

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MOST MEDICAID PAYMENTS
TEXAS 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**

**June 2015
A-06-14-00042**

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.

Most Medicaid payments Texas made to providers for full vials of Herceptin from 2010 through 2012 were incorrect and resulted in overpayments of approximately \$566,000 (Federal share).

INTRODUCTION

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 one 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 Texas Medicaid program.

OBJECTIVE

Our objective was to determine whether payments made by Texas Medicaid to providers for full vials of the drug Herceptin were correct.

BACKGROUND

The Medicaid program provides medical assistance to 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 Medicaid program. In Texas, the Texas Health and Human Services Commission (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) code 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 10mg.” As a result, 1 billing unit has 10 mg of reconstituted Herceptin and an entire multiuse vial of 440 milligrams would be reported as 44 billing units.

HOW WE CONDUCTED THIS REVIEW

The State agency processed 21,617 Herceptin claim lines totaling approximately \$34.2 million from January 1, 2010, through December 31, 2012. Of these claim lines, we reviewed 1,311 totaling approximately \$3.1 million (\$2.2 million Federal share) that had unit counts of 44, 88, 132, or 176, which represent billings equivalent to entire multiuse vials.

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 1,311 line items reviewed, 924 (70 percent) were incorrect and included overpayments of \$823,279 (\$566,368 Federal share). The 387 remaining line items were correct.

According to the Texas Medicaid Provider Procedures Manual (the Manual), the State agency requires claims to be true, accurate, and complete (§ 1.4.8) and allows for recoupment when services provided do not match the services claimed (§ 1.4.10).

On all of the incorrect line items, providers reported the units of service for the entire contents of one, two, three, or four vial(s), each containing 440 milligrams of Herceptin, rather than reporting the units of service for the amount actually administered.

For example, one provider administered 170 milligrams of Herceptin to a patient and billed for either 44 or 88 units of service (440 or 880 milligrams). On the basis of the HCPCS description of Herceptin (injection, trastuzumab, 10 milligrams), the number of units to be reported for 170 milligrams is 17. This error occurred on five separate occasions for one patient; as a result, the State agency paid the provider \$12,461 when it should have paid \$4,814, an overpayment of \$7,647.

The providers attributed the incorrect billing and overpayments to clerical errors, billing system errors, and misinterpretation of guidelines. 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 \$566,368 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.

TEXAS HEALTH AND HUMAN SERVICES COMMISSION COMMENTS

In written comments on our draft report, the State agency identified actions it had taken or planned to take to address our recommendations and included estimated target dates. The State agency's comments are included in their entirety as Appendix B.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

For the 3-year period January 1, 2010, through December 31, 2012, the State agency processed 21,617 Herceptin claim lines totaling approximately \$34.2 million. Of these 21,617 line items, we reviewed 1,311 totaling approximately \$3.1 million. These 1,311 lines had unit counts of 44, 88, 132, or 176, which represented billings equivalent to entire multiuse vials.

Our objective did not require a review of the State agency's overall internal control structure. Therefore, we limited our internal control review to State agency procedures related to the submission and processing of Herceptin claims.

We conducted our audit work from May 2014 through March 2015, which included contacting 57 Texas providers that received the selected Medicaid payments.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal and State laws, regulations, and guidance;
- held discussions with the State agency;
- obtained from the State agency Medicaid paid claims for which payments were made for HCPCS code J9355 (Herceptin) during the audit period;
- identified 1,311 line items in our scope that the State agency paid to 57 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 that the providers furnished to verify whether each selected line item was billed correctly; specifically, we reviewed documentation to support a physician's orders for the medication and the fact that the medication was administered;
- coordinated the recalculation of incorrect payments with the State agency;
- calculated the Federal share of incorrect payments, considering the Federal share in effect when an incorrect claim was paid and whether the incorrect claim was related to breast and cervical cancer;¹ and

¹ 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.

- communicated 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.

**APPENDIX B: TEXAS HEALTH AND HUMAN SERVICES COMMISSION
COMMENTS**



TEXAS HEALTH AND HUMAN SERVICES COMMISSION

KYLE L. JANEK, M.D.
EXECUTIVE COMMISSIONER

May 20, 2015

Ms. Patricia Wheeler
Regional Inspector General for Audit Services
Office of Inspector General, Office of Audit Services
1100 Commerce, Room 632
Dallas, Texas 75242

Reference Report Number A-06-14-00042

Dear Ms. Wheeler:

The Texas Health and Human Services Commission (HHSC) received a draft audit report entitled "Most Medicaid Payments Texas Made To Providers For Full Vials of Herceptin Were Incorrect" from the Department of Health and Human Services Office of Inspector General. The cover letter, dated April 20, 2015, requested that HHSC provide written comments, including the status of actions taken or planned in response to report recommendations.

I appreciate the opportunity to respond. Please find the attached HHSC management response which: (a) includes comments related to the content of the findings and recommendations; and (b) details actions HHSC has completed or planned.

If you have any questions or require additional information, please contact David M. Griffith, Director of HHS Risk and Compliance Management. Mr. Griffith may be reached by telephone at (512) 424-6998 or by e-mail at David.Griffith@hhsc.state.tx.us.

Sincerely,

A handwritten signature in blue ink, appearing to read "Kyle L. Janek".

Kyle L. Janek, M.D.

P. O. Box 13247 • Austin, Texas 78711 • 4900 North Lamar, Austin, Texas 78751 • (512) 424-6500

**Texas Health and Human Services Commission
Management Response to the
U.S. Department of Health and Human Services Office of Inspector General Report:

Most Medicaid Payments Texas Made to Providers for
Full Vials of Herceptin Were Incorrect**

Summary of Management Response

The Texas Health and Human Services Commission (HHSC) is committed to the integrity of the Medicaid program in Texas and the appropriate stewardship of both state and federal healthcare dollars. In spearheading these efforts, the HHSC Office of the Inspector General (OIG) monitors developments in the Medicare and Medicaid programs to identify aberrant billing practices and areas that have a high risk for improper payments.

The U.S. Department of Health and Human Services Office of Inspector General issued a series of audit reports in 2012 that highlighted the high percentage of improper Medicare payments associated with Herceptin, a high dollar breast cancer drug. As a consequence of these reports, HHSC OIG proactively and nearly one year before being notified of this audit took action to evaluate the risk and likelihood of similar improper Herceptin payments in the Texas Medicaid program. These efforts included identifying the top providers paid for Herceptin in calendar years 2010 through 2012 and subsequent provider claim reviews to determine if payments were appropriate. These efforts resulted in the recoupment of \$615,590 from Medicaid providers for improper Herceptin payments.

These efforts, as the results of this audit illustrate, warrant continued attention and monitoring of multiuse-vial drugs, like Herceptin. HHSC OIG will implement periodic and targeted claim queries to continue efforts to identify improper payments for Herceptin multiuse-vials in both the Texas Medicaid fee-for-service and managed care programs.

Detailed responses to each of the recommendations included in the report follow.

DHHS - OIG Recommendation: *We recommend that the State agency recover the identified overpayments and refund the \$566,368 Federal share to the Federal Government.*

HHSC Management Response:

Actions Planned:

HHSC has taken action and continues to recover improper provider payments for multiuse-vials of Herceptin. HHSC will continue to refund the federal share of these payments in accordance with 42 CFR Part 433, Subpart F.

Estimated Completion Date:

July 2015

Title of Responsible Person:

Director of Operations Management, Medicaid/CHIP Division

DHHS - OIG Recommendation: *We recommend that the State agency 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).*

HHSC Management Response:

Actions Planned:

HHSC OIG will implement periodic and targeted queries to continue efforts to identify incorrect billings for Herceptin multiuse-vials. When incorrect billings are identified, HHSC will recover the associated overpayment and will refund the federal share in accordance with applicable requirements.

Estimated Completion Date:

June 2015

Title of Responsible Person:

Director of Operations Management, Medicaid/CHIP Division
Manager of Research, Analysis and Detection, HHSC OIG

DHHS - OIG Recommendation: *We recommend that the State agency consider using the results of this audit in its provider education activities.*

HHSC Management Response:

Actions Planned:

To strengthen provider education on the appropriate billing of multiuse-vial drugs, HHSC directed the Medicaid claims administrator to post a banner message on its provider website and include information on weekly provider remittance and status reports regarding the appropriate billing of multiuse-vial drugs. These actions were completed in May 2015.

Providers identified by the targeted claim queries as improperly billing for multiuse-vial drugs will receive educational information on the appropriate practices when submitting claims for multiuse-vial drugs. Additional multiuse-vial drug policy changes will be

addressed through the HHSC Benefits Management Workgroup with an estimated target date of October 2015.

Estimated Completion Date:

October 2015

Title of Responsible Person:

Director of Operations Management, Medicaid/CHIP Division
Manager of Research, Analysis and Detection, HHSC OIG
Manager of Center for Policy and Outreach, HHSC OIG