REPORT OF THE DEPARTMENT OF
HEALTH REGULATORY BOARDS ON

Review of Need to Regulate Cytotechnologists and Cytotechnicians in Virginia

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

HOUSE DOCUMENT NO. 45

COMMONWEALTH OF VIRGINIA
RICHMOND
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COMMONWEALTH of VIRGINIA

Department of Health Professions

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January 17, 1989

TO: The Honorable Gerald L. Baliles
Governor of the Commonwealth of Virginia

The Members of the General Assembly of Virginia

It is my privilege to present the report constituting the response of the Board of Health Professions to the request contained in House Joint Resolution No. 83 of the 1988 Session of the General Assembly of Virginia.

This report provides findings of the Board regarding the need to regulate cytotechnologists and cytotechnicians in Virginia.

Bernard L. Henderson, Jr.

BLHjr/rbt
Enclosure

VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS

BOARD OF HEALTH PROFESSIONS

REVIEW OF THE NEED TO REGULATE CYTOTECHNOLOGISTS AND CYTOTECHNICIANS IN VIRGINIA

In Response To

House Joint Resolution Number 83

of the

1988 Session of the General Assembly of Virginia

January 1989
Richmond, Virginia

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HOUSE JOINT RESOLUTION NO. 83

Requesting the Council on Health Regulatory Boards to study the regulation of cytotechnicians.

Agreed to by the House of Delegates, February 4, 1988
Agreed to by the Senate, March 2, 1988

WHEREAS, at this time, cytotechnicians are not regulated in any way in Virginia; and

WHEREAS, cytotechnicians perform the analyses of Pap smears for women, the test which is used to detect cervical cancer; and

WHEREAS, following a year-long investigation, the Wall Street Journal published an extensive review of cytology laboratories entitled "Lax Laboratories"; and

WHEREAS, according to the Journal, low-rate, high-volume analyses of Pap smears is a lucrative business which is almost totally without regulation; and

WHEREAS, this industry depends on overworking cytotechnicians by paying on the basis of piece work and requiring a large volume of analyses in a given period; and

WHEREAS, although the appropriate minimum education for cytotechnicians is a college degree and specific additional training, many of such technicians have little or no training; and

WHEREAS, the capability to differentiate between types of cells and to identify abnormalities declines as an individual becomes fatigued or has been looking through a microscope for a period of time; and

WHEREAS, many cytotechnicians hold down more than one position in different laboratories and churn out analyses on an assembly line basis; and

WHEREAS, although it cannot be disputed that the use of the Pap smear has reduced the incidence of death from cervical cancer among women, there has been a recent increase of this dreaded disease, particularly among young women; and

WHEREAS, the error rate among cytotechnicians is at least ten percent, although most women believe that a negative Pap smear result assures them that they do not have cancer; and

WHEREAS, the Council on Health Regulatory Boards is charged, pursuant to § 54-955.1, with evaluating each health care profession and occupation in the Commonwealth to consider whether such profession or occupation should be regulated and to determine the degree of regulation to be imposed; and

WHEREAS, many professions and occupations regulated by the Commonwealth do not have responsibility or the potential for causing harm which is as onerous as that of cytotechnicians; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Council on Health Regulatory Boards is hereby requested to study regulation of cytotechnicians. In its study, the Council shall examine the job conditions of cytotechnicians in Virginia, the workload, and how such technicians are paid as well as the potential for harm that shoddy work or lack of expertise may cause.

The Council shall report its findings to the Governor and the General Assembly as provided in the procedures of the Division of Legislative Automated Systems for processing legislative documents by December 1, 1988.

VIRGINIA BOARD OF HEALTH PROFESSIONS
REVIEW OF THE NEED TO REGULATE
CYTOTECHNOLOGISTS AND CYTOTECHNICIANS

In Response to
House Joint Resolution Number 83
1988 Legislative Session of the
Virginia General Assembly

I. INTRODUCTION

House Joint Resolution Number 83 of the 1988 Legislative Session of the Virginia General Assembly requested the Board of Health Professions (formerly the Council on Health Regulatory Boards) to study the regulation of cytotechnicians and to report its findings to the 1989 General Assembly. The Resolution called especially for the Board to "examine the job conditions of cytotechnicians in Virginia, the workload, and how such technicians are paid as well as the potential for harm that shoddy work or lack of expertise may cause."

The Resolution presented the following assertions in support of the request:

- cytotechnologists are not regulated in Virginia;
- cytotechnologists perform analyses of Pap smears for women, the test used to detect cervical cancer;
- according to journalistic reports, low-rate, high-volume analyses of Pap smears is a lucrative business, operating with little regulation;
- the laboratory industry depends on overworked cytotechnicians by paying on the basis of piece work requiring a large volume of analyses in given time periods;
- the appropriate training for cytotechnicians is a college degree with specific additional training, yet many technicians have little or no training;
- the capability to differentiate types of cells and to identify abnormalities declines as an individual becomes fatigued;
- many cytotechnicians hold down more than one position and complete analyses on an assembly line basis;
- there are recent increases in the incidence of death from cervical cancer among young women, despite the reduction of these deaths due to the use of the Pap smear for early detection;

- the error rate among cytotechnicians is at least ten percent although most women believe that a negative Pap result assures them that they do not have cancer; and

- many professions and occupations are regulated in Virginia that do not have the responsibilities or potential for causing harm as do cytotechnologists.

House Joint Resolution No. 83 is closely related to the broader Senate Joint Resolution No. 62, also approved by the 1988 General Assembly. SJR 62 (appended) established a Joint Legislative Subcommittee charged to:

- examine the preparation and qualifications of medical technologists and cytotechnologists;

- review clinical laboratory testing including that performed in private physicians' offices;

- evaluate the need to regulate clinical laboratories and the appropriate supervision of medical directors; and

- evaluate the need for requisite standards for obtaining and preparing specimens.

To avoid duplication of effort and the possibility of conflicting conclusions, the Board of Health Professions determined at the outset to monitor closely the work of the Joint Legislative Subcommittee, chaired by Delegate Shirley F. Cooper, established to implement SJR 62. It was also agreed that the intent of HJR 83 was that the Board study the need to regulate both cytotechnologists and cytotechnicians.

As the work of the Board and of the Joint Legislative Subcommittee progressed it became ever more apparent that many of the problems cited in HJR 83 were being addressed by the Subcommittee and by newly enacted federal legislation intended to correct problems within the medical laboratory industry. Moreover, it became evident that, in light of these and other developments, recommendation of a specific, inflexible posture relative to the regulation of cytotechnologists or cytotechnicians might prove premature or counterproductive at this time.

It was determined that the Board of Health Professions' review would conclude with a report presenting basic information on (1) the professions of cytotechnology and cytotechnicianry (and related medical laboratory occupations) and (2) the nature of occupational regulation and its utility as a mechanism for the improvement of work conditions within the laboratory industry and of the quality of laboratory services.

The Board of Health Professions believes that any ultimate or final recommendation related to the regulation of laboratory personnel should be deferred until the effects of major reforms in the laboratory industry can be ascertained. The Joint Legislative Subcommittee Studying Clinical Laboratory Testing concurs in this view.

This interim report is organized as follows. First, an overview of allied health personnel who function in the clinical laboratory industry is provided, followed by a review of occupational regulation as an approach to quality control. The criteria used by the Board of Health Professions to evaluate the need to regulate cytotechnologists and cytotechnicians are then applied, and the report concludes with findings and recommendations that may be reliably proffered at this time.

II. CYTOTECHNOLOGISTS AND OTHER MEDICAL LABORATORY PERSONNEL

Clinical laboratory personnel are among ten groups of allied health professions studied during the past two years by the National Academy of Sciences' Institute of Medicine (IOM) with the support of the federal Health Resources and Services Administration. The Board of Health Professions, through its Ad-Hoc Committee on Allied Health Professions, was privileged to cooperate in this study which concluded with the publication in December, 1988 of a report Allied Health Services: Avoiding Crises (IOM, 1988). This authoritative report provides the basis for many of the observations to follow.

Clinical laboratory personnel perform a variety of tests used by physicians in the prevention, detection, diagnosis and treatment of diseases. The medical laboratory technologist--a generalist--dominates the field, but there are a number of specialties, including cytotechnology (the study of body cells), histology (the study of human tissues), microbiology (the study of microorganisms), blood bank technology (the preparation of blood for transfusion), and clinical chemistry (the analysis of body fluids). Within some specialties, including cytotechnology, there are further divisions of personnel differentiating technologists (typically prepared at the baccalaureate level) and technicians with associate, certificate-level, or on-the-job training (OJT).

According to IOM, technologists perform complex analyses, make fine-line discriminations, and correct errors. Having some knowledge of physiological conditions that could affect test results, they are able to recognize the interdependence of tests and to use their knowledge to confirm results and to assist physicians in determining the presence, extent and causes of disease. Technicians, on the other hand, more typically perform routine tests under appropriate supervision, although associate degree technicians may discriminate between similar items, correct errors by using established strategies, and monitor quality control programs using specific protocols (p. 21).

Because of the breadth of the field, accurate estimates of supply and demand of technologists and technicians are difficult to establish. One factor contributing to this difficulty is that employers often substitute on-the-job training for formal credentials, and hire individuals with health-related or science-based training rather than graduates of academic programs. Counts of OJT-prepared technicians are not captured in the usual data collection efforts which rely on the records of national certifying organizations and professional associations. This is particularly true in settings not regulated by government, for example, physicians' office laboratories (POLs). Given these caveats, the U.S. Bureau of Labor Statistics estimated that there

were more than 1/4 million medical laboratory personnel employed in 1986 and that nearly 2/3 of these positions were in hospitals.

Changes in the general contours of the laboratory industry will result in a decline in the ratio of hospital-based employment (from 63 percent in 1986 to 54 percent in the year 2000), and an increase in employment in physicians' offices (from 13 to 16 percent), medical and dental laboratories, and outpatient care facilities (from 14 to 18 percent of all employment) (Bureau of Labor Statistics, 1987). Reliable data specific to the demand for and supply of cytotechnologists and cytotechnicians are not available.

These industry-wide changes are driven by a number of factors including:

- o insurance industry and government polices related to third-party payment (and efforts to control test volumes);
- o technological changes;
- o public and private-sector testing policies, such as those concerning AIDS and substance abuse;
- o quality concerns; and
- o trends in state and federal regulation of laboratories and laboratory personnel.

Illustrative of market dynamics responding to these forces is the growth of physicians' office laboratories (POLs), estimated to perform as much as 50 percent of all laboratory tests. The explosive growth in POLs has been fueled by technology (computerized testing equipment capable of producing accurate results with little necessary training and requiring relatively small capital outlays), reimbursement incentives, and the general deregulation of the medical marketplace. Critics of POLs allege that many physicians and most personnel hired and provided OJT are not skilled in the operation of the equipment or in the interpretation of test results.

Current concerns with balancing supply and demand of medical laboratory personnel are related to recent declines in the numbers of educational programs producing laboratory personnel, decreased enrollments, attrition due to fear of disease, working conditions and wages, and a host of other factors.

Typical of allied health occupations, clinical laboratory professions are dominated by women. Only about 25 percent of all laboratory personnel are male. As with other predominately female allied health professions, salaries and wages are low (compared with other opportunities for women in the professional workplace), and wage compression is a factor influencing

attrition. The average monthly starting rate for medical technologists in 1986 was $1,630 and the average maximum rate was $2,174, a 33 percent difference. For technicians these rates were $1,222 and $1,622, and the difference was also 33 percent. By contrast, the average entry rate for computer programmers was $1,736, but the average maximum rate was $3,578, more than 100 percent higher (IOM, 1988:211). More information is needed relative to wages specific to cytotechnologists and cytotechnicians in Virginia and the nation.

The U.S. Bureau of Labor Statistics predicts that nearly 300,000 clinical laboratory personnel will be needed by the year 2000, an increase of 24 percent. Although the rate of growth will be below that projected for other allied health professions, the number of new jobs created (57,000) will be substantial (IOM, 1988:98).

The laboratory industry is resilient, however, and it is expected that national discrepancies between predicted demand and supply will self-correct. Because these discrepancies are not uniform, some state-level efforts may need to be directed to ensuring the supply of trained laboratory personnel. Concerns have been expressed especially for the predicted short supply of cytotechnologists and cytotechnicians in Virginia that will result from academic program closings.

Industry adjustments to supply problems, moreover, may include the hiring and training of increased numbers of OJTSs, further frustrating the efforts of specific technician groups, such as cytotechnicians, to "professionalize."

Problems in the Laboratory Industry

In recent years federal and state governments and the general public have become increasingly concerned with problems related to laboratory practices and the quality of laboratory test results. These concerns have heightened as media attention has focused on a variety of problems, often in sensational fashion. Among these concerns are:

- Pap, AIDS and blood-cholesterol test errors;
- the safety of the blood supply;
- the proliferation of testing in physicians' offices;
- the marketing of self-testing kits for use in the home for pregnancy testing and other purposes;
- the increase of testing by nonprofessionals in nontraditional test sites (drugstores, supermarkets and shopping malls);
- unreasonable workloads imposed on laboratory personnel;

- the incomparability of test results; and

- allegations of widespread profiteering, fraud, and kickback schemes.

Increasingly, media exposes are accompanied by reliable documentation.

A persistent difficulty, however, lies in identifying the specific causes of these problems, a necessary precondition to determining the correct public policy remedies. Yet the number of proposals for reform expands inexorably, and it is not always possible to separate legitimate proposals for reform from self-serving opportunism.

III. FEDERAL AND STATE REGULATORY EFFORTS AND PRIVATE CREDENTIALING

Until the enactment of H. R. 5471 (Clinical Laboratory Improvement Amendments of 1988, or "CLIA") in the final days of the 100th U.S. Congress, federal oversight of the laboratory industry was notably ineffective. While the earlier Clinical Laboratory Improvement Act of 1967 established standards for personnel and quality control in clinical laboratories, the number of exemptions from its provisions substantially weakened its utility. Other aspects of the law were criticized as insufficient or antedated responses to the current competitive climate in the industry.

CLIA 1988 addresses many, but not all, concerns relative to the laboratory industry. The Amendments provide for the regulation of all clinical laboratories except those conducting simple tests which "have an insignificant risk of an erroneous result." In the majority of cases, exempted laboratories will be those in physicians' offices. For those laboratories which must be certified, various quality assurance and quality control requirements are established, including proficiency testing programs and personnel standards. Announced and unannounced inspections of all clinical laboratories will be conducted, and disciplinary actions taken against laboratories will be reported to the public by the U.S. Secretary of Health and Human Services.

Especially significant are national standards for cytology services which will include: limitations on the number of slides analyzed per day by an individual; recordkeeping relative to work loads; criteria for rescreening; testing of proficiency; procedures for identifying inadequately prepared slides and for "assuring that no cytological diagnosis is rendered on such slides"; a requirement that all screening take place in a certified laboratory; and retention requirements for slides and inspection records.

At the state level, past efforts to regulate the laboratory industry or laboratory personnel have also been ineffective and uneven. Even among states having stringent requirements enforcement has been difficult since deficient laboratories simply establish bases in other states and continue to do business-as-usual on an interstate basis.

Very few states regulate laboratory personnel. The Institute of Medicine reports that only five states regulated medical technologists in 1987, the same number reported in a 1975 study of clinical laboratory personnel licensure, discussed below. Pressures to regulate laboratory personnel have been opposed by powerful business and professional interests, and the fragmentation of occupational titles within the industry detracts from the kind of professional solidarity typically necessary to license a profession.

Within the private, voluntary sector, a number of agencies and programs also function to assure the accuracy and quality of clinical laboratory testing. Hospitals are required by the Joint Commission on Accreditation of Healthcare Organizations to have accredited laboratories. Other entities, such as clinics and private physicians' offices are not under such an edict. The Commission on Laboratory Accreditation of the College of American Pathologists conducts quality assurance (onsite inspections and proficiency testing) of laboratories voluntarily seeking accreditation. Agencies that certify laboratory personnel include the Board of Registry of the American Society of Clinical Pathologists, the American Medical Technologists, the National Certification Agency for Medical Laboratory Personnel, and the International Society of Clinical Laboratory Technologists. An appended statement from one faction among many organizational interests illustrates the political climate within the industry.

These programs are not seen as sufficient to ensure universal compliance with appropriate standards, largely because of the voluntary nature of personnel certification programs, and because laboratory accreditation programs extend typically to institutionally-based laboratories and do not include the newer settings for clinical laboratory work (such as POLs). It is for these reasons that CLIA '88 was argued to be necessary.

The existence of private accreditation and certification programs is also used in arguments against state regulation of laboratory personnel.

More importantly, states have resisted pressures to license laboratory personnel on the basis of documentation that occupational regulation increases the cost of health care as well as evidence that its effectiveness as a quality control measure is at best equivocal. A fuller discussion of this evidence is important to decision making with respect to the desirability of state regulation of <u>cytotechnologists</u> and/or <u>cytotechnicians</u>.

IV. THE EFFECTS OF OCCUPATIONAL REGULATION ON COST AND QUALITY

Many of the concerns of House Joint Resolution No. 83 are expressed in terms of working conditions, low wages and other characteristics of the industry alleged to result in low quality and/or inaccuracy of clinical test results. Regulation of cytotechnologists and cytotechnicians is viewed by some as a remedy to these factors. When regulation of occupations and professions is under review, cost must always be a consideration.

Fortuitously, the regulation of clinical laboratory personnel has been the focus of an important study of of the effects of licensure on the cost and quality of services.

White (1979) in a book based on his doctoral dissertation for the Harvard University Department of Economics studied the cost and quality of clinical laboratory services, comparing jurisdictions with varying degrees of restrictive licensure. Jurisdictions in which laboratory personnel were licensed were categorized in two types: Type 1 jurisdictions (Florida, New York City, Nevada, and Tennessee) in which aides, technicians and technologists were licensed, but college degrees were not required for workers to perform tests; and Type 2 states (California and Hawaii) in which a college degree and formal training at the technologist level were required of all who function above the level of aide.

The findings of the study are of interest to advocates and opponents of licensure alike. First, the author cites studies demonstrating that licensure has no impact on quality, then his own analyses confirm that licensure significantly increases wages and alters the mix of labor in clinical laboratories. Wage costs in restrictive jurisdictions were at least 16 percent higher than in less restrictive states. No comparison is made between states having any form of licensure and those without regulation, but the inference is clear that wage increases in regulated states would be considerably higher than the 16 percent increase attributed to variation in restrictiveness among states with regulation.

More surprisingly, licensure appears to reduce upward mobility for laboratory workers, tending to reinforce the very labor market conditions which helped to create pressures for licensure. It does so by increasing labor market segmentation and truncating internal labor markets (White, 1988: 122). More bluntly, licensure in the clinical laboratory industry institutionalizes dead-end jobs.

Important as these findings may be, it is critical to differentiate concerns for work conditions, wages, and other costs and the sole legitimate purpose of state regulation of occupations and professions: the protection of the public

health, safety and welfare. While House Joint Resolution No. 83 is clearly concerned for public protection in terms of the need to increase accuracy and quality of laboratory testing, the assumption that occupational regulation will lead to improved work conditions and a consequent increase in accuracy and quality remains open to question.

V. SHOULD CYTOTECHNOLOGY BE REGULATED: A PRELIMINARY ASSESSMENT

The Virginia Board of Health Professions has adopted six formal criteria to guide evaluations of whether health occupations and professions should be regulated. These criteria were applied to the question of whether cytotechnologists and cytotechnicans should be regulated in the following discussion, based on information currently available.

- Criterion 1. The unregulated practice of an occupation will harm or endanger the health, safety, and welfare of the public. The potential for harm is recognizable and not remote or dependent on tenuous argument.

  The Council believes that the public is placed at unquestionable risk for harm by clinical laboratory testing that is inaccurate or of low quality. Whether this risk is caused by the unregulated practices of cytotechnologists and/or cytotechnicians, or whether it may emanate from the lack of standards imposed on the clinical laboratory industry is unclear. This question should be studied further as the results of new federal legislation and the recommendations of the Joint Legislative Subcommittee Studying Clinical Laboratory Testing become known.

- Criterion 2. The practice of an occupation requires a high degree of skill, knowledge, and training, and the public requires assurances of initial and continuing occupational competency.

  The practice of cytotechnology and cytotechnicianry require varying degrees of skill, knowledge and training. The public requires assurance of initial and continuing competency in these practices. However, the public does not contract directly with cytotechnologists and/or cytotechnicians. Assurances of competency and accuracy are important to those who contract with laboratories and may be available more reliably through institutional guarantees of quality and the imposition of contract requirements based on quality and not solely upon cost.

- Criterion 3. The functions and responsibilities of the practitioner require independent judgment and the members of the occupational group practice autonomously.

  While the functions and responsibilities of cytothechnologists may require independent judgment, it is not clear that the same level of critical thinking is required of cytotechnicians. Neither occupational group typically practices autonomously.

- o Criterion 4. The scope and practice of an occupation is distinguishable from other licensed and unlicensed occupations.

  The practice of cytotechnologists and cytotechnicians is distinguishable from other occupations and professions associated with clinical laboratories and from all other health professions and occupations.

- o Criterion 5. The economic impact on the public of regulating this occupational group is justified.

  Consideration of costs must always be entered in equation with public benefit. The specific benefits of regulation of cytotechnologists and/or cytotechnicians in increased accuracy and improved quality vs. the costs of regulating cytotechnologists and cytotechnicians have not been reliably studied. More information is necessary to determine if this criterion is met.

- o Criterion 6. There are no adequate alternatives to regulation of the occupation that will protect the public.

  The influences of strengthened federal programs to regulate the clinical laboratory industry and the recommendations of the Virginia Joint Legislative Committee Studying Clinical Laboratory Testing are expected to improve substantially the work conditions in laboratories and the quality and accuracy of test results. The effects of these initiatives should be documented reliably before the issue of regulating clnical laboratory personnel is further considered.

Of these criteria, the first is preeminent. That is, if the unregulated practice of an occupation presents no documentable risk to the public, no further consideration is required to conclude that regulation is unwarranted. Because the causes of risk to the public from inaccurate or low-quality test results cannot be sufficiently determined with the evidence at hand, the Board of Health Professions is unwilling to recommend state regulation of cytologists and/or cytotechnicians at this time.

VI. SUMMARY AND CONCLUSIONS

The Board of Health Professions has examined the available evidence supporting state regulation of cytotechnologists and/or cytotechnicians as well as arguments against such regulation.

The existence of serious problems within the clinical laboratory industry is beyond debate. The industry has been destabilized by a host of structural changes in the health care marketplace. These changes include substantial deregulation of the financing and delivery of health services, reimbursement incentives leading to decentralization of the industry, perverse incentives to compete for contracts on the sole or dominant basis of cost, profiteering, lack of ready availability of a sufficiently trained workforce and other factors. The public is placed at substantial risk as a result of this destabilization, and a variety of new initiatives at the federal level and in the Commonwealth are addressed to the management of this risk.

It is not clear that the causes of inaccuracy of laboratory test results, or other problems with quality, rest with the workforce which is comprised almost totally of laboratory employees who do not practice autonomously. Nor is it clear that the regulation of laboratory personnel of any title will lead to significantly improved quality of laboratory products. It is much more certain that state regulation of laboratory personnel will lead to escalation of laboratory costs which will be passed on to the consumer, to further segmentation of the workforce and to barriers to career mobility.

Under these conditions, the recommendation of state regulation of laboratory personnel (whether by registration, statutory certification or licensure) is, at present, unwarranted. Additional time is needed to trace the effects of new federal legislation and of corrective measures recommended for implementation by the Commonwealth by the Joint Legislative Subcommittee Studying Clinical Laboratory Testing.

The Board of Health Professions is prepared to reexamine the issue of state regulation of cytotechnologists and/or cytotechnicians at such time as evidence of the effects of these new initiatives directed toward reform in the clinical laboratory industry becomes available, and funding for such a reexamination is provided.

The Virginia Board of Health Professions appreciates this opportunity to be of service to the the government and the people of the Commonwealth.

APPENDICES

SENATE JOINT RESOLUTION NO. 62

Establishing a joint subcommittee to study clinical laboratory testing.

Agreed to by the Senate, March 11, 1988
Agreed to by the House of Delegates, March 11, 1988

WHEREAS, over the past three decades, thousands of women have undergone Pap smears, the microscopic analysis of cells from the female genital tract to detect cervical cancer; and

WHEREAS, it is estimated that 60,000 women develop cervical cancer and about 7,000 women die from the disease; and

WHEREAS, although the Pap smear has become one of the most common laboratory tests in the nation, it is believed to be one of the most inaccurate; and

WHEREAS, recently, considerable attention has been given to the alleged high failure rate of clinical laboratories to accurately analyze such tests, exacerbating the inaccuracy rate of such tests; and

WHEREAS, clinical laboratories testing and screening for other diseases can also provide false negatives and false positives, as in the testing for the human immunodeficiency virus; and

WHEREAS, the high failure rate of clinical laboratories to accurately analyze Pap smears is believed to be influenced by inadequate cell specimens obtained by health care professionals, high-volume, cut-rate laboratories which perform such analyses on a piecework basis, and overworked, undersupervised, poorly trained and paid technicians; and

WHEREAS, there is growth in clinical laboratory testing in physicians' offices and such testing may not be adequately conducted by trained professionals; and

WHEREAS, it is alleged that some physicians fail to take adequate cell specimens, Pap mills engage in competitive bidding for contracts, and some technicians work two or more jobs and are paid low salaries to perform key analyses; and

WHEREAS, refined sampling techniques, better education and increased compensation and qualifications for technicians, and regulation of clinical laboratories could reduce the high failure rate to accurately screen slides, thereby saving lives; now, therefore, be it

RESOLVED by the Senate, the House of Delegates concurring, That a joint subcommittee is established to study clinical laboratory testing in the Commonwealth. The joint subcommittee shall be composed of eight members to be appointed as follows: two members of the Senate Committee on Education and Health to be appointed by the Senate Committee on Privileges and Elections, one member from the House Committee on Education, and two members of the House Committee on Health, Welfare and Institutions to be appointd by the Speaker of the House, and three citizen members one whom shall be a member of the American College of Pathologists and two of whom shall be the Directors of Clinical Laboratories of the medical schools in the Commonwealth, to be appointed by the Governor. The joint subcommittee shall also ensure the participation of the Deans of the Medical Schools in the Commonwealth, representatives of the Association of Laboratory Technicians, the Association of Schools of Medical Technology, the American College of Preventive Medicine, the State Board of Medicine and other professionals and groups as may be identified in the course of the study. The Commissioner of Health shall serve ex officio.

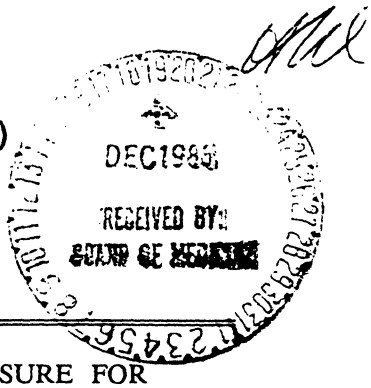
The joint subcommittee shall include in its deliberations a review of the preparation and qualifications of laboratory technicians, clinical laboratory testing, including that performed in private physicians' offices, the need to regulate clinical laboratories, and the appropriate supervision of medical directors and requisite standards for obtaining and preparing cell specimens.

All agencies of the Commonwealth shall provide assistance to the joint subcommittee in the manner it shall deem appropriate.

The joint subcommittee shall complete its work in time to submit its findings and recommendations to the Governor and to the 1989 General Assembly.

The indirect costs of this study are estimated to be $15,440; the direct costs of this study shall not exceed $8,640.

AMERICAN MEDICAL TECHNOLOGISTS' (AMT)
POSITION ON LICENSURE FOR MEDICAL LABORATORY PERSONNEL



AMERICAN MEDICAL TECHNOLOGISTS (AMT) OPPOSES LICENSURE FOR MEDICAL LABORATORY PERSONNEL. IT RECOMMENDS CERTIFICATION OF MEDICAL LABORATORY PERSONNEL AS AN ALTERNATIVE TO LICENSURE. AMT BELIEVES THAT CERTIFICATION IS A COST-EFFECTIVE MEASURE THAT REGULATORY AGENCIES CAN READILY ADOPT AND IMPLEMENT TO ASSURE THE PUBLIC THAT COMPETENT PRACTITIONERS ARE SUPPLYING QUALITY LABORATORY TESTING TO HEALTH CARE PROVIDERS AND CONSUMERS.

PREFACE - Within the last few years there has been increased activity in some states to initiate licensure for medical laboratory personnel and/or facilities. One organization, the American Society for Medical Technology (ASMT) and its constituent state societies, has been the prime mover behind this effort.

All organizations representing generalist laboratory practitioners, specialists, directors, supervisors, managers, medical assistants, physicians, manufacturers of laboratory supplies and equipment, and administrators and staff of health care facilities or regulatory agencies favor quality laboratory testing for the country's health care delivery system. Is licensure the best credentialing mechanism to accomplish quality assurance for medical laboratory personnel?

INTRODUCTION - Since its inception in 1939, AMT has championed the cause of a medical technologist directing a medical laboratory. It pioneered the certification of laboratory directors and supervisors. In 1968 it initiated a certification for medical laboratory technicians, and in 1971 introduced a program for certifying medical assistants. The latter work primarily in clinics and physician offices, and their training prepares them to perform basic laboratory procedures. In addition, AMT supports a career ladder concept whereby the laboratory practitioner through education and/or experience and appropriate examination can advance in the profession.

In the '40s, American Medical Technologists took the initiative in introducing licensure for medical technologists. At AMT's Fifth Annual Convention in 1943, the delegates adopted a model bill for use in states desiring to promote licensure for medical

technologists. Also, AMT made a concerted effort to enact licensure for medical technologists in New York State. The latter was looked upon as a key state which other states would emulate. At the time AMT believed that licensure would allow for medical technology practitioners to be measured against a uniform standard/examination and would override the voluntary system of certification offered by the American Society of Clinical Pathologists (ASCP). In those days, ASCP and ASMT collaborated on medical technologist certification and approval of medical technology education programs through the ASCP Board of Registry and the ASCP Board of Schools. The latter functioned in conjunction with the Council on Medical Education of the American Medical Association.

In his book, Public Health and Private Gain, William D. White writes: "The ASCP itself remained true to the anti-licensure, education-oriented strategy proposed by Dr. John Kolmer in 1925, and in 1937 the Registry officially came out against personnel licensure of any kind for technical personnel. Faced with the efforts of the AMT in this area, the ASCP adopted a defensive policy of opposing licensure unless it seemed certain to pass, in which case the ASCP advised state groups to employ a 'colonial' strategy and capture control of licensing activities for themselves. The ASMT joined this effort and in 1949 drew up a model bill designed expressly to be used as a last resort to capture control of licensure where attempts to introduce it seemed certain to succeed. Concisely summing up the purpose of this model bill, ASMT member Vernal Johnson wrote:

> This bill is intended as a measure of counter legislation, a weapon of self-defense, to be used by our members in states so threatened by unjust legislation.

Non-physician laboratory directors were also interested in licensure as a way of establishing their right to own and operate laboratories and to overcome the competitive advantage the ASCP system gave the pathologists. Some methods used by the College of American Pathologists against non-physician-operated laboratories were quite blatant and resulted in a 1969 consent decree in which pathologists were specifically enjoined against such practices as directly trying to prevent the use of commercial laboratories, boycotting institutions and/or persons who would use these laboratories or trying to prevent these laboratories from advertising in journals or at scientific meetings.

In the early '50s, because of the opposition from ASCP and ASMT, the AMT Board of Directors passed a resolution to stop any further attempts at licensure for medical technologists. The AMT Board further proposed that efforts in this area should have the interest and cooperation of the groups involved with medical technology certification and training, i.e., AMT, ASCP, and ASMT. In addition, the AMT Board voted to oppose legislation/ regulations that would discriminate against the AMT certificants.

Since the decades of the '40s and '50s, important changes have occurred in medical technology that impact on credentialing as it relates to medical laboratory personnel, facilities, and the delivery of quality laboratory services to the health care consumer community. Some of these are:

1. Recognition (1969) of the Accrediting Bureau of Medical Laboratory Schools (now the Accrediting Bureau of Health Education Schools) by the then U.S. Office of Education (now U.S. Department of Education) and subsequent recognition by the Council on Postsecondary Accreditation (COPA).

2. The National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) began operating in 1974, seven years after the call for an arbitration meeting to resolve the Board of Schools issues that arose from the 1969 unsuccessful bid by ASMT to wrest control of the Board of Schools and the Board of Registry from ASCP. NAACLS is an independent agency with equal representation from ASCP and ASMT. The Board of Registry remained with ASCP.

3. AMT established a medical laboratory technician certification; ASCP established a medical laboratory technician and medical laboratory assistant certification. The latter has since been discontinued.

4. ASMTs increased their use of political action as a means of gaining power.

5. The emergence of new organizations; among these were:

   A) The formation (1962) of the International Society for Clinical Laboratory Technology (ISCLT), an organization representing and certifying generalist clinical laboratory personnel at the technologist and technician levels.

   B) ASMT established an independent certification agency--the National Certification Agency for Medical Laboratory Personnel (NCAMLP--short title NCA)--generalist clinical laboratory specialty certifications.

   C) The emergence of phlebotomy certification and phlebotomy organizations.

   D) The formation of the National Commission for Health Certifying Agencies (NCHCA). This is now part of the National Organization for Competency Assurance (NOCA).

   E) The formation of the American Society of Allied Health Professions (ASAHP).

F) The emergence of organizations for medical assistants, i.e., Registered Medical Assistants of the AMT and the American Association for Medical Assistants.

G) The formation of the National Association of Health Career Schools.

6. The growth of specialty organizations (some with certification and/or registry components) such as:

A) The American Association for Clinical Chemistry (AACC).

B) The American Society for Microbiology (ASM).

C) The American Association of Blood Banks (AABB).

D) American Association of Bioanalysts (AAB).

E) Clinical Laboratory Management Association (CLMA).

F) Development of an Affiliate Membership in ASCP.

G) National Clinical Laboratory Association (NCLA).

H) Associations for Histologists, Cytologists.

I) The emergence of private proficiency testing programs through AAB and CAP.

J) Accreditation of clinical laboratories through the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and the College of American Pathologists (CAP).

7. The impact of Federal Legislation on hospital, independent, and interstate laboratories, i.e., Medicare, Medicaid, CLIA '67, CLIA '88 (H.R. 5471).

A) The development of the HHS Proficiency Examination (formerly HEW) to qualify medical technologists to work in independent laboratories.

8. The emergence of private, for-profit health care facilities and large commercial laboratories.

Though the above is not an exhaustive list, it vividly demonstrates the growth of the medical laboratory from a facility in the decades 1930-60 where the pathologist and medical technologist were the prime actors, to the '80s where laboratories are affected by technological advances, especially in automation/robotics; in numbers of generalist, specialist laboratory practitioners; laws/regulations and associations; a variety of facilities that are involved in myriad tests and testing procedures; and the qualifications of the people who

share the responsibility for quality assurance in our medical laboratories.

AFFIRMATION

1. That no one organization in isolation can speak for the medical laboratory and/or its personnel.

2. That there be in existence a realistic career ladder for generalist medical laboratory practitioners based on education and/or experience plus examinations and that this be established from the technician to the director level.

3. That licensure for medical laboratory practitioners is not in the best interest of the practitioner and does not guarantee the consumer the quality assurance claimed by the proponents of personnel licensure.

4. That health care facilities and state regulatory bodies rely on accreditation and certification instead of licensure.

5. That just as recognition of accrediting bodies falls within the scope of the U.S. Department of Education, recognition of certifying agencies should be carried out by the National Commission for Health Certifying Agencies of the National Organization for Competency Assurance.

6. That recognition of certification as a quality control mechanism is less costly and less cumbersome to administer than a licensure program.

7. That to be recognized as a profession/professional one does not need to use medicine's academic stepping stones as a model. Nor is it in the best interest of every allied health practice to seek independent practice status which is often the ultimate product of a licensure process. Current licensure initiatives tend to perpetuate the medicine model.

8. That generalist practitioners utilizing modern technology will be increasingly involved with data acquisition and data retrieval and that education programs must be quick to adapt to these changes. Licensure tends to control entry of new practitioners through strict educational levels.

9. That the diversity and number of interests representing medical laboratory personnel narrow the scope of practice for generalist medical laboratory practitioners.

THE ISSUES

In no other allied health occupation are there the diversity of organizational opinions/philosophies and number of organizations representing medical laboratory personnel as exist in medical technology. However, some would argue that all the various groups are not part of what is called "medical technology."

1. With regard to the four major organizations representing generalist laboratory practitioners, there is no consensus on state licensure for medical laboratory practitioners;

   A) AMT--opposes state licensure.

   B) ASCP/affiliates--maintain a neutral position on licensure, but where states have initiated licensure, they believe that national certification examinations should be recognized rather than duplicate examination preparation efforts.*

   C) ASMT--favors licensure.

   D) ISCLT--has historically been in favor of state licensure that is not unnecessarily restrictive.*

2. The Federal requirements prevail unless state laws are more stringent. It does not necessarily follow that "more stringent" translates into more competence and more quality. Impartial, unbiased data should be provided by proponents advocating more stringent state laws and/or regulations.

3. While ASMT purports to represent the profession of medical technology, its definitions of "Scope of Practice" and "Competencies for Personnel" are not necessarily shared by other medical laboratory organizations and credentialing bodies. ASMT only represents the collective thinking of their active membership component of their reported 23,000 total membership.

4. ASMT and NCAMLP (NCA) without consensus of other medical laboratory credentialing organizations have introduced terminology which they believe is more descriptive for the profession, i.e., "Clinical Laboratory Science" instead of "Medical Technology" and "Clinical Laboratory Scientist" instead of "Medical Technologist." These changes impact on current titles used by a vast majority of the current practitioners recognized by all health care providers, educational institutions, manufacturers of laboratory equipment and providers of services to the laboratories.

   ASMT as a proponent of state licensure is incorporating these titles in their proposed personnel legislation. It appears to be an attempt to legitimize through legislation what they cannot achieve through voluntary consensus.

* In response to AMT's telephone inquiry on October 31, 1988.

5. In an overly-regulated medical laboratory profession and with state licensure initiative calling for academic standards using medicine as a model and independent practice as a possible outcome, will the call for higher academic degrees produce an overly-educated population of generalist laboratory practitioners for the few laboratory positions that might be available to them? It is important that the call for more education be equated to quality and need.

6. What will be the impact of stringent regulations on manpower supply, especially in regard to care of those with sexually transmitted diseases, such as AIDS?

CONCLUSION

AMT reaffirms its opposition to state licensure for medical laboratory personnel unless there is consensus among all the groups representing generalist laboratory practitioners as to qualifications, titles, accreditation and certification policies. AMT reaffirms its position that licensure is a restrictive and protectionist measure and that certification is an acceptable alternative that can ensure quality in laboratory testing at less cost to the consumer. It reaffirms its belief that academic preparation at the technician and medical assistant levels is mandatory, but that the technician, either through additional education and/or experience and examination and through continuing education, be able to advance within the profession to a director position. Lack of an academic degree should not be a barrier to an individual who has initiative, interest and an innate ability to learn on the job and who desires to advance in his/her chosen profession of medical technology.

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