



Department of Public Health:

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

September 2008 Report 2007-040



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The Governor of California
President pro Tempore of the Senate
Speaker of the Assembly
State Capitol
Sacramento, California 95814

Dear Governor and Legislative Leaders:

As required by Chapter 74, Statutes of 2006, the Bureau of State Audits presents its audit report concerning the Department of Public Health's oversight of clinical laboratories. This report concludes that Laboratory Field Services (Laboratory Services) within the Department of Public Health has not provided the clinical laboratory oversight state law and regulations mandate. Specifically, Laboratory Services is not inspecting licensed laboratories every two years as the law requires and has inconsistently monitored laboratory proficiency testing. Also, Laboratory Services has struggled to respond to complaints. It closed many complaints without taking action, and its recently revised policies and procedures lack sufficient controls. Finally, Laboratory Services has the authority to sanction laboratories that do not comply with state laws and regulations, but it has imposed few sanctions recently and has no plans to increase its sanction efforts based on existing resources.

Laboratory Services attributes much of its inability to meet mandated responsibilities to a lack of resources and has only been successful in obtaining approval for two funding proposals for clinical laboratories in recent years. A lack of complete and accurate management data has also contributed to Laboratory Services' struggles in meeting its mandated responsibilities. Laboratory Services relies on a system that does not support all of its functions and on internal databases that lack necessary controls. Also, Laboratory Services has opportunities, such as through its license and registration renewal process and through contracting with external parties, to better leverage current resources to meet its mandated responsibilities. Finally, we determined that Laboratory Services raised its fees improperly one year and failed to impose two subsequent fee increases called for in the budget act. As a result, Laboratory Services did not collect more than \$1 million in fees from clinical laboratories.

Respectfully submitted,



ELAINE M. HOWLE, CPA
State Auditor

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Summary

Results in Brief

Laboratory Field Services (Laboratory Services) within the Department of Public Health (Public Health) is responsible for licensing, registering, and overseeing clinical laboratories. Clinical laboratories analyze human specimens such as blood, tissue, and urine so that medical professionals can make diagnoses and prescribe treatment. According to Laboratory Services, it was responsible for overseeing more than 7,900 licensed and registered clinical laboratories as of June 2007. Laboratory Services is located primarily in Richmond. Records indicate that of its 76 authorized positions in fiscal year 2007–08, Laboratory Services had assigned 22 positions to clinical laboratories.¹ To support its activities related to clinical laboratories, Laboratory Services collects fees from laboratories that obtain a license or registration. In fiscal year 2007–08, those fees provided Laboratory Services with more than \$2.1 million in revenue.

The California Business and Professions Code contains the requirement that a clinical laboratory hold a license or registration; both are valid for one year and require annual renewal. The complexity of the tests a clinical laboratory performs dictates whether the laboratory is licensed or registered. For example, clinical laboratories performing complex tests, such as hepatitis testing or certain sexually transmitted disease testing by DNA probe, must obtain licenses. Laboratories performing simpler tests, such as prepackaged manufactured tests with less chance of error or risk, must obtain registrations.

After it licenses or registers a laboratory, Laboratory Services assumes its oversight role. Clinical laboratories provide an essential service—producing test results for medical diagnosis and treatment—so the consequences of mistakes can be significant. State law and regulations mandate that Laboratory Services perform many oversight functions, including inspecting licensed laboratories every two years; monitoring the results of laboratories' proficiency testing, which laboratories must undergo to assess the accuracy of their work; maintaining a complaints function to receive and investigate allegations against clinical laboratories; and sanctioning laboratories that fail to correct deficiencies.

¹ Staff in many of the remaining positions perform duties related to Laboratory Services' responsibilities for licensing laboratory personnel and overseeing tissue banks and blood banks. Those oversight areas were not part of our audit.

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.*

However, Laboratory Services has not overseen clinical laboratories as state law and regulations mandate. Its oversight failings relate not only to laboratories in the State but also to laboratories holding California licenses but located outside the State. For example, Laboratory Services is not inspecting laboratories every two years as state law requires and has no plans to do so unless it receives additional resources. Further, Laboratory Services has inconsistently monitored laboratory proficiency testing, and its policies and procedures in that area are inadequate. Inspections help ensure that laboratories follow appropriate procedures and that laboratory personnel have appropriate qualifications. Proficiency testing demonstrates that a laboratory can perform tests and obtain accurate results. Without regular laboratory inspections and prompt and continuous reviews of proficiency-testing results, Laboratory Services could allow errors in laboratory processes to go uncorrected, leading to faulty test information that could result in medical misdiagnoses and treatment errors.

State law requires that Laboratory Services investigate consumer complaints. In late 2007 Laboratory Services had a backlog of complaints it had received, and it closed many cases without taking action. Although its records list 313 complaints received from January 2005 through December 2007, Laboratory Services has no assurance that number is accurate; nor could it confirm how many complaints it had investigated or closed.

Its chief told us that Laboratory Services periodically closed, without any investigation, complaints it considered no longer timely or having minimal public impact. We reviewed 30 complaints Laboratory Services decided to close—some without taking any action and others with some action taken. We disagreed with some of the decisions. For example, we identified five complaints alleging conditions with health and safety implications that Laboratory Services closed without taking any action. Three of the five complaints alleged that laboratories were operating without necessary licensure or were performing unauthorized testing. These types of complaints have health and safety implications because the test results clinical laboratories produce are the foundation of medical decisions regarding, for instance, the treatment of conditions such as diabetes or coronary disease. Additionally, our review of three other complaints prompted concerns that Laboratory Services did not act with the thoroughness or promptness the cases required. Particularly troubling was the case of a laboratory that was believed to have cross-contaminated blood samples, leading a medical professional to reportedly misdiagnose tuberculosis in a patient who consequently was hospitalized twice for complications from the prescribed tuberculosis treatments she received.

In an apparent effort to improve its processing of complaints, Laboratory Services created a complaints manager position and staffed it in January 2008. Subsequently, Laboratory Services revised its complaints policies and procedures. However, certain key controls in Laboratory Services' current complaints process are missing or insufficient. For example, the process lacks adequate controls to ensure that Laboratory Services' staff appropriately log, track, and prioritize complaints received. In fact, given the weaknesses in its process, Laboratory Services cannot be certain that it will fulfill its mandate to investigate consumer complaints, identify deficiencies, and ensure that clinical laboratories correct their deficiencies.

Laboratory Services may impose sanctions against laboratories for violations of law and regulations but has used that authority sporadically in recent years. Examples of sanctions that Laboratory Services may impose include civil money penalties, license revocation, and referral to law enforcement for criminal prosecution. Laboratory Services was unable to provide us with summary information on the number of sanctions it imposed from 2002 through 2007. Nonetheless, it acknowledged it had imposed a limited number of sanctions in recent years. Further, it does not plan to increase its sanctioning efforts based on existing resources. Sanctions provide tangible penalties for a laboratory's failure to comply with state law and regulations. Even if Laboratory Services were conducting ongoing oversight and responding vigorously to complaints, it could not enforce its oversight activities without sanctions, and laboratories could provide inadequate, incorrect, or even illegal services without consequences.

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 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 the Health Applications Licensing system (HAL) to support functions such as licensing, but that system does not provide all the support Laboratory Services requires. For example, HAL does not have sufficient fields to capture the complaints Laboratory Services receives. To make up for HAL's shortcomings, Laboratory Services has, over time, created several internal databases, but those databases lack the controls necessary to ensure that they contain accurate and complete information. All the internal databases we reviewed contain certain illogical, incomplete, or incorrect data and could not be used to track activities accurately or to make sound management decisions.

Laboratory Services has numerous mandated responsibilities and a finite number of staff. Although it may benefit from additional staff, Laboratory Services must demonstrate it has used existing resources strategically and has maximized their utility to the extent possible. During the audit, we identified several ways Laboratory Services could leverage its resources better to provide oversight of clinical laboratories. For instance, it could use its license and registration renewal process, as well as the inspections and proficiency-testing reviews its staff perform on behalf of the federal government, as oversight mechanisms. Further, although it has the authority to do so, Laboratory Services has not leveraged its resources by approving accreditation organizations or contracting some of its inspection and investigation responsibilities.² Exploring these ideas and others could help Laboratory Services better meet its mandated responsibilities for overseeing clinical laboratories.

In the course of our audit work, we determined that Laboratory Services had raised its fees improperly one year and failed to impose two subsequent fee increases called for in the budget act. As a result, Laboratory Services did not collect more than \$1 million in fees from clinical laboratories. However, even if it had collected the additional revenue, Laboratory Services could not have spent the funds without approval of the corresponding spending authority to make the revenue available.

Recommendations

Laboratory Services should perform all its mandated oversight responsibilities, including, but not limited to the following:

- Inspecting licensed laboratories every two years.
- Monitoring proficiency-testing results.
- Reviewing and investigating complaints and ensuring necessary resolution.
- Sanctioning laboratories as appropriate.

Laboratory Services should adopt and implement policies and procedures for promptly reviewing laboratories' proficiency-testing results and notifying them of failures. Laboratory Services also should strengthen its complaints process by identifying necessary controls, such as those needed for logging, tracking,

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

and prioritizing complaints; incorporating the controls into its complaints policies; and subsequently developing and implementing corresponding procedures.

Public Health, in conjunction with Laboratory Services, should ensure that Laboratory Services has sufficient resources to meet all its oversight responsibilities.

Laboratory Services should work with 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.

To demonstrate that it has used its existing resources strategically and has maximized their utility to the extent possible, Laboratory Services should identify and explore opportunities to leverage existing processes and procedures.

Laboratory Services should work with Public Health's budget section and other appropriate parties to ensure that it adjusts fees in accordance with the budget act.

Agency Comments

Public Health responded that it concurred with the recommendations and outlined a number of steps it will take to implement them.

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Introduction

Background

Clinical laboratories analyze human specimens such as blood, tissue, and urine so that medical professionals can make diagnoses and prescribe treatment. Laboratory Field Services (Laboratory Services) within the Department of Public Health (Public Health) is responsible for licensing, registering, and overseeing clinical laboratories.³ Laboratory Services says it was responsible for overseeing more than 7,900 licensed and registered clinical laboratories as of June 2007.

The requirement that a clinical laboratory be licensed or registered is contained in Section 1265 of the California Business and Professions Code. The complexity of the tests a clinical laboratory performs dictates whether the laboratory is licensed or registered. For example, clinical laboratories that perform tests of moderate to high complexity, such as hepatitis testing or certain sexually transmitted disease testing by DNA probe, must be licensed. Laboratories that perform the simpler so-called waived tests, with less chance of error or risk, such as prepackaged manufactured tests, must be registered; these laboratories are often located in physicians' offices. A license or registration is valid for one year and demands annual renewal for the laboratory to continue operating.

Until July 2007 Laboratory Services was part of the State's Department of Health Services. At that time, the Department of Health Services became two separate departments: Public Health and the Department of Health Care Services. Laboratory Services is a section within Public Health and is located primarily in Richmond. Records indicate that Laboratory Services had 76 authorized positions at the end of fiscal year 2007–08. Of those authorized positions, 22 were assigned responsibilities related to clinical laboratories, and 10 of those were in the professional classification of examiner.⁴

A clinical laboratory seeking initial licensure or registration or renewal of an existing license or registration must pay a fee. Laboratory Services puts the fees and other money it collects into the Clinical Laboratory Improvement Fund. It uses that money to support its licensing, registration, and oversight

³ State law gives Public Health the responsibility of licensing, registering, and overseeing clinical laboratories. Laboratory Services is the section within Public Health that carries out those responsibilities. For the purposes of this report, we say that state law places responsibilities for the various activities with Laboratory Services.

⁴ Laboratory Services also has responsibilities for laboratory personnel licensing, tissue banks, and blood banks. Staff in many of the remaining positions perform these duties. However, Laboratory Services' responsibilities in those areas were not part of our audit.

activities. Table 1 shows the fees clinical laboratories had to pay and the revenues Laboratory Services collected related to clinical laboratories for the past three fiscal years.

Table 1
Clinical Laboratory Fees and Revenues for
Fiscal Years 2005–06 Through 2007–08

FISCAL YEAR	NUMBER OF LICENSED AND REGISTERED LABORATORIES	INITIAL LICENSING FEE	LICENSE RENEWAL FEE	INITIAL REGISTRATION OR RENEWAL FEE*	TOTAL REVENUE
2005–06	6,555	\$978	\$910	\$59	\$2,139,511
2006–07	7,926	978	910	59	2,222,250
2007–08	9,736 [†]	978	910	59	2,157,079 [‡]

Source: Laboratory Field Services (Laboratory Services).

* Laboratories that perform microscopy procedures pay a registration fee of \$88. Microscopy involves viewing samples with a microscope.

[†] Laboratory Services' estimate as of February 2008.

[‡] Based on revenue figures through May 2008.

State-Mandated Responsibilities for Clinical Laboratory Oversight

Under state law, Laboratory Services is required to oversee clinical laboratories in a host of ways, including inspecting clinical laboratories, monitoring proficiency testing, annually renewing laboratories' licenses and registrations, receiving and investigating complaints, and sanctioning clinical laboratories that violate the law or regulations. Through these oversight activities, Laboratory Services can help to ensure that clinical laboratories are providing safe, quality services to the public.

The Business and Professions Code requires Laboratory Services to engage in two periodic oversight functions: conducting regular inspections and monitoring proficiency testing. Specifically, Section 1220(c) of the Business and Professions Code requires Laboratory Services to inspect each licensed clinical laboratory every two years.⁵ Laboratory Services is to notify the laboratory of any deficiencies revealed by the inspection and work with the laboratory to correct the deficiencies.

The second type of periodic oversight is proficiency testing, in which laboratories must participate consistent with the requirements set in Section 1220(a) of the Business and Professions

⁵ Registered laboratories are not subject to inspections every two years under the law, but Laboratory Services is authorized to inspect them at any time it sees fit.

Code.⁶ Proficiency testing provides an external evaluation of the accuracy of the laboratory's test results. In practice, a proficiency-testing provider distributes a specimen to a laboratory, which must evaluate the specimen and then submit the results to the provider. The proficiency-testing provider has a target value for the specimen, and on receiving the laboratory's assessment, the provider compares the laboratory's results to its target value to determine if the laboratory's evaluation was accurate. Laboratory Services' policy calls for it to receive and review a laboratory's proficiency-testing results and identify any instances of unsatisfactory performance. In those instances, according to its policy, Laboratory Services is to notify the laboratory and require a plan of corrective action. If the planned corrective action is not acceptable or its test results do not improve, Laboratory Services can bar the laboratory from providing those test services.

Section 1220(c) of the Business and Professions Code requires Laboratory Services to investigate complaints it receives about clinical laboratories and authorizes Laboratory Services to inspect clinical laboratories as part of a complaint investigation. As of January 2008 Laboratory Services had a complaints process in place and had developed policies and procedures to receive and investigate complaints.

Laboratory Services' oversight authority also includes sanctioning laboratories that do not adhere to state law and regulation. Sanctions can include monetary penalties, plans of correction, and license or registration revocation. When a laboratory's license or registration is revoked, the owner and operator of the laboratory automatically are barred from owning or operating a laboratory for two years.

Clinical Laboratory Improvement Amendments of 1988

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) is federal law enacted to ensure the accuracy and reliability of laboratory testing. Under this law, for the first time, federal regulation extended to all laboratories in the nation performing tests on human specimens so that medical professionals can diagnose or treat disease or illness or assess people's health. The federal Centers for Medicare and Medicaid Services (CMS) has primary responsibility under CLIA for regulating approximately 200,000 laboratories nationwide. By law, activities to enforce CLIA requirements must be self-funded. The laboratories subject

⁶ Excluded from the proficiency-testing requirements set in Business and Professions Code, Section 1220(a), are clinical laboratories that perform waived tests.

to CLIA must register for certification with the U.S. Department of Health and Human Services and pay an annual fee to cover the cost of inspections and other regulatory activities. CLIA groups laboratories into two categories—those performing waived tests and those performing moderately complex to highly complex tests—and the fees are set commensurate with the complexity of testing. California laboratories, with certain exceptions, are subject to both federal and state laws and regulations and thus are required to pay fees to both governments.

CLIA generally exempts waived tests, such as urine dipstick tests and finger-stick blood tests, from federal regulatory requirements if the laboratory performs those tests in strict compliance with the manufacturers' instructions. Moderate-to-high-complexity testing is subject to federal regulations that set minimum qualifications for all persons performing or supervising the tests and define the responsibilities of each position in the laboratory. Laboratories performing these tests also must participate successfully in proficiency testing—that is, achieve a certain minimum score, have systems and processes for monitoring testing equipment, and have procedures to ensure proper test performance and accurate test results, among other things. Finally, CLIA requires that certain laboratories undergo federal inspections every two years.

Although CMS has primary responsibility for enforcing CLIA, it has contracted with the State to provide the federally required oversight for laboratories within California. To perform CLIA-related duties as the state agent for CMS, Laboratory Services established a specific section that we refer to as the CLIA Section. Located in Los Angeles, the CLIA Section must follow federal regulatory requirements to issue CLIA certificates, perform inspections every two years, monitor proficiency-testing performance, and investigate complaints for laboratories subject to CLIA. Although we recognize that its responsibilities encompass the CLIA Section, we use the term *Laboratory Services* throughout the report in reference to its state-mandated oversight responsibilities.

Scope and Methodology

Chapter 74, Statutes of 2006, requires the Bureau of State Audits to review the clinical laboratory oversight programs of the Department of Health Services (now Public Health and referred to here as the department). Specifically, the law directs 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 specifies 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.

We identified and reviewed applicable state law and regulations as well as Laboratory Services' policies and procedures, to the extent they existed, related to performing oversight activities such as regular inspections, monitoring proficiency testing, receiving and investigating complaints, and imposing sanctions. We also obtained Laboratory Services' written representation of certain issues, including the extent to which it engaged in mandated oversight activities in the past and its plans for the future. Although our audit focused on Laboratory Services' ongoing oversight rather than its initial licensing efforts, we inquired about the extent to which there are laboratories that should be licensed but are not. Unlicensed laboratories are not yet subject to Laboratory Services' oversight.

At the start of the audit, Laboratory Services told us it has not conducted inspections of laboratories every two years as required by law. To determine whether the inspections the CLIA Section performed on behalf of the federal government mitigated Laboratory Services' lack of inspections for the State's program, we reviewed the similarities and identified the differences between federal and state inspection requirements. We also reviewed 15 inspections the CLIA Section conducted from January 2005 through December 2007 and assessed the extent to which they addressed state issues.

To determine whether Laboratory Services adhered to its policies and procedures regarding proficiency testing, for the period of January 2005 through December 2007, we assessed proficiency-testing results for 10 laboratories up to the point Laboratory Services identified whether testing failures occurred. Additionally, for the same period we reviewed 10 instances of proficiency-testing failures, including six for which Laboratory Services had responsibility, to assess whether Laboratory Services adhered to its policies and procedures during each phase of its review process, from identifying proficiency-testing failures to imposing sanctions. The CLIA Section had responsibility for reviewing the four remaining failures, and we noted no exceptions with its adherence to its policies and procedures.

We also assessed the extent to which Laboratory Services exercised its oversight of clinical laboratories through its license and registration renewals by reviewing five license renewals

and five registration renewals made in 2007. During this testing we questioned whether Laboratory Services had adjusted its license and registration renewal fees appropriately. Therefore, we reviewed state law, including the budget acts from fiscal years 2003–04 through 2007–08, and calculated the amount that laboratories were over- or undercharged. (See Table 2 on page 43.) The column titled “Net amount (over) or undercollected” reflects the difference between the fees that Laboratory Services collected and the fees it should have collected. We performed the following calculations: first, we divided the actual amount collected for each fiscal year 2003–04 through 2007–08 by 101.51 percent to yield the fee amount that Laboratory Services would have collected had it not increased its fees beginning in fiscal year 2003–04. Second, for fiscal year 2006–07, we multiplied the result from step one by 122.50 percent to yield the fee amount that Laboratory Services would have collected had it increased the fee properly beginning in fiscal year 2006–07. For fiscal year 2007–08, we applied the previous two changes in succession then multiplied the result by 107.61 percent to yield the fee amount that Laboratory Services would have collected had it increased the fee properly beginning in fiscal year 2007–08.

To better understand the nature of the complaints Laboratory Services received and its basis for closure, we reviewed 30 complaints that Laboratory Services received from January 2005 through December 2007. In cases in which it took no action, we asked Laboratory Services for its reasoning. We also reviewed complaints that prompted some action from Laboratory Services to understand the actions it took and whether additional opportunities for action existed. In addition, we reviewed Laboratory Services’ complaint policies and procedures for key controls we would expect to find in a process of that type, including controls ensuring that staff log, track, prioritize, and promptly handle information they receive. To develop our expectations of key controls, we identified and reviewed similar processes used by Public Health and other state departments having regulatory authority.

To help us identify and understand the magnitude and types of sanctions Laboratory Services has imposed on clinical laboratories, Laboratory Services directed us to its correspondence files; staff e-mail records, computer files, and personal recollections; and two database listings. From those sources we identified sanctions that Laboratory Services imposed from 2002 through 2007. We segregated that information by sanction type and selected items for further review. Based on Laboratory Services’ files, we determined whether it enforced each sanction—for example, collected all civil money penalties it imposed—and whether Laboratory Services documented its justification for each penalty.

We developed information related to Laboratory Services' attempts to obtain funding by reviewing pertinent documents the program supplied us and interviewing key departmental personnel.

To assess whether Laboratory Services had sufficient controls present in its internal databases to ensure that its data are reliable, we reviewed data reliability and control standards from various sources and identified fundamental types of controls that should be present in an information technology system. We then reviewed the databases that Laboratory Services uses for complaints and sanctions to ascertain the presence or absence of the controls. This included interviewing the Laboratory Services chief and information technology manager and reviewing pertinent documents. To understand the Health Applications Licensing system, we interviewed the manager of the system's support unit and reviewed pertinent documents.

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Chapter 1

LABORATORY FIELD SERVICES IS FAILING TO MEET ITS STATE MANDATE TO OVERSEE CLINICAL LABORATORIES

Chapter Summary

Laboratory Field Services (Laboratory Services) within the Department of Public Health (Public Health) has not provided the clinical laboratory oversight that state law and regulations mandate. The consequences of its failure to meet that mandate can seriously compromise public health. Specifically, Laboratory Services has not been inspecting clinical laboratories subject to its oversight either within or outside California every two years as state law requires, and it has no plans to do so with existing resources. Further, Laboratory Services has inconsistently monitored laboratory proficiency testing, which laboratories must undergo to assess the accuracy of their tests. Its policies and procedures regarding proficiency testing are inadequate, and the state regulations under which it operates contain outdated language. Finally, as its chief acknowledges, Laboratory Services has yet to identify many laboratories requiring licensure and in May 2008 placed a priority on this initial licensing activity. Without ongoing oversight of clinical laboratories, such as that provided by inspections every two years and proficiency-testing review, errors in laboratory processes could go uncorrected, potentially resulting in incorrect test results and medical misdiagnoses and treatment errors.

Laboratory Services has historically struggled to respond to complaints, and its use of sanctions is limited. In recent years, Laboratory Services has not always processed complaints systematically, and our review revealed it closed many complaints without taking any action and has not maintained information on the total number of complaints it has received, investigated, or closed. Additionally, although Laboratory Services may impose sanctions against laboratories for violations of law and regulations, it has done so sporadically in recent years. In the absence of ongoing oversight, complaints provide the primary opportunity for Laboratory Services to detect and correct laboratory deficiencies. By not giving adequate attention to complaints, Laboratory Services may be allowing laboratories to continue operating in a manner that jeopardizes the health and safety of patients of medical professionals using laboratory services. Further, even if it improved its oversight and complaint processes, Laboratory Services still could allow laboratories to provide inadequate, incorrect, or even illegal services because it does not adequately exercise its authority to sanction laboratories that violate state law and regulations.

Although required by state law and a critical component of the State's intended oversight structure, Laboratory Services is not inspecting clinical laboratories every two years.

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.

According to the Laboratory Services chief, before 1992 the federal Health Care Financing Administration—the predecessor to the Centers for Medicare and Medicaid Services (CMS)—funded inspections on some laboratories every two years. The Laboratory Services chief stated that in 1992 the federal government contracted with Laboratory Services to be the state agent for administering the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA). One of Laboratory Services' key duties as a state agent is to conduct inspections every two years, for federal purposes, of laboratories not subject to oversight by a federally approved accreditation organization.⁷ Laboratory Services has a specific section dedicated to administering CLIA, which we refer to as the CLIA Section.⁸ We discuss CLIA inspections further in Chapter 2. However, according to its chief, Laboratory Services has not conducted regular, two-year inspections for state purposes because Laboratory Services has not had the authorized positions or the spending authority to hire examiners to complete them.

Further, Laboratory Services does not conduct regular, two-year inspections of out-of-state laboratories. State law requires a laboratory located outside California but accepting specimens originating inside the State to have a state license or registration. Therefore, licensed laboratories located outside California are also subject to inspections every two years under state law. According to Laboratory Services, 91 laboratories outside California had California licenses as of June 2007. The Laboratory Services chief explained that performing routine inspections of out-of-state laboratories is not possible because Laboratory Services does not

⁷ An accreditation organization is a private nonprofit organization that CMS has approved to provide laboratory oversight. Federal regulations allow CMS to deem that a laboratory has met federal requirements through accreditation by one of these organizations.

⁸ We describe Laboratory Services' relationship to the CLIA Section in the Introduction.

have enough staff. Laboratory Services' failure to continuously oversee out-of-state laboratories is compounded by its practice of initially licensing the laboratories based solely on its review of the documentation submitted. In contrast to its practice for in-state laboratories, Laboratory Services does not conduct on-site inspections before deciding to license out-of-state laboratories.

According to its chief, Laboratory Services does not plan to conduct regular inspections of any laboratory, within or outside the State, unless it receives additional resources. The Laboratory Services chief told us there are three examiners dedicated to inspecting laboratories for initial licensure and to investigating complaints, and Laboratory Services intends to focus on these tasks rather than on performing inspections every two years.

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. 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 has inadequate policies and procedures and out-of-date regulations 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. Also, we identified several state regulations governing proficiency testing that state law had superseded when the Legislature adopted federal regulations. Lacking specific timelines and up-to-date regulations, Laboratory Services could apply proficiency-testing requirements inconsistently and create confusion within the regulated community.

Laboratory Services' proficiency-testing policies and procedures are inadequate, and its regulations are out of date.

Laboratory Services Inadequately Monitors Proficiency Testing

Proficiency testing is a process laboratories use to verify the accuracy and reliability of their tests. State law requires all laboratories to enroll in proficiency testing for each specialty and subspecialty in which it performs tests; except laboratories

do not have to enroll in proficiency testing for waived tests, or simple tests with a small chance of error or risk. Laboratory Services' policies and procedures call for it to review the proficiency-testing results and contact laboratories with unacceptable scores. State law has adopted federal regulations, which indicate when a score is acceptable. For example, a score of at least 80 percent in the subspecialty of parasitology is an acceptable score. The text box describes proficiency testing in more detail and defines a testing failure. According to its policies and procedures, Laboratory Services asks laboratories with testing failures to provide a plan of correction documenting the actions the laboratory has taken to ensure that deficiencies do not recur. Laboratory Services is to review the plan of correction and determine whether the laboratory has corrected the problem.

Laboratory Services and the CLIA Section split responsibility for reviewing proficiency-testing results of laboratories performing moderate-to-high-complexity testing. The CLIA Section is responsible for reviewing the proficiency-testing results of laboratories not subject to oversight from a federally approved accreditation organization. Laboratory Services is responsible for the remaining laboratories, including California-licensed out-of-state laboratories. Laboratory Services and the CLIA Section generally use the same process to identify proficiency-testing failures.

Laboratory Services does not identify all proficiency-testing failures or take action on identified failures. We examined six instances of proficiency-testing failures at five laboratories whose results Laboratory Services was responsible for reviewing. We found that Laboratory Services had not contacted the laboratories or had not identified all the failed tests in five of the six instances. Because of its inadequate

What Is Proficiency Testing?

Proficiency testing is a process laboratories use to verify the accuracy and reliability of their tests.

State Law

Business and Professions Code, Section 1220, adopts federal regulations regarding proficiency testing into state law.

Who Must Enroll?

Laboratories performing moderate-to-high-complexity tests in the following specialties must enroll in proficiency testing: microbiology, diagnostic immunology, chemistry, hematology, and immunohematology. Laboratories performing cytology tests (such as gynecologic exams) also must enroll in proficiency testing. However providers of cytology proficiency testing administer tests to, and report results on, individuals rather than laboratories.

How Does Proficiency Testing Work?

A proficiency testing provider distributes a specimen to a laboratory. The laboratory tests it and submits the results to the provider. The provider will compare the laboratory's results to a target value to determine if the laboratory's evaluation was accurate.

How Often Must Laboratories Test?

In most cases laboratories must engage in proficiency testing at least three times per year (each time is called an *event*). For example, the subspecialties of bacteriology and parasitology require three testing events, but mycobacteriology requires only two events.

What Is a Testing Failure?

State law requires that a laboratory performing moderate-to-high-complexity tests successfully participate in proficiency testing. Participation is unsuccessful if the laboratory does not achieve a minimum score in two consecutive or two out of three tests. For example, a laboratory receiving consecutive scores of 40, 100, and 60 in the parasitology subspecialty would be unsuccessful because it had two scores out of three below the minimum of 80.

Sources: California law, federal regulations, and Laboratory Field Services' Web site.

monitoring of proficiency testing, Laboratory Services may be allowing the continued operation of laboratories that conduct clinical tests in a manner that leads to inaccurate and unreliable results. This jeopardizes the ability of professionals who use the laboratories' services to make accurate medical decisions.

Additionally, Laboratory Services does not review proficiency-testing results for out-of-state laboratories. Laboratories located outside the State but with California licenses to perform tests of moderate to high complexity are subject to state proficiency-testing requirements. Discussions with the examiner reviewing proficiency-testing results confirmed that Laboratory Services does not review the proficiency-testing results of laboratories operating outside of California. The examiner stated in July 2008 that she plans to begin reviewing these testing results in September 2008.

Proficiency-Testing Policies and Procedures Lack Critical Timelines

Laboratory Services has not established timelines for some key stages in proficiency-testing monitoring, including how frequently it reviews test scores, the period within which it reviews plans of correction, and the amount of time a laboratory has to submit acceptable plans of correction before Laboratory Services imposes sanctions. One hallmark of a strong oversight process is established time frames within which the entity will take certain actions. It is important for Laboratory Services to have policies and procedures with clearly defined time frames because they provide a measuring point and help ensure that unacceptable conditions, such as proficiency-testing failures, are corrected promptly. It is also important that time frames Laboratory Services wants to impose on the laboratory community are in regulation so that Laboratory Services can enforce them effectively.

According to the chief of the Facility Licensing Section (facilities section chief), any timelines would need to be flexible to account for changes in workload. However, the current lack of timelines could lead to inconsistency within the proficiency-testing review process, with Laboratory Services rushing some laboratories through the process, giving others significant amounts of time, and providing no oversight to others. For example, in one case we reviewed, Laboratory Services sent a reminder notice in August 2007 after initially contacting a laboratory about its proficiency-testing failures. However, according to the examiner responsible for proficiency-testing monitoring, Laboratory Services did not follow up with the laboratory until June 2008, after we pointed out the lack of response.

It is important to have proficiency-testing policies and procedures with clearly defined time frames because they provide a measuring point and help ensure that unacceptable conditions are corrected promptly.

Laboratory Services has not enforced its policy to verify whether laboratories are enrolled in state-approved proficiency testing, which is key for ensuring that laboratories conduct their tests reliably and accurately.

Even though the examiner said she reviews results monthly, Laboratory Services did not contact laboratories monthly. For example, in two of the six instances of proficiency-testing failures we reviewed, Laboratory Services contacted the laboratories about unsuccessful proficiency testing in July 2007, in one instance approximately six months after the testing failure and in the other instance more than a year after the testing failure.⁹ In July 2008 Laboratory Services provided us with revised policies and procedures for proficiency testing, which includes a procedure to contact laboratories within 10 days of reviewing failed proficiency-testing results. However, the revisions do not state the frequency with which Laboratory Services would review proficiency test results. Also, they do not include timelines for reviewing laboratory plans of correction or sanctioning laboratories that do not submit acceptable plans of correction.

Finally, Laboratory Services 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. Since 1996 Laboratory Services has had a documented procedure for determining whether laboratories were enrolled in proficiency testing. The procedure involves comparing a proficiency-testing enrollment list compiled by testing providers with a list of known California laboratories compiled by Laboratory Services. When we asked why Laboratory Services did not follow the procedure, the facilities section chief stated it was not effective because some laboratories may be conducting moderate-to-high-complexity tests that are not regulated and thus not subject to proficiency testing. Laboratory Services removed the procedure in its revised policies and procedures dated July 2008. The facilities section chief said Laboratory Services would verify enrollment in proficiency testing during its regular inspections every two years. However, Laboratory Services is not conducting those inspections as required. Although Laboratory Services' written procedure for confirming enrollment in proficiency testing may not be effective, in the absence of inspections, it still would have been helpful in identifying some laboratories that should be enrolled in proficiency testing but were not.

⁹ Data on the exact dates of the proficiency tests were not available. Because three testing events occur each year and federal regulations require that the events be at approximately equal intervals throughout the year, we estimated that the events occurred on April 30, August 31, and December 31 of each year.

Another benefit of ensuring that laboratories are enrolled in proficiency testing is having a means to determine whether Laboratory Services is receiving proficiency-testing scores for each laboratory. Through our review, we identified one laboratory whose scores were missing from Laboratory Services' proficiency-testing data.

Some State Regulations Related to Proficiency Testing Are Outdated

We found three instances in which Laboratory Services had maintained state regulations that state law had superseded. In 1995 the Legislature amended state law to adopt federal regulations regarding proficiency testing. We expected to find that Laboratory Services had taken action to repeal outdated state regulations, thereby averting misunderstandings within Laboratory Services and between it and the regulated community. However, state regulations continue to require that proficiency-testing providers give tests to laboratories four times per year, despite amendments to state law that set the minimum number of annual tests at two or three, depending on the type of test. Further, state regulations define unsuccessful participation in proficiency testing as three consecutive failures, although state law, as amended to adopt federal regulations, defines unsuccessful participation as two consecutive failures or two out of three failures. Also, state regulations require that laboratories enroll in proficiency testing for all HIV tests, including waived tests, which is not consistent with amended state law that does not require proficiency testing for waived tests.

Laboratory Services is following the federal proficiency-testing requirements adopted by state law rather than state regulations, and in two cases it is working to change the outdated regulations. The first case began in July 2007 when Public Health granted a petition from the California Clinical Laboratory Association—an organization that advocates on behalf of clinical laboratories—to repeal a section of state regulations that included the definition of unsuccessful participation in proficiency testing. According to Public Health's legal counsel, a hearing on the matter was not scheduled as of late June 2008. In the second case, after receiving feedback from Public Health's legal counsel that it could not require proficiency testing for waived tests, in May 2008 the Laboratory Services chief submitted to Public Health revised regulations removing the requirement that laboratories enroll in proficiency testing for waived HIV tests. According to the Laboratory Services chief, the question of whether Laboratory Services could require proficiency testing for waived tests had been under consideration

Laboratory Services recently began implementing a plan to identify and license laboratories within California that are subject to licensure but have not applied for or obtained it.

for more than a year. She expects it will be more than a year before the regulatory process is complete and Public Health can adopt the new regulations.

Laboratory Services Is Focusing on Increasing Licensing of California Laboratories but Not Out-of-State Laboratories

Recognizing a problem within its licensing process, Laboratory Services recently developed and has begun 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. 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.

Although our audit focused on Laboratory Services' ongoing oversight rather than its initial licensing efforts, we inquired about the extent to which laboratories that should be licensed are not and thus are not subject to Laboratory Services' oversight. The Laboratory Services chief acknowledged in April 2008 that it had yet to identify many laboratories requiring licensure. In May 2008 Laboratory Services placed a priority on its initial licensing activities by assigning an examiner to contact unlicensed laboratories and work with them to obtain necessary state licensure. The facilities section chief stated that the examiner initially had identified approximately 80 unlicensed laboratories and had mailed notification letters to 10 of those laboratories as of early June 2008.

The initial focus of the licensing efforts is on large-volume laboratories that are subject to oversight by accreditation organizations. According to the facilities section chief, Laboratory Services considers large-volume accredited laboratories a priority because they have not been inspected by the State and may have significant deficiencies. Moreover, she stated that large-volume laboratories perform a higher number of tests and therefore have a greater potential to cause harm if they have quality issues.

Out-of-state laboratories performing testing on specimens originating in California are also subject to state licensing requirements. In 2005 Laboratory Services sent requests to laboratories asking them to provide the names and license numbers of the out-of-state laboratories to which they refer specimens. The facilities section chief stated that initial effort yielded a list of approximately 600 laboratories, most of which were not licensed by

California; however, Laboratory Services did not take further action to license those laboratories. 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 unlicensed out-of-state laboratories. Federal clinical laboratory oversight provides some assurance that out-of-state laboratories are free from major deficiencies, but state law requires these laboratories to obtain California licenses depending on the complexity of their testing, and it is important for Laboratory Services to have some degree of oversight of all laboratories that process human specimens originating in California.

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. Complaints provide Laboratory Services with opportunities to identify laboratories with poor practices that could produce inaccurate test results and thus endanger patient health.

State law mandates that Laboratory Services investigate complaints it receives. However, according to its chief, Laboratory Services has not, until recently, had dedicated staff to perform its complaints function. As a result, Laboratory Services asserts, it could perform only a cursory review of all complaints received, selecting the most serious complaints for 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.

The Laboratory Services chief told us that, from 2000 to 2008, she directed staff to help with complaints, but generally in conjunction with competing priorities. At times the Laboratory Services chief took responsibility for reviewing and investigating complaints, but an investigation could be as simple as making a telephone call or writing a letter. After obtaining approval for fiscal year 2006–07 for a position to handle complaints, Laboratory Services created and in January 2008 staffed a complaints manager position.

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

Laboratory Services lacks information to know the total number of complaints it has received, investigated, or closed during a specific period.

consistently enter complaints it received into that database or update its complaints data to reflect progress or resolution. In addition, in late 2007, just before filling the complaints manager position, Laboratory Services had a backlog of complaints and closed many without taking action. The Laboratory Services chief told us that clerical staff and program volunteers periodically helped review the complaints backlog and closed any complaints deemed untimely—generally, those six months or older—as well as any complaint with insufficient evidence to warrant further investigation or with potentially minimal public impact. However, Laboratory Services could not tell us how many complaints it had in the backlog or how many complaints it closed for those three reasons. 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.

Laboratory Services Often Closed Complaints After Little or No Investigation

To better understand the nature of the complaints Laboratory Services received and its basis for closure, we reviewed 30 complaints it 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. When we asked why it chose not to investigate those complaints, Laboratory Services explained it evaluated each complaint to determine whether it was serious enough to reassign staff to investigate and resolve it. According to Laboratory Services, it determined that the 16 complaints we asked about should not undergo investigation primarily because Laboratory Services lacked jurisdiction or did not have adequate staff. For example, Laboratory Services has identified billing disputes as out of its jurisdiction because the Business and Professions Code or the related regulations do not specifically grant Laboratory Services the authority to resolve those types of complaints. We recognize that Laboratory Services will receive some complaints that are out of its jurisdiction; however, for the six complaints that Laboratory Services told us it had no jurisdiction concerning the allegations, 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. Moreover, in half of the six cases, Laboratory Services took 10 months or more from the time it received the complaint to determine that it was not within its 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. Specifically, three complaints alleged that the laboratories were performing testing without state licenses or were performing unauthorized testing, including one laboratory that also lacked a CLIA certificate. Although Laboratory Services later determined that two of those three laboratories were registered by the State, it did so only after we brought the cases to staff's attention. The two remaining complaints with health and safety implications included one from a laboratory employee who alleged another employee made an error and had assigned and reported laboratory test results for the wrong patient, and one complaint that alleged a laboratory was using unlicensed personnel. These complaints have health and safety implications because the test results that clinical laboratories produce are the basis of medical decisions, such as treating diabetes or coronary disease. Without the assurances Laboratory Services provides through its licensing process, including validating test equipment and confirming that laboratory personnel have necessary qualifications, the public is at risk of laboratories performing tests they are not qualified to perform or perform incorrectly. According to the complaints manager, Laboratory Services lacked the staff needed to resolve all five of these complaints.

Of the remaining five complaints Laboratory Services closed without action and acknowledged having jurisdiction over, the allegations did not appear to have immediate health or safety implications. Among the allegations included in these complaints were unsanitary conditions for drawing blood and genetic test information posted on the Internet. Although these complaints could be considered lower priority, Laboratory Services could have done more than it did in some instances. For example, in one complaint alleging that a laboratory's directorship changed but was not reported to Laboratory Services as required by law, Laboratory Services could have performed some follow-up through its license renewal process, but it did not. In another case, Laboratory Services closed a complaint because it previously had reported the laboratory doctor to the Medical Board of California. Laboratory Services could have forwarded the new complaint to the Medical Board or ascertained the board's actions, but it did neither.

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.

Of 10 complaints we reviewed that Laboratory Services closed without action, we found five complaints that alleged conditions with health and safety implications.

One complaint Laboratory Services did not follow up on was a test error involving a patient that was reportedly misdiagnosed with tuberculosis.

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.

In one of the two test error complaints, the patient was reportedly misdiagnosed with tuberculosis and was hospitalized twice for side effects from the prescribed medications. The test error was believed to result from the laboratory cross-contaminating the blood samples. Despite the exchange of e-mails evident in Laboratory Services' files, the assigned examiner failed to follow up on the complaint. When we asked Laboratory Services why it did not pursue the case, the assigned examiner responded that the issue appeared to be resolved, and she put the matter out of her mind because she had many other duties and projects. The examiner also stated that staffing is sparse and activities have to be prioritized, but that in retrospect she believes she should have recommended that Laboratory Services impose sanctions against the laboratory. She further noted that because the laboratory was accredited—and therefore subject to oversight by an accreditation organization—it was not subject to routine inspections by the CLIA Section.

The second complaint involving a testing error occurred after a laboratory tested an outdated specimen and the test results were used to prescribe medical treatment for a patient. A Laboratory Services examiner sent a form letter to the complainant 428 days after receiving the complaint, acknowledging receipt of the complaint and stating Laboratory Services would determine the best method to proceed with investigating the incident. Although notes in the complaint file directed an examiner to send a letter to the laboratory, no such letter was in the file. Laboratory Services subsequently closed the complaint with the notation that the complainant had called and was satisfied. However, our review of the complaint file revealed that, although the complainant called to say he investigated the complaint himself, he did not say he was satisfied. In fact, he suggested that Laboratory Services "should be out of [the] complaint business if [it] cannot resolve problems sooner."

The third complaint that had health and safety implications and on which Laboratory Services took some action was against a laboratory with a history of performing testing without the necessary state and federal approvals. The CLIA Section filed a complaint with Laboratory Services. After learning the laboratory lost its accreditation under CLIA, the CLIA Section notified the laboratory it had to stop testing until it obtained a CLIA certificate.

On two occasions in 2005, the CLIA Section determined the laboratory had ignored orders to cease testing. Moreover, based on an on-site inspection, the CLIA Section determined that the laboratory needed a state license or registration to conduct its type of testing. Laboratory Services closed the complaint despite the laboratory's history of testing without necessary approvals and its apparent willful disregard of orders to stop testing.

For several of the 14 complaints on which Laboratory Services acted, our review revealed that the actions were not always sufficient to determine whether the allegations against the laboratory were valid or to ensure that the laboratories corrected deficiencies. We found that Laboratory Services closed four of the 14 complaints based on a laboratory's assurance that there was no issue as alleged. In addition, Laboratory Services referred two complaints to the CLIA Section for laboratory inspections; however, Laboratory Services did not follow up with the CLIA Section to ensure that the inspections occurred and the allegations were resolved.

Laboratory Services' Complaint Policies and Procedures Lack Sufficient Controls

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.

Laboratory Services updated its complaints policies and procedures after hiring a complaints manager in January 2008. The manager reviewed and revised the complaints policies and procedures, and in April 2008 staff received training on them. The policies and procedures contain certain controls. For example, all complaints received must be acknowledged by notifying the complainant in writing, and all complaints must be assigned a unique identifying number. However, certain key controls in Laboratory Services'

Our review revealed that Laboratory Services' actions were not always sufficient to determine whether the complaint allegations were valid or to ensure that the laboratories corrected deficiencies.

Certain key controls in Laboratory Services' recently revised complaint policies and procedures are missing or insufficient.

policies and procedures are missing or insufficient. For example, the revised policies and procedures are silent on how Laboratory Services will ensure that laboratories follow through with corrective action when they have substantiated complaints and are required to submit a plan of correction.

Key controls that are insufficient include Laboratory Services' processes for receiving and tracking complaints. Specifically, Laboratory Services' intake system allows any employee to receive a complaint, rather than having a dedicated telephone number, e-mail account, or postal mailbox. Laboratory Services' policy requires an employee receiving a complaint to forward it to the complaints manager. However, by allowing any employee to take a complaint, Laboratory Services increases the risk that a complaint will be lost or a matter of serious concern will be overlooked. Further, although Laboratory Services has a complaints database, it has not always entered received complaints into the database, and the database is not designed to show the stage of the process a complaint is in at any one time. Therefore, the database is a limited tool for logging and tracking complaints.

Laboratory Services' system for prioritizing complaints also is inadequate. In its previous policies and procedures, Laboratory Services specified a time frame for complaint investigation that reflected five priority levels. Although the revised procedures also set an investigation time frame, Laboratory Services reduced the priority levels to two: either an allegation poses an immediate and serious threat to patient health or it does not. We expect that complaints will reflect varying degrees of risk to public safety, ranging from little risk to an immediate and serious threat. A policy that defines the parameters beyond the two categories Laboratory Services has defined would allow it to prioritize its resources better.

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. According to the chief, in 1999 the program created a Special Investigation Section (investigation section) of 10 authorized positions dedicated to investigating billing fraud and quality issues in clinical laboratories. The Laboratory Services chief estimated that the work of the investigation section led to Laboratory Services revoking 30 laboratory licenses between 2000 and 2002. The Laboratory Services chief stated that, beginning in July 2002, six positions in the investigation section were eliminated or redirected because of budget cuts. She further told us that Laboratory Services imposed more than 20 civil money penalties in 2003 against laboratories for failure to renew licenses promptly. However, the Laboratory

Services chief asserted that staff were redirected to manage a new licensing requirement, effectively discontinuing the program's sanctioning efforts. The Laboratory Services chief also told us that from 2005 through 2007 Laboratory Services did not have staff dedicated to enforcement actions, conducted only one major investigation, and imposed a limited number of sanctions. The text box summarizes the types of sanctions Laboratory Services is authorized to impose.

Because it lacks an effective tracking mechanism, Laboratory Services could not identify the total number 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 in that six-year period. Most of the sanctions were imposed in 2002 and 2003. Although it could not demonstrate that during the six-year period it referred any clinical laboratory for criminal prosecution, the Laboratory Services chief stated that in 2003 one case was referred for criminal prosecution that involved a phlebotomy service using personnel without necessary certificates to perform phlebotomy.

To help us understand the magnitude and types of sanctions it has imposed on clinical laboratories, Laboratory Services directed us to its correspondence files; the e-mail records, computer files, and personal recollections of staff; and two database listings. However, Laboratory Services could not assure us that the sanctions information we identified from those sources was a complete representation of its sanctioning efforts.

The facilities section chief offered us sanctions data from two databases that we decided not to consider. First, the facilities section chief provided one database listing with summary information on laboratory owners and directors who had been sanctioned, but she was unable to explain the listing to us and she questioned the source and relevance of many of the data entries on the listing. Second, the facilities section chief told us she could have information about license terminations extracted from the Health Applications Licensing system. However, the facilities section chief said it is difficult to get accurate information from that system, so she does not use the data. She stated that poor data does not make a good management tool.

Sanctioning Efforts Laboratory Services Is Authorized to Make

- Impose civil money penalties ranging from \$50 per day to \$10,000 per day.
- Suspend or revoke a laboratory's license or registration.
- Direct the laboratory to take specific corrective action.
- Conduct monitoring at the laboratory's site and at the laboratory's expense.
- File a civil lawsuit.
- Exclude a laboratory from participating in federally funded health programs.
- Refer a laboratory to law enforcement authorities for criminal action.

Source: California Code of Regulations, Title 17.

Of the seven civil money penalties we reviewed, Laboratory Services could not demonstrate that it collected the penalties from two laboratories or even imposed the penalty on one laboratory. Although Laboratory Services demonstrated that it collected the penalties it imposed for the remaining five laboratories we reviewed, it could not substantiate how it calculated the penalties for any of the seven laboratories. State regulations require Laboratory Services to send a notice to a laboratory regarding penalties it intends to impose. Moreover, the notice must include the proposed penalty amount and the factors Laboratory Services considered in setting the penalty, such as the nature, scope, severity, and duration of the deficiency. Laboratory Services has discretion in setting a penalty within an allowable range, but neither its notices nor its files reflected how Laboratory Services exercised its discretion. Without information showing how a penalty was calculated, Laboratory Services cannot be certain that it imposes penalties consistently for similar circumstances.

Laboratory Services' information revealed five licensing sanctions it imposed between 2002 and 2007, including four licenses it terminated in 2002 and one temporary license suspension it imposed in 2005. Laboratory Services asserted that it had terminated licenses throughout the six-year period for reasons that included a laboratory's failure to renew its license and notification from CMS that it had terminated a laboratory's CLIA certificate. However, as discussed earlier, weaknesses in Laboratory Services' data-tracking methods prevented it from accurately identifying which licenses it had terminated.

When Laboratory Services revokes or suspends a laboratory's license, the laboratory cannot receive payments from federally funded health programs such as Medi-Cal and Medicare, and it is Laboratory Services' policy to notify Medi-Cal and CMS that it has taken action against a laboratory's license. 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 CMS about one laboratory, as its policy requires.

Laboratory Services makes limited use of directed plans of correction. Directed plans of correction are directions that Laboratory Services develops requiring a sanctioned laboratory to take specific corrective action within a specific time frame to achieve compliance. Laboratory Services' records show it imposed directed plans of correction on only three laboratories between 2002 and 2007, of which we reviewed one. Laboratory

Services notified the laboratory of the sanction in November 2003 after an inspection prompted by more than 40 complaints against the laboratory. Through its inspection Laboratory Services determined that the laboratory had numerous problems, including having unqualified personnel perform moderate-to-high-complexity tests, failing to supervise unlicensed personnel, and not complying with quality control standards. Laboratory Services noted that certain conditions also had been cited five years previously and that the laboratory had not corrected them as alleged.

As sanctions against this laboratory, Laboratory Services initially imposed a directed plan of correction, on-site monitoring, and civil money penalties. However, the Department of Health Services, of which Laboratory Services was then a part, negotiated with the laboratory and reached a settlement that focused only on civil money penalties and investigation costs. Nevertheless, Laboratory Services was not precluded from inspecting the laboratory again at any time. Given the laboratory's history of noncompliance and the magnitude of the complaints against it that Laboratory Services received, we question Laboratory Services' lack of subsequent on-site monitoring to ensure that the laboratory maintained compliance with state requirements. According to its chief, Laboratory Services believed that when ownership of the laboratory changed, the new owners would internally enforce strict compliance with state requirements. The Laboratory Services chief added that, despite its best intentions, Laboratory Services lacks the staff needed to perform on-site monitoring.

Laboratory Services acknowledged that it has imposed a limited number of sanctions. When we asked the Laboratory Services chief if she plans to increase sanctioning efforts, she responded that she does not anticipate performing any major investigations with the current staff available. She also stated that Laboratory Services will not impose sanctions on laboratories that fail to renew their licenses on time and will not perform required regular inspections that could lead to sanctioning. The Laboratory Services chief also asserted that, at current staffing levels, Laboratory Services will have to limit its enforcement efforts against laboratories that fail proficiency testing. However, as discussed previously, Laboratory Services staffed its complaints manager position, and the increased attention to complaints may result in sanctions.

Sanctions provide tangible penalties against laboratories failing to comply with laws and regulations. Even if Laboratory Services were conducting ongoing oversight and responding vigorously to complaints, without sanctions it cannot enforce its oversight activities. Therefore, laboratories providing inadequate, incorrect, or even illegal services may continue doing so without consequences.

Laboratory Services acknowledged that it has imposed a limited number of sanctions, and the chief stated that she does not anticipate performing any major investigations with the current staff available.

Recommendations

Laboratory Services should perform all its mandated oversight responsibilities for laboratories subject to its jurisdiction operating within and outside California, including, but not limited to the following:

- Inspecting licensed laboratories every two years.
- Monitoring proficiency-testing results.
- Reviewing and investigating complaints and ensuring necessary resolution.
- Sanctioning laboratories as appropriate.

Laboratory Services should 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 specified 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.

To update its regulations, Laboratory Services should review its clinical laboratory regulations and repeal or revise them as necessary. As part of its efforts to revise regulations, Laboratory Services should ensure that the regulations include requirements such as time frames it wants to impose on the laboratory community.

Laboratory Services should 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.

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. Further, Laboratory Services should establish procedures to ensure that it promptly forwards complaints for which it lacks jurisdiction to the entity having jurisdiction.

To strengthen its sanctioning efforts, Laboratory Services should do the following:

- Maximize its opportunities to impose sanctions.
- Appropriately justify and document the amounts of the civil money penalties it imposes.
- Ensure that it always collects the penalties it imposes.
- Follow up to ensure that laboratories take corrective action.
- Ensure that when it sanctions a laboratory it notifies other appropriate agencies as necessary.

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Chapter 2

PROBLEMS WITH RESOURCES HAVE CONTRIBUTED TO THE WEAKNESSES IN LABORATORY FIELD SERVICES' OVERSIGHT OF CLINICAL LABORATORIES

Chapter Summary

The chief of Laboratory Field Services (Laboratory Services) attributes much of its inability to meet its mandated responsibilities to a lack of resources. 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 the Health Applications Licensing system (HAL) to support functions such as licensing, but that system does not support all of Laboratory Services' activities. Moreover, several internal databases lack the controls necessary to ensure accurate and complete information.

Although it may benefit from additional staff, it is important that Laboratory Services demonstrate a strategic use of existing resources. We identified several opportunities for Laboratory Services to leverage resources it already has in place, such as its licensing and registration renewal process or its authority to contract with external parties.

Finally, we determined that Laboratory Services had raised its fees improperly one year and failed to impose two subsequent fee increases called for in the budget act. As a result, Laboratory Services did not assess and collect more than \$1 million in clinical laboratory fees. However, even if it had collected the additional revenue, Laboratory Services' ability to spend the funds depends on its obtaining the corresponding spending authority to make the revenue available.

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 eight positions that had funding eliminated through previous budget cuts. Two of those additional positions were intended to help Laboratory Services meet its

Laboratory Services has only been successful in obtaining approval for two funding proposals for clinical laboratories in recent years.

clinical laboratory oversight responsibilities. The funding proposal approved for fiscal year 2006–07 granted Laboratory Services 14 positions, seven of which were designated for clinical laboratory oversight activities: one examiner to administer the complaints and compliance program, four examiners to perform laboratory inspections, and two program technicians for clerical licensing support. Information that Laboratory Services provided us shows it began filling the positions in August 2006 and made its last appointment in April 2008. Laboratory Services reported that as of July 2008 one of the five examiner positions had not been filled. Of the remaining four examiner positions Laboratory Services was authorized, it reclassified one into a management position to fulfill the duties of Laboratory Services' assistant chief and designated three positions as responsible for initial licensing inspections and related work.

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 (Public Health) and the Department of Health Care Services. Public Health was organized into five centers, which are comparable to divisions; Laboratory Services became part of Healthcare Quality. We asked why Public Health has not submitted a funding proposal for Laboratory Services since it became a part of Public Health. 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.

Healthcare Quality does not believe the existence of a balance in the fund used to support Laboratory Services' activities would affect its consideration of rightsizing. At the end of fiscal year 2006–07, the Clinical Laboratory Improvement Fund (CLIF) had a reported \$2 million balance, and the most recent governor's budget estimated that the CLIF balance at the end of fiscal year 2007–08 was \$1.7 million. According to the assistant deputy director for Healthcare Quality, the reserve has been building up over the past few years because of revenue generated from the

increase in phlebotomy certification and laboratory licensure and registration. She told us that the desired amount of reserve for the CLIF is 5 percent of the budget and that Laboratory Services will use excess reserves for one-time investments to help it stabilize the program. For example, she anticipates the reserves would be used for items such as replacing Laboratory Services' information technology system.

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.

HAL generally does not have discrete fields or functionalities to support all of Laboratory Services' activities, including processing complaints and inspections, and sanctioning laboratories. For example, the complaints field in HAL is limited to a yes or no indicator, and Laboratory Services' policy requires staff only to add complaint numbers to the HAL comments field. HAL does not have fields to capture important information such as the nature of the complaint or the stage of the process the complaint is in. Additionally, HAL does not capture meaningful information regarding laboratory sanctions. Instead, HAL reflects sanctions with a license status code that indicates whether a license has been terminated, but other information is limited to what staff can enter in as comments. Without these functionalities, HAL's usefulness as a management tool is limited to a few purposes, such as storing license and registration application data, processing changes in laboratory ownership or directorship, and generating automatic renewal notices. It does not have the functionality to support some of Laboratory Services' most critical activities.

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.

The internal databases Laboratory Services has created to support its enforcement activities do not have sufficient controls to protect data reliability.

Laboratory Services also receives inadequate data from the internal databases it has created to support its enforcement activities. The databases do not have sufficient controls to protect data reliability. Over time Laboratory Services has developed at least four Microsoft Office Access (Access) databases to capture data for tracking and reporting complaints- and sanctions-related activities. We expected these internal databases to contain certain controls to ensure that staff enter information consistently and accurately, that only authorized users have access to the information, and that the risk of data loss is minimized. We focused our review of Laboratory Services' internal databases on those controls, although many other controls may be needed in any given circumstance, and found that the databases lack data entry controls needed to ensure accurate and complete information. For example, Laboratory Services has not developed documentation regarding the purposes or uses of the internal databases, has not created procedures to ensure that staff enter all data occurrences, and has no process for reviewing the data for accuracy. Further, Laboratory Services did not design the databases with defined formats for data entry or required fields for records submission.

Laboratory Services' lack of data entry controls has contributed to databases that cannot be relied on to supply it with accurate and complete data. The chief of the Facility Licensing Section (facilities section chief) admitted that data entry into these databases is generally infrequent and that she is aware of some databases containing incomplete information. Through our observation it was readily apparent that each of the four databases is incomplete. Moreover, three of the databases contain certain information that is incorrect or illogical. For example, the complaints database contains some dates that do not match the physical files and some data fields that are not always populated. Further, Laboratory Services did not enter all the complaints it received, and during the audit Laboratory Services could not provide us with summary data on complaints and sanctions because the information in the databases was incomplete.

We did find that certain security and data loss controls were established. For example, Laboratory Services is subject to Public Health's requirement for security controls in the form of hard drive encryption, password log-ons, and permissions that limit the staff's ability to open or modify files or folders. We also found that Public Health has a policy requiring nightly data backups that, if followed, would provide recovery and retention controls.

According to the facilities section chief, Laboratory Services has sought approval for upgrading or replacing HAL but has not made any formal requests for specific modifications to HAL to include the additional fields it needs. The facilities section chief asserted that, based on historical and anecdotal information, Laboratory Services

understood that it could not add data fields to HAL. However, the manager of the unit in the Information Technology Services Division responsible for supporting HAL told us that HAL could accommodate most field changes or data entry screen additions with varying levels of difficulty. The facilities section chief also stated that information technology staff within Laboratory Services do not have adequate time or knowledge to develop or support the internal databases. The Laboratory Services information technology manager is aware that her staff are unskilled in developing and supporting the internal databases, and she told us she has tried to get approval for an information technology position requiring database skills. She added that two of her information technology staff are enrolled in basic Access courses.

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.¹⁰ Exploring these ideas and others could help Laboratory Services better meet its mandated responsibilities.

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.

Laboratory Services Could Exercise Clinical Laboratory Oversight When It Renews Licenses and Registrations

As discussed in Chapter 1, Laboratory Services is not conducting inspections every two years as required by state law. Absent the inspections, Laboratory Services could use its renewal process to provide some laboratory oversight. For example, when licensed laboratories or certain registered laboratories apply for annual renewals, they are required to submit a list of personnel performing testing. Yet Laboratory Services does not review the list to determine whether laboratory personnel have the required state licenses showing they have the necessary education and experience. Our review of 10 laboratory renewals—five registration renewals and five license renewals—revealed that all required laboratories

¹⁰ An accreditation organization is a private, nonprofit organization the federal government has approved to provide laboratory oversight.

submitted personnel lists. However, although the form includes a space for entering the license or certificate numbers of testing personnel, according to the facilities section chief, Laboratory Services does not verify that the licenses are valid. She said that verifying personnel information during the renewal process has limited value and that reviewing the qualifications of laboratory personnel at an inspection would be of greater value. However, Laboratory Services is not performing those regular inspections. Further, the facilities section chief said that laboratories may verify online the licensing status of those they hire. Although state law and regulations do not require Laboratory Services to review these lists, doing so might be one way Laboratory Services could exercise some oversight.

Laboratory Services has another opportunity to enhance its oversight efforts by upgrading its procedures for reviewing whether a laboratory owner or director has had a license or registration revoked. Although Laboratory Services' desk procedures for license renewals instruct staff to check enforcement records related to laboratory directors, the procedures for registration renewals do not. State law generally prohibits an individual from owning or directing a laboratory for two years after the individual has had a laboratory license or registration revoked. According to the facilities section chief, Laboratory Services does not have the staff to check the status of owners or directors for each registration renewal. However, by having current staff spend a minimal amount of time checking the enforcement records of owners and directors of registered laboratories, Laboratory Services could gain the oversight needed to ensure that laboratories are not operating with unqualified owners or directors.

Accreditation Organizations and the CLIA Section Defined

An accreditation organization is a private nonprofit organization that CMS has approved to provide laboratory oversight. Federal regulations allow CMS to deem that a laboratory has met federal requirements through accreditation by one of these organizations. Accreditation organizations' standards must meet or exceed those in federal regulations.

CLIA is federal law enacted to ensure the accuracy and reliability of laboratory testing. CMS has primary responsibility under CLIA for regulating clinical laboratories nationwide. The CLIA Section of Laboratory Services performs CLIA-related duties as the state agent for CMS.

Sources: Title 42, Code of Federal Regulations, Section 493.551; CMS Web site; and Laboratory Field Services' documents.

Laboratory Services Could Benefit From a Process to Share State Concerns Identified During Federal Inspections

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) generally require that laboratories not subject to oversight by a federally approved accreditation organization be inspected every two years. To perform CLIA-related duties as the state agent for the federal Centers for Medicare and Medicaid Services (CMS), Laboratory Services established its CLIA Section. The CLIA Section conducts the laboratory inspections on behalf of the federal government every two years; it reported performing 619 of these inspections in federal fiscal year 2007. The text box provides additional information about accreditation organizations and the CLIA Section.

Because examiners in the CLIA Section are partly state funded and federal and state clinical laboratory requirements are similar, we expected to find that the section's inspections included some state oversight that might mitigate Laboratory Services' failure to perform state inspections. During its inspections, the CLIA Section reviews some areas of concern to the State, including whether a laboratory has a state license, is enrolled in proficiency testing, and has ensured that all personnel have the required state licenses. However, the CLIA Section chief stated her staff, according to CMS direction, cannot include state issues on the form used to report laboratory deficiencies. Although the CLIA Section shares some information with Laboratory Services, such as when it gives a laboratory an application for state licensure, the CLIA Section chief stated that the section does not routinely share the results of its inspections with Laboratory Services.

By sharing information it gathers from inspections, the CLIA Section could help mitigate Laboratory Services' failure to conduct inspections every two years for state purposes. For example, if the CLIA Section routinely notified Laboratory Services of identified deficiencies related to state requirements, Laboratory Services could follow up and ultimately sanction laboratories. Further, having the CLIA Section communicate relevant deficiencies to Laboratory Services is consistent with the CLIA Section being partly state funded.

Accreditation Organizations and Contracting Could Provide Laboratory Services With Additional Leveraging Opportunities

Laboratory accreditation and contracting are two other means for Laboratory Services to compensate for its lack of regular inspections. By state law Laboratory Services must deem laboratories to have met state licensure or registration requirements if a state or federally approved organization has accredited those laboratories. To obtain state approval, the accreditation organization must demonstrate to Laboratory Services that it has standards equal to or more stringent than state requirements for licensure and registration. The organization also must agree to allow Laboratory Services to inspect accredited laboratories randomly to validate compliance with state law. CMS has approved the use of accreditation organizations for federal purposes. About half of the laboratories in California performing moderate-to-high-complexity tests are accredited and not subject to routine federal inspections. Instead, to assess the effectiveness of the accreditation organizations' oversight, the CLIA Section conducts a relatively small number of inspections of accredited laboratories each year; it reported 36 in federal fiscal year 2007.

By sharing information it gathers from inspections, the CLIA Section could help mitigate Laboratory Services' failure to conduct inspections every two years for state purposes.

By making greater use of accreditation organizations, Laboratory Services could reduce the number of regular inspections it would need to conduct, as the federal government has done through its state agents.

The State has not approved any accreditation organizations. According to the Laboratory Services chief, accreditation organizations have a national focus and do not ensure compliance with state law. Further, in a 2006 memo the Laboratory Services chief expressed concern over the quality of the inspections conducted by the accreditation organizations. Laboratory Services also cited a 2006 study by the U.S. Government Accountability Office that found weaknesses in some accreditation organizations' oversight of clinical laboratories. Because Laboratory Services would need to approve accreditation organizations and monitor their compliance with state law, Laboratory Services may have the tools to address its own concerns. Laboratory Services also told us that it asked accreditation organizations a few years ago to apply to become authorized state laboratory inspectors but did not receive any formal applications. Low interest in the past should not preclude Laboratory Services from exploring additional ways to create a program for accreditation organizations and encourage participation. By making greater use of accreditation organizations, Laboratory Services could reduce the number of regular inspections it would need to conduct, as CMS has done through its state agents.

Finally, Laboratory Services has the authority to contract some of its duties. State law allows Laboratory Services to contract for inspectors, special agents, and investigators. According to the chief, Laboratory Services has had trouble recruiting qualified staff to fill vacant positions and has had difficulty obtaining the number of examiners necessary to conduct inspections every two years. Contracting for some duties could give Laboratory Services more flexibility in staffing its inspection and investigation functions than if it were to focus solely on hiring new examiners.

Although It Could Be Improved, Laboratory Services' Division of Responsibilities for Proficiency-Testing Reviews Is an Example of Leveraging

The way Laboratory Services delegates responsibilities for proficiency-testing reviews among its staff and that of the CLIA Section, although subject to improvement, provides an example of how Laboratory Services might leverage its resources. Currently, the CLIA Section reviews proficiency-testing results for nonaccredited laboratories, or about half of the laboratories conducting moderate-to-high-complexity tests in California. Laboratory Services reviews the remainder. This division of duties began in 2006 at the direction of CMS, which reportedly was concerned about how long Laboratory Services was taking to review proficiency-testing results.

The delegation process could be improved. When the CLIA Section sends enforcement recommendations to CMS, as federal procedures require, it also could forward the case to Laboratory Services

for review and potential sanctioning. Because federal and state proficiency-testing requirements are the same, the State also could exercise its sanction authority against laboratories that do not comply.

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 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. When we shared with Public Health our basis for concluding that the fee adjustments were incorrect, a member of Public Health’s legal staff told us she was not aware of any other statutory or regulatory provisions for fee adjustments.

As Table 2 shows, Laboratory Services failed to collect more than \$1 million from clinical laboratories from fiscal years 2003–04 through 2007–08. However, it should be noted that even if Laboratory Services had collected the additional funds, that revenue would not be available for Laboratory Services to spend unless the corresponding spending authority was approved through the annual budget process.

Table 2
Results of Miscalculating Fee Adjustments for
Fiscal Years 2003–04 Through 2007–08

FISCAL YEAR	TOTAL CLINICAL LABORATORY FEES COLLECTED	AUTHORIZED PERCENTAGE FEE INCREASE	ACTUAL PERCENTAGE FEE INCREASE	NET AMOUNT (OVER) OR UNDERCOLLECTED*
2003–04	\$1,564,863	0%	1.51%	(\$23,278)
2004–05	1,940,685	0	0	(28,868)
2005–06	2,139,511	0	0	(31,826)
2006–07	2,222,250	22.50	0	459,512
2007–08†	2,157,079	7.61	0	644,133
Total				\$1,019,673

Source: Bureau of State Audits’ analysis based on Laboratory Field Services’ revenue reports and annual budget acts.

* See the Scope and Methodology for an explanation of how we derived this column.

† Revenue through May 2008.

Laboratory Services relied on an incorrect provision of the budget act in calculating its fees. Specifically, effective July 1 of fiscal year 2003–04, Laboratory Services erroneously increased its fees by 1.51 percent because it applied the wrong provision of the department’s budget act appropriation. Additionally, for at least one of the fiscal years (2007–08) in which a fee increase was authorized, we found evidence of communication from the budget section within Public Health directing Laboratory Services not to raise its fees. However, the communication between the budget section and Laboratory Services cited the wrong provision of the budget act.

The Laboratory Services chief said she was responsible for calculating clinical laboratory fee changes, and she said it was very difficult to find the appropriate section of the budget act. At times she verified with the budget section within Public Health, or its predecessor the Department of Health Services, that Laboratory Services could or could not change its fees, but as described earlier, we noted at least one instance in which the budget section referred to an incorrect budget act provision. Laboratory Services used to have an analyst with responsibility for calculating fees but it lost that position, according to the Laboratory Services chief.

Recommendations

Public Health, in conjunction with Laboratory Services, should ensure that Laboratory Services has sufficient resources to meet all its oversight responsibilities.

Laboratory Services should 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.

To demonstrate that it has used existing resources strategically and has maximized their utility to the extent possible, Laboratory Services should identify and 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.

Laboratory Services should work with Public Health’s budget section and other appropriate parties to ensure that it adjusts fees in accordance with the budget act.

We conducted this review under the authority vested in the California State Auditor by Section 8543 et seq. of the California Government Code and according to generally accepted government auditing standards. We limited our review to those areas specified in the audit scope section of the report.

Respectfully submitted,



ELAINE M. HOWLE, CPA
State Auditor

Date: September 4, 2008

Staff: Karen L. McKenna, CPA, Audit Principal
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For questions regarding the contents of this report, please contact Margarita Fernández, Chief of Public Affairs, at (916) 445-0255.

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(Agency response provided as text only.)

California Department of Public Health
MS 0500, P.O. Box 997377
Sacramento, CA 95899-7377

August 19, 2008

Elaine M. Howle, State Auditor
Bureau of State Audits
555 Capitol Mall, Suite 300
Sacramento, CA 95814

Dear Ms. Howle:

The California Department of Public Health (CDPH) has prepared its response to Bureau of State Audits (BSA) draft report entitled, "Department of Public Health: Laboratory Field Services' Lack of Clinical Laboratory Oversight Places the Public at Risk." Please find the CDPH response to reported findings and recommendations enclosed. The CDPH appreciates the opportunity to provide the BSA with its response to the draft report.

Please contact Kathleen Billingsley, Deputy Director, Licensing and Certification, at (916) 440-7360 if you have any questions.

Sincerely,

(Signed by: Bonita J. Sorensen for)

Mark Horton, M.D. M.S.P.H.
Director

Enclosure

California Department of Public Health's Response to the
Bureau of State Audits' Draft Report Entitled:
Laboratory Field Services' Lack of Clinical Laboratory Oversight
Places the Public at Risk
September 2008
2007-040

Recommendation

Laboratory Services should perform all its mandated oversight responsibilities for laboratories subject to its jurisdiction operating within and outside California.

Response

The California Department of Public Health (CDPH) concurs with this recommendation and will take the necessary steps to ensure Laboratory Services is able to perform all of its mandated activities. Laboratory Services is assessing its workload needs and identifying additional resources to build the program. This is necessary to ensure its mission to provide oversight for clinical and public health laboratory operations and laboratory personnel is met.

California state law requires that each of the licensed clinical laboratories be subject to an initial onsite inspection, biennial inspections, proficiency testing enforcement and complaint investigations. Licensing laboratories is a state mandated and controlled function assuring that laboratories that provide services in California meet acceptable standards regarding scope of services, qualifications and training of staff, the physical layout and condition of laboratories, and systems governing the appropriateness and quality of the services provided.

Current staffing resources are not sufficient to conduct state mandated workload related to licensure and registration of these laboratories, and workload associated with biennial inspections, complaint investigations, proficiency testing oversight and enforcement actions in the clinical laboratories in California and out-of-state laboratories. In addition, state statutes and mandated activities have continued to expand, imposing significant workload on the program.

Laboratory Services will take steps that will include the maximum use of existing resources as well as an assessment to determine how many additional resources are needed. As required resources are added to the program, licensing fees will likely be increased to cover the costs. The steps that we will take are identified below.

Recommendation

- Inspecting licensed laboratories every two years.

Response

The CDPH concurs with the audit findings that Laboratory Services should inspect licensed laboratories every two years. As such, Laboratory Services will explore the use of contracting with accrediting organization inspectors, such as the College of American Pathologists, Joint Commission, AABB (formerly known as American Association of Blood Banks), American Osteopathic Association, American Society for Histocompatibility and Immunogenetics and COLA to conduct biennial inspections. These accrediting organizations will be contracted to conduct biennial inspections for compliance with state law in coordination with already scheduled federal accreditation inspections. In addition, Laboratory Services will continue to evaluate all workload and program activities and identify the need for additional resources as necessary.

Recommendation

- Monitoring proficiency testing results.

Response

The CDPH concurs that Laboratory Services should monitor proficiency testing results. At this time, Laboratory Services electronically monitors accredited laboratories for proficiency testing results. The Clinical Laboratory Improvement Amendment (CLIA) program monitors non-accredited laboratories for proficiency testing results and routinely conducts onsite surveys. Laboratory Services will utilize existing resources to modify the policy and procedures for proficiency testing to include timelines for key steps in the review process and follow-up with those laboratories that demonstrate unsuccessful testing performance.

Recommendation

- Reviewing and investigating complaints and ensuring necessary resolution.

Response

The CDPH concurs with the audit findings that Laboratory Services should review and investigate complaints to ensure necessary resolution. Laboratory Services is implementing a systematic approach that prioritizes complaints based on the potential for public health risk. Specifically, the system will include criteria for data integrity and monitoring complaint resolution, and will apply the same criteria to the current investigations backlog. Complaints with potential patient harm will be given highest priority for onsite inspections; while complaints involving lower risk (i.e. failure to report infectious disease results to the county health officer, lack of supervision for 2nd shift testing) will undergo a desk review which entails an offsite review of documents provided by the laboratory. If, after desk review, Laboratory Services assesses these complaints as a public health risk, the complaints will be reassigned accordingly and addressed as appropriate.

Additionally, Laboratory Services will require resources to develop a centralized public complaint processing system including enhanced internet access to initiate complaints, and to allow more stringent monitoring and tracking of complaint resolution.

Recommendation

- Sanctioning laboratories as appropriate.

Response

The CDPH concurs with the audit findings that Laboratory Services should sanction laboratories as appropriate. Laboratory Services is developing standardized policies and procedures on laboratory sanctions that will include consistency in the documentation, assessment, calculation and collection of civil monetary penalties. Laboratory Services will train staff in the development and issuance of sanctions in coordination with legal staff. These efforts will likely increase the number of sanctions issued.

In addition, Laboratory Services will work to improve its data collection efforts and that the information is standardized to reduce duplication efforts, decrease data integrity errors, ensure consistency throughout the data collection process, incorporate appropriate triggers for action, and enhance management report capability. In its assessment of program and workload needs, Laboratory Services will evaluate the need to enhance its the database tracking system that would include workload tracking, investigation status monitoring, clinic sanctions, revocations, suspensions, and alternative sanctions including onsite monitoring, and other related activities.

With existing resources, Laboratory Services will implement a quality assurance program initially focusing on terminated laboratories who have failed to renew or pay their fees on time. Laboratory Services will identify a random sample of terminated labs each month and verify that all agencies have been notified of the termination and the information has been documented in the system. This quality assurance program will ensure that Laboratory Services accurately identifies and enters into the database terminated laboratories.

Moreover, Laboratory Services will improve its documentation of cases that are referred to the Department of Health Care Services, federal Centers for Medicaid Services for Medicare, and other governmental agencies.

Recommendation

Laboratory Services should adopt and implement proficiency testing policies and procedures.

Response

The CDPH concurs with this recommendation. Within the constraints of existing resources, Laboratory Services will update current proficiency testing policy and procedures to incorporate federal timelines and implement education programs to train staff on these new requirements.

Recommendation

- Promptly review laboratories proficiency testing results and notify laboratories that fail.

Response

The CDPH concurs with the audit findings that Laboratory Services should promptly review laboratories proficiency testing results and notify laboratories that exhibit unsuccessful performance measures. To this end, Laboratory Services will review proficiency testing results monthly, promptly notify laboratories that fail to meet performance standards and require a plan of correction within the specified timeframe. In addition, in its assessment of program and workload needs, Laboratory Services will evaluate its ability to track the plans of correction and appropriate enforcement actions and identify the need for additional resources as necessary.

Recommendation

- Follow specified timelines for responding to laboratory's attempts to correct proficiency testing failures and for sanctioning laboratories that do not comply.

Response

The CDPH concurs with the audit findings that Laboratory Services should follow specified timelines for responding to a laboratory's attempts to correct proficiency testing failures and for sanctioning laboratories that do not comply. With existing resources, Laboratory Services will develop policies and procedures that conform to the federal timeline for correction of unsuccessful proficiency testing performance and develop standardized procedures for laboratory sanctions. This effort will likely increase the number of sanctions issued and allow Laboratory Services to consistently sanction laboratories that do not comply.

Recommendation

- Monitor the proficiency testing results of out-of-state laboratories.

Response

The CDPH concurs with the audit findings that Laboratory Services should monitor the proficiency testing results of out-of-state laboratories. With existing resources, Laboratory Services will initiate a pilot project that will test the ability to electronically monitor proficiency testing performance for out-of-state laboratories. We would obtain a listing of CLIA certificate numbers for each of the California licensed out-of-state labs and attempt to query the federal database for electronic proficiency testing results.

In its assessment of program and workload needs, Laboratory Services will evaluate, its ability to enforce proficiency testing failure, review of the plan of correction and monitor follow-up performance. In addition, Laboratory Services will consider contracting with accrediting organizations to perform out-of-state laboratory proficiency testing in coordination with regularly scheduled laboratory visits.

Recommendation

- Verify laboratories' enrollment in proficiency testing and ensure that Laboratory Services receives proficiency testing scores from all enrolled laboratories.

Response

The CDPH concurs with the audit findings that Laboratory Services should verify laboratories' enrollment in proficiency testing and ensure that Laboratory Services receives proficiency testing scores from all enrolled laboratories. Within existing resources, Laboratory Services will reevaluate the current process and develop a pilot project to determine the feasibility of matching Health Application Licensing System (HALs) licensing data with the electronic enrollment data received from proficiency testing providers. Ongoing monthly reviews of electronic transmission of proficiency testing scores for all California enrolled laboratories will be conducted.

Recommendation

To update its regulations, Laboratory Services should review its clinical laboratory regulations and repeal or revise them as necessary. As part of its efforts to revise regulations, Laboratory Services should ensure that the regulations include requirements such as the timeframes that Laboratory Services wants to impose on the laboratory community.

Response

The CDPH concurs with the audit findings that Laboratory Services needs to update its regulations. Laboratory Services has initiated a repeal of Title 17 CCR Section 1050 using input from the Clinical Laboratory Technology Advisory Committee (CLTAC). This action will eliminate inconsistencies in state law relating to the definition of unsuccessful proficiency testing. In addition, Laboratory Services has two other regulation packages under development to amend outdated regulations, including HIV laboratory approval and personnel licensing standards. These regulation packages will also incorporate input from the CLTAC.

Recommendation

Laboratory Services should 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.

Response

The CDPH concurs with the audit findings that Laboratory Services should continue its efforts to fully license California and out-of-state clinical laboratories performing tests on specimens originating from California. In May 2008, Laboratory Services initiated a process to identify and contact laboratories requiring licensure. Laboratory Services will reprioritize existing workload to increase laboratory licensure within California. In its assessment of program and workload needs, Laboratory Services will evaluate the resources needed to expand the initial licensure of out-of-state laboratories.

Recommendation

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, reviewing, logging, tracking, and prioritizing complaints, as well as ensuring that substantiated allegations are corrected. In addition, Laboratory Services should subsequently develop and implement corresponding procedures for each control. Further, Laboratory Services should establish procedures to ensure it promptly forwards complaints it lacks jurisdiction over to the entity having jurisdiction.

Response

The CDPH concurs with the audit findings that Laboratory Services should strengthen the complaint process by implementing controls and procedures. Laboratory Services is working to improve the tracking of complaints by implementing a systematic approach. Specifically, the system will prioritize complaints based on the potential for public health risk and include criteria for data integrity and monitoring complaint resolution, and apply these criteria to the investigations backlog. In addition, complaints for potential patient harm will be given highest priority for onsite inspections. Complaints involving lower risk of patient harm will undergo a desk review which is an offsite review of documents provided by the laboratory. If, after desk review, these complaints are assessed as a public health risk, Laboratory Services will respond accordingly. With the significant volume of complaints, additional resources will likely be needed to investigate complaints and follow up to ensure all substantiated allegations have been corrected.

In addition, Laboratory Services will implement a process to document and forward complaint information promptly to other entities with jurisdiction over non-laboratory complaints.

Recommendation

To strengthen its sanctioning efforts, Laboratory Services should maximize its opportunities to impose sanctions.

Response

The CDPH concurs with the audit findings that Laboratory Services should maximize its opportunities to impose sanctions. In April 2008, Laboratory Services trained staff to recognize and document areas of non-compliance and maximize sanctions. To move this effort forward, Laboratory Services will use existing resources to develop standardized procedures to effectively transmit non-compliance to the staff responsible for enforcement by monthly monitoring of proficiency testing results. In its assessment of program and workload needs, Laboratory Services will evaluate its ability to maximize the enforcement of unsuccessful proficiency testing performance.

Laboratory Services will also enhance communication with accrediting organizations to identify areas of non-compliance. If contracting with accrediting organization inspectors is successful, findings of non-compliance and increased referrals for sanctions will occur.

Recommendation

- Appropriately justify and document the amounts of the civil money penalties it imposes.

Response

The CDPH concurs with the audit findings that Laboratory Services should strengthen its sanctioning efforts by appropriately justifying and documenting the amounts of the civil money penalties it imposes. Within existing resources, Laboratory Services will develop standardized policies and procedures for imposing laboratory sanctions. These policies and procedures will focus on developing consistency in documentation, assessment, calculation and collection of civil monetary penalties. Laboratory Services will then train existing staff to ensure there is consistent application and documentation of civil money penalties imposed.

Recommendation

- Ensure that it always collects the civil money penalties it imposes.

Response

The CDPH concurs with the audit findings that Laboratory Services collects the civil money penalties it imposes. Within existing resources, policies and procedures will be developed and staff will be trained to ensure that penalties are collected and the sanction tracking database is documented in a timely manner. Laboratory Services has an existing database that tracks imposition and collection of civil money penalties. Laboratory Services will review this database to ensure that programming errors are addressed and sufficient controls are in place to provide accurate, effective management reports. If modifications to the database are needed, additional resources may be necessary.

Recommendation

- Perform follow-up measures to ensure that laboratories take necessary corrective action.

Response

The CDPH concurs with the audit findings that Laboratory Services should perform follow-up measures to ensure that laboratories take necessary corrective action. With its current resources, Laboratory Services is unable to perform follow-up on site inspections to substantiate that correction of deficiencies has occurred. In its assessment of program and workload needs, Laboratory Services will evaluate its ability to implement quality assurance measures for management to verify that laboratories have taken the appropriate corrective action.

Recommendation

- Ensure that when it sanctions a laboratory it notifies other appropriate agencies as necessary.

Response

The CDPH concurs with the audit findings that Laboratory Services should notify other appropriate agencies as necessary when a laboratory is sanctioned. Laboratory Services has routinely referred sanction actions to other agencies such as Medi-Cal, the California Medical Board, and the Center for Medicare & Medicaid Services. However, Laboratory Services lacks a mechanism to document this action. Within existing resources, Laboratory Services will revise the policies and procedures for laboratory sanctions to include a standardized process that will improve the documentation of cases referred to other governmental agencies.

Recommendation

Public Health, in conjunction with Laboratory Services, should ensure that Laboratory Services has sufficient resources to meet all its oversight responsibilities.

Response

The CDPH concurs with the audit findings that Laboratory Services should ensure that Laboratory Services has sufficient resources to meet all its oversight responsibilities. Laboratory Services will continue to evaluate the workload and program aspects to identify additional resources needed to meet its mandated workload while examining its current processes to ensure the existing resources are fully utilized. In the interim, Laboratory Services will explore contracting out with accrediting organizations to provide on-site inspections.

Additionally, Laboratory Services will enhance its recruitment efforts to obtain qualified candidates to fill existing vacancies and obtain approvals for competitive salaries. This effort will include the offering of continuous testing for the Examiner positions as well as advertising to professional organizations, CLTAC and internet sources.

Recommendation

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

Response

CDPH concurs with the audit findings that Laboratory Services should work with our Information Technology Services Division to ensure that its data systems appropriately support its needs. Laboratory Services has been working closely with ITSD to maximize the support given to HALs and is working to improve the management of HALs.

The CDPH concurs with the audit finding that as Laboratory Services continues to use its internally developed databases, it should ensure that it develops and implements appropriate system controls. Laboratory Services will identify those areas of critical control needs and prioritize the phasing in of system improvements of internal databases, including the ability to generate management reports. In its assessment of program and workload needs, Laboratory Services will evaluate the need for additional resources for system modifications.

Recommendation

To demonstrate that it has used existing resources strategically and has maximized their utility to the extent possible, Laboratory Services should identify and 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 biennial inspections.

Response

The CDPH concurs with the audit findings that Laboratory Services should use its existing resources to the fullest extent possible, including exercising its clinical laboratory oversight when renewing licenses and registrations. Laboratory Services is convening a workgroup of existing staff to explore opportunities to maximize utility and augment process efficiency.

Utilizing current resources, Laboratory Services will implement a quality assurance process to randomly verify license renewal data, including testing personnel licensure, supervisor and lab director qualifications, and previous enforcement actions. This will provide documentation that the laboratories are in compliance with state laboratory personnel requirements. In addition, Laboratory Services will explore the use of accrediting organization inspectors or contract inspectors to conduct inspections for compliance with state law.

As the state agency for the federal CLIA program, Laboratory Services will establish policies and procedures to require concurrent federal CLIA and state surveys are conducted simultaneously. Laboratory Services will utilize the state match associated with the federal workload to conduct concurrent survey workload when appropriate.

As state deficiencies are reported to Laboratory Services for enforcement action, additional resources will be needed to provide enforcement and oversight in addressing state compliance issues.

Recommendation

Laboratory Services should work with Public Health's budget section and other appropriate parties to ensure that it adjusts fees in accordance with the Budget Act.

Response

The CDPH concurs that Laboratory Services should work with the Administration Division and other appropriate parties to ensure that fees are adjusted in accordance with the Budget Act. Additionally, Laboratory Services shall develop and implement a process to be followed upon annual enactment of the Governors Budget to ensure fees are adjusted appropriately.

cc: Members of the Legislature
Office of the Lieutenant Governor
Milton Marks Commission on California State
Government Organization and Economy
Department of Finance
Attorney General
State Controller
State Treasurer
Legislative Analyst
Senate Office of Research
California Research Bureau
Capitol Press