Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

THE MEDICARE CONTRACTORS FOR JURISDICTION E OVERPAID CLAIMS FOR REPLACED CARDIAC MEDICAL DEVICES WHEN HOSPITALS HAD NOT REPORTED MANUFACTURER CREDITS

Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

Lori A. Ahlstrand
Regional Inspector General for Audit Services

March 2016
A-09-15-02029
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EXECUTIVE SUMMARY

From 2012 through 2014, the Medicare contractors for Jurisdiction E overpaid hospitals $2.1 million for selected inpatient and outpatient claims for replaced cardiac medical devices when the hospitals had not reported manufacturer credits.

WHY WE DID THIS REVIEW

For calendar years 2012 through 2014 (audit period), Medicare contractors nationwide paid hospitals $30 billion for certain inpatient and outpatient claims for cardiac medical devices (cardiac devices) potentially eligible for manufacturer credits. Previous Office of Inspector General reviews of hospitals’ compliance with Medicare billing requirements found that Medicare contractors overpaid hospitals for selected inpatient and outpatient claims because hospitals did not identify, obtain, or report manufacturer credits for replaced medical devices.

The objective of this review was to determine whether payments that Medicare contractors for Jurisdiction E made to hospitals for selected inpatient and outpatient claims for replaced cardiac devices complied with Medicare requirements for reporting manufacturer credits.

BACKGROUND

Common cardiac devices used to treat beneficiaries include defibrillators, pacemakers, and their associated electrical leads. These devices are implanted during either inpatient or outpatient procedures. Occasionally, devices may require replacement because of defects, recalls, battery depletions, or mechanical complications, which may be covered under manufacturer warranties. Federal regulations generally require a Medicare payment reduction for the replacement of a beneficiary’s implanted device if a hospital receives a full or partial credit from the manufacturer for a medical device that is covered under warranty or replaced because of a defect or recall. Federal guidance specifies how hospitals must report these credits on Medicare claims for replaced devices.

At the beginning of our audit period, Palmetto GBA, LLC (Palmetto), was the Medicare contractor for Jurisdiction E (which covers California, Hawaii, Nevada, and three Pacific territories). Effective September 2013, Noridian Healthcare Solutions, LLC (Noridian), became the Medicare contractor for Jurisdiction E. These Medicare contractors paid hospitals $3 billion for approximately 55,000 inpatient and 44,000 outpatient cardiac device claims with certain diagnosis-related-group or procedure codes subject to credit-reporting requirements. We reviewed a total of 191 claims with payments of $4.9 million that were at risk for overpayment. These claims had dates of service during our audit period and consisted of 52 inpatient and 139 outpatient claims. Because Noridian assumed responsibility for Jurisdiction E claims formerly paid by Palmetto, we have addressed our findings and recommendations to Noridian for review and comment.
WHAT WE FOUND

Payments that the Medicare contractors for Jurisdiction E made to hospitals for all 191 inpatient and outpatient claims for replaced cardiac devices did not comply with Medicare requirements for reporting manufacturer credits. The hospitals’ incorrect billing of these claims resulted in overpayments of $2,132,458 that the hospitals had not identified, refunded, or adjusted by the beginning of our audit.

For all 52 selected inpatient claims, hospitals received full manufacturer credits for replaced cardiac devices but did not adjust the claims with the proper condition and value codes to reduce payment as required. For all 139 selected outpatient claims, hospitals received full or partial credits for replaced cardiac devices but did not report the correct modifiers and reduce charges on the claims (2012 and 2013 claims) or did not adjust the claims with the proper condition and value codes to reduce payment as required (2014 claims).

Hospitals attributed the incorrect Medicare billings to inadequate policies and procedures for identifying and reporting manufacturer credits for replaced cardiac devices. Many hospitals stated that they lacked internal controls to coordinate functions among various departments when credits were received (e.g., the department that receives the credit and the department that bills Medicare). Other hospitals stated that they did not have adequate policies and procedures to identify the receipt of credits or that they lacked an understanding of manufacturer warranties.

During our audit period, the Medicare contractors provided limited guidance to hospitals on how they should report manufacturer credits for replaced medical devices. The Medicare contractors overpaid the hospitals because they had no specific controls to ensure that hospitals complied with Medicare requirements for reporting manufacturer credits.

WHAT WE RECOMMEND

We recommend that Noridian:

- recover the $2,132,458 in identified overpayments,
- use the results of this audit in its ongoing hospital education activities, and
- strengthen controls to ensure that hospitals comply with Medicare requirements for reporting manufacturer credits for replaced medical devices.

NORIDIAN COMMENTS AND OUR RESPONSE

In written comments on our draft report, Noridian concurred with all of our recommendations and provided information on actions that it had taken or planned to take to address our recommendations. Specifically, Noridian stated that it had (1) recovered more than $2 million in identified overpayments and would continue its efforts to recover the remaining overpayments (approximately $99,000), (2) provided education to hospitals related to changes in billing and reimbursement for medical device replacement and intended to post information on its Web site regarding Medicare requirements for reporting manufacturer credits for replaced medical devices.
devices, and (3) implemented claims processing controls through the Fiscal Intermediary Standard System to ensure that hospitals comply with Medicare’s credit-reporting requirements.

After reviewing Noridian’s comments, we concluded that Noridian’s education of hospitals and implementation of claims processing controls could potentially result in additional savings to Medicare.
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INTRODUCTION

WHY WE DID THIS REVIEW

For calendar years 2012 through 2014 (audit period), Medicare contractors nationwide paid hospitals $30 billion for certain inpatient and outpatient claims for cardiac medical devices (cardiac devices) potentially eligible for manufacturer credits. Previous Office of Inspector General reviews of hospitals’ compliance with Medicare billing requirements found that Medicare contractors overpaid hospitals for selected inpatient and outpatient claims because hospitals did not identify, obtain, or report manufacturer credits for replaced medical devices.¹

OBJECTIVE

Our objective was to determine whether payments that Medicare contractors for Jurisdiction E made to hospitals for selected inpatient and outpatient claims for replaced cardiac devices complied with Medicare requirements for reporting manufacturer credits.

BACKGROUND

The Medicare Program

Medicare provides health insurance for people aged 65 and over, people with disabilities, and people with permanent kidney disease. Medicare Part A provides inpatient hospital insurance benefits and coverage of extended care services for patients after hospital discharge, and Medicare Part B provides supplementary medical insurance for medical and other health services, including coverage of hospital outpatient services.

The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program. CMS pays Medicare claims through the Medicare contractor in each Medicare jurisdiction.

Medicare’s Inpatient Prospective Payment System

CMS pays hospital costs at predetermined rates for patient discharges under the inpatient prospective payment system (IPPS). The rates vary according to the Medicare Severity Diagnosis-Related Group (MS-DRG) to which a beneficiary’s stay is assigned. The MS-DRG payment is, with certain exceptions, intended to be payment in full to the hospital for all inpatient costs associated with the beneficiary’s stay.

Medicare’s Outpatient Prospective Payment System

CMS implemented an outpatient prospective payment system (OPPS), which is effective for services furnished on or after August 1, 2000. Under the OPPS, Medicare pays for hospital outpatient services on a rate-per-service basis that varies according to the assigned ambulatory

payment classification (APC). CMS uses Healthcare Common Procedure Coding System (HCPCS) codes and descriptors to identify and group the services within each APC group. All services and items within an APC group are comparable clinically and require comparable resources.

**Cardiac Medical Devices**

Common cardiac devices used to treat beneficiaries include defibrillators, pacemakers, and their associated electrical leads. These devices are implanted during either inpatient or outpatient procedures. Occasionally, devices may require replacement because of defects, recalls, battery depletions, or mechanical complications, which may be covered under manufacturer warranties.

**Manufacturer Credits and Payment Reductions for Replaced Medical Devices**

Device warranties vary among manufacturers, but a hospital will generally receive full or partial credit from a manufacturer for a medical device covered under warranty or replaced because of a defect or recall. Some manufacturers require that the hospital request the device credit. Other manufacturers automatically issue the credit if the device is returned and is under warranty or is determined to be defective. To obtain a credit, the hospital generally must send the replaced device back to the manufacturer within a specified time after the replacement procedure is performed. Most electrical leads for devices have lifetime warranties and could qualify for a full credit if the manufacturer verifies a lead malfunction.

Federal regulations generally require a Medicare payment reduction for the replacement of a beneficiary’s implanted device if a hospital receives a full or partial credit from the manufacturer for a medical device that is covered under warranty or replaced because of a defect or recall. Federal guidance specifies how hospitals must report these credits on Medicare claims for replaced devices.

**Responsibilities of Medicare Contractors**

CMS contracts with Medicare contractors to, among other things, process and pay claims submitted by hospitals, conduct reviews and audits, and safeguard against fraud and abuse. Medicare contractors must establish and maintain efficient and effective internal controls. These controls include automated data processing systems, which are intended to prevent increased program costs caused by incorrect or delayed payments.

**Palmetto GBA and Noridian Healthcare Solutions**

At the beginning of our audit period, Palmetto GBA, LLC (Palmetto), was the Medicare contractor for Jurisdiction E (which covers California, Hawaii, Nevada, American Samoa, Guam,

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2 HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

and Northern Mariana Islands). Effective September 2013, Noridian Healthcare Solutions, LLC (Noridian), became the Medicare contractor for Jurisdiction E.

**HOW WE CONDUCTED THIS REVIEW**

During our audit period (January 1, 2012, through December 31, 2014), the Medicare contractors for Jurisdiction E paid hospitals $3 billion for 54,936 inpatient and 44,310 outpatient cardiac device claims with certain MS-DRGs or HCPCS codes subject to Medicare requirements for reporting manufacturer credits. We reviewed a total of 191 claims with payments of $4,888,245 that were at risk for overpayment. These claims had dates of service during our audit period and consisted of 52 inpatient and 139 outpatient claims.

To identify recipients of replaced cardiac devices, we requested and received from three cardiac device manufacturers a listing of warranty credits issued to selected hospitals. We used computer matching, data mining, and other analytical techniques to identify claims at risk for noncompliance with Medicare billing requirements for reporting manufacturer credits. We evaluated compliance with selected billing requirements, but we did not use medical review to determine whether services were medically necessary.

Because Noridian assumed responsibility for Jurisdiction E claims formerly paid by Palmetto, we have addressed our findings and recommendations to Noridian for review and comment.

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

See Appendix A for the details of our scope and methodology.

**FINDINGS**

Payments that the Medicare contractors for Jurisdiction E made to hospitals for all 191 inpatient and outpatient claims for replaced cardiac devices did not comply with Medicare requirements for reporting manufacturer credits. The hospitals’ incorrect billing of these claims resulted in overpayments of $2,132,458 that the hospitals had not identified, refunded, or adjusted by the beginning of our audit.

For all 52 selected inpatient claims, hospitals received full manufacturer credits for replaced cardiac devices but did not adjust the claims with the proper condition and value codes to reduce payment as required. For all 139 selected outpatient claims, hospitals received full or partial credits for replaced cardiac devices but did not report the correct modifiers and reduce charges on the claims (2012 and 2013 claims) or did not adjust the claims with the proper condition and value codes to reduce payment as required (2014 claims).

Hospitals attributed the incorrect Medicare billings to inadequate policies and procedures for identifying and reporting manufacturer credits for replaced cardiac devices. Many hospitals
stated that they lacked internal controls to coordinate functions among various departments when credits were received (e.g., the department that receives the credit and the department that bills Medicare). Other hospitals stated that they did not have adequate policies and procedures to identify the receipt of credits or that they lacked an understanding of manufacturer warranties. During our audit period, the Medicare contractors provided limited guidance to hospitals on how they should report manufacturer credits for replaced medical devices. The Medicare contractors overpaid the hospitals because they had no specific controls to ensure that hospitals complied with Medicare requirements for reporting manufacturer credits.

**MANUFACTURER CREDITS FOR REPLACED CARDIAC DEVICES WERE NOT REPORTED ON INPATIENT CLAIMS**

**Federal Requirements**

Federal regulations require a reduction in the IPPS payment for the replacement of an implanted device if (1) the device is replaced without cost to the provider, (2) the provider receives full credit for the device cost, or (3) the provider receives a credit equal to 50 percent or more of the device cost (42 CFR § 412.89(a)).

The *CMS Medicare Claims Processing Manual* (the Manual) states that to bill correctly for a replacement device that was provided with a credit, a provider must code the Medicare claim with a combination of condition code 49 or 50 and value code FD (chapter 3, § 100.8).

**Hospitals Received Full Credits for Replaced Cardiac Devices but Did Not Adjust Inpatient Claims**

For all 52 selected inpatient claims, hospitals received full manufacturer credits for replaced cardiac devices but did not adjust the claims with the proper condition and value codes to reduce payment as required. For example, one hospital received a credit for an implantable cardioverter defibrillator but did not report condition code 49 (indicating replacement within the product life cycle) and value code FD (indicating a credit was received from the manufacturer for a replaced medical device) on the claim as required. As a result, the Medicare contractor paid the hospital $33,787 when it should have paid $14,837, resulting in an overpayment of $18,950. The hospital stated that the error was due to its lack of understanding of the manufacturer’s warranty.

As a result of the 52 errors, the Medicare contractors for Jurisdiction E paid hospitals $1,978,419 for inpatient claims when they should have paid $1,613,833, resulting in overpayments of $364,586.

**MANUFACTURER CREDITS FOR REPLACED CARDIAC DEVICES WERE NOT REPORTED ON OUTPATIENT CLAIMS**

**Federal Requirements**

Federal regulations require a reduction in the OPPS payment for the replacement of an implanted device if (1) the device is replaced without cost to the provider or the beneficiary, (2) the
provider receives full credit for the cost of the replaced device, or (3) the provider receives partial credit equal to or greater than 50 percent of the cost of the replacement device (42 CFR § 419.45(a)).

For services furnished on or after January 1, 2007, CMS requires the provider to report the modifier –FB and reduce charges on an outpatient claim that includes a procedure code for the insertion of a replacement device if the provider incurs no cost or receives full credit for the replaced device. In addition, CMS requires the provider to report the modifier –FC on an outpatient claim that includes a procedure code for the insertion of a replacement device if the provider receives a partial credit of 50 percent or more of the cost of a new replacement device (the Manual, chapter 4, § 61.3.3). For services furnished on or after January 1, 2014, CMS requires the provider to report a combination of condition code 49 or 50 and value code FD on an outpatient claim (the Manual, chapter 4, § 61.3.5).

Hospitals Received Full or Partial Credits for Replaced Cardiac Devices but Did Not Adjust Outpatient Claims

For all 139 selected outpatient claims, hospitals received full or partial manufacturer credits for replaced cardiac devices but did not report the correct modifiers and reduce charges on the claims (2012 and 2013 claims) or did not adjust the claims with the proper condition and value codes to reduce payment as required (2014 claims):

- For services provided before January 1, 2014, for 95 of the 139 outpatient claims, hospitals received full credits for replaced devices but did not report the –FB modifier and reduce charges on the claims. For an additional 2 of the 139 outpatient claims, hospitals received partial credits for replaced devices but did not report the –FC modifier on the claims.

- For services provided on or after January 1, 2014, for 42 of the 139 outpatient claims, hospitals received full manufacturer credits for replaced devices but did not adjust the claims with the proper condition and value codes to reduce payment as required.

The following illustrates examples of the hospitals’ billing errors:

- One hospital received a credit for an implantable cardioverter defibrillator but did not report modifier –FB and reduce charges on the claim as required. As a result, the Medicare contractor paid the hospital $26,500 when it should have paid $14,884, resulting in an overpayment of $11,616. The hospital stated that this error occurred because of inconsistent communication among staff of various departments involved with identifying and reconciling credits related to replaced cardiac devices.

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4 CMS provides guidance on how a provider should report no-cost and reduced-cost devices under the OPPS (CMS Transmittal 1103, dated November 3, 2006, and the Manual, chapter 4, § 61.3). If the provider receives a replacement device without cost from the manufacturer, the provider must report a charge of no more than $1 for the device.
• One hospital received a partial credit for an implantable pulse generator, or pacemaker, but did not report modifier –FC on the claim as required. As a result, the Medicare contractor paid the hospital $9,193 when it should have paid $5,376, resulting in an overpayment of $3,817. The hospital stated that this error occurred because it billed the claim before the credit was received and did not have clear policies and procedures for identifying and reporting manufacturer credits.

• One hospital received a credit for an electrical lead but did not report condition code 50 (indicating replacement for the known recall of a product) and value code FD (indicating a credit was received from the manufacturer for a replaced medical device) on the claim as required. As a result, the Medicare contractor paid the hospital $4,220 when it should have paid $2,518, resulting in an overpayment of $1,702. The hospital stated that this error occurred because it failed to apply the credit to the beneficiary’s account.

As a result of the 139 errors, the Medicare contractors for Jurisdiction E paid hospitals $2,909,826 for outpatient claims when they should have paid $1,141,954, resulting in overpayments of $1,767,872.

HOSPITALS LACKED ADEQUATE POLICIES AND PROCEDURES AND MEDICARE CONTRACTORS LACKED CONTROLS TO ENSURE COMPLIANCE WITH CREDIT-REPORTING REQUIREMENTS

Hospitals attributed the incorrect Medicare billings to inadequate policies and procedures for identifying and reporting manufacturer credits for replaced cardiac devices. Many hospitals stated that they lacked internal controls to coordinate functions among various departments when credits were received (e.g., the department that receives the credit and the department that bills Medicare). Other hospitals stated that they did not have adequate policies and procedures to identify the receipt of credits or that they lacked an understanding of manufacturer warranties.

During our audit period, the Medicare contractors provided limited guidance to hospitals on how they should report manufacturer credits for replaced medical devices. The Medicare contractors overpaid the hospitals because they had no specific controls to ensure that hospitals complied with Medicare requirements for reporting manufacturer credits.

RECOMMENDATIONS

We recommend that Noridian:

• recover the $2,132,458 in identified overpayments,

• use the results of this audit in its ongoing hospital education activities, and

• strengthen controls to ensure that hospitals comply with Medicare requirements for reporting manufacturer credits for replaced medical devices.
NORIDIAN COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Noridian concurred with all of our recommendations and provided information on actions that it had taken or planned to take to address our recommendations. Specifically, Noridian stated that it had (1) recovered more than $2 million in identified overpayments and would continue its efforts to recover the remaining overpayments (approximately $99,000), (2) provided education to hospitals related to changes in billing and reimbursement for medical device replacement and intended to post information on its Web site regarding Medicare requirements for reporting manufacturer credits for replaced medical devices, and (3) implemented claims processing controls through the Fiscal Intermediary Standard System to ensure that hospitals comply with Medicare’s credit-reporting requirements. Noridian’s comments are included in their entirety as Appendix B.

After reviewing Noridian’s comments, we concluded that Noridian’s education of hospitals and implementation of claims processing controls could potentially result in additional savings to Medicare.
APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

From January 1, 2012, through December 31, 2014, the Medicare contractors for Jurisdiction E paid hospitals $3 billion for 54,936 inpatient and 44,310 outpatient claims with certain MS-DRG or HCPCS codes related to the insertion of implantable cardiac devices (specifically, defibrillators, pacemakers, and associated electrical leads) subject to Medicare requirements for reporting manufacturer credits. We reviewed a total of 191 claims with payments of $4,888,245 that were at risk for overpayment. These claims had dates of service during our audit period and consisted of 52 inpatient and 139 outpatient claims.

We evaluated compliance with selected billing requirements, but we did not use medical review to determine whether services were medically necessary.

We did not review the overall internal control structure of the hospitals or the Medicare contractors because our objective did not require us to do so. Rather, we limited our review to (1) the hospitals’ internal controls to prevent incorrect billing of the selected claims and (2) the Medicare contractors’ internal controls to prevent overpayments of the selected claims. Our review allowed us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS’s National Claims History File, but we did not assess the completeness of the file.

We conducted our audit from April through December 2015 and performed fieldwork by contacting Noridian in Fargo, North Dakota, and 67 hospitals that received Medicare payments for the selected claims during our audit period.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- requested and received from three cardiac device manufacturers a listing of warranty credits issued to selected hospitals to identify recipients of replaced cardiac devices;
- matched those recipients to the Medicare enrollment database to identify Medicare recipients;
- used CMS’s National Claims History file to identify inpatient and outpatient claims billed with certain MS-DRG and HCPCS codes for which Medicare payments were made during our audit period;
• used computer matching, data mining, and other analytical techniques to identify claims at risk for noncompliance with Medicare billing requirements (i.e., claims that were not billed with the appropriate condition and value codes or modifiers for reporting manufacturer credits);

• selected 191 claims at risk of error, totaling $4,888,245, that the Medicare contractors paid to the 67 hospitals;

• reviewed available data from CMS’s Common Working File for the selected claims to determine whether the claims had been canceled or adjusted;

• requested that the hospitals conduct their own reviews of the selected claims to determine whether they correctly reported manufacturer credits for the replaced cardiac devices to Medicare;

• reviewed the hospitals’ determinations, itemized bills, and remittance advices to determine whether the manufacturer credits were reported correctly;

• calculated overpayment amounts in accordance with Federal requirements and Medicare payment procedures; and

• discussed the results of our review with Noridian officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.
January 13, 2016

Lori A. Ahlstrand, Regional Inspector General
Office of Inspector General – Office of Audit Services
90 7th Street, Suite 3-650
San Francisco, CA 94103

Dear Ms. Ahlstrand:

Noridian Healthcare Solutions, LLC (Noridian) appreciates the opportunity to comment on the Office of Inspector General’s (OIG) draft report entitled The Medicare Contractors for Jurisdiction E Overpaid Claims for Replaced Cardiac Medical Devices When Hospitals Had Not Reported Manufacturer Credits (A-09-15-02029). As noted in the report, responsibilities for the work reviewed in the audit transitioned from Palmetto GBA, LLC to Noridian in August 2013. Noridian assumes responsibility for all Jurisdiction E claims. Below are Noridian’s comments and responses to the OIG’s recommendations.

Noridian concurs with all of the recommendations outlined in this report.

OIG Recommendation: Noridian recover the $2,132,458 in identified overpayments.
Noridian Response: Noridian has reviewed the OIG provided spreadsheet and found that as of January 13, $2,033,721.52 has been collected on the overpayments identified. Demand letters were issued as appropriate and Noridian will continue debt collection activity on the remaining outstanding claims.

OIG Recommendation: Use the results of this audit in its ongoing hospital education activities.
Noridian Response: Noridian delivered education pertaining to changes in billing and reimbursement for medical device replacement for Jurisdiction E providers in the October 2015 Quarterly Release Training webinar. Noridian will also be posting an article or static page regarding Medicare requirements in reporting manufacturer credits for replaced medical devices by March 31, 2016.

OIG Recommendation: Strengthen controls to ensure that hospitals comply with Medicare requirements for reporting manufacturer credits for replaced medical devices.
Noridian Response: The Medicare Part A claims processing system, Fiscal Intermediary Standard System (FISS), has implemented controls to ensure that hospitals comply with Medicare requirements.

Nond1an Healthcare Solutions. LLC

A CMS Medicare Administrative Contractor
In summary, Noridian is aware of the concerns outlined in draft report A-09-15-02029 and is taking steps to address those concerns. We appreciate the opportunity to comment on this report and the recommendations. Should you have any additional questions on this response and Noridian’s actions, please contact me at (701) 277-2401 or through email at Paul.ODonnell@noridian.com.

Sincerely,

/Paul O’Donnell/

Paul O’Donnell
Senior Vice President and JE Project Manager

cc: Pamela Bragg, JE COR, CMS
Tom McGraw, CEO and President of Noridian Healthcare Solutions, LLC