



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Office of Audit Services, Region IX
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

November 17, 2011

Report Number: A-09-11-02065

Ms. Debra J. Herwaldt
Chief Financial Officer
Los Robles Hospital & Medical Center
215 West Janss Road
Thousand Oaks, CA 91360

Dear Ms. Herwaldt:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled *Review of Medicare Outpatient Billing for Selected Drugs at Los Robles Hospital & Medical Center*. 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 <http://oig.hhs.gov>.

If you have any questions or comments about this report, please do not hesitate to contact Tom Lin, Senior Auditor, at (415) 437-8360 or through email at Tom.Lin@oig.hhs.gov, or contact Alice Norwood, Audit Manager, at (415) 437-8360 or through email at Alice.Norwood@oig.hhs.gov. Please refer to report number A-09-11-02065 in all correspondence.

Sincerely,

/Lori A. Ahlstrand/
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Ms. Nanette Foster Reilly
Consortium Administrator
Consortium for Financial Management & Fee for Service Operations
Centers for Medicare & Medicaid Services
601 East 12th Street, Room 235
Kansas City, MO 64106

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF MEDICARE
OUTPATIENT BILLING FOR
SELECTED DRUGS AT
LOS ROBLES HOSPITAL &
MEDICAL CENTER**



Daniel R. Levinson
Inspector General

November 2011
A-09-11-02065

Office of Inspector General

<http://oig.hhs.gov>

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:

Office of Audit Services

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.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at <http://oig.hhs.gov>

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.

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

Pursuant to Title XVIII of the Social Security Act, the Medicare program provides health insurance for people aged 65 and over and those who are disabled or have permanent kidney disease. The Centers for Medicare & Medicaid Services administers the program.

Medicare guidance requires providers to submit accurate claims for outpatient services. Each submitted Medicare claim contains detail regarding each provided service (called a line item in this report). Providers should use the appropriate Healthcare Common Procedure Coding System (HCPCS) codes and report units of service as the number of times that a service or procedure was performed or, if the HCPCS code is associated with a drug, the number of units administered.

Los Robles Hospital & Medical Center (Los Robles) is an acute-care hospital located in Thousand Oaks, California. Based on data analysis, we reviewed \$562,748 in Medicare payments to Los Robles for 74 line items for injections of selected drugs that Los Robles billed to Medicare during our audit period (March 1, 2008, through April 30, 2011). These line items consisted of injections for alpha 1–proteinase inhibitor, infliximab, immune globulin, alteplase recombinant, epoetin alfa, and bortezomib.

OBJECTIVE

Our objective was to determine whether Los Robles billed Medicare for injections of selected drugs in accordance with Federal requirements.

SUMMARY OF FINDINGS

For 68 of the 74 line items reviewed, Los Robles did not bill Medicare in accordance with Federal requirements. Specifically, for 67 line items, Los Robles billed the incorrect number of units of service, and for 1 line item, Los Robles billed for a drug that was not administered. As a result, Los Robles received overpayments totaling \$73,804. Los Robles attributed the overpayments to its billing system and human error.

RECOMMENDATIONS

We recommend that Los Robles:

- refund to the Medicare administrative contractor \$73,804 in identified overpayments and
- ensure compliance with Medicare billing requirements.

LOS ROBLES HOSPITAL & MEDICAL CENTER COMMENTS

In written comments on our draft report, Los Robles concurred with our findings and provided information on actions taken to ensure compliance with Medicare billing requirements. Los Robles' comments are included in their entirety as the Appendix.

TABLE OF CONTENTS

	<u>Page</u>
INTRODUCTION	1
BACKGROUND	1
Medicare Requirements for Outpatient Claims	1
Selected Drugs	1
Los Robles Hospital & Medical Center	2
OBJECTIVE, SCOPE, AND METHODOLOGY	2
Objective	2
Scope.....	2
Methodology.....	3
FINDINGS AND RECOMMENDATIONS	4
FEDERAL REQUIREMENTS	4
INCORRECT BILLING	4
RECOMMENDATIONS	5
LOS ROBLES HOSPITAL & MEDICAL CENTER COMMENTS	5
APPENDIX	
LOS ROBLES HOSPITAL & MEDICAL CENTER COMMENTS	

INTRODUCTION

BACKGROUND

Pursuant to Title XVIII of the Social Security Act (the Act), the Medicare program provides health insurance for people aged 65 and over and those who are disabled or have permanent kidney disease. The Centers for Medicare & Medicaid Services (CMS) administers the program.

Medicare Requirements for Outpatient Claims

Medicare guidance requires providers to submit accurate claims for outpatient services. Each submitted Medicare claim contains detail regarding each provided service (called a line item in this report). Providers should use the appropriate Healthcare Common Procedure Coding System (HCPCS) codes and report units of service as the number of times that a service or procedure was performed or, if the HCPCS code is associated with a drug, the number of units administered.¹

Selected Drugs

The drugs we reviewed in this audit were alpha 1–proteinase inhibitor, infliximab, epoetin alfa, bortezomib, alteplase recombinant, and immune globulin.

Alpha 1–Proteinase Inhibitor

Alpha 1–proteinase inhibitor is an injectable drug used to treat alpha 1–antitrypsin deficiency in people who have symptoms of emphysema. Medicare requires providers to bill one service unit for each 10-milligram injection of alpha 1–proteinase inhibitor. The HCPCS code for this drug is J0256 and is described as “Injection, alpha 1–proteinase inhibitor – human, 10 [milligrams].”

Infliximab

Infliximab is an injectable drug used to treat rheumatoid and psoriatic arthritis, ulcerative colitis, Crohn’s disease, and ankylosing spondylitis. Medicare requires providers to bill one service unit for each 10-milligram injection of infliximab. The HCPCS code for this drug is J1745 and is described as “Injection infliximab, 10 [milligrams].”

Epoetin Alfa

Epoetin alfa is an injectable drug used to treat anemia. Medicare requires providers to bill one service unit for each 1,000 units of epoetin alfa. The HCPCS code for this drug is J0885 and is described as “Injection, epoetin alfa, (for non-esrd [end-stage renal disease] use), 1000 units.”

¹ HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

Bortezomib

Bortezomib is an injectable drug used to treat multiple myeloma and mantle cell lymphoma. Medicare requires providers to bill one service unit for each 0.1-milligram injection of bortezomib. The HCPCS code for this drug is J9041 and is described as “Injection, bortezomib, 0.1 [milligrams].”

Alteplase Recombinant

Alteplase recombinant is an injectable drug used to dissolve blood clots that have formed in the blood vessels and is used immediately after symptoms of a heart attack or stroke and to treat blood clots in the lungs. Medicare requires providers to bill one service unit for each 1-milligram injection of alteplase recombinant. The HCPCS code for this drug is J2997 and is described as “Injection, alteplase recombinant, 1 [milligram].”

Immune Globulin

Immune globulin is an injectable drug that boosts the body’s natural response in patients with compromised immune systems, e.g., patients with HIV/AIDS and premature babies. The drug also increases the number of platelets in patients with idiopathic thrombocytopenic purpura. Medicare requires providers to bill one service unit for each 500-milligram injection of immune globulin. The HCPCS code for this drug is J1566 and is described as “Injection, immune globulin, intravenous, lyophilized (e.g. powder), 500 [milligrams].”

Los Robles Hospital & Medical Center

Los Robles Hospital & Medical Center (Los Robles) is an acute-care hospital located in Thousand Oaks, California. Los Robles’ claims are processed and paid by Palmetto GBA, LLC (Palmetto), the Medicare administrative contractor.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Los Robles billed Medicare for injections of selected drugs in accordance with Federal requirements.

Scope

We reviewed \$562,748 in Medicare payments to Los Robles for 74 line items that we judgmentally selected as potentially at risk for billing errors during our audit period (March 1, 2008, through April 30, 2011). These line items consisted of:

- 65 line items for alpha 1–proteinase inhibitor totaling \$528,879,
- 2 line items for infliximab totaling \$11,473,

- 2 line items for immune globulin totaling \$9,645,²
- 3 line items for alteplase recombinant totaling \$8,390,
- 1 line item for epoetin alfa totaling \$3,040, and
- 1 line item for bortezomib totaling \$1,321.

We identified these payments through data analysis.

We did not review Los Robles's internal controls applicable to the 74 line items because our objective did not require an understanding of controls over the submission of claims. Our review allowed us to establish reasonable assurance of the authenticity and accuracy of the data obtained from the National Claims History file for our audit period, but we did not assess the completeness of the file.

We conducted our audit from April to September 2011. Our fieldwork including contacting Los Robles, located in Thousand Oaks, California.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- used CMS's National Claims History file to identify paid Medicare claims for alpha 1–proteinase inhibitor, infliximab, immune globulin, alteplase recombinant, epoetin alfa, and bortezomib during our audit period;
- used computer matching, data mining, and analysis techniques to identify line items potentially at risk for noncompliance with Medicare billing requirements;
- identified 74 line items totaling \$562,748 that Medicare paid to Los Robles;
- contacted Los Robles to determine whether the information conveyed in the selected line items was correct and, if not, why the information was incorrect;
- reviewed documentation that Los Robles furnished to verify whether each selected line item was billed correctly;
- calculated overpayments using corrected payment information processed by Palmetto; and
- discussed the results of our review with Los Robles.

² For the two line items for immune globulin, Los Robles billed Medicare in accordance with Federal requirements.

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 objective.

FINDINGS AND RECOMMENDATIONS

For 68 of the 74 line items reviewed, Los Robles did not bill Medicare in accordance with Federal requirements. Specifically, for 67 line items, Los Robles billed the incorrect number of units of service, and for 1 line item, Los Robles billed for a drug that was not administered. As a result, Los Robles received overpayments totaling \$73,804. Los Robles attributed the overpayments to its billing system and human error.

FEDERAL REQUIREMENTS

Section 9343(g) of the Omnibus Budget Reconciliation Act of 1986, P.L. No. 99-509, requires hospitals to report claims for outpatient services using HCPCS codes.

Section 1833(e) of the Act states: “No payment shall be made to any provider of services ... unless there has been furnished such information as may be necessary in order to determine the amounts due such provider ... for the period with respect to which the amounts are being paid”

CMS’s *Medicare Claims Processing Manual*, Pub. No. 100-04 (the Manual), chapter 4, section 20.4, states: “The definition of service units ... is the number of times the service or procedure being reported was performed.”

The Manual, chapter 17, section 90.2.A, states: “It is ... of great importance that hospitals billing for [drugs] make certain that the reported units of service of the reported HCPCS code are consistent with the quantity of a drug ... that was used in the care of the patient.” If the provider is billing for a drug, according to chapter 17, section 70, of the Manual, “[w]here HCPCS is required, units are entered in multiples of the units shown in the HCPCS narrative description. For example, if the description for the code is 50 mg, and 200 mg are provided, units are shown as 4”

Chapter 1, section 80.3.2.2, of the Manual states: “In order to be processed correctly and promptly, a bill must be completed accurately.”

INCORRECT BILLING

For 67 line items reviewed, Los Robles billed Medicare for the incorrect number of units of service:

- For 63 line items for alpha 1–proteinase inhibitor, Los Robles billed the incorrect number of units of service. Rather than billing from 1,776 to 2,373 service units, Los Robles

billed from 1,803 to 2,748 service units. The incorrect billing resulted in overpayments totaling \$61,366.³

- For the two line items for infliximab, Los Robles billed the incorrect number of units of service. Rather than billing 56 service units, Los Robles billed 112 and 120 service units, resulting in overpayments totaling \$6,234.
- For the one line item for epoetin alfa, Los Robles billed the incorrect number of units of service. Rather than billing 20 service units, Los Robles billed 400 service units, resulting in an overpayment of \$2,888.
- For the one line item for bortezomib, Los Robles billed the incorrect number of units of service. Rather than billing 22 service units, Los Robles billed 44 service units, resulting in an overpayment of \$660.

For the one line item for alteplase recombinant, Los Robles billed Medicare for 100 units of alteplase recombinant that was not administered, resulting in an overpayment of \$2,656.

In total, Los Robles received overpayments of \$73,804. Los Robles attributed the overpayments to its billing system and human error.

RECOMMENDATIONS

We recommend that Los Robles:

- refund to the Medicare administrative contractor \$73,804 in identified overpayments and
- ensure compliance with Medicare billing requirements.

LOS ROBLES HOSPITAL & MEDICAL CENTER COMMENTS

In written comments on our draft report, Los Robles concurred with our findings and provided information on actions taken to ensure compliance with Medicare billing requirements. Los Robles' comments are included in their entirety as the Appendix.

³ Los Robles identified 3 additional line items for alpha 1–proteinase inhibitor for which the hospital billed 218, 229, and 292 service units when it should have billed 2,216, 2,223, and 2,290 service units, respectively. The result of these errors was included in determining the net overpayment amount of \$61,366.

APPENDIX

APPENDIX: LOS ROBLES HOSPITAL & MEDICAL CENTER COMMENTS



215 West Janss Road • Thousand Oaks, California 91360
805-497-2727 • 818-707-0116
Toll-Free Physician Referral Line: 1-888-852-LRHM
www.losrobleshospital.com

Los Robles Hospital & Medical Center Review of Medicare Outpatient Billing for Selected Drugs Written Comments to Report Number A-09-11-02065

FINDINGS AND RECOMMENDATIONS

- 63 line items for alpha1-proteinase inhibitor billed with incorrect number of units of service.
We concur with the findings. This was due to a systems issue that could not handle the large number of units billed requiring a manual work-a-round. Los Robles has corrected the work-a-round method to ensure correct billing.
- Two line items for infliximab billed with incorrect number of units of service
We concur with findings. This drug was scanned twice in error into the E-MAR system by the nurse. Education has been given to the staff regarding this error.
- One line item for epoetin alfa billed with incorrect number of units of service.
We concur with findings. The wrong number of units was entered with a procedure code that was set-up in the chargemaster with a drug multiplier. This caused an explosion of units. Education has been given to staff regarding 1) choosing the correct billing code and 2) entering the correct units that reflect the billing code.
- One line item for bortezomib billed with incorrect number of units of service
We concur with findings. This drug was also scanned twice in error into the E-MAR system by the nurse. Again, this is human error and education has been given to the staff.
- One line item for alteplase billed for drug that was not administered.
We concur with findings. The patient cancelled and the pharmacy failed to credit the charge. Education was given to staff regarding improving communication between departments.


Debra J. Herwaldt, CFO
Los Robles Hospital & Medical Center