



NEW YORK STATE
DEPARTMENT OF HEALTH
OFFICE OF THE MEDICAID INSPECTOR GENERAL

REVIEW OF BIO-REFERENCE LABORATORIES, INC.
CLAIMS FOR LABORATORY SERVICES
PAID FROM
JANUARY 1, 2006 – DECEMBER 31, 2009

FINAL AUDIT REPORT

James G. Sheehan
Medicaid Inspector General

September 3, 2010

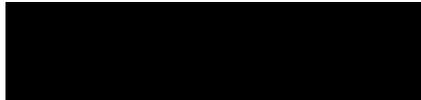


STATE OF NEW YORK
OFFICE OF THE MEDICAID INSPECTOR GENERAL
800 North Pearl Street
Albany, NY 12204

DAVID A. PATERSON
GOVERNOR

JAMES G. SHEEHAN
MEDICAID INSPECTOR GENERAL

September 3, 2010



Bio-Reference Laboratories, Inc.
481 Edward H. Ross Drive
Elmwood Park, NJ 07407-3118

Re: Final Audit Report
Audit #: 10-1935

Dear 

Enclosed is the Office of the Medicaid Inspector General (OMIG) final audit report entitled "Review of Bio-Reference Laboratories, Inc." (Bio-Reference) paid claims for Laboratory services covering the period January 1, 2006 through December 31, 2009.

In the attached final report, the OMIG has detailed our objectives and scope, procedures, laws, regulations, rules and policies, sampling technique, findings, provider rights, and statistical analysis.

The OMIG has attached the sample detail for the paid claims determined to be in error. This audit report incorporates consideration of any additional documentation and information presented in response to the draft report dated July 21, 2010. The mean point estimate overpaid is \$409,468. The lower confidence limit of the amount overpaid is \$188,516. We are 95% certain that the actual amount of the overpayment is greater than the lower confidence limit. This audit may be settled through repayment of the lower confidence limit of \$188,516.

[REDACTED]
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If Bio-Reference has any questions or comments concerning this report, please contact [REDACTED] or through email at [REDACTED]. Please refer to report number 10-1935 in all correspondence.

Sincerely,

[REDACTED]
Director of Provider Audit
Bureau of Fee for Service Audit
Office of the Medicaid Inspector General

[REDACTED]
Enclosure

CERTIFIED MAIL # [REDACTED]
RETURN RECEIPT REQUESTED

OFFICE OF THE MEDICAID INSPECTOR GENERAL

www.omig.ny.gov

The mission of the Office of the Medicaid Inspector General (OMIG), as mandated by New York Public Health Law § 31 is to preserve the integrity of the New York State Medicaid program by preventing and detecting fraudulent, abusive and wasteful practices within the Medicaid program and recovering improperly expended Medicaid funds.

DIVISION OF MEDICAID AUDIT

The Division of Medicaid Audit professional staff conducts audits and reviews of Medicaid providers to ensure compliance and program requirements and, where necessary, to recover overpayments. These activities are done to monitor the cost-effective delivery of Medicaid services for prudent stewardship of scarce dollars; to ensure the required involvement of professionals in planning care to program beneficiaries; safeguard the quality of care, medical necessity and appropriateness of Medicaid services provided; and, to reduce the potential for fraud, waste and abuse.

DIVISION OF MEDICAID INVESTIGATIONS

The Division of Medicaid Investigations (DMI) investigates potential instances of fraud, waste, and abuse in the Medicaid program. DMI deters improper behavior by inserting covert and overt investigators into all aspects of the program, scrutinizing provider billing and services, and cooperating with other agencies to enhance enforcement opportunities. Disreputable providers are removed from the program or prevented from enrolling. Recipients abusing the system are not removed from this safety net, but their access to services is examined and restricted, as appropriate. DMI maximizes cost savings, recoveries, penalties, and improves the quality of care for the state's most vulnerable population.

DIVISION OF TECHNOLOGY AND BUSINESS AUTOMATION

The Division of Technology and Business Automation will continue to support the data needs for the OMIG in the form of audit and investigative support, data mining and analysis, system match and recovery, through the use of commercial data mining products and procurement of expert service consultants.

OFFICE OF COUNSEL TO THE MEDICAID INSPECTOR GENERAL

The Office of Counsel to the Medicaid Inspector General promotes the OMIG's overall statutory mission through timely, accurate and persuasive legal advocacy and counsel.

EXECUTIVE SUMMARY

BACKGROUND

Pursuant to Title XIX of the Social Security Act, 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. In New York State, the Department of Health (DOH) administers the Medicaid program. As part of this responsibility, the OMIG conducts audits and reviews of various providers of Medicaid reimbursable services, equipment and supplies. These audits and reviews are directed at ensuring provider compliance with applicable laws, regulations, rules and policies of the Medicaid program as set forth by the Departments of Health and Mental Hygiene [Titles 10, 14 and 18 of the Official Compilation of Codes, Rules and Regulations of the State of New York] and the Medicaid Provider Manuals.

A clinical laboratory is a facility for the examination of materials derived from the human body for the diagnosis, prevention or treatment of disease or assessment of a health condition. These laboratories are classified as either hospital based or independent. A hospital laboratory is a clinical laboratory operated by, or under the supervision of, a certified hospital or its organized medical staff. An independent laboratory is a clinical laboratory that is independent of a certified hospital or its organized medical staff. The following are considered independent laboratories: commercial for-profit laboratories, physician's office laboratories, public health laboratories and free-standing clinic laboratories located in Article 28 certified diagnostic and treatment centers.

All laboratory services must be medically necessary and related to the specific complaints and symptoms of the patient. Laboratories may bill for properly ordered tests that are within its area of competence. Laboratory services may be provided upon the written order of a qualified physician, nurse practitioner, nurse mid-wife, physician's assistant, dentist or podiatrist. The specific standards and criteria for laboratories are contained in Title 18 NYCRR Section 505.7 and the MMIS Provider Manual for Laboratory.

OBJECTIVE AND SCOPE

The objective of our audit was to ensure Bio-Reference's compliance with applicable federal and state laws, regulations, rules and policies governing the New York State Medicaid Program. With respect to Laboratory services, our audit covered services paid by Medicaid from January 1, 2006 through December 31, 2009.

SUMMARY OF FINDINGS

We inspected a random sample of 200 dates of service with \$8,148.18 in Medicaid payments. Of the 200 services in our random sample, 46 services had at least one error and did not comply with state requirements. Of the 46 noncompliant services, none contained more than one deficiency. Specifics are as follows:

<u>Error Description</u>	<u>Number of Errors</u>
1. Incorrect Procedure Code Billed	19
2. Missing Documentation of Service	10
3. Missing Provider Signature on Order	10
4. No Written order/Authenticated Request	7

Based on the procedures performed, the OMIG has determined Bio-Reference was overpaid \$677.22 in sample overpayments with an extrapolated point estimate of \$409,468. The lower confidence limit of the amount overpaid is \$188,516.

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INTRODUCTION

BACKGROUND

Medicaid Program

Pursuant to Title XIX of the Social Security Act, 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.

New York State's Medicaid Program

In New York State, the Department of Health (DOH) is the State agency responsible for operating the Medicaid program. Within DOH, the Office of Health Insurance Programs administers the Medicaid program. DOH uses the electronic Medicaid New York Information system (eMedNY), a computerized payment and information reporting system, to process and pay Medicaid claims, including Laboratory services claims.

As part of this responsibility, the OMIG conducts audits and reviews of various providers of Medicaid reimbursable services, equipment and supplies. These audits and reviews are directed at ensuring provider compliance with applicable laws, regulations, rules and policies of the Medicaid program as set forth by the Departments of Health and Mental Hygiene [Titles 10, 14 and 18 of the Official Compilation of Codes, Rules and Regulations of the State of New York] and the Medicaid Provider Manuals.

New York State's Laboratory Services Program

A clinical laboratory is a facility for the examination of materials derived from the human body for the diagnosis, prevention or treatment of disease or assessment of a health condition. These laboratories are classified as either hospital based or independent. A hospital laboratory is a clinical laboratory operated by, or under the supervision of, a certified hospital or its organized medical staff. An independent laboratory is a clinical laboratory that is independent of a certified hospital or its organized medical staff. The following are considered independent laboratories: commercial for-profit laboratories, physician's office laboratories, public health laboratories and free-standing clinic laboratories located in Article 28 certified diagnostic and treatment centers.

All laboratory services must be medically necessary and related to the specific complaints and symptoms of the patient. Laboratories may bill for properly ordered tests that are within its area of competence. Laboratory services may be provided upon the written order of a qualified physician, nurse practitioner, nurse mid-wife, physician's assistant, dentist or podiatrist. The specific standards and criteria for laboratories are contained in Title 18 NYCRR Section 505.7 and the MMIS Provider Manual for Laboratory.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The objective of our audit was to ensure Bio-Reference's compliance with applicable Federal and State laws, regulations, rules and policies governing the New York State Medicaid Program and to verify that:

- Medicaid reimbursable services were rendered for the dates billed;
- appropriate rate or procedure codes were billed for services rendered;
- patient related records contained the documentation required by the regulations; and,
- claims for payment were submitted in accordance with DOH regulations and the appropriate Provider Manuals.

Scope

Our audit period covered payments to Bio-Reference for Laboratory services paid by Medicaid from January 1, 2006, through December 31, 2009. Our audit universe consisted of 120,926 claims totaling \$5,263,067.

During our audit, we did not review the overall internal control structure of Bio-Reference. Rather, we limited our internal control review to the objective of our audit.

Methodology

To accomplish our objective, we:

- reviewed applicable federal and state laws, regulations, rules and policies;
- held discussions with Bio-Reference management personnel to gain an understanding of the Laboratory services program;
- ran computer programming application of claims in our data warehouse that identified 120,926 paid Laboratory services claims, totaling \$5,263,067;
- selected a random sample of 200 services from the population of 120,926 services; and,
- estimated the overpayment paid in the population of 120,926 services.

For each sample selection we inspected, as available, the following:

- Medicaid electronic claim information
- Patient record, including, but not limited to:
 - Laboratory Fiscal Orders
 - Laboratory Test Reports
- Any additional documentation deemed by Bio-Reference necessary to substantiate the Medicaid paid claim

LAWS, REGULATIONS, RULES AND POLICIES

The following are applicable Laws, Regulations, Rules, and Policies of the Medicaid program referenced when conducting this audit:

- Department of Health and Mental Hygiene [Titles 10, 14, and 18 of the Official Compilation of Codes, Rules and Regulations of the State of New York (10 NYCRR, 14 NYCRR, 18 NYCRR)].
- Medicaid Management Information System and eMedNY Provider Manual.
- Specifically, 18 NYCRR Part 504, Part 505, Part 517; 10 NYCRR Part 58; Medicaid Provider Manual for Laboratories.
- In addition to any specific detailed findings, rules and/or regulations which may be listed below, the following regulations pertain to all audits:

Regulations state: "By enrolling the provider agrees: (a) to prepare and to maintain contemporaneous records demonstrating its right to receive payment . . . and to keep for a period of six years from the date the care, services or supplies were furnished, all records necessary to disclose the nature and extent of services furnished and all information regarding claims for payment submitted by, or on behalf of, the provider . . . (e) to submit claims for payment only for services actually furnished and which were medically necessary or otherwise authorized under the Social Services Law when furnished and which were provided to eligible persons; (f) to submit claims on officially authorized claim forms in the manner specified by the department in conformance with the standards and procedures for claims submission; . . . (h) that the information provided in relation to any claim for payment shall be true, accurate and complete; and (i) to comply with the rules, regulations and official directives of the department."
18 NYCRR Section 504.3

Regulations state: "All bills for medical care, services and supplies shall contain: . . . (8) a dated certification by the provider that the care, services and supplies itemized have in fact been furnished; that the amounts listed are due and owing . . . ; that such records as are necessary to disclose fully the extent of care, services and supplies provided to individuals under the New York State Medicaid program will be kept for a period of not less than six years from the date of payment . . . ; and that the provider understands that payment and satisfaction of this claim will be from Federal, State and local public funds and that he or she may be prosecuted under applicable Federal and State laws for any false claims, statements or documents, or concealment of a material fact provided. . . ."

18 NYCRR Section 540.7(a)

Regulations state: "An overpayment includes any amount not authorized to be paid under the medical assistance program, whether paid as the result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse or mistake."
18 NYCRR Section 518.1(c)

Furthermore, according to regulations, all providers must prepare and maintain contemporaneous records demonstrating their right to receive payment under the medical assistance program. In addition, the provider must keep, for a period of six years, all records necessary to disclose the nature and extent of services furnished and the medical necessity therefore, including any prescription or fiscal order for the service or supply. This information is subject to audit for a period of six years and must be furnished, upon request.

18 NYCRR Section 517.3(b)

DETAILED FINDINGS

The OMIG's review of Medicaid claims paid to Bio-Reference from January 1, 2006, through December 31, 2009 identified 28 claims with at least one error, for a total sample overpayment of \$677.22 (Attachment C).

Sample Selection

1. Incorrect Procedure Code Billed

12, 26, 28, 31, 37, 42, 43, 45, 76,
104, 143, 163, 164, 198

Regulations state that "Payment for laboratory services provided by independent laboratories will be made only for individually ordered tests. No payment will be made for tests ordered as groupings or combinations . . .

Regulations also state that "The clinical parameters for which standing orders are permitted . . .

18 NYCRR Section 505.7 (b)(1)(ii), (g)(4)

The MMIS Laboratory Provider Manual requires that, "travel expenses for phlebotomy (blood draws) are not a covered service if they are solely to draw blood from patients in a skilled nursing facility; draw blood from a recipient who receives medical services"

MMIS Provider Laboratory Manual Section II, Page 11

In addition, the MMIS DOH Medicaid Updates state that "Claims for laboratory services must include one or more appropriate ICD-9-CM codes to indicate patient diagnosis, symptomology, and/or reason for the test(s). . . .

MMIS Medicaid Update August /2005

In 11 instances pertaining to 11 patients, travel expenses were claimed for patients drawn in a skilled nursing facility. A Thyroid Function Test was overbilled in 2 instances pertaining to 1 patient. In another instance pertaining to 1 patient, a chart note indicated a standing order for CMP (80053). In 5 instances pertaining to 1 patient billing with a diagnosis code of V72.6 were also disallowed.

2. Missing Documentation of Service

66, 82, 109, 125, 135, 151

Regulations require that the Medicaid provider agrees, "to prepare and to maintain contemporaneous records demonstrating its right to receive payment under the medical assistance program and to keep for a period of six years. . . all records necessary to disclose the nature and extent of services furnished. . . ."

18 NYCRR Section 504.3 (a)

In 10 instances pertaining to 6 patients, there were no documents submitted for the tests billed.

3. Order Not Signed by Qualified Practitioner

72, 75, 143, 158, 190

Regulations state, "that a "*Fiscal order for laboratory services* means a qualified practitioner's authenticated request. . . Authentication of fiscal orders shall be by a qualified practitioner or by designation. . . ."

18 NYCRR Section 505.7(b)(1)(i)

In 10 instances pertaining to 5 patients, there was no provider signature on the lab order form.

4. No Written Order/Authenticated Request

47, 56, 101

Regulations state, "Laboratory services may be provided by a laboratory only upon a fiscal order for laboratory services. . ."

Regulations also state that a "*Fiscal order for laboratory services*" means a qualified practitioner's authenticated request to a clinical laboratory for the provision of a test, examination and/or analysis on behalf of a recipient of MA. . . "

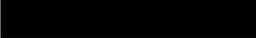
18 NYCRR Section 505.7(b)(1)(c)(1)

In 7 instances pertaining to 3 patients, there was no written order or authenticated request, as needed, for the service billed.

PROVIDER RIGHTS

In accordance with 18 NYCRR Part 518 which regulates the collection of overpayments, your repayment options are described below. If you decide to repay the lower confidence limit amount of \$188,516, one of the following repayment options must be selected within 20 days from the date of this letter:

OPTION #1: Make full payment by check or money order within 20 days of the date of the final report. The check should be made payable to the New York State Department of Health and be sent with the attached Remittance Advice to:


New York State Department of Health
Medicaid Financial Management
GNARESP Corning Tower, Room 1237
Albany, New York 12237-0048

OPTION #2: Enter into a repayment agreement with the Office of the Medicaid Inspector General. If your repayment terms exceed 90 days from the date of the final report, recoveries of amounts due are subject to interest charges at the prime rate plus 2%. If the process of establishing the repayment agreement exceeds 20 days from the date of the final report, the OMIG will impose a 15% withhold after 20 days until the agreement is established.

Furthermore, the OMIG may require financial information from you to establish the terms of the repayment agreement. If additional information is requested, the OMIG must receive the information within 30 days of the request or a 50% withhold will be imposed. OMIG acceptance of the repayment agreement is based on your repaying the Medicaid overpayment as agreed. The OMIG will adjust the rate of recovery, or require payment in full, if your unpaid balance is not being repaid as agreed. The OMIG will notify you no later than 5 days after initiating such action. If you wish to enter into a repayment agreement, you must forward your written request within 20 days to the following:

Bureau of Collections Management
New York State Office of the Medicaid Inspector General
800 North Pearl Street
Albany, New York 12204


If within 20 days, you fail to make full payment or contact the OMIG to make repayment arrangements, the OMIG will establish a withhold equal to 50% of your Medicaid billings to recover payment and liquidate the lower confidence limit amount, interest and/or penalty, not barring any other remedy allowed by law. The OMIG will provide notice to you no later than 5 days after the withholding of any funds. In addition, if you receive an adjustment in your favor while you owe funds to the State, such adjustment will be applied against the amount owed.

If you choose not to settle this audit through repayment of the adjusted lower confidence limit, you have the right to challenge these findings by requesting an administrative hearing where the OMIG would seek and defend the point estimate of \$409,467. As allowed by state regulations, you must make your request for a hearing, in writing, within sixty (60) days of the date of this report to:

General Counsel
Office of Counsel
New York State Office of the Medicaid Inspector General
800 North Pearl Street
Albany, New York 12204

Questions regarding the request for a hearing should be directed to [REDACTED]
Office of Counsel, at [REDACTED]

Issues you may raise shall be limited to those issues relating to determinations contained in the final audit report. Your hearing request may not address issues regarding the methodology used to determine the rate, or any issue that was raised at a proceeding to appeal a rate determination.

At the hearing you have the right to:

- a) be represented by an attorney or other representative, or to represent yourself;
- b) present witnesses and written and/or oral evidence to explain why the action taken is wrong; and
- c) cross examine witnesses of the Department of Health and/or the OMIG.

The OMIG reserves the right to conduct further reviews of your participation in the Medicaid Program, take action where appropriate, and recover monies owed through the initiation of a civil lawsuit or other legal mechanisms including but not limited to the recovery of state tax refunds pursuant to Section 206 of the Public Health Law and Section 171-f of the State Tax Law.

**NEW YORK STATE
OFFICE OF THE MEDICAID INSPECTOR GENERAL
REMITTANCE ADVICE**

NAME AND ADDRESS OF AUDITEE



Bio-Reference Laboratories, Inc.
481 Edward H. Ross Drive
Elmwood Park, NY 07407-3118

AMOUNT DUE: \$188,516

PROVIDER ID # [REDACTED]

AUDIT #10-1935

AUDIT	<input checked="" type="checkbox"/>	PROVIDER
	<input type="checkbox"/>	RATE
	<input type="checkbox"/>	PART B
TYPE	<input type="checkbox"/>	OTHER:

CHECKLIST

1. To ensure proper credit, please enclose this form with your check.
2. Make checks payable to: *New York State Department of Health*
3. Record the Audit Number on your check.
4. Mail check to:

[REDACTED]
New York State Department of Health
Medicaid Financial Management, B.A.M.
GNARESP Corning Tower, Room 1237
File #10-1935
Albany, New York 12237-0048

Thank you for your cooperation.

SAMPLE DESIGN AND METHODOLOGY

Our sample design and methodology are as follows:

- Universe - Medicaid claims for Laboratory services paid during the period January 1, 2006, through December 31, 2009.
- Sampling Frame - The sampling frame for this objective is the Medicaid electronic database of paid Bio-Reference claims for Laboratory services paid during the period January 1, 2006, through December 31, 2009.
- Sample Unit - The sample unit is a Medicaid claim paid during the period January 1, 2006, through December 31, 2009.
- Sample Design – Simple sampling was used for sample selection.
- Sample Size – The sample size is 200 dates of service.
- Source of Random Numbers – The source of the random numbers was the OMIG statistical software. We used a random number generator for selecting our random sampling items.
- Characteristics to be measured - Adequacy of documentation received supporting the sample claims.
- Treatment of Missing Sample Services - For purposes of appraising items, any sample service for which Bio-Reference could not produce sufficient supporting documentation was treated as an error.
- Estimation Methodology – Estimates are based on the sample data using per unit estimates.

SAMPLE RESULTS AND ESTIMATES

Universe Size	120,926
Sample Size	200 DOS
Sample Book Value	\$8,148.18
Sample Overpayments	\$677.22
Net Financial Error Rate	8%
Mean Dollars in Error	\$3.3861
Standard Deviation	15.58
Point Estimate of Total Dollars	\$409,468
Confidence Level	90%
Lower Confidence Limit	\$ 188,516