



CALIFORNIA STATE AUDITOR

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FACT SHEET

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Report: 2007-040

The California State Auditor released the following report today:

Department of Public Health

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

BACKGROUND

Clinical laboratories analyze human specimens such as blood, tissue, and urine so medical professionals can make diagnoses and prescribe treatment. The Department of Public Health's Laboratory Field Services (Laboratory Services) is responsible for licensing, registering, and overseeing these clinical laboratories. Laboratory Services is required to inspect licensed laboratories, monitor proficiency testing, investigate complaints it receives against laboratories, and sanction laboratories that fail to correct deficiencies. To cover the cost of carrying out these responsibilities, Laboratory Services collects fees from the laboratories it oversees.

KEY FINDINGS

Our review of Laboratory Services' oversight of clinical laboratories revealed the following:

- Although it is required to inspect both in-state and out-of-state clinical laboratories that accept specimens originating inside the State every two years, it has not done so nor does it plan to conduct such inspections unless it receives additional resources. As of June 2007 Laboratory Services had not inspected 1,970 licensed laboratories that it should have nor had it inspected 91 out-of-state laboratories either when originally licensed or subsequently.
- It has inadequate policies and procedures and outdated regulations regarding proficiency testing—an external evaluation to verify the accuracy and reliability of laboratories' test results for those laboratories performing moderate-to-high-complexity tests.
- Laboratory Services' policies and procedures lack key controls to promptly log, prioritize, track, and investigate complaints it receives. It had a backlog of complaints and closed many of them without taking action.
- It has imposed few sanctions in recent years. Moreover, because it lacks an effective tracking mechanism, it could not identify the total number and types of sanctions it did impose.
- Information technology resources do not support all Laboratory Services' needs or supply complete and accurate management data related to the work it performs, further hindering it from meeting its mandated responsibilities. Its internal databases that support its enforcement activities contain some illogical, incomplete, or incorrect data that could not be used to effectively track activities or make sound decisions.
- It could use its existing resources more strategically and maximally by exercising more oversight when it renews licenses and registrations such as verifying that laboratory personnel have required licenses during the renewal process. Further, it has not taken advantage of its authority to approve accreditation organizations that can provide laboratory oversight or contract some of its inspection and investigations responsibilities.
- It incorrectly adjusted the fees it charges to laboratories, resulting in more than \$1 million in lost revenue.

KEY RECOMMENDATIONS

We made many recommendations to Laboratory Services including that it ensure it performs all its mandated oversight responsibilities regarding inspecting laboratories, monitoring testing results, and reviewing and investigating complaints. We also identified areas where Laboratory Services could use existing resources more strategically and maximize their utility, and we recommended that it identify and explore opportunities to leverage existing processes and procedures. Moreover, we recommended that Laboratory Services ensure that its data systems support its needs.

