

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**LOUISIANA MADE INCORRECT
HERCEPTIN PAYMENTS TO
MEDICAID PROVIDERS**

*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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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.

From 2011 through 2014, Louisiana made incorrect Herceptin payments to Medicaid providers, which resulted in overpayments of approximately \$2.1 million (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 (mg). 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 mg 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 Louisiana Medicaid program.¹

OBJECTIVE

Our objective was to determine whether certain payments that Louisiana made to providers for 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 Louisiana, the Department of Health (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.

One requirement is that the State agency describe its payment rates methodology for each type of service included in the State's Medicaid program. In Louisiana, the State agency used a fee-for-service methodology when paying claims for professional services rendered in doctors' offices, and it used cost-to-charge ratios when paying claims for services rendered in an outpatient facility.

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 mg 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.

¹See Appendix A for related Office of Inspector General reports.

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 narrative description of “injection, trastuzumab 10 mg.” As a result, 1 billing unit has 10 mg of reconstituted Herceptin, and an entire multiuse vial of 440 mg would be reported as 44 billing units.

HOW WE CONDUCTED THIS REVIEW

The State agency paid 3,561 Herceptin claim lines totaling approximately \$11.2 million from January 1, 2011, through December 31, 2014. Of these claim lines, we reviewed 1,952 (totaling approximately \$8.2 million) that had unit counts that appeared to be for full vials, or more than two vials, or that had an average paid amount per unit of \$70 or higher.

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 contains the details of our audit scope and methodology.

FINDINGS

Most Medicaid payments that the State agency made to providers for Herceptin were incorrect. Of the 1,952 line items reviewed, 1,576 (81 percent) were incorrect and included overpayments of \$2,935,616 (\$2,148,861 Federal share). The 376 remaining line items were correct.

The State agency requires providers to demonstrate that claims for goods and services are rendered to the appropriate beneficiary and that the goods and services rendered are the appropriate quality and quantity (Louisiana Administrative Code § 4115).

Providers billed and were paid for Herceptin doses for which they could not provide medical documentation, or the medical documentation they provided did not support the claim lines. For example, one provider administered 228 mg of Herceptin to a patient and billed for 44 units of service (440 mg). On the basis of the HCPCS description of Herceptin (injection, trastuzumab, 10 mg), the number of units to be reported for 228 mg is 23. This error occurred on seven separate occasions for one patient; as a result, the State agency paid the provider \$14,360 when it should have paid \$7,506, an overpayment of \$6,854.

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 claim edits it had in place during our audit period did not prevent the overpayments.

RECOMMENDATIONS

We recommend that the State agency:

- recover the identified overpayments and refund the \$2,148,861 Federal share to the Federal Government,
- consider implementing or updating system edits that identify for review Herceptin claims that appear to be 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 did not concur with our recommendations. Regarding the first recommendation, the State agency indicated that we audited interim payments based on cost-to-charge ratios calculated from the latest filed cost reports and not final reimbursement amounts determined through the cost report settlement process. The State agency also said that due to the nature of the drug and dispensing practices, there is no way of determining from a claims-level review whether the drug on a particular claim was for a single use or reconstituted for multiple uses and that a medical-level review is necessary. Regarding the second and third recommendations, the State agency indicated that it cannot agree with the findings presented until a further internal investigation and review of Herceptin claims has been completed. The State agency's comments are included in their entirety as Appendix C.

Regarding our first recommendation, we identified claims that were incorrectly paid and accurately calculated overpayments based on the amounts the State agency paid when the claims were processed. The State agency provided us with paid Herceptin claims for our review and we audited that data. The State agency paid more money than it should have for 81 percent of the claims in our review because the providers billed for more Herceptin than they actually administered. The State agency should collect the overpayments associated with the amounts it overpaid. Such collections are included in the final cost report settlement process.

We were, in fact, able to determine whether the providers correctly billed for Herceptin during a claims-level review of Herceptin claims, which included consideration of whether the drug was used as a single-use solution. We obtained from the providers the physician orders for Herceptin and the administration records that showed the amount of Herceptin that was actually administered. We also asked the providers to compare their records of how much Herceptin they administered with the amount of Herceptin for which they billed, and to tell us whether they believed they billed the claims correctly. In every instance in which the physician order and administration record revealed that the number of Herceptin billing units administered was less than the amount that was billed, the providers either acknowledged in writing that they had incorrectly billed for Herceptin or did not dispute our findings when we contacted them.

Additionally, the manufacturer's label for Herceptin indicates that it should be reconstituted as a multiuse solution, except for those instances in which a patient has hypersensitivity to benzyl alcohol. In those cases, Herceptin may be reconstituted without a preservative to yield a single-use solution. None of the documentation we obtained indicated that the patients had a hypersensitivity to benzyl alcohol, and not one of the providers told us that the drug was used as a single-use solution. Thus, for the claims we reviewed, we believe that Herceptin was reconstituted as multiuse solutions and that a medical review is not necessary to determine whether these claims were overpaid.

Regarding the second and third recommendations, our audit revealed that providers billed for more units of Herceptin than were actually administered, and we believe that system edits and provider education will help the State agency minimize these errors in the future.

APPENDIX A: RELATED OFFICE OF INSPECTOR GENERAL REPORTS

Report Title	Report Number	Date Issued
<i>Indiana Made Incorrect Medicaid Payments to Providers for Full Vials of Herceptin</i>	<u>A-05-15-00035</u>	5/16/2016
<i>Most Medicaid Payments Oklahoma Made to Providers for Full Vials of Herceptin Were Correct</i>	<u>A-06-15-00023</u>	10/15/2015
<i>Most Medicaid Payments Arkansas Made to Providers for Full Vials of Herceptin Were Incorrect</i>	<u>A-06-14-00032</u>	7/27/2015
<i>Most Medicaid Payments Texas Made to Providers for Full Vials of Herceptin Were Incorrect</i>	<u>A-06-14-00042</u>	6/4/2015
<i>Most Medicaid Payments the State of Illinois Made to Providers for Full Vials of Herceptin Were Incorrect</i>	<u>A-05-14-00023</u>	2/2/2015

APPENDIX B: AUDIT SCOPE AND METHODOLOGY

SCOPE

For the 4-year period January 1, 2011, through December 31, 2014, the State agency paid 3,561 Herceptin claim lines totaling approximately \$11.2 million. Of these 3,561 claim lines, we reviewed 1,952 totaling approximately \$8.2 million.

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 2015 through April 2016, which included contacting 27 Louisiana providers that received the selected Medicaid payments

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal and State laws, regulations, and guidance;
- obtained from the State agency Medicaid paid claims for which payments were made for HCPCS code J9355 (Herceptin) during the audit period;
- calculated a weighted average of the State agency's professional fee paid for 1 unit of Herceptin during our audit period (\$54) and then added an additional 30 percent (\$16) to our weighted average to determine our threshold paid per unit amount (\$70);
- identified paid Herceptin claim lines that had unit counts that appeared to be for full vials (i.e., 1, 2, 44, or 88), or more than 2 vials (more than 88 units), or that had an average paid amount per unit of \$70 or higher.;
- selected 1,952 total claim lines for review that the State agency paid to 27 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;
- calculated the revised payment amounts of incorrect claim lines;

- calculated the Federal share of incorrect payments, considering the Federal share in effect when an incorrect claim line was paid and whether the incorrect claim line was related to breast and cervical cancer;² 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.

² 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 C: LOUISIANA DEPARTMENT OF HEALTH COMMENTS

John Bel Edwards
GOVERNOR



Rebekah E. Gee MD, MPH
SECRETARY

State of Louisiana

Louisiana Department of Health
Bureau of Health Services Financing

July 8, 2016

Patricia Wheeler
Regional Inspector General for Audit Services
Office of Audit Services, Region VI
Office of the Inspector General
U.S. Department of Health and Human Services
1100 Commerce Street, Room 632
Dallas, TX 75242

Re: Report Number: A-06-15-00037

Dear Ms. Wheeler:

The Louisiana Department of Health (the "Department") is in receipt of the U.S. Department of Health and Human Services, Office of the Inspector General (OIG) draft report entitled *Louisiana Made Incorrect Herceptin Payments to Medicaid Providers*. Although Department personnel here did not receive the underlying audit information used for the draft report until yesterday and have not had the opportunity to review this information exhaustively, it is apparent that the audit scope and the methodology used by the OIG did not consider or take into account the reimbursement methodology utilized by the Medicaid program in Louisiana. For this reason, the Department cannot agree with the audit findings or the recommendations as presented by the OIG in the draft report at this time.

The Louisiana Department of Health does not concur that the State agency recover the identified overpayments and refund the \$2,148,861 Federal share to the Federal Government.

The findings that underlie the OIG draft report largely concern Medicaid reimbursement claims for Herceptin from outpatient hospitals. It must be emphasized that the reimbursement methodology utilized by Louisiana Medicaid for claims has been approved by the Centers for Medicare & Medicaid Services (CMS) as part of the Louisiana State Medicaid Plan. Further, this reimbursement methodology has been written into the state regulatory scheme for Louisiana Medicaid under Title 50 of the Louisiana Administrative Code. As it pertains to the reimbursement methodology for

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outpatient hospital claims specifically, these regulations can be found at 50 La. Admin. Code Pt V, 5107 *et seq.*

This CMS approved reimbursement methodology for Medicaid claims from outpatient hospitals encompasses a cost settlement process. As part of this process, an outpatient hospital first receives an interim payment for a Medicaid claim relating to that hospital's cost to charge ratio as calculated from the latest filed cost report of that hospital. This interim payment is thus made based on an estimate of cost. Final reimbursement, that is an adjustment of the interim payments for actual cost, is made later when the hospital submits its Medicaid cost report for the cost reporting year in which the services were incurred for the claim submitted to Louisiana Medicaid. When this cost report is submitted to and reviewed by Louisiana Medicaid, overpayments or underpayments are at that point settled by Louisiana Medicaid.

The audit scope of the draft report covered the four-year period from January 1, 2011, through to December 31, 2014. It is apparent from the review of the underlying audit information done thus far by Department personnel that the claims examined by the OIG in that four-year period are based on the interim payment amounts made on claims by Louisiana Medicaid and not on the final reimbursement amounts determined through the cost report settlement process. In addition, as of the date of this letter final cost settlement determination is only complete on approximately half of the cost reports from providers for the applicable cost-reporting years. It is anticipated that the remainder will be fully completed and final cost settlement determined within the next two years. Once this process has been completed, it may even be determined that some providers were underpaid for claims.

Louisiana Medicaid is currently investigating the situation in light of the OIG's draft report. A claims-level review is necessary as part of this investigation. Further, owing to the nature of the drug and dispensing practices, there would be no way of determining from a claims-level review whether the drug on a particular claim was used as a single use or reconstituted for multiuse. To elaborate, vials of Herceptin may be administered as a single use or reconstituted for multiuse at the point of dispensing. When reconstituted for multiuse, the drug must be reconstituted, for example, in a sterile aqueous solution with a preservative. Unused Herceptin reconstituted without a preservative at the point of dispensing must then be discarded. Therefore, a medical-level review is also necessary as part of this investigation to determine whether reimbursement claims were made for vials of Herceptin wasted in this process as opposed to claims for amounts actually administered to Medicaid recipients. Additionally, a medical-level review would also determine, for example, whether reimbursement claims were made for partial vials as opposed to entire vials, which practice would constitute potential improper allocation of billing, but not overpayment for claims.

Louisiana Medicaid will need a more detailed report of the information and findings utilized by the OIG in its draft report to aid in this process. With this

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information Louisiana Medicaid will conduct its own internal review to determine whether actual overpayments occurred for Herceptin Medicaid claims during the four-year period in question.


The Louisiana Department of Health does not concur that the State agency consider implementing or updating system edits that identify for review Herceptin claims that appear to be equivalent to the dosage of an entire vial.

The Department reimburses Medicaid claims in accordance with CMS approved cost settlement reimbursement methodology incorporated into the Louisiana State Medicaid Plan and the Louisiana Administrative Code. As explained above, the Department cannot agree with the audit findings presented by the OIG in the draft report until a further internal investigation and review of Herceptin claims for the four-year period in question has been completed. Because the OIG did not consider the cost settlement process utilized by Louisiana Medicaid in its audit, it is not evident on the basis of the draft report that such system edits are, in fact, needed at this time.

The Louisiana Department of Health does not concur that the State agency consider using the results of the OIG audit in its provider education activities.

The Department cannot agree with or utilize the results of the OIG audit until a further internal investigation and review of Herceptin claims for the four-year period in question has been completed.

Sincerely,


Jen Steele
Medicaid Director
Bureau of Health Services Financing

Cc: Vikki Wachino, CMCS Deputy Administrator and Director