



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Office of Audit Services
1100 Commerce, Room 632
Dallas, Texas 75242

August 5, 2005

Report Number: A-06-04-00091

Ms. Marti Mahaffey
President and COO
TrailBlazer Health Enterprises, LLC
8330 LBJ Freeway, Executive Center 3
Dallas, Texas 75243

Dear Ms. Mahaffey:

Enclosed are two copies of the Department of Health and Human Services (HHS), Office of Inspector General (OIG) final report entitled "Review of the Services Related To The Placement of Arterial Stents". A copy of this report will be forwarded to the action official noted below for his review and any action deemed necessary.

Final determination as to actions taken on all matters reported will be made by the HHS action official named below. We request that you respond to the HHS action 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.

In accordance with the principles of the Freedom of Information Act (5 U.S.C. § 552, as amended by Public Law 104-231), OIG reports issued to the department's grantees and contractors are made available to members of the press and general public to the extent information contained therein is not subject to exemptions in the Act which the department chooses to exercise. (See 45 CFR Part 5.)

If you have any questions or comments about this report, please do not hesitate to call me at 214-767-8414 or through e-mail at gordon.sato@oig.hhs.gov, or contact Sam Patterson, Audit Manager, at 405-605-6179 or through e-mail at sam.patterson@oig.hhs.gov.

To facilitate identification, please refer to report number A-06-04-00091 in all correspondence relating to this report.

Sincerely yours,

A handwritten signature in black ink that reads "Gordon L. Sato".

Gordon L. Sato
Regional Inspector General
for Audit Services

Enclosures-as stated

Page 2 – Ms. Marti Mahaffey

Direct Reply to HHS Action Official:

James R. Farris, MD
Regional Administrator
Centers for Medicare and Medicaid Services
1301 Young Street, Room 714
Dallas, Texas 75202-4348

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF THE SERVICES
RELATED TO THE PLACEMENT
OF ARTERIAL STENTS**



**Daniel R. Levinson
Inspector General**

**August 2005
A-06-04-00091**

Notices

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

In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), Office of Inspector General, Office of Audit Services reports are made available to members of the public to the extent the information is not subject to exemptions in the act. (See 45 CFR Part 5.)

OAS FINDINGS AND OPINIONS

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

EXECUTIVE SUMMARY

BACKGROUND

An arterial stent is used to hold open an artery wall after angioplasty clears the artery of blockage. The traditional stent is called a “bare metal stent.” After surgery, some patients experience re-growth of blockage in the artery, which can require subsequent invasive procedures. In April 2003, the Food and Drug Administration (FDA) approved a drug-coated stent designed to prevent this re-growth.

TrailBlazer Health Enterprises, LLC (TrailBlazer) is a Medicare contractor responsible for processing and paying arterial stent claims billed to Medicare by Texas providers. TrailBlazer paid about \$14 million for Medicare Part B of A stent-related services provided during calendar year 2002. TriCenturion is a Program Safeguard Contractor under contract with the Centers for Medicare and Medicaid Services (CMS) that has jurisdiction over Texas providers.

OBJECTIVES

The objective of our audit was to determine whether 72 paid Medicare claims for outpatient stent placement services provided in calendar year 2002 were:

- reasonable, necessary, and allowable under Medical rules;
- supported by adequate documentation; and
- properly coded.

SUMMARY OF FINDINGS

TriCenturion determined that 20 of the 72 claims reviewed included services that did not meet Medicare reimbursement requirements. These errors resulted in total overpayments of \$35,291 and comprised:

- four claims that were fully denied because medical necessity was not sufficiently documented in the medical records, resulting in overpayments of \$13,265;
- nine claims that were either partially or fully denied because the medical records did not support the service billed, resulting in overpayments of \$11,735; and
- seven claims that were either partially or fully denied due to improper coding, resulting in overpayments of \$10,291.

These errors may have occurred because the providers did not have procedures in place to ensure that the services billed met Medicare requirements. We have provided TrailBlazer with a detailed schedule of the overpayments attributed to each provider.

RECOMMENDATIONS

We recommend that TrailBlazer:

- recover the \$35,291 in overpayments made to the 15 providers included in our review; and,
- through various forms of communication, provide education to these providers to ensure that the claims they submit for reimbursement for stent services meet Medicare's requirements.

AUDITEE COMMENTS

In TrailBlazer's written response to our draft report, a TrailBlazer official generally agreed with our findings and recommendations to recover the overpayments and provide education to the specific providers included in this review to ensure compliance with Medicare requirements. This official stated that TrailBlazer had recovered all of the overpayments except for one claim in the amount of \$4,598. This official explained that the provider filing this original claim appealed the overpayment determination and a full reversal had been granted.

TrailBlazer's response is included in its entirety in the Appendix.

OFFICE OF INSPECTOR GENERAL RESPONSE

After receiving TrailBlazer's written comments to our draft report, we contacted TrailBlazer officials to discuss the claim for \$4,598 that was not recovered. These officials explained that the paid claim amount we selected for our review represented the amount paid to the provider after a previous denial of the claim was overturned. As a result, in our final report the overpayment amount to be recovered has been reduced by \$4,598.

INTRODUCTION

BACKGROUND

The Purpose and Use of Arterial Stents

Coronary artery disease is a major health problem in the United States. There has been much progress in recent years in new ways to treat this disease. Angioplasty is a technique that is used to open an area of an artery that has blockage. Following angioplasty, an arterial stent is mounted on a collapsed balloon catheter. When the balloon is inflated, the stent expands and pushes against the inner wall of the artery. This holds the artery open when the balloon is deflated and removed, thus improving blood flow through the artery.

The traditional arterial stent is called a “bare metal stent” and consists of a stainless-steel tube with slots. After surgery, some patients experience re-growth of blockage in the artery, which can require subsequent invasive procedures. In April of 2003, the FDA approved the drug-coated stent, which holds the artery open and releases medication into the body to help reduce the recurrence of arterial blockage. These stents are being used with the intent of decreasing the rate of subsequent invasive procedures.

Medicare’s Coverage Related to Arterial Stents

Medicare Part A (inpatient hospital services) and Part B of A (outpatient hospital services) provide for the payment of arterial stent placement services to treat Medicare beneficiaries with arterial blockage. This report addresses the Medicare Part B of A claims. Providers that bill Medicare for outpatient stent-related services are paid based on service groupings called Ambulatory Payment Classifications (APCs). These providers are paid fixed amounts based on the applicable APCs.

TrailBlazer is a Medicare contractor responsible for processing and paying arterial stent claims billed to Medicare by Texas providers. TrailBlazer paid about \$14 million for Medicare Part B of A stent-related services provided during calendar year 2002.

TriCenturion is a Program Safeguard Contractor, under contract with the Centers for Medicare and Medicaid Services (CMS) that has jurisdiction over Texas providers.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

The objective of our audit was to determine whether 72 paid Medicare claims for outpatient stent placement services provided in calendar year 2002 were:

- reasonable, necessary, and allowable under Medicare rules;
- supported by adequate documentation; and
- properly coded.

Scope

From Medicare's National Claims History File, we obtained a listing of 4,605 Texas outpatient stent claims paid during calendar year 2002. The claims included the following APCs:

- 0104 – Transcatheter Placement of Intracoronary Stents;
- 1874 – Stent, coated/covered with delivery system;
- 1875 – Stent, coated/ covered without delivery system;
- 1876 – Stent, non-coated/ non-covered with delivery system; and
- 1877 – Stent, non-coated/ covered with delivery system.

We selected a nonstatistical sample of 100 claims from this listing. Of these 100 claims, TrailBlazer processed 72 claims and made payments of about \$320,000. We will report the results of the medical review of these 72 claims to TrailBlazer for proper disposition. We will not, however, provide separate reports to each provider included in our review.

Another Medicare contractor processed the remaining 28 claims. We will report separately to that contractor on those claims.

We did not review TrailBlazer's management controls because the objectives of this audit did not require an understanding or assessment of its management controls.

Methodology

After selecting the 100 claims in our sample, we obtained copies of the medical records from each of the Medicare providers that submitted the claims. We provided copies of the medical records to TriCenturion. TriCenturion conducted a medical review of each of the claims in our sample to determine if the services billed on these claims met Medicare reimbursement requirements. TriCenturion provided us with the results of its medical review.

After reviewing TriCenturion's results, we met with TrailBlazer and CMS officials in Dallas, TX, to discuss them. During this meeting, we informed TrailBlazer officials that we would provide them with a report disclosing the medical review results for the 72 claims TrailBlazer processed. TrailBlazer officials stated that they would be able to recover any overpayments based on TriCenturion's medical review.

We conducted our audit in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

TriCenturion determined that 20 of the 72 claims reviewed included services that did not meet Medicare reimbursement requirements. These errors resulted in total overpayments of \$35,291 and included:

- four claims that were fully denied because medical necessity was not sufficiently documented in the medical records, resulting in overpayments of \$13,265;
- nine claims that were either partially or fully denied because the medical records did not support the service billed, resulting in overpayments of \$11,735; and
- seven claims that were either partially or fully denied due to improper coding, resulting in overpayments of \$10,291.

These errors may have occurred because the providers did not have procedures in place to ensure that the services billed met Medicare requirements. We have provided TrailBlazer with a detailed schedule of the overpayments attributed to each provider.

CRITERIA THE PROVIDERS ARE REQUIRED TO FOLLOW

Services Must Be Reasonable, Necessary, and Allowable Under Medicare Rules

Title XVIII of the Social Security Act, section 1862(a)(1)(A), states that no payment may be made under Medicare Part A or Part B for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Medicare Part A Newsletter No. 03-97, dated October 9, 1997 states that the operative report must clearly support the findings and the medical necessity of the angiographic study.

Services Must Be Supported by Adequate Documentation

The 42 CFR § 482.24(c) requires providers to maintain records containing sufficient documentation to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.

Services Must Be Properly Coded

Various criteria outline specific medical coding requirements. The American Medical Association (AMA) provides guidelines for Common Procedural Terminology (CPT) coding.

Additionally, newsletters published on the TrailBlazer Web site provide coding guidance. Some examples are:

- Medicare Part A Newsletter No. 3-00 dated July 14, 2000, p. 8, which identifies the correct procedure codes used to bill for the procedure to remove a clot (thrombectomy); and
- Medicare Part A Newsletter 5-96 dated October 10, 1996, p. 44, which explains that a hierarchical coding scheme is used when multiple types of coronary intervention are employed in a single session. Rather than bill for all procedures performed on a single artery, the provider should bill only the most complex procedure.

CONDITIONS RESULTING FROM NOT FOLLOWING THE REQUIRED CRITERIA

Services Not Sufficiently Documented for Medical Necessity

For four claims reviewed, TriCenturion found that the providers did not sufficiently document the medical necessity of the services in the medical records. For example, in some cases TriCenturion found that:

- The medical record did not contain sufficient information to support the medical necessity of thrombectomy with angioplasty and stent deployment.
- The medical record had no background information, such as a chief complaint or history and physical information indicating why the patient underwent thrombectomy with angioplasty and stent placement.

Services Not Supported by Medical Records

For nine claims reviewed, TriCenturion found that the medical records did not sufficiently support the services billed. For example, in some cases TriCenturion found that the medical records reflected the following:

- The angioplasty or the stent placement services billed were not performed.
- The internal radiation therapy (brachytherapy) billed was not documented.
- Cardiac rehabilitation services billed were not supported by clinical documentation for the dates of services on the claim.
- Stent placement services were billed for two separate arteries; however, the medical record reflected stenting of only one artery.

Services Not Properly Coded

For seven claims reviewed, TriCenturion found that the provider used improper coding. The following are some examples of the types of coding errors TriCenturion identified:

- In two instances, the provider failed to use the proper CPT codes for the procedure to remove a clot (thrombectomy), as outlined in the TrailBlazer newsletters and in the AMA guidelines.

- In two instances, the provider billed for both the stent placement and the procedure used to dissolve clots in arteries (thrombolysis). TriCenturion staff stated that, in the hierarchical coding scheme, thrombolysis is superseded by stent placement and, therefore, should not have been billed in addition to the stent placement.

POSSIBLE REASONS WHY MEDICARE REQUIREMENTS WERE NOT FOLLOWED

These errors may have occurred because the providers did not have procedures in place to ensure that the services for which they billed met Medicare requirements. In addition, the providers may need additional education covering proper billing practices for stent services.

EFFECT ON THE MEDICARE PROGRAM

The Medicare overpayments related to the 20 claims totaled \$35,291 and consisted of the following:

- four claims that were fully denied because medical necessity was not sufficiently documented in the medical records, resulting in overpayments of \$13,265;
- nine claims that were either partially or fully denied because the medical records did not support the service billed, resulting in overpayments of \$11,735; and
- seven claims that were either partially or fully denied due to improper coding, resulting in overpayments of \$10,291.

RECOMMENDATIONS

We recommend that TrailBlazer:

- recover the \$35,291 in overpayments made to the 15 providers included in our review; and,
- through various forms of communication, provide education to these providers to ensure that the claims they submit for reimbursement for stent services meet Medicare's requirements.

AUDITEE COMMENTS

In TrailBlazer's written response to our draft report, a TrailBlazer official generally agreed with our findings and recommendations to recover the overpayments and provide education to the specific providers included in this review to ensure compliance with Medicare requirements. This official stated that TrailBlazer had recovered all of the overpayments except for one claim in the amount of \$4,598. This official explained that the provider filing this original claim appealed the overpayment determination and a full reversal had been granted.

TrailBlazer's response is included in its entirety in the Appendix.

OFFICE OF INSPECTOR GENERAL RESPONSE

After receiving TrailBlazer's written comments to our draft report, we contacted TrailBlazer officials to discuss the claim for \$4,598 that was not recovered. These officials explained that the paid claim amount we selected for our review represented the amount paid to the provider after a previous denial of the claim was overturned. As a result, in our final report the overpayment amount to be recovered has been reduced by \$4,598.

APPENDIX



8330 LBJ Freeway
Executive Center III
Dallas, Texas 75243-1213

Marti Mahaffey
Executive Vice President and
Chief Operating Officer

April 12, 2005

Mr. Gordon L. Sato
Regional Inspector General for Audit Services
Office of Inspector General
1100 Commerce Street
Room 632
Dallas, Texas 75242

Re: CIN: A-06-04-00091

Dear Mr. Sato:

In response to your draft audit report *Review of the Services Related to the Placement of Arterial Stents*, we appreciate the opportunity to provide our comments for your consideration. We support your efforts highlighting the vulnerabilities associated with processing this specific type of Medicare claims. Further, we agree with your findings and recommendations to continue our efforts to educate the specific providers included in this review to ensure that their services meet Medicare requirements and to recover the specific overpayments identified. All of the overpayments have been recovered except for one claim in the amount of \$4,598.34. The provider filing this original claim appealed the overpayment determination and a full reversal was granted.

Again, we appreciate this opportunity to provide our comments. If you have any questions please let me know.

Sincerely,


Marti Mahaffey
President and Chief Operating Officer

Cc: James Randolph Farris, M.D., CMS
John Delaney, CMS