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September 22, 1975

Suzanne Dandoy, M.D., M.P.H.
Acting Director
Department of Health Services
1740 West Adams
Phoenix, Arizona 85007

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Dear Doctor Dandoy:

This is in response to your request that we review A. R. S. Section 36-463. E to determine whether the Director of the Department of Health Services may revoke a provisional clinical laboratory license in the event the licensee fails to carry out a plan of correction in accordance with the provisions of the plan.

A. R. S. Section 36-463, subsection E, provides:

E. When an inspection or investigation of a laboratory reveals a deficiency or deficiency of a minor nature, but the director has cause to believe that the immediate interests of the general public would be best served by affording the laboratory the opportunity to correct such deficiency or deficiencies, the department shall issue a provisional license for a period of time not to exceed six months providing the applicant agrees to carry out a plan acceptable to the department to eliminate the deficiency or deficiencies within the term of the provisional license. The fee for a provisional license shall be the same as for an annual license. No provisional license shall be renewed. A laboratory shall be relicensed after the expiration of its provisional license only if the licensee has fully corrected all conditions constituting failure to comply with requirements for licensure. (Emphasis added)

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The essential issue here is whether the licensee's agreement to carry out an acceptable plan is all this is required of the licensee during the term of the provisional license, or whether failure by the licensee to meet a specific timetable or other conditions which may be set out in such a plan constitutes grounds upon which the Director of the Department of Health Services may revoke the license prior to its expiration.

The objective of subsection E is to provide a means whereby the license of a clinical laboratory whose services are needed by the community may be afforded an opportunity to correct minor deficiencies while continuing in operation. The number, nature, and time period needed to correct the identified deficiencies undoubtedly are the factors to be taken into account when determining the term of the provisional license. In a situation where there are several minor deficiencies, some of which would require a longer period for correction than others, the approved plan might specify a short period for correction of one or more deficiencies and a longer period, or periods, for correction of the others. In such a situation, the provisional licensee's failure to make the earlier corrections would be a breach of a condition upon which the issuance of his provisional license was predicated and could justify its revocation before the completion of the term of the provisional license, provided all statutory procedural requirements for license revocation are followed.

The principal purpose of clinical laboratory licensure is to protect the public from hazards which might result from their improper operation. Section 1 of the Licensure and Regulation of Clinical Laboratories Act., ch. 109, Laws 1969, provided:

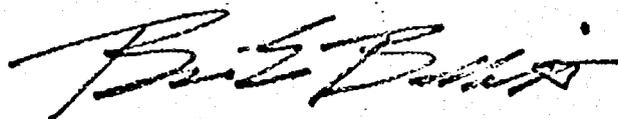
The operation of clinical laboratories in the state of Arizona is declared to affect the public health, safety and welfare. It is further declared that the purpose of this act is to provide for the better protection of public health through the development, establishment, and enforcement of standards for the licensure of clinical laboratories, by providing qualifications for the directors of such clinical laboratories, and by insuring that the tests performed by the clinical laboratories are performed with a high degree of scientific and professional competency. (Emphasis added)

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Certainly the Legislature did not intend that the owner of a laboratory, which was found to have minor deficiencies and which was being operated under a provisional license in order that the clinical laboratory could remain operational while these deficiencies were being corrected, would be given an operational carte blanche during the term of such license and need only comply with applicable requirements at the end of the license term. If such were the case, the Director could rarely issue a provisional license for a period longer than needed to correct the most immediately correctable deficiency and at the same time administer the provisions of the Act in accordance with the legislative purpose quoted above. Such limitation of the scope within which a provisional license could beneficially be issued would be contrary to the apparent legislative intent that the Director have wide administrative latitude to approve plans of correction which would best afford the licensee the opportunity to correct all deficiencies of a minor nature while continuing to provide services needed by the public.

It is, therefore, our opinion that A. R. S. Section 36-463. E authorizes the issuance of a provisional clinical laboratory license which could be revoked during its term if any of the conditions upon which it had been issued were not substantially met by the licensee in accordance with the plan developed and approved by the department.

Sincerely,



BRUCE E. BABBITT
Attorney General

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