstyr.

JUSTER SKINNENS LÆNGDE
1. Hvert par skaller, (2 øvre og 2 nedre), skal være i den samme position (**Figur 1**). At undlade dette kan det forårsage forskydning af hængsel og skred af skinnen.
2. Tryk knappen ned på hver af skallerne og for skallen hen til den nødvendige længde (**Figur 2**).

PÅSÆT SKINNEN
3. Åbn den midterste strop og placer skinnen under patientens ben (**Figur 3**). Sørg for at hængslerne er i korrekt position ved at justere den midterste strop og pude.
4. Hængslerne er centreret halvvejs mellem for- og bagsiden af kneet (**Figur 4**).
5. Hængsler og skaller er parallelle (**Figur 5**).
6. Før remmen gennem D-ringen og fastgør igen "han" enden på remmen for at sikre den (**Figur 3**)
7. Den midterste rem skal spændes så fast som muligt, uden at hindre blodomløbet. Juster remmenes længde gennem hængselarmens d-ringe. Juster skinnens position.

JUSTER REMLÆNGDEN FOR SKALLERNE
8. Juster lægskallerne, så hængslerne er parallelle med skinnebenet. Fastgør rem 1 (**Figur 5**). Træk remmen til, før remmen gennem D-ringen og fastgør igen "han" enden på remmen.
9. Juster lårskallerne, så hængslerne er parallelt med lårbenet.
10. Fastgør rem 2, 3 og 4 (**Figur 5**) ved at anvende samme procedure.
11. Når den ønskede remlængde er opnået, fjernes beskyttelsen fra velcroen på skallen og den mellemste rem (**Figur 6**). Pres remmen mod velcroen for at fæstne den.
12. Efter stropperne er fæstnede, check skinnernes stilling igen og juster om nødvendigt. Efterlad remmene fastgjorte på velcroen langs skallerne. Skinnen er nu korrekt justeret for patienten. Fremtidige påføring og korrekt placering kan nemt foretages ved at fastgøre remme langs den forreste del af skinnens stilling.

BEVÆGELSESOMRÅDE
13. Tryk og indstil den til den ønskede ekstensionsindstilling (**Figur 7**).
14. Tryk og indstil den til den ønskede fleksionsindstilling (**Figur 7**).
15. Efter at bevægelsesområdet er fastsat, sæt bevægelsesområdets fjederlås på plads (**Figur 8**).
16. Juster begge hængsler.
BEMÆRK: Bevægelsesområdets lås skal ikke anvendes for 105 grader

PLEJE OG VEDLIGEHOLDELSE
Foringer kan håndvaskes med koldt vand. De skal hængetørre.

GARANTI
Ossurs post operative skinneprodukter er til bortkastning efter brug og til begrænset anvendelse. De ikke er beregnet til langvarig brug. Vi garanterer vores produkter mod defekter i materialer og udførelse på følgende måde: 30 dage for dele der har kontakt med huden (skum og stropper) og 90 dage for skaller og hængsler. Da vi ikke kan kontrollere den måde, hvorpå disse anordninger tilpasses, påføres, justeres eller anvendes, er denne garanti ikke gældende for produkter, som er blevet forsømt, misbandlet, feilagtigt anvendt eller forkert tilpasset. Der er ingen garantier, udtrykt eller underforstået, andre end de ovenfor anførte.

SVENSKA

FÖRSIKTIGHET
Denna produkt får endast användas under överinseende av legitimerad sjukvårdspersonal. Du måste vara noga med att följa vårdpersonalens råd när du använder denna eller annan medicinsk utrustning.
JUSTERA ortosens LÄNGD
1 Varje par med skal (2 övre och 2 nedre) måste vara inställda i samma position (figur 1). Underlåtelse att göra detta kan orsaka felställning och att stödet glider.
2 Tryck ned knappen på varje skal och dra skalet till önskad längd (figur 2).

PLACERA ORTOSEN
3 Lossa bandet i mitten och placera ortosen under patientens ben (figur 3). Placera leden i korrekt position genom att justera bandet i mitten och kudden.
4 Lederna ska placeras mitt emellan knäets fram- och baksida (figur 4).
5 Lederna och skalen är parallella (figur 5).
6 Dra bandet genom D-ringen och fäst kardborredelen på bandets baksida för att säkra denna (figur 3).
7 Bandet i mitten ska dras åt så hårt som möjligt utan att förhindra cirkulationen. Justera band längden genom ledarmens D-ringar Korrekt position på ortosen.

JUSTERA BANDLÄNGDEN PÅ SKALET
8 Justera vadskalet så att lederna är parallella med skenbenet. Fäst band 1 (figur 5). Dra åt bandet ordentligt, dra den igenom D-ringen och fäst kardborredelen på bandets baksida.
9 Justera lårskalen så att lederna är parallella med femur
10 Fäst banden 2, 3 och 4 (figur 5) på samma sätt.
11 När önskad bandlängd har uppnåtts lossar du kardborredelen från skalet och bandet i mitten (figur 6). Tryck bandet mot kardborredelen för att säkra den.
12 När banden har fästs kontrollerar du ortosens position på nytt och justera den om det behövs. Låt banden vara fästa vid kardborrebanden längs hela skalet. Ortosen har nu lämplig storlek för patienten. Användning och placering kan i framtiden enkelt göras genom att fästa banden längs stödets framsida.

RÖRELSEOMFÅNG
13 Tryck och ställ in önskad extensionsposition (figur 7).
14 Tryck och ställ in önskad flexionsposition (figur 7).
15 När rörelseomfånget har ställts in trycker du fjädrarna för rörelseomfång på plats (figur 8).
16 Justera båda lederna.
OBS! Rörelseomfångslåset får inte användas vid 105 grader

SKÖTSEL OCH UNDERHÅLL
Polstringen kan tvättas för hand i kallt vatten. Hängtorkas.

GARANTI
Össurs postoperativa ortos produkter är avsedda för engångsbruk, produkter som är avsedda för begränsad användningstid inte att användas vid långvarigt bruk. Vi garanterar att våra produkter är fria från brister i material och tillverkning enligt följande: 30 dagar för delar som kommer i kontakt med huden (kuddar och band), och 90 dagar för skal och leder. Eftersom vi inte kan kontrollera hur sådana produkter passas in, placeras, justeras eller används, gäller inte denna garanti för produkter som utsatts för försummelse, missbruk, applicerats på ett felaktigt sätt eller inte passats in ordentligt. Det finns inga andra garantier, vare sig uttryckliga eller underförstådda, utöver de ovan angivna.

SUOMI

HUOMIO
Tuotetta tulee käyttää ainoastaan hoitoalan ammattilaisen ohjauksessa. Tämän tai muiden lääketieteellisten laitteiden käytössä on noudatettava tarkkaan hoitoalan ammattilaisen ohjeita.

ORTOOSIN PITUUDEN SÄÄTÄMINEN
1. Molemmat mansettiparit (2 ylä- ja 2 alamansettia) on asetettava samaan asentoon (Kuva 1). Muussa tapauksessa ortoosinivelet eivät ehkä pysy paikallaan, ja ortoosi saattaa lipsua.
2. Paina kunkin mansetin painiketta ja liu'uta mansetti vaaditun pituiseksi (Kuva 2).

ORTOOSIN PUKEMINEN
3. Avaa keskihihna ja aseta ortoosi potilaan jalan alapuolelle (Kuva 3). Saat aikaan oikean ortoosinivelen asennon säätämällä keskihihnaa ja pehmustetta.
4. Ortoosinivelet keskitetään jalan sivulle polven puoliväliin (Kuva 4).
5. Ortoosinivelet ja mansetit ovat samansuuntaiset (Kuva 5).
6. Vie hihna D-renkaan läpi ja kiinnitä tarranauhaliuskan pää taakse hihnaan sen kiinnittämiseksi (Kuva 3).
7. Keskihihna pitäisi kiristää mahdollisimman tiukalle verenkiertoa häiritsemättä Säädä hihnan pituutta ortoosinivelen varren d-renkaiden avulla. Korjaa ortoosin asentoa.

MANSETIN HIHNAN PITUUDEN SÄÄTÄMINEN
8. Kohdista pohjemansetit, niin että ortoosinivelet ja sääriluu ovat yhdensuuntaisia. Kiinnitä hihna 1 (Kuva 5). Vedä hihna kireälle, vie se D-renkaan läpi ja kiinnitä tarranauhan pää hihnaan.
9. Kohdista reisimansetit niin, että ortoosinivelet ja reisiluu ovat yhdensuuntaisia.
10. Kiinnitä hihnat 2, 3 ja 4 (Kuva 5) saman toimenpiteen avulla.
11. Kun haluttu pituus on saatu aikaan, poista tarran suojus mansetista ja keskihihnasta (Kuva 6). Kiinnitä hihna painamalla se tarraa vasten.
12. Kun hihnat on kiinnitetty, tarkista ortoosin asento uudelleen ja säädä sitä tarvittaessa. Jätä hihnat kiinni mansettien tarranauhoihin. Ortoosi on nyt säädetty potilaan kokoon sopivaksi. Jatkossa ortoosin voi pukea ja asettaa vaivatta oikein kiinnittämällä hihnat ortoosin etuosaan.

LIIKELAAJUUS
13. Työnnä ja aseta haluttuun ojennusasentoon (Kuva 7).
14. Työnnä ja aseta haluttuun koukistusasentoon (Kuva 7).
15. Kun liikelaajuus on asetettu, aseta liikelaajuuden jousilukitus paikalleen (Kuva 8).
16. Säädä molempia ortoosiniveliä.
HUOMAUTUS: Liikelaajuuden lukitusta ei saa käyttää 105 asteen kohdalla

HOITO JA HUOLTO
Pehmusteet voidaan pestä käsin kylmällä vedellä. Ripusta kuivumaan.

TAKUU
Ossurin leikkauksen jälkeiset ortoosituotteet ovat kertakäyttöisiä laitteita, joiden käyttö on rajallista. Niitä ei ole tarkoitettu pitkäaikaiskäyttöön. Tuotteillemme myönnettävä takuu kattaa materiaali- ja valmistusvirheet. Ihokontaktissa olevien osien (vaahtomuovi ja hihnat) takuu on 30 vuorokautta ja mansettien ja ortoosinivelten takuu 90 vuorokautta. Koska emme voi valvoa laitteiden sovittamista, pukemista, säätöä tai käyttöä, tämä takuu ei koske tuotteita, joihin on kohdistunut laiminlyöntejä tai joita on käytetty, puettu tai sovitettu virheellisesti. Yllä mainitun takuun lisäksi ei myönnetä mitään muita nimenomaisia tai oletettuja takuita.

NEDERLANDS

ATENÇÃO
Este produto apenas deve ser utilizado sob supervisão de um profissional de cuidados de saúde licenciado. Deve ter em atenção os conselhos do seu profissional de cuidados de saúde quando utilizar este ou qualquer outro dispositivo médico.

AJUSTAR O COMPRIMENTO DA JOELHEIRA
1. Todos os pares de estruturas (2 superiores e 2 inferiores) devem estar ajustadas para a mesma altura (Figura 1). Se não for o caso, poderá causar um desalinhamento da articulação e o deslizamento da joalheira.
2. Pressione os botões em todas as estruturas e deslize-as até obter o comprimento necessário (Figura 2).

APLICAR A JOALHEIRA
3. Desaperte a correia intermédia e coloque a joalheira por debaixo da perna do paciente (Figura 3). Obtenha a posição correcta da articulação ajustando a correia intermédia e a almofada.
4. As articulações encontram-se centradas a meio entre a parte frontal e a parte traseira do joelho (Figura 4).
5. As articulações e estruturas estão paralelas (Figura 5).
6. Passe a correia pelo anel em D e fixe a extremidade da fita de ganchos de volta na correia de forma segura (Figura 3).
7. A correia intermédia deverá ser apertada o mais firmemente possível, sem restringir a circulação. Ajuste o comprimento da correia através dos anéis em D do braço da articulação Posição correcta da joalheira.

AJUSTE O COMPRIMENTO DA CORREIA DA ESTRUTURA
8. Alinhe as estruturas da barriga da perna de forma que as articulações fiquem paralelas à tíbia. Segure a correia 1 (Figura 5). Puxe firmemente a correia, passe-a através do anel em D e fixe a extremidade dos ganchos novamente à correia.
9. Alinhe as estruturas da coxa de forma que fiquem paralelas com o fémur.
10. Fixe as correias 2, 3 e 4 (Figura 5) utilizando o mesmo procedimento.
11. Quando é alcançado o comprimento desejado da correia, remova a cobertura dos ganchos na estrutura e na correia intermédia (Figura 6). Pressione a correia contra o lado dos ganchos da fita e fixe.
12. Depois de as correias estarem seguras, verifique novamente a posição da joalheira e ajuste-a, caso necessário. Deixe as correias fixas do lado dos ganchos da fita, ao longo das estruturas. A joalheira tem agora o tamanho indicado para o paciente. Assim, será muito fácil aplicar e ajustar o posicionamento correcto em futuras utilizações, apertando as correias ao longo da frente da posição da joalheira.

INTERVALO DE MOVIMENTO
13 Empurre e ajuste para a posição de extensão desejada (Figura 7).
14 Empurre e ajuste para a posição de flexão desejada (Figura 7).
15 Depois do Intervalo de Movimento estar ajustado, empurre os Fechos Molas do Intervalo de Movimento para os devidos lugares (Figura 8).
16. Ajuste as articulações de ambos os lados.
NOTA: O Fecho do Intervalo de Movimento não deve ser utilizado a 105°

CUIDADOS E MANUTENÇÃO
Os revestimentos podem ser lavados à mão com água fria. Pendure para secar.

GARANTIA
Os produtos de apoio pós-operatório da Ossur são dispositivos descartáveis, de utilização limitada e não tencionados para utilização a longo prazo. Garantimos a qualidade dos nossos produtos contra defeitos de material e de fabrico nas seguintes condições: 30 dias para as peças que têm contacto com a pele (espuma e correias) e 90 dias para as estruturas e articulações. Visto não podermos controlar a forma como estes dispositivos são adaptados, aplicados, ajustados ou utilizados, esta garantia não se aplica aos dispositivos que foram negligenciados, abusados, incorrectamente aplicados ou adaptados. Não há garantias, expressas ou implícitas, que se estendam para além das garantias acima referidas.

PORTUGUÊS

LET OP
Dit product mag enkel gebruikt worden onder toezicht van een erkende gezondheidswerker. Het is belangrijk dat u rekening houdt met de aanbevelingen van de gezondheidswerker als u dit of andere medische apparaten aanwendt.

DE LENGTE VAN DE BRACE AANPASSEN
1. Elk paar schalen, (2 bovenste en 2 onderste), dient op dezelfde positie worden ingesteld (Afbeelding 1). Als deze niet op dezelfde positie staan, kan dit leiden tot verkeerde uitlijning van het scharnier en de brace laten slippen.
2. Op beide schalen de knoppen indrukken en vervolgens verschuiven tot de vereiste lengte (Afbeelding 2).

DE BRACE AANBRENGEN
3. Maak de middelste band los en plaats de brace onder het been van de patiënt (Afbeelding 3). Stel het scharnier op de correcte positie in door de middelste band en het vulstuk aan te passen.
4. De scharnieren worden in het midden geplaatst, halverwege de voor- en achterzijde van de knie (Afbeelding 4).
5. Scharnieren en schalen lopen evenwijdig (Afbeelding 5).
6. Steek de band door de d-ring en bevestig de klittenbandsluiting op de band (Afbeelding 3).
7. De middelste band dient zo stevige mogelijk aangespannen te worden zonder hierbij de bloedcirculatie te hinderen. Pas de lengte van de band aan door de scharnierarm en de d-ringen. Correcte braceopositie.

DE LENGTE AANPASSEN VAN DE SCHAALBAND
8. Lijn de kuitschalen uit zodat de scharnieren evenwijdig lopen met de tibia. Bevestig band 1 (Afbeelding 5). Span de band aan, steek hem door de d-ring en bevestig de klittenbandsluiting op de band.
9. Lijn de dijbeenschalen uit zodat deze evenwijdig lopen met het femur.
10. Maak nu banden 2, 3, en 4 (Afbeelding 5) vast op dezelfde manier.
11. Als de gewenste bandlengte is bereikt, kunt u de klittenbandbescherming tussen de schaal en middelste band verwijderen (Afbeelding 6). Druk de band vervolgens stevig tegen de klittenband om deze te bevestigen.
12. Als alle banden zijn vastgemaakt, kunt u de positie van de brace nogmaals controleren en deze, indien nodig, aanpassen. Laat de banden op de klittenband bevestigd aan de zijde van de schalen. De brace heeft nu de correcte maat voor de patiënt. Het aantrekken en correct positioneren van de brace kan vanaf nu eenvoudig gebeuren door de banden aan te spannen langs de voorzijde.

BEWEGINGSBEREIK
13. Indrukken en op de gewenste extensiepositie instellen (Afbeelding 7).
14 Indrukken en op de gewenste flexiepositie instellen (Afbeelding 7)
15. Plaats de veervergrendelingen voor bewegingsbereik nadat u het bewegingsbereik heeft ingesteld (Afbeelding 8).
16. Pas, indien nodig, de scharnieren aan.
OPMERKING: De vergrendeling voor bewegingsbereik mag niet gebruikt worden op stand 105 graden.

REINIGING EN ONDERHOUD
Liners mogen in een handwasje met koud water worden gereinigd. Ophangen en laten drogen.

GARANTIE
De post-operatieve braces van Össur zijn persoonlijke producten voor eenmalig gebruik en zijn niet bedoeld voor langdurig gebruik. Onze producten vallen onder de volgende garantiebepalingen m.b.t. fabricage en materiaalfouten: 30 dagen op onderdelen die in aanraking komen met de huid (schuimrubber en banden) en 90 dagen op de schalen en scharnieren. Aangezien we geen controle kunnen uitoefenen op de wijze waarop zulke apparaten worden aangemeten, toegepast, aangepast of gebruikt, is deze garantie niet van toepassing op producten die verwaarloosd, misbruikt, verkeerd toegepast of niet correct aangemeten zijn. Naast de bovenvermelde garantiebepalingen zijn geen andere garanties van kracht.

EN - Caution: This product has been designed and tested based on single patient usage and is not recommended for multiple patient use. If any problems occur with the use of this product, immediately contact your medical professional.

DE- Zur Beachtung: Dieses Produkt ist für die Anwendung bei ein und demselben Patienten vorgesehen und geprüft. Der Einsatz für mehrere Patienten wird nicht empfohlen. Wenn beim Tragen dieses Produkts Probleme auftreten, sofort den Arzt verständigen.

FR- Attention: Ce produit a été conçu et testé pour être utilisé par un patient unique et n'est pas préconisé pour être utilisé par plusieurs patients. En cas de probleme lors de l'utilisation de ce produit, contactez immédiatement un professionnel de santé.

ES- Atención: Este producto se ha diseñado y probado para su uso en un paciente único y no se recomienda para el uso de varios pacientes. En caso de que surja algún problema con el uso este producto, póngase inmediatamente en contacto con su profesional médico.

IT- Avvertenza: Questo prodotto è stato progettato e collaudato per essere utilizzato per un singolo paziente e se ne sconsiglia l'impiego per più pazienti. In caso di prob- lemi

DA- Forsigtig: Dette produkt er beregnet og afprøvet til at blive brugt af én patient. Det

der opstår problemer i forbindelse med anvendelsen af dette produkt.

SV- Var försiktig: Produkten har utformats och testats baserat på användning av en

uppstå problem vid användning av produkten ska du omedelbart kontakta din läkare.

NL- Opgelet: Dit product is ontworpen en getest voor eenmalig gebruik. Hergebruik van dit product wordt afgeraden. Neem bij problemen met dit product contact op met uw medische zorgverlener.

PT- Atenção: Este produto foi concebido e testado com base na utilização num único doente e não está recomendado para utilização em múltiplos doentes. Caso ocorra algum problema com a utilização deste produto, entre imediatamente em contacto com o seu

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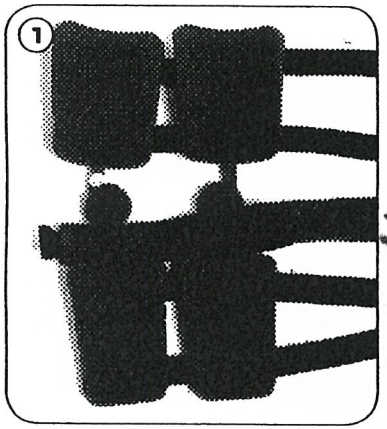
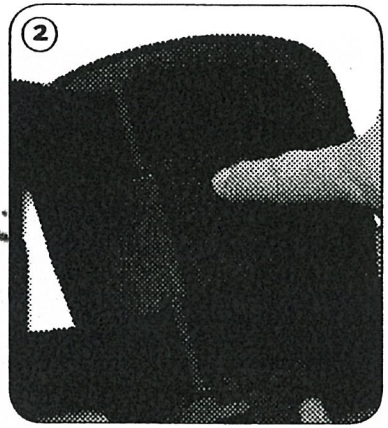
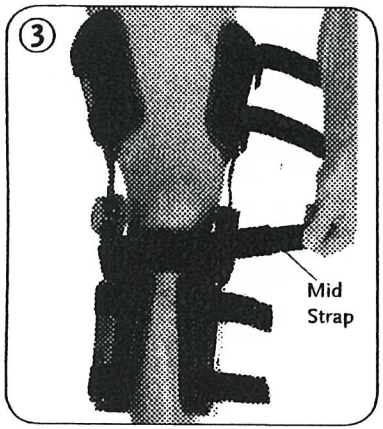
Instructions for Use

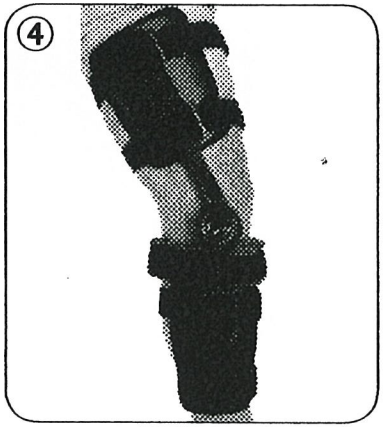
Rehab

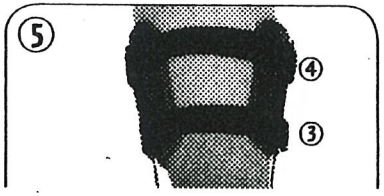
ÖSSUR
Life Without Limitations

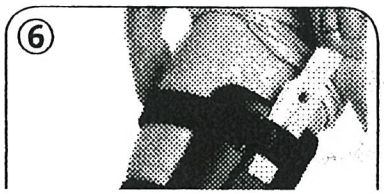












ENGLISH

CAUTION
This product is to be used only under the supervision of a licensed health care professional. Care must be taken to follow the advice of the healt care professional when using this or any medical device.

ADJUST THE BRACE LENGTH

1 Each pair of shells, (2 upper and 2 lower), must be set to the same position **(Figure 1)**. Failure to do so could cause hinge malalingment and brace slippage.
2 Depress button on each shell and slide shell to required length **(Figure 2)**.

APPLY THE BRACE

3 Undo mid-strap and place brace under patient´s leg **(Figure 3)**. Attain correct hinge position by adjusting the mid-strap and pad.
4 Hinges are centered halfway between the front and back of the knee **(Figure 4)**.
5 Hinges and shells are parallel **(Figure 5)**.
6 Pass strap throug the d-ring and fasten the hook tap end back onto the strap to secure **(Figure 3)**.
7 The mid-strap should be tightened as firmly as possible without restricting circulation. Adjust stap length through hinge arm d-rings
Correct Brace Position.

ADJUST THE SHELL STRAP LENGTH

8 Align calf shells so hinges are parallel to tibia. Secure strap 1 **(Figure 5)**. Pull strap tight, pass strap through d-ring and fasten the hook tab end back onto the strap.
9 Align thigh shells so hinges are parallel with the femur.
10 Secure straps 2,3, and 4 **(Figure 5)** using same procedure.
11 When desired strap length is achieved remove hook cover on shell and mid-strap **(Figure 6)**. Press strap against hook to secure.
12 After straps are secured, check brace position again and adjust if necessary. Leave straps fastened at hook contact along shells. The brace is now properly sized for the patient. Future application and correct positioning can be done easily by fastening straps along the front of the brace position.

RANGE OF MOTION

13 Push and set to desired extension position **(Figure 7)**.
14 Push and set to desired flexion position **(Figure 7)**.
15 After Range of Motion is set push Range Of Motion Spring Locks into place **(Figure 8)**.

16 Make adjustments to both hinges.
NOTE: Range of Motion Lock is not to be used in the 105 degree

CARE AND MAINTENANCE
Liners may be hand washed with cold water. Hang to dry.

WARRANTY
Ossur post operative bracing product are disposable, limited use devices not intended for long term use. We warrant our products against defects in material and workmanship in the following

(Abbildung 7).
15. Wenn der Bewegungsspielraum eingestell Bewegungsspielraums zurück **(Abbildung**
16. Passen Sie beide Gelenke an.
HINWEIS: Das Schloss des Bewegungssp verwendet werden.

REINIGUNG UND PFLEGE
Die Polster können mit kaltem Wasser von Ha

GARANTIE
Die postoperativen Orthesenprodukte von Öss Nutzungsdauer, die nicht für den langfristigen die folgende Garantie gegen Material- und Ver der Haut haben (Schaumstoff und Riemen) un Art und Weise kontrollieren können, wie die Hi verwendet werden, gilt diese Garantie nicht fü falsch angelegt oder nicht richtig angepasst w implizierte, als die oben angegebenen werden

FRA

PRÉCAUTIONS
Ce produit ne doit être utilisé que sous la supe de respecter les conseils du professionnel de de tout autre dispositif.

AJUSTEZ LA LONGUEUR DE L'ORTHÈSE

1 Chaque paire de coques (2 supérieures e **(Figure 1)**. Un non-respect de cette indi alignement de la charnière et de faire gliss
2 Appuyez sur le bouton situé sur chaque longueur souhaitée **(Figure 2)**.

POSEZ L'ORTHÈSE

3 Défaites la sangle centrale et placez l'orth **(Figure 3)**. Pour obtenir une position cor rembourrage.
4 Les charnières sont centrées à mi-hauteur
5 Les charnières et les coques sont parallèle
6 Faites passer la sangle dans l'anneau en fixation sur la sangle pour la fixer **(Figure**
7 La sangle centrale doit être serrée autant longueur de la sangle grâce aux anneaux l'orthèse.

AJUSTEZ LA LONGUEUR DE LA SANGLE DE

8 Alignez la coque de mollet de façon à ce la sangle 1 **(Figure 5)**. Tirez fermement s redoublez le filet d'implantation du croche