NEW YORK IMPROPERLY CLAIMED FEDERAL MEDICAID REIMBURSEMENT FOR THE DRUG HERCEPTIN OVER A 3-YEAR PERIOD
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EXECUTIVE SUMMARY

New York improperly claimed approximately $300,000 in Federal Medicaid reimbursement for the drug Herceptin over a 3-year period.

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. 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 State Medicaid programs including the New York Medicaid program.

The objective of this review was to determine whether the New York Department of Health’s (State agency’s) claims for Medicaid reimbursement for the drug Herceptin complied with applicable Federal and State requirements.

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 New York, 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. Further, the State agency has established guidelines for claims reimbursement and provides oversight for compliance with Federal requirements.

Herceptin is a monoclonal antibody, one of a group of drugs designed to attack specific cancer cells. Its 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.

Medicaid providers bill the State agency for Herceptin using a 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 Medicaid beneficiary. 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.
In New York, the State agency reimburses Medicaid providers for certain chemotherapy drugs, including Herceptin, based on the providers’ acquisition costs for the drug dose administered to the beneficiary.

**HOW WE CONDUCTED THIS REVIEW**

For the period July 1, 2011, through June 30, 2014 (audit period), the State agency claimed Medicaid reimbursement totaling approximately $14 million ($8 million Federal share) for 12,215 Herceptin claim lines (referred to as claims in this report). We reviewed 991 claims totaling approximately $2.6 million ($1.5 million Federal share) that had (1) unit counts in multiples of 44, (2) unit counts of 70 or more, or (3) a billing unit of 1 and for which the provider was reimbursed more than $1,000, for service dates during the audit period. We also reviewed provider invoices to verify acquisition costs.

**WHAT WE FOUND**

Most of the State agency’s claims for Federal Medicaid reimbursement for Herceptin that we reviewed were incorrect. Of the 991 claims reviewed, 8 claims were correct and 800 were incorrect. The incorrect payments resulted in overpayments of $502,927 ($300,311 Federal share) and underpayments of $172,262 ($95,746 Federal share). The remaining 183 claims had an immaterial payment difference amount of $10 or less and were removed from our overpayment and underpayment calculations.

Of the 800 incorrect claims, 269 contained more than 1 error:

- For 722 claims, the State agency improperly reimbursed providers based on the providers’ submitted costs rather than their acquisition costs. Specifically, the State agency reimbursed providers submitted costs when the invoiced acquisition cost of the drug dose administered amount was either lower (329 claims) or higher (393 claims).

- For 269 claims, providers incorrectly reported the unit of service (e.g., 44 units for a full vial instead of 1 unit for every 10 milligrams of reconstituted Herceptin). (These errors are also included in the above finding because the claims were not properly submitted for reimbursement. This is also reflected in our recommendations.)

- For 78 claims, providers did not provide documentation to support their claimed amount. Specifically, providers (1) could not support the acquisition costs for the drug doses administered with invoices (60 claims) or (2) did not provide documentation for (or could not support) the administration of Herceptin (18 claims).

For the incorrect claims with underpayments of $172,262 ($95,746 Federal share), we notified the State agency of our findings so that it could review the claims and determine if the associated providers should resubmit the claims for additional reimbursement.

The incorrect payments occurred because the State agency did not adequately monitor providers to ensure they complied with Federal and State requirements. Specifically, the State agency
(1) did not have sufficient billing system edits in place to prevent or detect incorrect payments, and (2) did not verify the acquisition cost for claims filed electronically; therefore, it paid providers based on submitted amounts only. Providers attributed their incorrect billings to clerical errors, provider billing systems, and inability to locate documentation.

WHAT WE RECOMMEND

We recommend that the State agency:

- refund $300,311 to the Federal Government,
- require providers to submit records of their acquisition costs to ensure accurate reimbursement,
- implement or update billing system edits to identify for review multiuse vial drugs 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 AND OUR RESPONSE

In written comments on our draft report, the State agency agreed with three of our five initial recommendations and described actions that it planned to take to address these recommendations. The State agency did not indicate concurrence or nonconcurrence with our first recommendation (financial disallowance). Specifically, the State agency stated that its Office of Medicaid Inspector General will review the invoice data and supporting documentation associated with the 800 claims identified in our draft report and recover any overpayments that are determined to be inappropriate. Regarding a recommendation on identified underpayments, the State agency stated that providers are responsible for ensuring the accuracy of claims submitted for Medicaid reimbursement and, therefore, it is their responsibility to identify any errors made in a claim submission—not the State agency’s.

After reviewing the State agency’s comments, we removed the recommendation related to identified underpayments.
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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. Previous Office of Inspector General (OIG) 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 State Medicaid programs. Appendix A contains a list of related OIG Medicaid Herceptin reports.

OBJECTIVE

The objective of this review was to determine whether the New York Department of Health’s (State agency’s) claims for Medicaid reimbursement for the drug Herceptin complied with applicable Federal and State regulations.

BACKGROUND

The Medicaid Program

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. 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. Further, the State agency has established guidelines for claims reimbursement and provides oversight for compliance with Federal requirements.

How New York Reimburses Medicaid Providers for Herceptin

Herceptin is one of a group of drugs designed to attack specific cancer cells. Its 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.

In New York, Medicaid providers bill the State agency for Herceptin using a 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 beneficiary. 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.

The State agency reimburses Medicaid providers for certain chemotherapy drugs, including Herceptin, furnished by physicians to beneficiaries based on the providers’ acquisition costs for the drug dose administered to the beneficiary.¹

**HOW WE CONDUCTED THIS REVIEW**

For the period July 1, 2011, through June 30, 2014 (audit period), the State agency claimed Medicaid reimbursement totaling approximately $14 million ($8 million Federal share) for 12,215 Herceptin claim lines (referred to as claims in this report). We reviewed 991 claims totaling approximately $2.6 million ($1.5 million Federal share) that had (1) unit counts in multiples of 44, (2) unit counts of 70 or more, or (3) a billing unit of 1 and for which the provider was reimbursed more than $1,000, for service dates during the audit period. We also reviewed provider invoices to verify acquisition costs.

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.

See Appendix B for the details of our scope and methodology.

**FINDINGS**

Most of the State agency’s claims for Federal Medicaid reimbursement for the drug Herceptin that we reviewed were incorrect. Of the 991 claims reviewed, 8 claims were correct and 800 were incorrect. The incorrect payments resulted in overpayments of $502,927 ($300,311 Federal share) and underpayments² of $172,262 ($95,746 Federal share). The remaining 183 claims had an immaterial payment difference amount of $10 or less and were removed from our overpayment and underpayment calculations.

¹ Title 10 § 86-8.10 of the New York Compilation of Codes, Rules, & Regulations (NYCRR) lists ambulatory patient groups (APGs) excluded from the State’s methodology for reimbursing most services provided by hospital outpatient departments. These APGs are paid under what is known as the Ordered Ambulatory Fee Schedule. Section 4.20 of the State’s Policy and Billing Guidance Ambulatory Patient Groups Provider Manual contains a link to a list of carved-out procedures, and that link identifies J9355, Trastuzumab injection, as a Class V Chemotherapy Drug that is carved-out of the APG payment methodology. According to the Ordered Ambulatory Fee Schedule, for “J9355 Trastuzumab, 10 mg” and other chemotherapy drugs, the provider must insert the “acquisition cost per dose in the amount charged field on the claim form,” and reimbursement is based on “the acquisition cost to the provider of the drug dose administered to the patient.”

² For incorrect claims with underpayments, we notified the State agency of our findings so that it could review the claims and determine if the associated providers should resubmit the claims for additional reimbursement.
The table below summarizes the error categories and the number of incorrect claims for each category.

<table>
<thead>
<tr>
<th>Error Category</th>
<th>Number of Incorrect Claims a</th>
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</thead>
<tbody>
<tr>
<td>Reimbursement improperly based on submitted costs</td>
<td>722</td>
</tr>
<tr>
<td>Incorrect number of units of service</td>
<td>269</td>
</tr>
<tr>
<td>No supporting documentation for acquisition cost or drug administered</td>
<td>78</td>
</tr>
</tbody>
</table>

a The total exceeds 800 because 269 claims (all the claims with incorrect number of units of service) contained more than 1 error.

The incorrect payments occurred because the State agency did not adequately monitor providers to ensure they complied with Federal and State requirements. Specifically, the State agency (1) did not have sufficient billing system edits in place to prevent or detect incorrect payments, and (2) did not verify the acquisition cost for claims filed electronically; therefore, it paid providers based on submitted amounts only. Providers attributed the incorrect billings to clerical errors, provider billing systems, and inability to locate documentation.

**REIMBURSEMENT IMPROPERLY BASED ON SUBMITTED COSTS**

The State agency reimburses providers their actual costs for certain drugs. The providers are expected to limit their Medicaid claim amounts to the actual invoice costs of the drug doses administered. The providers are expected to maintain auditable records of the actual itemized invoice cost of the drug, including the numbers of doses of the drug represented on the invoice.

For 722 claims, the State agency improperly reimbursed providers based on their submitted drug costs—not their invoiced acquisition costs. For these claims, providers were reimbursed for submitted costs when the invoiced acquisition costs of the drug dose administered amount was either lower (329 claims) or higher (393 claims). For example, the State agency reimbursed one provider $3,098 ($1,549 Federal share) for 44 units of Herceptin. However, the provider should have been reimbursed $1,004 ($502 Federal share), resulting in an overpayment of $2,094 ($1,047 Federal share). This type of error occurred on 68 separate occasion for this provider, resulting in overpayments of $52,451 ($30,096 Federal share).

In total, the State agency paid 82 providers $1,803,215 ($1,059,873 Federal share) when it should have paid $1,687,365 ($990,510 Federal share), an overpayment of $288,112 ($165,109 Federal share) and underpayment of $172,262 ($95,746 Federal share).

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3 New York Social Services Law § 367-a.9.(a). Certain drugs provided by hospital outpatient departments under the New York Medicaid program by medical practitioners and claimed separately by the practitioners are reimbursed at the practitioners’ actual costs. Medicaid does not intend to pay more than the acquisition cost of the drug dosage, as established by invoice, to the practitioner.

4 New York State Ordered Ambulatory Fee Schedule.
INCORRECT NUMBER OF UNITS OF SERVICE

The State agency reimburses providers based on the providers’ acquisition costs and the dose administered to the Medicaid beneficiary.5

For 269 claims, providers reported incorrect units of service (e.g., reported units for a full vial (44 units) and not the actual units of service for the amount of drug dose administered). For example, one provider administered 60 milligrams of Herceptin to a beneficiary 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 that should be reported for 60 milligrams is 6. This provider incorrectly billed in this manner on three separate occasions for one beneficiary, resulting in overpayments of $7,395 ($3,698 Federal share).

In total, the State agency paid 42 providers $617,817 ($354,231 Federal share) when it should have paid $491,057 ($278,154 Federal share), an overpayment of $233,521 ($134,443 Federal share) and underpayment of $106,761 ($58,365 Federal share).6

LACK OF SUPPORTING DOCUMENTATION

The State agency’s Physician’s Provider Manual indicates that expenditures are allowable only to the extent that, when a claim is filed, a provider has adequate supporting documentation in readily reviewable form to assure that all applicable Federal requirements have been met. The provider will maintain auditable records of the actual itemized invoice cost of the drug, including the numbers of doses of the drug represented on the invoice. The State agency does not intend to pay more than the acquisition cost of the drug dosage, as established by invoice, to the provider.7

For 60 claims, providers stated they were unable to provide invoice documentation to support the acquisition cost of services rendered. Lack of supporting documentation for the acquisition costs of services rendered for these claims resulted in overpayments of $181,071 ($116,351 Federal share). In addition, ten providers billed for 18 claims for which the providers did not provide any documentation to support that a beneficiary had received Herceptin on the date of service billed.8 In total, the State agency overpaid the providers $33,743 ($18,850 Federal share).


6 These dollar amounts are also included in the calculation of overpayments and underpayments in the previous findings because the claims were not properly submitted for reimbursement. This is also reflected in our recommendations.

7 New York State Physician’s Provider Manual, Procedure Code Section, Section 2- Medicine, Drugs and Drug Administration (New York Department of Health).

8 Totals include: three claims from one provider that stated records were lost in a fire and no electronic copies were maintained, two claims from one bankrupt provider where the bankruptcy counsel could not produce records.
RECOMMENDATIONS

We recommend that the State agency:

- refund $300,311 to the Federal Government,
- require providers to submit records of their acquisition costs to ensure accurate reimbursement,
- implement or update billing system edits to identify for review multiuse vial drugs 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 AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the State agency agreed with three of our five initial recommendations and described actions that it planned to take to address these recommendations. The State agency did not indicate concurrence or nonconcurrence with our first recommendation (financial disallowance). Specifically, the State agency stated that its Office of Medicaid Inspector General will review the invoice data and supporting documentation associated with the 800 claims identified in our draft report and recover any overpayments that are determined to be inappropriate. Regarding a recommendation on identified underpayments, the State agency stated that providers are responsible for ensuring the accuracy of claims submitted for Medicaid reimbursement and, therefore, it is their responsibility to identify any errors made in a claim submission—not the State agency’s.

After reviewing the State agency’s comments, we removed the recommendation related to identified underpayments. The State agency’s comments are included in their entirety as Appendix C.

9 In our draft report, we recommended that the State agency review the $95,746 in identified underpayments and determine if providers should be reimbursed additional funds. We have revised our final report to remove this recommendation based on the comments provided by the State agency in response to our draft report.
## APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

<table>
<thead>
<tr>
<th>Report Title</th>
<th>Report Number</th>
<th>Date Issued</th>
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</thead>
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<tr>
<td>Most Medicaid Payments Oklahoma Made to Providers for Full Vials of Herceptin Were Incorrect</td>
<td>A-06-15-00023</td>
<td>10/15/2015</td>
</tr>
<tr>
<td>Most Medicaid Payments Arkansas Made to Providers for Full Vials of Herceptin Were Incorrect</td>
<td>A-06-14-00032</td>
<td>7/27/2015</td>
</tr>
<tr>
<td>Most Medicaid Payments Texas Made to Providers for Full Vials of Herceptin Were Often Incorrect</td>
<td>A-06-14-00042</td>
<td>6/4/2015</td>
</tr>
<tr>
<td>Most Medicaid Payments the State of Illinois Made to Providers for Full Vials of Herceptin Were Incorrect</td>
<td>A-05-14-00023</td>
<td>2/2/2015</td>
</tr>
</tbody>
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APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

For the period July 1, 2011, through June 30, 2014 (audit period), the State agency claimed Medicaid reimbursement totaling approximately $14 million ($8 million Federal share) for 12,215 Herceptin claim lines (referred to as claims in this report). We reviewed 991 claims totaling approximately $2.6 million ($1.5 million Federal share) that had (1) unit counts in multiples of 44, (2) unit counts of 70 or more, or (3) a billing unit of 1 for which the provider was reimbursed more than $1,000, for service dates during the audit period. We also reviewed provider invoices to verify acquisition costs.

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.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal and State laws, regulations, and guidance;
- met with the State agency officials to gain an understanding of the procedures for processing the claims for Herceptin;
- obtained paid claims for which payments were made for HCPCS code J9355 (Herceptin) during the audit period;
- identified 991 claims in our scope that the State agency paid to 92 providers;
- requested providers furnish documentation to support the service billed, including the:
  - physician’s orders showing the drug, date and amount ordered,
  - drug administration record supporting the date, time and amount administered,
  - original or revised claims form submitted, and
  - invoice for the purchased of Herceptin showing date and acquisition cost;
- reviewed provider documentation to verify whether each selected line item was billed correctly; specifically, we reviewed documentation to support a physician’s orders for the medication, the dose administered, and acquisition cost;
- summarized results of the review;
- calculated incorrect payment amounts; and
discussed the results of our review with State agency officials.

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.
July 8, 2016

Mr. James P. Edert
Regional Inspector General for Audit Services
Department of Health and Human Services - Region II
Jacob Javitz Federal Building
26 Federal Plaza
New York, New York 10278

Ref. No: A-02-15-01013

Dear Mr. Edert:


Thank you for the opportunity to comment.

Sincerely,

Sally Dreslin
Sally Dreslin, M.S., R.N.
Executive Deputy Commissioner

Enclosure
New York State Department of Health
Comments on the
Department of Health and Human Services
Office of Inspector General
Draft Audit Report A-02-15-01013 entitled
“New York Improperly Claimed Federal Medicaid Reimbursement for the
Drug Herceptin Over a 3-year Period”

The following are the New York State Department of Health’s (Department) comments in response to the Department of Health and Human Services, Office of Inspector General (OIG) Draft Audit Report A-02-15-01013 entitled, “New York Improperly Claimed Federal Medicaid Reimbursement for the Drug Herceptin Over a 3-year Period.”

Background:

New York State (NYS) is a national leader in its oversight of the Medicaid Program. With the transition to care management, the Office of the Medicaid Inspector General (OMIG) continues to improve upon our processes and direct our resources to match this changing direction in the Medicaid program. In conjunction with the Department, NYS will continue its focus on achieving improvements to the Medicaid program and aggressively fighting fraud, waste and abuse wherever it exists.

Under Governor Cuomo’s leadership, the Medicaid Redesign Team (MRT) was created in 2011 to lower health care costs and improve quality of care for its Medicaid members. Since 2011, Medicaid spending has remained under the Global Spending Cap, while at the same time providing health care coverage to an additional 1,405,500 fragile and low income New Yorkers. Additionally, Medicaid spending per recipient has decreased to $7,868 in 2014, consistent with levels from a decade ago.

Recommendation #1:

Refund $300,311 to the Federal Government.

Response #1

OMIG will request and review the invoice data and supporting documentation for the 800 claims identified by OIG, and recover any overpayments that are determined to be inappropriate.

Recommendation #2:

Review the $95,746 in identified underpayments and determine if providers should be reimbursed additional funds.

Response #2:

The Medicaid system (eMedNY) compares the provider’s submitted charges with the Average Sales Price for the drug on file, and reimburses the provider the lower of the two amounts. Providers must ensure the accuracy of all claims submitted to Medicaid. For physician-administered drugs, providers are to report the actual acquisition cost of the drug. If a provider determines an error has been made in claim submission and/or reimbursement, it is the provider’s responsibility, not the Department’s, to identify such claims and resubmit a claim adjustment.
Recommendation #3:
Require providers to submit records of their acquisition costs to ensure accurate reimbursement.

Response #3:
Providers consistently billing incorrectly for Herceptin provided in multiuse vials will be identified through targeted claim queries, put on edit 1142 (provider on review) and required to submit both the invoice reflecting the provider’s acquisition cost and the medical record reflecting the dosage provided.

Recommendation #4:
Implement or update billing system edits to identify for review multiuse vial drugs billed with units of service equivalent to the dosage of an entire vial(s).

Response #4
The Department will request OMIG perform periodic targeted reviews of Herceptin (J9355) claims to identify errors in billing for Herceptin supplied in multiuse vials.

Recommendation #5:
Use the results of this audit in its provider education activities.

Response #5:
A Medicaid Update article will be published by the end of August 2016 educating providers on how to bill correctly for practitioner-administered drugs supplied in multiuse vials. At the time of the next scheduled update, Provider Manuals will be revised to reflect this information.