GAO

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Washington, D.C. 20548

Human Resources Division

H8-0111

February 29, 1988

The Honorable Ron Wyden
Chairman, Subcommittee on Regulation
and Business Opportunities
Committee on Small Business
House of Representatives

Dear Mr. Chairman:

In response to your January 5, 1988, request and later discussions with your office we are providing information on the states' regulation of clinical laboratories. There are three types of laboratories subject to state regulation. They are independent, hospital, and physician office laboratories. It is estimated there are at least 90,000 of these laboratories in operation in the United States.

In doing our work we relied primarily on a review of the "Laboratory Regulation Manual", published and updated periodically by Aspen Publishers, Inc. This manual covers all aspects of federal and state laboratory regulation. The information we analyzed was current as of January 1987 and does not reflect changes in state laws and regulations since then. We also contacted program officials in 11 states to obtain further clarification concerning the extent of state regulatory requirements for the three types of laboratories. In analyzing state regulatory programs we considered five elements to be most important. These are licensure, proficiency testing programs, quality control programs, personnel requirements and standards, and inspection authority.

We found that as of January 1987, the regulation of clinical laboratories varied among the 50 states for the 3 categories of laboratories. For example:

-- Thirteen states did not regulate independent laboratories.

-- Seventeen states issued licenses to hospital laboratories as separate entities while 23 additional states required licensed hospitals to have laboratories that met certain requirements.

-- Only 14 states had programs to regulate physician office laboratories. In most cases, regulation of these laboratories was limited and was based primarily on the number of physicians involved in the operation of the laboratories. (For example, some states regulated physician office laboratories if groups of 4 or more physicians maintained the laboratory). Other states imposed specific requirements on physician office laboratories if they conducted certain types of tests.

As arranged with your office we are providing a glossary of terms used in this document and other information including a graph showing the number of states with regulatory programs that contain each of the five program elements and U.S. maps depicting the extent of state regulation of the three types of laboratories. We categorized the states as full regulation states if their regulatory programs contained all five program elements discussed above. Limited regulation states depicted on the maps are those in which some, but not all, of these elements were present in states' programs. Because of the limitations of states' regulation of physician office laboratories, the map and associated narrative discusses only those states with programs to regulate these laboratories.

Should you need additional information concerning this material please call Mr. Daniel W. Blades on 443-2040 or me on 275-6207.

Sincerely yours,

David P. Baine

David P. Baine
Associate Director

Enclosures

1 - Glossary of terms
2 - Bar graph showing state regulation of clinical laboratories
3 - U.S. map and discussion of state regulation of independent laboratories
4 - U.S. map and discussion of state regulation of hospital laboratories
5 - U.S. map and discussion of states that regulate physician office laboratories

ENCLOSURE 1

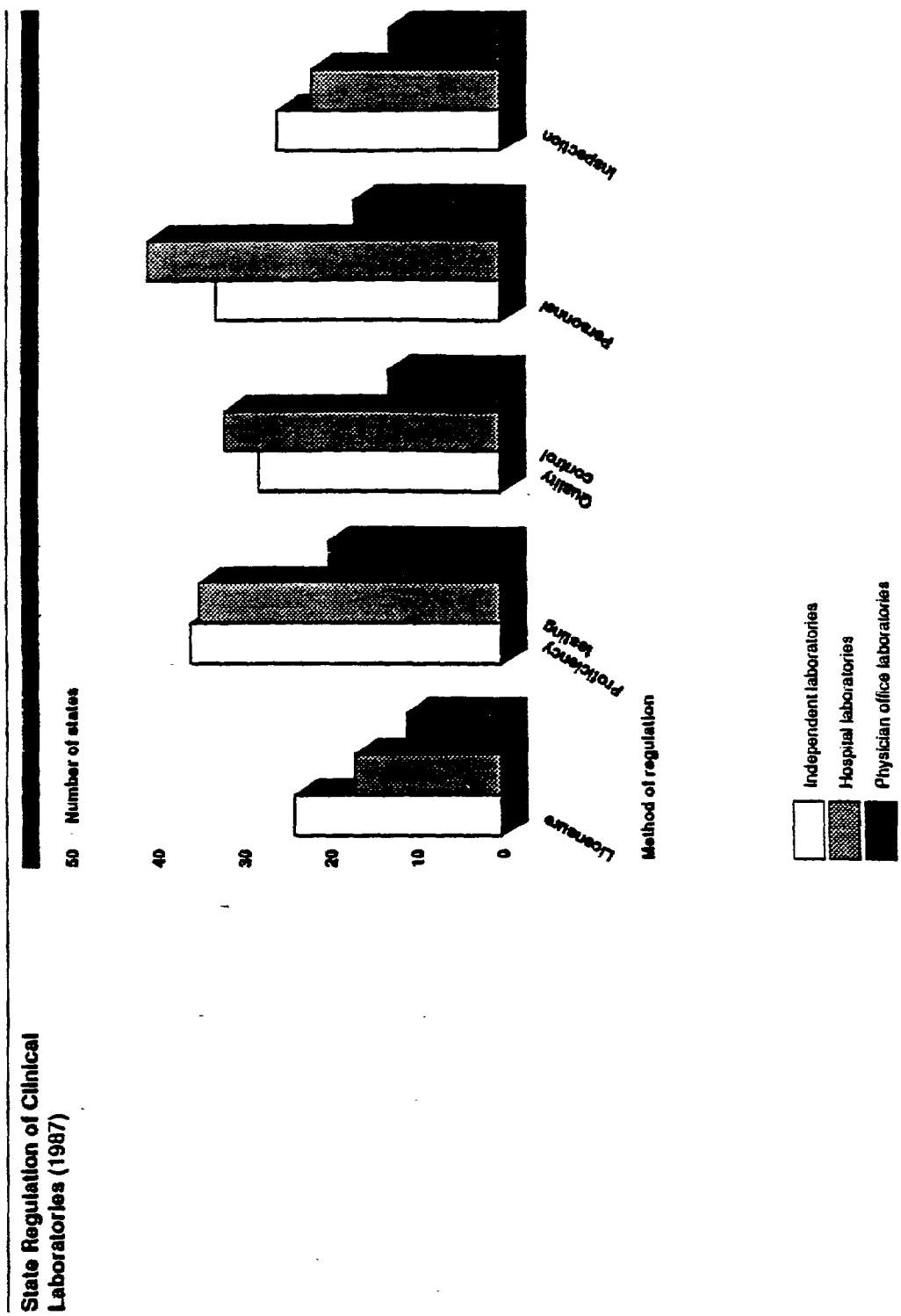
GLOSSARY

Clinical Laboratory	a facility that performs tests or investigative procedures for the benefit of human patients.
Full Regulation State	a state in which the laboratory regulation program includes provisions for licensure, proficiency testing, quality control, personnel requirements, and inspection.
Hospital Laboratory	a clinical laboratory that is accountable administratively to the hospital's central management and medically to its organized medical staff. Most hospital laboratories are physically located in hospitals but co-location is not required.
Independent Laboratory	a clinical laboratory that is independent of all other providers of direct patient care.
Inspection	an on-site visit to the laboratory by state program inspectors to determine whether the facility is complying with laboratory program requirements.
Licensure	the requirement that the laboratory receive a separate license, certification or accreditation from a governmental agency as a prerequisite of doing business.
Limited Regulation State	a state in which the laboratory regulation program includes some but not all of the aspects of a full regulation state.
Personnel Requirements	education and experience requirements for the professional and technical laboratory personnel.
Physicians' Office Laboratory	a laboratory, located in a physician's office, used to perform tests or procedures as an adjunct to treating his or her patients.

ENCLOSURE 1

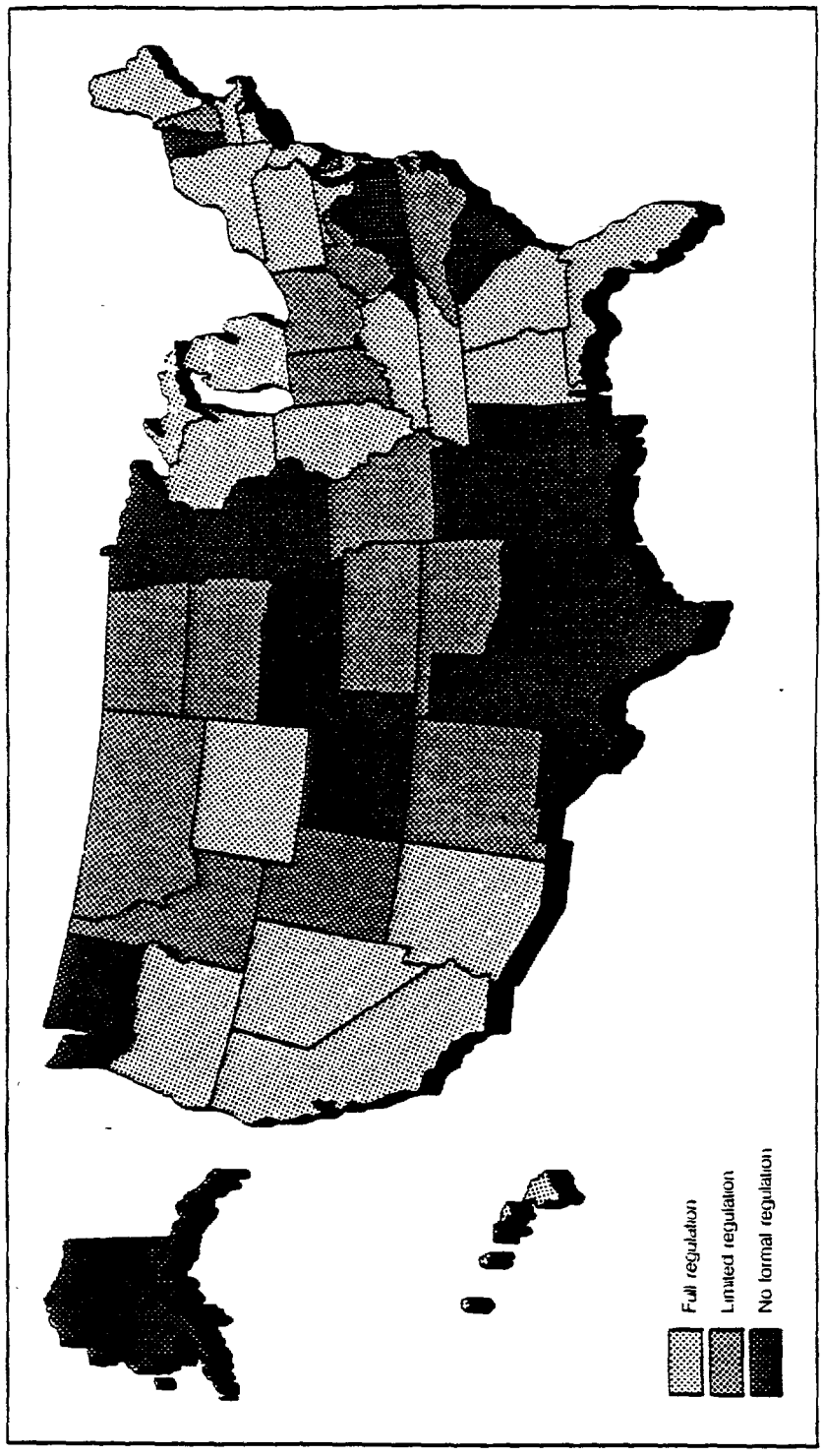
Proficiency Testing	a method of externally validating the level of a laboratory's performance. Clinical laboratories test specimens supplied by a state or another outside agency which knows what each specimen contains. The laboratory's results are compared to the known values of the specimens to determine the laboratory's level of accuracy.
Quality Control	internal procedures to facilitate consistently accurate and precise laboratory performance. Elements of quality control programs generally include the adequacy of facilities, equipment and instruments; preventive and corrective maintenance; proper labeling and storage of reagents; use of control materials; statistical analysis of results; accurate recordkeeping; and development of complete procedure manuals.

ENCLOSURE 2


State Regulation of Clinical Laboratories (1987)
Number of states
50
40
30
20
10
0
Licensure
Proficiency testing
Quality control
Personnel
Inspection
Method of regulation
Independent laboratories
Hospital laboratories
Physician office laboratories

ENCLOSURE 3

State Regulation of Independent Laboratories (1987).



ENCLOSURE 3

STATE REGULATION OF INDEPENDENT LABORATORIES

I. Licensing

Twenty-four states licensed independent laboratories. In 21 states, these licenses covered requirements for quality control, proficiency testing, personnel and inspection. Available information did not indicate specific inspection authority in three states. In some of the 24 states, licenses were required for specific classes of tests. Therefore, independent laboratories had to obtain a number of licenses if they wished to do a wide variety of tests.

Twenty states (2 of which were discussed above) required state approval if laboratories performed certain types of tests. These tests included premarital and prenatal syphilis testing, prenatal rubella testing, phenylketonuria testing, alcohol analysis and pulmonary function tests. In 12 of the 20 states, quality control, proficiency testing, and personnel standards, where required, applied only to these specific tests.

One state, although it did not license independent laboratories, required that these laboratories establish programs for quality control, proficiency testing, and personnel and be subject to inspection.

Thirteen states did not regulate independent laboratories. However, in six of these states, although approval was required to perform certain tests, there were no regulatory requirements attached to the approval.

ENCLOSURE 3

II. Proficiency Testing

Proficiency testing for independent laboratories was required in 36 states. Twelve states required laboratories to participate in either a state-operated or a state-approved program. Thirteen states did not offer a state-operated program but required laboratories to participate in a state-approved program. In the remaining 11 states, proficiency testing was limited to specific tests the laboratories were approved to perform. Testing programs offered by the American Association of Bioanalysts, the American Society of Internal Medicine, and the College of American Pathologists were among those programs approved by the states.

III. Quality Control

Twenty-nine states required independent laboratories to establish and maintain quality control programs. Quality control measures could include procedure manuals for all tests performed; calibration and/or sterilization of equipment; use of reference or control sera (measurement standard); storage of equipment and samples; preparation, use, storage and expiration dates of reagents and solutions. In four of these states quality control requirements were limited to specific tests.

IV. Personnel

Personnel is the most widely regulated aspect of independent laboratory operations. Thirty-three states have specific personnel licensing or other requirements for independent laboratories. These requirements varied widely from state to state and can be generally characterized as follows:

ENCLOSURE 3

-- Five states required that most personnel be licensed or certified.

-- Five states required that only directors be licensed or certified. Four of these five states had specific education and experience requirements for most other laboratory personnel.

-- Five states had education and experience requirements for most laboratory personnel.

-- Eight states had education and experience requirements for only directors or supervisors.

-- Two states had specific education and experience requirements for a limited number of laboratory personnel.

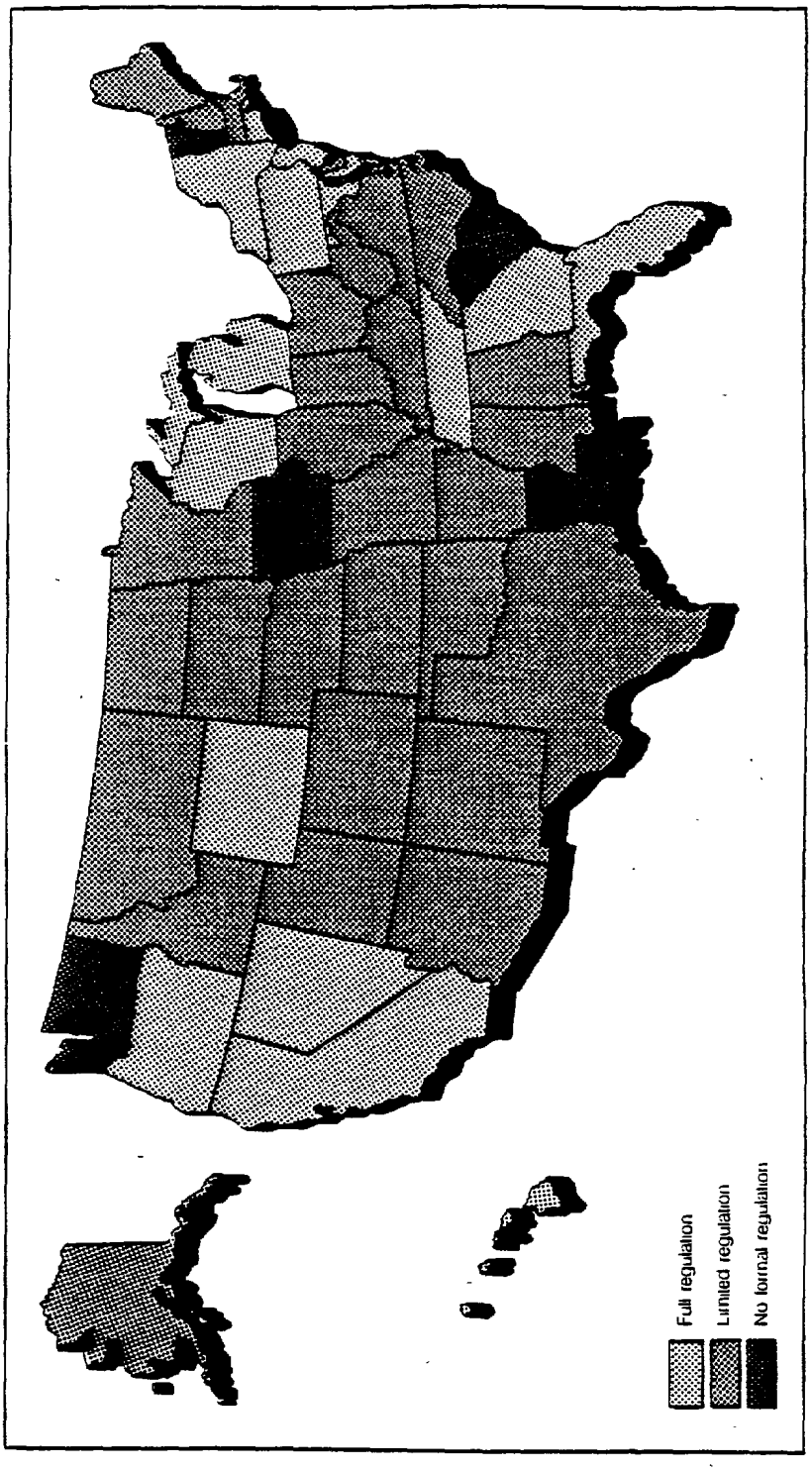
-- Eight states imposed education and experience requirements on only personnel who were responsible for specific tests.

V. Inspection

Twenty-six states had specific authority to inspect independent laboratories.

ENCLOSURE 4

State Regulation of Hospital Laboratories (1987).



ENCLOSURE 4

STATE REGULATION OF HOSPITAL LABORATORIES

I. Licensing

Seventeen states licensed hospital laboratories as separate entities. In 15 of these 17 states, licensure covered requirements for quality control, proficiency testing, personnel and inspection. Available information did not indicate whether or not the two remaining states had specific inspection authority.

Twenty-three states did not require separate licenses for hospital laboratories but required licensed hospitals to have laboratories that met certain requirements. These requirements ranged from minimum standards, such as for the qualifications of a laboratory director, to extensive requirements for quality control, proficiency testing, personnel and inspection.

In 11 states, (6 of which were included above) laboratories that wished to perform specific tests including prenatal and premarital syphilis testing, prenatal rubella, alcohol testing, and phenylketonuria testing were required to be state approved. In five states quality control, proficiency testing, and personnel standards, where required, applied only to those specific tests.

Five states did not specifically regulate hospital laboratories. In two of these states, approval was required to perform specific tests, but there was no regulatory requirements attached to the approval.

ENCLOSURE 4

II. Proficiency Testing

Proficiency testing of hospital laboratories was required in 35 states. Fourteen states required laboratories to participate in either a state-operated or a state-approved program. Fifteen states did not offer a state-operated proficiency testing program but required laboratories to participate in a state-approved program. In the remaining six states, proficiency testing was limited to specific tests the laboratories were approved to perform. Testing programs offered by the American Association of Bioanalysts, the American Society of Internal Medicine, and the College of American Pathologists were among the programs approved by the states.

III. Quality Control

Thirty-two states specified that certain quality control standards be met for hospital laboratories. Quality control measures could include procedure manuals for all tests performed; calibration and/or sterilization of equipment; use of reference or control sera (measurement standard); storage of equipment and samples; and preparation, use, storage and expiration dates of reagents and solutions.

IV. Personnel

Personnel is the most widely regulated aspect of hospital laboratory operations. Forty-one states had specific requirements for personnel. These requirements, however, varied widely from state to state and can be generally characterized as follows:

-- Five states required that most personnel be licensed or certified.

ENCLOSURE 4

-- Five states required that only directors be licensed or certified. Four of these five had specific requirements for most other laboratory personnel.

-- Six states had education and experience requirements for most laboratory personnel.

-- Eleven states had education and experience requirements for only directors or supervisors.

-- Four states imposed education and experience requirements on only personnel that were responsible for specific tests.

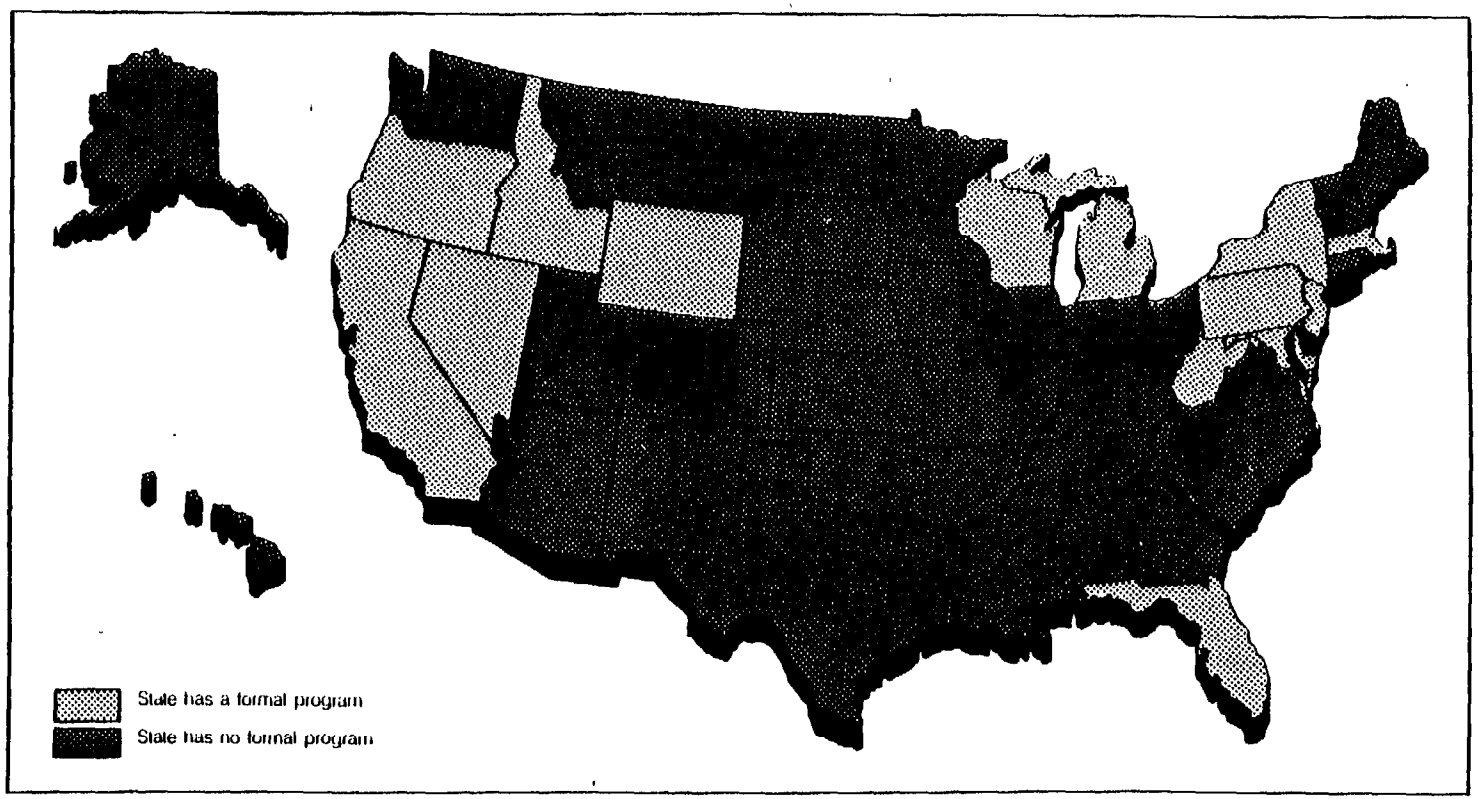
-- The remaining ten states had more general, requirements for laboratory personnel in hospitals.

V. Inspection

Twenty-two states had specific authority to inspect hospital laboratories.

ENCLOSURE 5

States That Regulate Physicians' Office Laboratories (1987).



ENCLOSURE 5

ENCLOSURE 5

STATE REGULATION OF PHYSICIAN OFFICE LABORATORIES

As of January 1987, fourteen states had programs to regulate physician office laboratories to some extent. These states are discussed below.

CALIFORNIA

Although physician office laboratories were exempt from state regulation all physicians' laboratories were required to comply with the state proficiency testing requirements. The state had the authority to deny reimbursement for Medi-Cal claims to physicians not in compliance.

FLORIDA

Groups of six or more physicians maintaining a laboratory were required to meet the state's requirements for independent laboratories.

IDAHO

Physician office laboratories were exempt from state regulation if the physician personally did the testing. Any delegation to physicians' staffs negated the exemption and would subject the laboratories to the state independent laboratory regulations.

MARYLAND

Groups of four or more physicians maintaining a laboratory were required to meet the state's requirements for independent laboratories. Some groups of four or more were exempt from state regulation, if the laboratory performed only specific tests described in the regulations. All exempt physicians, however, were required to comply with the state's proficiency testing program.

ENCLOSURE 5

MASSACHUSETTS

Groups of three or more physicians maintaining a laboratory were required to comply with state independent laboratory regulations.

MICHIGAN

Groups of six or more physicians maintaining a laboratory were required to comply with state independent laboratory regulations.

NEVADA

All physician office laboratories were required to register with the state Board of Health. Laboratories were exempt from regulation, however, if the physician did the testing or only certain tests were done by laboratory personnel under the direct supervision of the physician.

NEW JERSEY

Groups of five or more physicians maintaining a laboratory were required to meet state independent laboratory regulations.

NEW YORK

Groups of two or more physicians maintaining a laboratory were required to meet state requirements for independent laboratories.

OREGON

Groups of five or more physicians maintaining a laboratory were required to meet state independent laboratory regulations.

PENNSYLVANIA

Physician office laboratories were regulated based on the complexity of testing performed. State regulations specified three levels of laboratories. Level I laboratories needed only to register with the state. Level II laboratories were required to register and meet proficiency testing and quality control standards. Level III laboratories were required to be fully licensed and meet state independent laboratory regulations.

ENCLOSURE 5

WEST VIRGINIA

Physician office laboratories were exempt from state regulations. To participate in the state Medicaid program, however, laboratories were required to meet state requirements for quality control, proficiency testing, and personnel. These laboratories were also subject to inspection.

WISCONSIN

Groups of three or more physicians maintaining a laboratory were required to comply with state independent laboratory regulations.

WYOMING

The state grouped physician office laboratories into three levels based on the complexity of the tests performed. Physician office laboratories performing tests specified in the state statute as level III tests were required to be licensed, meet proficiency testing standards, and certain personnel and recordkeeping standards. These laboratories were also subject to biennial inspection. There were no regulatory requirements for the other testing levels.

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In addition to the above several other states required approval if laboratories wished to perform certain tests. These tests include prenatal and premarital syphilis, rubella, phenylketonuria, alcohol and pulmonary function tests. Quality control, proficiency and personnel requirements related only to those specific tests.