The Commonwealth of Massachusetts

AUDITOR OF THE COMMONWEALTH

ONE ASHBURTON PLACE, ROOM 1819
BOSTON, MASSACHUSETTS 02108

A. JOSEPH DeNUCCI
AUDITOR

TEL. (617) 727-6200

NO. 2007-5128-7S1

INDEPENDENT STATE AUDITOR'S REPORT ON CERTAIN ACTIVITIES OF THE DEPARTMENT OF PUBLIC HEALTH'S CHILDHOOD LEAD POISONING PREVENTION PROGRAM

OFFICIAL AUDIT REPORT

DECEMBER 18, 2007

TABLE OF CONTENTS/EXECUTIVE SUMMARY

The Childhood Lead Poisoning Prevention Program (CLPPP) was established in 1971 for the prevention, screening, diagnosis, and treatment of lead poisoning, including the elimination of sources of poisoning through research, educational, epidemiological, and clinical activities. CLPPP, which is administered by the Department of Public Health, provides a range of services to the children of the Commonwealth of Massachusetts, their families, and others with an interest in the prevention of lead poisoning. In order to accomplish the fundamental goals of identifying lead poisoned children and ensuring that they receive medical and environmental services as well as preventing further cases of lead poisoning, CLPPP has developed links with a wide array of professionals and programs that provide services to children. The purpose of our review was to follow-up on the issue identified in our prior audit (No. 2001-0290-3) and determine whether audit recommendations have been implemented and noted deficiencies have been corrected.

Our prior audit of CLPPP disclosed that private laboratories were frequently not complying with the mandatory reporting requirements for analyzed blood specimens for potential lead poisoning. Our follow-up review disclosed that of the 70,585 administered screenings performed by 71 private laboratories, 35 private laboratories reported 893 occurrences with blood lead levels of 15 mcg/dl or greater. The reporting requirement for this blood level is within seven days. On average, private laboratories took eight days to report their results; however, eight laboratories averaged between 11 and 47 days to report. Our analysis also disclosed that approximately 24% of the 893 incidences, or 212 reported incidences from 22 laboratories, revealed a more serious blood level of 25 mcg/dl or greater. This included five laboratories, two of which are out-of-state, that on average exceeded the mandatory three business days allowed according to DPH's standards, reporting on average, between five and 19 days. Private laboratory reporting delays may deprive lead poisoned children from timely admittance to CLPPP's Case Management system and entitled management services. Furthermore, our review revealed that although the CLPPP took some corrective measures to resolve this issue, such as establishing accessibility to the State Laboratory Institute database and issuing noncompliance letters to laboratories that were not submitting blood analyses test results in a timely manner, the issue of timely reporting by private laboratories continues without any enforcement action taken by CLPPP for those laboratories that do not comply with the reporting requirements. In fiscal year 2006, we identified 14 private laboratories that CLPPP sent multiple letters to. Of those 14 laboratories, five received four or more letters identifying that they were not in compliance with DPH's timely reporting standards. Additionally, one laboratory received seven letters indicating they were not in compliance with standards for reporting their blood level test results.

In its response to the audit report, DPH stated that because the Childhood Lead Poisoning Prevention Program regulations lacked sufficient enforcement mechanisms, support and assistance was sought and received from the DPH Bureau of Quality Assurance and Control (BQAC), Clinical Laboratory Program (CLP) and the Office of the General Counsel attorney for clinical labs. Utilizing CLP enforcement mechanisms, Statement of Deficiencies were prepared by the Health Standards and Quality Bureau /CLP and mailed to labs that had submitted test results for children whose blood levels were above 25ug/dL beyond the three working days time frame in 2006. The Statement of Deficiencies letter is an initial enforcement step to ensure statutory and regulatory compliance. Massachusetts laboratories are familiar with such letters and are generally aware that by not submitting a Plan of Correction (POC) in response to such letters may threaten their state or federal status and may subject them to a range of sanctions. DPH further indicated that the initial enforcement mechanism was particularly effective in this instance and that a POC was received by BQAC within the acceptable ten-day timeframe from each of the laboratories that were issued a Statement of Deficiencies. The POC's were reviewed by the BQAC's Clinical Laboratory Program and deemed acceptable. Lastly, DPH drafted a follow up letter in the event it did not hear from a lab that receives the SOD/request for POC letter. Further, there have been no test results that were submitted later than the required working days in 2007 for children whose BLL was >25ug/dL.

INTRODUCTION

Background

The Childhood Lead Poisoning Prevention Program (CLPPP) was established in 1971 for the prevention, screening, diagnosis, and treatment of lead poisoning, including the elimination of sources of poisoning through research, educational, epidemiological, and clinical activities. CLPPP provides a range of services to the children of the Commonwealth of Massachusetts, their families, and others with an interest in the prevention of lead poisoning. In order to accomplish the fundamental goals of identifying lead poisoned children and ensuring that they receive medical and environmental services as well as preventing further cases of lead poisoning, CLPPP has developed links with a wide array of professionals and programs that provide services to children.

CLPPP is mandated by Chapter 111, Sections 189A through 199B of the Massachusetts General Laws. Under Section 193, CLPPP is required to establish a program for the early identification of cases of lead poisoning, including systematically screening all children under the age of six years for the presence of lead poisoning. Section 193 also directs CLPPP to promulgate regulations establishing the means by which and the intervals at which children under six years of age shall be screened for lead poisoning and the guidelines for the medical follow-up of children found to be lead poisoned. CLPPP regulations are delineated under Department of Public Health's 105 Code of Massachusetts Regulations 460.

Audit Scope, Objectives, and Methodology

In accordance with Chapter 11, Section 12, of the General Laws, we have conducted a follow-up audit of the Department of Public Health's CLPPP for the period through December 29, 2006. The purpose of our audit was to determine whether CLPPP had implemented the appropriate internal control changes based on our previous audit (Audit No. 2001-0290-3) to ensure that the private laboratories analyzing pediatric blood specimens for lead poisoning comply with universal and mandatory reporting requirements promulgated by CLPPP. Our review was conducted in accordance with applicable generally accepted government auditing standards for performance audits.

To meet our objectives, we reviewed the major activities performed by CLPPP. We interviewed CLPPP officials, reviewed relevant laws and regulations, and prepared flowcharts on the major

activities of the program. Testing was performed on program activities as we determined necessary. Accordingly, our audit included those areas we believed to be at high risk based upon our assessment of internal controls.

Based upon our review, we determined that, except for the issue discussed in the Audit Results section of our report, CLPPP has adequate internal controls and complied with applicable laws and regulations for those areas reviewed. For illustrative purposes, our report includes a listing of laboratories with multiple violations for the period ended December 29, 2006 (see Appendix I) and a chart showing the steady decline in the Commonwealth's number of identified cases of lead poisoning from fiscal years 1995 to 2006 (see Appendix II).

AUDIT RESULTS

STATUS OF PRIOR AUDIT RESULTS

Private Laboratories Not Reporting Test Results in a Timely Manner – Partially Resolved

Our prior audit of the Childhood Lead Poisoning Prevention Program (CLPPP) disclosed that private laboratories were frequently not complying with universal and mandatory reporting requirements for analyzed blood specimens for lead poisoning. Our analysis showed that private laboratories reported blood analyses to the State Laboratory Institute (SLI) on average of three to seven business days beyond the mandated one-week guideline. In addition, four of 32 private laboratories averaged at least 25 days to report their blood results to the SLI. Also these four private laboratories neglected to report 13 known cases of lead poisoned children to the SLI within CLPPP's mandatory three business days. These private laboratories may have not been in adherence with established reporting regulations, in part, because CLPPP did not have a clear understanding of its responsibility for enforcing these regulations. As a result, the program lacked the necessary operational and administrative control procedures needed to ensure that universal and mandatory reporting regulations were being adhered to. Private laboratory reporting delays deprive lead poisoned children from timely admittance to CLPPP's Case Management System and entitled case management services.

Based on our prior review we recommended that CLPPP coordinate its efforts with DPH, the SLI, and private laboratories on developing methods that would enhance compliance with existing regulations. We further recommended that CLPPP aggressively follow-up and take the appropriate action for those instances when private laboratories continued to overlook reporting requirements. Detailed polices and procedures should be developed to monitor and ultimately correct untimely reporting. Finally, we recommended that if private laboratories did not comply or improve, CLPPP should seek legal assistance from within DPH.

In response to the audit, CLPPP indicated that the full State Laboratory Institute database would be accessible by its regional offices so that case management nurses can participate in monitoring of laboratory reporting results. Furthermore, for each laboratory that exceeds the mandated reporting deadline, a letter would be sent out to those labs informing them of their lack of reporting results in a timely manner. Specifically, the Director of CLPPP indicated that laboratories that do not demonstrate the appropriate improvement would be subject to

heightened attention and follow-up review. In addition, in order to provide a more meaningful tool for effective compliance, CLPPP stated that they would actively explore all possibilities with DPH's Office of General Counsel in amending the Department's laboratory licensing regulations to incorporate requirements for the reporting of cases of lead poisoning and all screening results as a condition for licensure.

Our follow-up audit disclosed that CLPPP had taken some positive steps in coordinating their work with the private laboratories to improve reporting requirements for analyzed blood specimens for lead poisoning. Specifically, CLPPP began issuing letters (see Appendix III) to laboratories that did not submit blood analysis test results in a timely manner as required pursuant to Massachusetts General Law, Chapter 111, Section 191 and Massachusetts Regulation, 105 CMR 460.070. However, our review disclosed that even with the issuance of noncompliance letters, there were still a number of laboratories reporting blood analyses to the SLI three to seven business days beyond the mandated reporting times during fiscal year 2006. Our review further noted that CLPPP had not taken any further enforcement action in response to those repeat offenders, other than the issuance of the noncompliance letter.

In examining CLPPP's patient-based computer system of private laboratory analysis downloaded from the SLI, CLPPP's records show that, during fiscal year 2006, 71 private laboratories administered 70,585 venous screenings, as opposed to the less reliable capillary screenings. Our review disclosed that, similar to the prior audit results, private laboratories continued to exceed CLPPP's universal reporting requirement to the SLI. However, for reporting purposes, our examination of private laboratory analyses was limited to reported blood levels equal to or exceeding 15 mcg/dl[1] and greater then or equal to 25 mcg/dl. We selected these levels because CLPPP personnel explained that within the medical profession, these blood levels are generally associated with the potential beginnings of adverse effects.

Our review disclosed that, of the 70,585 screening, 35 private laboratories reported 893 occurrences with blood lead levels of 15 mcg/dl or greater. The reporting requirement for this blood level is within seven days of the test. On average, private laboratories took eight days to report their results, however, eight laboratories averaged between 11 and 47 days. The following

[1] Microgram per deciliter

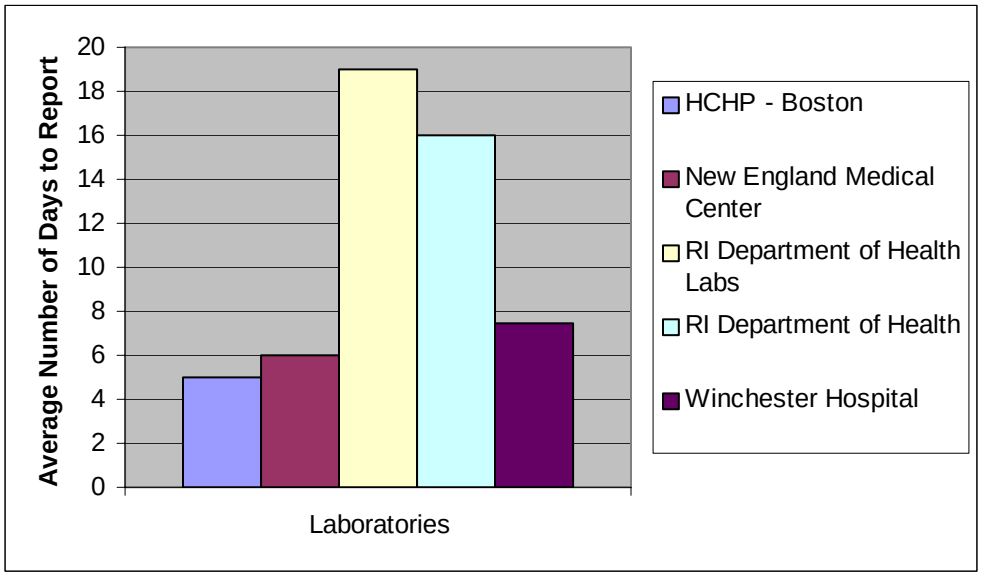
table illustrates the aging of the average number of days that private laboratories reported to SLI during fiscal year 2006.

Reported levels of >15 mcg/dl
Average Number of Days Reported

Average Number of Days	Number of Laboratories
1-5	18
6-10	9
11-15	5
16-47	3

Furthermore, our analysis disclosed that approximately 24% of the 893 incidences, or 212 reported incidences from 22 laboratories, revealed the more serious blood level of 25 mcg/dl or greater. This included five laboratories, two of which are out-of-state, that on average, exceeded the mandatory three business days reporting requirement, reporting on average, between five and 19 days. The following chart illustrates the five private laboratories' inadequate reporting practices:

Average Number of Days to Report Results
[>=25mcg/dl]
(Laboratories exceeding 3 days)



As in the prior audit, the CLPPP Director indicated that on some occasions, private laboratories called directly to the program if a specific case warranted immediate attention. Nonetheless, the Director could not provide us with supporting documentation as evidence of the timely reporting of known cases of childhood lead poisoning.

Massachusetts's regulations mandate that private laboratories are to submit their results within specified times, especially in known cases of lead poisoning. Specifically, the DPH's 105 Code of Massachusetts Regulations (CMR) 460.040, Mandatory Reporting of Cases of Lead Poisoning, states in part, that:

> *Pursuant to M.G.L. c. 111, § 191, physicians, other health care providers, and private laboratories shall report all cases of childhood lead poisoning known to them to the Director within three working days of identification, unless previously reported.*

Additionally, 105 CMR 460.070, Universal Reporting of Erythrocyte Protoporphyrin and Blood Lead Results, states, in part, that:

> *Laboratories, which analyze blood specimens drawn pursuant to 105 CMR 460.050 for lead… shall report all results to the State Program [SLI]. This requirement shall apply to analyses performed in all laboratories other than those in the State Program. Such reports shall be made within one week of the analysis.*

As part of our review, we also examined the letters sent to the private laboratories informing them of their noncompliance with DPH's blood reporting standards. The letters sent out were identical in nature identifying either a violation of the three-day reporting requirement for blood levels greater then or equal to 25 mcg/dl; or in violation of greater than seven days reporting time for blood levels greater then 15 mcg/dl. In fiscal year 2006, we identified 14 private laboratories that CLPPP sent multiple letters to. Of those 14 laboratories, five received four or more letters identifying that they were not in compliance with DPH's timely reporting standards. Furthermore, one laboratory received seven letters indicating they were not in compliance in reporting their blood level test results.

As a result of our testing of the private laboratories and reviewing compliance letters, we interviewed the Director of CLPPP regarding the issue of multiple violation letters being sent out without any further enforcement taken. Specifically, we inquired if they had pursued any additional enforcement tools to be included in their reporting procedure, such as ensuring timeliness as recommended in our previous audit. In response to our inquiry, the Director of

the CLPPP program indicated that a DPH Deputy General Counsel had advised him that no additional enforcement actions existed within the context of the Childhood Lead Poisoning Prevention regulations.

As a result, and after meeting with the Director, we met on January 29, 2007 with DPH officials, which included the Associate Commissioner for the Center for Environmental Health at the Department of Public Health to review our audit results concerning the noncompliance with timeliness of reporting. The Associate Commissioner indicated at that meeting that she would be personally involved in amending the controls and actions taken with those private laboratories, which did not comply. Furthermore, she indicated that she would work with DPH's legal counsel to ensure the enforcement of timely reporting.

Following this meeting on February 15, 2007, we received a revised draft deficiency letter from the Associate Commissioner (see Appendix IV). The new deficiency letter incorporated language from the original noncompliance letter along with a new requirement that the noncompliant laboratory submit an acceptable Plan of Correction to the Director of the Clinical Laboratory Program. The deficiency letter stated that an acceptable Plan of Correction must:

> *(1) include the month, day, year a deficiency will be corrected; (2) indicate how the deficiency will be or has been corrected; and, (3) be signed and dated by the Laboratory Director. You may include any documentation that will support your written Plan of Correction.*

Additionally, the deficiency letter:

> *…advised that in conformation with 42 USC 1306(d) (disclosure information) the deficiency letter together with your written Plan of Correction will be forwarded to the Health Standards and Quality Bureau (HSQB) and will be filed as a public record.*
>
> *If your written Plan of Correction is not forwarded … within the designated time period, the deficiency letter will be forwarded to HSQB, together with a statement that you failed to file such a plan.*

However, upon further review, we found that the deficiency letter did not include further disciplinary actions that would be taken by CLPPP if private laboratories did not comply with the mandatory reporting deadlines. In response to our concerns with the deficiency letter, a facsimile transmission dated February 21, 2007, was sent on behalf of the Director of the Clinical Laboratory Program to the Office of the State Auditor with details indicating actions to

be taken if noncompliance was found with private laboratories. Specifically, the facsimile transmission stated the following:

> *The failure of a laboratory to provide an appropriate, timely and acceptable response to the state of deficiencies may result in the following actions:*
>
> 1. *Publication of lack of compliance*
> 2. *Limitation or suspension of approval to perform testing within the law*
> 3. *Sanctions including civil monetary penalties and fines*
> 4. *Revocation of license/certification with resultant loss of revenue (not recognized as an acceptable provide of Medicare/Medicaid services)*

While our testing did not indicate that any child was adversely affected with the delayed reporting of blood specimens for lead poisoning, children who do not receive treatment in a timely manner could result in further adverse medical affects attributed to the lack of prompt intervention taken. Private laboratory reporting delays could deprive lead poisoned children of admittance into CLPPP's Case Management System and entitled case management services in a timely manner. Therefore, further adherence to CLPPP's established reporting requirement represents a critical element in determining program effectiveness. As a result of these issues, children with elevated levels of lead poisoning are possibly not being identified or treated in a timely manner.

Consequently, the program continues to lack the necessary operational and administrative control procedures needed to ensure that universal and mandatory reporting regulations were being adhered to.

Importantly, lead is a poison that affects virtually every system in the body, and is particularly harmful to the developing brain and nervous system of young children. A prior study by Herbert Needleman for the New England Journal of Medicine indicated that a lead poisoned child could lose between three to five IQ points as a result of exposure to high amounts of lead.

Recommendation

CLPPP should continue to coordinate its efforts with DPH, the SLI, and private laboratories on ensuring compliance with existing regulations. CLPPP should continue to aggressively follow up and take appropriate action for those instances where private laboratories continue to overlook

reporting requirements. The critical importance of timely reporting, especially cases involving elevated blood levels, should be emphasized, and adherence with established regulations should continued to be also reiterated.

Auditee's Response

Because the Childhood Lead Poisoning Program regulations lacked sufficient enforcement mechanisms, support and assistance was sought and received from the DPH Bureau of Quality Assurance and Control (BQAC), Clinical Laboratory Program (CLP) and the Office of the General Counsel attorney for clinical labs. Utilizing CLP enforcement mechanisms, Statement of Deficiencies were prepared by HSQB/CLP and mailed to labs who had submitted test results for children whose blood levels were above 25ug/dL beyond the three working days time frame in 2006. A Statement of Deficiencies letter is an initial enforcement step to ensure statutory and regulatory compliance. Massachusetts laboratories are familiar with such letters and are generally aware that a failure to submit a Plan of Correction in response to such letters may threaten their state or federal status and may subject them to a range of sanctions. It is important to stress that this initial enforcement mechanism was particularly effective in this instance. A Plan of Correction was received by BQAC within the acceptable ten-day timeframe from each of the laboratories that were issued a Statement of Deficiencies. The Plan were reviewed by the BQAC's Clinical Laboratory Program and deemed acceptable.

Nonetheless, we have drafted a follow up letter (see Appendix V) in the event we should ever not hear from a lab that receives the SOD/request for POC letter. Further, there have been no test results that were submitted later than the required working days in 2007 for children whose BLL was >25ug/dL.

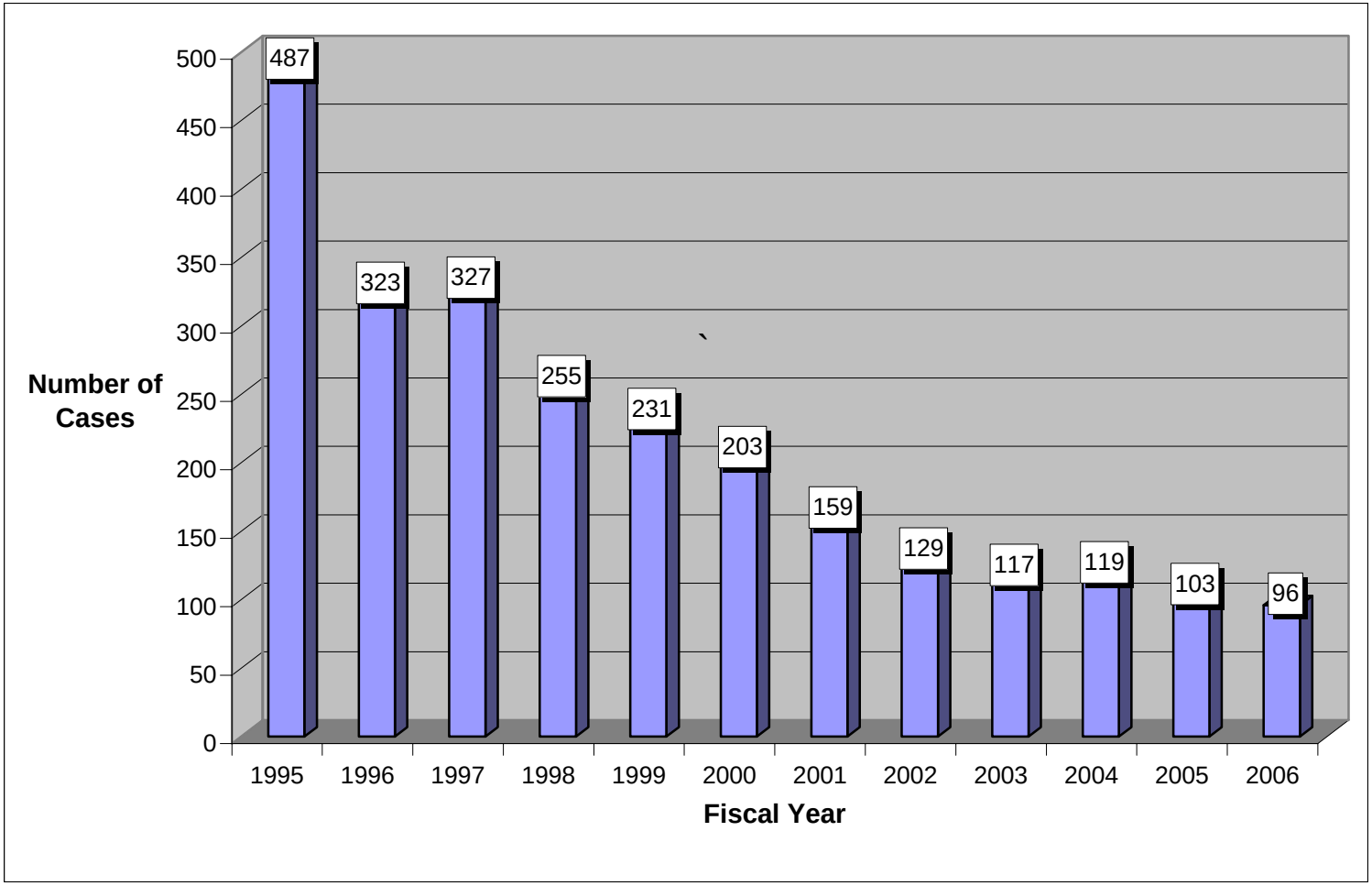
APPENDIX I

Listing of Laboratories with Multiple Violations As of December 29, 2006

Laboratory	Number of Violations
Bridgewater Goddard Park	2
Children's Hospital	2
Dartmouth Pediatrics	7
Franciscan Children's Hospital	3
Labor of America	6
Lexington Pediatrics	2
Mill River Pediatrics	4
Morton Hospital Medical Center	2
Pediatric Associates of Brockton	3
Pediatric Health Care at Newton Wellesley	3
South End Community Health Center	4
Specialty Laboratories	2
UMass Memorial Health Center	4
Woburn Pediatrics	3

APPENDIX II

Childhood Lead Poisoning Prevention Program
Newly Identified Lead Cases
Fiscal Year 1995 to 2006
(25mcg/dl or above)



APPENDIX III

Initial Laboratory Noncompliance Letter

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

MITT ROMNEY
GOVERNOR

KERRY HEALEY
LIEUTENANT GOVERNOR

RONALD PRESTON
SECRETARY

PAUL J. COTE, JR.
COMMISSIONER

April 14, 2005

Dear Director,

The Massachusetts Childhood Lead Screening Laboratory compiles a monthly statistical report to ensure private laboratories are in compliance with the Massachusetts lead reporting regulation. This letter is to inform you that your laboratory is not in compliance with the regulation during the month of January. I have included the regulations for your review and I hope this information is helpful. Compliance to the regulations is the responsibility of all laboratories testing children who live in Massachusetts.

Massachusetts regulation, 105 CMR 460.070, requires laboratories analyzing blood specimens for lead pursuant to the mandatory screening schedule (105 CMR 460.050), to report ALL data which includes demographic information to the Massachusetts Department of Public Health within ONE WEEK.

Pursuant to M.G.L. c. 111, δ 191 physicians, other health care providers and private laboratories shall report all cases of childhood lead poisoning (blood lead level >24 ug/dL) within THREE WORKING DAYS of identification, unless previously reported. Should a child suffer multiple episodes of lead poisoning, each episode must be reported. Reporting in this way assures that a poisoned child is quickly identified and entered into case management service.

The Childhood Lead Poisoning Prevention Program's director encourages all laboratories to report electronically regardless of the sample volume. Laboratories analyzing a small volume of lead sample can apply to the state program to waiver the electronic reporting requirement. A waiver of electronic reporting is contingent on prompt reporting and may be revoked. All applications for waiver must be submitted to Mr. Paul Hunter, Director of the Childhood Lead Poisoning Prevention Program.

If you have any questions or concerns, please contact me at (413) 586-7525.

Sincerely,

Carol Caulton, RN
Director of Case Management Services

APPENDIX IV

Draft Laboratory Deficiency Letter

DEVAL L. PATRICK
GOVERNOR
TIMOTHY P. MURRAY
LIEUTENANT GOVERNOR
JUDYANN BIGBY, MD
SECRETARY
PAUL J. COTE, JR.
COMMISSIONER

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Care Quality
Clinical Laboratory Program
99 Chauncy Street, 2nd Floor, Boston, MA 02111
(617) 753-8439/8438 (617) 753-8240 - Fax

May 29, 2007

Name
Address
City
State

RE: Mandatory reporting of childhood blood lead levels

Dear ,

The purpose of this letter is to inform you that the Department has found _____Laboratory to have engaged in a deficient practice with respect to the reporting of lead levels. Pursuant to to M.G.L. c.111, 191, "physicians, other health care providers **and private laboratories shall report all cases of childhood lead poisoning (>=25ug/dL) known to them, to the Director within three working days of identification, unless previously reported**. Should a child suffer multiple episodes of lead poisoning, each episode must be reported." (105 CMR 460.050). All clinical laboratories are required to report blood lead results to the Director of the Massachusetts Childhood Lead Poisoning Prevention Program.

Further, "laboratories and health care providers' practices that analyze blood specimens drawn pursuant to 105 CMR 460.050 for lead and erythrocyte protoporphyrin **shall report all results to the State Program in a secure electronic format approved by the Director. Such reports shall be made within one week of the analysis.** The Director may waive the electronic reporting requirement for laboratories or health care providers' practices that report only a small volume of results." (105 CMR 460.070).

The Center for Environmental Health has notified this office that your laboratory has failed to report childhood blood lead results according to the Massachusetts regulation 105 CMR 460.000.

Enclosed is a Statement of Deficiencies generated as a result of the delays in your result reporting to the Childhood Lead Prevention Program. Please submit an acceptable Plan of Correction to Roberta Teixeira, Director, Clinical Laboratory Program, at the above address. The plan must be received by the office by _____.

An acceptable Plan of correction must: (1) include the month, day, year a deficiency will be corrected; (2) indicate how the deficiency will be or has been corrected; and, (3) be signed and dated by the Laboratory Director. You may include any documentation that will support your written Plan of Correction.

You are advised that in conformation with 42 USC 1306(d) (disclosure information) the deficiency letter together with your written Plan of Correction will be forwarded to the Health Standards and Quality Bureau (HSQB) and will be on file as a public record.

If your written Plan of Correction is not forwarded to this office within the designated time period, the deficiency letter will be forwarded to HSQB, together with a statement that you failed to file such a plan. Please retain a copy of the Statement of Deficiencies and Plan of Correction for your files. PLEASE COMPLETE THE PLAN OF CORRECTION ON THE FORM PROVIDED IN A LEGIBLE MANNER.

Thank you for your cooperation,

Respectfully yours,

-if CAP, JCAHO, or COLA accredited, cc to Ricki Strader, DPH
cc Facility File

document1

APPENDIX V

Follow-Up Letter for Non-responsive Laboratory Plan of Correction

DEVAL L. PATRICK
GOVERNOR
TIMOTHY P. MURRAY
LIEUTENANT GOVERNOR
JUDYANN BIGBY, MD
SECRETARY
JOHN AUERBACH
COMMISSIONER

Organization address goes here

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Care Quality
Clinical Laboratory Program
99 Chauncy Street, 2nd Floor, Boston, MA 02111
(617) 753-8439/8438 (617) 753-8240 - Fax

«DATEPOC2»

RE: CLIA NUMBER

Dear _____:

Please be advised that your Plan of Correction submitted in response to a mandatory reporting of childhood lead levels deficiency letter dated _____, is unacceptable for the following reason(s):

1. It was not submitted in a timely manner
2. It was not an adequate plan
3. It was not an appropriate plan
4. It was not a complete plan
5. It was not responsive to the request

Your Plan of Correction is being returned to you in order for you to make the adjustments noted above. Please return the Plan of Correction, with the necessary adjustments, to this office by _____ .

Failure to submit an acceptable Plan of Correction may affect the Federal certification and/or State Licensure of your laboratory services and may result in sanctions, such as:

1. **Publication of lack of compliance**
2. **Limitation or suspension of approval to perform testing within the law**
3. **Sanctions including civil monetary penalties and fines**
4. **Revocation of license/certification**

If you have any questions please contact this office at the address or phone number noted above.

Thank you for your cooperation.

Respectfully yours,

Health Care Facility Surveyor

c:\documents and settings\scondon\local settings\temporary internet files\olkbc7\clinical labs lead compliance followup letter1.doc