

## Legislative Auditor

# OVERVIEW

## SUNSET EVALUATION REPORT: REGULATION OF CLINICAL LABORATORY PERSONNEL

Honolulu, Hawaii

December 1989

### Summary

Clinical laboratories employ a range of professional and technical personnel--from laboratory directors to technologists and technicians--whose job it is to examine substances of the human body and report their findings to physicians. Physicians use this information to diagnose, treat, and prevent diseases and disabilities.

Because of the importance of this field of work, many private agencies certify clinical laboratory personnel. Some, such as the National Registry of Microbiologists, focus on a particular type of worker. Others, such as the American Medical Technologists, certify a variety of laboratory workers and promote their interests. In addition, federal and state laws and rules govern their practice in many ways. Congress recently enacted the Clinical Laboratory Improvement Amendments of 1988, which significantly strengthened the standards and regulatory requirements for clinical laboratories.

There is little uniformity in the way different states regulate these personnel. Hawaii is one of only five states that license clinical laboratory directors and technical personnel. The Laboratories Branch of the Department of Health administers the program.

As required by the Sunset Law, the auditor reviewed the need to regulate the practices of these workers. Clinical laboratory practice was found to be potentially harmful. Inaccurate tests can mask serious illnesses, lead to unnecessary treatment, and result in death, disability, stress, and financial ruin. However, the best way to protect the public is to license the laboratories, not the many types of workers. Standards can then be set for key technical personnel working in these facilities. This approach can avoid the inefficiencies and problems of the current program.

### FINDINGS

*Because of the potential for harm, clinical laboratory practice needs to be regulated. However, licensing all personnel is ineffective, difficult to enforce, expensive, and redundant. It is difficult to define the scope of practice and standard of training for each of the many specialties in the field. Licensing of personnel can limit the supply of professionals, keep laboratories from responding to changing demands, and lead to higher costs.*

*Clinical laboratory testing is a process that must be effective in its entirety. Licensing of laboratories is the best way to protect the public against inaccurate and unreliable test results. It encompasses the entire testing process and avoids the pitfalls of licensing individual laboratory workers.*

*The licensing program faces some serious problems. The statutes are too vague to support a licensing*

*effort, and the rules are outdated and inappropriate. The administration of the program has been unsystematic, often characterized by arbitrary decisions and inadequate documentation.*

### RECOMMENDATIONS

*The Legislature should remove the regulation of laboratory personnel from the statutes. The best way to protect the public is to license clinical laboratories and to set standards for key personnel in these facilities.*

*The Department of Health should discontinue the current program that licenses laboratory personnel. It should revise the rules on clinical laboratories to conform with and complement the federal Clinical Laboratory Improvement Amendments of 1988. This new law establishes a mandatory certification (licensing) program for all clinical*

*laboratories in the United States. It requires labs to meet federal standards that include personnel standards, undergo periodic inspections, and participate in proficiency testing programs.*

### RESPONSE

*The Department of Health disagrees with the recommendation to discontinue licensing clinical laboratory personnel. It feels regulation is needed to prevent unqualified persons from practicing. We continue to maintain that the public can be best protected by federal and state licensing of laboratories.*

*The department plans to remedy the limitations in the current regulatory program by adopting new rules and studying a bill to establish a licensing board. We do not believe these approaches are sufficient.*