

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**MASSACHUSETTS GENERALLY  
IMPLEMENTED RECOMMENDATIONS  
FROM PRIOR REVIEW OF CLAIMS FOR  
HOSPITAL OUTPATIENT CLINICAL  
LABORATORY SERVICES**

*Inquiries about this report may be addressed to the Office of Public Affairs at  
[Public.Affairs@oig.hhs.gov](mailto:Public.Affairs@oig.hhs.gov).*



Michael J. Armstrong  
Regional Inspector General

November 2012  
A-01-12-00005

# *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.

## EXECUTIVE SUMMARY

### BACKGROUND

Pursuant to Title XIX of the Social Security Act (the Act), 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. Each State 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. The Massachusetts Executive Office of Health and Human Services, Office of Medicaid (State agency), is responsible for administering MassHealth, the Massachusetts Medicaid program, in compliance with Federal and State statutes and administrative policies.

Hospital outpatient clinical diagnostic laboratory services are furnished in a hospital laboratory for the purpose of providing information for the diagnosis, prevention, or treatment of disease or for the assessment of a medical condition. Tests are ordered by a physician or a qualified nonphysician practitioner who is treating the patient. According to section 6300.2 of the CMS State Medicaid Manual, Medicaid reimbursement for clinical diagnostic laboratory tests may not exceed the amount set in the Medicare Clinical Laboratory Fee Schedule (Medicare fee schedule).

We issued a report in 2004 to the State agency on the results of an audit of clinical diagnostic laboratory services for the period of July 1999 through March 2002. The audit identified hospital outpatient laboratory claims totaling \$8.2 million (\$4.1 million Federal share) that exceeded the Medicare fee schedule payment amounts. These overpayments occurred because the State agency did not have adequate procedures to ensure that amounts claimed for Medicaid laboratory services and submitted for Federal reimbursement did not exceed the amount set in the Medicare fee schedule. Accordingly, we recommended that the State agency:

- make an adjustment on the next quarterly report of expenditures for \$8.2 million (\$4.1 million Federal share) and
- ensure that amounts claimed for hospital laboratory services and submitted for Federal reimbursement do not exceed the Medicare fee schedule amounts.

The State agency disagreed with our findings. Specifically, the State agency stated that we lacked sufficient legal basis to conclude that it had exceeded the Medicare upper payment limit for laboratory services. The State agency stated that its billing system for claiming Medicaid costs for Federal reimbursement complied with 42 CFR § 447.321(b), which states that aggregate Medicaid payments may not exceed the upper payment limit. However, section 1903(i)(7) of the Act imposes a more specific limit for clinical diagnostic laboratory tests which supersedes the more general CMS requirements on aggregate limits for certain categories of services. Therefore, we concluded in our previous report that the State agency's disagreement was invalid.

## **OBJECTIVE**

Our objective was to determine whether the State agency had implemented our prior recommendations (1) to refund \$4.1 million in Medicaid overpayments and (2) to ensure that amounts claimed for hospital outpatient clinical diagnostic laboratory services and submitted for Federal reimbursement do not exceed the Medicare fee schedule amounts.

## **SUMMARY OF FINDINGS**

The State agency implemented the first recommendation from our prior audit. Specifically, the State agency made an adjustment on its next quarterly report of expenditures for \$8.2 million (\$4.1 million Federal share). In general, the State agency implemented our prior audit's second recommendation to ensure that amounts claimed for laboratory services and submitted for Federal reimbursement do not exceed the Medicare fee schedule amounts. However, for a small number of services (57,412 of the 17,979,166 services that we reviewed) the State agency paid hospital providers more than the payment amounts in the Medicare fee schedule. As a result, the Federal reimbursement claimed by the State agency exceeded the rates allowed by Federal and State requirements by \$1,094,560 (\$616,832 Federal share).

The Medicaid overpayments occurred because the State agency occasionally did not follow its existing policies and procedures to ensure that the amounts claimed for hospital outpatient clinical laboratory services and submitted for Federal reimbursement did not exceed the allowable payment amounts.

## **RECOMMENDATIONS**

We recommend that the State agency:

- refund \$616,832 to the Federal Government and
- follow its existing policies and procedures to ensure that the amounts claimed for hospital outpatient clinical laboratory services and submitted for Federal reimbursement do not exceed the Medicare fee schedule amounts.

## **STATE AGENCY COMMENTS**

In written comments on our draft report, the State agency agreed with our findings. The State agency's comments are included in their entirety as the Appendix.

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## INTRODUCTION

### BACKGROUND

#### Medicaid Program

Pursuant to Title XIX of the Social Security Act (the Act), 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. Each State 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. The Massachusetts Executive Office of Health and Human Services, Office of Medicaid (State agency), is responsible for administering MassHealth, the Massachusetts Medicaid program, in compliance with Federal and State statutes and administrative policies.

#### Medicaid Coverage of Clinical Diagnostic Laboratory Services

Hospital outpatient clinical diagnostic laboratory services are furnished in a hospital laboratory for the purpose of providing information for the diagnosis, prevention, or treatment of disease or for the assessment of a medical condition. Tests are ordered by a physician or a qualified nonphysician practitioner who is treating the patient. Clinical laboratory services involve the following types of examination of materials derived from the human body: biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examinations of materials.

Hospital providers use CMS's Healthcare Common Procedural Coding System (HCPCS) codes to claim clinical laboratory costs for reimbursement from the State agency. The State agency seeks Federal reimbursement for amounts paid on behalf of Medicaid beneficiaries. The Federal Government pays its share of State Medicaid expenditures, including claims for clinical diagnostic laboratory services, according to a formula established in section 1905(b) of the Act. That share is known as the Federal medical assistance percentage (FMAP). The FMAP in Massachusetts ranged from 50.00 percent to 61.59 percent during our audit period.

According to section 6300.2 of the CMS State Medicaid Manual, Medicaid reimbursement for clinical diagnostic laboratory tests may not exceed the amount set in the Medicare Clinical Laboratory Fee Schedule (Medicare fee schedule).

#### Prior Office of Inspector General Report

We issued a report in 2004 to the State agency on the results of an audit of hospital outpatient clinical diagnostic laboratory services for the period of July 1999 through March 2002.<sup>1</sup> The audit identified hospital outpatient laboratory claims totaling \$8.2 million (\$4.1 million Federal

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<sup>1</sup> *Review of Claims Paid for Clinical Diagnostic Laboratory Services Under the Massachusetts Revised Fee Schedule—July 1999 Through March 2002* (A-01-02-00015).

share) that exceeded the Medicare fee schedule payment amounts. These overpayments occurred because the State agency did not have adequate procedures to ensure that amounts claimed for Medicaid laboratory services and submitted for Federal reimbursement did not exceed the amount set in the Medicare fee schedule. Accordingly, we recommended that the State agency:

- make an adjustment on the next quarterly report of expenditures for \$8.2 million (\$4.1 million Federal share) and
- ensure that amounts claimed for hospital laboratory services and submitted for Federal reimbursement do not exceed the Medicare fee schedule amounts.

The State agency disagreed with our findings. Specifically, the State agency stated that we lacked sufficient legal basis to conclude that it had exceeded the Medicare upper payment limit for laboratory services. The State agency stated that its billing system for claiming Medicaid costs for Federal reimbursement complied with 42 CFR § 447.321(b), which states that aggregate Medicaid payments may not exceed the upper payment limit. However, section 1903(i)(7) of the Act imposes a more specific limit for clinical diagnostic laboratory tests which supersedes the more general CMS requirements on aggregate limits for certain categories of services. Therefore, we concluded in our previous report that the State agency's disagreement was invalid. CMS concurred with our finding and recovered \$4.1 million from the State agency on December 31, 2004.

## **OBJECTIVE, SCOPE, AND METHODOLOGY**

### **Objective**

Our objective was to determine whether the State agency had implemented our prior recommendations (1) to refund \$4.1 million in Medicaid overpayments and (2) to ensure that amounts claimed for hospital outpatient clinical diagnostic laboratory services and submitted for Federal reimbursement do not exceed the Medicare fee schedule amounts.

### **Scope**

We reviewed Medicaid hospital outpatient clinical diagnostic laboratory services that were submitted by providers and claimed by the State agency for Federal reimbursement on Form CMS-64, Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program. The State agency claimed \$169,318,677 (\$93,594,798 Federal share) for Medicaid hospital outpatient clinical laboratory services provided during calendar years 2006 through 2010.<sup>2</sup>

Our objective did not require an understanding or assessment of the complete internal control structures at the State agency. Rather, we limited our review to those controls that were significant to the objective of our audit.

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<sup>2</sup> We limited our review to HCPCS codes listed on the Medicare fee schedules for each calendar year. Our review did not include HCPCS codes without CMS-established payment limits.

We performed our fieldwork at the State agency in Boston and Quincy, Massachusetts, from March through August 2012.

## **Methodology**

To accomplish our audit objective, we:

- reviewed applicable Federal and State laws, regulations, and guidance and the CMS-approved State plan;
- reviewed our prior audit report on Massachusetts clinical diagnostic laboratory services;
- interviewed officials from CMS, the Medicare carrier for Massachusetts, and the State agency;
- verified that the State agency refunded \$4.1 million to the Federal Government for Medicaid overpayments identified in our prior audit; and
- obtained a computer-generated file from the Massachusetts Medicaid Management Information System (MMIS) containing all claims for Medicaid hospital outpatient clinical laboratory services submitted by the State agency with HCPCS codes on the Medicare fee schedule and service dates during the period of January 1, 2006, through December 31, 2010, to:
  - evaluate the file to identify 17,979,166 Medicaid hospital outpatient clinical laboratory services totaling \$169,318,677 (\$93,594,798 Federal share);
  - compute what the Medicare payment limit should be for each service by multiplying the Medicare fee schedule rate by the number of units billed, per HCPCS code;
  - calculate the difference between the Medicaid amount claimed (paid amount) and the Medicare payment limit for each service; and
  - total the differences to determine the amount that the State agency was reimbursed in excess of the Medicare fee schedule.

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 objective.

## FINDINGS AND RECOMMENDATIONS

The State agency implemented the first recommendation from our prior audit. Specifically, the State agency made an adjustment on its next quarterly report of expenditures for \$8.2 million (\$4.1 million Federal share). In general, the State agency implemented our prior audit's second recommendation to ensure that amounts claimed for laboratory services and submitted for Federal reimbursement do not exceed the Medicare fee schedule amounts. However, for a small number of services (57,412 of the 17,979,166 services that we reviewed) the State agency paid hospital providers more than the payment amounts in the Medicare fee schedule. As a result, the Federal reimbursement claimed by the State agency exceeded the rates allowed by Federal and State requirements by \$1,094,560 (\$616,832 Federal share).

The Medicaid overpayments occurred because the State agency occasionally did not follow its existing policies and procedures to ensure that the amounts claimed for hospital outpatient clinical laboratory services and submitted for Federal reimbursement did not exceed the allowable payment amounts.

### FEDERAL AND STATE REQUIREMENTS

Section 1903(i)(7) of the Act, which is expanded in section 6300 of the CMS *State Medicaid Manual*, provides that no Federal financial participation would be available to any amounts expended for clinical diagnostic laboratory tests that exceeded the amount that would be recognized under the Medicare program.

The Massachusetts State Plan Attachment 4.19-B states that the maximum payment for a laboratory service shall be the lowest of (1) the maximum amount identified on the fee schedule in the Code of Massachusetts Regulations, (2) the usual and customary fee, or (3) the amount recognized under Medicare.

CMS's *Medicare Claims Processing Manual*, chapter 16, section 20, states that clinical laboratory tests are reimbursed on the basis of the Medicare fee schedule published annually by CMS. For each HCPCS code, Medicare pays the lesser of (1) actual charges, (2) the national limitation amount on the CMS fee schedule, or (3) the CMS fee schedule amount for the State or local geographic area.

### MEDICAID PAYMENTS EXCEEDED AMOUNTS ALLOWED BY MEDICARE

The State agency generally claimed Federal Medicaid reimbursement for hospital outpatient clinical diagnostic laboratory services in accordance with Federal and State requirements. Of the 17,979,166 services that we reviewed, the Medicaid payments made by the State agency for 17,921,754 services did not exceed the Medicare fee schedule amounts. However, for the remaining 57,412 services the State agency paid providers more than would have been paid under the Medicare program. As a result, the Federal reimbursement claimed by the State agency exceeded the rates allowed by Federal and State requirements by \$1,094,560 (\$616,832 Federal share).

We determined whether the Medicaid payments for hospital outpatient clinical diagnostic laboratory services were made in accordance with Federal and State requirements by calculating the allowable and unallowable paid amounts for each individual service. For example, during calendar year 2008 a provider billed \$187 to the State agency for one unit of service for HCPCS code 87901 (genotype DNA HIV reverse testing). The State agency paid this amount to the provider and claimed the same amount for Federal Medicaid reimbursement. On the Medicare fee schedule for 2008, the national limit was \$360 per unit and the State limit for Massachusetts was \$115 per unit. Since the State limit was lower than both the actual charge and the National limit, we determined that the allowable amount payment was \$115 for one unit. As a result, we identified a Medicaid overpayment in the amount of \$72 for this claim (\$187 minus \$115). In total, we identified Medicaid payments that exceeded the amounts allowed by Medicare for each calendar year as follows:

Calendar Year	Claimed Services		Services Exceeding Medicare Fee Schedule	
	Number of Line Items	Paid Amount	Number of Line Items	Unallowable Amount
2006	3,210,638	\$30,153,760	7,761	\$213,050
2007	3,392,988	31,669,852	8,622	130,296
2008	3,585,826	32,852,772	10,159	135,897
2009	3,788,364	35,552,754	18,235	339,789
2010	4,001,350	39,089,539	12,635	275,528
<b>TOTAL</b>	<b>17,979,166</b>	<b>\$169,318,677</b>	<b>57,412</b>	<b>\$1,094,560</b>

## CAUSE OF MEDICAID OVERPAYMENTS

The Medicaid overpayments occurred because the State agency occasionally did not follow its existing policies and procedures to ensure that the amounts claimed for hospital outpatient clinical laboratory services and submitted for Federal reimbursement did not exceed the allowable payment amounts.

## RECOMMENDATIONS

We recommend that the State agency:

- refund \$616,832 to the Federal Government and
- follow its existing policies and procedures to ensure that the amounts claimed for hospital outpatient clinical laboratory services and submitted for Federal reimbursement do not exceed the Medicare fee schedule amounts.

## **STATE AGENCY COMMENTS**

In written comments on our draft report, the State agency agreed with our findings. The State agency's comments are included in their entirety as the Appendix.

# **APPENDIX**

APPENDIX: STATE AGENCY COMMENTS



DEVAL L. PATRICK  
Governor

TIMOTHY P. MURRAY  
Lieutenant Governor

*The Commonwealth of Massachusetts  
Executive Office of Health and Human Services  
Office of Medicaid  
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Boston, MA 02108*



JUDYANN BIGBY, M.D.  
Secretary

JULIAN J. HARRIS, M.D.  
Medicaid Director

November 16, 2012

Michael J. Armstrong  
Regional Inspector General for  
Audit Services  
Office of Audit Services  
JFK Federal Building  
15 New Sudbury Street, Room 2425  
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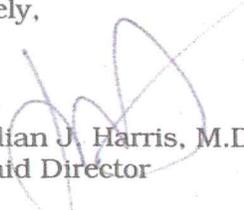
Re: Report Number: A-01-12-0005

Dear Mr. Armstrong:

Thank you for the opportunity to respond to the above referenced report titled *Massachusetts Generally Implemented Recommendations From Prior Review of Claims for Hospital Outpatient Clinical Laboratory Services* (Report Number: A-01-12-0005). The Executive Office of Health and Human Services is committed to ensuring the integrity of the MassHealth program. Accordingly, we appreciate the comprehensive review your office has conducted. We are pleased your office has found MassHealth has been, in general, compliant with the previous audit findings from 2004 (A-01-02-00015).

In the attached response, we have reproduced your office's findings and recommendations. In addition, we have summarized in the body of our response each instance of concurrence with a statement describing the corrective action plan we have already taken or are planning. If you have any questions or would like to discuss, please let us know.

Sincerely,



Dr. Julian J. Harris, M.D., M.B.A., M.Sc.  
Medicaid Director

Attachments (3)

Attachment to November 15, 2012 Letter to Michael Armstrong from Dr. Julian J. Harris  
Findings and recommendations as presented in Draft Report A-01-12-00005 with EOHHS  
responses

## **OIG Findings and Recommendations (Draft Report: A-01-12-00005)**

### **FINDINGS and RECOMMENDATIONS**

The State agency implemented the first recommendation from our prior audit. Specifically, the State made an adjustment on its next quarterly report of expenditures of \$8.2 million (\$4.1 million Federal share). In general, the State agency implemented our prior audit's second recommendation to ensure that amounts claimed for laboratory services and submitted for Federal reimbursement do not exceed the Medicare fee schedule amounts. However, for a small number of services (57,412 of the 17,979,166 services that we reviewed) the State agency paid hospital providers more than the payment amounts in the Medicare fee schedule. As a result, the Federal Reimbursement claimed by the State agency exceeded the rates allowed by Federal and State requirements by \$1,094,560 (\$616,832 Federal share).

The Medicaid overpayments occurred because the State agency occasionally did not follow its existing policies and procedures to ensure that the amounts claimed for hospital outpatient clinical laboratory services and submitted for Federal reimbursement did not exceed the Medicare fee schedule amounts.

#### **Federal and State Requirements**

Section 1903(i)(7) of the Act, which is expanded in section 6300 of the CMS State Medicaid manual, provides that no Federal financial participation would be available to any amounts expended for clinical diagnostic laboratory tests that exceeded the amount that would be recognized under the Medicare program.

The Massachusetts State Plan Attachment 4.19-B states that the maximum payment for a laboratory service shall be the lowest of (1) the maximum amount identified on the fee schedule in the Code of Massachusetts Regulations, (2) the usual and customary fee, or (3) the amount recognized under Medicare.

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#### **Medicaid Payments Exceeded Amounts Allowed by Medicare**

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Total	17,979,166	\$169,318,677	57,412	\$1,094,560

#### Cause of Medicaid Overpayments

The Medicaid overpayments occurred because the State agency occasionally did not follow its existing policies and procedures to ensure that the amounts claimed for hospital outpatient clinical laboratory services and submitted for Federal reimbursement did not exceed the Medicare fee schedule payment amounts.

#### Recommendations:

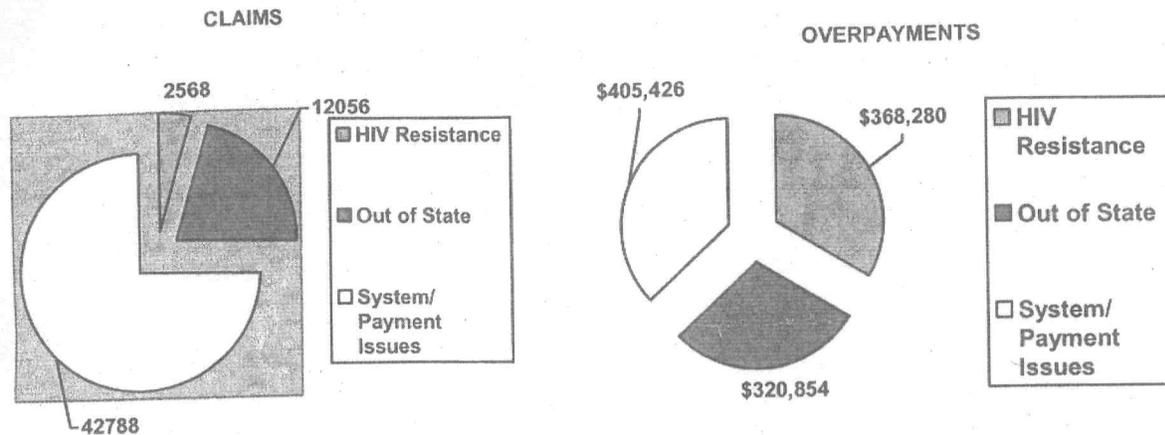
We recommend that the State agency:

- Refund \$616,832 to the Federal Government and
- Follow its existing policies and procedures to ensure that the amounts claimed for hospital outpatient clinical laboratory services and submitted for federal reimbursement do not exceed the Medicare fee schedule amounts.

## EOHHS Response

### Overview

MassHealth has reviewed the list of 57,412 claim lines totaling \$1,094,560 that the OIG is alleging has been overpaid. In an effort to consolidate this list of claims, we have prepared the following charts. These charts combine the 5 years of OIG alleged claim overpayments and places these into three distinct groupings which we will use to better illustrate our findings.



### System/Payment Issues

MassHealth acknowledges that 42,788 claims were overpaid (totaling \$405,426) over the five year audit period due to NewMMIS implementation issues, variant payment methodologies, and MMIS claim payment system issues. The following table further categorizes these claims so that we can better explain which of these claims were overpaid and what corrective action we are planning (if not already done). Since these claims did not comply with the agreement set forth under the previous audit (Report Number A-01-02-00005), MassHealth will repay CMS its federal share for the \$405,426 in overpayments found under the OIG's draft report.

Category	Claims	\$	Corrective Action
Services with Professional Component Surgical Rates and Clinical Laboratory Rates	35,903	\$245,521	MassHealth will review the current MMIS payment structure, as well as the fee schedules, to determine the best possible solution to ensure appropriate payment of the following HCPCS codes: 83020, 83912, 84165, 84166, 84181, 84182, 85390, 85576, 86255, 86256, 86320, 86325, 86327, 86334, 86335, 87164, 87207, 88371, 88372, and 89060.
Chronic Outpatient Hospitals (Prov Type 82)	4,565	\$63,105	MassHealth is reviewing the MMIS payment system for these services to ensure these providers are correctly paid the clinical laboratory fee going forward.
Semi- Acute Outpatient Hospitals (Prov Type 75)	441	\$14,696	Effective January 2011, new rates were established for this provider type. MassHealth now pays at 66.58% of costs for all services provided. This new rate methodology should allow MassHealth to be compliant for most laboratory services.
Other	1879	\$82,104	MassHealth will review its MMIS payment system and update any known payment defect if it hasn't done so already. The successful implementation of the NewMMIS system should have alleviated many of the issues which caused these claim overpayments.

### **Out of State Acute Outpatient Hospital Payments**

#### **Statement**

The OIG identified 12,056 claims totaling \$320,854 in potential overpayments which were paid to out of state acute outpatient hospitals. Since these claims did not comply with the agreement set forth under the previous audit (Report Number A-01-02-00005), MassHealth will repay CMS its federal share of the \$320,854 overpaid due to this non-compliant payment methodology.

#### **Corrective Action**

MassHealth has already taken corrective action to ensure out of state hospital laboratory services are paid correctly going forward. Effective 5/25/2012, MassHealth began paying laboratory services performed by out of state hospitals at the rates set forth in the DHCFF clinical laboratory fee schedule (114.3 CMR 20.00). Acute Outpatient Hospital Transmittal Letter 27 (AOH.27- Attachment 2) introduced this updated payment methodology. Laboratory services performed by out of state hospitals are now paying correctly.

### **HIV Resistance Testing**

#### **Statement**

The OIG identified 2568 claims totaling \$368,280 in potential overpayments which were paid to hospital providers for HIV resistance testing (HCPCS code 87901- Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, reverse transcriptase and protease regions). These claims were paid correctly according to the rates set forth in the DHCFF clinical laboratory fee schedule (114.3 CMR 20.00).

HIV resistance testing was first added as a covered service beginning January 1, 2002. Prior to its adoption, MassHealth received a State Medicaid Director letter from January 2001 (State Med Let Jan 01- Attachment 3) instructing agencies to pay for HIV resistance testing. The letter directed states to set a rate necessary to assure adequate access for these services<sup>1</sup>. During the rate development process, the Division of Health Care Finance and Policy (now operating as the Center for Health Information and Analysis) spoke with health care advocates and surveyed other Medicaid payers to determine an appropriate reimbursement as instructed by the State Medicaid directive. It was determined that the rate should be based on a percentage of the National Medicare rate for these services rather than the lesser MA Medicare rate. Since its adoption as a covered service, the rates for this service has been set at a percentage of the higher National Medicare rate as opposed to the lesser MA Medicare rate.

MassHealth acknowledges the rates for this service exceeded the MA Medicare rate and thus we have not been compliant with the terms set forth under the previous audit (Report Number A-01-02-00005). MassHealth will repay CMS its federal share of the \$368,280 which was overpaid for these services. MassHealth will work with the Center for Health Information and Analysis to set a rate that does not exceed the MA Medicare rate going forward.

#### **Conclusion**

MassHealth acknowledges that it has overpaid for the services referenced above. MassHealth will repay CMS its federal share (\$616,832) of the \$1,094,560 found by the OIG as overpayments. In addition, MassHealth will work on a corrective action plan for those services identified as overpayments to ensure that the amounts claimed for hospital outpatient clinical laboratory services and submitted for federal reimbursement do not exceed MA Medicare fee schedule amounts.

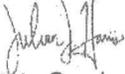
<sup>1</sup> As stated under the section titled Cost in the above referenced letter: *Reimbursement for the genotype assay test range from \$250 to \$500 and \$625 to \$900, respectively. State Medicaid Agencies choosing to cover these tests should determine an adequate payment amount with their providers in their States to assure appropriate access to these tests. Payment should meet Federal requirements of economy and efficiency while assuring appropriate access to these services. Section 1903(i)(7) of the Social Security Act and section 6300 of the State Medicaid manual provide that Medicaid payments cannot exceed what Medicare would pay for these tests (the Medicare upper limit) when Medicare establishes a national limitation amount (NLA).*



Commonwealth of Massachusetts  
Executive Office of Health and Human Services  
Office of Medicaid  
[www.mass.gov/masshealth](http://www.mass.gov/masshealth)



MassHealth  
Transmittal Letter AOH-27  
May 2012

**TO:** Acute Outpatient Hospitals Participating in MassHealth  
**FROM:** Julian J. Harris, M.D., Medicaid Director   
**RE:** *Acute Outpatient Hospital Manual (Out-of-State Services)*

This letter transmits revisions to the *Acute Outpatient Hospital Manual* that clarify when out-of-state services are covered by MassHealth. It also describes changes in out-of-state acute outpatient hospital rates that are addressed in MassHealth's administrative and billing regulations. See 130 CMR 450.233.

#### **Out-of-State Acute Outpatient Hospital Rates**

Effective for May 25, 2012, MassHealth is changing the way it pays for out-of-state acute outpatient hospital services. Effective for services provided on or after May 25, 2012, out-of-state acute outpatient hospitals will be paid at the median payment amount per episode (PAPE) in effect for in-state acute hospitals on the date of service, as calculated by EOHHS, or in accordance with the applicable fee schedule established by the Division of Health Care Finance and Policy for services for which in-state acute hospitals are not paid the PAPE.

These rates will be updated each subsequent MassHealth Hospital Rate Year (HRY). The MassHealth HRY generally is in effect from October 1, through September 30, of a given year, and are published on the MassHealth Web site at [www.mass.gov/masshealth/pubs](http://www.mass.gov/masshealth/pubs). Click on Special Notices for Hospitals.

These regulations are effective May 25, 2012.

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#### **Questions**

If you have any questions about the information in this transmittal letter, please contact MassHealth Customer Service at 1-800-841-2900, e-mail your inquiry to [providersupport@mahealth.net](mailto:providersupport@mahealth.net), or fax your inquiry to 617-988-8974.

#### **NEW MATERIAL**

(The pages listed here contain new or revised language.)

##### **Acute Outpatient Hospital Manual**

Pages 4-5 and 4-6

#### **OBSOLETE MATERIAL**

(The pages listed here are no longer in effect.)

##### **Acute Outpatient Hospital Manual**

Pages 4-5 and 4-6 — transmitted by Transmittal Letter AOH-18



Commonwealth of Massachusetts  
Executive Office of Health and Human Services  
Office of Medicaid  
[www.mass.gov/masshealth](http://www.mass.gov/masshealth)



MassHealth  
Transmittal Letter AOH-27  
May 2012

**TO:** Acute Outpatient Hospitals Participating in MassHealth  
**FROM:** Julian J. Harris, M.D., Medicaid Director   
**RE:** *Acute Outpatient Hospital Manual (Out-of-State Services)*

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Commonwealth of Massachusetts MassHealth Provider Manual Series	Subchapter Number and Title 4. Program Regulations (130 CMR 410.000)	Page 4-6
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(B) Out of State

(1) Out-of-state hospital outpatient and hospital-licensed health center services provided to an eligible MassHealth member are covered in the following instances:

- (a) emergency care hospital outpatient services provided to a member;
- (b) hospital outpatient services provided to a member whose health would be endangered if the member were required to travel to Massachusetts;
- (c) hospital outpatient services provided to a member when MassHealth determines on the basis of medical advice that the medical service is more readily available in the other state;
- (d) it is general practice for members in a particular locality to use medical resources in another state;
- (e) hospital outpatient services provided to a member who is authorized to reside or who is placed out of state by the Massachusetts Department of Social Services or by a Chapter 766 core team evaluation;
- (f) hospital outpatient services provided to a member who has been authorized by the MassHealth agency to reside in an out-of-state nursing facility; or
- (g) when prior authorization has been obtained from the MassHealth agency for nonemergency services provided to a member by an out-of-state hospital outpatient department that is more than 50 miles from the Massachusetts border.

(2) To participate in MassHealth, an out-of-state hospital outpatient department or hospital-licensed health center must obtain a MassHealth provider number and meet the following criteria:

- (a) it operates under a hospital license from or is approved as a hospital by the governing or licensing agency in its state;
- (b) it participates in the Medicare program; and
- (c) it participates in that state's Medicaid program (or equivalent).

(3) Payment for out-of-state hospital outpatient and hospital-licensed health center services is made in accordance with 130 CMR 450.233.

410.405: Noncovered Services

(A) The MassHealth agency does not pay for any of the following services:

- (1) nonmedical services, such as social, educational, and vocational services;
- (2) cosmetic surgery;
- (3) canceled or missed appointments;
- (4) telephone conversations and consultations;
- (5) court testimony;
- (6) research or the provision of experimental, unproven, or otherwise medically unnecessary procedures or treatments, specifically including, but not limited to, sex-reassignment surgery, thyroid cartilage reduction and any other related surgeries and treatments, including pre- and post-sex-reassignment surgery hormone therapy. Notwithstanding the preceding sentence, the MassHealth agency will continue to pay for post-sex-reassignment surgery hormone therapy for which it had been paying immediately prior to May 15, 1993;
- (7) the provision of whole blood; however, administrative and processing costs associated with the provision of blood and its derivatives are covered; and
- (8) the treatment of male or female infertility (including, but not limited to, laboratory tests, drugs, and procedures associated with such treatment).

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Trimester – one of three three-month terms in a normal pregnancy. If the pregnancy has existed for less than 12 weeks, the pregnancy is in its first trimester. If the pregnancy has existed for 12 or more weeks but less than 24 weeks, the pregnancy is in its second trimester. If the pregnancy has existed for 24 or more weeks, the pregnancy is in its third trimester. For the purposes of 130 CMR 410.000, the elapsed period of gestation is calculated in accordance with regulations of the Massachusetts Department of Public Health.

Unit-Dose Distribution System – a means of packaging or distributing drugs, or both, devised by the manufacturer, packager, wholesaler, or retail pharmacist. A unit dose contains an exact dosage of medication and may also indicate the total daily dosage or the times when the medication should be taken. Such unit doses may or may not be in unit-dose packaging.

Vocational Rehabilitative Services – services such as vocational assessments, job training, career counseling, and job placement.

#### 410.403: Eligible Members

- (A) (1) MassHealth Members. MassHealth covers outpatient hospital services only when provided to eligible MassHealth members, subject to the restrictions and limitations described in MassHealth regulations. 130 CMR 450.105 specifically states, for each MassHealth coverage type, which services are covered and which members are eligible to receive those services.
- (2) Recipients of the Emergency Aid to the Elderly, Disabled and Children Program. For information on covered services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program, see 130 CMR 450.106.
- (B) For information on verifying member eligibility and coverage type, see 130 CMR 450.107.

#### 410.404: Provider Eligibility

Payment for the services described in 130 CMR 410.000 is made only to hospital outpatient departments participating in MassHealth on the date of service.

- (A) In State
- (1) To participate in MassHealth, acute hospital outpatient departments and hospital-licensed health centers located in Massachusetts must
- operate under a hospital license issued by the Massachusetts Department of Public Health;
  - have a signed provider agreement that specifies a payment methodology with the MassHealth agency; and
  - participate in the Medicare program.
- (2) To participate in MassHealth, nonacute hospital outpatient departments located in Massachusetts must
- operate under a hospital license issued by the Massachusetts Department of Public Health or the Massachusetts Department of Mental Health;
  - have a signed provider agreement for participation in MassHealth; and
  - participate in the Medicare program.

**SMDL #01-005**

January 8, 2001

Dear State Medicaid Director:

This letter provides information about two relatively new laboratory tests for the management of Human Immunodeficiency Virus (HIV) disease to assist State Medicaid agencies in establishing policies regarding coverage, coding, and reasonable payment for these tests. The two tests are genotype human immunodeficiency virus type-1 (HIV-1) testing (mutation analysis) for drug resistance and phenotype HIV-1 drug susceptibility (commonly referred to as resistance) testing.

Because the technology to perform these tests has only recently become widely available, State Medicaid Agencies and other public and private health insurers are now faced with many complex issues concerning coverage, payment, and coding. Laboratories, manufacturers, community-based AIDS organizations, public health researchers, and health insurers have also asked HCFA for guidance and assistance regarding these tests.

**Standards of Care**

On January 19, 2000, a panel of experts convened by the U.S. Department of Health and Human Services and the Henry J. Kaiser Family Foundation updated their guidance on clinical practices for the treatment of HIV infection, entitled "Guidelines for the Use of Antiretroviral Agents in HIV Infected Adults and Adolescents." The Guidelines are generally accepted as the standard of care in the United States. With regard to drug resistance testing, the Guidelines state that both the genotype and phenotype drug resistance assays are recommended in certain circumstances.

The guidelines recommend resistance testing in two situations: (1) When the patient presents with virologic failure during Highly Active Antiretroviral Therapy (HAART), and (2) When the patient has suboptimal suppression of viral load after initiation of antiretroviral therapy. The Guidelines state that resistance testing is generally not recommended with chronic HIV infection prior to initiation of therapy, after discontinuation of drugs, and when the patient's plasma viral load is less than 1000 HIV RNA copies/mL. In the presence of acute HIV infection, the Guidelines state that the provider should consider resistance testing. Since the publication of the Guidelines in January, two additional studies have been completed that confirm the effectiveness of genotypic testing.

**Coverage**

While there has been concern that none of the available genotype and phenotype tests have received approval from the Food and Drug Administration (FDA), only "test kits" for interstate commerce require this approval. Currently, most genotype and all phenotype testing is being performed under the "homebrew" status and therefore is not subject to FDA approval. Some manufacturers are currently seeking FDA approval for genotype test kits. One manufacturer has a genotype kit that has received an FDA status of Investigational Device Exemption (IDE). The FDA regulates how these non-FDA approved laboratory tests can be used, marketed, and distributed.

While this information is important to States, HCFA and State Medicaid Agencies are not responsible under Federal regulations for knowing whether laboratories or manufacturers are complying with FDA requirements or for ensuring compliance with these requirements, nor is FDA approval of a test/procedure a prerequisite for Medicaid coverage. A State Medicaid agency can decide to cover an FDA-approved or non-FDA approved laboratory test if the agency determines the test to be medically necessary and if the test is provided by a qualified Medicaid laboratory that is certified in accordance with the Clinical Laboratory Improvement Act (CLIA) to perform such tests. In some States however, the Medicaid program is required by State law to cover only FDA-approved products and therefore, the State Medicaid agency must follow its own regulations.

If you have any questions that relate to FDA compliance requirements for HIV tests, you may contact the Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Compliance & Biologics Quality, Division of Case Management, 1401 Rockville Pike, suite 400 South, HFM-610, Rockville, MD 20852, (301) 827-6201.

### **Cost**

Reimbursement for the genotype assay test and phenotype assay test range from \$250 to \$500 and \$625 to \$900, respectively. State Medicaid agencies choosing to cover these tests should determine an adequate payment amount with the providers in their States to assure appropriate access to these tests. Payment should meet Federal requirements of economy and efficiency while assuring appropriate access to these services. Section 1903(i)(7) of the Social Security Act and section 6300 of the State Medicaid Manual provide that Medicaid payments cannot exceed what Medicare would pay for these tests (the 'Medicare upper limit') when Medicare establishes a national limitation amount (NLA). HCFA has set an NLA for the Medicare program for these two tests effective January 1, 2001. Instructions on the fee schedule, (Medicare Program Transmittal AB-00-109), can be found at <http://www.hcfa.gov/pubforms/transmit/AB00109.pdf>.

### **Coding**

The American Medical Association (AMA) has developed three new Current Procedural Terminology (CPT) codes for the resistance tests. The effective date for these codes is January 1, 2001. Genotype testing has one CPT code (87901). Phenotype testing has two codes. The primary (87903) covers the first ten drugs that are tested. The second code (87904) is to be used for each additional drug, up to five drugs. The CPT manual specifies that code 87904 must be used in conjunction with 87903.

### **Conclusion**

Based upon the information contained in this letter, the technical attachment, and the Guidelines regarding the recommended and optimal use of resistance testing, State Medicaid agencies should provide coverage of these tests under the specific clinical conditions outlined in the Guidelines and should determine what reimbursement is reasonable to assure appropriate access to care.

We have enclosed some technical information about these tests that we believe will be helpful to you and your State in establishing coverage and reimbursement. The Guidelines are available upon request by calling 1-800-448-0440 or may be downloaded from the Internet at <http://www.hivatis.org/guidelines/adult/text/>. We hope that this information proves useful in your implementation of this new laboratory test. If you have questions, please call Kurt Hartmann at (410) 786-0400.

Sincerely,

/s/  
Timothy M. Westmoreland  
Director