



Department of Health

Clinical Laboratory Evaluation Program

Report 2008-S-88



Thomas P. DiNapoli

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State of New York Office of the State Comptroller

Division of State Government Accountability

October 8, 2009

Richard F. Daines, M.D.
Commissioner
Department of Health
Corning Tower
Empire State Plaza
Albany, New York 12237

Dear Dr. Daines:

The Office of the State Comptroller is committed to helping State agencies, public authorities and local government agencies manage government resources efficiently and effectively and, by so doing, providing accountability for tax dollars spent to support government operations. The Comptroller oversees the fiscal affairs of State agencies, public authorities and local government agencies, as well as their compliance with relevant statutes and their observance of good business practices. This fiscal oversight is accomplished, in part, through our audits, which identify opportunities for improving operations. Audits can also identify strategies for reducing costs and strengthening controls that are intended to safeguard assets.

Following is a report of our audit of the Department of Health's Clinical Laboratory Evaluation Program. This audit was performed pursuant to the State Comptroller's authority under Article V, Section 1 of the State Constitution and Article 11, Section 8 of the State Finance Law.

This audit's results and recommendations are resources for you to use in effectively managing your operations and in meeting the expectations of taxpayers. If you have any questions about this report, please feel free to contact us.

Respectfully submitted,

*Office of the State Comptroller
Division of State Government Accountability*



State of New York Office of the State Comptroller

EXECUTIVE SUMMARY

Audit Objectives

Our objectives were to determine whether the Department of Health (Department) properly licensed and inspected clinical laboratories and whether the Department followed up on complaints about clinical laboratories in a timely manner.

Audit Results-Summary

We conclude that the clinical laboratories (laboratories) regulated by the Department are licensed and inspected, as required. However, we found that some inspections and follow ups on high priority complaints were not conducted within required time frames.

The proper performance of diagnostic laboratory tests is a matter of vital concern, affecting the public health, safety and welfare of all New York State residents. The Department's Wadsworth Center (Wadsworth) is responsible for the accuracy and reliability of the testing conducted by all laboratories throughout New York State, as well as out-of-state and international laboratories that accept clinical specimens obtained in New York State. Wadsworth's Clinical Laboratory Evaluation Program (CLEP) ensures that laboratories are licensed and inspected as required, and that complaints lodged against them are followed up on within the required time frames. CLEP conducts on-site inspections, while other Wadsworth staff perform proficiency testing, and evaluate the qualifications of laboratory personnel.

A laboratory must have a New York State certified laboratory director on staff, meet on-site inspection requirements, and complete a permit process, before it is licensed. Laboratories must undergo initial inspections within 120 days from the date they apply for a license, and pass routine inspections at least every two years thereafter.

As part of the permit process, laboratories are required to pass proficiency tests in each of the categories they hold a valid permit for. If a laboratory fails a proficiency test in one permit category, it must pass the next two proficiency tests in that category in order to retain its permit. Failing a proficiency test in one permitted category has no effect on the laboratory's ability to continue to perform testing in other permit categories.

To determine whether the Department was complying with its licensing and inspecting requirements, we randomly selected 50 of the 873 licensed laboratories that had approved permits for all of

their testing areas as of June 16, 2008. For our sampled laboratories, 92 inspections (13 initial and 79 routine) should have been performed by this date. Of the 13 laboratories requiring initial inspections, eight had their inspections performed on time, and two requested additional time to prepare for their respective inspections. However, the remaining three initial inspections (23 percent) were performed between 6 and 69 days beyond the 120 day time limit without valid reasons. Failure to conduct initial inspections on time delays the applicant laboratory's ability to conduct business and serve patients.

For the 42 laboratories requiring routine inspections, including 5 of the 13 that required initial inspections, 21 (50 percent) had at least one routine inspection performed late. Of the 79 routine inspections performed, 25 (32 percent) were performed between 1 and 22 months beyond the required two-year time limit. Through inspections, proficiency testing and the evaluation of personnel qualifications, Wadsworth seeks to ensure the accuracy and reliability of laboratory test results. If CLEP does not complete routine inspections within the required two years, it further delays the identification of laboratories using improper procedures. These improper procedures can lead to inaccurate test results or erroneous diagnoses, and contribute to an inappropriate method of treatment for patients.

Wadsworth officials responded that, due to budget restraints, they have not been fully staffed and therefore have not been able to meet the inspection timeframe requirements.

Complaints lodged against laboratories are received by the Wadsworth's Laboratory Investigative Unit (LIU). The LIU assigns a priority level of 0 (zero) to 4 to each complaint, then forwards the complaints to CLEP for follow up action. Once the complaint is validated, CLEP is required to develop a plan of action (Plan), outlining the steps the cited laboratory needs to take to address the complaint. The Plan must be completed within a certain time frame depending on the complaint's priority level. For example, a Priority 0 complaint requires a Plan be created within 24 hours of referral, while a Priority 1 complaint requires a Plan be developed within three days of receipt. However we found that certain complaints in CLEP's database did not denote a priority classification (unclassified).

According to CLEP's database, for the period April 1, 2006 through June 19, 2008, 225 complaints were referred to CLEP. These included 48 Priority 1 (urgent) complaints, and 44 complaints with no associated classification (unclassified). We randomly selected 10 of the 48 Priority 1 complaints and found that for 8 of them (80 percent), the Plans were prepared late by an average of five days, ranging from 1 to 10 days beyond the 3-day time limit. We also selected a random sample of 10 of the 44 unclassified complaints from CLEP's database. We determined that these 44 complaints were initially assigned a classification by LIU but their respective classifications were not transferred to CLEP's database. We found that one of these 44 was actually a Priority 1 complaint; however, CLEP prepared the Plan five days beyond the required three-day time limit. The Plans for the remaining nine unclassified complaints were developed on time based on their respective initial LIU classifications.

Wadsworth officials informed us that the number of complaints they received in 2007 increased significantly in comparison to prior years and this has hindered them from following up on all

complaints in a timely manner. Not following up on complaints within the required time frames, particularly those classified as high-risk (e.g. Priority 1), may adversely affect the health and well-being of persons using laboratory services.

Wadsworth officials also explained that the intent of developing Plans within the required time frames, is to ensure that an “action” be initiated within the required timeframe. In this regard, Wadsworth officials stated that in early 2009, they plan to implement new policies and procedures which will change the requirement of developing a Plan, to initiating an action, within the required time frame for each priority.

Our audit report contains two recommendations addressing the Department’s compliance with required timeframes. Department officials agreed with our recommendations.

This report, dated October 8, 2009, is available on our website at: <http://www.osc.state.ny.us>.
Add or update your mailing list address by contacting us at: (518) 474-3271 or
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Introduction

Background

The Federal Center for Medicare and Medicaid Services (CMS) regulates all clinical laboratory testing (except research) on humans in the United States pursuant to the Clinical Laboratory Improvement Amendments (CLIA88). Congress enacted CLIA88 to ensure the accuracy and reliability of all laboratory testing. Under CLIA88, all moderate and high complexity clinical laboratories must undergo on-site surveys (inspections) at least once every two years. Clinical laboratories in the State of New York have been exempted from this requirement by CMS because the Department has established laboratory quality standards that are at least as stringent as those required by CLIA88. To remain exempt, New York State must continue to enforce its more stringent standards.

The proper performance of diagnostic laboratory tests is a matter of vital concern, affecting the public health, safety and welfare of all New York State residents. The Department of Health's (Department) Wadsworth Center (Wadsworth) is responsible for the accuracy and reliability of testing conducted by all clinical laboratories (laboratories) and blood banks throughout New York State, as well as out-of-state and international laboratories that accept clinical specimens obtained in New York State. Wadsworth's Clinical Laboratory Evaluation Program (CLEP) ensures that laboratories are properly licensed and inspected, and that complaints are followed up on within required time frames. CLEP staff along with other Wadsworth staff conduct on-site inspections and proficiency testing, and evaluate the qualifications of laboratory personnel.

Before it is licensed (permitted), a laboratory must have a New York State certified laboratory director on staff, meet on-site inspection requirements, and complete a permit process for each area of testing it wishes to perform - up to a maximum of 21 categories. New York State Public Health Law requires any person operating as a laboratory director to hold a valid Certificate of Qualification (Certificate). A Certificate is issued by the Department and is valid for two years. Once a certified director is appointed, the associated laboratory can apply for a permit which is valid for one year.

As part of the permit process, laboratories are required to pass proficiency tests in all the categories (e.g., urinalysis, HIV test) they hold a valid permit for. For each category of testing a laboratory performs, Wadsworth prepares samples with pre-determined results and sends them to the laboratory for testing. The laboratory reports its result to the Department which compares the results to the pre-determined results for accuracy. Wadsworth is responsible for administering the proficiency tests throughout the year. If laboratories

do not submit their proficiency test results on time to the Department, they will automatically be given a failing score. Further, if a laboratory fails a proficiency test in one of its permitted categories, the laboratory must pass the next two proficiency tests in that category in order to retain its permit. A failing grade in one category does not affect a laboratory's permit status in other categories.

Department standards require new laboratories applying for a permit to have an initial on-site inspection within 120 days from the date of application. During the initial inspection, equipment and test methods are reviewed. Once a laboratory receives its permit, it is required to undergo routine inspections at least once every two years. During routine inspections, the inspector reviews testing methods for selected categories. On-site inspections may also identify the need for corrective action and make specific recommendations to address such. Follow-up inspections may be performed to determine whether the recommended actions were taken.

CLEP may also perform follow up inspections when a technical "watch" or "compliance hold" is placed on a laboratory. A technical watch is placed on a laboratory when problems have been identified and they become a concern to CLEP. If while on a technical watch, the laboratory has failed to improve and the deficiencies have reached a level of causing imminent danger to a patient, then the laboratory may be placed on a compliance hold and referred to the Wadsworth's Office of Regulatory Affairs for additional sanctions or enforcement action.

Complaints about a laboratory are received by Wadsworth's Laboratory Investigative Unit (LIU). The LIU assigns a priority level of between 0 (zero) to 4 to each complaint, then forwards the complaints to CLEP for follow up action. CLEP is required to develop a plan of action (Plan) which outlines the steps to be taken to address the complaint. The Plan must be completed within a certain time frame depending on the complaint's priority level. For example, a Priority 0 complaint requires a Plan be developed within 24 hours after receipt, while a Priority 1 complaint requires a Plan within three days of the referral. However, certain complaints did not appear to be assigned a classification (unclassified).

For the period, April 1, 2006 through June 30, 2008, CLEP completed 1,747 inspections. This included 1,000 routine inspections, 138 follow-ups and 609 inspections for various reasons such as initial inspections and complaint investigations. As of June 16, 2008, CLEP's database listed 969 laboratories with various approval statuses. Of the 969 laboratories, 873 had approved permits in all testing categories they performed, the permits of 68 of the laboratories were pending approval, and 28 laboratories were approved in some of their testing categories but were awaiting approval for others.

**Audit
Scope and
Methodology**

We audited the Department to determine whether it properly licensed and inspected clinical laboratories, and whether it followed up on complaints about clinical laboratories, in a timely manner. To accomplish our audit objectives, we interviewed agency officials, reviewed applicable Federal and State laws and regulations, and examined the Department's relevant policies and procedures. Our audit covered the period April 1, 2006 through October 10, 2008.

We randomly selected 50 laboratories to determine whether initial and routine inspections were completed within the required time frames. Our testing included two routine inspection cycles for established laboratories, and the initial inspection (and if applicable - routine inspections) for newly approved laboratories. For our sampled 50 laboratories, 79 routine inspections and 13 initial inspections should have been performed. We also reviewed these laboratories to determine whether they passed proficiency tests, and whether their directors had valid certificates of qualification.

CLEP received 225 complaints from LIU between April 1, 2006 and June 19, 2008. To determine whether complaints were followed up on, and required Plans developed within the required time frames, we randomly selected 10 of the 48 Priority 1 complaints, and 10 of the 44 unclassified complaints. We selected the Priority 1 complaints because they were the highest risk level complaint that CLEP received. We sampled the unclassified complaints to determine whether they were actually high-risk complaints and not followed up on accordingly.

We conducted our performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

In addition to being the State Auditor, the Comptroller performs certain other constitutionally and statutorily mandated duties as the chief fiscal officer of New York State. These include operating the State's accounting system; preparing the State's financial statements; and approving State contracts, refunds, and other payments. In addition, the Comptroller appoints members to certain boards, commissions and public authorities, some of whom have minority voting rights. These duties may be considered management functions for purposes of evaluating organizational independence under generally accepted government auditing standards. In our opinion, these functions do not affect our ability to conduct independent audits of program performance.

Authority The audit was performed pursuant to the State Comptroller’s authority as set forth in Article V, Section 1 of the State Constitution and Article II, Section 8 of the State Finance Law.

Reporting Requirements A draft copy of this report was provided to Department officials for their review and comment. Their comments were considered in preparing this final report.

In general, Department officials agree with our findings and recommendations and plan to implement our recommendations as appropriate.

Within 90 days of the issuance of this report, in accordance with Secion 170 of the Executive Law, the Commissioner of the Department shall report to the Governor, the State Comptroller, and the leaders of the Legislature and fiscal committees, indicating the steps taken by officials to implement our report recommendations, and where they have not been implemented, the reasons therefor.

Contributors to the Report Major contributors to this report include Frank Patone, Al Kee, Todd Seeberger, Theresa Nellis-Matson, Melissa Davie, Jennifer Bachinsky, Michael Sulem and Sue Gold.

Audit Findings and Recommendations

Licensing and Inspecting Process

To determine whether the Department was complying with its licensing and inspection requirements, we selected a random sample of 50 of the 873 clinical laboratories whose testing categories had all been approved as of June 16, 2008. Our sample was comprised of 35 laboratories located in New York State, 13 located out-of-state and 2 located out of the country. Our sampled laboratories should have received 13 initial inspections, and 79 routine inspections by this date. Although each of the sampled laboratories was properly inspected and licensed, we found that CLEP had not performed all required inspections within required timeframes.

Of the 13 laboratories requiring initial inspections, we determined that eight had their inspections conducted within the required timeframe. The inspections for two other laboratories were not performed on time because their officials had requested additional time to prepare for the inspections. Wadsworth officials told us that even though these initial inspections were not performed as required, there was no risk to patients because the laboratories were not accepting New York specimens. The three remaining initial inspections were for laboratories located outside New York State and were conducted between 6 and 69 days beyond the required 120 day time limit. Wadsworth officials stated that the reason for the delayed inspections was that CLEP waited until the inspections could be scheduled in conjunction with other laboratories in the same geographical area. Even though this may be a practical reason, delays in conducting the initial inspections impact the laboratories' ability to conduct business.

For the 42 laboratories requiring routine inspections, including five of the 13 which received initial inspections, 21 (50 percent) had at least one routine inspection that was conducted late. Of the 79 routine inspections conducted, 25 (32 percent) were conducted between 1 and 22 months beyond the required two-year time limit. Of the 21 laboratories:

- 11 laboratories (11 inspections) were located in New York State
- 8 laboratories (11 inspections) were located out-of-state
- 2 laboratories (3 inspections) were located out of the country

Wadsworth officials replied that they have not been fully staffed during the audit period due to budget restraints, and thus could not meet the inspection frequency requirements. Wadsworth officials supported this assertion with a staffing chart illustrating their staff shortage during the audit period. They also showed us their in-house inspection monitoring reports indicating

increased inspection efficiency when a trainee inspector had evolved to performing inspections on his own rather than accompanying a veteran inspector. They also noted that the 11 late out-of-state inspections were at laboratories which are also monitored by Federal organizations. As such, they give priority to New York State laboratories since they are not monitored by other oversight organizations.

We agree that New York State laboratories take inspection priority. However, if CLEP is unable to complete routine inspections within the required two years, improper or inappropriate testing methodologies will remain unchecked longer than they should, and can lead to inaccurate test results, erroneous diagnoses and contribute to inappropriate treatment for a patient.

We determined that all 50 clinical directors had valid Certificates, as required. We also determined that 31 of the 50 sampled laboratories passed the proficiency tests for each of their approved testing categories. The remaining 19 had failed a proficiency test in one of their testing categories but subsequently passed the next two proficiency tests in those categories.

Recommendation

1. Periodically revisit Department staffing needs and redeploy qualified staff to CLEP as appropriate to meet regulatory timeframes for inspections.

Complaint Process

Federal Law defines a complaint as an allegation of non-compliance with Federal and/or State requirements. CMS requires State agencies to have written policies and procedures to ensure appropriate action is taken once a complaint is received. These policies and procedures must include response times for handling a complaint, as well as the rationale for prioritizing the complaint for investigation.

Wadsworth's Office of Regulatory Affairs is responsible for the handling of laboratory-related complaints. Within this Office, LIU receives complaints from patients, health care providers and laboratory employees. Examples of complaints received by LIU include laboratories losing specimens and poor blood-taking techniques. LIU classifies and prioritizes complaints according to their respective severity level and then forwards them with the assigned classifications to CLEP for follow-up action. CLEP is required to develop a plan of action (Plan) to address the complaint within the required time frame based on the complaint classification. Plan steps may require CLEP to perform an on-site investigation.

According to LIU officials, the required time frames for Plan development based on assigned classifications are as follows:

Priority	Classification	Days to Develop a Plan of Action
0	Immediate	Within 24 Hours
1	Urgent	1 to 3 days
2	Executive Correspondence Unit (ECU)	1 to 3 days
3	Moderate	Within 30 days
4	Low	Within 45 days

According to CLEP’s database for the period April 1, 2006 through June 19, 2008, 225 complaints were referred to CLEP. Of these 225 complaints, 48 were classified as Priority 1 complaints, and 44 did not denote an associated classification. Although these complaints had initially been assigned a classification category by LIU, the classification category was not entered into CLEP’s database. To determine whether a Plan was developed for the complaints within the required timeframes, we randomly selected 10 of the 48 Priority 1 complaints and 10 of the 44 unclassified complaints for review. Although CLEP staff had developed Plans for each of the 20 complaints, they had not all been developed within the required timeframes as follows:

- For 8 of the 10 sampled Priority 1 complaints (80 percent), the Plans were developed beyond the three day time limit by an average of five days, each ranging from 1 to 10 days. Sampled complaints included a specimen mix-up by one laboratory and delayed test results at another.
- For the 10 unclassified complaints, we obtained their originally assigned classifications and determined that one of them was actually a Priority 1 complaint yet CLEP developed the Plan five days beyond the required three-day time limit. The required Plans were completed timely for the remaining nine unclassified complaints.

If high-risk complaints, such as specimen mix-ups and delayed test results, are not acted upon in a timely manner, the health and well-being of patients may be at considerable risk.

Wadsworth officials told us that the number of complaints they received in 2007 increased significantly in comparison prior to years and this hindered them from following up on complaints in a timely manner. Wadsworth officials also explained that their intent is to ensure that follow up “action” on a complaint be initiated within the required time frames, and not to merely develop a written Plan. An initial action may include contacting the laboratory for more information, assessing the complaint with an

investigator to schedule an onsite inspection, or requesting Proficiency Test information. They further said that the action(s) taken depend on the nature and severity of the complaint. In this regard, Wadsworth officials noted that in early 2009, they plan to implement new policies and procedures that will change the requirement of developing a Plan, to initiating an action, within the required time frame for each complaint classification.

- Recommendation**
2. As with inspection requirements, reassess current Department staffing and workload and redeploy qualified staff to assist CLEP in following up on complaints to ensure that each is addressed within the required time frames.

AGENCY COMMENTS



Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Richard F. Daines, M.D.
Commissioner

James W. Clyne, Jr.
Executive Deputy Commissioner

August 26, 2009

Mr. Frank Patone, CPA, Audit Director
Office of the State Comptroller
Division of State Government Accountability
123 William Street – 21st Floor
New York, New York 10038

Dear Mr. Patone:

Enclosed are the New York State Department of Health's comments on the Office of the State Comptroller's draft audit report 2008-S-88 on "Clinical Laboratory Evaluation Program."

Thank you for the opportunity to comment.

Sincerely,

James W. Clyne, Jr.
Executive Deputy Commissioner

Enclosure

cc: Robert W. Reed
Lawrence Sturman, M.D, Ph.D.
Stephen Abbott
Victoria Derbyshire, Ph.D
Dr. Richard Jenny

**Department of Health
Comments on the
Office of the State Comptroller's
Draft Audit Report 2008-S-88 on
"Clinical Laboratory Evaluation Program"**

The following are the New York State Department of Health (Department) comments in response to the Office of the State Comptroller's (OSC) draft audit report 2008-S-88 on "Clinical Laboratory Evaluation Program."

Recommendation #1:

Periodically revisit Department staffing needs and redeploy qualified staff as appropriate to meet regulatory timeframes for inspections.

Recommendation #2:

As with inspection requirements, reassess current Department staffing and workload and redeploy qualified staff to assist in following up on complaints to ensure that each is addressed within the required time frame.

Response #1 and #2:

The Department agrees with the OSC recommendations and will periodically reassess staffing and workloads and, to the extent feasible, redeploy qualified staff to meet required timeframes for performing inspections and investigating complaints. However, it should be recognized that only staff with specific skills, education and experience can conduct inspections and investigate complaints, limiting the size of the candidate pool available for redeployment. As a possible solution, the Department will additionally evaluate existing policies and procedures to determine if changes can be implemented to improve timeliness without hiring additional staff which is precluded by the current economic environment.