

Department of Public Health

Laboratory Field Services' Lack of Clinical Laboratory Oversight Places the Public at Risk

REPORT NUMBER 2007-040, SEPTEMBER 2008

Laboratory Field Services' response as of September 2009

Chapter 74, Statutes of 2006, required the Bureau of State Audits to review the clinical laboratory oversight programs of the Department of Health Services (now the Department of Public Health and referred to here as the department). Specifically, the law directed us to review the extent and effectiveness of the department's practices and procedures regarding detecting and determining when clinical laboratories are not in compliance with state law and regulations; investigating possible cases of noncompliance, including investigating consumer complaints; and imposing appropriate sanctions on clinical laboratories found noncompliant. The law also specified we review the frequency and extent of the department's use of its existing authority to assess and collect civil fines and refer violators for criminal prosecution and bar their participation from state and federally funded health programs, and its use of any other means available to enforce state law and regulations regarding clinical laboratories. Laboratory Field Services (Laboratory Services) within the department is responsible for licensing, registering, and overseeing clinical laboratories. Specifically, we found:

Finding #1: Laboratory Services is not inspecting laboratories every two years as required.

Laboratory Services is not inspecting clinical laboratories every two years, which is required by state law and is a critical component of the State's intended oversight structure. State law requires Laboratory Services to conduct inspections of licensed clinical laboratories no less than once every two years. According to Laboratory Services, 1,970 licensed laboratories required such inspections in California as of June 2007. Based on the state requirement, we expected to find that Laboratory Services was conducting regular inspections. Although inspections help ensure that laboratories follow appropriate procedures and that personnel have appropriate qualifications, Laboratory Services has not conducted any regular, two-year inspections of clinical laboratories.

Further, state law requires a laboratory located outside California but accepting specimens originating inside the State to have a state license or registration. However, Laboratory Services does not conduct regular, two-year inspections of out-of-state laboratories. According to Laboratory Services, 91 laboratories outside California had California licenses as of June 2007.

We recommended that Laboratory Services perform all its mandated oversight responsibilities for laboratories subject to its jurisdiction operating within and outside California, including inspecting licensed laboratories every two years.

Audit Highlights . . .

Our review of Laboratory Field Services' (Laboratory Services) clinical laboratory oversight activities revealed the following:

- » *It is not inspecting laboratories every two years as state law requires and has no plans to do so unless it receives additional resources.*
- » *Laboratory Services has inconsistently monitored laboratory proficiency testing, and its policies and procedures in that area are inadequate.*
- » *It closed many complaints without taking action, and Laboratory Services' recently revised complaint policies and procedures lack sufficient controls.*
- » *Laboratory Services has sporadically used its authority to impose sanctions against laboratories for violations of law and regulations.*
- » *The chief of Laboratory Services attributes its inability to meet its mandated responsibilities primarily to a lack of resources; it has only been successful in obtaining approval for two recent funding proposals.*
- » *Because it had raised its fees improperly one year and failed to impose two subsequent fee increases the budget act called for, Laboratory Services did not collect more than \$1 million in fees from clinical laboratories.*

Department's Action: Partial corrective action taken.

Laboratory Services reported that it has established priorities to assure key program activities are conducted, including inspecting laboratories every two years as required. It told us that it has inspected 160 laboratories not previously inspected on the required two year cycle. In addition, Laboratory Services stated that legislation was being considered to allow Laboratory Services to approve accreditation organizations to conduct some inspections every two years on its behalf after January 2011. This legislation was subsequently enacted as law in October 2009.¹

Finding #2: Inconsistent monitoring and inadequate policies and procedures weaken Laboratory Services' oversight of proficiency testing.

State law stipulates that laboratories performing tests considered moderately to highly complex must enroll and achieve a certain minimum score in proficiency testing, a process to verify the accuracy and reliability of clinical laboratory tests. It is Laboratory Services' policy to monitor proficiency-testing results. However, we found that it did not identify or take action on some testing failures. Specifically, Laboratory Services had not contacted the laboratories or had not identified all the failed tests in five of the six instances we reviewed. Further, it did not review the proficiency-testing results of laboratories located outside California that are subject to the testing. Because the goal of proficiency testing is to verify the reliability and accuracy of a laboratory test, without adequate monitoring, Laboratory Services cannot ensure that laboratories are reporting accurate results to their customers.

Laboratory Services also did not enforce its policy to verify whether laboratories are enrolled in state-approved proficiency testing. State law requires that laboratories conducting moderate-to-high-complexity tests enroll in a state-approved proficiency-testing program. This is a condition of licensure, but it is also important to verify enrollment on an ongoing basis because proficiency testing is a key method for ensuring that laboratories conduct their tests reliably and accurately.

Finally, Laboratory Services has inadequate policies and procedures regarding proficiency testing. For example, the policies and procedures do not specify timelines for key steps in the proficiency-testing review process, including how frequently Laboratory Services will review proficiency-testing results. Lacking specific timelines, Laboratory Services could apply proficiency-testing requirements inconsistently and create confusion within the regulated community.

We recommended that Laboratory Services perform all its mandated oversight responsibilities for laboratories subject to its jurisdiction operating within and outside California, including monitoring proficiency testing results.

We also recommended that Laboratory Services adopt and implement proficiency-testing policies and procedures for staff to do the following:

- Promptly review laboratories' proficiency-testing results and notify laboratories that fail.
- Follow specific timelines for responding to laboratories' attempts to correct proficiency-testing failures and for sanctioning laboratories that do not comply.
- Monitor the proficiency-testing results of out-of-state laboratories.
- Verify laboratories' enrollment in proficiency testing, and ensure that Laboratory Services receives proficiency-testing scores from all enrolled laboratories.

¹ This legislation, which was enacted as Chapter 201, Statutes of 2009, is the same legislation discussed in findings 5, 6, and 8.

Department's Action: Partial corrective action taken.

Laboratory Services stated that it reviews electronic proficiency test results once each month and since August 2008 has notified 195 laboratories of a first proficiency testing failure within 30 days of reviewing the test data. Further, it received documentation from 99 percent of the laboratories notified. Upon review, Laboratory Services reported that the documentation demonstrated adequate corrective action within the required time frame. Laboratory Services modified its procedures to incorporate federal timelines related to proficiency testing. However, it stated that it was unable to comply with timelines for subsequent failures because the notice to laboratories that is necessary to conduct further enforcement action was under review. Laboratory Services told us that it expects to have approval by fall 2009 of this notice. Laboratory Services also stated that it has determined that the manual method of retrieving out-of-state proficiency test reports does not result in meaningful information and that electronic data cannot be generated; however, an enterprise system that is being planned may accommodate the data. Finally, Laboratory Services noted that it is unable to assure using electronic means that all laboratories are enrolled in proficiency testing appropriate to their specialties.

Finding #3: Laboratory Services is focusing on increasing licensing of California laboratories but not out-of-state laboratories.

Recognizing a problem within its licensing process, in May 2008 Laboratory Services began implementing a plan to identify and license laboratories within California that are subject to licensure but have not applied for or obtained it. However, Laboratory Services has not placed the same priority on identifying and licensing laboratories operating outside the State that receive and analyze specimens originating in the State, even though these laboratories are subject to California law. Laboratory Services plans to continue processing applications for licenses and renewals that out-of-state laboratories submit voluntarily, but it does not plan to perform any additional activities. According to the Laboratory Services chief, insufficient staffing has always prevented Laboratory Services from properly administering the licensing of out-of-state laboratories and pursuing licensed out-of-state laboratories. By not enforcing licensing requirements, Laboratory Services cannot ensure that out-of-state laboratories are performing testing to state standards established to protect California residents.

We recommended that Laboratory Services continue its efforts to license California laboratories that require licensure. Further, it should take steps to license out-of-state laboratories that perform testing on specimens originating in California but are not licensed, as the law requires.

Department's Action: Partial corrective action taken.

Laboratory Services told us that it continues to identify and contact laboratories in California that require licensure. However, it also told us that it had placed on hold its project to identify and license out-of-state laboratories requiring licensure. Laboratory Services stated that it has no full-time civil service staff to perform these duties.

Finding #4: Laboratory Services has struggled to respond to complaints, and its new complaints process lacks sufficient controls.

Laboratory Services has not always dealt systematically with complaints as required. It receives complaints from several sources, including consumers, whistleblowers, various public agencies, and other laboratories. State law mandates that Laboratory Services investigate complaints it receives, but it often closed complaints after little or no investigation. Laboratory Services acknowledges it investigated only a small percentage of the complaints it received and conducted only one major investigation during the three-year period ending December 2007. Moreover, Laboratory Services lacks information to know the total number of complaints it has received, investigated, or closed during a specific period. Although Laboratory Services internally developed a database to capture complaints information, it

did not consistently enter complaints it received into that database or update its complaints data to reflect progress or resolution. Laboratory Services' complaints database lists 313 complaint records for the three-year period between January 2005 and December 2007; however, Laboratory Services has no assurance that number is accurate.

We reviewed 30 complaints Laboratory Services received between January 2005 and December 2007 and later closed. Among the complaints we reviewed, we found 16 that Laboratory Services closed without taking action. Laboratory Services told us it did not have jurisdiction over six of these complaints; however, we did not find evidence that it alerted the complainant to that fact when the complainant was known or that Laboratory Services forwarded the complaint to an entity that had jurisdiction. Of the 10 complaints Laboratory Services closed without action and over which it acknowledged having jurisdiction, we found five complaints that alleged conditions with health and safety implications, raising concerns about Laboratory Services' decision to close them.

The second category of complaints we identified comprised 14 cases in which Laboratory Services took some type of action—for instance, sending a letter, making a telephone call, or referring the allegation to another entity. However, Laboratory Services did not conduct on-site laboratory investigations in response to the allegations related to any of the complaints in this category. Although Laboratory Services' files suggest it took some action in response to all 14, we are particularly concerned that the action Laboratory Services took was inadequate or not timely for three complaints having health and safety implications. For example, two complaints alleged that laboratories made testing errors that resulted in the patients receiving unnecessary medical treatment.

Certain key controls in Laboratory Services' complaint policies and procedures are missing or insufficient. Typically, an entity with a complaints process establishes certain key controls to ensure that staff promptly log, prioritize, track, and handle information they receive. Moreover, controls should exist to make certain that substantiated allegations are corrected. Laboratory Services needs controls such as logging and tracking to be able to account for each complaint it receives and to confirm that each complaint is being addressed. Tracking also gives management necessary estimates of workload. The controls of prioritizing and setting time frames are important for Laboratory Services to address serious complaints first and all complaints promptly. Finally, Laboratory Services' follow-up on corrective action is necessary to ensure that the basis of the complaint is removed or resolved. We did not find these controls in Laboratory Services' complaints policies and procedures.

We recommended that Laboratory Services perform all its mandated oversight responsibilities for laboratories subject to its jurisdiction operating within and outside California, including, but not limited to reviewing and investigating complaints and ensuring necessary resolution.

We also recommended that Laboratory Services establish procedures to ensure that it promptly forwards complaints for which it lacks jurisdiction to the entity having jurisdiction. Further, to strengthen its complaints process, Laboratory Services should identify necessary controls and incorporate them into its complaints policies. The necessary controls include, but are not limited to, receiving, logging, tracking, and prioritizing complaints, as well as ensuring that substantiated allegations are corrected. In addition, Laboratory Services should develop and implement corresponding procedures for each control.

Department's Action: Partial corrective action taken.

Laboratory Services stated that it is continuing its complaint review and prioritization based on high, medium, or low potential risk to public health. It stated that it has received 187 complaints since September 2008, investigated 140, and performed on-site inspections for four complaints. The remaining complaints are waiting resolution or were referred to other agencies. Laboratory Services told us that it is attempting to use in-house information technology to track and categorize complaints but has not yet added necessary fields to the existing licensing database, the Health Applications Licensing system (HAL). Laboratory Services is part of the Enterprise Online Licensing

project, which is expected to replace HAL in 2013. Laboratory Services stated that it lost General Fund resources for its complaints position, but continues to do the work through a special funded position. It did not indicate whether it had developed necessary controls and corresponding procedures.

Finding #5: Laboratory Services has imposed few sanctions in recent years.

Laboratory Services did not always have staff dedicated to its sanctioning efforts from 1999 through 2007. Because it lacks an effective tracking mechanism, Laboratory Services could not identify the total number of and types of sanctions it imposed. Therefore, we had to consider various records to compile a list of imposed sanctions. We focused our review on Laboratory Services' records from 2002 through 2007. Our review of those records revealed that Laboratory Services imposed 23 civil money penalties, terminated five licenses, and directed three plans of corrective action during that six-year period. Most of those sanctions were imposed in 2002 and 2003. Of the seven civil money penalties we reviewed, Laboratory Services could not demonstrate that it collected the penalties from two of the laboratories or imposed the penalty on one laboratory, nor could it substantiate how it calculated the penalties. Our review of two license terminations showed that in both cases Laboratory Services imposed the sanctions after the laboratories failed to apply promptly for new licenses when the directorship changed. Although Laboratory Services enforced both sanctions and required the laboratories to obtain new licenses, it could not provide documentation that it notified a federally funded health program as its policy requires.

We recommended that Laboratory Services perform all its mandated oversight responsibilities for laboratories subject to its jurisdiction operating within and outside California, including sanctioning laboratories as appropriate.

We also recommended that, to strengthen its sanctioning efforts, Laboratory Services maximize its opportunities to impose sanctions, appropriately justify and document the amounts of the civil monetary penalties it imposes, ensure that it always collects the penalties it imposes, follow up to ensure that laboratories take corrective action, and ensure that when it sanctions a laboratory it notifies other appropriate agencies as necessary.

Department's Action: Partial corrective action taken.

Laboratory Services stated that it completed its policy and procedures for enforcement of unsuccessful proficiency testing and continues to follow them for initial instances of proficiency testing failures. As discussed previously, the notice to laboratories that is necessary to conduct further enforcement action is under review. Laboratory Services told us that the amount of a civil money penalty and the calculation for the assessment will be documented in the notice that it sends to a laboratory as well as the laboratory file. It stated that it is in the process of writing formal policies and procedures that explain the current practice of how a civil money penalty assessment is determined. Laboratory Services noted that it collected over \$30,000 for four sanctions, but had not developed an electronic mechanism to alert staff about ongoing enforcement actions. It acknowledged that ongoing monitoring will be required. Laboratory Services was awaiting the outcome of legislation that would allow it to work with accreditation organizations for monitoring proficiency testing beginning in 2011. This legislation was subsequently enacted as law in October 2009. Laboratory Services reported that it has established timelines requiring laboratories to take corrective action and to provide it documentation. However, it noted that it lacks the resources necessary to develop or implement policies and procedures for evaluating laboratories' corrective action for appropriateness. Laboratory Services told us that it notifies other appropriate agencies of sanctions including Medi-Cal. It is also meeting quarterly with the Center for Medicare and Medicaid Services (CMS) to improve communication about sanctions.

Finding #6: Laboratory Services believes that limited resources have affected its meeting its mandates.

The Laboratory Services' chief attributes much of its inability to meet its mandated responsibilities to a lack of resources. Laboratory Services has only been successful in obtaining approval for two funding proposals for clinical laboratories in recent years. A funding proposal approved for fiscal year 2005–06 resulted in additional spending authority for two positions intended to help Laboratory Services meet its clinical laboratory oversight responsibilities. A funding proposal approved for fiscal year 2006–07 granted Laboratory Services seven positions designated for clinical laboratory oversight activities.

To gain perspective on Laboratory Services' funding issues, we spoke with the deputy director and assistant deputy director for the Center for Healthcare Quality (Healthcare Quality). On July 1, 2007, the Department of Health Services was split into two departments: The Department of Public Health (department) and the Department of Health Care Services. The department was organized into five centers, which are comparable to divisions; Laboratory Services became part of Healthcare Quality. We asked why the department has not submitted a funding proposal for Laboratory Services since it became a part of the department. We also asked about future funding proposals. According to its assistant deputy director, Healthcare Quality needs to assess Laboratory Services, understand its unique features and issues, and prioritize its needs. The assistant deputy director stated that Healthcare Quality wants to fully understand Laboratory Services' operations and history before determining the steps needed to meet Laboratory Services' mandates and to ensure that public health and safety is protected. The assistant deputy director told us that the analysis could lead Healthcare Quality to consider rightsizing Laboratory Services. The assistant deputy director explained that rightsizing is the process for ensuring that revenues collected will fully meet program expenditures. In doing so, expenditures need to be assessed and projected based on workload mandates and program needs.

We recommended that the department, in conjunction with Laboratory Services, ensure that Laboratory Services has sufficient resources to meet all its oversight responsibilities.

Department's Action: Partial corrective action taken.

Laboratory Services stated that it has completed a workload evaluation and identified the resources necessary to conduct a comprehensive laboratory oversight program. It stated it was awaiting the outcome of legislation that will allow it to recognize accreditation organizations to perform onsite inspections and proficiency testing monitoring for licensed laboratories. This legislation was subsequently enacted as law in October 2009. Further, Laboratory Services reported that it has examined its current processes and will leverage existing resources until additional staff can be acquired. However, despite recruiting efforts in 2008 and 2009, few candidates were identified, and Laboratory Services believes that salary disparity with private industry and state mandated furloughs make it difficult to attract and hire qualified candidates.

Finding #7: Laboratory Services' information technology resources do not support all its needs or supply complete and accurate data.

A lack of complete and accurate management data related to the work it performs also has contributed to Laboratory Services' struggles in meeting its mandated responsibilities. Laboratory Services relies on HAL to support licensing, registration, and renewal functions; however, HAL cannot adequately support Laboratory Services' activities related to complaints and sanctions. For example, HAL does not have sufficient fields to capture complaints Laboratory Services receives. To compensate for that and other data-capturing shortcomings of HAL, Laboratory Services has created several internal databases over the years. However, those databases lack the controls necessary to ensure accurate and complete information. All the internal databases we reviewed contain some illogical, incomplete, or incorrect data and could not be used to track activities effectively or to make sound management decisions.

We recommended that Laboratory Services work with its Information Technology Services Division and other appropriate parties to ensure that its data systems support its needs. If Laboratory Services continues to use its internally developed databases, it should ensure that it develops and implements appropriate system controls.

Department's Action: Partial corrective action taken.

Laboratory Services told us that it is seeking to hire staff with information technology database skills to help improve its internal databases and develop management reports. In addition, Laboratory Services reported that it is participating in the department-wide Enterprise Online Licensing project, which is expected to be complete by 2013. In the interim, existing staff have updated the complaint database tracking system to Access 2003 and developed queries for reports.

Finding #8: Laboratory Services has opportunities to leverage its resources better.

Because it has numerous mandated responsibilities for a finite staff to fulfill, it is important that Laboratory Services demonstrate that it is using its existing resources strategically and maximally. During the audit, we identified several opportunities for Laboratory Services to provide oversight of clinical laboratories by leveraging its resources better, including its license and registration renewal process and the inspections and proficiency-testing reviews its staff currently perform on behalf of the federal government. Further, Laboratory Services has not taken advantage of its authority to approve accreditation organizations or contract some of its inspection and investigation responsibilities.² Exploring these ideas and others could help Laboratory Services better meet its mandated responsibilities.

We recommended that, to demonstrate that it has used existing resources strategically and has maximized their utility to the extent possible, Laboratory Services explore opportunities to leverage existing processes and procedures. These opportunities should include, but not be limited to, exercising clinical laboratory oversight when it renews licenses and registrations, developing a process to share state concerns identified during federal inspections, and using accreditation organizations and contracts to divide its responsibilities for inspections every two years.

Department's Action: Partial corrective action taken.

Laboratory Services reports that it is using the California Corporation Board Web site to determine the current corporation status and will not process an application until the corporation is in good standing. In addition, it told us that it reviews 10 percent of personnel licensure status on renewal of laboratory licenses. Further, it verifies with the Medical Board of California a medical director's current license status. Laboratory Services told us that it meets with CMS quarterly to further improve communication and coordination of inspections. As discussed previously, Laboratory Services was awaiting the outcome of legislation to allow accreditation organizations to conduct inspections every two years. This legislation was subsequently enacted as law in October 2009. Laboratory Services reported that it coordinates initial state licensing surveys with surveys its staff conduct on behalf of the federal government and that staff use a checklist to assess some state requirements during periodic laboratory inspections on behalf of the federal government.

Finding #9: Improperly imposed and revised fees led to a substantial revenue loss.

As Laboratory Services pursues additional resources and strives to ensure that it maximizes its use of existing resources, it is important to demonstrate that it has assessed fees appropriately. In three instances since fiscal year 2003–04, Laboratory Services incorrectly adjusted the fees it charged to clinical laboratories, resulting in more than \$1 million in lost revenue. According to state law, Laboratory Services must adjust its fees annually by a percentage published in the budget

² An accreditation organization is a private, nonprofit organization the federal government has approved to provide laboratory oversight.

act. From fiscal years 2003–04 through 2007–08, the budget acts included two fee increases: an increase of 22.5 percent effective July 1 of fiscal year 2006–07 and an increase of 7.61 percent effective July 1 of fiscal year 2007–08. However, Laboratory Services raised fees by 1.51 percent effective July 1 of fiscal year 2003–04, when it was not authorized to do so, and failed to raise fees effective July 1 of fiscal years 2006–07 and 2007–08, when it should have done so. Laboratory Services relied on an incorrect provision of the budget act in calculating its fees, and we found evidence of communication from the budget section within the department directing Laboratory Services not to raise its fees and citing the wrong provision of the budget act.

We recommended that Laboratory Services work with the department’s budget section and other appropriate parties to ensure that it adjusts fees in accordance with the budget act.

Department’s Action: Corrective action taken.

Laboratory Services stated that it developed policy and procedures to adjust fees and implemented them after the October 2008 Budget Bill was signed. It told us that it retains documentation of the fee adjustment for each year in its policy and procedure manual. Although the department concluded that it did not have the authority to retroactively adjust fees for previous years, we confirmed that the department adjusted fees in accordance with the budget act for fiscal year 2008–09.