Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF TUFTS MEDICAL CENTER CLAIMS THAT INCLUDED MEDICAL DEVICE REPLACEMENTS

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Office of Inspector General

http://oig.hhs.gov

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EXECUTIVE SUMMARY

Tufts Medical Center did not fully comply with Medicare requirements for billing inpatient and outpatient claims for replaced medical devices, resulting in net overpayments of at least $118,000 over more than 2 years.

WHY WE DID THIS REVIEW

This review is a followup of our prior report, *Medicare Compliance Review of Tufts Medical Center for Calendar Years 2009 and 2010*, which identified a high-risk area for incorrect billing of cardiac medical devices. Using data analysis techniques and medical device warranty credit information, we identified hospital claims for the replacement of defective medical devices that were at risk for noncompliance with Medicare billing requirements.

The objective of this review was to determine whether Tufts Medical Center (Tufts) complied with Medicare requirements for billing inpatient and outpatient services for replaced medical devices on selected claims.

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) pays inpatient hospital costs at predetermined rates for patient discharges. The rates vary according to the diagnosis-related group (DRG) to which a beneficiary's stay is assigned. The 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. CMS pays for hospital outpatient services on a rate-per-service basis that varies according to the assigned ambulatory payment classification.

Tufts, located in Boston, Massachusetts, is a 415-bed academic medical center.

Our audit covered $523,608 in Medicare payments to Tufts for 18 claims for replaced medical devices, consisting of 15 inpatient and 3 outpatient claims. These claims had dates of service in calendar years (CYs) 2012, 2013, or 2014 and included CY 2011 claims that received a manufacturer's credit in CY 2012.

WHAT WE FOUND

Tufts complied with Medicare billing requirements for 4 of the 18 inpatient and outpatient claims we reviewed. However, Tufts did not fully comply with Medicare requirements for the remaining 14 claims, resulting in net overpayments of $118,219 for CYs 2011 through 2014. Specifically, 12 inpatient claims had errors, resulting in net overpayments of $106,595, and 2 outpatient claims had errors, resulting in overpayments of $11,624. These errors occurred primarily because Tufts (1) staff had inadequate education on inpatient level-of-care criteria and lacked the documentation necessary to determine the appropriate level of service and (2) lacked the level of oversight and the coordination between departments to correctly report the device credits it received for warranteed or recalled medical devices.

WHAT WE RECOMMEND

We recommend that Tufts:

- refund to the Medicare contractor $118,219, consisting of $106,595 in net overpayments for 12 incorrectly billed inpatient claims and $11,624 in overpayments for 2 incorrectly billed outpatient claims;

- strengthen controls to ensure full compliance with Medicare requirements; and

- ensure that credits for medical devices subsequent to our audit period are correctly identified and reported.

TUFTS MEDICAL CENTER COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Tufts concurred with our findings and recommendations. Tufts stated that the inpatient admissions associated with our first finding were appropriate and medically necessary, but it concurred with our finding because it stated its claims did not "provide sufficient information to determine whether payment could be supported" for the level of care. Tufts stated that it has refunded the Medicare contractor for the overpayments we identified in our review and described its efforts to strengthen controls to ensure compliance with Medicare requirements, including the initiation of a taskforce to identify claim errors subsequent to our audit period.

We acknowledge Tufts' efforts to strengthen its controls to comply with Medicare requirements.

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INTRODUCTION

WHY WE DID THIS REVIEW

This review is a followup of our prior report, *Medicare Compliance Review of Tufts Medical Center for Calendar Years 2009 and 2010*, which identified a high-risk area for incorrect billing of cardiac medical devices.[1] Using data analysis techniques and medical device warranty credit information, we identified hospital claims for the replacement of defective medical devices that were at risk for noncompliance with Medicare billing requirements.[2]

OBJECTIVE

Our objective was to determine whether Tufts Medical Center (Tufts) complied with Medicare requirements for billing inpatient and outpatient services for replaced medical devices on selected claims.

BACKGROUND

The Medicare Program

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 contracts with Medicare contractors to, among other things, process and pay claims submitted by hospitals.

Hospital 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 diagnosis-related group (DRG) to which a beneficiary's stay is assigned and the severity level of the patient's diagnosis. The 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.

Hospital Outpatient Prospective Payment System

CMS implemented an outpatient prospective payment system (OPPS), which is effective for services furnished on or after August 1, 2000, for hospital outpatient services. Under the OPPS,

[1] *Medicare Compliance Review of Tufts Medical Center for Calendar Years 2009 and* 2010 (A-01-12-00503). Available online at http://oig.hhs.gov/oas/reports/region1/11200503.asp.

[2] For calendar years (CYs) 2010 through 2014, we issued 112 final reports to hospitals nationwide containing $9.9 million in overpayments for incorrectly reported medical device manufacturer warranty credits.

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.[3] All services and items within an APC group are comparable clinically and require comparable resources.

Medicare Requirements for Hospital Claims and Payments

Medicare payments may not be made for items and services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" (the Social Security Act (the Act), § 1862(a)(1)(A)). In addition, the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (§ 1833(e)).

Federal regulations state that the provider must furnish to the Medicare contractor sufficient information to determine whether payment is due and the amount of the payment (42 CFR § 424.5(a)(6)).

Federal regulations also state that payment to a provider is to be reduced by applicable credits as appropriate (42 CFR §§ 412.89 and 419.45).

The *Medicare Claims Processing Manual* (the Manual) requires providers to complete claims accurately so that Medicare contractors may process them correctly and promptly (Pub. No. 100-04, chapter 1, § 80.3.2.2). The Manual states that providers must use HCPCS codes for most outpatient services (chapter 23, § 20.3).

Tufts Medical Center

Tufts, located in Boston, Massachusetts, is a 415-bed academic medical center.

HOW WE CONDUCTED THIS REVIEW

We matched the warranty credits that medical device companies issued to Tufts for devices that were covered under warranty or replaced because of recalls during CYs 2012 through 2014 and identified claims that are at risk for noncompliance with Medicare billing requirements. Our audit covered $523,608 in Medicare payments to Tufts for 18 claims for replaced medical devices, consisting of 15 inpatient and 3 outpatient claims. These claims had dates of service in CYs 2012, 2013, or 2014 and included CY 2011 claims that received a manufacturer's credit in CY 2012.

We limited our review to 18 claims the hospital billed for replaced medical devices. We evaluated compliance with selected billing requirements but did not use medical review to determine whether the services were medically necessary. This report focuses on a selected risk

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

area and does not represent an overall assessment of all claims submitted by Tufts for Medicare reimbursement.

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

Appendix A contains the details of our scope and methodology.

FINDINGS

Tufts complied with Medicare billing requirements for 4 of the 18 inpatient and outpatient claims we reviewed. However, Tufts did not fully comply with Medicare requirements for the remaining 14 claims, resulting in net overpayments of $118,219 for CYs 2011 through 2014. Specifically, 12 inpatient claims had errors, resulting in net overpayments of $106,595, and 2 outpatient claims had errors, resulting in overpayments of $11,624. These errors occurred primarily because Tufts (1) staff had inadequate education on inpatient level-of-care criteria and lacked documentation necessary to determine the appropriate level of service and (2) lacked the level of oversight and the coordination between departments to correctly report the device credits it received for warranteed or recalled medical devices.

BILLING ERRORS ASSOCIATED WITH INPATIENT CLAIMS

Tufts incorrectly billed Medicare for 12 of 15 selected inpatient claims, which resulted in net overpayments of $106,595.[4]

Medical Device Claims Incorrectly Billed as Inpatient

Medicare payments may not be made for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" (the Act, §1862(a)(1)(A)).

For 4 of the 15 selected claims, Tufts incorrectly billed Medicare Part A for beneficiary stays that should have been billed as outpatient or outpatient with observation.[5] Tufts officials attributed the patient admission errors to inadequate education on inpatient level-of-care criteria

[4] "Billing errors associated with inpatient claims" in the amount of $106,595 is a combination of overpayments of $138,076 for "medical device claims incorrectly billed as inpatient" and $27,400 for "manufacturer credits for replaced medical devices not reported" less underpayments of ($24,500) for "manufacturer credit for replaced medical device incorrectly reported" and ($34,381) for **"**medical device claim incorrectly billed due to a coding error."

[5] One of the four claims incorrectly billed as inpatient also had a second type of error for a manufacturer credit for a replaced medical device not reported for CY 2013.

and the lack of documentation necessary to determine the appropriate level of service. As a result of these errors, Tufts received overpayments of $138,076.[6]

Manufacturer Credits for Replaced Medical Devices Not Reported

Federal regulations require reductions in the IPPS payments 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). The Manual states that to bill correctly for a replacement device that was provided with a credit, hospitals must code Medicare claims with a combination of condition code 49 or 50, along with value code "FD" (chapter 3, § 100.8).

For 6 of the 15 selected claims, Tufts received reportable medical device credits from manufacturers but did not adjust its inpatient claims with the appropriate value and condition codes to reduce the payments as required. (One claim had a date of service in CY 2011 with a manufacturer's credit received in CY 2012, three claims had dates of services in CY 2013, and two claims had dates of service in CY 2014.) Tufts officials stated that the errors occurred because Tufts lacked the level of oversight and coordination between departments to correctly report the device credits received for warranteed or recalled medical devices. As a result of these errors, Tufts received overpayments of $27,400.

Manufacturer Credit for Replaced Medical Device Incorrectly Reported

For 1 of the 15 selected claims, Tufts reported the FD value code for the incorrect amount creating an underpayment of $24,500. Tufts officials stated that the error occurred because they did not appropriately coordinate functions among various departments to ensure that it submitted the claim correctly. As a result of this error, Tufts received an underpayment of $24,500.

Medical Device Claim Incorrectly Billed Due to a Coding Error

For 1 of the 15 selected claims, Tufts reported the wrong DRG code resulting in an underpayment of $34,381. Tufts officials stated that the error occurred because Tufts did not appropriately coordinate functions among various departments to ensure that it submitted the claim correctly. As a result of this error, Tufts received an underpayment of $34,381.

[6] Tufts may be able to bill Medicare Part B for all services (except for services that specifically require an outpatient status) that would have been reasonable and necessary had the beneficiary been treated as a hospital outpatient rather than admitted as an inpatient. We were unable to determine the effect that billing Medicare Part B would have on the overpayment amount because these services had not been billed or adjudicated by the Medicare administrative contractor prior to the issuance of our draft report.

BILLING ERRORS ASSOCIATED WITH OUTPATIENT CLAIMS

Tufts incorrectly billed Medicare for two of the three selected outpatient claims, which resulted in overpayments of $11,624.

Manufacturer Credits for Replaced Medical Devices Not Reported

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). For services furnished on or after January 1, 2007, and before December 31, 2013, CMS requires the provider to report the modifier "FB" and reduced charges on a 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.[7] For services furnished after January 1, 2014, an "FD" value code must be reported; this replaces the previously required "FB" modifier.[8]

For two of the three claims that we reviewed, Tufts incorrectly billed Medicare for replaced devices:

- For one of the selected claims, Tufts received full credit for a replaced device, but did not report the FB modifier or reduce charges on its claim.

- For one of the selected claims, Tufts received full credit for a replaced device, but did not report the FD value code or reduce charges on its claim.

Tufts officials stated that the errors occurred because they did not appropriately coordinate functions among various departments to ensure that they submitted claims correctly. As a result of these errors, Tufts received overpayments of $11,624.

RECOMMENDATIONS

We recommend that Tufts:

- refund to the Medicare contractor $118,219, consisting of $106,595 in net overpayments for 12 incorrectly billed inpatient claims and $11,624 in overpayments for 2 incorrectly billed outpatient claims;

- strengthen controls to ensure full compliance with Medicare requirements; and

[7] 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).

[8] CMS no longer recognize in the OPPS the FB or FC modifiers to identify a device that is furnished without cost or with a full or partial credit (CMS guidance in Transmittal 2845, dated December 27, 2013, effective January 1, 2014).

- ensure that credits for medical devices subsequent to our audit period are correctly identified and reported.

TUFTS MEDICAL CENTER COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Tufts concurred with our findings and recommendations. Tufts stated that the inpatient admissions associated with our first finding were appropriate and medically necessary, but it concurred with our finding because it stated its claims did not "provide sufficient information to determine whether payment could be supported" for the level of care. Tufts stated that it has refunded the Medicare contractor for the overpayments we identified in our review and described its efforts to strengthen controls to ensure compliance with Medicare requirements, including the initiation of a taskforce to identify claim errors subsequent to our audit period.

We acknowledge Tufts' efforts to strengthen its controls to comply with Medicare requirements. Tufts comments are included in their entirety as Appendix B.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered $523,608 in Medicare payments to Tufts for 18 claims for replaced medical devices consisting of 15 inpatient and 3 outpatient claims. These claims had dates of service in CYs 2012, 2013, or 2014 and included CY 2011 claims that received a manufacturer's credit in CY 2012.

We limited our review of Tufts' internal controls to those applicable to the inpatient and outpatient area of review because our objective did not require an understanding of all internal controls over the submission and processing of claims. This report focuses on the selected risk area and does not represent an overall assessment of all claims submitted by Tufts for Medicare reimbursement.

We conducted our review from June through October 2015.

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 Tufts to identify recipients of devices that prematurely failed;
- matched those recipients to the Medicare enrollment database to identify Medicare recipients;
- extracted Tufts' inpatient and outpatient paid claim data from CMS's National Claims History file for CYs 2012 through 2014;
- used data analysis techniques to identify claims potentially at risk for noncompliance with selected Medicare billing requirements;
- selected a judgmental sample of 18 claims (15 inpatient and 3 outpatient) for detailed review;
- reviewed available data from CMS's Common Working File for the selected claims to determine whether the claims had been cancelled or adjusted;
- reviewed Tufts' medical records to determine whether inpatient claims should have been billed as outpatient claims;
- requested that Tufts conduct its own review of the selected claims to determine whether the services were billed correctly;

- discussed the incorrectly billed claims with Tufts personnel to determine the underlying causes of noncompliance with Medicare requirements;

- calculated the correct payments for those claims requiring adjustments; and

- discussed the results of our review with Tufts 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.

APPENDIX B: TUFTS MEDICAL CENTER COMMENTS

The principal teaching hospital for Tufts University School of Medicine

Tufts Medical Center

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March 10, 2016

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REPORT NUMBER: A-01-15-00503

Dear Mr. Lamir:

I am writing in receipt of the draft report from your office entitled *Review of Tufts Medical Center Claims That Included Medical Device Replacements.* Tufts Medical Center is committed to maintaining principles of ethical business conduct and compliance with the rules and regulations governing Federal health care programs and we appreciate the opportunity to respond.

The following is our response to the report findings and recommendations.

Finding for Billing Errors Associated with Inpatient Claims

#1) Medical Device Claims Incorrectly Billed as Inpatient
Tufts Medical Center concurs that four Inpatient claims failed to provide sufficient information to determine whether payment could be supported for Inpatient level of care. However, we believe that the clinical determination by the physician was appropriate and medically necessary based on recommendation of the Heart Rhythm Society. The decision to admit a patient is a complex medical judgment which must account for a number of factors. Therefore, we believe that each of the 4 inpatient admissions did meet clinical requirement for services, but due to the lack of physician documentation for the Inpatient stay, we will return payment.

#2) Manufacturer Credits for Replaced Medical Devices Not Reported
Tufts Medical Center agrees with the OIG findings. A new medical device policy has been created and a new tracking tool has been initiated to more clearly define each department's role in the communication process when a replacement of a device occurs. A monitoring process was added to our billing system to flag a replacement potential claim to ensure that the claim is reviewed and resubmitted for correction to ensure that duplicate reimbursement was not received.

#3) Manufacturer Credit for Replaced Medical Device Incorrectly Reported
Tufts Medical Center agrees with the OIG findings. Our response is the same for #2.

#4) Medical Device Claim Incorrectly Billed Due to a Coding Error
Tufts Medical Center agrees with the OIG findings. Our response is the same for #2.

Finding for Billing Errors Associated with Outpatient Claims

#1) Manufacturer Credits for Replaced Medical Devices Not Reported
Tufts Medical Center agrees with the OIG findings. Our response is the same for #2 in Finding for Billing Errors Associated with Inpatient Claims.

OIG Recommendations

The OIG has made the following three recommendations:

- Refund to the Medicare Contractor $118,219, consisting of $106,595 in net overpayments for 12 incorrectly billed inpatient claims and $11,624 in overpayments for 2 incorrectly billed outpatient claims.
- Strengthen controls to ensure full compliance with Medicare requirements; and
- Ensure that credits for medical devices subsequent to our audit period are correctly identified and reported.

We note that the OIG's findings include both instances of Medicare overpayment and underpayment of claims. Tufts Medical Center concurs with all findings where medical device billing errors occurred and has already refunded the Medicare contractor for those claims via the submission of corrected claims in the billing system. To the extent that Tufts Medical Center concurs with the finding of incorrect billing as Inpatient claims, we also attribute the billing errors to communication gaps that existed during the review period. We have certainly developed a more comprehensive utilization management process to include a concurrent review of the medical necessity of Medicare admissions. Level of care determinations remain a focus for our physicians and utilization review staff. The complex reporting requirements and Medicare guidance which has undergone multiple revisions has contributed to the potential for errors.

With respect to the second recommendation, Tufts Medical Center has a continuous process to implement improvements to our internal controls, policies and procedures, education strategies and the internal auditing and monitoring of our activities related to Medicare compliance. The OIG audit provided us with an opportunity to further enhance our compliance efforts and to increase system monitoring. We continue to work with relevant staff to understand the complexities associated with the Medicare device credit reporting.

With respect to the third recommendation, Tufts Medical Center has initiated a task force to analyze all medical device replacements that have occurred since the audit period and have systematically identified any other issues of claims errors. Any medical devices that qualified for repayment to a Medicare contractor had a corrected claim submitted to resolve payment issues.

Nothing herein should be deemed an admission by Tufts Medical Center of any regulatory violations and Tufts Medical Center reserves the right to appeal any and all claims denied by the Medicare Administrative Contractors.

Finally, we appreciate the professionalism, cooperation and collegiality of the OIG Auditors during the review. If you have additional concerns in regards to our actions taken, or would like to obtain additional information, please contact me at (617) 636-9229 or via email at cmerski@tuftsmedicalcenter.org.

Sincerely,

Cara L. Merski
Chief Compliance and Privacy Officer
Tufts Medical Center

CC:
Michael Wagner, CEO, Tufts Medical Center
Saul Weingart, CMO, Tufts Medical Center