

Audit Report

**Department of Health and Mental Hygiene
Laboratories Administration**

September 2009



OFFICE OF LEGISLATIVE AUDITS
DEPARTMENT OF LEGISLATIVE SERVICES
MARYLAND GENERAL ASSEMBLY

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Karl S. Aro
Executive Director

DEPARTMENT OF LEGISLATIVE SERVICES
OFFICE OF LEGISLATIVE AUDITS
MARYLAND GENERAL ASSEMBLY

Bruce A. Myers, CPA
Legislative Auditor

September 30, 2009

Delegate Steven J. DeBoy, Sr., Co-Chair, Joint Audit Committee
Senator Verna L. Jones, Co-Chair, Joint Audit Committee
Members of Joint Audit Committee
Annapolis, Maryland

Ladies and Gentlemen:

We have audited the Department of Health and Mental Hygiene – Laboratories Administration for the period beginning April 11, 2006 and ending March 15, 2009. The Administration provides laboratory testing to assist physicians and health officials in the prevention, diagnosis, and control of human diseases.

Our audit disclosed that the Administration had not revised its laboratory testing fee schedule annually to recover all related costs, as required. As a result, we estimate that unrecovered laboratory costs totaled approximately \$1.4 million in fiscal years 2007 and 2008. In addition, adequate internal controls were not established over the issuance of and destruction of controlled dangerous substance permits.

The Department of Health and Mental Hygiene's response to this audit, on behalf of the Administration, is included as an appendix to this report. We wish to acknowledge the cooperation extended to us during the course of this audit by the Administration.

Respectfully submitted,

Bruce A. Myers, CPA
Legislative Auditor

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* Denotes item repeated in full or part from preceding audit report

Background Information

Agency Responsibilities

The Laboratories Administration is responsible for providing laboratory testing to assist physicians and health officials in the prevention, diagnosis, and control of human diseases. According to the State's records, during fiscal year 2008, the Administration's central laboratory in Baltimore City and its two regional laboratories conducted approximately 11 million laboratory tests, and the Administration's expenditures totaled approximately \$22.9 million.

Status of Findings From Preceding Audit Report

Our audit included a review to determine the status of the five findings contained in our preceding audit report dated October 17, 2006. We determined that the Administration satisfactorily addressed three of these findings. The remaining two findings are repeated in this report.

Findings and Recommendations

Laboratory Testing Fees

Finding 1

Laboratory testing fees were not revised annually, as required, resulting in a potential loss of income of approximately \$1.4 million.

Analysis

The Laboratories Administration did not revise its laboratory testing fee schedule annually, as required by State regulations. Although the Secretary of the Department of Health and Mental Hygiene (DHMH) recently approved the Administration's revised laboratory fee schedule effective July 1, 2008, some of the rates had not been revised since July 1, 2003. Consequently, for several tests for which the Administration was required to charge fees to recover the related costs, there was no assurance the fees were sufficient during the majority of the audit period. For example, during the audit period the fee charged, until July 1, 2008, for newborn screening tests was \$42 per infant; however, based on the Administration's calculations during our prior audit, the laboratory fee for newborn screenings should have been \$54 per infant to recover all related costs during fiscal year 2005. Assuming lab fee costs for newborn screenings approximated the costs for fiscal year 2005, we estimated a potential loss of collections for the 121,000 infants tested in fiscal years 2007 and 2008 of approximately \$1.4 million. Effective July 1, 2008, the fee increased to \$60 per infant.

State regulations require the Administration to annually calculate a fee for each type of laboratory service performed, subject to the approval of the Secretary of the DHMH. For several services, the regulations further require that the fees be sufficient to recover all related laboratory testing costs. According to the Administration's records, fiscal year 2008 laboratory testing fees collected totaled \$3.2 million.

Recommendation 1

We recommend that the Administration annually calculate and revise its fees for laboratory testing services on an annual basis, as required by State regulations.

Controlled Dangerous Substance Permits

Finding 2

Internal controls over controlled dangerous substance permits and the related collections were inadequate.

Analysis

The Administration had not established adequate internal controls over controlled dangerous substance (CDS) permits and the related cash receipts. Specifically, we noted the following conditions:

- An independent supervisory review was not performed prior to issuing the CDS permits to ensure that a fee had been received and deposited for each permit issued. A similar comment was included in our preceding audit.
- Prenumbered CDS permits were not independently accounted for as to issued, voided, or on-hand. Specifically, the employee responsible for accounting for the permits issued from stock, as recorded on the manual control log, also had unrestricted access to the CDS permit database. A similar comment was included in our preceding audit. Furthermore, we noted that the manual control log of issued permits was not reconciled to the number of permits issued per the database. In this regard, for two of five days tested, the manual control log indicated a higher number of permits issued than the database. Consequently, there is a lack of assurance as to the accuracy of the permits issued according to the database.
- The Administration did not require that the destruction of unused CDS permits be performed or witnessed by at least two employees and be documented. Rather, the Administration returned the unused permits to the printing contractor for destruction and the contractor provided the Administration with a letter attesting to the destruction of the unused permits. As a result, unused CDS permits could be used for unauthorized purposes. The Administration returned approximately 13,000 unused CDS permits to the printing contractor for destruction during the audit period.

According to the Administration's records, permit fees totaling approximately \$1.8 million were collected and approximately 21,000 CDS permits were issued for fiscal year 2008. CDS permits are issued to businesses and practitioners (such as doctors) that are authorized to handle any drug classified by the federal government as a controlled dangerous substance, and are renewed every two years.

Recommendation 2

We recommend that the Administration

- a. have an employee independent of the permit processing function verify, prior to issuing permits, that a fee has been received and deposited for each permit issued (repeat);**
- b. have an independent employee periodically account for prenumbered CDS permits as to issued, voided, or on hand (repeat);**
- c. ensure that the CDS permit database records are complete and accurate by reconciling the manual control log to the database; and**
- d. ensure that the destruction of CDS permits is witnessed by at least two Administration employees and is properly documented.**

We advised the Administration on accomplishing the necessary separation of duties using existing personnel.

Finding 3

Adequate controls over the CDS permit database had not been established.

Analysis

The Administration had not established adequate controls over the CDS permit database. Specifically, nine Division of Drug Control employees had incompatible duties since they had access to the database's automated mail log, which initiated the permit issuance process, as well as the capability to issue CDS permits on the database. As a result, improper permits could be issued. In addition, three of these employees had unrestricted access to the CDS permit database that allowed them to modify critical information (such as changes to permit eligibility status from suspended to active). Although, the Administration had established a verification process whereby a Division supervisory employee would review modifications to the database on a test basis, the employee performing the verification also had unrestricted access to the CDS permit database. As a result, there is a lack of assurance as to the information in the database and the propriety of the permits issued from the database.

A similar comment regarding the lack of independent supervisory review of modifications of critical information to the database was included in our preceding audit report.

Recommendation 3

We recommend that the Administration

- a. establish effective access controls over the CDS permit database by limiting access to critical functions, including modifications to the database and printing of CDS permits; and**
- b. establish procedures to ensure that supervisory personnel, who do not have access to make changes on the CDS permit database, verify the propriety of modifications of critical information to that database, and that such reviews be documented (repeat).**

Audit Scope, Objectives, and Methodology

We have audited the Laboratories Administration of the Department of Health and Mental Hygiene for the period beginning April 11, 2006 and ending March 15, 2009. The audit was conducted 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.

As prescribed by State Government Article, Section 2-1221 of the Annotated Code of Maryland, the objectives of this audit were to examine the Administration's financial transactions, records and internal controls, and to evaluate its compliance with applicable State laws, rules, and regulations. The areas addressed by the audit included cash receipts, including laboratory testing fees and control dangerous substance permit fees; accounts receivable; and corporate purchasing cards. We also determined the status of the findings included in our preceding audit report.

In planning and conducting our audit, we focused on the major financial-related areas of operations based on assessments of materiality and risk. Our audit procedures included inquiries of appropriate personnel, inspection of documents and records, and observations of the Administration's operations. We also tested transactions and performed other auditing procedures that we considered necessary to achieve our objectives. Data provided in this report for background or informational purposes were deemed reasonable, but were not independently verified.

Our audit did not include certain support services provided to the Administration by the Department's Office of the Secretary and related units. These support services (such as payroll, maintenance of accounting records and related fiscal functions) are included within the scope of our audit of the Office of the Secretary.

Our audit did not include an evaluation of internal controls for federal financial assistance programs and an assessment of the Administration's compliance with federal laws and regulations pertaining to those programs because the State of Maryland engages an independent accounting firm to annually audit such programs administered by State agencies, including the Administration.

The Administration's management is responsible for establishing and maintaining effective internal control. Internal control is a process designed to provide reasonable assurance that objectives pertaining to the reliability of financial records, effectiveness and efficiency of operations including safeguarding of assets, and compliance with applicable laws, rules, and regulations are achieved.

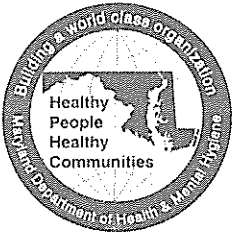
Because of inherent limitations in internal control, errors or fraud may nevertheless occur and not be detected. Also, projections of any evaluation of internal control to future periods are subject to the risk that conditions may change or compliance with policies and procedures may deteriorate.

Our reports are designed to assist the Maryland General Assembly in exercising its legislative oversight function and to provide constructive recommendations for improving State operations. As a result, our reports generally do not address activities we reviewed that are functioning properly.

This report includes findings relating to conditions that we consider to be significant deficiencies in the design or operation of internal control that could adversely affect the Administration's ability to maintain reliable financial records, operate effectively and efficiently, and/or comply with applicable laws, rules, and regulations. Our report also includes a finding regarding a significant instance of noncompliance with applicable laws, rules, or regulations. Other less significant findings were communicated to the Administration that did not warrant inclusion in this report.

The response from the Department of Health and Mental Hygiene, on behalf of the Administration, to our findings and recommendations is included as an appendix to this report. As prescribed in the State Government Article, Section 2-1224 of the Annotated Code of Maryland, we will advise the Department regarding the results of our review of its response.

APPENDIX



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – John M. Colmers, Secretary

September 30, 2009

Mr. Bruce A. Myers, CPA
Legislative Auditor
Office of Legislative Audits
301 West Preston Street
Baltimore, MD 21201

Dear Mr. Myers:

This is in response to your September 15, 2009 letter that included the draft audit report for the Laboratories Administration for the period beginning April 11, 2006 and ending March 15, 2009. Attached you will find the Administration's response and plan of correction that addresses each audit recommendation. I will work with the Administration to promptly address all audit exceptions. In addition, our Office of the Inspector General will follow-up on the recommendations to ensure compliance.

If you have any questions or require additional information, please do not hesitate to contact me at (410) 767-6505 or Thomas Russell of my staff at (410) 767-5862.

Sincerely,

John M. Colmers
Secretary

cc: Frances B. Phillips, R.N., M.H.A., Deputy Secretary, Public Health Services, DHMH
Peter Sybinski, Ph.D., Chief of Staff to the Deputy Secretary, Public Health Services, DHMH
Thomas V. Russell, Inspector General, DHMH
Ellwood L Hall, Jr., Assistant Inspector General, DHMH
Wendy Kronmiller, Chief of Staff to the Office of the Secretary, DHMH
John M. DeBoy, Dr. P.H., Director, Laboratories Administration, DHMH

Findings and Recommendations

Laboratory Testing Fees

Finding 1

Laboratory testing fees were not revised annually, as required, resulting in a potential loss of income of approximately \$1.4 million.

Auditor's Recommendation 1

We recommend that the Administration annually calculate and revise its fees for laboratory testing services on an annual basis, as required by State regulations.

Administration's Response 1

We partially concur with the auditor's finding. The Administration performs over 600 different types of laboratory tests for which we only charge for approximately 10 tests. This is a labor-intensive exercise since we have to calculate the cost of each test we perform although we do not charge for over 98% of them.

We have requested the Division of Cost Accounting and Reimbursement to amend the regulations under COMAR 10.02.06 requiring the fee schedule to be revised at least once every three years rather than on an annual basis.

The fee for newborn screening tests is now under COMAR 10.10.13 which sets the fee of \$70 for each newborn infant. This fee became effective January 1, 2009. The calculation for the newborn screening fee is not required to be done on an annual basis under this particular regulation.

The Administration will comply with the existing regulations to revise its fee schedule on an annual basis until the applicable amendment to COMAR is promulgated. This is anticipated to be completed by June 30, 2010 in order for the revised fees to be effective July 1, 2010.

Controlled Dangerous Substance Permits

Finding 2

Internal controls over controlled dangerous substance permits and the related collections were inadequate.

Auditor's Recommendation 2

We recommend that the Administration

- a. have an employee independent of the permit processing function verify, prior to issuing permits, that a fee has been received and deposited for each permit issued (repeat);**
- b. have an independent employee periodically account for prenumbered CDS permits as to issued, voided, or on hand (repeat);**
- c. ensure that the CDS permit database records are complete and accurate by reconciling the manual control log to the database; and**
- d. ensure that the destruction of CDS permits is witnessed by at least two Administration employees and is properly documented.**

We advised the Administration on accomplishing the necessary separation of duties using existing personnel.

Administration's Response 2

We partially concur with the auditor's finding. The CDS permit database is programmed not to print a permit unless full and complete payment has been made to the registrant's account, however, it could appear to be printing permits without a payment as was found by the OLA. When a partial payment for a CDS permit is entered into the database and then a subsequent partial payment is entered to bring that same account to fully paid status, the record could show that the permit has been printed without a payment if our payment entry procedures are not followed. We are retraining personnel to ensure that partial payments are added to the initial renewal event in the system. We will monitor partial payments to ensure that the procedures are followed and that the database changes have corrected the condition that OLA uncovered during their review.

The Deputy Chief of the Division of Drug Control has been reviewing the documentation to account for the prenumbered CDS permits whether it has been received, issued, voided or is on-hand. In the preceding audit report, we indicated that the security level for all employees had been changed. Due to staffing shortages, the security level of certain employees was changed to allow the processing of CDS applications in a timely manner. Subsequently, when the positions were filled, the security levels were not reset to previous security levels. The Deputy Chief's security level will be changed to "Data Entry" which will prevent him from being able to make changes to the database. This is anticipated to be completed by November 30, 2009.

The CDS permit database is not currently capturing the prenumbered CDS Certificate Control numbers when the permits are printed. The database will be modified to allow the capture of the prenumbered control numbers as part of the printing process. A log will be generated showing the range of numbers printed

on that particular day and verified with the manual control log. This is anticipated to be completed by June 30, 2010.

The Administration will require that the destruction of unused CDS permits be performed or witnessed by at least two employees and be properly documented. This will be implemented immediately.

Finding 3

Adequate controls over the CDS permit database had not been established.

Auditor's Recommendation 3

We recommend that the Administration

- a. establish effective access controls over the CDS permit database by limiting access to critical functions, including modifications to the database and printing of CDS permits; and**
- b. establish procedures to ensure that supervisory personnel, who do not have access to make changes on the CDS permit database, verify the propriety of modifications of critical information to that database, and that such reviews be documented (repeat).**

Administration's Response 3

We concur with the auditor's finding. The security levels for all employees will be reviewed and changed to limit access to the CDS permit database. Certain employees will only have access to certain parts of the database system, such as the mail log, check log, printing of CDS permits, etc. This is anticipated to be completed by November 30, 2009.

The Deputy Chief of the Division of Drug Control has been reviewing and documenting the modifications to the database to verify the propriety of critical changes made to the CDS permit database. This was noted and corrected in the previous audit, but due to staff shortages, changes were made to allow the processing of CDS applications in a timely manner. Subsequently, when the positions were filled, the security levels were not reset to previous security levels. The Deputy Chief's security level will be changed to "Data Entry" which will prevent him from being able to make changes to the database. This is anticipated to be completed by November 30, 2009.

AUDIT TEAM

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