July 17, 2012

Report Number: A-09-12-02023

Mr. Mike Scialdone
Interim Chief Executive Officer and
    Chief Compliance Officer
Memorial Health System
1400 East Boulder Street
Colorado Springs, CO  80909

Dear Mr. Scialdone:

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 Memorial Health System. 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.


If you have any questions or comments about this report, please do not hesitate to contact Iman Zbinden, Senior Auditor, at (619) 557-6131, extension 109, or through email at Iman.Zbinden@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-09-12-02023 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 355  
Kansas City, MO  64106
Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF MEDICARE OUTPATIENT BILLING FOR SELECTED DRUGS AT MEMORIAL HEALTH SYSTEM

Daniel R. Levinson
Inspector General

July 2012
A-09-12-02023
The Office of Inspector General (OIG) protects 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.

Memorial Health System (Memorial) is a level-II trauma center with three hospitals and outlying clinics located in Colorado Springs, Colorado. Based on data analysis, we reviewed $139,210 in Medicare payments to Memorial for 17 line items for injections of selected drugs that Memorial billed to Medicare during our audit period (January 1, 2008, through April 30, 2011). These line items consisted of injections for alpha 1–proteinase inhibitor, trastuzumab, pemetrexed, cetuximab, and immune globulin.

OBJECTIVE

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

SUMMARY OF FINDINGS

For 16 of the 17 line items reviewed, Memorial did not bill Medicare in accordance with Federal requirements. Specifically, Memorial billed the incorrect number of units of service. As a result, Memorial received overpayments totaling $110,373. Memorial attributed the overpayments to billing system and clerical errors.

RECOMMENDATIONS

We recommend that Memorial:

- refund to the Medicare administrative contractor $110,373 in identified overpayments

- ensure compliance with Medicare billing requirements.
MEMORIAL HEALTH SYSTEM COMMENTS

In written comments on our draft report, Memorial concurred with our findings and provided information on actions that it had taken to address our recommendations. Memorial’s comments are included in their entirety as the Appendix.
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>SECTION</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INTRODUCTION</strong></td>
<td>1</td>
</tr>
<tr>
<td><strong>BACKGROUND</strong></td>
<td>1</td>
</tr>
<tr>
<td>Medicare Requirements for Outpatient Claims</td>
<td>1</td>
</tr>
<tr>
<td>Selected Drugs</td>
<td>1</td>
</tr>
<tr>
<td>Memorial Health System</td>
<td>2</td>
</tr>
<tr>
<td><strong>OBJECTIVE, SCOPE, AND METHODOLOGY</strong></td>
<td>2</td>
</tr>
<tr>
<td>Objective</td>
<td>2</td>
</tr>
<tr>
<td>Scope</td>
<td>2</td>
</tr>
<tr>
<td>Methodology</td>
<td>3</td>
</tr>
<tr>
<td><strong>FINDINGS AND RECOMMENDATIONS</strong></td>
<td>4</td>
</tr>
<tr>
<td><strong>FEDERAL REQUIREMENTS</strong></td>
<td>4</td>
</tr>
<tr>
<td><strong>INCORRECT BILLING</strong></td>
<td>4</td>
</tr>
<tr>
<td><strong>RECOMMENDATIONS</strong></td>
<td>5</td>
</tr>
<tr>
<td><strong>MEMORIAL HEALTH SYSTEM COMMENTS</strong></td>
<td>5</td>
</tr>
<tr>
<td><strong>APPENDIX</strong></td>
<td></td>
</tr>
<tr>
<td>MEMORIAL HEALTH SYSTEM COMMENTS</td>
<td></td>
</tr>
</tbody>
</table>
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, trastuzumab, pemetrexed, cetuximab, 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].”

Trastuzumab

Trastuzumab is an injectable drug used to treat breast cancer that has progressed after treatment with other chemotherapy. Medicare requires providers to bill one service unit for each 10-milligram injection of trastuzumab. The HCPCS code for this drug is J9355 and is described as “Injection, trastuzumab, 10 [milligrams].”

Pemetrexed

Pemetrexed is an injectable drug used to treat malignant mesothelioma and certain types of non-small cell lung cancer. Medicare requires providers to bill one service unit for each 10-milligram injection of pemetrexed. The HCPCS code for this drug is J9305 and is described as “Injection, pemetrexed, 10 [milligrams].”

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

Cetuximab is an injectable drug used to treat cancers of the colon and rectum. Medicare requires providers to bill one service unit for each 10-milligram injection of cetuximab. The HCPCS code for this drug is J9055 and is described as “Injection, cetuximab, 10 [milligrams].”

Immune Globulin

Immune globulin is an injectable drug used to treat primary immune deficiency conditions (e.g., chronic inflammatory demyelinating polyneuropathy). 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), not otherwise specified, 500 [milligrams].”

Memorial Health System

Memorial Health System (Memorial) is a level-II trauma center with three hospitals and outlying clinics located in Colorado Springs, Colorado. Memorial’s claims are processed and paid by TrailBlazer Health Enterprises, LLC (TrailBlazer), the Medicare administrative contractor.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

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

Scope

We reviewed $139,210 in Medicare payments to Memorial for 17 line items that we selected as potentially at risk for billing errors during our audit period (January 1, 2008, through April 30, 2011). These line items consisted of:

- 12 line items for alpha 1–proteinase inhibitor totaling $101,665,
- 2 line items for trastuzumab totaling $16,735,
- 1 line item for pemetrexed totaling $9,298,
- 1 line item for cetuximab totaling $6,401, and
- 1 line item for immune globulin totaling $5,111.²

We identified these payments through data analysis.

² For the one line item for immune globulin, Memorial billed Medicare in accordance with Federal requirements.
We did not review Memorial’s internal controls applicable to the 17 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.

Our fieldwork included contacting Memorial, located in Colorado Springs, Colorado.

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, trastuzumab, pemetrexed, cetuximab, and immune globulin 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 17 line items totaling $139,210 that Medicare paid to Memorial;
- contacted Memorial to determine whether the information conveyed in the selected line items was correct and, if not, why the information was incorrect;
- reviewed documentation that Memorial furnished to verify whether each selected line item was billed correctly;
- calculated overpayments using corrected payment information processed by TrailBlazer; and
- discussed the results of our review with Memorial.

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 16 of the 17 line items reviewed, Memorial did not bill Medicare in accordance with Federal requirements. Specifically, Memorial billed the incorrect number of units of service. As a result, Memorial received overpayments totaling $110,373. Memorial attributed the overpayments to billing system and clerical errors.

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 16 line items reviewed, Memorial billed Medicare for the incorrect number of units of service:

- For the 12 line items for alpha 1–proteinase inhibitor, Memorial billed the incorrect number of units of service. Rather than billing from 361 to 569 service units, Memorial billed from 3,610 to 5,690 service units. The incorrect billing resulted in overpayments totaling $93,013.

- For the two line items for trastuzumab, Memorial billed the incorrect number of units of service. Rather than billing 59 and 88 service units, Memorial billed 176 and 126 service units, respectively. The incorrect billing resulted in overpayments totaling $8,938.
• For the one line item for pemetrexed, Memorial billed the incorrect number of units of service. Rather than billing 100 service units, Memorial billed 200 service units. The incorrect billing resulted in an overpayment of $4,782.

• For the one line item for cetuximab, Memorial billed the incorrect number of units of service. Rather than billing 70 service units, Memorial billed 150 service units. The incorrect billing resulted in an overpayment of $3,640.

In total, Memorial received overpayments of $110,373. Memorial attributed the overpayments to billing system and clerical errors.

RECOMMENDATIONS

We recommend that Memorial:

• refund to the Medicare administrative contractor $110,373 in identified overpayments and

• ensure compliance with Medicare billing requirements.

MEMORIAL HEALTH SYSTEM COMMENTS

In written comments on our draft report, Memorial concurred with our findings and provided information on actions that it had taken to address our recommendations. Memorial’s comments are included in their entirety as the Appendix.
APPENDIX
May 31, 2012

Ms. Lori A. Ahlstrand  
Regional Inspector General for Audit Services  
Office of Audit Services, Region IX  
901 7th Street Suite 3-640  
San Francisco, CA 94103  

RE: Report Number A-09-12-02023

Dear Ms. Ahlstrand:

We are in receipt of your draft report dated May 24, 2012. In response to your request, this letter contains Memorial Health System’s (“MHS”) comments with respect to the draft report. We would like to thank the auditors involved in this review. They were very thorough, professional and helpful.

As you may know, the audit that is the subject of the draft report involved a review of various injectable medications including; alpha 1-protienase inhibitor, trastuzumab, pemetrexed and cetuximab.

MHS concurs with the findings set forth in the draft report.

It is also important to note that MHS undertook its own audit in May of 2011 with respect to various injectable medications. In accordance with the findings of the MHS auditors, MHS did reimburse Medicare in the amount noted in the draft audit report.

**Nature of Corrective Action Taken or Planned.**

1. **Alpha 1-protienase inhibitor**

   Prior to April 7, 2010, MHS was billing Medicare per vial irrespective of the amount of medication actually administered to the patient. The billing practices have since been changed to incremental billing (billing only for the amount ordered) so that the bill issued to Medicare reflects the actual amount of the medication administered to the beneficiary based on service units wherein one service unit is billed for every 10-milligram injection of an Alpha 1-protienase inhibitor.
2. **Trastuzumab**

MHS was billing Medicare in 10 milligram increments based on a 440 mg vial irrespective of the amount of medication actually administered. In trying to correct the error and bill only for the amount administered, MHS encountered number rounding issues that increase the dose, in most cases, to the next whole number, causing the system to continue to overbill. The billing functions and number rounding issues have since been changed to incremental billing (billing only for the amount ordered) without rounding to the nearest whole number. The bill issued to Medicare now reflects the actual amount of the medication administered to the beneficiary based on service units wherein one service unit is billed for every 10 milligram injection of Trastuzumab.

3. **Pemetrexed**

MHS billed Medicare in error for 200 service units rather than 100 service units of Pemetrexed. This was a clerical error. Education was provided to the billing staff with respect to self-auditing procedures and review procedures to prevent clerical errors.

4. **Cetuximab**

MHS billed Medicare in error for 150 units rather than 70 units of Cetuximab. Again, similar to the billing error that occurred with Pemetrexed mentioned above, this was clerical error. As also mentioned above, education was provided to the billing staff with respect to self-auditing procedures and review procedures to prevent clerical errors.

Please do not hesitate to contact me with any questions or concerns. We appreciate the ability to comment on the draft report.

Sincerely,

Milo Scialdone
Interim CEO, Chief Compliance Officer
Memorial Health System