The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

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The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

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August 21, 2013

Report Number: A-06-12-00034

Mr. Robert Hatcher  
Chief Financial Officer  
Advisor to Compliance  
1415 Tulane Avenue  
New Orleans, LA  70112

Dear Mr. Hatcher:

Enclosed is the U.S. Department of Health & Human Services (HHS), Office of Inspector General (OIG), final report entitled Medicare Compliance Review of Tulane Medical Center of New Orleans for Calendar Years 2010 and 2011. We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at https://oig.hhs.gov.

If you have any questions or comments about this report, please do not hesitate to call me, or contact Michelle Richards, Audit Manager, at (214) 767-9202 or through email at Michelle.Richards@oig.hhs.gov. Please refer to report number A-06-12-00034 in all correspondence.

Sincerely,

/Patricia Wheeler/
Regional Inspector General  
for Audit Services

Enclosure
Direct Reply to HHS Action Official:

Nanette Foster Reilly  
Consortium Administrator  
Consortium for Financial Management & Fee for Service Operations  
Centers for Medicare & Medicaid Services  
601 East 12th Street, Room 355  
Kansas City, MO 64106
EXECUTIVE SUMMARY

BACKGROUND

Title XVIII of the Social Security Act (the Act) established the Medicare program, which provides health insurance coverage to people aged 65 and over, people with disabilities, and people with end-stage renal disease. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program.

Section 1886(d) of the Act established the inpatient prospective payment system (IPPS) for inpatient hospital services. Under the IPPS, CMS pays 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 implemented an outpatient prospective payment system (OPPS) for hospital outpatient services, as mandated by the Balanced Budget Act of 1997, P.L. No. 105-33, and the Medicare, Medicaid, and SCHIP (State Children’s Health Insurance Program) Balanced Budget Refinement Act of 1999, P.L. No. 106-113. Under the OPPS, Medicare pays for hospital outpatient services on a rate-per-service basis that varies according to the assigned ambulatory payment classification.

Prior Office of Inspector General (OIG) audits, investigations, and inspections identified certain hospital claims that are at risk for noncompliance with Medicare billing requirements. OIG identified these types of hospital claims using computer matching, data mining, and analysis techniques. This review is part of a series of OIG reviews of Medicare payments to hospitals for selected claims for inpatient and outpatient services.

Tulane Medical Center of New Orleans (the Hospital) is a 354-bed hospital located in New Orleans, Louisiana. Medicare paid the Hospital approximately $113 million for 5,874 inpatient and 89,428 outpatient claims for services provided to beneficiaries during calendar years 2010 and 2011 (audit period) based on CMS’s National Claims History data.

Our audit covered $1,517,875 in Medicare payments to the Hospital for 125 claims that we judgmentally selected as potentially at risk for billing errors, consisting of 79 inpatient and 46 outpatient claims.

OBJECTIVE

Our objective was to determine whether the Hospital complied with Medicare requirements for billing inpatient and outpatient services on selected claims.

SUMMARY OF FINDINGS

The Hospital complied with Medicare billing requirements for 64 of the 125 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare
billing requirements for the remaining 61 claims, resulting in overpayments of $523,928 for the audit period. Specifically, 35 inpatient claims had billing errors, resulting in overpayments of $476,010, and 26 outpatient claims had billing errors, resulting in overpayments of $47,918. These errors occurred primarily because the Hospital did not have adequate controls to prevent incorrect billing of Medicare claims within the selected risk areas that contained errors.

RECOMMENDATIONS

We recommend that the Hospital:

- refund to the Medicare contractor $523,928, consisting of $476,010 in overpayments for 35 incorrectly billed inpatient claims and $47,918 in overpayments for 26 incorrectly billed outpatient claims, and

- strengthen controls to ensure full compliance with Medicare requirements.

TULANE MEDICAL CENTER COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the Hospital disagreed with our findings and recommendations for 20 inpatient claims that it should have billed as outpatient or outpatient with observation services and the 26 outpatient Lupron claims that it billed using an incorrect HCPCS code. The Hospital agreed with our findings and recommendations for the remaining claims and described actions it has taken to strengthen its internal controls to ensure full compliance with Medicare requirements. The Hospital stated that it is committed to operating in compliance with applicable rules and regulations and will intensify its efforts to improve its internal controls. After reviewing the Hospital’s comments, we maintain that our findings and recommendations are valid.
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INTRODUCTION

BACKGROUND

Title XVIII of the Social Security Act (the Act) established the Medicare program, which provides health insurance coverage to people aged 65 and over, people with disabilities, and people with end-stage renal disease. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program. Medicare Part A provides inpatient hospital insurance benefits and coverage of extended care services for patients after hospital discharge. Medicare Part B provides supplementary medical insurance for medical and other health services, including coverage of hospital outpatient services.

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

Hospital Inpatient Prospective Payment System

Section 1886(d) of the Act established the inpatient prospective payment system (IPPS) for inpatient hospital services. Under the IPPS, CMS pays 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 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) for hospital outpatient services, as mandated by the Balanced Budget Act of 1997, P.L. No. 105-33, and the Medicare, Medicaid, and SCHIP (State Children’s Health Insurance Program) Balanced Budget Refinement Act of 1999, P.L. No. 106-113. The OPPS 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.

Hospital Payments at Risk for Incorrect Billing

Prior Office of Inspector General (OIG) audits, investigations, and inspections identified certain hospital claims that are at risk for noncompliance with Medicare billing requirements. OIG identified these types of hospital claims using computer matching, data mining, and analysis techniques. Examples of the types of claims at risk for noncompliance included the following:

---

1 In 2009, SCHIP was formally redesignated as the Children’s Health Insurance Program.

2 HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.
• inpatient short stays,
• inpatient claims paid in excess of charges,
• inpatient claims billed with high-severity-level DRG codes,
• outpatient billing for Lupron injections, and
• outpatient claims billed with modifier 59.

For the purposes of this report, we refer to these areas at risk for incorrect billing as “risk areas.”

This review is part of a series of OIG reviews of Medicare payments to hospitals for selected claims for inpatient and outpatient services.

**Medicare Requirements for Hospital Claims and Payments**

Section 1862(a)(1)(A) of the Act states that 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.” In addition, § 1833(e) of the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider.

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

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

**Tulane Medical Center of New Orleans**

Tulane Medical Center of New Orleans (the Hospital) is a 354-bed hospital located in New Orleans, Louisiana. Medicare paid the Hospital approximately $113 million for 5,874 inpatient and 89,428 outpatient claims for services provided to beneficiaries during calendar years 2010 and 2011 (audit period) based on CMS’s National Claims History data.

**OBJECTIVE, SCOPE, AND METHODOLOGY**

**Objective**

Our objective was to determine whether the Hospital complied with Medicare requirements for billing inpatient and outpatient services on selected claims.
Scope

Our audit covered $1,517,875 in Medicare payments to the Hospital for 125 claims that we judgmentally selected as potentially at risk for billing errors. These 125 claims consisted of 79 inpatient and 46 outpatient claims and had dates of service during the audit period.

We focused our review on the risk areas that we had identified as a result of prior OIG reviews at other hospitals. We evaluated compliance with selected billing requirements and subjected 31 claims to focused medical review to determine whether the services were medically necessary.

We limited our review of the Hospital’s internal controls to those applicable to the inpatient and outpatient areas of review because our objective did not require an understanding of all internal controls over the submission and processing of claims. We established reasonable assurance of the authenticity and accuracy of the data obtained from the National Claims History file, but we did not assess the completeness of the file.

This report focuses on selected risk areas and does not represent an overall assessment of all claims submitted by the Hospital for Medicare reimbursement.

Our fieldwork included contacting the Hospital, located in New Orleans, Louisiana, from June 2012 through May 2013.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted the Hospital’s inpatient and outpatient paid claim data from CMS’s National Claims History file for the audit period;
- used computer matching, data mining, and analysis techniques to identify claims potentially at risk for noncompliance with selected Medicare billing requirements;
- judgmentally selected 125 claims (79 inpatient and 46 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 the itemized bills and medical record documentation provided by the Hospital to support the selected claims;
- requested that the Hospital conduct its own review of the selected claims to determine whether the services were billed correctly;
• used an independent contractor to determine whether 31 selected claims met medical necessity requirements;

• discussed the incorrectly billed claims with Hospital 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 Hospital 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.

FINDINGS AND RECOMMENDATIONS

The Hospital complied with Medicare billing requirements for 64 of the 125 selected inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 61 claims, resulting in overpayments of $523,928 for the audit period. Specifically, 35 inpatient claims had billing errors resulting in overpayments of $476,010, and 26 outpatient claims had billing errors resulting in overpayments of $47,918. These errors occurred primarily because the Hospital did not have adequate controls to prevent incorrect billing of Medicare claims within the selected risk areas that contained errors. For the results of our review by risk area, see Appendix A.

BILLING ERRORS ASSOCIATED WITH INPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 35 of the 79 selected inpatient claims, which resulted in overpayments of $476,010.

Incorrectly Billed as Inpatient

Section 1862(a)(1)(A) of the Act states that 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.”

For 31 of the 79 selected claims, the Hospital incorrectly billed Medicare Part A for beneficiary stays that should have been billed as outpatient or outpatient with observation services. Hospital officials attributed the errors to a failure to correctly apply level-of-care criteria, a failure to obtain a higher level second review or to communicate the determination, and incomplete
physician documentation. As a result of these errors, the Hospital received overpayments of $417,750.3

Incorrectly Billed Diagnosis-Related Group Codes

Section 1862(a)(1)(A) of the Act states that 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.” In addition, the Manual, chapter 1, § 80.3.2.2, states: “In order to be processed correctly and promptly, a bill must be completed accurately.”

For 4 of the 79 selected inpatient claims, the Hospital billed Medicare for incorrect DRG codes. Hospital officials stated that these errors occurred because Hospital staff misapplied coding guidelines or failed to ask the physician for clarification. As a result of these errors, the Hospital received overpayments of $58,260.

BILLING ERRORS ASSOCIATED WITH OUTPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 26 of the 46 selected outpatient claims, which resulted in overpayments of $47,918.

Incorrectly Billed Lupron Injections

Section 1862(a)(1)(A) of the Act states that 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.” In addition, § 1833(e) of the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider.

Lupron is a drug commonly used to treat certain cancers. The U.S. Food and Drug Administration approved different dosages of Lupron for the treatment of different diagnoses. Lupron is used to treat (1) uterine disorders, in doses of 3.75 mg once a month or 11.25 mg once every 3 months (HCPCS code J1950), and (2) prostate cancer, in doses of 7.5 mg once a month, 22.5 mg once every 3 months, or 30 mg once every 4 months (HCPCS code J9217). A Local Coverage Determination (LCD) addressing Lupron billing4 states that HCPCS code J1950 is not to be used for prostate cancer.

3 The Hospital 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 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 report.

4 Pinnacle Business Solutions, Inc., issued the LCD, “Luteinizing Hormone-Releasing Hormone Analogs for the Treatment of Malignant Neoplasm of the Prostate, #AC-07-004 V9 (Rev. Eff. 09/15/2008).” An LCD is a determination by a Medicare contractor on whether an item or service is covered by Medicare. Pinnacle was the Medicare contractor for Louisiana during our audit period.
For all of the 26 selected claims for Lupron injections, the Hospital incorrectly billed HCPCS code J1950 for the treatment of prostate cancer. Hospital officials stated that the LCD applied only to physician services; therefore, the Hospital’s existing controls did not adequately prevent incorrect billing of Medicare claims. As a result of these errors, the Hospital received overpayments of $47,918.

RECOMMENDATIONS

We recommend that the Hospital:

- refund to the Medicare contractor $523,928, consisting of $476,010 in overpayments for 35 incorrectly billed inpatient claims and $47,918 in overpayments for 26 incorrectly billed outpatient claims, and
- strengthen controls to ensure full compliance with Medicare requirements.

TULANE MEDICAL CENTER COMMENTS

In written comments on our draft report, the Hospital disagreed with our findings and recommendations for 20 inpatient claims that it should have billed as outpatient or outpatient with observation services. The Hospital stated that it acted in accordance with Medicare policy because it provided care and treated the patients as ordered by their physicians and because of the clinical presentation of the patient at the time of service.

The Hospital also disagreed with our findings and recommendations on the 26 outpatient Lupron claims that it billed using an incorrect HCPCS code. The Hospital stated that long-standing CMS guidance provides that when there are HCPCS codes for multiple doses of the same drug, the HCPCS code with the lowest dose may be used for billing purposes. The hospital further stated that the LCD referenced in the draft report did not pertain to it; that LCD applies to carrier-processed physician office claims, not to fiscal intermediary-processed hospital outpatient claims billed under Part A. The hospital added that, without specific CMS instruction to the contrary, the Hospital billed at the lowest dosage HCPCS code available (HCPCS J1950).

The Hospital agreed with our findings and recommendations for the remaining claims and described actions it has taken to strengthen its internal controls to ensure full compliance with Medicare requirements. The Hospital stated that it is committed to operating in compliance with applicable rules and regulations and will intensify its efforts to improve its internal controls.

The Hospital’s comments are included in their entirety as Appendix B.
OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing the Hospital’s comments, we maintain that our findings and recommendations are valid.

For the 20 inpatient claims that that Hospital should have billed as outpatient or outpatient with observation services, we used an independent medical review contractor to determine whether the claims met inpatient medical necessity requirements. The contractor examined all of the medical records and documentation the Hospital submitted and carefully considered this information to determine whether it billed the claims according to Medicare requirements. Based on the contractor’s conclusions, we determined that the 20 inpatient claims should have been billed as outpatient or outpatient with observation services.

For the 26 outpatient claims for Lupron injections that the Hospital billed using an incorrect HCPCS code, we maintain that the Hospital’s use of multiple units of HCPCS code J1950 (3.75mg of Lupron) to bill for the single 3-month doses of 22.5mg that it administered to advanced prostate cancer patients was improper because code J9217 applies to 22.5mg doses. Since 1995, the FDA has approved the Lupron 3-month dose of 22.5mg solely for advanced prostate cancer, and, since 2001, the FDA has approved the 3.75mg dose specifically for uterine disorders. Pinnacle was the Part A fiscal intermediary and Part B carrier for Louisiana during our audit period. Hospital outpatient claims are paid under Part B. Thus, Pinnacle’s LCD stating that HCPCS code J1950 is not to be used for prostate cancer would apply to all Part B claims paid by Pinnacle.

We continue to recommend that the Hospital refund the full $523,928 in Medicare overpayments.
APPENDIXES
### APPENDIX A: RESULTS OF REVIEW BY RISK AREA

<table>
<thead>
<tr>
<th>Risk Area</th>
<th>Selected Claims</th>
<th>Value Of Selected Claims</th>
<th>Claims With Over-payments</th>
<th>Value Of Over-payments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inpatient</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Short Stays</td>
<td>40</td>
<td>$588,527</td>
<td>27</td>
<td>$350,890</td>
</tr>
<tr>
<td>Claims Paid in Excess of Charges</td>
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<td>320,627</td>
<td>7</td>
<td>97,881</td>
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<tr>
<td>Claims Billed With High-Severity-Level Diagnosis-Related Group Codes</td>
<td>20</td>
<td>484,724</td>
<td>1</td>
<td>27,239</td>
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<td><strong>Inpatient Totals</strong></td>
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<td>$1,393,878</td>
<td>35</td>
<td>$476,010</td>
</tr>
<tr>
<td><strong>Outpatient</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lupron Injections</td>
<td>26</td>
<td>$63,079</td>
<td>26</td>
<td>$47,918</td>
</tr>
<tr>
<td>Claims Billed With Modifier -59</td>
<td>20</td>
<td>60,918</td>
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<td>0</td>
</tr>
<tr>
<td><strong>Outpatient Totals</strong></td>
<td>46</td>
<td>$123,997</td>
<td>26</td>
<td>$47,918</td>
</tr>
<tr>
<td><strong>Inpatient and Outpatient Totals</strong></td>
<td>125</td>
<td>$1,517,875</td>
<td>61</td>
<td>$523,928</td>
</tr>
</tbody>
</table>

Notice: The table above illustrates the results of our review by risk area. In it, we have organized inpatient and outpatient claims by the risk areas we reviewed. However, we have organized this report’s findings by the types of billing errors we found at Tulane Medical Center. Because we have organized the information differently, the information in the individual risk areas in this table does not match precisely with this report’s findings.
July 25, 2013

BY Federal Express and Electronic Mail

Patricia Wheeler
Regional Inspector General for Audit Services
Office of Inspector General
Office of Audit Services, Region VI
1100 Commerce Street, Room 632
Dallas, Texas 75242

Re: Response to the Draft Report regarding the Medicare Compliance Review of Tulane Medical Center of New Orleans, Report Number: A-06-12-00034

Dear Ms. Wheeler:

Tulane Medical Center ("Tulane" or "Hospital") is in receipt of the draft report from the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") (A-06-12-00034), dated June 4, 2013, entitled "Medicare Compliance Review of Tulane Medical Center of New Orleans for Calendar Years 2010 and 2011" (referred to herein as "Draft Report"). As permitted by the terms of the Draft Report, this letter sets forth the Hospital’s objections to the OIG’s findings with respect to both the inpatient and outpatient claims at issue; and (2) the OIG's recommendation that the Hospital refund to the Medicare contractor a total of $523,928 in "overpayments."

I. Background

The OIG did not audit Tulane due to any perceived improper billing or compliance practices. Rather, the OIG selected Tulane as part of an ongoing national auditing initiative focused on certain risk areas for hospitals across the country. Indeed, as of the date of this letter, the OIG’s national initiative has resulted in the publication of Medicare Compliance reports relating to 61 hospitals in 24 states, the District of Columbia, and Puerto Rico.1

In this case, the OIG’s audit considered five risk areas ("Risk Areas"): (1) inpatient

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1 Tulane Medical Center is a 348-bed acute care hospital located in New Orleans, Louisiana.
claims for "short stays", (2) inpatient claims paid in excess of charges, (3) inpatient claims with high-severity diagnosis-related group ("DRG") codes, (4) outpatient claims for Lupron injections and (5) outpatient claims with modifier 59.

The audit of Tulane covered 125 claims involving one or more of the Risk Areas with dates of service in calendar years 2010-2011 ("Audit Period"), selected by the OIG as potentially at risk for billing errors. After the OIG judgmentally selected the sample of 125 claims (representing $1,517,875 in Medicare reimbursement), the claims were subject to a substantive review. Of the 125 claims, there were 79 inpatient claims: 40 short stays, 19 claims paid in excess of charges and 20 high-severity level DRG codes. The remaining forty-six (46) outpatient claims included: 26 Lupron injection claims and 20 claims billed with modifier 59. Of the 125 claim sample, the OIG subjected 31 to focused medical review through an OIG contractor. The OIG also asked the Hospital to self-evaluate claims.

II. Draft Report Findings

At the conclusion of the OIG’s review, it found that Tulane complied with Medicare billing requirements during the Audit Period for 64 of the 125 judgmentally selected claims. The OIG concluded that 61 claims of the 125 were allegedly billed in error, for a total alleged overpayment of $523,928 — a claims error rate of 49 percent, but a financial error rate of 34.5 percent.

The more specific findings break down as follows:

- With regard to the 79 inpatient claims, the OIG identified 35 alleged erroneous claims in two categories: (1) inpatient claims the Hospital billed Medicare Part A for beneficiary stays that the OIG claims should have been billed as outpatient or outpatient with observation services (hereinafter referred to as "Short Stays") and (2) claims the OIG identified as billed under the wrong DRG code.

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3 It is the Hospital’s understanding that a “short stay” for purposes of the Audit included a claim with an admission and discharge on the same calendar day and a claim in which discharge occurred on the day immediately following the day of admission.
5 Despite Tulane’s request for information and detail, the OIG has not explained why it chose to use a judgmentally selected sample size of 125 claims.
6 Id. at Appendix.
7 Id. at 3.
8 Id. at 4.
9 The OIG notes in the Draft Report Appendix that certain claims were reviewed based on a specific Risk Area, but the OIG’s findings are organized by type of billing error. Thus, a claim that was judgmentally selected based on one Risk Area, such as high-severity-level DRG, may be included in the OIG’s findings section related to Short Stays.
- 31 allegedly erroneous claims, to which OIG ascribed an alleged overpayment value of $417,750, were for Short Stays that the OIG contends should have been billed as outpatient stays.\textsuperscript{10}
- The OIG identified four allegedly erroneous claims related to incorrect DRG codes, to which it ascribed an alleged overpayment value of $58,260.\textsuperscript{11}
- With regard to the 46 outpatient claims, the OIG identified 26 alleged erroneous claims for Lupron injections, to which it ascribed an alleged overpayment value of $47,918. The OIG did not identify any errors associated with claims billed with modifier 59.\textsuperscript{12}

The OIG proceeds to recommend that Tulane refund $523,928 in Medicare overpayments. It also recommends that the Hospital "strengthen controls to ensure full compliance with Medicare requirements."\textsuperscript{13} For the reasons set forth below, the Hospital takes strong exception to these recommendations.

III. Tulane’s Response to the Draft Report

A. Tulane contests numerous substantive findings in the Draft Report with respect to inpatient claims

Specifically, the OIG concluded that 35 inpatient claims were billed incorrectly and these were in two categories: (1) Short Stays and (2) incorrect DRG codes.

Tulane respectfully disagrees with the OIG with regard to 20 of these 35 claims on the clinical merits, or on over half of the OIG’s conclusions. Tulane had these claims re-reviewed by independent, nationally recognized, third party reviewers who are physician experts in Medicare rules and regulations. These independent physician experts concluded that, on the merits, Tulane billed for the proper setting of care in 20 of the alleged 31 cited errors with respect to Short Stay claims. Thus, only 11 (not 31) of the Short Stay claims may have been billed in error.\textsuperscript{14}

Tulane respectfully submits that, despite the OIG’s contention, Tulane did have "a reasonable basis for assuming payment was correct" for the 20 Short Stay claims because it complied with the Medicare Benefit Policy Manual ("MBPM"), Ch. 1, § 10. Specifically, the MBPM provides that "a patient is considered an inpatient if formally admitted as an inpatient

\textsuperscript{10} Draft Report, at 4.
\textsuperscript{11} Id. at 5.
\textsuperscript{12} Id. at 5-6.
\textsuperscript{13} Id. at 6.
\textsuperscript{14} These claims are Sample Numbers: IP Paid-Charges # 2, 7, 8; and Short Stays # 5, 14, 17, 25, 28, 30, 39, and 40.
with the expectation that he or she will remain at least overnight and occupy a bed even though it later develops that the patient can be discharged or transferred to another hospital and not actually use a hospital bed overnight. Thus, as long as there is an "expectation" of an overnight stay, whether the patient is — in fact — discharged after six, 12 or 18 hours (for example) is irrelevant: the patient was properly treated as a inpatient.

Moreover:

The physician or other practitioner responsible for a patient's care at the hospital is also responsible for deciding whether the patient should be admitted as an inpatient... the decision to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of factors, including the patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting.

In other words, there should be deference afforded to the patient's physician and this critical, complex medical decision should not be summarily second-guessed by the OIG after-the-fact. Given that Tulane provided care and treated the patient in the status as ordered by his/her physician, and given the clinical presentation of the patient at the time of service, Tulane submits that it acted in accordance with Medicare policy, as further confirmed by the results of the independent third party physician review of the cases. Thus, Tulane contends that there is a lack of evidence to support the OIG's claim that these 20 Short Stay claims were incorrectly billed as inpatient, and therefore they do not constitute an "overpayment."

With regard to DRG coding issues, Tulane concedes to OIG's finding that four claims were billed in error. The incorrect coding occurred as a result of misapplication of the coding guidelines. The findings from the Draft Report were reviewed with the Hospital Coding Team and additional education was provided. The Hospital continues to have processes in place to provide ongoing auditing, monitoring, and feedback of the coding performed in order to minimize and eliminate errors, as well as to identify opportunities for improvement. Timely feedback and education is consistently provided to all of the coders.

B. Tulane contests substantive findings in the Draft Report with respect to Lupron injection outpatient claims

Specifically, the OIG concluded that 26 outpatient claims for Lupron injections were billed incorrectly. Tulane respectfully challenges the OIG's position with respect to all 26 of

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15 Medicare Benefit Policy Manual ("MBPM"), Ch. 1, § 10.
16 Id.
17 These claims are Sample Numbers: IP High Severity DRG # 2; IP Paid>Charges # 1, 19; and Short Stay # 35.
these claims on the clinical merits, or on one hundred percent of the OIG’s conclusions. Tulane submits that the OIG did not apply the correct coverage criteria, applicable during the Audit Period (2010 - 2011), when determining that the claims were erroneously billed.

The OIG report indicates that "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'" and that "the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider." With respect to the 26 claims identified by the OIG for treatment of prostate cancer, Hospital unequivocally asserts that they were billed correctly, using J1950, Leuprolide injection, per 3.75 mg, based upon the following:

- **Long-standing CMS guidance provides that when HCPCS codes exist for multiple doses of the same drug, it is appropriate to use the HCPCS code with the lowest dose for billing purposes.**
  - Since 2000, CMS has indicated that the APC payment amount for drugs and biologicals is established at the lowest dosage level.
  - Between 2000 and 2008, the CMS Outpatient Prospective Payment System ("OPPS") generally recognized only the HCPCS code for the lowest available administrative dose of a drug when multiple HCPCS codes existed for the drug. "In general, OPPS recognizes the lowest available administrative dose of a drug if multiple HCPCS codes exist for the drug." Without specific CMS instruction to the contrary, Hospital billed at the lowest dosage HCPCS code available, namely HCPCS J1950.
  - In fact, in the most recently published OPPS Proposed Rule for 2014, CMS states that "in consideration of CMS' previous policy that generally recognized only the lowest dosage HCPCS code for a drug or biological for OPPS payment", CMS continues to find that not requiring hospitals to report all drug and biological HCPCS codes "allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code."

- **The Local Coverage Determination ("LCD") referenced by the OIG in the Draft Report, AC-07-004 V9 (Rev. Eff. 09/15/2008) was issued by Pinnacle Medicare Services (PBSI) [00528]- LA. However, the Contractor Type listed is "Carrier" indicating that the LCD applies only to "Carrier" processed claims, i.e.,

16 These claims are Sample Numbers: Lupron Injections # 1 through 26.
19 *Draft Report* at 5.
22 Attached hereto at Tab A.
physician office claims. This LCD does not pertain to hospital outpatient
claims billed under Part A and there were no applicable LCDs pertaining to
Tulane for billing of hospital outpatient claims during the Audit Period. In
the absence of specific guidance from Medicare or the Medicare contractor
regarding the appropriate use of these HCPCS codes during this time period,
Tulane followed guidance from CMS allowing the use of the HCPCS code with
the "lowest dosage" when multiple HCPCS codes exist for the same drug.

Tulane respectfully submits that OIG's findings with respect to the outpatient Lupron
injection claims are contrary to CMS' own guidance (or lack of a specific CMS hospital
outpatient billing directive) and not pursuant to a then existing LCD directly applicable to hospital
outpatient claims.

IV. Tulane's Internal Controls

Tulane is a responsible provider of healthcare items and services with a deep
commitment to operating in compliance with applicable rules and regulations. As part of this
commitment, the Hospital routinely examines its coding and billing practices and procedures
with the objective of achieving ever-improved accuracy and completeness.

Tulane is, and has always been, committed to operating in compliance with applicable
rules and regulations. While Tulane fundamentally disagrees with the OIG's findings with
respect to over two-thirds (or 46 claims) of the 61 claims as issue, the Hospital takes any finding
of potential errors seriously. Tulane will intensify its efforts to attend to any opportunities for
improvements, including continuing its efforts on patient status cases.

In order to ensure that medical necessity for either an inpatient or an outpatient stay is
verified, Tulane already has a process that requires a review to be conducted on all Medicare
patients utilizing nationally recognized criteria at the time of admission. An internal review team
conducts reviews and utilizes external physician consultants for verification on defined
populations, thereby enabling adjustments prior to final billing. The OIG's determinations
notwithstanding, the Hospital has an impressive record in connection with appealing and
reversing RAC findings of error. Specifically, with respect to claims for services provided during
the Audit Period, involving one or more of the Risk Areas, Tulane has a 100 percent success
rate for RAC appeal decisions received to date. This strongly suggests that the Hospital's
internal controls are fully operational, highly effective, and comport with applicable laws,
regulations and agency guidance.
On behalf of Tulane, we thank you in advance for your consideration of our position and stated concerns. We will make ourselves available to you in the event that you have any questions or require further information.

Sincerely,

/Robert Hatcher/

Robert Hatcher
Chief Financial Officer
Advisor to Compliance

cc: John Heurtin, VP of Finance
Robert Lynch, MD, Chief Executive Officer
Tab A
**Luteinizing Hormone-Releasing Hormone Analogs for the Treatment of Malignant Neoplasm of the Prostate #AC-07-004 V9 (Rev. Eff. 09/15/2008)**

<table>
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<th>Contractor Information</th>
<th>Coding Information</th>
<th>General Information</th>
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<tr>
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<tr>
<td><strong>Contractor Business Name</strong></td>
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<td><strong>AMA CPT / ADA CDT Copyright Statement</strong></td>
<td>CPT codes, descriptions and other data only are copyright 2008 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Clauses Apply.</td>
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<td><strong>CMS National Coverage Policy</strong></td>
<td>☐ Title XVIII of the Social Security Act, section 1862(a)(1)(A). This section allows coverage and payment for only those services that are considered to be medically reasonable and necessary. ☐ Title XVIII of the Social Security Act, section 1833(e). This section prohibits Medicare payment for any claim which lacks the necessary information to process the claim.</td>
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### Indications and Limitations of Coverage and/or Medical Necessity

In order to be covered under Medicare, use of a drug or biological must be safe and effective and otherwise reasonable and medically necessary. Drugs or biologicals approved for marketing by the FDA are considered safe and effective for purposes of this requirement when used for approved indications as specified on the labeling. Medical necessity is, however, determined by the Carrier at the local level.

Carriers implement Local Coverage Determinations (LCDs) to apply the standard of reasonable and necessary in situations not covered by specific National Coverage Determinations (NCDs). The underlying issue in the application of Social Security 1862A(a)(1)(A) is: if two services are clinically comparable, Medicare does not cover the additional expense of the more costly one, because this additional expense is not attributable to an item or service that is medically reasonable and necessary.

Therefore, Medicare will only pay for the least costly agent. The beneficiary may be charged up to the price difference between the least costly and the more costly medication as established by ASP. The beneficiary indicates acceptance of the additional payment by signing an Advanced Beneficiary Notice for each injection and a GA modifier is required on claim submission.

LHRH/GnRH drugs are covered for patients with palliative treatment of advanced prostate cancer when orchiectomy or estrone administration are either not indicated or are unacceptable to the patient.

**A. LHRH/GnRH INJECTIONS:**

The Carrier has completed a broad and extensive review of the medical literature and has concluded that there is no demonstrable difference in clinical efficacy between J9202 (Goserelin Acetate), J9217 (Leuprolide Acetate or Eligard), and J3315 (Trelstar), and J9999 (Firmagon [degarelix]) when used for the palliative treatment of advanced prostate cancer. No more than 7.5 mg of leuprolide depot will be covered per month.

Prior to effective date 09/15/2008, the Arkansas Consortium policy used a grandfather date for consideration of the more costly drug. Effective 09/15/2008, this grandfather is no longer
taken into consideration and the least costly alternative will apply to all beneficiaries receiving LHRH/GnRH drugs for prostate cancer.

Reimbursement for LHRH injections for prostate carcinoma will be the lesser of either the billed charges or reimbursement rates set by the ASP for whichever drugs is least costly. There are five injectable forms of LHRH/GnRH approved for malignant neoplasm of the prostate and the LCA provision will apply to any future LHRH/GnRH drugs which are determined to be equivalent.

These drugs are approved by Part B Medicare for office service only. Self-administration of these injections is non-covered.

B. LRHR/GnRH IMPLANTS:
Drug company information describes up to 20% of intolerance to the implantable form and 20% lack of response to the drugs in general. Therefore, the provider should consider that there would have been a demonstrated tolerance and response to the drugs prior to the use of long term implantable form. The implantable form may be used for this purpose in patients whom have a reasonable expectation of surviving at least 12 months.

Viadur and Vantas implants are synthetic nonapeptide analogs of naturally occurring gonadotropin-releasing hormones (GnRH) or luteinizing hormone releasing hormone (LHRH). These subcutaneous implants are indicated in the palliative treatment of advanced prostate cancer.
• Viadur (J9219) is a leuprolide acetate implant that received FDA approval on March 3, 2000. Viadur delivers leuprolide acetate over 12 months at a controlled rate.
• Vantas (J9225) is a histrelin implant that received FDA approval on October 12, 2004. Vantas delivers histrelin continuously for 12 months.

The Carrier has completed a broad and extensive review of the medical literature and has concluded that there is no demonstrable difference in clinical efficacy between Viadur and Vantas. Therefore, the Carrier will reimburse any implantable versions utilized for the palliative treatment of advanced prostate cancer based upon the least costly alternative.

The Carrier bases the reimbursement for either implant for prostate carcinoma on the lower rate of the two as established by the Average Sales Price (ASP). There are two implantable forms of LHRH/GnRH, but the LCA provision will apply to any future LHRH/GnRH implants used for the indication of prostate cancer and determined to be equivalent.

<table>
<thead>
<tr>
<th>Coding Information</th>
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</thead>
<tbody>
<tr>
<td>Bill Type Codes</td>
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</tbody>
</table>
Bill Type and the policy should be assumed to apply equally to all claims.

| Revenue Codes | Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

Revenue codes only apply to providers who bill these services to the fiscal intermediary. Revenue codes do not apply to physicians, other professionals and suppliers who bill these services to the carrier.

Please note that not all revenue codes apply to every type of bill code. Providers are encouraged to refer to the FISS revenue code file for allowable bill types. Similarly, not all revenue codes apply to each CPT/HCPCS code. Providers are encouraged to refer to the FISS HCPCS file for allowable revenue codes.

Revenue codes 096X, 097X and 098X are to be used only by Critical Access Hospitals (CAHs) choosing the optional payment method (also called Option 2 or Method 2) and only for services performed by physicians or practitioners who have reassigned their billing rights. When a CAH has selected the optional payment method, physicians or other practitioners providing professional services at the CAH may elect to bill their carrier or assign their billing rights to the CAH. When professional services are reassigned to the CAH, the CAH must bill the FI using revenue codes 096X, 097X or 098X.

| CPT/HCPCS Codes | This policy does not take precedence over the Correct Coding Initiative (CCI). Consult current correct coding guidelines for applicable specific code combinations or reductions in payment due to specific codes billed.

The following short descriptors are in accordance with the AMA copyright agreement. Please refer to the current HCPCS book for full descriptions.

LHRH/GnRH INJECTABLES:

13315
INJECTION, TRIPTORELIN PAMOATE, 3.75 MG

J9292
GOSERELIN ACETATE IMPLANT, PER 3.6 MG
Not Otherwise Classified (NOC)

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<tr>
<td>ICD-9 Codes that DO NOT Support Medical Necessity</td>
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### Non-Medical Necessity ICD-9 Codes Asterisk Explanation

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### Coding Guidelines

#### General Information

**Documentation Requirements**
1. Documentation supporting the medical necessity of this item, such as ICD-9-CM codes, must be submitted with each claim. Claims submitted without such evidence will be denied as not being medically necessary.
2. The patient's medical record must be clear and legible.
3. All coverage requirements must be met for the procedure to be allowed, and documentation must show that the service was reasonable and medically necessary for the billed diagnosis.
4. Medical records need not be submitted with the claim; however, they must be furnished to Medicare upon request.

#### Appendices

**Utilization Guidelines**
1. When billing an injectable form, utilize the appropriate HCPCS code applicable with multiple NOS to achieve the mg administered. The 12 month long-acting implants (J9219 or J9225) must always be filed with a unit number of one.
2. Since J1950 is for 3.75 mg and the dosage for prostatic cancer starts at 7.5 mg, HCPCS code J1950 is not payable for ICD-9-CM code 185, 198.82, or 233.4.

**Sources of Information and Basis for Decision**
2. USPDI, 2006 Compendia Listing:
   - Pages 1906-1911: Leuprolide Acetate, Eligard, Lupron, Lupron Depot, Viadur
   - Pages 2902-2904: Trelstar Depot (Triptorelin)
3. The Federal Drug Administration approval letters.
4. CMS Manual System, Pub. 100-8, Medicare Program Integrity Manual, Chapter 13, sections:
   - 13.3 Individual Claim Determination;
   - 13.4.A Least Costly Alternative; and
   - 13.5.4 Alternative service must be tried first.
5. Local Medical Review Policies/Local Coverage Determinations:
   - Consolidated LCD from PBSI consortium - Leuprolide Acetate/Goserelin (Gonadotropin Releasing Hormone Analogs), AC-01-019;
   - Arkansas - Leuprolide acetate/Goserelin (Gonadotropin Releasing Hormone Analogs), AR-95;
   - Louisiana - Leuprolide Acetate (Lupron)/Goserelin Acetate (Zoladex), LA-99-002;
   - Missouri - Leuprolide Acetate (Lupron)/Goserelin Acetate (Zoladex)/Leuprolide Acetate Implant (Viadur), #118;
   - New Mexico - Leuprolide Acetate & Goserelin Acetate or
Leuprolide Acetate Implant (Viadur), 96-030; and
• Oklahoma - Leuprolide Acetate & Goserelin Acetate or Leuprolide Acetate Implant (Viadur), 96-030.
8. AHFS, 2007 Compendia Listing:
   • Pages 1110-1118: Leuprolide Acetate Injection, Eligard, Lupron, Lupron Depot
   • Pages 1056-1058: Goserelin Acetate (Zoladex)
   • Pages 1058-1059: Histrelin Acetate (Vantas)
   • Pages 1221-1222: Triptorelin (Trelstar Depot)

Advisory Committee

Meeting Notes

The Arkansas consortium combined LCD was presented in May 2007 and accepted in AR, LA, OK, NM, and MO. A revised policy removing the grandfather clause was presented at the May 2008 CACs in AR and LA and accepted.

"This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from all recognized specialties within the state including, but not limited to, radiation oncology and urology."*

Start Date of Comment Period
09/01/2009

End Date of Comment Period
10/31/2009

Start Date of Notice Period
N/A

Revision History Number
#9 - 08/17/2009
#8 - 07/31/2008 (comment and notice provided)
#6 - 05/14/2008
#4 & #5 - 02/25/2008

Revision History Explanation
#9 - 08/04/2009 Opened comment period for addition of Firmagon (Degarelix) (09/01/2009 - 10/31/2009) for Arkansas and Louisiana Part B. Presented to CACs in September 2009

[#8 - Corrected typographical error in MCD version by deleting duplicated 1st sentence.]

07/17/2008 #6 Finalized in accordance with changes noted in 04/23/2008 Revision History. Effective 9/15/2008, the grandfather clause will no longer apply and all patients are subject to the least costly alternative (LCA) provision. The Carrier can implement LCA based upon CMS Publication 100-8, section 13.5.4.

05/31/2008 #6 PBSI policy retired in Missouri due to workload transition to J5 MAC contractor (Wisconsin Physicians Services).
04/23/2008 #6
Opened comment period for the removal of the grandfather clause (05/01/08-06/30/2008) for Arkansas and Louisiana Part B. Presented to the CACs in May 2008. Specific changes will be documented when the comment period is closed.

02/29/2008 - #4 & #5
Revised short descriptor for J9225 effective 1/1/2008.

PBSI policy retired in New Mexico and Oklahoma due to workload transition to J4 MAC contractor (Trailblazer Health Enterprises, LLC).

08/21/2007
HCPCS code J1950 was added during the comment period based upon recommendations received. Addition is to clarify that this HCPCS code is not to be used for prostate cancer.