Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MOST MEDICAID PAYMENTS ARKANSAS MADE TO PROVIDERS FOR FULL VIALS OF HERCEPTIN WERE INCORRECT

Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

Patricia Wheeler
Regional Inspector General
for Audit Services

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Office of Inspector General

http://oig.hhs.gov

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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.

INTRODUCTION

Most Medicaid payments Arkansas made to providers for full vials of Herceptin from July 1, 2010, through June 30, 2013, were incorrect and resulted in overpayments of approximately $131,000 (Federal share).

WHY WE DID THIS REVIEW

Herceptin, also known as trastuzumab, is a Medicaid-covered drug used to treat breast cancer that has spread to other parts of the body and is supplied in a multiuse vial containing 440 milligrams. Eighteen previous Office of Inspector General reviews found that overpayments were made on Medicare claims for full vials of Herceptin. Specifically, of the line items reviewed, 77 percent were incorrect and included overpayments of about $24.2 million. On nearly all of the incorrect line items in previous reviews, the providers reported the units of service for the entire content of 1 or more vial(s), each containing 440 milligrams of Herceptin, rather than reporting the units of service for the amount actually administered. Because of the significant error rate in the Medicare program, we expanded our review of Herceptin billing to the Arkansas Medicaid program.

OBJECTIVE

Our objective was to determine whether payments that the Arkansas Department of Human Services (the State agency) made to providers for full vials of the drug Herceptin were correct.

BACKGROUND

The Medicaid program provides medical assistance to certain low-income individuals and individuals with disabilities. The Federal and State Governments jointly fund and administer the Medicaid program. At the Federal level, the Centers for Medicare & Medicaid Services (CMS) administers the program. In Arkansas, the State agency administers its Medicaid program in accordance with a CMS-approved State plan. Although the State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements.

Herceptin is a monoclonal antibody, one of a group of drugs designed to attack specific cancer cells. The manufacturer supplies the drug in a carton containing a multiuse vial of 440 milligrams of Herceptin and one vial of bacteriostatic water for injection (BWFI). A vial of Herceptin, when reconstituted with BWFI and stored properly, can be used for up to 28 days.

Providers bill the State agency using the appropriate Healthcare Common Procedure Coding System (HCPCS) codes and the appropriate quantity of the drug administered. The number of units billed should correspond to the quantity of Herceptin actually administered to the patient. The HCPCS code for Herceptin is J9355, with a description of "injection, trastuzumab 10 mg." As a result, 1 billing unit has 10 milligrams of reconstituted Herceptin, and an entire multiuse vial of 440 milligrams would be reported as 44 billing units.

HOW WE CONDUCTED THIS REVIEW

For the 3-year period July 1, 2010, through June 30, 2013, the State agency processed 2,646 outpatient service line items of Herceptin totaling approximately $4.56 million. Of these line items, 145, totaling $386,000 ($303,000 Federal share), had unit counts of 44 or 88, which represent billings equivalent to entire multiuse vials.[1]

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

Appendix A contains the details of our audit scope and methodology.

FINDINGS

Most Medicaid payments that the State agency made to providers for full vials of Herceptin were incorrect. Of the 145 line items reviewed, 138 (95 percent) were incorrect and included overpayments of $165,624 ($130,581 Federal share).[2] The seven remaining line items were correct. The providers attributed the incorrect claims to clerical errors and to billing systems that could not prevent or detect the incorrect billing of units of service. The State agency made these incorrect payments because it did not have sufficient edits in place during our audit period to prevent or detect the overpayments.

OVERPAYMENTS OCCURRED ON MOST LINE ITEMS

The *Arkansas Medicaid Provider Manual* (the Manual) requires that provider records support the level of services billed to Medicaid (§ 142.300) and that a provider refund the Medicaid program if an overpayment occurs (§ 321.000).

Providers reported incorrect units of service on 137 line items and received overpayments totaling $163,397 ($128,776 Federal share). Providers billed Medicaid for full vials of Herceptin, which contain 440 milligrams, rather than billing only for the amount actually administered.

For example, one provider administered 150 milligrams of Herceptin to a patient and billed for 44 units of service (440 milligrams). On the basis of the HCPCS description of Herceptin (injection, trastuzumab, 10 milligrams), the number of units to be reported for 150 milligrams is 15. This error occurred on 21 separate occasions for 1 patient; as a result, the State agency paid the provider $47,392 when it should have paid $16,156, an overpayment of $31,236.

[1] Of the 145 line items, 5 had unit counts greater than 88. Although these line items did not represent billings equivalent to a full vial, these high-unit items were included because they were likely to be incorrect.

[2] The Federal matching percentage ranged from 70.17 to 80.95 percent during our audit period.

Additionally, a provider billed Medicaid twice for the same service date. The provider billed Medicaid for the service date and the day before the service date. Medicaid paid for both line items, but the provider had supporting documentation for only one service date. This line item is considered to be in error, resulting in an overpayment totaling $2,257.

The providers attributed the incorrect claims to clerical errors and to billing systems that could not prevent or detect the incorrect billing of units of service. The State agency made these incorrect payments because it did not have sufficient edits in place during our audit period to prevent or detect the overpayments.

RECOMMENDATIONS

We recommend that the State agency:

- recover the identified overpayments and refund the $130,581 Federal share to the Federal Government,

- consider implementing or updating system edits that identify for review multiuse-vial drugs that are billed with units of service equivalent to the dosage of an entire vial(s), and

- consider using the results of this audit in its provider education activities.

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the State agency agreed that it owed $130,581 to the Federal Government but stated that it had decided to forego recoupment from the providers because the State agency's policies were unclear at the time. The State agency also stated that it had drafted rule changes to prevent incorrect billing of multiuse vials in the future and that it plans to conduct provider education activities on new multiuse-vial rules. The State agency's comments are included in their entirety as Appendix B.

While we acknowledge that the State agency can decide not to recoup the overpayments from the providers, we continue to recommend that the State agency refund the full amount to the Federal Government.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

For the 3-year period July 1, 2010, through June 30, 2013, the State agency processed 2,646 outpatient service line items of Herceptin totaling approximately $4.56 million. Of these line items, we reviewed 145 line items totaling $386,000. All 145 line items had unit counts of 44 or 88, which represent billings equivalent to entire multiuse vials.[3]

We limited our review of the State agency's internal controls to those that were applicable to the selected payments because our objective did not require an understanding of all internal controls over the submission and processing of claims.

We conducted fieldwork from March 2014 through February 2015 at the State agency in Little Rock, Arkansas, and contacted 16 Arkansas providers that received the selected Medicaid payments.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal and State laws, regulations, and guidance;
- interviewed State agency and fiscal agent personnel to gain an understanding of the internal controls related to the processing of claims;
- obtained from the State agency Medicaid paid claims in which payments were made for HCPCS code J9355 (Herceptin) for service dates during the audit period;
- identified 145 line items in our scope that the State agency paid to 16 providers;
- contacted providers that received Medicaid payments associated with the selected line items to determine whether the information conveyed in the selected line items was correct and, if not, why the information was incorrect;
- reviewed documentation (a physician's order for medication and the administration of the medication for the amount ordered) that the providers furnished to verify whether each selected line item was billed correctly;
- calculated the overpayments;

[3] Of the 145 line items, 5 had unit counts greater than 88. Although these line items did not represent billings equivalent to full vials, these high-unit items were included because they were likely to be incorrect.

- calculated the Federal share of incorrect payments on the basis of the Federal share in effect when an incorrect claim was paid and on whether the incorrect claim was related to breast and cervical cancer;[4] and

- discussed the results of our review with the State agency.

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.

[4] The Federal Government's share of most Medicaid expenditures varies by State, depending on each State's per capita income. Also, the States will receive a higher, variable rate for optional breast and cervical cancer services.

APPENDIX B: STATE AGENCY COMMENTS

ARKANSAS DEPARTMENT OF HUMAN SERVICES

Division of Medical Services

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June 16, 2015

PATRICIA WHEELER
REGIONAL INSPECTOR GENERAL
OFFICE OF INSPECTOR GENERAL
1100 COMMERCE STREET, ROOM 632
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Re: Herceptin Draft Report

Dear Ms. Wheeler

I am writing in reference to your letter of April 27, 2015 concerning the Office of Inspector General's draft report entitled *Most Medicaid Payments Arkansas Made to Providers for Full Vials of Herceptin Were Incorrect.* The Department's responses to each of the recommendations contained in the draft report are listed below:

- The Department concurs with the finding that the payments were made in error resulting in $130,581 Federal share being owed to the Federal Government. After consultation with the Department's program administrators, a decision was made to forego recoupment from providers since the policy at the time was unclear on the billing procedures for Herceptin.
- The Department has drafted rule changes that will be implemented to prevent the incorrect billing of multi-use vials in the future. These rule changes are subject to legislative approval before implementation.
- The Department will conduct provider education activities upon implementation of the new rules for multi-use vials.

Please do not hesitate to call if I can be of further assistance.

Sincerely,

Michael Crump
Assistant Director- Operations
Division of Medical Services

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