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California law limits the direction of **full service** Clinical Laboratories to just two professional groups: Physicians and Clinical Laboratory Bioanalysts.

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## **THE PAST:**

The profession of Medical Technology was created in California with the passage of the Clinical Laboratory Act in 1937. That law created two levels of clinical laboratory professionals: Clinical Laboratory Technicians and Clinical Laboratory Technologists. In the 1950's the names were changed, Technicians became Technologists and Technologists became Bioanalysts.

The Technologists name has recently been changed to Clinical Laboratory Scientist. In the 1960's an earned master's degree in a biological science was added as a requirement for Bioanalyst licensing.

State law requires bioanalyst candidates, through written and oral examinations to demonstrate knowledge and competence in the clinical laboratory field. In contrast, any M.D. regardless of competence as a laboratorian is, under the statutes, qualified to direct a clinical laboratory. Medicare regulations place some limitations on all Clinical Laboratory directors except for Clinical Pathologists and "Grandfathered" Bioanalysts. Finally, in 1987, a state law was passed which requires that hospital laboratories must be, with rare exception, directed by Pathologists.

California Bioanalyst's have a long and distinguished history beginning before there was an identified laboratory profession, when the powerful medical establishment considered laboratory work to be "Laboratory Medicine". In the early 1930's they started the first blind inter-laboratory testing program in the United States, a sustained informal program which preceded Dr. Sunderman's 1947 publication of such an idea by more than a decade. The program was conceived as an educational tool intended to help in improving clinical laboratory work. The pioneers started an organization called the California Association of Clinical Laboratories (CACL). They were a driving force in the creation of the Clinical Laboratory Act.

In 1951 Lucien Hertert, the man who coined the term "Bioanalyst", helped organize the Council of American Bioanalysts and launched an effort to create a national identity for Bioanalyst laboratory directors. The Council was later merged with the National Association of Clinical Laboratories to form the American Association of Bioanalysts (AAB). In the 1960's, to attract Bioanalysts who were not laboratory directors, they renamed CACL and it became CAB, the California Association of Bioanalysts.

When the Medicare Law was passed in 1965, Bioanalysts were considered professionally inferior by those charged with writing Medicare regulations. Importantly, AAB was an established national organization by that time and it served as a natural base from which to attack the popular assumption that the Doctorate degree equated to a guarantee of professional competence as a Clinical Laboratory Director.

After intense effort, a compromise was reached and federal regulators agreed to "grandfather" Bioanalyst laboratory directors into the Medicare program. The compromise required Bioanalyst directed laboratories to prove their competence through the inter-laboratory testing program functioning in California. Given the circumstances, CAB presented the complete operating system to AAB. Nurtured by AAB, the program has continued to grow and evolve alongside several other such programs. Over time, however, the inter-laboratory testing requirement limited to Bioanalysts was seen as discriminatory and it soon became a requirement for all Medicare approved laboratories. Thus the Medicare Proficiency Testing requirement is directly traceable to the compromise which Grandfathered Bioanalysts into the Medicare program. Beginning in 1991, in the hands of federal regulators, what began in California in the 1930's as an educational innovation has evolved into a highly effective measuring stick for assessing clinical laboratory competence. California Laboratory Field Services has shown proficiency testing can be used successfully for that purpose by developing a program to analyze proficiency testing data received electronically from the national proficiency testing services.

The compromise which Grandfathered Bioanalysts into the Medicare program did nothing to change the fundamental requirement that laboratory directors have doctorate degrees. Since California Bioanalysts were licensed at the master's level the regulations were devastating to the profession. From 1971 to 1986 there was too little incentive for qualified Medical Technologists to make the effort to

become Bioanalysts. If the license was not to disappear, one of two things had to happen. First, in the 1970's CAB tried to establish a doctorate degree in Bioanalysis. A curriculum for the degree was created and the University of the Pacific accepted it. The program failed because, despite an extended, wide ranging effort, CAB could not find the required \$50,000 in funding.

In 1983, an attack on the federal doctorate requirement itself was begun. Working through Professor Richard Baily of U.C. Berkeley and the Laboratory Field Services Section of California State Department of Health Services, CAB financed a statistical study made by graduate student Michael Kinney. The study, using proficiency test results, was designed to test the assumption that laboratories directed by people with Doctorate degrees performed in a way which was measurably superior to those directed by Bioanalysts. The study, completed in 1984 and referenced below, showed no discernible difference in the quality of results. The study was so scientifically correct that it has never been attacked from any quarter. In fact the study design and its findings were so important that it led to two related federal studies by the same investigator.

Armed with these powerful studies showing professional equivalency and supported by other professional organizations, most notably the California Association of Public Health Laboratory Directors. CAB petitioned Congressman Henry Waxman to address the problem. Congressman Waxman responded and managed to amend the Omnibus Budget Reconciliation Act (OBRA) of 1986 in such a way that the prerogatives of California Bioanalysts were largely restored.

## **THE PRESENT:**

Now is the time for Clinical Laboratory Scientists to dedicate themselves to taking control of their professions, from Phlebotomist and Laboratory Aid through Laboratory Director. The forgoing history shows what can be accomplished by a small, dedicated group. Think, what could be done by a large group or groups, well-organized, well-coordinated, well financed and possessed with a set of integrated, comprehensive goals.

Now is the time for the leaders of all Clinical Laboratory Scientist associations to recognize and appreciate the fact that Bioanalysis is the top of the "career ladder". It is the position with the most stature and every Clinical

Laboratory Scientist who becomes a Bioanalyst ads just that much more prestige to the profession.

The leaders must recognize that there are so few new Bioanalysts entering the field that the license is on the verge of extinction. They must understand that Bioanalysts are becoming too old and too few to effectively defend the integrity of the license. They must understand that Clinical Laboratory Scientists individually and collectively need to do all in their power to license more Bioanalysts. Failure to do so will, by default, leave the Physician all alone at the top of the ladder.

### **THE FUTURE:**

Much of what happens to the profession of Medical Technology in the coming years will depend upon public policy decisions by government. It is the responsibility of the profession to position itself to influence those decisions and to respond to the challenges, whatever they may be.

Some assertions about the future can be made with confidence. The rate of technological growth will continue to accelerate. New technologies will appear which will require more licensed laboratorians who are well trained and knowledgeable. Economic imperatives will drive advances in automation and that with the simplification of methodologies will shift much of the routine work load to automation and to unlicensed workers.

As mentioned above, it is possible for Clinical Laboratory Scientists to dominate the profession. To that end, however, they need to become as goal oriented as the pioneers of the 1930's. The challenge is not much different. With specific reference to the Bioanalyst license, if the top of the ladder is to remain an attainable goal and if the barriers to unfettered use of the license are to be removed, two things are necessary. Support by the full weight of the Medical Technology profession and many, many Bioanalyst licensees positioned to perform as directors and clamoring for full professional rights to do so.

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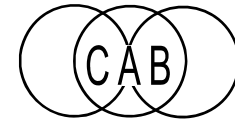
2. Kenney, Michael L. Laboratory Performance and

Regulatory Requirements. An Emperical Assessment of the Quality Assurance Effects of Selected Regulatory Requirements on The Performance of Clinical Laboratories. Prepared for Technology, Evaluation and Assistance Division, Laboratory Program Office. Centers for Disease Control, United States Department of Health and Human Services. 1985.

3. Kenney, Michael L. and Greenberg, Don P. Final Report on Assessment of Clinical Laboratory Regulations. Prepared for Office of the Assistant Secretary for Planning and Evaluation. U.S. Dept. of Health and Human Services. 1986.

# California Association of Bioanalysts

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## **Bioanalysts:**

- . Past**
- . Present**
- . Future**