DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Audits and Evaluations

VETERANS HEALTH ADMINISTRATION

Use of Not Otherwise Classified Codes for Prosthetic Limb Components

AUDIT | REPORT #16-01913-223 | AUGUST 27, 2018

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Executive Summary

Why the OIG Did This Audit

The OIG evaluated the merits of two anonymous allegations received in January and February 2016. The complainant alleged that the Veterans Health Administration (VHA) was overpaying for prosthetic items because it was incorrectly using Not Otherwise Classified (NOC) codes to classify and subsequently reimburse vendors for these items. Incorrectly using an NOC code can result in an overpayment, because payments for these items are not based on the use of pre-established reimbursement rates. According to the OIG's analysis of data from the National Prosthetic Patient Database, VHA spent approximately $38 million on prosthetic items classified using an NOC code from October 2014 through July 2017.

VA uses the U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services' (CMS) Healthcare Common Procedure Coding System (HCPCS) Level II L codes and associated pricing to classify prosthetic and orthotic items and to determine how much to reimburse non-VA providers for the items and related services.[1] VA uses CMS-established NOC codes to classify prosthetic and orthotic items that existing CMS HCPCS Level II L codes do not adequately describe. VHA's Prosthetic and Sensory Aids Service (PSAS) issued guidance to medical facilities and Veterans Integrated Service Networks (VISNs) that contained pricing methodologies to reimburse vendors for NOC-classified prosthetic and orthotic items. For NOC-classified items, PSAS's guidance allows medical facilities to reimburse vendors for the prosthetic item's purchase price and a markup of either 50 percent or $16,100, depending on the specific item provided.

What the OIG Did

The OIG started its work in October 2016 and interviewed current and former PSAS officials, as well as officials from VA's Office of General Counsel and VHA's Procurement and Logistics Office who were knowledgeable about VHA's use of NOC codes and the pricing markup methodology for vendor reimbursement for NOC-classified prosthetic components. The audit team also interviewed facility prosthetics employees to learn more about how prosthetists identified and assigned NOC codes to prosthetic items. In addition, the OIG interviewed representatives from CMS as well as representatives from CMS's pricing, data analysis, and coding contractor to learn more about the CMS HCPCS Level II coding system.

[1] VA's *Medical L-Code Usage for Orthotic and Prosthetic Limb Components – Not Otherwise Specified/Classified* memorandum, issued in February 2013, states that using L codes and Medicare pricing is appropriate for VA to procure prosthetic items and services.

The OIG obtained a data extract from the National Prosthetics Patient Database of all prosthetic items classified using an NOC code from October 2014 through September 2016. According to OIG's analysis, this data extract contained nearly 6,000 NOC-classified transactions with a total cost of about $24 million. From the universe of 6,000 transactions, the audit team selected and reviewed all 19 prosthetic transactions with a value in excess of $70,000 each. The audit team also selected and reviewed a random sample of 58 prosthetic transactions with values of $30,000 to $69,999. The OIG team also obtained updated National Prosthetics Patient Database data from October 2014 through July 2017 to determine how frequently VHA prosthetists incorrectly classified the prosthetic items reviewed by the audit team. Appendix B provides additional information on how the OIG conducted its work.

What the OIG Found

The OIG substantiated the allegation that VHA overpaid vendors for prosthetic items by incorrectly using NOC codes. VHA overpaid vendors about $7.7 million from October 2014 through July 2017.[2] The OIG determined the $7.7 million overpaid to vendors to be an improper payment. According to VHA Directive 1045, *Healthcare Common Procedure Coding System (HCPCS) List for Prosthetic Limb and/or Custom Orthotic Device Prescription*, December 30, 2013, prosthetists should use NOC codes only when a prosthetic item does not have or has not been assigned a CMS HCPCS Level II L code. Prosthetists are required to follow CMS guidelines and policies regarding the application of CMS HCPCS Level II L codes to classify orthotic and prosthetic devices. The OIG found prosthetists incorrectly used NOC codes to classify prosthetic items when existing CMS HCPCS Level II L codes adequately described the items. Specifically, the OIG found that prosthetists incorrectly used NOC codes to classify certain prosthetic items, such as some microprocessor knee units manufactured by Ossur and Ottobock, the Michelangelo Hand, and the Touch Bionics i-Limbs, even though CMS HCPCS Level II L codes that adequately described these items existed.

The incorrect use of an NOC code to specifically classify the Ottobock X2, X3, and Genium microprocessor knee units occurred because the former National Program Director, Prosthetic and Orthotic Clinical Service, issued incorrect guidance instructing prosthetists to use an NOC code specifically for these three types of Ottobock-manufactured microprocessor knee units.[3,4] He said issuing guidance to use an NOC code to classify these items was necessary because

[2] The overpayment amount is based on the cost VHA reimbursed vendors for the specific prosthetic items reviewed by the audit team. The overpayment calculation does not include the cost of other components included in the fabrication of a prosthetic limb such as test sockets, sockets, and suspension-locking mechanisms.
[3] The former National Program Director, Prosthetic and Orthotic Clinical Service, Joseph Miller, PhD, was a GS-15 who left VA in September 2016.
[4] PSAS's *Instructions to the Field: L Code Usage for Otto Bock X2 and Genium Knee Units* (August 2011) and PSAS's *Instructions to the Field: L Code Usage for Otto Bock X3 and Genium Knee Units* (August 2013). The first instruction was updated in March 2013. These documents will be referred to as "PSAS Ottobock microprocessor knee instructions" in this report.

CMS did not create a new HCPCS Level II L code for the Ottobock X3 microprocessor knee unit's new features. Furthermore, he said VHA had no legal authority to classify the Ottobock microprocessor knee units.

While these Ottobock knee units allow users to climb stairs and walk backwards, and even submerse the knee in water—as in the case of the X3—existing CMS HCPCS Level II L codes are appropriate to classify these items because the descriptions provided by the codes adequately describe these prosthetic items. For example, L5856 is the code that describes any lower extremity endoskeletal knee-shin system prosthesis that includes a microprocessor control feature, as well as a swing and stance phase. This code describes the Ottobock X2, X3, and Genium microprocessor knee units; as such, it should be one of the codes used to classify these items. In addition, the OIG found the manufacturer, Ottobock, as well as private insurers and the CMS pricing, data analysis, and coding contractor, recommended the use of existing CMS HCPCS Level II L codes—L5828, L5845, L5848, and L5856—to classify these items.

The OIG determined the Deputy Chief, Patient Care Services Officer for Rehabilitation and Prosthetic Services, did not establish an effective oversight and reporting structure to ensure the appropriateness of the PSAS Ottobock microprocessor knee instructions coding guidance. As a result, the former National Program Director, Prosthetic and Orthotic Clinical Service, was able to issue incorrect guidance, despite the existence of CMS HCPCS Level II L codes and the fact that members of the PSAS Orthotic and Prosthetic L Code Committee did not concur with this guidance.[5]

The incorrect use of NOC codes to classify other prosthetic items such as the Ossur Power knee, the Touch Bionics i-Limb, the Michelangelo Hand, and the i-Limb Digit Thumb occurred because facility prosthetists incorrectly classified these items with an NOC code, despite the existence of appropriate CMS HCPCS Level II L codes. Facility prosthetists incorrectly used NOC codes because they were either unaware existing codes adequately described the prosthetic items or because they allowed vendors to classify the items with an NOC code. Facility prosthetists' incorrect use of NOC codes to classify prosthetic items went undetected because PSAS lacked effective processes and procedures such as performing routine reviews of National Prosthetic Patient Database data to monitor the use of NOC codes. The National Director, PSAS, told the OIG that the PSAS National Program Office does not have oversight responsibility including how facilities use NOC codes. Instead, PSAS relies on VISN prosthetic representatives to ensure prosthetists are properly using CMS HCPCS Level II L codes or NOC codes to classify prosthetic components, as required by VHA Directive 1045. However, the OIG found that VISN prosthetic representatives did not monitor or report on facilities' use of NOC codes to ensure proper usage.

[5] The PSAS Orthotic and Prosthetic L Code Committee was established to help clarify and determine the use of L codes for orthotic and prosthetic items.

Because facility prosthetists incorrectly used NOC codes to classify prosthetic items for reimbursement, VHA paid more than it would have paid if prosthetists had used the correct CMS HCPCS Level II L codes. For example, the Touch Bionics i-Limb classified with the correct CMS HCPCS Level II L code costs VHA about $27,000. In contrast, VHA facilities paid vendors from $31,604 to $61,702 for the same items when they were classified using an NOC code.[6]

The OIG also found that VHA was at risk of paying too much for prosthetic items classified with an NOC code. According to a VA Office of General Counsel decision, VAOPGCADV 12-2010, dated November 24, 2010, reimbursement for items classified using NOC codes should reasonably approximate the cost and profit associated with the services provided by vendors. However, PSAS issued guidance in March 2013 and August 2013 that allowed for a cost-plus-$16,100-markup for the Ottobock X2, X3, and Genium microprocessor knee units, which was contrary to the VA Office of General Counsel's decision.[7] PSAS also issued a prosthetic limb contract template in August 2014 that contained a cost-plus-50 percent-markup for all NOC-classified prosthetic items. The OIG determined that these markups—allowed under PSAS's guidance and prosthetic limb contract template—were excessive because they did not reasonably approximate vendors' service costs and profits, as required by the VA Office of General Counsel's decision, VAOPGCADV 12-2010.

Furthermore, the across-the-board 50 percent markup did not take into account that reasonable costs and profits do not increase in direct proportion to the cost of the item. Consider, for example, using the predetermined 50 percent markup, a vendor would automatically be reimbursed $25,000 for a $50,000 item, regardless of the amount of time required to service the prosthetic item. In contrast, a vendor would only be reimbursed an additional $250 for a $500 prosthetic item even if this item required more extensive vendor-provided service hours before the item could be issued to a veteran.

PSAS was unable to provide the OIG with any documentation to support how either markup reasonably approximates the cost and profit associated with vendor-provided services. The OIG determined that the Deputy Chief, Patient Care Services Officer for Rehabilitation and Prosthetic Services, did not implement effective oversight and review processes to ensure PSAS's pricing methodologies were adequately supported and reviewed appropriately before being issued. As a result, VHA is at risk of reimbursing excessive amounts for the cost and profit associated with vendor-provided services.

[6] The prices reflected in the price range represent the amount paid by VHA for those specific items, not the entire prosthetic limb. Vendors separately identified and priced other components used in the fabrication of a prosthetic limb, such as sockets, test sockets, and suspension-locking mechanisms, on invoices submitted to VHA.
[7] PSAS's Ottobock microprocessor knee instructions, dated March 2013 and August 2013.

What the OIG Recommended

The OIG made five recommendations to the Executive in Charge, VHA:

- Review the PSAS Ottobock microprocessor knee instructions (August 2011, March 2013, and August 2013), coordinate with appropriate officials to determine which CMS HCPCS Level II L codes are appropriate to classify these items for reimbursement, and issue revised guidance.
- Coordinate with appropriate officials to establish a formal oversight and reporting structure that defines the roles and the responsibilities of the PSAS Orthotic and Prosthetic L Code Committee, as well as who has the authority to approve recommendations for the use of CMS HCPCS Level II L codes to classify specific prosthetic components for reimbursement.
- Develop and implement effective processes and procedures to monitor the use of NOC codes and communicate these procedures to the VISNs to ensure compliance with VHA Directive 1045 and the CMS HCPCS Level II Coding Procedures.
- Coordinate with the appropriate officials to develop and implement processes and procedures to ensure any pricing guidance with regard to the pricing of prosthetic items classified using an NOC code is developed and concurred with by VA's Office of General Counsel and VA's Procurement and Logistics Office prior to issuance.
- Issue corrected guidance to replace PSAS's Ottobock microprocessor knee instructions (March 2013 and August 2013) and the prosthetic limb contract template issued in August 2014 by coordinating with appropriate officials to develop and implement pricing guidance to ensure VA pays a fair and reasonable price for items classified using an NOC code.

Management Comments

The Executive in Charge, VHA, concurred with the recommendations. The Executive in Charge provided acceptable action plans with completion dates targeted for no later than June 2019. The OIG will monitor VHA's progress and follow up on the implementation of the recommendations until all proposed actions are completed.

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Contents

Abbreviations

CMS	Centers for Medicare and Medicaid Services
FY	Fiscal Year
HCPCS	Healthcare Common Procedure Coding System
NPPD	National Prosthetics Patient Database
NOC	Not Otherwise Classified
OAL	Office of Acquisitions and Logistics
OGC	Office of General Counsel
OIG	Office of Inspector General
PDAC	Pricing, Data Analysis, and Coding Contractor
PL&O	Procurement and Logistics Office
PSAS	Prosthetic and Sensory Aids Service
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

Objective

In January and February 2016, the OIG received two anonymous allegations that the Veterans Health Administration (VHA) was overpaying for some prosthetic items because prosthetists were incorrectly using Not Otherwise Classified (NOC) codes. Incorrect use of an NOC code can result in an overpayment, because payments for these items are not based on the use of pre-established reimbursement rates. The OIG conducted this audit to assess whether prosthetists were incorrectly using NOC codes and whether this resulted in VHA paying higher prices to vendors for prosthetic items that were priced and purchased using an NOC code. The OIG also assessed whether facility prosthetists complied with the requirements of VHA Directive 1045 when classifying prosthetic items for vendor-reimbursement from October 2014 through July 2017.[8] According to the OIG's analysis of data from the National Prosthetic Patient Database (NPPD), VHA spent approximately $38 million on prosthetic items classified using NOC codes from October 2014 through July 2017.

Healthcare Common Procedure Coding System

VA uses the Centers for Medicare and Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Level II L codes to classify prosthetic items.[9] VA also uses CMS's HCPCS Level II L codes to determine how much to reimburse non-VA providers for prosthetic items and related services.[10] Level II of the HCPCS is a comprehensive and standardized coding system that classifies similar products that are medical in nature into categories. Level II of the HCPCS comprises alphanumeric codes that are used primarily to identify products, supplies, and services not included in Level I of the HCPCS. Examples of Level II items include ambulance services, durable medical equipment, prostheses, orthotics, and supplies when used outside a physician's office. For each alphanumeric code, there is descriptive terminology that identifies a category of like items or services. These codes typically do not identify specific products or brand/trade names. According to the CMS *HCPCS Level II Coding Procedures*, revised November 13, 2015, there are national HCPCS codes that represent approximately 6,000 separate categories of like items that encompass millions of products from different

[8] VHA Directive 1045, *Healthcare Common Procedure Coding System (HCPCS) List for Prosthetic Limb and/or Custom Orthotic Device Prescription*, December 30, 2013.

[9] HCPCS is maintained by the U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services and is divided into two principal subsystems, referred to as Level I and Level II. Level I of the HCPCS is a uniform coding system consisting of descriptive terms and identifying codes used primarily to identify medical services and procedures furnished by physicians and other health care professionals.

[10] Medical L-Code Usage for Orthotic and Prosthetic Limb Components – Not Otherwise Specified/Classified memorandum issued in February 2013.

manufacturers. Medicare and other insurers generally use the HCPCS codes to classify items and services for billing purposes.

CMS HCPCS Level II L code information is available to VHA prosthetists through a website maintained by CMS's pricing, data analysis, and coding contractor (PDAC). PDAC is responsible for providing suppliers and manufacturers with assistance in determining which CMS HCPCS code should be used to describe durable medical equipment, prosthetics, orthotics, and supplies. VHA prosthetists are responsible for developing the appropriate CMS HCPCS list for all prosthetic items and custom orthotic device prescriptions. VA uses CMS-established NOC codes to classify prosthetic and orthotic items for which existing CMS HCPCS Level II L codes do not adequately describe the items.

Organizational Structure for VHA's Prosthetic Policies

According to the Deputy Chief, Patient Care Services Officer for Rehabilitation and Prosthetic Services, VHA's prosthetic coding guidance is developed and issued by the National Program Director, Prosthetic and Orthotic Clinical Service, on behalf of VHA's Prosthetic and Sensory Aids Service (PSAS). The National Program Directors of the Prosthetic and Orthotic Clinical Service and PSAS report to the Deputy Chief, Patient Care Services Officer for Rehabilitation and Prosthetic Services. The Patient Care Services Officer for Rehabilitation and Prosthetic Services reports directly to the Acting Assistant Deputy Secretary for Health for Patient Care Services, who reports to the Deputy Under Secretary for Health for Policy Services, who reports directly to the Under Secretary for Health.

Figure 1 details the organizational structure for PSAS and the Prosthetic and Orthotic Clinical Service.

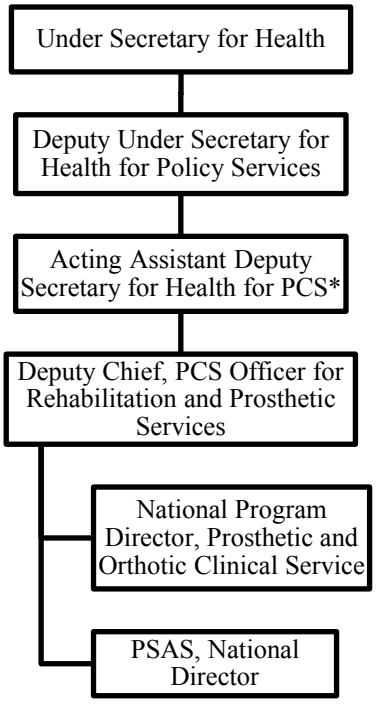

Figure 1. *PSAS and the Prosthetic and Orthotic Clinical Service*
**PCS=Patient Care Services*

Source: OIG analysis of VHA organizational chart, dated June 2017, and Rehabilitation and Prosthetic Services organizational chart, dated September 2016

PSAS Orthotic and Prosthetic L Code Committee

According to PSAS's National Director, the National Program Director for VHA's Prosthetic and Orthotic Clinical Service established the PSAS Orthotic and Prosthetic L Code Committee in 2010 to develop guidance to clarify the use of L Codes for orthotic and prosthetic limb products. The *Medical L-Code Usage for Orthotic and Prosthetic Limb Components – Not Otherwise Specified/Classified* memorandum, issued by the Deputy Under Secretary for Health for Operations Management in February 2013, charges the PSAS Orthotic and Prosthetic L Code Committee with clarifying and determining the use of L codes for orthotic and prosthetic items. The Acting National Program Director, Prosthetic and Orthotic Clinical Service, reported to the OIG that the committee comprises eight facility prosthetists; one Veterans Integrated Service Network (VISN) prosthetic representative; and the National Program Director, Prosthetic and Orthotic Clinical Service. According to a committee member, the committee reports to the National Program Director, Prosthetic and Orthotic Clinical Service.

Artificial Limb Contract Template for Vendor Reimbursement for Prosthetic Items

In August 2014, the Deputy Chief, Patient Care Services Officer for Rehabilitation and Prosthetic Services, announced to the field the availability of a contract template that included a methodology to reimburse vendors for prosthetic items that are not adequately described with CMS HCPCS Level II L codes. This template requires VISNs and facilities to increase their vendor reimbursement rates with a 50 percent markup for prosthetic items coded for reimbursement with an NOC code.

Prior OIG Report

The OIG reported in *Audit of the Management and Acquisition of Prosthetics Limbs* (March 8, 2012, Report No. 11-02254-102) that VHA was at risk of paying excessive prices for prosthetic limbs because it was purchasing some items without specific pricing guidance. The OIG found VHA did not have guidance in place on how to reimburse vendors for items classified using an NOC code. The OIG recommended the Under Secretary for Health establish reasonable pricing standards for prosthetic limb items that were not classified by CMS. The Under Secretary of Health agreed to determine the feasibility of establishing a pricing standard for items not classified by CMS.

Results and Recommendations

Finding 1: VHA Incorrectly Allowed the Use of NOC Codes to Reimburse Vendors and Overpaid for Prosthetic Limb Components

The OIG substantiated the allegation that VHA was overpaying for prosthetic components because facility prosthetists were incorrectly using NOC codes. According to VHA Directive 1045, prosthetists should only use NOC codes when a prosthetic item does not have or has not been assigned a CMS HCPCS Level II L code. The OIG found from October 2014 through July 2017 that facility prosthetists incorrectly used NOC codes to classify prosthetic items and as a result overpaid vendors. For example, the OIG found VHA paid vendors from $31,604 to $61,702 for the Touch Bionics i-Limb hand instead of the about $27,000 this item usually costs. In another instance, VHA paid vendors from $36,341 to $96,000 for the Ottobock X2, X3, and Genium microprocessor knee units (Ottobock microprocessor knee units), when it should have paid about $34,000 for each unit.[11]

The OIG identified two main reasons why facility prosthetists incorrectly used NOC codes. First, the OIG found that PSAS issued incorrect classification guidance to facility prosthetists for the Ottobock microprocessor knees units. The former National Program Director for VHA's Prosthetic and Orthotic Clinical Service issued instructions in 2011 and 2013 to facility prosthetists to use NOC codes, rather than existing CMS HCPCS Level II L codes, to classify these microprocessor knees and provide reimbursement to vendors.[12, 13] The vendor reimbursement rates using these NOC codes significantly exceeded CMS HCPCS Level II L code reimbursement rates for these items.

Second, the OIG found that facility prosthetists did not comply with VHA Directive 1045, which requires prosthetists to ensure that other items included in the OIG's review, such as the BiOM T2 Ankle and Foot Systems, the Ossur Power Knee, Touch Bionics i-Limbs, Michelangelo Hand, and i-Limb Digit Thumb, were properly classified with the correct CMS HCPCS Level II L code or NOC code for vendor reimbursement. For example, the OIG found that facility prosthetists incorrectly applied NOC codes—most commonly the NOC L5999 code—because

[11] The prices reflected in the price ranges provided for both the Ottobock microprocessor knee units and the Touch Bionics i-Limb hand represent the amount paid by VHA for those specific items, not the entire prosthetic limb. Vendors separately identify and price other components used in the fabrication of a prosthetic limb, such as sockets, test sockets, and suspension-locking mechanisms, on invoices submitted to VHA.

[12] The former National Program Director, Prosthetic and Orthotic Clinical Service, Joseph Miller, PhD, was a GS-15 who left VA in September 2016.

[13] PSAS's Instructions to the Field: L Code Usage for Otto Bock X2 and Genium Knee Units (August 2011) and PSAS's Instructions to the Field: L Code Usage for Otto Bock X3 and Genium Knee Units (August 2013). The first instruction was updated in March 2013. These documents will be referred to as "PSAS Ottobock microprocessor knee instructions" in this report.

they were unaware that existing codes adequately described the prosthetic items. In addition, the OIG found facility prosthetists allowed vendors to classify prosthetic items with NOC codes.[14] In these instances, the incorrect use of NOC codes resulted in higher vendor reimbursement rates. PSAS's National Director reported that PSAS does not monitor facility prosthetists' use of NOC codes and expects VISN prosthetic representatives to do so. However, VISN prosthetic representatives do not monitor the accuracy at which facility prosthetists use NOC codes to reduce VHA's risk of overpaying for prosthetic items, despite VHA Directive 1045 requirements to do so.

As a result, VHA overpaid vendors about $7.7 million from October 2014 through July 2017 for prosthetic items that the audit team reviewed and for which CMS HCPCS Level II L codes were available to determine vendor reimbursement rates.[15] The OIG determined the $7.7 million overpaid to vendors to be an improper payment because VHA would have reimbursed vendors different amounts if facility prosthetists used the correct CMS HCPCS Level II L codes to classify the items.[16] VHA is at risk of overpaying vendors an estimated $13.6 million over the next five years if NOC codes continue to be misused to determine vendor reimbursement rates for prosthetic items for which CMS HCPCS Level II L codes already exist.

Facility Prosthetists Incorrectly Used NOC Codes to Classify Prosthetic Items

The OIG sampled 77 prosthetic purchases with values of $30,400 to $92,000 made from October 2014 through September 2016 with a combined value of about $4.8 million from NPPD. The OIG determined prosthetists incorrectly classified all 77 items with NOC codes. VHA prosthetists classified items captured in the OIG's sample such as the Touch Bionics i-Limb, the Michelangelo Hand, the BiOM T2 Ankle and Foot Systems, the Ossur Power Knee, as well as Ottobock microprocessor knee units, using the NOC code L5999 or L7499. The OIG found existing CMS HCPCS Level II L codes adequately described these sampled items. For example, CMS's HCPCS Level II L code L6880 encompasses the prosthetic hands included in the sample, because it covers any electric hand with independently articulating digits.[17] In addition, representatives from PSAS and the PSAS Orthotic and Prosthetic L Code Committee also

[14] VHA Directive 1045 requires facility prosthetists to develop the HCPCS list for prosthetic limb and/or custom orthotic device prescriptions and prohibits contract vendors' involvement in the development of these lists.

[15] The overpayment amount is based on the cost VHA reimbursed vendors for the specific prosthetic items reviewed by the audit team. The overpayment calculation does not include the cost of other components included in the fabrication of a prosthetic limb such as test sockets, sockets, and suspension-locking mechanisms.

[16] According to the Office of Management and Budget Circular A-123, Appendix C, Part I-A (2), *Requirements for Effective Estimation and Remediation of Improper Payments*, "an improper payment is any payment that should not have been made or that was made in an incorrect amount under statutory, contractual, administrative, or other legally applicable requirements."

[17] CMS HCPCS Level II L code L6880 describes a switch or myoelectric-controlled hand prosthesis and includes all articulating digits and motors. The OIG determined this code was appropriate to describe the Touch Bionics i-Limb and Michelangelo Hand reviewed by the audit team.

confirmed that existing CMS HCPCS Level II L codes adequately described the sampled items and that prosthetists should not have used NOC codes to classify these items for reimbursement.

The OIG expanded its analysis of NPPD data through July 2017 to determine if facility prosthetists incorrectly classified additional items related to the prosthetic items reviewed by the audit team. The audit team's analysis of NPPD data from October 2014 through July 2017 found an additional 265 prosthetic purchases related to the items included in the sample that facility prosthetists incorrectly classified.

PSAS Issued Incorrect Classification Guidance to Facility Prosthetists

The former National Program Director, Prosthetic and Orthotic Clinical Service, told the OIG that instructions directing facility prosthetists to use an NOC code (L5999) to specifically classify the Ottobock microprocessor knee units for vendor reimbursement were necessary because existing CMS HCPCS Level II L codes did not adequately describe these items.[18, 19] According to the former National Program Director, Prosthetic and Orthotic Clinical Service, CMS should have created a new L code for new features included on the X2, X3, and Genium and because a new L code was not created, the use of an NOC code was warranted. He also stated that manufacturers do not always submit their new products to CMS, because CMS does not always agree that the item's technology is something new or different.

The OIG determined that the former National Program Director, Prosthetic and Orthotic Clinical Service's guidance was incorrect, because CMS's HCPCS Level II codes L5828, L5845, L5848, and L5856 adequately describe the Ottobock microprocessor knee units for classification and subsequent vendor reimbursement. For example, L5856 is the appropriate code to use for any lower extremity endoskeletal knee-shin system prosthesis that includes a microprocessor control feature, as well as a swing and stance phase. This code describes the microprocessor technology included in the Ottobock microprocessor knee units; as such, it should be one of the codes used to classify these items.

The audit team also found the PSAS Orthotic and Prosthetic L Code Committee developed draft guidance in September 2016 related to the Ottobock X3 microprocessor knee unit. This draft guidance identifies L5828, L5845, L5848, and L5856 as the appropriate CMS HCPCS Level II L codes to use when classifying the Ottobock X3 microprocessor knee unit and states the use of NOC codes are not authorized.[20] According to a member of the PSAS Orthotic and Prosthetic

[18] The audit team interviewed the former National Program Director, Prosthetic and Orthotic Clinical Service, in July 2017 after he left VA.

[19] According to Ottobock, the Ottobock X3 and Genium are microprocessor-controlled prosthetic knees that provide users with increased functionality and a natural walking experience. Both products include features that allow users to climb stairs and walk backwards, while the X3 includes additional features that allow users to run and fully submerge the prosthetic knee in water. These items are manufactured by Ottobock, a privately held medical technology and services company headquartered in Duderstadt, Germany.

[20] *VHA OPS L Code Committee Recommendation: Ottobock C-Leg 4, Including X3*, September 1, 2016.

L Code Committee, the draft guidance has not been issued to the field because it is waiting for legal review. Furthermore, the OIG found that a precedent was set for the use of existing CMS HCPCS Level II L codes to classify the Ottobock microprocessor knee units. Specifically, the audit team found the manufacturer Ottobock, as well as private health insurers and PDAC, use these CMS HCPCS Level II L codes to classify the Ottobock microprocessor knee units for classification and reimbursement.

The former National Program Director, Prosthetic and Orthotic Clinical Service, also reported that his field instructions to facility prosthetists were necessary because VHA had no legal authority to classify the Ottobock microprocessor knee units with CMS HCPCS Level II L codes and needed to wait for CMS to do so. The OIG determined, however, that VHA—through PSAS's Orthotic and Prosthetic L Code Committee—does make recommendations to medical facilities regarding the use of CMS HCPCS Level II L codes to classify prosthetic items, which are then used as a basis to determine vendor reimbursement rates. For example, in July 2015, PSAS's Orthotic and Prosthetic L Code Committee issued a list of recommended CMS HCPCS Level II L codes that facility prosthetists should use when classifying the C-Leg 4 microprocessor knee system—manufactured by Ottobock—to determine a basis for vendor reimbursement. This guidance identified the CMS HCPCS Level II L codes L5828, L5845, L5848, and L5856 as the codes that adequately described this device and that the use of an NOC code is not authorized.

The C-Leg 4 includes features that are similar to the Ottobock X2, X3, and Genium microprocessor knee units. According to Ottobock, this device allows the user to navigate ramps, climb stairs, and walk backwards. The C-Leg 4 is also submersible in water for up to 30 minutes. According to a PSAS Orthotic and Prosthetic L Code Committee member, the former National Program Director, Prosthetic and Orthotic Clinical Service, was part of the PSAS Orthotic and Prosthetic L Code Committee until his departure from VA in late 2016.

Based on the above information, the OIG determined the CMS HCPCS Level II L codes L5828, L5845, L5848, and L5856 to be appropriate for classifying the Ottobock microprocessor knee units. The use of these codes would have resulted in lower vendor reimbursement rates in nearly all cases when compared to the NOC L5999 code. The Executive in Charge, VHA, should review the PSAS Ottobock microprocessor knee instructions (August 2011, March 2013, and August 2013), coordinate with appropriate officials to determine which CMS HCPCS Level II L codes are appropriate to classify these items for reimbursement, and issue revised guidance.

PSAS Orthotic and Prosthetic L Code Committee Advised Against Using NOC Codes for Ottobock Microprocessor Knee Units

Guidance developed by the former National Program Director, Prosthetic and Orthotic Clinical Service, instructed facility prosthetists to use NOC codes to classify the Ottobock microprocessor knee units for vendor reimbursement against the advice of the PSAS Orthotic

and Prosthetic L Code Committee, according to committee officials. These committee officials told the audit team that they disagreed with the former National Program Director, Prosthetic and Orthotic Clinical Service's NOC-code instruction for the Ottobock microprocessor knee units that was issued in August 2011, because CMS HCPCS Level II L codes that adequately described these items existed. The OIG found committee members made the former National Program Director, Prosthetic and Orthotic Clinical Service, aware of their concerns as early as 2010.

Committee Members Did Not Make Higher Level Officials Aware of Their Concerns

These committee officials, however, did not take steps to elevate their concerns regarding the use of NOC codes, rather than existing CMS HCPCS Level II L codes, to classify Ottobock microprocessor knee units. The OIG was not able to identify any evidence that PSAS Orthotic and Prosthetic L Code Committee officials made higher level officials such as the National Director, PSAS, or the Deputy Chief, Patient Care Services Officer for Rehabilitation and Prosthetic Services—both with the authority to rescind the former National Program Director, Prosthetic and Orthotic Clinical Service's guidance—aware of their concerns.

These PSAS Orthotic and Prosthetic L Code Committee officials also did not notify VA's Office of General Counsel (OGC) about their concerns. The Deputy Chief, Patient Care Services Officer for Rehabilitation and Prosthetic Services, reported to the OIG that VA OGC reviews all the PSAS Orthotic and Prosthetic L Code Committee's guidance before it is issued to the facilities. A former Deputy Assistant General Counsel reported to the audit team that they generally recalled reviewing the former National Program Director, Prosthetic and Orthotic Clinical Service's guidance to classify the Ottobock microprocessor knee units using NOC code L5999, but said they did not work directly with the PSAS Orthotics and Prosthetics L Code Committee and were not aware of committee members' concerns regarding the guidance. The OIG believes members of the PSAS Orthotic and Prosthetic L Code Committee should have taken steps to make higher level officials aware of their concerns about classifying the Ottobock microprocessor knee units with an NOC code.

No Oversight and Monitoring of PSAS Orthotic and Prosthetic L Code Committee Actions and Guidance

The Deputy Chief, Patient Care Services Officer for Rehabilitation and Prosthetic Services, did not establish an effective oversight and reporting structure to ensure coding guidance developed by the former National Program Director, Prosthetic and Orthotic Clinical Service, was appropriate. The Deputy Chief reported to the OIG that the former National Program Director, in his role as the National Director for VHA's Prosthetic and Orthotic Clinical Service, was responsible for developing coding guidance. Furthermore, the Deputy Chief said that as long as

VA OGC reviewed and approved the guidance, she would approve the guidance for issuance to the field.

According to the Government Accountability Office's *Standards for Internal Control in the Federal Government*, management should establish an organizational structure, assign responsibility, and delegate authority. The Deputy Chief, Patient Care Services Officer for Rehabilitation and Prosthetic Services, should have clearly defined the PSAS Orthotic and Prosthetic L Code Committee's roles, authorities, and oversight responsibilities, which would have limited the former National Program Director, Prosthetic and Orthotic Clinical Service's ability to unilaterally develop and issue guidance against the recommendations of the committee.

The Executive in Charge, VHA, should coordinate with appropriate officials to establish a formal oversight and reporting structure that defines the roles and the responsibilities of the PSAS Orthotic and Prosthetic L Code Committee, as well as who has the authority to approve recommendations regarding the use of CMS HCPCS Level II L codes to classify specific prosthetic components for reimbursement.

No Requirement to Monitor Prosthetists' Use of NOC Codes

Prosthetists' noncompliance with VHA Directive 1045 went undetected because PSAS does not have effective processes and procedures. For example, PSAS does not use NPPD data to monitor and ensure that facility prosthetists are following CMS guidelines and policies by properly classifying locally purchased prosthetics with HCPCS codes for vendor reimbursement. PSAS also does not have procedures in place to monitor the extent to which facility prosthetists, rather than vendors, are developing HCPCS lists for locally purchased prosthetic items such as the Ossur Power Knee, the Michelangelo Hand, and the Touch Bionics i-Limbs. VHA Handbook 1173.1 requires the National Director, PSAS, to be responsible for the overall field consistency of VHA's prosthetics program, which should include ensuring consistent use and pricing of NOC codes.[21] However, the National Director, PSAS, told the OIG that the PSAS National Program Office does not have oversight responsibility and does not monitor how facilities use NOC codes to ensure these codes are used correctly.

The National Director, PSAS, told the audit team that VISN prosthetic representatives are responsible for ensuring compliance with VHA Directive 1045. The OIG found that VISN prosthetic representatives were not conducting any type of monitoring to ensure facility prosthetists were properly using NOC codes.

According to the Government Accountability Office's *Standards for Internal Control in the Federal Government*, management should exercise oversight to ensure compliance with applicable laws and regulations and relevant government guidance. PSAS should develop and implement processes and procedures with the capacity to identify prosthetic components

[21] VHA Handbook 1173.1, *Eligibility*, November 2000.

incorrectly classified by prosthetists and routinely review facilities' NOC code utilization and pricing. The Executive in Charge, VHA, should develop and implement effective processes and procedures to monitor the usage and pricing of NOC codes. These procedures should be communicated to the VISNs to ensure compliance with VHA Directive 1045 and the CMS HCPCS Level II Coding Procedures.

VHA at Risk of Overspending $13.6 Million on Incorrectly Coded Prosthetic Items over the Next Five Years

Because of the lack of oversight and monitoring of prosthetists use of NOC codes, VHA overpaid vendors approximately $650,000 for prosthetic items such as the Touch Bionics i-Limb and the Michelangelo Hand when facility prosthetists either incorrectly classified these items using an NOC code or allowed vendors to classify the items using an NOC code.

Furthermore, because of the incorrect guidance issued by the former National Program Director, Prosthetic and Orthotic Clinical Service, VHA typically paid higher prices for the Ottobock microprocessor knee units. The OIG found VHA overpaid vendors approximately $7 million for the Ottobock microprocessor knee units from October 2014 through July 2017.

Table 1 provides examples of the prices VHA paid when prosthetic items such as the Ottobock X3 and Genium microprocessor knees, the Touch Bionics i-Limb, and the Michelangelo Hand were coded for reimbursement with NOC codes as compared to what VHA would have paid if these same items were coded with the appropriate CMS HCPCS Level II L code.

Table 1: Comparison of Reimbursement Prices for Prostheses Coded with CMS HCPCS Level II L Codes as Compared to NOC Codes (October 2014–July 2017)

Prosthetic Item	CMS HCPCS Level II L Code Reimbursement	Prices VHA Paid When Coded with Incorrect NOC Code Actual*
Ottobock Microprocessor Knee Units	$34,429	$36,341 to $96,000
Bionics i-Limb	$27,380	$31,735 to $61,702
Michelangelo Hand	$27,380	$31,604 to $35,573

Source: OIG analysis of NPPD data from October 2014 through July 2017
**Prices identified reflect the amount paid by VHA for the specific components identified in the table. The prices included in the table do not reflect the cost of other components that are included in the fabrication of a prosthetic limb, such as sockets, test sockets, or locking-suspension mechanisms.*

The OIG found VHA unnecessarily spent approximately $7.7 million from October 2014 through July 2017 on prosthetic items that were incorrectly classified with NOC codes.[22] In total, VHA will overpay about $13.6 million for prosthetic items in the next five years, if the current practice persists of misusing NOC codes to classify and reimburse vendors for items for which a CMS HCPCS Level II L code exists.

Conclusion

The OIG substantiated the allegation that prosthetists incorrectly used NOC codes. Because the Deputy Chief, Patient Care Services Officer for Rehabilitation and Prosthetic Services, did not implement an effective oversight and reporting structure to ensure guidance developed by the former National Program Director, Prosthetic and Orthotic Clinical Service, complied with recommendations from the PSAS Orthotic and Prosthetic L Code Committee, VHA's interests were not protected. As a result, VHA overpaid vendors for the Ottobock microprocessor knee units. VHA's interests were put further at risk because PSAS failed to implement effective processes and procedures to monitor facility prosthetists' use of NOC codes. Failure to monitor facility prosthetists' use of NOC codes further exposed VHA to the risk of overpaying vendors for other prosthetic items for which a CMS HCPCS Level II L code exists.

[22] The overpayment amount is based on the cost VHA reimbursed vendors for the specific prosthetic items reviewed by the audit team. The overpayment calculation does not include the cost of other components included in the fabrication of a prosthetic limb such as test sockets, sockets, and suspension-locking mechanisms.

Recommendations 1–3

1. The Executive in Charge, Veterans Health Administration, should review the Prosthetic and Sensory Aids Service Ottobock microprocessor knee instructions (August 2011, March 2013, and August 2013), coordinate with appropriate officials to determine which Centers for Medicare and Medicaid Services' Healthcare Common Procedure Coding System Level II L codes are appropriate to classify these items for reimbursement, and issue revised guidance.
2. The Executive in Charge, Veterans Health Administration, should coordinate with appropriate officials to establish a formal oversight and reporting structure that defines the roles and the responsibilities of the Prosthetic and Sensory Aids Service Orthotic and Prosthetic L Code Committee, as well as who has the authority to approve recommendations for the use of the Centers for Medicare and Medicaid Services' Healthcare Common Procedure Coding System Level II L codes to classify specific prosthetic components for reimbursement.
3. The Executive in Charge, Veterans Health Administration, should develop and implement effective processes and procedures to monitor the use of Not Otherwise Classified codes and communicate these procedures to the Veterans Integrated Service Networks to ensure compliance with Veterans Health Administration Directive 1045, *Healthcare Common Procedure Coding System (HCPCS) List for Prosthetic Limb and/or Custom Orthotic Device Prescription* (December 30, 2013) and the Centers for Medicare and Medicaid Services' Healthcare Common Procedure Coding System Level II Coding Procedures.

Management Comments

The Executive in Charge, Veterans Health Administration, concurred with Recommendations 1 through 3 and provided action plans with completion dates targeted for no later than April 2019. To address Recommendation 1, the Executive in Charge reported that a team will complete a review of coding and pricing guidance for the Ottobock microprocessor knee for accuracy and revise this guidance as appropriate. The review will include CMS HCPCS Level II L codes and VA procurement authorities. To address Recommendation 2, VHA will formally charter its Orthotic and Prosthetic L Code Guidance Committee and define the committee's responsibilities and VHA's accountability for oversight and reporting. To address Recommendation 3, VHA will develop methods to monitor the use of NOC codes, communicate the monitoring plan to the field, and ensure compliance with VHA's policies to include VHA Directive 1045.

OIG Response

The OIG considers these implementations plans responsive and will monitor their implementation until all proposed actions are completed. Appendix D includes the full text of the Executive in Charge's comments.

Finding 2: PSAS Issued Pricing Guidance That Placed VHA at Risk of Paying Inflated Prices for NOC-Classified Prosthetic Items

PSAS issued guidance that allowed VHA to reimburse vendors at unreasonable prices for NOC-classified prosthetic items. PSAS issued guidance to facilities in March 2013 and August 2013, developed by the former National Program Director, Prosthetic and Orthotic Clinical Service, that established a cost-plus-$16,100-markup reimbursement methodology for the Ottobock microprocessor knee units.[23] Separately, PSAS also developed a prosthetic limb contract template and issued it to facilities and VISNs in August 2014 that included a cost-plus-50 percent-markup reimbursement methodology for all NOC-coded prosthetic items.

According to a November 2010 recommendation made by VA OGC, reimbursement of items classified using NOC codes should reasonably approximate the cost and profit associated with services provided by vendors. In this case, the cost-plus-$16,100-markup reimbursement methodology for the Ottobock microprocessor knee units and the cost-plus-50 percent-markup reimbursement proved to be unsatisfactory. For example, the across-the-board 50 percent markup does not take into account that reasonable costs and profits do not increase in direct proportion to the cost of the item. The OIG determined both markup methodologies to be unreasonable because there was no basis to support how either methodology reasonably approximated the cost and profit associated with the vendor's services.

The issuance of guidance containing unreasonable methodologies for reimbursing vendors went undetected because the Deputy Chief, Patient Care Services Officer for Rehabilitation and Prosthetic Services, did not implement effective oversight and review processes to ensure the pricing methodologies were adequately supported and reviewed before being issued. As a result, VHA is at risk of reimbursing excessive amounts for the cost and profit associated with vendor provided services.

PSAS Pricing Guidance Disregarded Guidance Provided by VA OGC

In November 2010, VA OGC provided the former National Program Director, Prosthetic and Orthotic Clinical Service, with advice on the establishment of a pricing methodology for the reimbursement of prosthetic items classified using NOC codes.[24] In the report, VA OGC advised against the use of a pricing formula presented by the former National Program Director that would reimburse vendors the wholesale price of the prosthetic item, plus a percentage markup. VA OGC questioned the validity of the proposed formula because the markup percentages were not supported by cost or pricing data.

[23] PSAS's Ottobock microprocessor knee instructions, March 2013 and August 2013.

[24] VA OGC memorandum VAOPGCADV 12-2010, November 24, 2010.

VA OGC also stated that despite the broad authority granted to VA in 38 United States Code 8123 to procure prosthetic items, purchases must be made at fair and reasonable prices and reimbursement amounts should reasonably approximate the costs and profit of the services provided.[25] As such, any guidance with regard to the reimbursement of NOC-classified items should provide a basis for ensuring reimbursement amounts reasonably approximate the cost and profit associated with the services provided.

No Basis to Support How Markups Approximate Vendor Cost and Profit

Despite the recommendation from VA OGC, PSAS issued guidance developed by the former National Program Director, Prosthetic and Orthotic Clinical Service, that contained pricing methodologies that included a fixed markup amount. This guidance allowed VHA to reimburse vendors—in the event that a local contract did not address pricing—for the Ottobock microprocessor knee units' purchase price plus a markup of $16,100.[26]

In addition, a prosthetic limb contract template was issued in August 2014 to VISNs that included a purchase price plus 50 percent markup reimbursement methodology for prosthetic items classified with an NOC code. Representatives from PSAS told the OIG that the former National Program Director, Prosthetic and Orthotic Clinical Service, developed the pricing guidance issued. The former National Program Director and representatives from PSAS were unable to provide the audit team with any documentation that justified how the $16,100 markup or the 50 percent markup reasonably approximated the cost and profit associated with services provided by vendors.

$16,100 Markup Not Reasonable

Members of the PSAS Orthotic and Prosthetic L Code Committee agreed with the OIG that reimbursing vendors $16,100 for services associated with the Ottobock microprocessor knee units was unreasonable. Five VHA prosthetists told the OIG that adjusting and programming Ottobock microprocessor knee units takes no longer than two hours. As a result, VHA's $16,100 reimbursement for services would equal about $8,000 an hour for services related to an Ottobock microprocessor knee unit. In comparison, vendors can be reimbursed at the rate of $30 per 15 minutes or $120 per hour according to a PSAS contract template for semi-annual service including the repair and replacement of minor parts for prosthetic items.

[25] 38 United States Code 8123, *Procurement of Prosthetic Appliances*, "The Secretary may procure prosthetic appliances and necessary services required in the fitting, supplying, and training and use of prosthetic appliances by purchase, manufacture, contract, or in such other manner as the Secretary may determine to be proper, without regard to any other provision of law."

[26] PSAS's Ottobock microprocessor knee instructions, March 2013 and August 2013.

The OIG recognizes that additional services such as post-fitting visits may be required to adjust the prosthetic limb and its individual components, including the Ottobock Microprocessor knee units, and that the cost and profit associated with these services may be included in the original price paid for each of the individual components. However, the use of the $16,100 fixed amount does not consider the individual needs of each veteran, nor does it consider what a fair and reasonable price would be for the cost and profit associated with any additional required services.

Consider, if a veteran required four post-fitting visits at an hour apiece to adjust the Ottobock microprocessor knee unit, the total time associated with the initial programming and subsequent visits would be about six hours. The reimbursement for these services would equal about $2,700 an hour for just the services related to the Ottobock microprocessor knee unit. However, if a veteran only required one post-fitting visit, a vendor would be reimbursed about $5,400 an hour for about three hours of work (two hours to initially program the device and one additional hour for the subsequent visit).

50 Percent Markup Not Reasonable

According to the former Acting National Program Director, Prosthetic and Orthotic Clinical Service, the cost-plus-50 percent-markup reimbursement methodology, as developed by the former National Program Director, Prosthetic and Orthotic Clinical Service, included in the contract template was not reasonable. The former Acting National Program Director told the audit team that the methodology created a very high profit margin for high-priced items, which often involve the same amount of work as lower-priced items. For example, prior to issuing an item to a veteran, a vendor may expend the same amount of or even more service hours on a $500 prosthetic item that it would expend on a $50,000 prosthetic item. However, under PSAS's reimbursement methodology VHA would pay the vendor only $250 for the vendor-provided service hours expended on the lower priced but more time-intensive prosthetic item. The more expensive, but not necessarily more time-intensive prosthetic item would cost VHA an additional $25,000 in markups.

Absent documentation to support the basis for the $16,100 and 50 percent markups, the OIG concluded the rates developed by the former National Program Director, Prosthetic and Orthotic Clinical Service, were unreasonable and ignored the previous guidance issued by VA OGC in 2010. Failure to develop a pricing methodology that ensures reimbursement at fair and reasonable prices puts VHA at risk of paying inflated prices. In addition, VHA is also at risk of paying excessive profits to vendors for services that may not require a significant amount of effort to accomplish the services provided.

PSAS Lacks Effective Processes and Procedures to Ensure Guidance Resulted in the Reimbursement of Fair and Reasonable Prices

The former National Program Director, Prosthetic and Orthotic Clinical Service's development and the subsequent issuance of guidance that contained unreasonable pricing methodologies went undetected because the Deputy Chief, Patient Care Services Officer for Rehabilitation and Prosthetic Services, did not implement effective oversight and review processes to ensure the pricing methodologies were adequately supported and reviewed by appropriate individuals prior to issuance.

According to the *Medical L-Code Usage for Orthotic and Prosthetic Limb Components – Not Otherwise Specified/Classified* memorandum issued in February 2013, PSAS, in conjunction with VHA's Procurement and Logistics Office (PL&O) and VA OGC, provided recommendations for billing prosthetic items classified using NOC codes. This memo states VHA Orthotic and Prosthetic Service is not responsible for determining cost formularies and contracts for the provision of orthotic and prosthetic services require review prior to implementation.

In addition, in response to a recommendation made in the *Audit of the Management and Acquisition of Prosthetics Limbs* (March 8, 2012, Report No. 11-02254-102), VHA reported in December 2013 that PSAS, PL&O, and the VA Office of Acquisitions and Logistics (OAL) collaboratively developed a national contract template. However, PSAS officials and the Deputy Chief, Patient Care Services Officer for Rehabilitation and Prosthetic Services, were unable to provide the audit team with any documentation that offices such as VA OGC, OAL, or PL&O reviewed the pricing methodologies developed by the former National Program Director, Prosthetic and Orthotic Clinical Service, that were included in the Ottobock microprocessor knee unit guidance or the prosthetic limb contract template.

No Reviews of Contract Template by PL&O or OAL

The OIG coordinated with representatives from PL&O and OAL who were supposed to have had some involvement in the development of the prosthetic limb contract template. The individuals the audit team contacted had little, if any, involvement in the development of the prosthetic limb contract template or the development of the 50 percent markup:

- Associate Director, VHA Procurement Office of PL&O, said its involvement with regard to the prosthetic limb contract template was limited to distributing the template to the field.
- A PL&O management analyst said they performed some research as part of a team who worked on the prosthetic limb contract template; however, this individual had no knowledge of the 50 percent markup included in the template.

- Two OAL contract specialists said they were not involved with the development of the prosthetic limb contract template.
- An OAL senior contract specialist reported attending some teleconference calls with representatives from PSAS, PL&O, and OAL; however, this individual did not recall the discussion of any language specifically allowing vendors to charge 1.5 times the invoice price.

No Reviews by VA OCG

The OIG also coordinated with representatives from VA OGC to obtain evidence of its involvement in the review of the pricing methodologies. The OIG spoke with the former Deputy Assistant General Counsel who said they performed reviews of guidance developed by the former National Program Director, Prosthetic and Orthotic Clinical Service, but did not recall reviewing the Ottobock microprocessor knee unit guidance issued in 2013 or the prosthetic limb contract template. In addition, the OIG spoke to a current VA OGC employee who said there were no records of any reviews performed by the general counsel with regard to the Ottobock microprocessor knee unit guidance or the prosthetic limb contract template.

The lack of documentation to support any reviews is indicative of the ineffective processes and procedures in place to ensure pricing guidance for NOC-classified items was developed and reviewed in conjunction with VA OGC, PL&O, or OAL prior to issuance. The lack of processes and procedures allowed the former National Program Director, Prosthetic and Orthotic Clinical Service, to develop pricing methodologies that provided no basis for how the methodologies approximated the cost and profit associated with services provided by vendors, thereby placing VHA at risk of reimbursing vendors at unreasonable prices.

According to the Government Accountability Office's *Standards for Internal Control in the Federal Government*, management should exercise oversight to ensure compliance with applicable laws, regulations, and government guidance. Implementation of effective processes and procedures would have allowed PSAS to assess whether the pricing methodologies were developed and concurred with by the appropriate VA OGC and PL&O officials, thereby ensuring the methodologies resulted in the reimbursement of fair and reasonable prices. The Executive in Charge, VHA, should coordinate with appropriate officials to develop and implement processes and procedures to ensure any pricing guidance with regard to the pricing of prosthetic items classified using NOC codes is developed and concurred with by VA OGC and PL&O prior to issuance.

Facilities and VISNs Are Still Using PSAS's Reimbursement Guidance and Template

As of July 2017, facilities and VISNs continued to rely on PSAS's reimbursement guidance for the Ottobock microprocessor knee units and continued to use PSAS's prosthetic limb contract

template. Until PSAS takes steps to ensure that VHA is paying fair and reasonable prices for NOC-classified prosthetic items, VHA will continue to be at risk of paying inflated prices for these items, as well as potential excessive profits to vendors. The following examples illustrate VHA's risk of paying unreasonable prices and profits as long as facilities continue their reliance on PSAS's incorrect pricing guidance.

Example 1

A facility that implemented PSAS's prosthetic limb contract template reimbursed a vendor the purchase price of a prosthetic item and about $24,000 for the cost and profit associated with the services provided for the item. No other documentation was provided to the OIG to support how the $24,000 reasonably approximated the cost, such as the vendor's time, effort, and profit.

Example 2

A single vendor provided veterans with 40 microprocessor knee units from October 2014 through July 2017. This vendor provided services in VISN 22, which implemented PSAS's prosthetic limb contract. VHA reimbursed this vendor the cost of each microprocessor knee unit, plus an average markup of more than $13,000 per item. As a result, this vendor was paid about $530,000 for just the cost and profit of their services.

The Executive in Charge, VHA, should issue corrected guidance to replace the PSAS Ottobock microprocessor knee instructions (March 2013 and August 2013) and the prosthetic limb contract template issued in August 2014, by coordinating with appropriate officials to develop and implement pricing guidance that will allow for the reimbursement of prosthetic items classified using NOC codes at fair and reasonable prices.

Conclusion

The OIG determined PSAS issued pricing guidance that included pricing methodologies that allowed for the reimbursement of prosthetic items classified using NOC codes at unreasonable prices. The inclusion of the unreasonable pricing methodology went undetected because the Deputy Chief, Patient Care Services Officer for Rehabilitation and Prosthetic Services, did not implement effective oversight and review processes to ensure the pricing methodologies were adequately supported and reviewed by appropriate individuals prior to issuance. Without implementing effective controls to ensure reasonable pricing of NOC code-categorized prosthetic items, VHA is at continued risk of paying unreasonable prices for these items.

Recommendations 4–5

4. The Executive in Charge, Veterans Health Administration, should coordinate with the appropriate officials to develop and implement processes and procedures to ensure any pricing guidance with regard to the pricing of prosthetic items classified using a Not Otherwise Classified code is developed and concurred with by VA Office of General Counsel and Veterans Health Administration's Procurement and Logistics Office prior to issuance.
5. The Executive in Charge, Veterans Health Administration, should issue corrected guidance to replace the Prosthetic and Sensory Aids Service Ottobock microprocessor knee instructions (March 2013 and August 2013) and the prosthetic limb contract template issued in August 2014, by coordinating with appropriate officials to develop and implement pricing guidance to ensure VA pays a fair and reasonable price for items classified using a Not Otherwise Classified code.

Management Comments

The Executive in Charge, Veterans Health Administration, concurred with Recommendations 4 and 5 and provided action plans with completion dates targeted for no later than June 2019. To address Recommendation 4, the Executive in Charge reported that VHA will coordinate with VA OGC and PL&O to assure concurrence and compliance with the use of NOC codes assigned to orthotic and prosthetic devices. Furthermore, VHA will provide the methods used to develop and implement processes and procedures for issuing pricing guidance with regard to prosthetic items classified with NOC codes. To address Recommendation 5, VHA will review and revise, as appropriate, guidance related to the coding and pricing of Ottobock microprocessor prosthetic knees.

OIG Response

The OIG considers these implementation plans responsive and will monitor their implementation until all proposed actions are completed. Appendix D includes the full text of the Executive in Charge's comments.

Appendix A: Background

Rehabilitation and Prosthetic Services

According to VHA's Rehabilitation and Prosthetic Services staff, they are responsible for the national policies and programs for medical rehabilitation, prosthetic, and sensory aids services that promote the health, independence, and quality of life for veterans with disabilities. Rehabilitation and Prosthetic Services comprises national programs for Audiology and Speech Pathology, Blind Rehabilitation, Chiropractic Care, Physical Medicine and Rehabilitation, PSAS, and Recreation Therapy. Rehabilitation and Prosthetic Services provides program and policy direction for over 8,000 rehabilitation care and prosthetic services providers. Figure 2 details VHA's Rehabilitation and Prosthetic Services organizational structure.

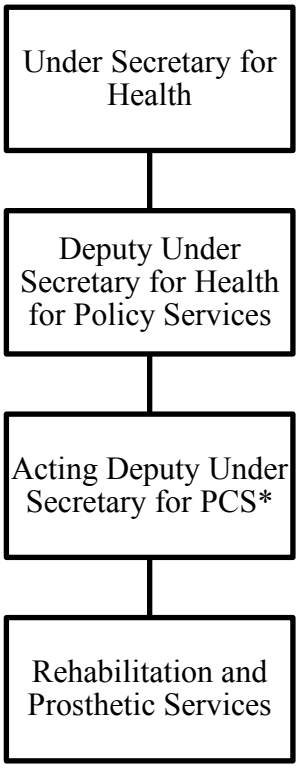

Figure 2. *VHA Organizational Structure*
**PCS=Patient Care Services*
Source: OIG analysis of VHA Organizational Chart, dated June 2017

CMS HCPCS Level II Coding Procedures

CMS HCPCS Level II Coding Procedures (November 13, 2015) establishes the CMS HCPCS Level II coding system as a comprehensive and standardized system that classifies similar products into categories of like items. CMS HCPCS Level II codes typically do not identify specific products or brand/trade names. CMS HCPCS Level II codes can be assigned to a

specific product and brand/trade name at the request of the manufacturer. To do so, the manufacturer of the product must submit a request to the CMS pricing, data analysis, and coding contractor. The CMS PDAC reviews products and identifies the code(s) applicable to specific products.

NPPD

VHA's National Prosthetics Patient Database (NPPD) captures data on veterans, their eligibility, and the type of prosthetic treatment they received at a facility. The database also captures facility information on prosthetic costs, vendor sources, and purchasing agents.

Appendix B: Scope and Methodology

Scope

The OIG conducted this audit from October 2016 through June 2018. The audit scope included a review of PSAS's use of NOC codes to classify prosthetic items and provide subsequent reimbursement to vendors from October 2014 through July 2017. The audit scope also included a review of guidance provided by PSAS and the use of a markup to provide reimbursement to vendors for items classified using NOC codes.

Methodology

To gain an understanding of how VHA used NOC codes to classify prosthetic components for vendor reimbursement, the audit team reviewed applicable CMS, PSAS, and VHA policies, procedures, and directives. The audit team interviewed current and former PSAS officials, as well as officials from VA OGC and VHA's PL&O, who were knowledgeable about VHA's use of NOC codes and the pricing markup methodology for vendor reimbursement for NOC-classified prosthetic components. To learn more about how prosthetists identified and assigned NOC codes to prosthetic components, the audit team interviewed six facility prosthetics employees. In addition, the OIG interviewed representatives from CMS as well as representatives from CMS's pricing, data analysis, and coding contractor to learn more about the CMS HCPCS Level II coding system.

NPPD Data

To assess the extent to which prosthetists incorrectly used NOC codes, the OIG team used NPPD data from October 2014 through July 2017. The OIG obtained a data extract from NPPD of all prosthetic items coded using NOC codes. According to OIG's analysis, the NPPD data extract from October 2014 through September 2016 contained nearly 6,000 NOC code transactions with a total cost of about $24 million. Of this amount, the OIG found that 307 NOC-coded transactions with a cost of at least $30,000 accounted for about $17 million, or about 72 percent, of the total costs of items coded using NOC codes. From the 307 transactions, the OIG selected all 19 prosthetic transactions with a value of $70,000 or more to review. The OIG also randomly sampled 58 transactions with values of $30,000 to $69,999 to review from this data extract. To assess the extent to which prosthetists properly classified the 77 NOC-coded transactions selected for review, the OIG team reviewed supporting documentation such as vendor invoices, quotes, purchase orders, and prosthetic consults provided by VISN prosthetic representatives.[27]

[27] The following six prosthetic items—the Ottobock microprocessor knee units, the BiOM T2 Ankle and Foot Systems, the Ossur Power Knee, the Touch Bionics i-Limbs, the Michelangelo Hand, and the i-Limb Digit Thumb—made up the items included in the 77 transactions selected for review.

The OIG team also obtained updated NPPD data from October 2014 through July 2017 to determine how frequently VHA prosthetists incorrectly classified the prosthetic items reviewed by the audit team. According to OIG's analysis, the audit team found an additional 265 items related to the six prosthetic items reviewed that VHA prosthetists incorrectly classified using an NOC code.

Questioned Cost Calculation

To calculate the $7.7 million overpayment from October 2014 through July 2017, the OIG took the difference between what VHA paid to vendors for these items and what VHA would have paid had facility prosthetists classified the prosthetic items using the appropriate CMS HCPCS Level II L code. January 2017 ceiling prices for CMS HCPCS Level II L codes were used to calculate reimbursement amounts of prosthetic items had NOC codes not been used. January 2017 ceiling prices were used because they provided the most conservative estimate of prices based upon the scope of the audit that included October 2014 through July 2017 transactions.

To estimate the overpayment to vendors over the next five years, the OIG calculated an average annual overpayment based on the questioned cost of $7.7 million from October 2014 through July 2017 and projected this amount over five years.

Fraud Assessment

The audit team assessed the risk that fraud, violations of legal and regulatory requirements, and abuse could occur during this audit. The audit team exercised due diligence in staying alert to any fraud indicators by taking actions, such as coordinating with the OIG's Office of Investigations to determine if there were any overbilling cases involving the misuse of NOC codes. During the course of the audit, the audit team referred several matters to the OIG's Office of Investigations.

Data Reliability

The OIG used computer-processed data from NPPD to identify the total number of prosthetic items coded by prosthetists with an NOC code. To assess the reliability of NPPD data, the OIG team compared a sample of NPPD transactions to supporting source documentation such as prosthetic consults and hard copy vendor invoices. The OIG concluded that NPPD data on prosthetic components coded using an NOC code were appropriate and sufficient for the purposes of this audit.

Government Standards

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions

based on our audit objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

Appendix C: Potential Monetary Benefits in Accordance with Inspector General Act Amendments

Recommendation	Explanation of Benefits	Better Use of Funds (in millions)	Questioned Costs (in millions)
1 and 3	Funds unnecessarily spent because prosthetists incorrectly coded prosthetic items using an NOC code, which could have been better used by VHA		$7.7[29]
	Value of overpayments to vendors over the next five years if appropriate corrective action is not taken	$13.6[28]	
	Total	**$13.6**	**$7.7**

[28] To estimate the overpayment to vendors over the next five years, the OIG calculated an average annual overpayment based on the questioned cost of $7.7 million from October 2014 through July 2017 and projected this amount over five years.

[29] The questioned cost of $7.7 million represents the amount VHA overpaid vendors from October 2014 through July 2017. The OIG took the difference between what VHA paid to vendors for these items and what VHA would have paid had facility prosthetists classified the prosthetic items using the appropriate CMS HCPCS Level II L codes. Appendix B provides more details on OIG's scope and methodology.

Appendix D: Management Comments

Date: July 18, 2018

From: Executive in Charge, Office of the Under Secretary for Health (10)

Subj: OIG Draft Report, Audit of the Use of Not Otherwise Classified Codes for Prosthetic Limb Components (VIEWS 00075219)

To: Assistant Inspector General for Audits and Evaluations (52)

1. Thank you for the opportunity to review the Office of Inspector General (OIG) draft report, Alleged Overpayment for Prosthetic Items. The Veterans Health Administration (VHA) concurs with recommendations 1-5 and provides the attached action plan.

2. Implementation of the action plan will enhance the Department's procurement and provisions of artificial limbs. VHA has processes in place for determining and issuing appropriate coding guidance. While Centers for Medicare and Medicaid Services (CMS) Health Care Procedure Coding System (HCPCS) L Codes exist for various devices, such codes may not be appropriate for newly developed devices that are not submitted to CMS for determination (e.g., the Genium X-3 Knee). The recommendations provided in this report will assist VHA to further advance coding practices to ensure existing codes are not imposed, misapplied or limit Veterans' access to new technologies, while also promoting fair and reasonable payment for new technologies.

3. Implementation will further support VHA's efforts to enhance its provision of Orthotic and Prosthetic (O&P) Services, in conjunction with other new initiatives recently implemented, such as (1) direct scheduling and same day access for O&P services for established patients; (2) piloting implementation of the FLOW initiative that integrates information technology processes to automate, standardize, and manage the acquisition of prosthetic limbs, and (3) implementation of centralized ordering through the Denver Logistics Center to increase consistency of ordering, pricing, and associated logistics.

4. If you have any questions, please email Karen Rasmussen, M.D., Director, Management Review Service at VHA10E1DMRSAction@va.gov.

(*original signed by)*

Carolyn M. Clancy, M.D.

Attachment

For accessibility, the original format of this appendix has been modified to comply with Section 508 of the Rehabilitation Act of 1973, as amended.

VETERANS HEALTH ADMINISTRATION (VHA)
Action Plan

OIG Draft Report: Audit of the Use of Not Otherwise Classified Codes for Prosthetic Limb Components

Date of Draft Report: June 8, 2018

Recommendations/ Actions	Status	Completion Date

Recommendation 1: The Executive in Charge, Veterans Health Administration, should review the Prosthetic and Sensory Aids Service Ottobock microprocessor knee instructions (August 2011, March 2013, and August 2013), coordinate with appropriate officials to determine which Centers for Medicare and Medicaid Services' Healthcare Common Procedure Coding System Level II L codes are appropriate to classify these items for reimbursement, and issue revised guidance.

VHA Comments: Concur.

VHA agrees that Ottobock microprocessor knee coding and pricing guidance should be reviewed for accuracy. A team will be developed to complete this review.

Upon completion of this action, VHA will provide documentation that the designated responsible Department of Veterans Affairs (VA) officials have reviewed the guidance with regard to proper classification of the Ottobock microprocessor knee for reimbursement, and revised the guidance as appropriate. The review will include:

(1) Centers for Medicare and Medicaid Services' (CMS) Healthcare Common Procedure Coding System (HCPCS) Level II L codes; and
(2) VA procurement authorities.

Status: In process Target Completion Date: April 2019

Recommendation 2: The Executive in Charge, Veterans Health Administration, should coordinate with appropriate officials to establish a formal oversight and reporting structure that defines the roles and the responsibilities of the Prosthetic and Sensory Aids Service Orthotic and Prosthetic L Code Committee, as well as who has the authority to approve recommendations for the use of the Centers for Medicare and Medicaid Services' Healthcare Common Procedure Coding System Level II L codes to classify specific prosthetic components for reimbursement.

VHA Comments: Concur.

VHA will formally charter its Orthotic and Prosthetic (O&P) L Code Guidance Committee, defining the scope of the Committee's responsibilities and VHA's accountability for oversight and reporting.

Upon completion of this action, VHA will provide the official charter and supporting documents of the revised O&P L Code Guidance Committee to include: Membership (including liaisons from the VHA Procurement and Logistics Office and the VA Office of General Counsel), scope, objectives, responsibilities, decision processes, appeals processes, and process for review, oversight and approval by appropriate VHA leaders.

Status: In process Target Completion Date: April 2019

Recommendation 3: The Executive in Charge, Veterans Health Administration, should develop and implement effective processes and procedures to monitor the use of Not Otherwise Classified codes and communicate these procedures to the Veterans Integrated Service Networks to ensure

compliance with Veterans Health Administration Directive 1045, Healthcare Common Procedure Coding System (HCPCS) List for Prosthetic Limb and/or Custom Orthotic Device Prescription (December 30, 2013) and the Centers for Medicare and Medicaid Services' Healthcare Common Procedure Coding System Level II Coding Procedures.

VHA Comments: Concur.

VHA will devise methods to: (1) monitor the use of Not Otherwise Classified (NOC) Level II codes, (2) communicate the monitoring plan to the field (including Veterans Integrated Service Network level representatives), and (3) assure compliance with VHA policies.

Upon completion of this action, VHA will provide documentation of the review for VHA coding utilization policy (i.e. Directive 1045 and any associated revision), the newly developed process for tracking compliance with VHA policy (i.e. Directive 1045), and the communication of coding recommendations and utilization of codes for Orthotic and Prosthetic devices (to include NOC Codes and Healthcare Common Procedure Coding System-L Codes).

Status: In process Target Completion Date: April 2019

Recommendation 4: The Executive in Charge, Veterans Health Administration, should coordinate with the appropriate officials to develop and implement processes and procedures to ensure any pricing guidance with regard to the pricing of prosthetic items classified using a Not Otherwise Classified code is developed and concurred with by VA Office of General Counsel and Veterans Health Administration's Procurement and Logistics Office prior to issuance.

VHA Comments: Concur.

VHA will coordinate with the VA Office of General Counsel (OGC) and the VHA Procurement and Logistics Office to assure concurrence and compliance with the use of Not Otherwise Classified (NOC) codes assigned to Orthotic and Prosthetic devices.

Upon completion of this action, VHA will provide documentation of: Coordination with VA OGC Procurement Law and the VA Office of Acquisition, Logistics and Contracting, and the methods used to develop and implement processes and procedures for issuing pricing guidance with regard to prosthetic items classified using an NOC code.

Status: In process Target Completion Date: June 2019

Recommendation 5: The Executive in Charge, Veterans Health Administration, should issue corrected guidance to replace the Prosthetic and Sensory Aids Service Ottobock microprocessor knee instructions (March 2013 and August 2013) and the prosthetic limb contract template issued in August 2014, by coordinating with appropriate department officials to develop and implement pricing guidance to ensure VA pays a fair and reasonable price for items classified using a Not Otherwise Classified code.

VHA Comments: Concur.

VHA will review and, as determined appropriate, revise guidance related to the coding and pricing of Ottobock Microprocessor knees.

Upon completion of this action, VHA will provide documentation of results of the review of processes, guidance, and any newly developed or revised guidance issued and implemented, as appropriate, related to Otto Bock knee systems.

Status: In process Target Completion Date: June 2019

OIG Contact and Staff Acknowledgments

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