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NO. 2001-0290-3

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

OFFICIAL AUDIT REPORT

JANUARY 29, 2001

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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 an audit of the Department of Public Health's CLPPP for the period July 1, 1998 to June 30, 2000. The purpose of our audit was to determine whether CLPPP had established appropriate internal controls to ensure that private laboratories analyzing pediatric blood specimens for lead poisoning comply with universal and mandatory reporting requirements promulgated by CLPPP. Additionally, our audit included an examination of lead poisoning cases to determine property owner compliance with CLPPP lead paint containment and

abatement regulations as well as to assess the timeliness and effectiveness of CLPPP's Case Management System for children identified with elevated blood lead levels. 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 administrative controls and complied with applicable laws and regulations for those areas reviewed. For illustrative purposes, a chart is presented in the Appendix depicting the steady decline in the Commonwealth's number of identified cases of lead poisoning from fiscal year 1995 to fiscal year 2000.

AUDIT RESULTS

Private Laboratories Not Reporting Test Results in a Timely Manner

Our review of the Childhood Lead Poisoning Prevention Program (CLPPP) revealed that private laboratories were frequently not in adherence with universal and mandatory reporting requirements for analyzed blood specimens for lead poisoning during the period July 1, 1998 through June 30, 2000 (fiscal years 1999 and 2000). Private laboratory reporting delays deprive lead poisoned children from timely admittance to CLPPP's Case Management System and entitled case management services.

According to Chapter 111, Section 193, of the Massachusetts General Laws, CLPPP maintains a program for the early identification of lead poisoning. Specifically, CLPPP provides mandatory screening of children for lead poisoning between the ages of twelve months and 72-months. Pediatric blood specimens drawn pursuant to the above law are sent either to the State Laboratory Institute (SLI) or to private laboratories for analysis. Private laboratories submit data results to the SLI where they are entered and merged with SLI data to form a comprehensive database for pediatric blood level results. On a daily basis, the CLPPP central office and regional nurses download both SLI and private laboratory results for review.

Massachusetts regulations mandate that private laboratories are to submit their results within specified times, especially in known cases of lead poisoning. Specifically, the Department of Public Health's (DPH) 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.

Our review disclosed that private laboratories repeatedly did not comply with CLPPP reporting requirements, contrary to 105 CMR 460.070. In fact, our analysis showed that, on average, private laboratories reported blood analyses to the SLI three days and seven days beyond the mandated one-week guideline during fiscal years 1999 and 2000, respectively.

As a result, we examined CLPPP's patient-based computer system of private laboratory analyses downloaded from the SLI. Our examination did not include blood analyses administered by the SLI, but focused entirely on analyses performed by private laboratories. The focus on private laboratories was based upon our review of 64 pediatric blood specimens analyzed by the SLI that indicated blood results were reported within one day. Further, the SLI Director of Environmental Chemistry stated that 98% of SLI blood specimens are analyzed and reported (entered into database for pediatric blood lead results) within 24 hours with the remaining specimens reported within 48 hours by SLI.

During fiscal year 1999, 29 private laboratories—25 in state and four out of state—analyzed a total of 124,952 screenings, or approximately 50% of all pediatric blood specimens drawn to determine lead concentration. As previously mentioned, CLPPP regulations require that laboratories analyzing blood specimens drawn pursuant to 105 CMR 460.050 (which includes private laboratories) are to report such results to the SLI within one week. To that end, we examined compliance with 105 CMR 460.070 by examining the amount of time from when private laboratories process blood analyses to when they report such results to the SLI.

The results of our test indicated that, during fiscal year 1999, private laboratories, on average, took 10 days to report blood-screening results to the SLI, including a low of two days and a high of 31 days. In fact, only one of the 29 private laboratories determining lead concentration had an average reporting time less than CLPPP's one-week requirement. The table below further illustrates an aging of the average number of days that private laboratories reported results to the SLI during fiscal year 1999.

Average Number of Days	Number of Laboratories
2-8	6
9-17	14
18-25	6
26-32	3
Total	29

For fiscal year 2000, our examination of private laboratory analyses was limited to reported blood lead levels equal to or exceeding 15 mcg/dl.[1] We selected this level because CLPPP personnel explained that within the medical profession this blood level is generally associated with the potential beginnings for adverse effects.

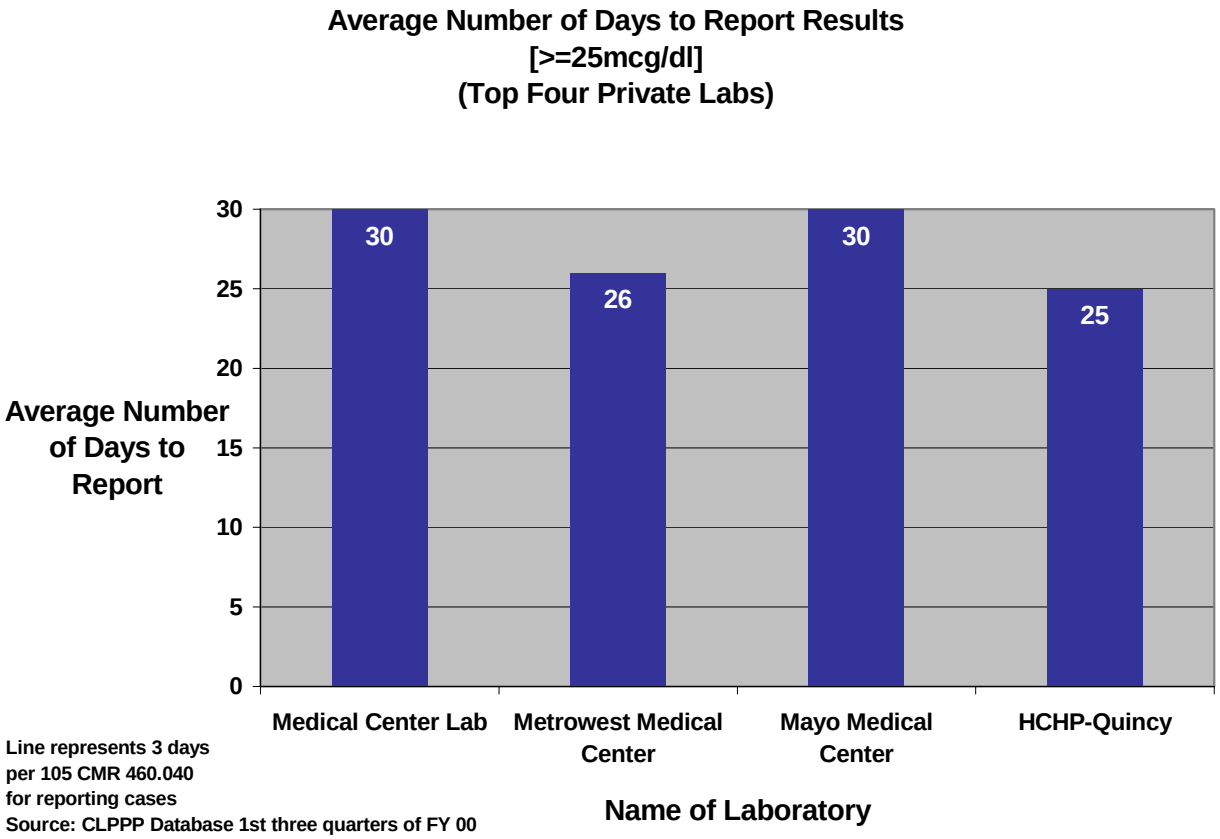
CLPPP records showed that, during fiscal year 2000, 32 private laboratories administered a total of 132,784 screenings, an increase of over 6% from fiscal year 1999. Our examination revealed that, similar to the fiscal year 1999 test results, private laboratories during fiscal year 2000 had continually exceeded CLPPP's universal reporting requirement of reporting blood results within one week to the SLI. On average, private laboratories took 14 days to report their results, with a low of two days and a high of 62 days. The table below illustrates an aging of the average number of days that private laboratories reported results to the SLI during fiscal year 2000.

Average Number of Days	Number of Laboratories
2-15	10
16-31	10
32-47	9
48-62	3
Total	32

Our analysis disclosed that, of the 132,784 screenings, private laboratories reported 653 occurrences with blood lead levels of 15 mcg/dl or greater. Approximately 21% of these cases, or 136 instances,

[1] Microgram per deciliter

revealed a blood lead level of 25 mcg/dl or greater[2]. A closer review showed that four of the 32 private laboratories took at least 25 days to report their blood results to the SLI. Moreover, we determined that these same four private laboratories neglected to report 13 known cases of lead poisoned children to the SLI within CLPPP's mandatory three business days. The following chart clearly illustrates the four private laboratories' inadequate reporting practices.



The CLPPP Director indicated that on some occasions private laboratories call directly to the program if a specific case warranted immediate attention. Nonetheless, the Director was not able to provide us with supporting documentation as evidence of the timely reporting of known cases of childhood lead poisoning. Although the Director also commented that letters were issued to private laboratories

[2] Level is considered lead poisoned per state regulations based on guidelines issued by the Center for Disease Control (CDC).

regarding concerns with the timeliness of reports, specific examples supporting this claim were not provided.

To assess the timeliness and effectiveness of CLPPP services once a child enters into its program, we followed the 13 known cases of lead poisoning noted earlier through CLPPP's Case Management System. Without exception, our examination noted that case management records clearly documented the prompt admittance into CLPPP's Case Management System for all 13 children reviewed who were victims of lead poisoning. Case records also showed that each child was examined by a doctor and assigned to a regional nurse and a social worker. Moreover, each case adequately documented the treatment and services offered to each child and the results of follow-up blood lead concentration screenings. In each of the 13 cases reviewed, blood lead levels steadily declined and the child was discharged from the program.

The fact that the four private laboratories did not report these 13 cases to SLI within the mandatory time period may have been due, in part, to CLPPP not having a clear understanding of its responsibility for enforcing 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. Although CLPPP believed that the SLI was responsible for enforcing reporting regulations, the SLI Director of Environmental Chemistry stated that CLPPP was ultimately responsible for enforcement of the regulations. Further, CLPPP's Director asserted that these delays were also caused by a lack of uniform reports, use of a batching system whereby multiple tests accumulate before being submitted to the SLI, and use of a mail system instead of reporting results electronically. In July, CLPPP initiated a corrective measure that proposed an amendment to the Lead Law requiring all laboratories to report test results electronically.

Private laboratory reporting delays deprive lead poisoned children from timely admittance to CLPPP's Case Management System and entitled case management services. Therefore, adherence to CLPPP's established reporting requirement represents a critical element in determining program effectiveness. Moreover, CLPPP's lack of necessary operational and administrative controls for such a crucial program component heightens reporting delays, impeding its 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.

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 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 coordinate its efforts with DPH, the SLI, and private laboratories on developing methods that will enhance compliance with existing regulations. CLPPP should aggressively follow-up and take appropriate action for those instances where private laboratories continue to overlook reporting requirements. For instance, issuing periodic status reports to private laboratories that depict previous reporting inadequacies would make these laboratories more aware of delays. Detailed policies and procedures should be developed to monitor and ultimately correct untimely reporting. The critical importance of timely reporting, especially cases involving elevated blood levels, should be emphasized, and adherence with established regulations should also be reiterated. If private laboratories fail to comply or improve, CLPPP should seek legal assistance from DPH's counsel and, if necessary, the Attorney General's Office.

Auditee's Response:

> The data reports on which this audit was conducted are based on two dates – date tested and date entered. "Date tested" is the date the blood sample was analyzed by the private laboratory. "Date entered" is the date the test result was entered into the screening database by the State Laboratory Institute (SLI). This date is not necessarily the date on which the data was received at SLI. There are a variety of personnel, systemic or other factors that from time to time delay the entry of laboratory data. This of course is particularly true for laboratory results received on paper, rather than electronically. While every effort is made to minimize such delays, by definition, they skew the data. Efforts are underway to identify an appropriate data field to record "date received" in the database, which would replace date entered in future data analyses and thus accurately reflect laboratory reporting performance. With regard to results received on paper, new regulations requiring electronic reporting, expected to go into effect in January 2001, will result in significantly reducing delays.
>
> A number of initiatives will be undertaken to improve the accuracy of data monitoring reports. A basic one is the development of an algorithm to adjust data to reflect the occurrence of weekends, and if possible, holidays, in the calculation of receipt of reports of lead poisoning within three working days. Secondly, the algorithm will be used in the calculation of the number of days a

laboratory exceeds the three working days and/or calendar week reporting requirements. CLPPP will assume direct responsibility for producing monthly reports monitoring the timeliness of private laboratory reporting.

The audit, based as it was on raw data, has highlighted the need for a careful trouble shooting and appropriate cleansing of raw data in order to produce meaningful reports that accurately reflect individual laboratory reporting performance. This scrutiny of the raw data will be conducted jointly by CLPPP and SLI. Databases as extensive and complex as this one inevitably include statistical outliers. One current example of such an outlier is a recently uncovered test result, which should and will be entered into the database, dated 1994.

Case management nurses occasionally receive calls directly from physicians . . . with a test result if it warrants immediate attention. The audit noted that documentation of this fact is not always completed. Such documentation will now be routinely added to the case progress report.

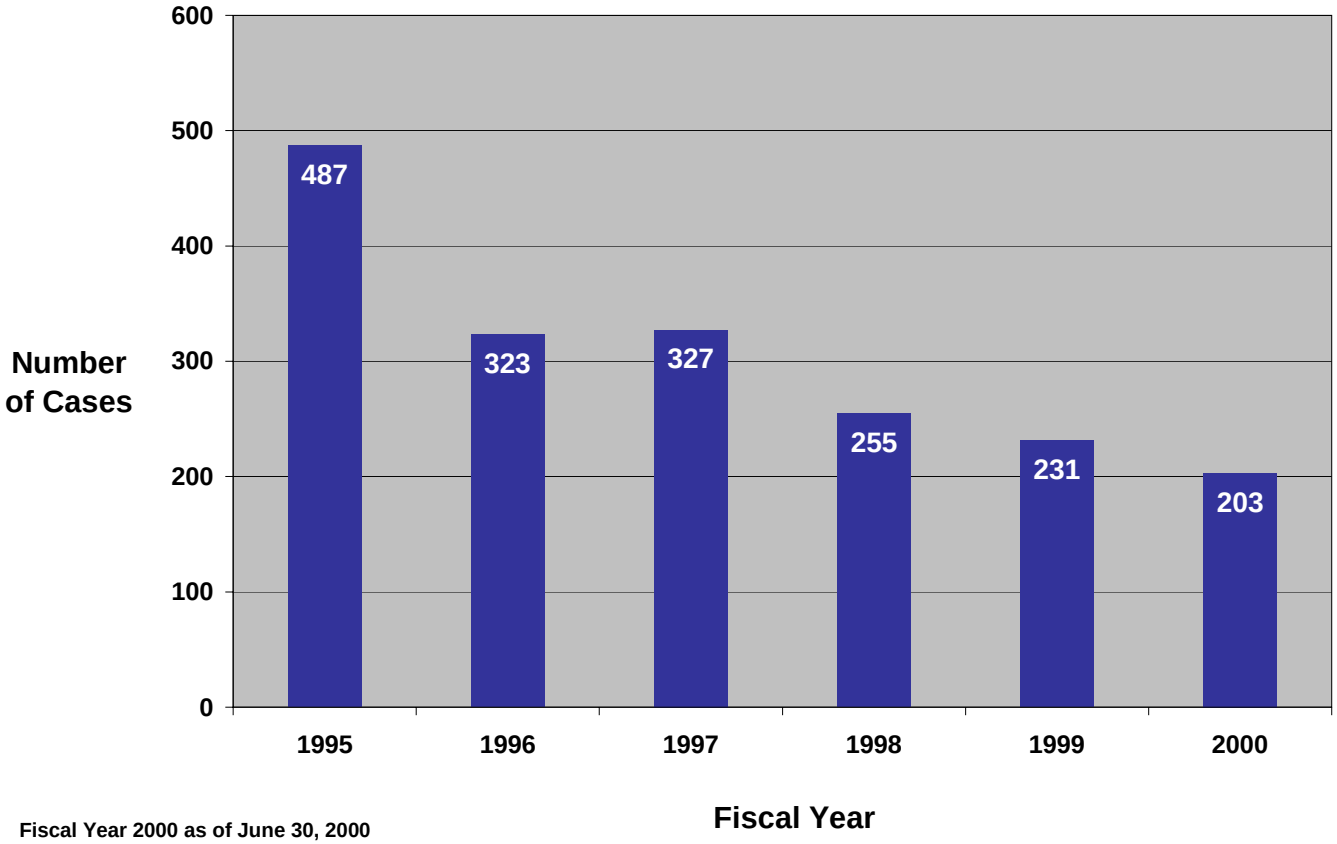
At present, the full laboratory database is inaccessible from regional offices, so that case management nurses cannot participate in the monitoring of laboratory reporting. Methods of enhancing accessibility to the regional offices are currently being explored.

Each laboratory that exceeds a mandated reporting deadline will now receive, on a monthly basis, a letter from the Director of CLPPP detailing its recent reporting performance. The performance of each laboratory will be tracked. Laboratories that do not demonstrate appropriate improvement will receive heightened attention and follow-up. Such follow-up will include but not be limited to a coordinated effort with the Department's Division of Health Care Quality, Laboratory Certification Bureau. Timeliness of reporting is part of the revised Clinical Laboratory Improvement Act Amendment (CLIA) certification process. CLPPP is also actively exploring the possibility with the Department's Office of General Counsel of 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. This would give CLPPP an even more meaningful tool to effect compliance. An assessment of the performance of out-of-state laboratories indicates that a parallel action to license them is not needed.

The audit has highlighted the need for improved communication between CLPPP and SLI and a clearer understanding of respective responsibilities for laboratory reporting and data monitoring. Considerable progress has already been made, as evidenced by the assignment of respective data monitoring and enforcement roles. A mutual commitment to meet at least quarterly has been made, while a working schedule of monthly meetings has been set. These coordinated meetings have already begun.

APPENDIX

Childhood Lead Poisoning Prevention Program
Newly Identified Lead Cases
Fiscal Year 1995 to Fiscal Year 2000 (25 mcg/dl or above)



Fiscal Year 2000 as of June 30, 2000
Data found in CLPPP Annual Report.