### Department of Health & Human Services

## OFFICE OF INSPECTOR GENERAL

## QUESTIONABLE BILLING BY SUPPLIERS OF LOWER LIMB PROSTHESES



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#### **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.
- 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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#### **BACKGROUND**

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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.<sup>2</sup> 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.<sup>3</sup>

<sup>&</sup>lt;sup>1</sup> 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.

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

<sup>&</sup>lt;sup>3</sup>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 <a href="http://www.stopmedicarefraud.gov/HEATnews/puertorico.html">http://www.stopmedicarefraud.gov/HEATnews/puertorico.html</a> 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.<sup>4</sup>

#### **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.<sup>5</sup>

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

<sup>&</sup>lt;sup>4</sup> DOJ and HHS, *HEAT Task Force Success*, Accessed at http://www.stopmedicarefraud.gov/heatsuccess/index.html on January 11, 2010.

<sup>&</sup>lt;sup>5</sup> 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.<sup>6</sup>

In addition, 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. 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. 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. 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.<sup>10</sup> The local coverage determination specifies how suppliers

<sup>&</sup>lt;sup>6</sup> The Act § 1862(a)(1)(A), 42 U.S.C. § 1395y(a)(1)(A).

<sup>&</sup>lt;sup>7</sup> 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).

<sup>&</sup>lt;sup>8</sup> CMS, *DMEPOS Quality Standards*, October 2008.

 $<sup>^9</sup>$  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.

<sup>&</sup>lt;sup>10</sup> 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. <sup>11</sup>

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,

<sup>&</sup>lt;sup>11</sup> 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.

 $<sup>^{12}\,\</sup>mathrm{While}$  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.<sup>15</sup> 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.<sup>16</sup>

#### 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.

<sup>&</sup>lt;sup>13</sup> 76 Fed. Reg. 5862, 5867 (Feb. 2, 2011).

<sup>&</sup>lt;sup>14</sup> 42 CFR § 424.518 (b)(1)(x) and (c)(1)(ii), effective March 25, 2011.

<sup>&</sup>lt;sup>15</sup> 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.

<sup>&</sup>lt;sup>16</sup> 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<sup>17</sup> 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. <sup>18</sup> 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. <sup>19</sup> 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, <sup>20</sup> (3) did not meet potential functional level requirements, <sup>21</sup> (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.

<sup>&</sup>lt;sup>17</sup> Note that we did not include DME claims.

<sup>&</sup>lt;sup>18</sup> We included all claims from the 50 States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, American Samoa, and Guam.

<sup>&</sup>lt;sup>19</sup> 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."

 $<sup>^{20}</sup>$  The supplier should bill for prostheses for both limbs on the same claim, using a right and a left modifier.

<sup>&</sup>lt;sup>21</sup> 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. 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:

<sup>&</sup>lt;sup>22</sup> 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.<sup>23</sup>
- 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.<sup>24</sup>
- 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.<sup>25</sup>
- High average payment per beneficiary for above-the-knee prostheses.<sup>26</sup> We based this measure on the total payment for

<sup>&</sup>lt;sup>23</sup> 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.

<sup>&</sup>lt;sup>24</sup> OIG analysis of prostheses claims data from the National Claims History File for 2009.

<sup>&</sup>lt;sup>25</sup> 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.

<sup>&</sup>lt;sup>26</sup> 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.<sup>27</sup> 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.

 $<sup>^{27}</sup>$  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.

<sup>&</sup>lt;sup>28</sup> 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.



# 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.<sup>29</sup> 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%			

<sup>\*</sup> 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.

 $<sup>^{29}</sup>$  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 \ Unusually High			
	Suppliers	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		

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

#### 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

<sup>\*\*</sup> 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.

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**					

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.

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.

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

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

## 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.



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.

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					

<sup>\*</sup> 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.



#### **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.

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.

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#### 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.

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#### **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

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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

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