REPORT OF THE BOARD OF HEALTH

ON THE STUDY OF

CLINICAL LABORATORIES IN VIRGINIA

DECEMBER, 1969

SENATE DOCUMENT No. 7

COMMONWEALTH OF VIRGINIA
Department of Purchases and Supply
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REPORT OF THE BOARD OF HEALTH ON THE STUDY OF CLINICAL LABORATORIES IN VIRGINIA

Richmond, Virginia
December, 1969

To:
THE HONORABLE MILLS E. GODWIN, JR., *Governor of Virginia*
and
THE GENERAL ASSEMBLY OF VIRGINIA

Pursuant to the provisions of Senate Joint Resolution No. 55 of the 1968 session of the General Assembly of Virginia, I am pleased to transmit herewith the report of the Board of Health on the study of clinical laboratories in Virginia.

It is the hope of the Board that this study may contribute to the health and well-being of the citizens of the Commonwealth.

Respectfully submitted,

ROBERT S. HUTCHESON, JR., M. D.
President, State Board of Health

BACKGROUND

House Bill No. 857*, providing for the inspection and licensure of certain medical laboratories in the State, was introduced in the House of Delegates of the 1968 Session of the General Assembly by its patron, Dr. William Ferguson Reid, on February 8, 1968 and referred to the Committee on General Laws. The State Board of Health became directly involved in this proposed legislation when it was recommended in the Committee that HB 857 be amended to make the Board of Health responsible for its enforcement rather than the Board of Medical Examiners. At that time it became apparent that practically no information was available in the State Health Department or any other State agency concerning the medical laboratories of the State.

Senate Joint Resolution No. 55** was then introduced in the Senate by its patron, Dr. J. D. Hagood. It was adopted by the Senate with the House concurring. This Resolution reads in part as follows:

> . . . . the General Assembly of Virginia requests the State Board of Health to study the operations of clinical laboratories in the State to determine the nature and extent of problems resulting from hazards of improper performance of tests and their effect on the health, safety and welfare of the people of Virginia and to investigate the desirability of and costs involved in enacting legislation such as that embodied in said House Bill No. 857. The Board is also requested to report on the impact of various federal programs such as Medicare and Medicaid on the operations of such laboratories and on the provisions of a law to effect the general purposes of House Bill No. 857.

The information for this report has been compiled from several sources, among which were the results of a voluntary proficiency testing program conducted by the Central Laboratory of the Department; a report of a survey of medical laboratories in the State made by the management consultant firm of Booz, Allen and Hamilton for the Comprehensive Health Planning Council***; the records of the Medicare and Medicaid Sections of the Department; from the Federal Laboratory Improvement Act of 1967 dealing with the licensure of laboratories involved in interstate commerce; and questionnaires received from laboratories that participated in the voluntary proficiency testing program and in the annual syphilis serology evaluation program conducted by the Department.

STUDY PLAN

Following the adjournment of the 1968 Session of the General Assembly plans were developed by the Department to gather information requested in Senate Joint Resolution No. 55. These plans consisted of two major efforts: a voluntary proficiency testing program conducted by the Central Laboratory among the medical laboratories of the State in the fields of microbiology, clinical chemistry, and serology other than syphilis serology; and a detailed survey of the facilities, services and personnel of these laboratories.

A letter describing the plan for the voluntary proficiency testing program and inviting the laboratory to participate was mailed on August 15, 1968 to 218 laboratories whose names appeared on an unofficial list of laboratories gathered from various sources over the years by the Central Laboratory. Replies were received from 133 of these laboratories. Ninety-three indicated a desire to participate in one or more of the three categories included in the program; 3 withdrew from the program; and 3 were found to be located in other states im-

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* Full text filed as Schedule A.
** Full text filed as Schedule B.
*** Full report on file at State Health Department.

mediately adjacent to Virginia. Results from these 6 laboratories were not considered in this report. The remaining 87 laboratories consisted of 52 hospital, 23 independent, and 12 governmental laboratories. Additional information on these laboratories is presented under the results of the proficiency testing program.

The second major effort of the Department to gather the information for the Resolution was to conduct a survey of the medical laboratories of the State. Since much of this information would be of value in state-wide or regional health planning by the Council on Comprehensive Health Planning, this survey became a joint effort of the Council and the Central Laboratory. The management consultant firm of Booz, Allen and Hamilton was employed to conduct the survey. It showed that there are 191 medical laboratories in the State that fall within the provisions of HB 857.

PROFICIENCY TESTING

Eighty-seven, or 45%, of the 191 medical laboratories in the State participated in at least one category of the proficiency testing program. Three of the 84 laboratories that participated in the clinical chemistry program failed to report any results. Five of the 67 laboratories that participated in the serology other than syphilis serology category failed to report any results. Seven of 65 laboratories failed to report any results on the microbiology survey.

The 87 participants reported results of 2,435 tests. One hundred and forty-two, or 5.8%, of the results were considered deviations from the control or participant laboratories. Fifty-seven, or 6.4%, of the 886 clinical chemistry tests performed by the 81 laboratories in the program were incorrect. Nineteen, or 1.8%, of the 1,027 serology tests other than syphilis serology made by 62 laboratories were incorrect. Sixty-six, or 12.6%, of the 524 tests reported by the 58 laboratories in microbiology were incorrect.

Table I shows the educational background of the directors of the 87 laboratories that participated in the proficiency testing program.

TABLE I

	Total	Educational Background					
		M.D. Path.	M.D.	Ph.D.-D.Sc.	MA/MS	BA/BS	No Degree
Total	87	55	3	2	.....	12	15
Hospital	52	43	.....	1	.....	5	3
Independent	23	11	2	1	.....	3	6
Government	12	1	1	.....	.....	4	6

Table II shows the hospital bed capacity and educational background of the laboratory directors for the 55 hospitals that participated in the proficiency testing program.

TABLE II

Educational Background	Hospital Bed Capacity				
	50	50-100	101-301	301-500	500+
MD-Pathologist	7	8	18	7	3
Ph.D/DSc					1
MD					1
BA/BS	1	4	1		
No degree		2	2		

Table III lists the number of deviations reported by type of laboratory and by educational background of the director.

TABLE III

No. Deviations	MD-Path.			M.D.			PhD-DSc			BA/BS			No Degree		
	Hos.	Ind.	Gov.	Hos.	Ind.	Gov.	Hos.	Ind.	Gov.	Hos.	Ind.	Gov.	Hos.	Ind.	Gov.
1	34	5			3	1	1			4		3	1	4	2
2	9	3	1							5	2	2	1	2	
3	5														
4	1	1													
5										1					
No. Participants	43	11	1		2	1	1			5	3	4	3	6	6

Microbiology: Pure cultures of coagulase positive staphylococcus, beta hemolytic streptococci, C. diphtheriae, Shigella sonnei, Proteus mirabilis, Salmonella typhi, Salmonella typhimurium, Pseudomonas aeruginosa, Serratia, and streptococcus faecalis were distributed to each of the 65 laboratories that agreed to participate in this category for identification.

Reports were received from 58 of these laboratories. Incorrect identifications were made in 66 instances, or 12.6%, of the 524 results reported by the 58 participants. Sixteen laboratories reported no incorrect results (excluding those laboratories that reported on less than half of the specimens). Twenty-two laboratories reported incorrect results on one specimen, 13 on two specimens, and 4 reported incorrect results on three specimens.

Clinical Chemistry: Specimens for the determination of glucose, uric acid, and blood urea nitrogen were distributed to each of the 84 laboratories that agreed to participate in this category. Reports were received from 81 of these laboratories.

Forty-five laboratories reported results on all specimens within two standard deviations of the mean of the other participants (excluding two laboratories that tested less than half the specimens). Twenty laboratories reported one determination beyond two standard deviations of the mean of the other participants; nine reported 2 determinations; one reported 3 determinations; two reported 4; and

one laboratory reported 5 determinations beyond two standard deviations of the mean of the other participants.

Serology: Specimens for infectious mononucleosis, brucellosis, proteus OX19 and OX2 agglutination tests and for antistreptolysin O titer were distributed to 62 laboratories that agreed to participate in this category. Reports were received from 57 of these laboratories. Three laboratories reported results on two occasions that deviated from the control laboratory and other participants. Thirteen laboratories reported results that deviated on one occasion each from the control laboratory and the other participants.

EFFECT OF LEGISLATION SUCH AS HB-857

From information available to us from various sources, we find there are 191 medical laboratories in the State that probably would be subject to licensure under the provisions of a Laboratory Licensure Law such as HB-857.

The "Survey of Facilities, Services and Personnel in the Clinical Laboratories in Virginia" conducted by Booz, Allen and Hamilton, Management Consultants, included 146 of these laboratories in their comprehensive study.

Of these 146 medical laboratories 76 indicated that the laboratory was directed by a physician certified or board eligible in anatomical and/or clinical pathology; 25 medical laboratories indicated that the laboratory was directed by a physician; 2 indicated the laboratory was directed by a person with an earned Doctorate (PhD, DSc, etc.); 1 indicated the laboratory was directed by a person with a Master's degree; 6 laboratories were directed by a person with a Bachelor's degreee with a science major; 16 indicated a person without a college degree directed the laboratory; and 20 did not respond to this part of the questionnaire.

In addition, some information obtained from other sources is available on an additional 28 medical laboratories that did not participate in the survey. Twenty of these laboratories are directed by a physician certified or board eligible in anatomical and/or clinical pathology; 3 are directed by a physician; 1 is directed by a person with a Master's degree; 1 laboratory is directed by a person with a Bachelor's degree with a science major; and 3 laboratories are directed by a person without a college degree.

From the available information on these 174 laboratories the following is an analysis of the effect on the medical laboratories of Virginia if they were required to be licensed under a Laboratory Licensure Law such as HB-857.

Twenty laboratories did not have or did not report a director in the survey conducted by Booz, Allen and Hamilton. These could not qualify for licensure due to the HB-857 requirement: "The Board shall not issue a license to a laboratory which does not have a laboratory director." (Page 4, line 11.)

Of the 28 physician directors, 9 have less than 7 years' experience as a laboratory director. Of the 19 directors with no college degree with a science major, 3 have less than 7 years' experience as a laboratory director. These 12 directors would not meet the requirement: "He for a period of 7 consecutive years immediately prior to the effective date hereof, was the director of a laboratory in this state." (Page 3, line 3) and, therefore, these laboratories could not be licensed under HB-857 with the present directors.

Section 1 (2) defines the laboratory director as the person who gives "active participation in its operation" and "shall actively direct, supervise, and be responsible for the work". The Booz, Allen and Hamilton laboratory survey reported that of the one hundred sixteen laboratories replying to the question, almost one-half reported that their director was responsible for three or more laboratories.

Limitations on the number of laboratories one individual could direct probably would depend on the interpretation of this section by the "Board".

Page 3, line 7 of HB-857 states that "Provided that the laboratory, in the event the director qualifies under (2) or (3) above, shall perform only those laboratory tests and procedures that are within the specialities in which the laboratory director is qualified." This requirement pertains to all laboratories directed by a non-pathologist. Although no specialty categories are enumerated in HB-857, those used in the "Conditions For Coverage of Services of Independent Laboratories" by the Federal Health Insurance for the Aged (Medicare, Medicaid) are: microbiology, hematology, immunohematology, clinical chemistry, tissue pathology, and exfoliative cytology.

Our interpretation of the directors' qualifications (Section 5) is that a non-pathologist physician would be included under subsection (3). It is difficult to judge to which of the above specialty categories the physician would be limited. Since a later requirement limits the specialties of immunohematology, tissue pathology and exfoliative cytology to physicians who are certified or board eligible in anatomical and/or clinical pathology, we would assume the non-pathologist physician qualified only in the specialties of microbiology, hematology and clinical chemistry. As for the non-physician director, determination of the limitations as to the specialties they could qualify for offering services would have to await the rules and regulations prescribed by the "Board". Undoubtedly, all medical laboratories offer some services in these three specialty categories. Therefore, some curtailment of laboratory services might be necessary in some laboratories with their present director in order to be licensed under a Laboratory Licensure Law similar to HB-857.

HB-857 specifically limits the performance of tests in the specialty of immunohematology to a pathologist directed laboratory. General blood grouping and Rh typing are considered with the specialty of immunohematology. Substantially all the 50 non-pathologist directed laboratories surveyed in the Booz, Allen and Hamilton study performed blood grouping and Rh typing and although specific information is not available, probably the majority of the non-pathologist directed laboratories in the State offer services in immunohematology. Depending upon the interpretation of this specialty many laboratories might be prohibited from performing tests in immunohematology. This same problem may exist in the specialty of exfoliative cytology in the area of screening of gynecological smears.

In summary, if a laboratory licensure law similar to HB-857 were enacted, our findings indicate that at least 32 of 174 laboratories on which information is available could not qualify for licensure under the provisions of this law. In addition, depending on interpretations by the "Board", limitations as to the services offered and number of laboratories directed by one individual might significantly affect a number of other laboratories.

Undoubtedly, a licensure law of the medical laboratories in Virginia would significantly affect the personnel and operation of those being licensed and the agency administering and enforcing the provisions of the law. However, as pointed out in the Booz, Allen and Hamilton study, "In the opinion of experts in the laboratory field licensure, adequate quality control programs, and mandatory proficiency testing are all necessary to insure high standards of laboratory performance".

CURRENT STATUS OF LABORATORY APPROVAL PROGRAMS IN VIRGINIA

The State Health Department approves laboratories to perform specific examinations required under certain laws, rules and regulations enforced by the Department.

The laws of Virginia relating to premarital and prenatal examinations for syphilis require that these tests be made by the State Department of Health or by a laboratory approved for such purpose by the State Health Commissioner. One hundred and forty-seven (147) laboratories are participating in the present serological evaluation study conducted by the Department for approval to perform blood tests for syphilis under these laws. The laboratories are evaluated annually on the basis of results reported by them on the 75 unknown serum specimens submitted to each during the year.

The Public Health Service delegates responsibility to the Department to survey and approve laboratories to examine milk for interstate shipment and water for use on interstate common carriers.

Thirteen public health laboratories and seven animal disease and dairy laboratories operated by the State Department of Agriculture and Commerce are approved annually for the examination of Grade A raw and pasteurized milk and dairy products for interstate shipment. Approval is based on the results reported by each laboratory on the examination of twenty unknown milk and cream samples distributed during the year. Eighteen filter plant and public health laboratories are approved by the Department for the bacteriological examination of water for use on common carriers in interstate commerce each year.

One hundred and twenty-nine or 67.5% of the 191 laboratories in the State that would be effected by HB-857 have been certified as meeting the conditions of coverage under medicare and medicaid.

IMPACT OF FEDERAL HEALTH INSURANCE PROGRAMS ON LABORATORY LICENSURE

The Federal Health Insurance Laws, Title 18 and 19, commonly referred to as Medicare and Medicaid and the Laboratory Improvement Act of 1967 regulating laboratories in interstate commerce, established standards for laboratories providing services under these laws. The criteria for the approval of laboratories under Medicare and Medicaid are identical.

Nine-two of the 105 general hospitals in the State that have been certified to provide services for Medicare patients were approved by the Joint Commission on Accreditation of Hospitals (JCAH). The approval of a hospital by JCAH automatically applies to the laboratory. The remaining 13 general hospitals were approved under the Medicare program. Two tuberculosis, 11 psychiatric, and 2 dental hospitals were also approved. In addition, 24 independent laboratories have been approved in the State to provide services for Medicare patients. About 600,000 citizens of Virginia are covered by these two programs.

Five laboratories, 3 independent and 2 general hospital laboratories, are participating in the program conducted by the National Communicable Disease Center for approval of laboratories examining specimens in interstate commerce. In the event that a laboratory licensure law is passed by the Legislature which is equal to or more strict than the Federal requirements it is very likely that the responsibility for licensing these laboratories will be delegated to the State.

BENEFITS OF LICENSURE

Regulations of clinical laboratories and their personnel by a law comparable to the model law recommended by the Council of State Governments* would contribute to improvement in the accuracy and reliability of laboratory results by limiting the laboratory to the performance of tests only in those categories for which its director and technical personnel meet the prescribed qualifications and in which the laboratory has demonstrated its capability in a proficiency testing program.

The licensure of clinical laboratories and their personnel would benefit the patient by making it possible for the physician to provide better quality medical care through application of more accurate and reliable laboratory results to the diagnosis, prevention, and treatment of disease.

WHAT OTHER STATES HAVE DONE

Tables I and II† taken from material presented by Oliver J. Neibel, LL.B., at the Legal Conference for Medical Society Representatives, AMA, on October 4, 1968, show the status of clinical laboratory laws and legislation recently introduced but not enacted by a number of the States. Sixteen states have adopted clinical laboratory laws. In fifteen states the health department is the enforcing agency. During the period 1966-1968 legislation to licensure laboratories and/or personnel was introduced but not enacted in seventeen states.

WHAT ABOUT VIRGINIA?

The response to the voluntary proficiency testing program conducted by the Central Laboratory and the results reported by the participating laboratories was most satisfactory.

Eighty-seven, or 54%, of the 191 laboratories in the State participated in at least one category of the proficiency testing program. These 87 laboratories reported results on 2,435 tests. One hundred and forty-two or 5.8% of the results were considered deviations from the control or participant laboratories. These results, from a representative cross-section of the State's laboratories, are far superior to those frequently quoted in articles dwelling on the deficiencies of medical laboratory results.

One hundred and five hospital laboratories and 24 independent laboratories in the State have been approved for Medicare and Medicaid. Five laboratories are in a program conducted by the National Communicable Disease Center, PHS, to grant them approval to examine specimens in interstate commerce. The rapid changes in technology and the automation of laboratory tests; the possibilities of the development of large regional or area laboratories; the purchase of indeendent laboratories by large organizations seeking diversification and expansion; the possibilities of the establishment of chains or franchised laboratories; the scarcity of all types of medical and paramedical personnel; and the increasing demands on the whole medical complex make it questionable whether the additional burden of licensure of laboratories and laboratory personnel should be entertained at this time in view of what appears to be reasonably good laboratory practice in the State.

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* Full text filed as Schedule C.
† Tables filed Schedule D.

ESTIMATED COST OF OPERATING A LABORATORY LICENSURE PROGRAM

These estimates are based upon the assumption that approximately 191 medical laboratories would be subject to a licensure law similar to HB-857. In addition, they are based on a plan of annual visits to each laboratory, training personnel and a proficiency testing program similar to that done by the State Health Department Laboratory in 1968-1969.

If the 1,196+ technical personnel (other than directors) were required to register approximately $6,000 more would be needed if they were put into a management information system.

Certification Inspector (average salary)	$10,512.00
Certification Inspector Assistant (average salary)	8,040.00
Technician B	5,640.00
Clerk-Typist C	4,920.00
Travel—250 days at $25.00/day	6,250.00
Materials for proficiency testing and survey	2,000.00
Equipment and materials for training	5,000.00
Office equipment and supplies	5,200.00
Consultant fees	2,000.00
Management information system for technical personnel	6,000.00
	$55,562.00

RECOMMENDATIONS

At its meeting of December 3, 1969, the Board of Health gave full consideration to all aspects of the study of clinical laboratories in Virginia and voted that this report should contain the following recommendations:

That the Board of Health recognizes the benefits resulting from the licensure of clinical laboratories but recommends postponing legislation for the time being pending further clarification of the impact of Medicare, Medicaid, and the federal Laboratory Improvement Act of 1967 which governs interstate commerce; however, in the event the General Assembly entertains passage of legislation in this field, the Board recommends that such legislation be similar to the model law prepared by the Council of State Governments and be administered by an appropriate state agency.

Schedule A

HOUSE BILL NO. 857

Offered February 9, 1968

A BILL to provide for the inspection and licensing of certain laboratories, and to appropriate a sum therefor.

Patron—Mr. Reid

Referred to the Committee on General Laws

Be it enacted by the General Assembly of Virginia:

1. § 1. When used in this Act unless expressly stated otherwise:

(1) "Medical laboratory" or "laboratory" means any facility for microbiological, serological, immunohemotological, cytological, histological, chemical, hematological, biophysical or other methods of examination of tissues, secretions and excretions of the human body for the purpose of aiding in the diagnosis, prevention, or treatment of disease or the assessment of disease or infirmity.

(2) "Laboratory director" means the person who is responsible for and administers the technical and scientific operation of a medical laboratory, including selection and supervision of procedures, reporting of findings, and active participation in its operations to such extent as may be necessary to assure compliance with this Act. He shall be responsible for the proper performance of all work in the laboratory and shall actively direct, supervise, and be responsible for the work of all subordinates.

(3) "Board" means the Board of Medical Examiners for the State of Virginia.

§ 2. This Act applies to all public and private medical laboratories in this State except:

(1) A laboratory of any college, university, or school which is conducted for the training of its students, provided that the results of any examinations performed in such laboratory are not used in the diagnosis and treatment of disease;

(2) Laboratories operated by the Federal Government;

(3) Laboratories operated jointly by not more than two duly licensed physicians exclusively in connection with the diagnosis and treatment of their own patients provided, however, if any referral work is received in the laboratory all provisions of this Act shall apply.

§ 3. No person, corporation, partnership or other form of business entity shall operate, conduct, issue a report from or maintain a medical laboratory without first obtaining a license therefor issued by the Board pursuant to this Act. The license shall be effective for twelve months and shall be renewable annually on its anniversary date. A reasonable fee as prescribed by the Board shall accompany the original application and any renewal request. The license shall be valid only for the laboratory premises for which it is issued and shall be prominently displayed in such laboratory. A license issued under this Act shall automatically become void thirty (30) days after a change in the identity of the laboratory director or in the ownership or location of the laboratory.

§ 4. An application for a license shall be made on a form as designated by the Board. It shall be under oath and shall contain at least the following information:

(1) The name and location of the laboratory.

(2) The name of the laboratory director.

(3) The name of the owner or owners of the laboratory; if a corporation, the names or officers, directors and beneficial owners of 10% or more of its shares.

(4) A description of the program and services provided by the laboratory.

(5) Such other information as the Board may deem necessary or expedient in carrying out its powers and duties under the Act.

§ 5. The laboratory director must meet one of the following requirements:

(1) He is a physician certified in anatomical and/or clinical pathology by the American Board of Pathology or possesses qualifications which are equivalent to those required for such certification.

(2) He holds an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as his major subject and (a) is certified by the American Board of Microbiology, the American Board of Clinical Chemistry, or other national accrediting board acceptable to the Secretary in one of the laboratory specialities, or (b) subsequent to graduation, has had four or more years of general clinical laboratory training and experience, of which at least two years were spent acquiring proficiency in one of the laboratory specialities in a clinical laboratory—with a director at the doctoral level—of a hospital, university, or medical research institution.

(3) He, for a period of seven consecutive years immediately prior to the effective date hereof, was the director of a laboratory in this state which meets the standards and requirements in effect for laboratories throughout such period;

Provided that the laboratory, in the event the director qualifies under (2) or (3) above, shall perform only those laboratory tests and procedures that are within the specialities in which the laboratory director is qualified; and,

Provided that the Board may as a condition precedent to the issuance of an original license hereunder to a director qualifying under (3) above, require such individual to pass an examination in the event that it deems such examination necessary to determine the competence of the individual to direct a laboratory; and,

Provided further that only a laboratory whose director is qualified under (1) above shall perform tests in the specialities of immunohematology, tissue pathology and exfoliative cytology.

§ 6. The Board may prescribe and publish rules and regulations for laboratories relating to:

(1) The qualifications of laboratory directors and technical personnel as to education, training and experience.

(2) The location and construction of laboratories including plumbing, heating, lighting, ventilation, electrical services and similar conditions which shall insure the conduct and operation of the laboratory in a manner which will protect the public health.

(3) Sanitary conditions within the laboratory and its surroundings, including water supply, sewage, the handling of specimens and matters of general hygiene which shall insure the protection of the public health.

(4) Equipment essential to proper conduct and operation of a laboratory.

(5) The procedure which the Board will follow in issuing, renewing, denying, suspending or revoking a license, and in the enforcement of this Act.

§ 7. The Board shall appoint a medical laboratory advisory committee consisting of five persons, at least three of whom shall be licensed to practice medicine in this State and selected from a list of nominees by the Medical Society of Virginia, which committee shall meet at least quarterly and on call of any two members of the committee, and shall advise the Board on the administration and enforcement of this Act.

§ 8. The Board is authorized to inspect the premises and operations of all laboratories and to require submission of reports for the purpose of determining compliance with the provisions of this Act. The Board may require that such reports be under oath and be signed by the owner and/or director of the laboratory. The Board shall keep a registration list of all qualified laboratories meeting the minimum standards and qualifications of this Act. The Board shall not issue a license to a laboratory which does not have a laboratory director.

§ 9. (a) Except as otherwise prescribed by law, a laboratory shall examine specimens only at the request of a licensed physician or other person authorized by law to use the findings of laboratory tests and examinations in his practice, and shall report the results of tests only to such persons or their authorized representative. The laboratory report shall contain the name of the laboratory and of the laboratory director. If a specimen is accepted by a laboratory and is referred to another laboratory, the name and address of such other laboratory and its director shall be clearly shown by the referring laboratory on the report to the person requesting the procedure. No interpretation, diagnosis, prognosis or suggested treatment shall appear on the laboratory report form except that a report made by a physician licensed to practice in this State may include such information.

(b) No person other than a licensed physician or one authorized by law shall manipulate a person for the collection of specimens except that technical personnel of a laboratory may collect blood, remove stomach contents, or collect material for smears and cultures under the direction of a licensed physician.

§ 10. No person, partnership, association or corporation shall within this State, either directly or indirectly, advertise or solicit business for any laboratory whether such laboratory is situated in this State or any other state, or provide rebates or other fee-splitting arrangements with respect to laboratory services. However, a simple announcement of available services may be provided to licensed practitioners of the healing arts. The contractual provision of laboratory services for a fixed fee independent of the number of specimens submitted for such services is prohibited.

§ 11. No person, partnership, association, corporation or laboratory shall send a specimen for examination to any laboratory, the principal place of business of which is outside this State unless such laboratory has applied to the Board for approval and has been approved by and registered with the Board as meeting the minimum standards for laboratories as provided in this Act.

§ 12. A license may be denied, suspended or revoked if the laboratory director or any other employee of the laboratory

(1) Has violated any provision of this Act;

(2) Has been guilty of misreprenestation in obtaining a license;

(3) Has been convicted of a felony or crime involving moral turpitude arising out of or in connection with the operation of the laboratory;

(4) Being a practitioner of medicine has violated any provision of Chapter 12 of Title 54 of the Code of Virginia which would justify the revocation or suspension of his license to practice medicine;

(5) Has knowingly permitted the use of the name of a licensed laboratory or its director by an unlicensed laboratory.

§ 13. The operation or maintenance of a laboratory in violation of this Act is declared to be a public nuisance. The Board may, in addition to other remedies, prosecute an action for an injunction to restrain such violations or to enjoin the future operation of the laboratory until compliance with the provisions of the Act has been obtained.

§ 14. In addition to revocation or suspension of a license granted hereunder as provided in § 12 and to the use of the injunctive process as provided in § 13, any person who violates this Act shall be guilty of a misdemeanor and upon conviction thereof shall be punished by a fine of not more than $100 for the first offense and not more than $500 for each successive offense and each day such violation is continued after the first conviction shall be considered a successive offense.

§ 15. The proper operation of medical laboratories within the State is a matter of vital concern, since they provide essential health services by aiding other medical practitioners in the diagnosis and treatment of disease. It is the purpose of this Act to develop, establish and enforce (1) minimum standards for the licensure of medical laboratories, and (2) minimum qualifications for laboratory directors and technical personnel.

§ 16. This Act shall be enforced by the Board.

§ 17. If any clause, sentence, paragraph, section or part of this Act shall be adjudged by any court of competent jurisdiction to be invalid, the judgment shall not affect, impair or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, paragraph, section or part thereof directly involved in the controversy in which the judgment shall have been rendered.

§ 18. This Act may be cited as the Medical Laboratory Licensing Act.

2. A sum sufficient is hereby appropriated from the general fund of the State treasury to be expended in the enforcement of the provisions of this Act.

Schedule B

SENATE JOINT RESOLUTION NO. 55

Requesting the State Board of Health to study the practices of and methods to improve the performance of clinical laboratories in Virginia.

Offered February 23, 1968

Patron—Mr. Hagood

Referred to the Committee on Rules

Whereas, studies by the National Communicable Disease Center and others have demonstrated that serious deficiencies exist in the nation's clinical laboratories; and

Whereas, such studies indicate that unsatisfactory performance, varying from ten to eighty percent, is demonstrated by such laboratories in bacteriological testing, simple clinical tests, blood groupings and typings, hemoglobin measurements, differential characterization of blood cells and measurements of serum electrolytes; and

Whereas, there also exists considerable variation in results from laboratory to laboratory, and the overall conclusion of such studies is that in more than twenty-five percent of all tests some erroneous results are obtained; and

Whereas, millions of dollars are being wasted each year in payments for inaccurate tests and an amount beyond monetary value in human life and suffering is being wasted; and

Whereas, there is a demanding need for information on the extent of this problem in Virginia and on the desirability and costs involved in enforcing an inspection and licensure law, such as House Bill No. 857 introduced at this Session of the General Assembly, which would affect an estimated one hundred forty-five to one hundred fifty laboratories in the State operated by hospitals, clinics, health departments, corporations, groups and private physicians; now, therefore, be it

Resolved by the Senate of Virginia, the House of Delegates concurring, That the General Assembly of Virginia requests the State Board of Health to study the operations of clinical laboratories in the State to determine the nature and extent of problems resulting from hazards of improper performance of tests and their effect on the health, safety and welfare of the people of Virginia and to investigate the desirability of and costs involved in enacting legislation such as that embodied in said House Bill No. 857. The Board is also requested to report on the impact of various federal programs such as Medicare and Medicaid on the operations of such laboratories and on the provisions of a law to effect the general purposes of House Bill No. 857.

The Board should complete its investigation and report its findings and recommendations to the Governor and the General Assembly no later than November one, nineteen hundred sixty-nine.

Schedule C

REGULATION OF CLINICAL LABORATORIES AND THEIR PERSONNEL

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REGULATION OF CLINICAL LABORATORIES AND THEIR PERSONNEL

In recent years the public has become aware of the desirability of regulating clinical laboratories and their personnel. Various studies have indicated that a substantial number of laboratory tests may be performed or reported incorrectly.

The following draft is the product of extended consultation with an advisory group composed of leaders in the professions dealing with clinical laboratories and, hopefully, represents the most enlightened professional thinking on an approach to the problem of regulation.

The Act would apply to all laboratories except those operated by the United States Government, those operated exclusively for teaching and research, and small laboratories used by physicians in connection with their private practice.

Licensing procedures are provided for both clinical laboratories and personnel. The licensing program and standards would be established by the appropriate State department and licenses could be suspended or revoked for specified offenses. The draft also includes a prohibition against fee-splitting and solicitation of business, and provides a penalty section for violations. In general, the suggested Act parallels standards found in federal legislation and regulations.

Suggested Legislation

[Title should conform to State requirements. The following is a suggestion: "An Act to provide for the regulation of clinical laboratories and their personnel and for related purposes."]

(Be it enacted, etc.)

Section 1. Purposes and Fndings.

The legislature finds that clinical laboratories provide essential services to the medical practitioner and, through him, for the patient by furnishing vital information for the diagnosis, prevention, or treatment of any disease, or impairment of, or the assessment of the health of, man. Consequently, the regulation of clinical laboratories and the prescribing of qualifications for professsional and technical personnel employed thereby is necessary in the public interest in order to reduce the hazards of improper performance.

Section 2. Exemptions.

(a) This Act shall not apply to clinical laboratories:

(1) Operated by the United States Government.

(2) Operated jointly by not more than two duly licensed physicians exclusively in connection with the diagnosis and treatment of their own patients.

(3) Operated and maintained exclusively for research and teaching purposes, involving no patient or public health services.

(b) Notwithstandig anything in this Act to the contrary, the provisions of Section 7 (b) shall apply to clinical laboratories described in item (a)(2) of this Section.

Section 3. Definitions.

As used in this Act:

(1) "Person" means any individual, firm, partnership, association, corporation, the State, or any municipality or other subdivision thereof, or any other entity whether organized for profit or not.

(2) "Department" means the [State Department of Public Health, including the State Board of Health where applicable.]

(3) "Board" means the [State Board of Public Health.]

(4) "Clinical laboratory" means a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, man.

(5) "Director" means an individual in overall charge of the technical and scientific operations of the laboratory including the reporting of findings of laboratory tests.

(6) "Supervisor" means an individual, other than the director, who may supervise technical personnel, perform tests requiring special scientific skills, and is held responsible for the proper performance of all clinical laboratory procedures within his area of special competence and the reporting of results.

(7) "Technologist" means an individual who performs tests which require the exercise of independent judgment and responsibility, with minimal supervision by the director or supervisor, in only those specialties or subspecialties in which he is qualified by education, training and experience.

(8) "Personnel" means the director, supervisor, and technologist.

Section 4. Powers of the Department.

In addition to powers conferred elsewhere in this Act, the Department may:

(1) Issue, amend, and repeal rules and regulations for the implementation of this Act, after consultation with one or more advisory committees authorized in Section 9.

(2) Establish and enforce standards governing the construction, renovation, maintenance, safety, and sanitary requirements pertaining to clinical laboratories to the extent that they are not otherwise subject to requirements imposed by law or municipal ordinance.

(3) Prescribe qualifications for any one or more categories of clinical laboratory personnel, including microbiology, serology, chemistry, hematology, immuno-hematology, biophysics, cytology, pathology, or other specialties. To the extent feasible such qualifications shall take into consideration standards formulated by appropriate professional associations.

(4) Formulate and administer or contract with appropriate professional organizations for such formulation and administration of, written, oral, and practical examinations to determine the qualifications of clinical laboratory personnel for the purpose of licensure.

Section 5. Licenses.

(a) No clinical laboratory shall be operated without a license issued and in force pursuant to this Act unless it is a function of a hospital licensed by the State.

(b) No individual shall function as a director, supervisor, or technologist unless he is the holder of a license issued and in force pursuant to this Act, or he is a licensed practitioner of [the healing arts] who possesses additional qualifications in clinical laboratory science specified by the Department.

(c) Applications for licenses shall be made to the Department on forms prescribed by it. The application shall indicate the procedures or categories of procedures to be performed and shall contain such additional information as the Department may require. Each application shall be accompanied by the fee prescribed by the Department, and no such fee shall be returnable, whether or not the license applied for is issued.

(d) The license applied for shall be issued, if the Department finds that all requirements therefor are met, or, in the case of a new clinical laboratory not yet in operation, that the owner is in a position to meet them. A license shall authorize the performance of one or more procedures or categories of procedures and shall be valid for [one year] from the date of issue, unless sooner canceled, suspended, or revoked.

(e) A clinical laboratory license may be denied, revoked, suspended, limited, or renewal thereof denied for knowingly:

(1) Making false statements of material information on an application for clinical laboratory license or any other documents required by the Department;

(2) Permitting unauthorized persons to perform technical procedures or to issue or sign reports;

(3) Demonstrating incompetence in the performance or reporting of clinical laboratory examinations and procedures.

(4) Performing a test for or rendering a report to a person not authorized by law to receive such services;

(5) Referring a specimen for examination to a clinical laboratory in this State which has not been licensed under this Act;

(6) Making a report on clinical laboratory work actually performed in another clinical laboratory without designating the name of the director and the name and address of the clinical laboratory in which the test was performed;

(7) Lending the use of the name of the licensed clinical laboratory or its personnel to an unlicensed clinical laboratory;

(8) Violating or aiding and abetting in the violation of any provision of this Act or the rules or regulations promulgated hereunder; or

(9) Violating any other provisions of law applicable to the proper operation of a clinical laboratory.

(f) A clinical laboratory personnel license may be denied, revoked, suspended, limited, or renewal thereof denied for knowingly;

(1) Making a false statement of material information on an application for a license or any other document required by the Department;

(2) Performing or attempting to perform or representing himself as entitled to perform any clinical laboratory procedure or category of procedures not authorized in his license;

(3) Demonstrating incompetence in the performance or reporting of clinical laboratory examinations or procedures;

(4) Performing a test for or making a report thereon to a person not authorized by law to receive such reports;

(5) Violating or aiding and abetting in the violation of any provision of this Act or the rules or regulations promulgated hereunder; or

(6) Violating any other provisions of law applicable to the proper operation of a clinical laboratory.

(g) A license shall be valid only in the hands of the person or persons to whom it is issued and shall not be the subject of sale, assignment, or transfer, voluntary or involuntary, nor shall a license be valid for any premises other than those for which issued until the new premises are approved by the Department.

(h) Each clinical laboratory shall have a licensed director. Unless specifically authorized by the Department, an individual shall not be permitted to direct more than three clinical laboratories.

(i) A clinical laboratory license shall specify on the face thereof the names of the owner and director, and procedures or categories of procedures authorized, the period for which it is valid, and the location at which such procedures must be performed. The license shall be displayed at all times in a prominent place where it may be viewed by the public.

(j) If a clinical laboratory carries on one or more of its functions at one or more separate locations, a license shall be required for each such location.

(k) Licenses issued pursuant to this Act shall be subject to renewal in accordance with rules and regulations of the Department.

(l) The Department shall fix and publish, and from time to time revise, a schedule of fees for applications and renewals. Such fees for clinical laboratory licenses shall be in amounts calculated to defray the costs of necessary inspections, evaluations, and investigations related thereto, but no fee for application or renewal of a personnel license shall be in excess of [$25].

(m) Any person who knowingly or with reasonable cause to know makes a false or misleading statement of a material fact in connection with any application for a license or renewal thereof pursuant to this Act, in addition to any other penalty or remedy, is guilty of perjury.

Section 6. Acceptance, Collection, Identification, and Examination of Specimens.

(a) A clinical laboratory shall examine human specimens only at the request of a licensed physician, dentist, or other person authorized by law to use the findings of laboratory examinations.

(b) The results of a test shall be reported only to or as directed by the licensed physician, dentist, or other authorized person who requested it. Such reports shall include the name of the director and the name and address of the clinical laboratory in which the test was actually performed.

(c) All specimens accepted by a clinical laboratory shall be tested on the premises, unless forwarded to another properly licensed clinical laboratory.

(d) Only a licensed physician or a person authorized by law shall manipulate a person for the collection of specimens, except that duly licensed clinical laboratory personnel may, upon the written request or confirmation of a licensed physician, dentist, or other person authorized by law, or in connection with the taking of specimens for a purpose covered by subsection (i) hereof, collect human blood or materials for smears or cultures.

(e) No person shall represent, or maintain an office or specimen collection station or other facility for the representation of any clinical laboratory situated in this State or any other State which makes examinations in connection with the

diagnosis and control of diseases unless the clinical laboratory so represented shall meet or exceed the minimal standards issued by the Department pursuant to this Act and the regulations issued hereunder.

(f) The Department may require laboratories to show evidence that specimens shipped through the mails and accepted by them for analysis are sufficiently stable for the determinations requested.

(g) Records involving clinical laboratory services and copies of reports of laboratory tests shall be kept for the period of time and in a manner prescribed by the Department.

(h) Each clinical laboratory shall establish its own quality control program acceptable to the Department including use of, where applicable, reference or control reagents, standards, serums or other biological or chemical samples, concurrent calibration standards, and control chart recordings.

(i) Subsections (a), (b), and (c) hereof shall not apply to the taking, examination, or testing of specimens by a clinical laboratory or its perosnnel solely in order to test the accuracy or sufficiency of its procedures, or equipment or in order to make improvements in the same.

Section 7. Reporting.

(a) The Department may require reporting by clinical laboratories of evidence of such infectious diseases as the Department may prescribe. The Department may furnish or approve forms for such reporting. The reports shall not be construed as constituting a diagnosis nor shall any clinical laboratory making reports be held liable for having violated a trust or confidential relationship. The reports submitted shall be deemed confidential and not subject to public inspection.

(b) Every director of a clinical laboratory shall report to the Department such information regarding the operation of the clinical laboratory as may be requested by the Department or required by the rules and regulations of the Department in order to aid in the proper administration of this Act.

Section 8. Inspection and Evaluation.

(a) The Department shall make periodic inspections of every clinical laboratory, at its discretion, but in no case less often than [once in each year]. For the purposes of this subsection, the employees or agents of the Department shall have the right of entry into the premises of the laboratory during the hours of operation.

(b) The Department shall operate a clinical laboratory evaluation program and shall prescribe standards of performance in the examination of specimens. As part of the clinical laboratory evaluation program, the Department may require the clinical laboratory to analyze test samples submitted or authorized by the Department and report on the results of such analyses.

Section 9. Advisory Committees.

The Department shall appoint one or more multidisciplinary committees to assist it in the administration of this Act.

Section 10. Hearings and Judicial Review.

(a) No license issued pursuant to this Act may be suspended, revoked, or denied without a hearing, if requested by the holder of or applicant for the license on due notice. If a hearing is requested, the Department shall make written findings of facts and conclusions on which its action is based.

(b) Any action of the Department taken pursuant to or under the color of this Act shall be reviewable as provided in the [State administrative procedure act]. [If there is no State administrative procedure act, or if a special review procedure is desired, make appropriate provisions.]

Section 11. Substitution of Qualifications.

In determining the qualifications of an applicant, the Department may accept training and experience acquired prior to the effective date of this Act in lieu of education.

Section 12. Effect of Act.

Nothing in this Act shall authorize any person to practice medicine or to furnish the services of physicians for the practice of medicine. This Act does not repeal or in any manner affect any provisions of the laws of this State relating to the practice of medicine.

Section 13. Prohibitions, Penalties, and Enforcement.

(a) No person shall:

(1) Solicit referral of specimens to his or any other clinical laboratory or contract to perform clinical laboratory examinations of specimens in a manner which offers or implies an offer of rebate, fee-splitting inducements or arrangements, or other remuneration.

(2) Violate or aid or abet the violation of any provision of this Act, or the rules or regulations in force pursuant hereto.

(b) Any act or omission prohibited by subsection (a) hereof shall be punishable as a misdemeanor.

(c) Whether or not there is a prosecution pursuant to subsection (b) hereof, any act, omission or course of conduct prohibited by subsection (a) hereof may be prevented, corrected, or penalized by injunction or any other remedy. Suit shall be [by the Department] [by the Attorney General on referral of the Department].

(d) Nothing in this Act shall prevent or limit any private cause of action or the recovery thereon.

Effective Date.

[Insert effective date.]

[If a State desires to include detailed qualifications for the director of a clinical laboratory, it may refer to definitions contained in Title 20, Section 405.1312(b), Code of Federal Regulations.]

Schedule D

CLINICAL LABORATORY LAWS

Jurisdiction	Laboratories Issued	Year Enacted	Year Major Amendments Enacted	Responsible Agency
Federal	License	1967		U.S. Department of Health, Education and Welfare
California	Permit	1941	1951 1957 1963	State Department of Public Health
Connecticut	Registration	1961		State Department of Health
Florida	Registration	1967		State Board of Health
Illinois	License	1965		Department of Public Health
Kentucky	License	1968		State Department of Health
Maine	License	1967		Department of Health and Welfare
Maryland	Permit	1939	1966	Board of Health and Mental Hygiene
Michigan	License	1968		Department of Public Health
Nevada	License	1967		State Board of Health
New Jersery	Registration	1953		Board of Medical Examiners
New York	Permit	1964		Department of Health
Oregon	Certificate of Approval	1935		State Board of Health
Pennsylvania	Permit	1951		Department of Health
Rhode Island	License	1961		Department of Health
Tennessee	License	1967		State Department of Public Health
Wisconsin	Certificate of Approval	1951		State Board of Health
Puerto Rico	License	1962		Department of Health

LEGISLATION INTRODUCED BUT NOT ENACTED

	Laboratory Licensure Law	*Laboratory Personnel Licensure Law*
Alaska	1967 and 1968	
Arizona	1966, 1967 and 1968	
Delaware	1967 and 1968	
Florida		1967
Georgia		1967 and 1968
Illinois		1967
Kansas	1968	
Massachusetts	1967	
Michigan	1967	
Missouri	1967	1967
New York		1967
North Dakota	1967	
Ohio	1967 and 1968	1967
Oklahoma	1968	1968
Oregon	1967	
Utah		1967
Virginia	1968	