

The California State Auditor released the following report today:

Follow-Up: California Department of Public Health

Laboratory Field Services Is Unable to Oversee Clinical Laboratories Effectively, but a Feasible Alternative Exists

BACKGROUND

Clinical laboratories (labs) 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 labs. Laboratory Services is required to inspect licensed labs and verify the reliability and accuracy of their tests through a process known as *proficiency testing*. It also investigates complaints it receives against licensed or registered labs and can sanction labs that fail to correct deficiencies. To cover the cost of carrying out these responsibilities, Laboratory Services collects fees from the labs it oversees. In September 2008 we issued results on our audit of Laboratory Services' oversight of labs and made numerous recommendations.

KEY FINDINGS

During our follow-up audit of Laboratory Services' progress in addressing certain issues raised in our 2008 audit, we noted the following:

- Laboratory Services continues to inadequately oversee labs.
 - ✓ It is not performing recurring inspections of labs—in 2013 and 2014, it only inspected about half of the labs requiring biennial inspections.
 - ✓ Although 16 percent of the licensed labs are out-of-state and are required to participate in proficiency testing, Laboratory Services still does not promptly review these test results despite our recommendation made seven years ago.
 - ✓ It does not always investigate complaints timely and has only imposed four facility-related sanctions since 2008.
- Laboratory Services also has not responded to recommendations we made seven years ago regarding managing its resources and thus, it continues to inadequately manage the program.
 - ✓ It has overcharged labs more than \$1 million since January 2014 and continues to charge incorrect fees.
 - ✓ From fiscal years 2008–09 through 2013–14, it collected \$12.6 million more in revenue from license and registration fees than it needed for the level of oversight it provided.
 - ✓ Laboratory Services faces significant staffing challenges and has failed to plan for retirements through succession planning.
 - ✓ Despite staffing issues, it has not taken advantage of accreditation organizations to help it fulfill some of its duties.
- Laboratory Services has not updated or substantially improved its information technology systems to adequately support its activities—the problematic conditions that we identified in our 2008 audit were generally unchanged.
- The State's requirements for oversight of labs largely duplicate mandates at the federal level and thus, we question whether a separate state approach is needed. Further, there are processes in place at the federal level that ensure federal mandates are effectively administered.

KEY RECOMMENDATIONS

We recommended that the Legislature eliminate the State's redundant and ineffective oversight of labs and ensure labs do not pay unnecessary or duplicative fees by repealing existing requirements that labs receive state-issued licenses or registrations.

Until State law is changed, Laboratory Services should develop a corrective action plan that identifies resource needs and time frames for implementing the recommendations from our 2008 audit, including that it:

- Inspect labs every two years and timely identify all labs that fail proficiency testing.
- Improve its complaints policy and procedures and dedicate sufficient staff to its sanctioning efforts.
- Develop a process to annually adjust its fees and maximize opportunities to partner with accreditation organizations.