

Alaska State Legislature

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Senator Bettye Davis

SB 67 26-LS0270\E

"An Act relating to the licensing of clinical laboratory science professionals; and providing for an effective date."

SPONSOR STATEMENT

SB 67 establishes a volunteer Advisory Board of Clinical Laboratory Science Professionals to assist the Department of Commerce, Community and Economic Development in the licensing, regulation, and discipline of the hundreds of laboratory science professionals in Alaska. The five-member board will be appointed by the governor to three-year staggered terms. One shall be a public member and four will be licensed clinical laboratory science professionals. The license is valid for three years unless it is relinquished, suspended, or revoked. SB 67 is applicable to all new persons employed in the field in Alaska; and two years after the effective date of this Act to all persons employed in the field within the five years immediately preceding the effective date of this act - thus effectively granting a grace period for compliance by current employees. SB 67 does not impose mandatory continuing education unless required in continuing certification by the credentialing agency.

SB 67 requires licensing of clinical laboratory science professionals and certification and participation in certification maintenance programs for licensure and renewal. This will ensure that qualified professional are performing diagnostic testing while controlling the cost of licensure. Multiple credentialing agencies that certify clinical laboratory science professional have established education and training requirement for the clinical laboratory science professionals. The applicant submits documentation of the required education and training in order to sit for the competency based certification exam. Credentialing agencies require documentation of continuing competency for recertification every three years.

Licensure will ensure only qualified professionals perform diagnostic testing in protection of the public. Most health care professions are licensed in Alaska. Clinical laboratory science professionals and radiologic technologists are not currently licensed by the State, yet they perform the majority of diagnostic testing in Alaska. Over 70% of all medical decisions are based on diagnostic testing. Inaccurate test results by unqualified technicians can delay appropriate care, lead to inappropriate or harmful diagnoses or treatments that could result in injury or death. The complexity and importance of laboratory science in modern medicine makes it imperative that medical laboratory personnel possess the qualifications necessary to ensure their professional competence.

Wage and vacancy surveys comparing states with and without licensure do not bear out critics fears that licensure of laboratory personnel will increase shortages and raise wages when health care costs are constantly escalating. There is currently a shortage of most health care professionals. This in itself has more effect on increasing wages than licensure and certification. Conversely, it may be argued that if jobs pay more, more people will be drawn into the field to reduce shortages.

Clinical laboratory science professionals are licensed or certified in 13 states and Puerto Rico. These states are CA, FL, GA, HI, LA, MT, NV, NY, ND, OR, RI, TN, WV. There are some differences in licensure among states. Certification is a less restrictive form of occupational regulation than licensure. Some states require mandatory continuing education. New York State passed legislation in 2005 after 20 years of “being on the table,” requiring licensure or certification of an estimated 30,000 clinical laboratory technologists (CLT), cytotechnologists (CT), and clinical laboratory technicians (CLTN).

Concerns of increased laboratory testing in the United States supports licensing and certification. The Centers for Medicare and Medicaid Service (CMS) regulates all laboratory testing except research on humans through the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) warned of growing inadequacy of training and lack of qualified laboratory personnel by JCAHO President, Dr. Dennis O’Leary, in an address before the House of Representatives in 2006. Commenting on the June, 2006 Government Accountability Office (GAO) study, “*Clinical Lab Quality: CMS and survey organization oversight should be strengthened,*” Dr. O’Leary stated:

“The Joint Commission believes that personnel standards currently required by CLIA are insufficient to adequately protect patients and public health. For example, CLIA requires only an Associate Degree and minimal laboratory training to perform tests of high complexity, and lacks personnel requirements for waived tests which account for 81 percent of the testing that takes place in the nation’s laboratories. . . .Today, the problems underlying failures in laboratory performance most commonly cited by experts in the field are the growing shortage of laboratory technologists and the inadequacy of their training. These shortcomings become especially glaring in the face of the expanding array and increasing complexity of laboratory tests in hospitals.”

Waived tests under CLIA are simple, low-risk tests which can be performed with no routine regulatory oversight in physicians’ offices and various other locations. The increase in numbers of waived tests has increased dramatically as laboratory testing technology continues to evolve. Since CLIA was implemented, waived testing has steadily increased in the United States. Advances in technology have made formerly complex tests much simpler, such as tests for cholesterol, and glucose. Many tests can now be performed using compact or hand-held devices by personnel with limited experience and training. CLIA Certificates of Waiver test sites may perform fewer than 2,000 tests per year in physicians’ offices to millions per year in hospitals.

Waiver test sites generally take measures to test correctly, but quality concerns have been raised by CMS and Centers for Disease Control due to high personnel turnover rates, lack of understanding about good laboratory practices, and inadequate training. (DHHS, Morbidity and Mortality weekly Report, November 11, 2005/Vol.54/No.RR-13). SB 67 will help protect patients undergoing laboratory tests in Alaska, whether complex, or waived. Moreover, licensure under SB 67 will provide for the first time mandatory credentials and standards of competence which will assist employers in screening and hiring clinical laboratory science professionals.