

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MOST MEDICAID PAYMENTS THE
STATE OF ILLINOIS MADE TO
PROVIDERS FOR FULL VIALS OF
HERCEPTIN WERE INCORRECT**

*Inquiries about this report may be addressed to the Office of Public Affairs at
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Office of Inspector General

<http://oig.hhs.gov>

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EXECUTIVE SUMMARY

Most Medicaid payments the State of Illinois made to providers for full vials of Herceptin were incorrect and resulted in overpayments of about \$668,000 (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 we 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 the billing for Herceptin to the Illinois Medicaid program.

The objective of our review was to determine whether payments made by Illinois to providers for the drug Herceptin were in accordance with applicable State and Federal regulations.

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 Illinois, the Department of Healthcare and Family Services (the State agency) administers its Medicaid program in accordance with the CMS-approved State plan. Although the State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements.

In Illinois, reimbursement for outpatient services is on a fee-for-service basis. The State agency makes payment for allowable services at the lower of the provider's usual and customary charges or the State agency's maximum established rates.

Providers must certify that they have rendered the services or provided the items being billed and also must maintain records that document the care for which payment is claimed. For chemotherapy drugs, providers bill using the appropriate Healthcare Common Procedure Coding System (HCPCS) codes, the corresponding National Drug Code, and the appropriate quantity of the drug administered. The number of units billed should correspond to the quantity of Herceptin administered (service rendered) to the patient. The HCPCS code for Herceptin is J9355, with a narrative description of "injection, trastuzumab 10mg." An entire multiuse vial of

440 milligrams of reconstituted Herceptin when administered would be reported as 44 units for billing.

HOW WE CONDUCTED THIS REVIEW

The State agency processed 10,478 outpatient service line items of Herceptin totaling approximately \$21 million from July 1, 2010, through June 30, 2013. Of these line items, 848 totaling approximately \$3.2 million had unit counts of 44 or 88 that represent billings equivalent to entire multiuse vials.

WHAT WE FOUND

Most Medicaid payments that the State agency made to providers for full vials of Herceptin were incorrect. Of the 848 line items reviewed, 681 (80 percent) were incorrect and included overpayments of about \$1.2 million (\$667,511 Federal share) of the approximately \$3.2 million reviewed. The 167 remaining line items were correct.

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

The providers attributed the incorrect payments to clerical and billing system errors that could not prevent or detect the incorrect billing 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.

WHAT WE RECOMMEND

We recommend that the State agency:

- recover the identified overpayments and refund \$667,511 to the Federal government,
- implement or update 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
- use the results of this audit in its provider education activities.

STATE AGENCY COMMENTS

In written comments to our draft report, the State agency concurred with our recommendations and provided information on actions that it plans to take to address our recommendations.

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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 we 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 the billing for Herceptin to the Illinois Medicaid program.

OBJECTIVE

The objective of our audit was to determine whether payments made by Illinois to providers for the drug Herceptin were in accordance with applicable State and Federal regulations.

BACKGROUND

The Medicaid Program: How It Is Administered

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 Illinois, the Department of Healthcare and Family Services (the State agency) administers its Medicaid program in accordance with the CMS-approved State plan. Although the State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements.

The Illinois Medicaid Program Reimburses Outpatient Services on a Fee-for-Service Basis

Reimbursement for outpatient services in Illinois is on a fee-for-service basis.¹ The State agency makes payment for allowable services at the lower of the provider's usual and customary charges or the State agency's maximum established rates.

¹ Under a fee-for-service arrangement, health care providers are paid for each service rendered (i.e., office visit, lab test, or procedure).

Providers must certify that they have rendered the services or provided the items being billed and also must maintain records that document the care for which payment is claimed. For chemotherapy drugs, providers bill the State agency using the appropriate Healthcare Common Procedure Coding System (HCPCS) codes, the corresponding National Drug Code (NDC)² and the appropriate quantity of the drug administered. The number of units billed should correspond to the quantity of Herceptin actually administered (service rendered) to the patient.

Herceptin Attacks Specific Cancer Cells

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 20-milliliter vial of bacteriostatic water for injection (BWFI) containing a solution of 1.1 percent of benzyl alcohol as a preservative. A vial of Herceptin, when reconstituted with BWFI and stored properly, can be used for up to 28 days. When a patient is allergic to benzyl alcohol, sterile water without a preservative should be used and any unused portion of the mixture discarded. The HCPCS code for Herceptin is J9355, with a narrative description of “injection, trastuzumab 10mg.” An entire multiuse vial of 440 milligrams of reconstituted Herceptin when administered would be reported as 44 units for billing.

HOW WE CONDUCTED THIS REVIEW

The State agency processed 10,478 outpatient service line items of Herceptin totaling approximately \$21 million from July 1, 2010, through June 30, 2013. Of these line items, 848 totaling approximately \$3.2 million had unit counts of 44 or 88 that represent billings equivalent to entire multiuse vials.³

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 and Appendix B contains applicable Federal and State requirements.

² The NDC serves as a universal product identifier for drugs using a unique three-segment number.

³ Of the 848 line items, 51 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.

FINDINGS

Most Medicaid payments that the State agency made to providers for full vials of Herceptin were incorrect. Of the 848 line items reviewed, 681 (80 percent) were incorrect and included overpayments of about \$1.2 million (\$667,511 Federal share)⁴ of the approximately \$3.2 million reviewed. The 167 remaining line items were correct.

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

The providers attributed the incorrect payments to clerical and billing systems errors that could not prevent or detect the incorrect billing 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

Incorrect Number of Units of Service

Providers reported incorrect units of service on 675 line items, resulting in overpayments totaling \$1,119,675 (\$649,535 Federal share). Providers billed Medicaid for entire vials containing 440 milligrams of Herceptin, rather than billing only for the amounts actually administered.

For example, one provider administered 180 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 180 milligrams is 18.⁵ This error occurred on 28 separate occasions for 1 patient; as a result, the State agency paid the provider \$81,731 when it should have paid \$33,435, an overpayment of \$48,296.

Unsupported Services

Providers billed Medicaid for 6 line items for which the providers did not provide supporting documentation. These line items are considered to be in error, resulting in overpayments totaling \$30,379 (\$17,976 Federal share).

⁴ The Federal matching percentage ranged from 50 percent to 65.12 percent during our audit period.

⁵ If the drug dose used in the care of a patient is not a multiple of the HCPCS code dosage descriptor, the provider rounds to the next highest unit on the basis of the HCPCS long descriptor to report the dose.

RECOMMENDATIONS

We recommend that the State agency:

- recover the identified overpayments and refund \$667,511 to the Federal government,
- implement or update 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
- use the results of this audit in its provider education activities.

STATE AGENCY COMMENTS

In written comments to our draft report, the State agency concurred with our recommendations and provided information on actions that it plans to take to address our recommendations. The State agency's comments are included in their entirety as Appendix C.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

The State agency processed 10,478 outpatient service line items of Herceptin totaling approximately \$21 million during our audit period. Of these 10,478 line items, we reviewed 848 totaling approximately \$3.2 million. These 848 lines had unit counts of 44 or 88 that represented billings equivalent to entire multiuse vials.⁶

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 the fieldwork for this review from February through September 2014 and contacted 46 providers in Illinois that received the selected Medicaid payments.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal and State laws, regulations, and guidance;
- obtained Medicaid paid claims in which payments were made for HCPCS code J9355 (Herceptin) for service dates during the audit period, from the State agency;
- identified 848 line items in our scope that the State paid to 46 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:
 - the medical condition of the beneficiary in determining the necessity of the medication,
 - a physician's orders for the medication,
 - the fact that the medication was administered, and

⁶ Of the 848 line items, 51 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.

- the type of solution that was used to reconstitute the Herceptin (BWFI containing 1.1 percent benzyl alcohol or sterile water);
- coordinated the calculation of overpayments 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.

APPENDIX B: FEDERAL AND STATE REQUIREMENTS

FEDERAL REQUIREMENTS

Pursuant to section 1902(a)(27)(A) of the Social Security Act, States must have agreements in place requiring providers to keep such records as are necessary to fully disclose the extent of the services provided to individuals receiving assistance under the State plan.

Pursuant to section 2497.1 of the *State Medicaid Manual*, expenditures are allowable only to the extent that, when a claim is filed, you have adequate supporting documentation in readily reviewable form to assure that all applicable Federal requirements have been met.

STATE REQUIREMENTS

Pursuant to 89 Illinois Administrative Code, Section 148.140, reimbursement for hospital outpatient services shall be made on a fee-for-service basis. Fee-for-service reimbursement levels shall be at the lower of the hospital's usual and customary charge to the public or the Department's statewide maximum reimbursement screens. Hospitals will be required to bill the Department utilizing specific service codes.

Pursuant to 89 Illinois Administrative Code, Section 140.20 (a)(2)(A), when claims for payment are submitted to the Department, providers shall certify that they have personally rendered the services and provided the items for which charges are being made.

Pursuant to 89 Illinois Administrative Code, Section 140.28, providers shall maintain in the regular course of business any and all professional records that relate to the quality of care given by the provider or that document the care for which payment is claimed, including medical records for applicants and recipients of public assistance.

Pursuant to the *Illinois' Practitioner's Handbook*, providers must bill chemotherapy drugs using the appropriate HCPCS codes, indicating the quantity and the corresponding NDC(s).

APPENDIX C: STATE AGENCY COMMENTS



Pat Quinn, Governor
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December 24, 2014

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Re: Draft Audit Report A-05-14-00023

Dear Ms. Fulcher:

Thank you for providing the opportunity to comment on your draft audit report entitled "*Most Medicaid Payments the State of Illinois Made to Providers for Full Vials of Herceptin Were Incorrect.*"

The Department concurs with the recommendations. HFS will post adjustments to recoup payments made for the unused portion of the medication. HFS is close to completion of the adjustment process to recoup funds from providers who billed inappropriately. As the adjustments apply, HFS will return the match to the Federal government. In addition, HFS will evaluate system edits and determine a systematic solution to prevent or detect the overpayments. HFS is in the process of developing a new MMIS system, so at that time, the edits will be implemented. We have posted a provider notice dated 11-10-14 outlining policy for multi-dose vials.

We appreciate the work completed by your audit team. If you have any questions or comments about our response to the audit, please contact Amy Lyons, External Audit Liaison, at (217) 557-0576 or through email at amy.lyons@illinois.gov.

Sincerely,

A handwritten signature in black ink that reads 'Julie Hamos'.

Julie Hamos
Director

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