REPORT OF THE
JOINT SUBCOMMITTEE STUDYING

Clinical Laboratory Testing

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

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REPORT OF THE JOINT SUBCOMMITTEE STUDYING CLINICAL LABORATORY TESTING

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To: The Honorable Gerald L. Baliles, Governor of Virginia,
and
The General Assembly of Virginia

I. ORIGIN OF THE STUDY

Recently, a national controversy related to clinical laboratory testing, particularly the analyses of Pap smears, developed which was fueled by a year-long investigation by the Wall Street Journal and coverage by several of the television journalists. The Wall Street Journal investigation resulted in the publication of an extensive review of cytology laboratories entitled "Lax Laboratories."

In Virginia, the public became concerned about clinical laboratory testing through the Wall Street Journal review, the national television presentations and a series of reports on medical laboratories which was aired by Channel 4 News in Washington, D.C. Virginia's citizens became aware that there are no state laws to regulate private laboratories performing Pap smear analyses and other types of medical tests. Many of these citizens contacted their representatives in the General Assembly to express their concerns.

As a result of an outpouring of public concern, five resolutions were introduced during the 1988 Session of the General Assembly which focused on the study of cytology laboratories, cytotechnologists or clinical laboratory testing (HJR 142, HJR 83, SJR 34, SJR 62 and SJR 68). In addition, one bill was introduced to require regulation of cytotechnologists. Two of the resolutions, SJR 62 and HJR 83, were approved. House Joint Resolution 83 requested the Council on Health Regulatory Boards to study the regulation of cytotechnologists. The vehicle for the present study, SJR 62, requested the formation of a Joint Subcommittee to study clinical laboratory testing.

As set forth in SJR 62, the Joint Subcommittee was asked to examine: the preparation and qualifications of laboratory technicians; clinical laboratory testing, including that performed in private physicians' offices; the need to regulate clinical laboratories; the appropriate supervision by medical directors; and the requisite standards for obtaining and preparing cell specimens for analyses.

The Joint Subcommittee consisted of two members of the Senate, Richard L. Saslaw of Springfield and Elliot S. Schewel of Lynchburg; three members

of the House of Delegates, Robert W. Ackerman of Fredericksburg, Shirley F. Cooper of Yorktown and Robert Tata of Virginia Beach; and three citizen members, Dr. Joseph H. Callicott, Dr. Robert J. Faulconer and Dr. George P. Vennart. Dr. C.M.G. Buttery, Commissioner of the Department of Health, served as an ex-officio member of the Subcommittee. Delegate Cooper served as the chairman and Senator Saslaw served as the vice-chairman.

II. FEDERAL LAW AND OTHER REGULATORY ACTIVITIES

The Clinical Laboratory Improvement Act of 1967 and the Clinical Laboratory Improvement Amendments of 1988

The Clinical Laboratory Improvement Act of 1967 (CLIA) established standards for personnel and quality control for the regulation of laboratories that are "engaged in the laboratory examination of, or other laboratory procedures relating to, specimens solicited or accepted in interstate commerce directly or indirectly...." This law applied to laboratories which accepted more than 100 specimens for analyses in interstate commerce per year. The U.S. Department of Health and Human Services is responsible for implementation of this law.

Since its passage in 1967, this act had not been revised until 1988 and some experts were of the opinion that it contained some outdated requirements such as a requirement that "at least a 10-percent random sample of gynecological smears which have been interpreted to be in one of the benign categories by personnel..." be rescreened by the laboratory director or a qualified supervisor. Further, certain laboratories were excepted from this federal law such as physicians office laboratories and laboratories only conducting analyses for insurance policy writing.

Because of the many controversies related to clinical laboratory testing, there were several bills introduced in Congress relating to CLIA. H.R. 5471, which represented a compromise between many interests, was passed during the last days of the 100th Congress. This bill addressed many of the national concerns about clinical laboratory testing. For example, the following provisions are included in H.R. 5471:

1. All clinical laboratories including physicians' office laboratories will be regulated except for those conducting simple tests which "have an insignificant risk of an erroneous result." (See (d)(2) and (d)(3) of H.R. 5471.) Laboratories conducting these simple tests will be physicians' office laboratories. Upon application, these laboratories would be issued a certificate of waiver.

2. All regulated laboratories must be accredited by an approved "accreditation body."

3. All accrediting bodies will be subject to evaluations and must meet certain criteria.

4. All laboratories must adhere to uniform standards "to assure consistent performance...." These standards include quality assurance and quality control programs, uniform record keeping, equipment and facilities requirements and operational requirements as well as personnel standards, quarterly proficiency testing (the proficiency testing programs will include a procedure for the grading of

proficiency testing as well as onsite testing or other testing to evaluate the PT program). In addition, the Secretary may include other requirements. These standards will be premised on the level of sophistication of the testing performed in the laboratory.

5. Conditions on continued operation if the proficiency testing program provides evidence of poor performance. Such conditions may include training, enhanced proficiency testing or some combination of these two.

6. Proficiency testing results will be made available to the public on request.

7. National standards for cytology services will be established which include limitations on the number of slides analyzed in a 24-hour period by one individual, strict record keeping of work loads (number of slides and number of hours worked), criteria for rescreening, testing of individual personnel's proficiency through announced or unannounced onsite testing, 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 inspections.

8. Inspections for all clinical laboratories will be both announced and unannounced.

9. Penalties and sanctions are established such as plans of corrections for deficiencies, fines, onsite monitoring (which will be paid for by the laboratory being monitored), suspension and revocation of certification. If a certificate is revoked, the owner or operator will not be eligible to own or operate a certified laboratory for 2 years.

10. The Secretary will publish information on laboratories including those which are the subject of any disciplinary actions.

In addition, the Secretary of Health and Human Services is required to conduct certain studies related to the efficacy of proficiency testing, the correlation between personnel standards and accuracy of test results, the correlation between quality assurance/quality control programs and the accuracy of test results, the effects of inaccurate test results on diagnosis and treatment, and the effect on testing accuracy of errors occurring in the testing process. The Secretary is required to report to Congress on these matters by May 1, 1990.

The parts of the Act relating to inspections, intermediate sanctions, suspension, revocations and limitations on certificates, injunctions, judicial review, sanctions and fees became effective on January 1, 1989 except that all references to standards continue to mean those standards in effect on December 31, 1988. On January 1, 1990, the rest of the Act becomes effective except that for laboratories which were not previously subject to CLIA the personnel requirements and compliance with the standards will not be required until July 1, 1991. The provisions on the national cytology standards will become effective on January 1, 1990.

Medicaid and Medicare requirements

The Medicaid and Medicare regulations require at least one inspection per year by the state agency which certifies providers for reimbursement (the Virginia Department of Health, Division of Licensure and Certification). Federal standards are used for these inspections. However, laboratories operated by private providers are not required to meet these federal standards nor are such laboratories subjected to this inspection even if the tests are conducted for Medicare beneficiaries or Medicaid recipients and are, therefore, reimbursed with public funds. However, the Omnibus Budget Reconciliation Act of 1987 requires physicians office laboratories conducting a high volume of Medicare testing to be regulated by January 1, 1990.

Other regulatory activities

The Joint Commission for Accreditation of Healthcare Organizations (formerly, the Joint Commission for Accreditation of Hospitals) requires all accredited hospitals to maintain accredited laboratories. Further, as part of the hospital licensure program in Virginia, hospital laboratories are inspected at least once a year.

The Division of Consolidated Laboratories of the Virginia Department of General Services conducts voluntary proficiency testing for laboratories engaging in blood serology testing.

Some other private programs for assuring the quality of laboratory analyses are (please note that this list is not inclusive):

1. Members of the American Clinical Laboratory Association utilize controls in addition to the federal Medicare/Medicaid regulations or the CLIA standards.

2. Various medical technicians and technologists may seek certification from 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.

3. The American Public Health Association publishes "Quality Assurance Practices for Health Laboratories."

4. The Commission on Laboratory Assessment (COLA) has been established by a consortium of concerned medical organizations to provide a voluntary program of proficiency testing for physicians office laboratories.

5. The College of American Pathologists provides voluntary quality assurance and proficiency testing for clinical laboratories.

Various states have laws regulating clinical laboratories, medical technologists and cytotechnologists, etc. For example, approximately 34 states have some form of regulatory laws enacted. Among these 34 states, 16 states purport to regulate physicians office laboratories to varying degrees. Some of these

states require proficiency testing of regulated laboratories, some require inspections and a few have established personnel standards for regulated laboratories (see A Brief Summary of State Regulation of Laboratories in Appendices).

III. A BRIEF ANALYSIS OF THE ISSUES

The issues related to unregulated clinical laboratory testing have been primarily focused on allegations related to analyses of Pap Smears. The allegations have been made that private, for profit laboratories conducting analyses of Pap smears are cut-rate, high volume businesses, which pay poorly, expect workers to perform under poor work conditions and depend on the public perception of the medical profession as infallible in order to maintain public confidence. Laboratories conducting other types of analyses (chemical, e.g., glucose, urea, cholesterol; hematological, e.g., blood cell counts, hemoglobin levels; microbiological, e.g., throat cultures, TB Smears, etc.) have been alleged to suffer from inadequacies related to competency of the personnel and laboratory management. However, it should be stressed that many good laboratories are operating in Virginia and the nation and that the issues related to clinical laboratory testing should be carefully and objectively assessed. The following issues which have been reported in the media, discussed in trade journals or suggested by experts may deserve examination:

1. The practice among unregulated cytology laboratories, particularly the so-called "Pap Mills," of contracting for piece work analyses of specimens, which causes laboratory technicians to analyze large numbers of specimens in a short time. Many technicians hold down full time jobs and then do independent contract work (piece work) at home. The quality of the analyses suffers as a result of fatigue and boredom leading to reports of incorrect readings of 10% or more.

2. The practice of hiring poorly trained or untrained personnel to conduct laboratory procedures in physicians' offices, e.g., glucose, cholesterol, hemoglobin. Many of these individuals have only a high school education or minimal training. These individuals frequently do not have the necessary background to conduct these tests properly. Physicians do not have the time or expertise to supervise or check the performance of these personnel.

3. The need for innovative approaches to education in the Commonwealth for medical technologists and cytotechnologists at or below the baccalaureate level. Lack of interest caused by low professional status has caused the demise of some of these programs in Virginia.

4. A shortage in the supply of certified medical technologists and cytotechnologists because of loss of interest in the profession. The loss of interest in the profession appears to be related to a lack of professional status and the fact that most of the medical technologists and cytotechnologists are women and more lucrative opportunities are now available for women. Further, there is some indication that the Pap smear controversy has increased disinterest in the profession.

5. Inadequacy of the compensation for the medical technologists and cytotechnologists is one of the factors creating the practice of hiring poorly trained personnel and is also one of the factors causing the lack of interest in the profession.

6. Insufficient understanding by physicians of the importance of proper timing and conditions for testing of various kinds, e.g., understanding of the effects of diet on cholesterol levels, cell samples for Pap smears taken at the wrong time of month.

7. Inadequate cell sampling for the performance of proper evaluations of Pap smears. The lack of understanding of the importance of background data on the individual being tested and the problem of inadequate cell sampling may work together to prevent proper diagnosis.

8. The scope of immediate and long term effects of faulty analyses. It is difficult to ascertain the effects of errors in testing on the quality of care. Incorrect analyses may prevent timely diagnosis and implementation of an effective treatment plan. Some experts in medical testing state that false negative test results are more dangerous to the patient than false positive test results. Indeed, false negative tests can create a false sense of security for the patient who may not seek treatment for a serious condition even though he has symptoms because he believes he is "alright."

9. Lack of accountability because laboratory testing is primarily an unregulated activity and because the public has little or no understanding of the potential ramifications of inaccurate test results.

10. The quality of the cytologic analysis (Pap smears) performed for public health clinics in Virginia may be influenced by the procurement process which requires the issuance of the contract to the lowest bidder for services.

11. Accreditation of laboratories is strictly voluntary under most circumstances. Hospitals are required by the Joint Commission on Accreditation of Healthcare Organizations to have accredited laboratories. However, 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.

12. The public is uninformed and under the erroneous impression that laboratories are regulated. Citizens need to be educated to inquire about the analyses of tests, whether the technicians are trained and whether the physician has in-house readings conducted or uses an outside laboratory and if such laboratory is accredited.

13. There is substantial controversy among medical and allied health experts concerning the most appropriate and efficacious method for training technologists and for assuring laboratory quality - some support state and/or federal regulation, others lean towards voluntary methods of seeking improvement.

14. Direct reimbursement of physicians' offices by insurance companies for tests performed by outside laboratories creates a potential for conflict of interest because physicians assess an additional charge and may, therefore, have an incentive to use certain tests. It has been alleged that this is a case of profiting without performing services and also may increase the use of unregulated

laboratories because such laboratories are able to perform tests at less costs, thereby providing the physician with a better profit margin. Many professional associations believe this practice should be eliminated and that laboratories should be directly reimbursed by third party payors.

IV. WORK OF THE JOINT SUBCOMMITTEE

The Joint Subcommittee conducted six meetings, one of which was a public hearing. During its first meeting, the joint subcommittee received a technical briefing from its staff that included an analysis of clinical laboratory issues and an evaluation of applicable federal laws and other regulatory activities. At the first meeting presentations were made by Dr. C.M.G. Buttery, Commissioner of the State Department of Health and Ms. Donna C. Odom, Chairman of the Department of Medical Technology of the Medical Colleges of Virginia.

At the first meeting it was noted that clinical laboratory test results are directly related to decisions affecting an individual's health and life. Members of the Joint Subcommittee stressed 100 percent accuracy in clinical laboratory test analyses as the goal for Virginia to pursue. A primary topic of the first meeting was the demand for more laboratory technologists in Virginia. Members addressed this issue, in conjunction with an alleged reduction in the quality of clinical laboratory services, as well as the qualifications of personnel, as major issues contributing to the controversy surrounding clinical lab testing.

At the second meeting, the Joint Subcommittee received presentations from Dr. John M. Daniel, a practicing physician in Richmond; Dr. Robert Heide, Norfolk Member of the National Laboratory Committee for the American Society of Internal Medicine; Dr. Bernard A. Tisdale, Associate Director of the Blackstone Family Practice Center; Ms. Sharon A. Wentland, Legislative Liaison, Virginia Society of Cytology; Ms. Dottie Massei, President and Ms. Linda Posenau, Vice President, Virginia Society of Cytology; Mr. Alvin M. Salton, Chairman for Government and Professional Relations, American Association of Bioanalysts; and Mr. J. Brian Munroe, Regional Manager, State Government Affairs of Hoffman-La Roche Laboratories.

The focus of the second meeting was on issues of accurate clinical laboratory services, monitoring procedures for quality assurance in physician's laboratories, mandatory or voluntary proficiency testing of laboratories, laboratory testing from the perspective of rural medical centers, educational and training requirements for cytotechnologists and programs for attracting students to the field of cytotechnology.

During the third meeting, the Joint Subcommittee received a review of state regulations of clinical laboratories from its staff. Presentations were made by Dr. William B. Zeiler, President of the College of American Pathologists; Ms. Margie Kilty, Executive Director of the Commission on Office Laboratory Assessment; Ms. Clara Birdsong and Mr. Charles J. Airaghi, Board Members of the Virginia State Society of American Medical Technologists; and Dr. Donna Brodd, Academic Programs Coordinator with the State Council of Higher Education of Virginia. The Joint Subcommittee also heard testimony from six individuals during the public hearing portion of the meeting.

The third meeting was devoted to an assessment of the quality control mechanisms of various states for clinical laboratories, voluntary versus mandatory accreditation programs for laboratories, personnel, quality control and the requirements of such programs, discussion of restrictive licensure programs, a report on cytotechnology programs available in Virginia's institutions of higher education as well as statistics on the number of students and graduates of these programs, evaluation of ways to increase the number of cytotechnologists qualified to work in the Commonwealth and discussion of maximum workload standards for personnel in a single workday.

The fourth meeting was devoted to a work session. The Joint Subcommittee discussed the review of issues and alternatives presented by its staff and made tentative recommendations.

During the fifth meeting, also a work session, the Joint Subcommittee discussed its proposed recommendations to the General Assembly, as drafted by its staff. These recommendations were finalized during the sixth meeting and the draft report was distributed.

V. FINDINGS OF THE JOINT SUBCOMMITTEE

The Joint Subcommittee gave considerable time to discussion on ways to improve the cytology services contracted for public health clinics by the Department of Health. The Joint Subcommittee heard from Commissioner Buttery and Dr. William J. Frable, Director of Surgical and Cytopathology, at the Medical College of Virginia, concerning the problems related to obtaining quality cytology services for clients of public health clinics. At this time, the Department of Health contracts with a laboratory in Texas for all cytology services. Much concern was voiced about the quality of this work and how quality and costs of services interact because of the Procurement Act. Dr. Frable and a number of other individuals expressed substantial doubts about the efficacy of basing the contract awards on costs and discussed measures for ensuring the quality of these services. Several of the members felt that the most viable way of controlling the quality of cytology services would be to contract with laboratories located in the Commonwealth. It was the consensus of the Joint Subcommittee that having the work performed within the state would provide more opportunity for monitoring quality.

Dr. Buttery noted that the bid for the contract would be reissued in February. A number of individuals stated that steps needed to be taken immediately to avoid being forced to contract with any laboratory whose quality is questionable. It was noted that, at this time, there may not be adequate laboratory services in the Commonwealth to provide all of the public health cytology analyses. However, it was felt that over a period of a few years it would be possible to "bring the cytology services back to Virginia." Several people noted that the Department may want to consider contracting for these services on a regional basis (there are five health services areas in the state) in order to allow more local control and monitoring and to avoid overburdening the laboratories with work. Dr. Buttery

stated that contracting for cytology and related services outside the Procurement Act would be more costly and that such an action would require additional, perhaps substantial, appropriations. The beneficial effects of quality services in terms of preventing serious illnesses through accurate diagnoses were also debated. Based on this discussion, the Joint Subcommittee decided to recommend that contracts for cytology and related services be excepted from the Procurement Act in order to authorize the Commissioner to contract with qualified laboratories providing cytology and related services on a noncompetitive basis. Several of the members of the Committee endorsed the concept of regional contracts.

Based on expert testimony, the Joint Subcommittee discussed various approaches to certification of clinical laboratories and credentialing of staff. Comments revolved around the issue of whether voluntary or mandatory accreditation should be recommended for clinical laboratories licensed in the Commonwealth. The Joint Subcommittee evaluated a number of regulatory mechanisms in place in other states. Discussion also included a review of H.R. 5471, passed during the final days of the 100th Congress, requiring that all clinical laboratories (with some exceptions) must adhere to uniform standards of quality assurance and quality control programs, uniform record keeping, equipment and facilities requirements and operational requirements as well as personnel standards, quarterly proficiency testing and any other requirements deemed appropriate. The consensus was that, for the moment, issues specific to Virginia should be addressed; however, no new state programs related to credentialing of professionals of certification of clinical laboratories should be implemented at this time. The Joint Subcommittee believes that many of the problems related to regulation of clinical laboratories and laboratory personnel have been addressed by H.R. 5471 and that a period of monitoring of the implementation of the federal amendments would be appropriate. However, the members agreed that the viability of requiring proficiency testing of laboratory personnel at the state level should be studied.

The Joint Subcommittee received much testimony indicating that there is a growing shortage of medical technologists and technicians and cytotechnologists and cytotechnicians. According to a report delivered to the Joint Subcommittee by Dr. Donna Brodd, Academic programs Coordinator for the State Council of Higher Education for Virginia, there are five community colleges and two private institutions in Virginia which offer programs for medical laboratory technicians. Data also indicate that there has been a substantial decrease in the number of full-time equivalent students in the community college programs from 1982 to 1987 with 137 FTE students reported in 1982 and 85 FTE students reported in 1987. This may be partly attributed to an increase in the number part-time students.

Twenty institutions report granting 974 bachelor's degrees in medical laboratory technology since 1977. Many of the programs appear to be three plus one programs which offer three years of formal instruction and one year of hospital-based experiential credit. Only Norfolk State University, Old Dominion University and Virginia Commonwealth University (MCV) include clinical instruction in their medical technology programs. Old Dominion University and Virginia Commonwealth University have medical technology programs offering master's degrees.

It was noted that nationally and in Virginia there has been a substantial reduction in the number of education programs for medical technologists and cytotechnologists in recent years. For example, Virginia had at least three cytotechnology programs several years ago. None of these programs exist now (DePaul Hospital, the Medical College of Virginia and the University of Virginia). At this time, the only cytotechnology program is offered by Old Dominion University as an interdisciplinary studies degree with a certificate in cytotechnology. There is some indication that, when the organizations certifying cytotechnologist began requiring degrees, the number of students began to decline and some programs were eliminated. It is possible that many students who would be interested in cytology are not able to afford four years of college or are turned off by the heavy requirements for entry in the profession vis-a-vis the anticipated compensation.

A study conducted by the Council on Medical Education of the American Medical Association on the shortage of allied health personnel stated that "...AMA statistics show a steady decline in the numbers of programs, enrolled students, and graduates since 1983, with a disproportionate decline in hospital-based programs. Program numbers have declined from 3,070 to 2,843 during that period; enrollment has declined from 87,270 to 75,879; and graduates have dropped from 38,027 to 32,976"(Section on Medical Schools Interim Meeting, Report D of the Council on Medical Education, Allied Health Personnel Shortage, December 3-4, 1988, American Medical Association, Dallas, Texas, p. 6).

This study also reported that the Bureau of Labor Statistics "reports that changing demographics--both the aging of the population and the declining number of young people -- will lead to an increased need for health care services and fewer young people available to select health careers. In addition, new careers for women are now attracting students who might formerly have selected an allied health profession. Students who have the ability to succeed in mathematics, science, and computer technology required by many health care fields are being attracted to careers offering higher salaries, more status, and greater opportunity for advancement" (CME Rep. D, p. 4).

The members of the Joint Subcommittee discussed the possibility that the issue of underpaid cytotechnologists as a deterrent to recruitment of additional personnel may disappear. Discussion focused on the fact that because there is a limited or dwindling population of trained and certified cytotechnologists, laboratories may be forced to pay accordingly for qualified personnel. Comments focused on the desirability of making cytotechnology more attractive as a career by increasing publicity about the profession, its rewards, and the need for such individuals. Additionally, discussion concerned the value of and means to implementing cytotechnology programs at Virginia institutions of higher education as well as enhancing the program being implemented by Old Dominion University. Some of the members of the Committee were of the opinion that programs at some level below the baccalaureate degree would be appropriate and that such programs might become more acceptable alternatives in future years. Comments addressed the possibility of developing scholarships or forgiving student loans for individuals who pursue and complete a program of cytotechnology studies. The Joint Subcommittee expressed its interest in pursuing the development of a public/private partnership for the implementation of such scholarship or loan programs. It was

noted that at least one large company had made a commitment to assist if a public/private partnership program could be designed. The Joint Subcommittee recognized the potential for crises in shortages of medical technologies, medical technicians, cytotechnologists and cytotechnicians. The members have come to realize that strategies for ameliorating this potential must be implemented.

The statutory responsibilities of the Board on Education for Health Professions and Occupations within the State Council of Higher Education related to "continuous in-depth study of educational needs of nursing and allied health professions and occupations" and the development of "proposals for meeting changing needs" were noted (See § 23-9.10:1 of the Code of Virginia). It was also observed that the Council has statutory responsibilities for reviewing and approving or disapproving new programs pursuant to § 23-9.6:1. The Joint Subcommittee was of the opinion that the most appropriate method for promoting the initiation of new programs in medical technology and cytotechnology was to request the Council and the Board to examine the problems related to the availability of training for medical technologists and cytotechnologists and to make recommendations to remedy the inadequate supply of such personnel.

Experts testified that, because of technical advances, there has been considerable improvement in the quality of physicians office laboratories, although it was also noted that virtually none of these laboratories are regulated in any way. Further, testimony presented to the Congressional Subcommittee on Oversight of Government Management of the Senate Committee on Governmental Affairs (Judith T. Barr, Sc.D., Chairperson, Government Affairs Committee of the American Society for Medical Technology) indicated that as high as 75% of physicians' offices perform laboratory services, that there is great diversity in the number and kinds of tests conducted, and that many of these laboratory tests are conducted by individuals with little or no training. The Joint Subcommittee discussed what form of regulation, if any, would be appropriate. It was observed that many of these laboratories will be covered by the new federal amendments. Members also noted that there are organizations which maintain voluntary accreditation programs for physicians office labs, such as the recently incorporated Commission on Laboratory Assessment. Representatives of the Medical Society of Virginia maintained that physicians office laboratories provide quality services which benefit patients by being conveniently and immediately available. For these reasons, the Joint Subcommittee concluded that it was not appropriate at this time to propose mandated regulation of POLs. However, the Joint Subcommittee felt that physicians should be encouraged to participate in the COLA program.

The Joint Subcommittee's discussion included the efficacy of requiring standardized terminology, establishment of workload guidelines with no more than a set maximum number of tests to be performed by an individual in any eight hour work day and proficiency testing. Many individuals had expressed concern about establishing limitations on the numbers of slides that could be analyzed in a work day because of the shortage of cytotechnologists and the differences in individual's capabilities. Similar comments had been made about the possibility of restricting PAP smear analyses to the laboratory setting. It was also noted that such restrictions could adversely affect the retention rate of personnel because it would

reduce the earning capacity of many cytotechnologists. The Joint Subcommittee became convinced that any reduction in the number of professionals in the medical technology and cytotechnology professions could have dire effects on patient care and the costs of care. Because the new federal law already includes restrictions on the number of slides analyzed per day and record keeping requirements, the Joint Subcommittee did not feel that any additional state standards were necessary.

The Joint Subcommittee attempted to address the issue of reimbursement for testing and mark-ups by physicians for testing conducted by reference laboratories. No consensus could be reached at this time on this complicated and difficult issue. The Committee observed that, although efforts to resolve this issue at the federal level have met with strong opposition, Congress may be addressing this problem again in the coming year.

After some discussion of the issues related to reimbursement for testing and physicians interests in laboratories, the Joint Subcommittee concluded that physicians' ownership of clinical laboratories should be subject to the disclosure provisions of §54.1-2964 of the Code of Virginia. It was believed that disclosure of such financial interests would provide patients with some information on which to base future health care services decisions.

The Joint Subcommittee also discussed communications between physicians and patients concerning test results. It was the consensus of the Committee that disclosure of test results directly to the patient was usually appropriate; however, several members described circumstances under which direct disclosure to the patient might not be beneficial. Even though some testimony was received by the Committee to the effect that most physicians communicate test results either orally or in writing to their patients, the Subcommittee emphasized that it considered deeming lack of communication to mean negative results was an unacceptable practice. "If you don't hear from us, everything is alright" provides great potential for error in the opinion of the Joint Subcommittee. However, in view of the many difficulties in formulating a workable law for proper communications between physicians and patients, the Joint Subcommittee decided that the task of encouraging proper and appropriate disclosure of tests results should, at this time, rest with the medical community.

VI. RECOMMENDATIONS OF THE JOINT SUBCOMMITTEE

Based on the findings detailed above, the Joint Subcommittee Studying Clinical Laboratory Testing recommends that:

1. The Commissioner of the Department of Health be authorized to contract for cytology and related services without complying with the Procurement Act (see H.B. 1622 in Appendices).

2. A statute be adopted requiring that consumers be provided a warning when purchasing home testing kits to the effect that clinical testing can be inaccurate under the best of circumstances when conducted by professionals; therefore, the results of the tests should be validated by obtaining professional medical consultation and, if recommended, another test (see H.B. 1621 in Appendices).

3. A resolution be introduced requesting the Medical Society of Virginia and the Board of Medicine to physicians to participate in the voluntary accreditation program of the Commission on Office Laboratory Assessment (see HJR 355 in Appendices).

4. A resolution be introduced requesting the Medical Society of Virginia and the Board of Medicine to promote appropriate physician-patient communication concerning test results (see HJR 353 in Appendices).

5. A resolution be introduced requesting the Virginia Hospital Association to encourage its members to subject medical testing conducted outside of central laboratories to quality assurance procedures (see HJR 354 in Appendices).

6. A resolution be introduced requesting the State Council of Higher Education to assume a leadership role in developing certain programs (see HJR 352 in Appendices).

7. Section 54.1-2964 of the Code of Virginia be amended to provide that physicians must disclose any material financial interest or ownership interest in an outside laboratory used to perform tests for their patients (see H.B. 1620 in Appendices).

8. A resolution be introduced requesting Old Dominion University, in cooperation with the State Council of Higher Education and the Virginia Community College System, to study the feasibility of developing educational alternatives for medical technologists and cytotechnologists (see HJR 331 in Appendices).

9. The Joint Subcommittee's study be continued in order to evaluate initiatives to attract and retain high quality individuals in the cytology and medical technology professions; examine ways to ensure accurate medical testing without imposing unnecessary or stringent regulation, such as proficiency testing programs; evaluation appropriate procedures for the reporting of test results to patients; identify ways to ensure the high quality of the cytology and related services provided to public health clients in the Commonwealth; monitor the regulatory effects of the new federal law known as the "Clinical Laboratory Improvement Amendments of 1988"; cooperate with the Board of Health Professions in examining issues related to cytotechnologists and medical technologists; assess the billing and charging issues related to clinical laboratory services; and monitor the studies requested of state agencies (see HJR 356 in Appendices).

VII. CONCLUSIONS

During the course of this study, the members of the Joint Subcommittee have come to understand how very difficult and complicated the issues related to medical testing. The Joint Subcommittee realizes that medical tests are a vital part of health care that has been largely untouched by public policy. The Joint Subcommittee wishes to stress that the personnel shortages which have been described to it could become personnel crises unless remedial measure are developed. Steps must be taken to ensure that an adequate supply of medical

technologists and cytotechnologists as well as technicians in these fields will be maintained. In addition, there are many ethical and fiscal issues within the clinical laboratory testing area, which have great influence on the quality and costs of health care and should be the subject of sincere debate and compromise among all involved segments of the health care industry. One example of these issues is direct reimbursement of clinical laboratories by third party payors.

The Joint Subcommittee strongly supports the concept of contracting for public health cytology and related services with laboratories located in the Commonwealth. It appears obvious to the Committee that the quality of services could be monitored and, therefore, maintained with much greater efficiency if these services are performed in the state. The Joint Subcommittee realizes that this action would increase the costs of the services; however, the benefits in terms of preventive health care could offset these costs.

The Joint Subcommittee reiterates its opinion that physicians office laboratories should seek voluntary accreditation and that all medical testing, regardless of its level of sophistication, should be subject to quality controls and proficiency testing. Further, the members are hopeful that the discussion of communications between physicians and their patients which was begun by this study will continue and will result in more information flowing to the health care consumers in order to enable these consumers to participate in decisions about their health care.

The Joint Subcommittee wishes to emphasize that, in its opinion, the recommendations made during this year of the study are only a good beginning towards resolving the many crucial problems related to clinical laboratory testing. However, changing demographics in the availability of training and the relationship of training to accuracy of test results, salary projections, working conditions, and labor market needs must be assessed and, if possible, adjusted in order to assure accurate medical testing and, therefore, diagnoses for the citizens of Virginia.

The Joint Subcommittee wishes to thank the many experts and citizens who assisted with this study - the list is long and includes many prestigious names.

Respectfully submitted,

Delegate Shirley F. Cooper, Chairman

Senator Richard L. Saslaw, Vice-Chairman

Senator Elliot S. Schewel

Delegate Robert W. Ackerman

Delegate Robert Tata

Joseph H. Callicott, Jr., M.D.

Robert J. Faulconer, M.D.

George P. Vennart, M.D.

APPENDICES

Senate Joint Resolution No. 62, 1988 - Enabling legislation

A Brief Summary of State Regulation of Laboratories

Degrees Conferred in Medical Technologies in Virginia *

F.T.E. Enrollment in Medical Technologies in Virginia *

Issues and alternatives Paper

House Bill No. 1620, 1989 (See recommendation 7, page 13.)

House Bill No. 1621, 1989 (See recommendation 2, page 12.)

House Bill No. 1622, 1989 (See recommendation 1, page 12.)

House Joint Resolution No. 331, 1989 (See recommendation 8, page 13.)

House Joint Resolution No. 352, 1989 (See recommendation 6, page 13.)

House Joint Resolution No. 353, 1989 (See recommendation 4, page 13.)

House Joint Resolution No. 354, 1989 (See recommendation 5, page 13.)

House Joint Resolution No. 355, 1989 (See recommendation 3, page 13.)

House Joint Resolution No. 356, 1989 (See recommendation 9, page 13.)

Please note that, when two copies of any bill or resolution implementing a recommendation are provided, the first copy is the introduced bill or resolution and the second copy is the approved bill or resolution.

* Prepared by Dr. Donna Brodd, State Council of Higher Education

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 finds 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.

A BRIEF SUMMARY OF STATE REGULATION OF LABORATORIES

States Regulating Hospital and/or Independent Laboratories are: Alabama, Alaska, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New York, Oregon, Pennsylvania, Puerto Rico, Rhode Island, Tennessee, Utah, Vermont, Washington, West Virginia, Wisconsin, Wyoming.

States Regulating Physicians' Office Laboratories are: California, Florida (group practice of six or more), Idaho, Illinois, Maine, Maryland (group practice of four or more), Massachusetts (group practice of three or more), Michigan (group practice of six or more), Nevada, New Jersey (group practice of five or more), Oregon, Pennsylvania, Puerto Rico, West Virginia, Wisconsin, (group practice of 3 or more) Wyoming.

States Requiring Proficiency Testing of Regulated Laboratories Including Physicians' Office Laboratories: California, Florida, Idaho, Illinois, Maine, Maryland, Massachusetts, Michigan, Nevada, New Jersey, Oregon, Pennsylvania, Puerto Rico, West Virginia, Wisconsin, Wyoming.

States Requiring Inspections of Regulated Laboratories Including Physicians' Office Laboratories: Florida, Hawaii, Idaho, Illinois, Maine, Maryland, Massachusetts, Michigan, Nevada, New Jersey, Oregon, Pennsylvania, Puerto Rico, West Virginia, Wisconsin, Wyoming.

States Regulating the Personnel of Laboratories Including Physicians' Office Laboratories: Florida, Massachusetts, Michigan, Nevada, New Jersey, Oregon, Pennsylvania, Puerto Rico, West Virginia, Wisconsin, Wyoming.

Some Unique Characteristics of State Regulatory Programs:

California requires all laboratories to do proficiency testing.

Connecticut requires all unregulated laboratories to register yearly.

Georgia does not regulate physicians' office laboratories if they only do testing for their patients (which basically means POL's are not regulated).

Hawaii may require proficiency testing of any laboratory.

Idaho requires all laboratories to register; regulates according to the complexity of the testing.

Illinois has a recently passed law (April, 1988) which establishes levels of regulation for all laboratories (unless the organization is licensed under another law); requires the appointment of a clinical laboratory science board consisting of physicians and technologists; includes criteria for laboratory personnel.

Maine will require proficiency testing for all regulated laboratories; some simple tests will be excepted. Massachusetts has similar provisions.

Maryland regulates all categories of laboratories, but exempts physicians' office laboratories if only do tests on patients; requires rules which will limit the number of slides a cytotechnologist may analyze; prohibits piecework and take home work; requires procedure for handling broken slides; requires rejection of unsatisfactorily prepared specimens (slides); prohibits the use of out-of-state, unlicensed laboratories (i.e., Maryland state licensed laboratories); requires proficiency testing of all cytology laboratories.

Nebraska has a new law establishing requirements for training, regulating clinical laboratory technologists and trainees and regulating the personnel according to complexity of the tests.

Nevada may require all laboratories to perform proficiency testing and also may require inspections.

New Jersey may be going to regulation of all laboratories with levels of requirements.

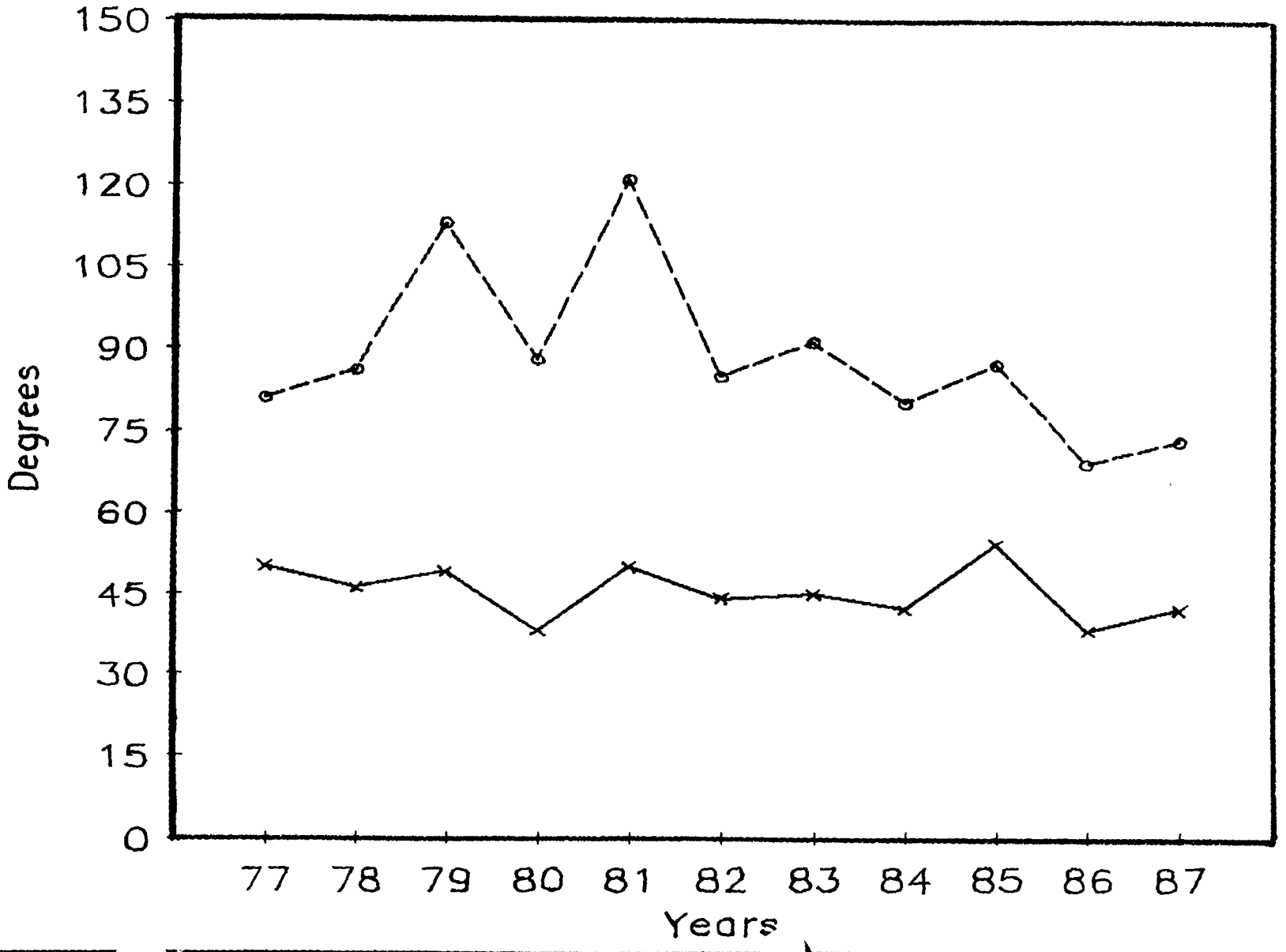
Pennsylvania requires proficiency testing, does inspections and also sets requirements for personnel.

West Virginia only regulates physicians' office laboratories participating in Medicaid.

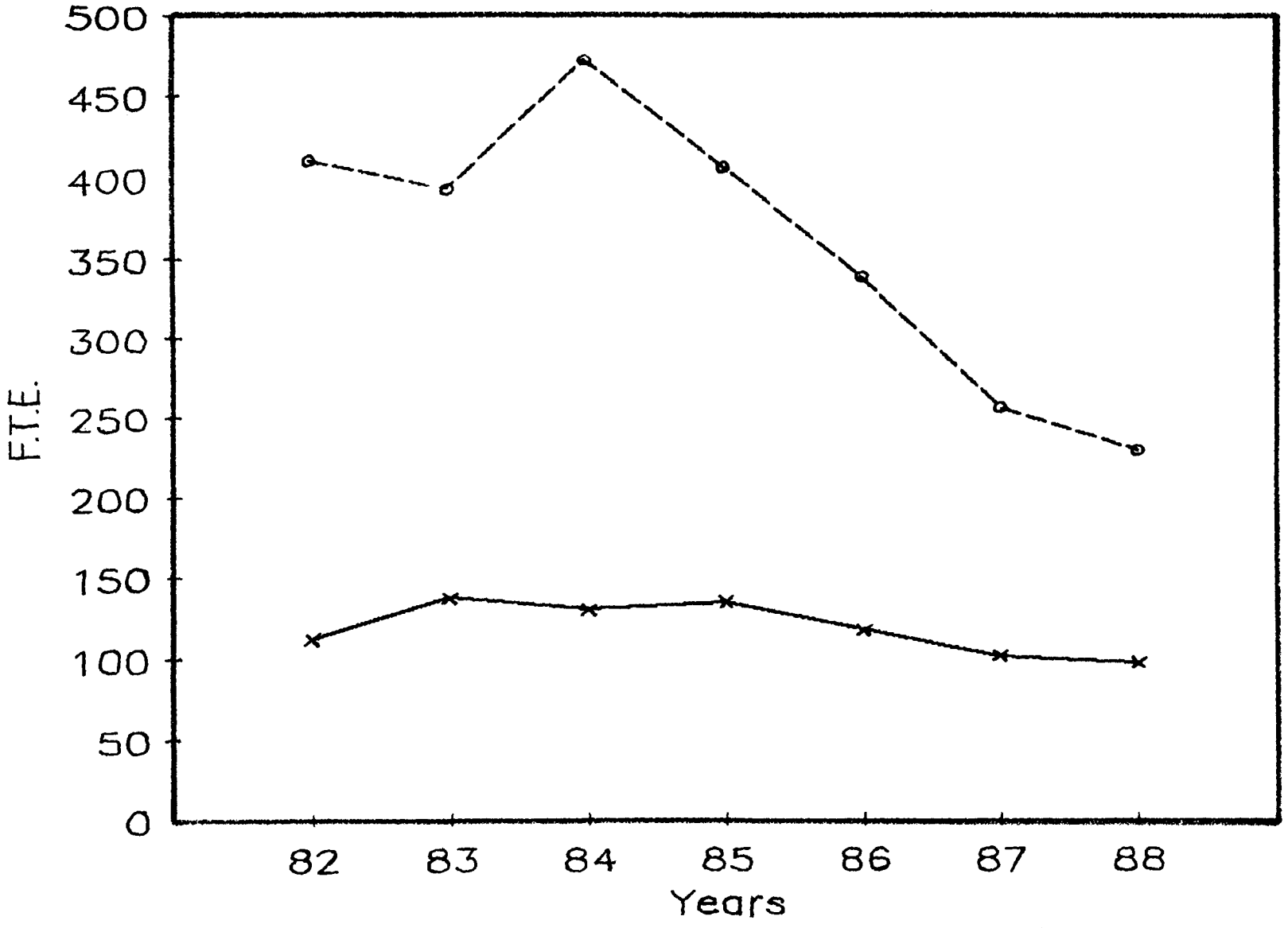
Wyoming is planning to regulate according to the complexity of the testing; already regulates reference laboratories.

Degrees Conferred in Medical Technologies

Associate Degrees in Med. Lab. Technology — solid line
Bachelor's Degrees in Medical Technology — dotted line



F.T.E. Enrollment in Medical Technologies
Medical Lab Technologies — solid line
Medical Technology — dotted line
Public Institutions only



Senate Joint Resolution No. 62 established this joint subcommittee and directed it to:

1. Examine the preparation and qualifications of medical technologists and cytotechnologists;

2. Review clinical laboratory testing including that performed in private physicians' offices;

3. Evaluate the need to regulate clinical laboratories and the appropriate level of supervision of medical directors; and

4. Evaluate the need for requisite standards for obtaining and preparing cell specimens.

During the final days of the 100th Congress, H.R. 5471 was passed - an event relevant to your decision-making process. This bill addresses many, but not all, of the concerns of this subcommittee. It contains the following provisions:

1. All clinical laboratories including physicians' office laboratories will be regulated except for those conducting simple tests which "have an insignificant risk of an erroneous result." (See (d)(2) and (d)(3) of H.R. 5471.) Laboratories conducting these simple tests will be physicians' office laboratories. Upon application, these laboratories would be issued a certificate of waiver.

2. All regulated laboratories must be accredited by an approved "accreditation body."

3. All accrediting bodies will be subject to evaluations and must meet certain criteria.

4. All laboratories must adhere to uniform standards "to assure consistent performance by laboratories...." These standards include quality assurance and quality control programs, uniform record keeping, equipment and facilities requirements and operational requirements as well as personnel standards, quarterly proficiency testing (the proficiency testing programs will include a procedure for the grading of proficiency testing as well as on-site testing or other testing to evaluate the PT program). In addition, the Secretary may include other requirements. These standards will be premised on the level of sophistication of the testing performed in the laboratory.

5. Conditions on continued operation if the proficiency testing program provides evidence of poor performance such as training, enhanced proficiency testing or some combination of these two.

6. Proficiency testing results will be made available to the public on request.

7. National standards for cytology services will be established which include limitations on the number of slides analyzed in a 24-hour period by one individual, strict record keeping of work loads (number of slides and number of hours worked), criteria for rescreening, testing of

individual personnel's proficiency through announced or unannounced on-site testing, 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, retention requirements for slides and inspections.

8. Inspections for all clinical laboratories will be both announced and unannounced.

9. Penalties and sanctions are established such as plans of corrections for deficiencies, fines, on-site monitoring (which will be paid for by the laboratory being monitored), suspension and revocation of certification. If a certificate is revoked, the owner or operator will not be eligible to own or operate a certified laboratory for 2 years.

10. The Secretary will publish information on laboratories including those which are the subject of any disciplinary actions.

Most of the act becomes effective on 1/1/89 (inspections, intermediate sanctions, suspension, revocation, injunctions and court review and fees). Laboratories which have not been covered by CLIA prior to this act will be covered on 7/1/91 and personnel requirements and compliance inspections every 2 years will begin on 7/1/91. Many of the other provisions including those on the national cytology standards will become effective on 1/1/90.

Several problems which are unique to Virginia have not been addressed by the federal legislation as well as several problems which are not unique to the Commonwealth. These issues are set out below.

I. How can the concerns about the cytology services contracted for public health clinics by the Department of Health be resolved?

The Commissioner has stated that the Department is currently developing standards for laboratory contracts for cytology services. He also related that the costs of the services only become an issue if the laboratory meets the requirements of the request for bids. However, these statements have not resolved the concerns of many citizens about the quality of the services presently being provided. The following alternatives are offered:

A. Status quo. Do nothing and rely on the Commissioner and the Department to purchase the best services for the lowest price.

B. Direct a resolution to the Commissioner and the Department directing them to develop strict standards for laboratory contracts for cytology services.

C. Sponsor a bill placing in law a requirement that the Commissioner and the Department develop strict standards for laboratory contracts for cytology services. Such a statute could contain specific criteria, e.g., the use of an enhanced proficiency testing program.

D. Require in law that rescreening be conducted for all at risk public health patients and that no diagnosis be made on the basis of a single test result for public health patients.

II. How can the concerns about the increase in the number of tests and the sites of testing be resolved?

One of the primary concerns of the clinical laboratory industry is the proliferation of testing, e.g., for example, home testing, supermarket testing, etc. These tests may not be accurate and can created a false sense of security or anxiety among consumers.

A. Status quo. Do nothing and depend on the Federal Food and Drug Administration and the liability implications for the pharmaceutical industry to control this situation.

B. Provide in statute that home tests and testing conducted outside a laboratory by nonprofessionals must contain a warning that clinical testing can be inaccurate under the best of circumstances when conducted by professionals; therefore, the results of the tests should be validated by obtaining professional medical consultation and, if recommended, another test.

C. Memorialize Congress to investigate this situation and to provide legislation to prevent a problem before a serious one develops.

III. How can the quality of the testing in many physician's office laboratories which will not be regulated under the new federal act be assured?

Many physicians's office laboratories in Virginia will not be regulated under the new federal provisions. The question is whether any laboratory test is so simple that the office conducting the test should be left completely unregulated. Various solutions could be found, which would not cost the Commonwealth any money, for resolving this situation if the Subcommittee finds that it is desirable.

A. Status quo. Do nothing and depend on the provisions of the federal law and the integrity of the medical profession to assure this quality.

B. Provide a resolution recommending that the Medical Society of Virginia encourage its members to participate in the program being developed by the Commission on Laboratory Assessment.

C. Introduce a statute requiring all physician's office laboratories which will be excepted under the amendments to CLIA to participate in the program being developed by the Commission on Laboratory Assessment.

IV. How can the controversy surrounding the direct billing of laboratory services be resolved?

This issue was not addressed in the federal legislation because of the threat by the medical community to derail the bill. It has been alleged that direct reimbursement of physicians' offices by insurance companies for tests performed by reference laboratories creates a potential for conflict of interest because physicians assess an additional charge and may, therefore, have an incentive to use certain tests and certain laboratories (unaccredited, unregulated laboratories, since reimbursement may be obtained by physicians from Medicaid and

Medicare regardless of the status of the laboratory). It has been argued that this is a case of profiting without performing services and that reimbursement of physicians' offices for testing may create an incentive to use cheaper, unregulated laboratories because of the potential to maximize profits.

A. Status quo. Do nothing and allow the medical community and the laboratory community to resolve this issue between them.

B. Amend the insurance statues to require direct reimbursement of reference and hospital laboratories for testing performed for physicians' offices.

C. Direct a resolution to the Medical Society of Virginia requesting that the members be encourage to resolve this issue voluntarily in cooperation with the insurance industry and the clinical laboratory industry.

V. How can the problem related to physician reluctance to disclosed testing results to patients be resolved?

Many physicians provide their patients with copies of test results as a matter of course. However, there are still physicians who feel that the patient does not need to receive copies of test results because he would not understand the language anyway and it is better for the patient to receive a modified explanation of the test results from the physician. The consumer attitude towards this situation is undergoing change, however. Many consumers feel that since they are paying for the service, they should receive a copy of any test results and that the physicians's explanation should relate to the language in the test result.

A. Status quo. Do nothing and assume that the growing sophistication among consumers in conjunction with growing physician awareness of patient attitudes will resolve this issue.

B. Introduced a resolution requesting the Medical Society of Virginia to cooperate in educating the members about this situation and to encourage treating physicians to provide copies of tests results to patients in order to initiate the critical involvement of the patient in his own care.

C. Introduce a bill requiring all physicians to provide patients with copies of all test results and to relate their explanations to the test results.

VI. How can the issue related to physician self-referrals to clinical laboratories in which they own an interest be resolved?

This issue was not addressed by the federal legislation because of the threat to derail the legislation by the medical community. Section 54-278.3 of the Code of Virginia requires all practitioners of the healing arts to disclose ownership interest in facilities engaged in the provision of health-related services when referring patients. However, this section does not appear to address the issue of self-referral to laboratories.

A. Status quo. Do nothing and assume that the federal legislation will be amended to resolve this issue in the future.

B. Amend Section 54-278.3 to provide that physicians must disclose any ownership interest in a laboratory used to perform tests for their patients. Such legislation could specifically note reference and hospital laboratories and require that the patient be offered an option to have the test performed by another facility.

C. Introduce a bill to prohibit physician self-referral to reference or hospital laboratories.

VII. How can the need for cytotechnologists and medical technologists be addressed?

It has been noted that nationwide the programs for technologists have decreased from 108 to 33 over a few years. There is little doubt that a shortage of medical technologists and cytotechnologists has already occurred and will only get worse unless something can be done to alleviate the problems. Many of the causes of this shortage are similar to the causes of the nurses shortage. This is a woman's profession, the pay may not be adequate, opportunities for advancement may be few and women are able to enter more lucrative, prestigious professions. Old Dominion University established a program for cytotechnologists which has received no applications. This type of issue is difficult to address legislatively; however, some efforts can be suggested.

A. Status quo. Do nothing and assume that the demand for the services of medical technologists and cytotechnologists will initiate remedies.

B. Require or encourage ODU to develop and implement an aggressive, attractive marketing program for its new curriculum.

C. Request ODU to cooperate with the Department of Education and the school divisions to recruit at the high school level, e.g., guidance counselors could be instructed at their annual meeting about the profession and its attributes.

D. Direct a resolution to hospital and reference laboratories encouraging them to develop merit pay scales, improved starting salaries and to develop career opportunities for medical technologists and cytologists.

E. Direct a resolution to ODU requesting the study of the feasibility of developing a 2 plus 1 program for medical technologists and cytotechnologists in cooperation with one or more of the community colleges, e.g., Thomas Nelson and Tidewater.

F. Develop a scholarship program for medical technologists and cytotechnologists. Such a a program could be a public/private partnership.

VIII. Should the State establish a regulatory program which is equivalent to or more stringent than the federal program?

The federal law will allow states to run their own programs. However, since Virginia does not have a program, the expense could be

considerable. It does not appear that federal money will be appropriated to assist the states with establishing any regulation. Fees appear to be the mechanism for funding the operation of the additional requirements. Therefore, the cost of initiating any program and the fact that the federal program will include many of the elements needed to ensure the public health and safety would require that any such new program receive careful evaluation.

A. Status quo. Do nothing and monitor the development of the federal program to ascertain its effectiveness.

B. Introduce a bill establishing a regulatory program consistent with the federal bill.

C. Introduce legislation intended to fill in the gaps of the federal legislation.

IX. Should the work of the joint subcommittee be continued to 1989?

There are still many problems deserving examination in this area. For example, a scholarship program would be desirable; however, the State is being deluged with requests for money for extending or establishing programs. It might be efficacious to extend this study to develop a public/private partnership for the resolution of the shortage of medical technologists and cytotechnologists.

A. Status quo. Allow the study to expire after this year and assume that any remaining issues will be resolved by the federal legislation.

B. Introduce a continuing resolution to examine any or all of the following issues:

1. The formation of a public/private partnership to encourage entrance in the medical technology and cytotechnology professions.

2. The efficacy of requiring all laboratories to be regulated by the Commonwealth.

3. The efficacy of requiring the registration of all laboratories, i.e., for the collection of data on the number, personnel needs, etc.

4. The monitoring of the results of the Council on Health Regulatory Boards study of regulation of cytotechnologists.

5. The effectiveness of the recommendations of the Council.

6. The monitoring of the publicity efforts for the ODU program.

7. The efficacy of requiring all cytopathology labs to adhere to the ASCP Committee guidelines (as finalized).

8. Whether all cytotechnologists should be required to be certified.

1989 SESSION

LD6924441

HOUSE BILL NO. 1620

Offered January 24, 1989

A BILL to amend and reenact § 54.1-2964 of the Code of Virginia, relating to disclosure of interest in referral facilities and clinical laboratories.

Patrons--Cooper, Cunningham, J. W., Christian, Councill, Munford, Van Landingham, Keating, Robinson, Moss, Stieffen, Martin, Tata, Grayson, Copeland, Crenshaw, Purkey, Brown, Jones, J. C., Crouch, Van Yahres and Woods; Senators: Miller, Y. B., Schewel and Saslaw

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Referred to the Committee on Health, Welfare and Institutions

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Be it enacted by the General Assembly of Virginia:

1. That § 54.1-2964 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-2964. Disclosure of interest in referral facilities and clinical laboratories.--A. Any practitioner of the healing arts shall, prior to referral of a patient to any facility or entity engaged in the provision of health-related services, appliances or devices, including but not limited to physical therapy, hearing testing, or sale or fitting of hearing aids or eyeglasses provide the patient with a notice in bold print that discloses any known material financial interest of or ownership by the practitioner in such facility or entity and states that the services, appliances or devices may be available from other suppliers in the community. In making any such referral, the practitioner of the healing arts may render such recommendations as he considers appropriate, but shall advise the patient of his freedom of choice in the selection of such facility or entity. This section shall not be construed to permit any of the practices prohibited in § 54.1-2914.

In addition, any practitioner of the healing arts shall, prior to ordering any medical test from an independent clinical laboratory for a patient, provide the patient with notice in bold print that discloses any known material financial interest or ownership by the practitioner in such laboratory unless the independent clinical laboratory is operated by a publicly held corporation. The practitioner shall inform the patient about the accreditation status and credentials of the laboratory.

B. The Attorney General, a Commonwealth's attorney, the attorney for a city, county or town, or any aggrieved patient may cause an action to be brought in the appropriate circuit court in the name of the Commonwealth, of the county, city or town, or of any aggrieved patient, to enjoin any violation of this section. The circuit court having jurisdiction may enjoin such violations, notwithstanding the existence of an adequate remedy at law. When an injunction is issued, the circuit court may impose a civil fine to be paid to the Literary Fund not to exceed $1,000. In any action under this section, it shall not be necessary that damages be proven.

Official Use By Clerks	
Passed By The House of Delegates	**Passed By The Senate**
without amendment ☐	without amendment ☐
with amendment ☐	with amendment ☐
substitute ☐	substitute ☐
substitute w/amdt ☐	substitute w/amdt ☐
Date: _____	Date: _____
_____	_____
Clerk of the House of Delegates	Clerk of the Senate

An Act to amend and reenact § 54.1-2964 of the Code of Virginia, relating to disclosure of interest in referral facilities and clinical laboratories.

[H 1620]

Approved MAR 20 1989

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-2964 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-2964. Disclosure of interest in referral facilities and clinical laboratories.—A. Any practitioner of the healing arts shall, prior to referral of a patient to any facility or entity engaged in the provision of health-related services, appliances or devices, including but not limited to physical therapy, hearing testing, or sale or fitting of hearing aids or eyeglasses provide the patient with a notice in bold print that discloses any known material financial interest of or ownership by the practitioner in such facility or entity and states that the services, appliances or devices may be available from other suppliers in the community. In making any such referral, the practitioner of the healing arts may render such recommendations as he considers appropriate, but shall advise the patient of his freedom of choice in the selection of such facility or entity. This section shall not be construed to permit any of the practices prohibited in § 54.1-2914.

In addition, any practitioner of the healing arts shall, prior to ordering any medical test from an independent clinical laboratory for a patient, provide the patient with notice in bold print that discloses any known material financial interest or ownership by the practitioner in such laboratory unless the independent clinical laboratory is operated by a publicly held corporation. The practitioner shall inform the patient about the accreditation status and credentials of the laboratory.

B. The Attorney General, a Commonwealth's attorney, the attorney for a city, county or town, or any aggrieved patient may cause an action to be brought in the appropriate circuit court in the name of the Commonwealth, of the county, city or town, or of an aggrieved patient, to enjoin any violation of this section. The circuit court having jurisdiction may enjoin such violations, notwithstanding the existence of an adequate remedy at law. When an injunction is issued, the circuit court may impose a civil fine to be paid to the Literary Fund not to exceed $1,000. In any action under this section, it shall not be necessary that damages be proven.

_____

President of the Senate

_____

Speaker of the House of Delegates

Approved:

_____

Governor

1989 SESSION

LD6921441

HOUSE BILL NO. 1621

Offered December 8, 1988

A BILL to amend the Code of Virginia by adding a section numbered 18.2-502.2, relating to warning on certain medical tests; penalty.

Patrons--Cooper, Cunningham, J. W., Christian, Andrews, Councill, Medico, Rollins, Byrne, Keating, Munford, Van Landingham, Marshall, Robinson, Moss, Stieffen, Crouch, Tata, Ackerman, Grayson, Stambaugh, Copeland, Crenshaw, Brown, Van Yahres and Woods; Senators: Miller, Y. B., Schewel and Saslaw

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Referred to the Committee on Health, Welfare and Institutions

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Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered 18.2-502.2 as follows:

§ 18.2-502.2. Warning required for certain medical tests; penalty.--No commercial medical testing kit designed for consumer home use shall be sold in this Commonwealth unless a warning is provided to the consumer to the effect that such tests may produce erroneous results and that medical testing is most accurate when performed by professionals within the controlled conditions of a laboratory. The consumer shall be advised to seek professional medical consultation and, if recommended, another test for validation of such test results.

Any person who violates the provisions of this section shall be guilty of a Class 4 misdemeanor.

Official Use By Clerks	
Passed By The House of Delegates	**Passed By The Senate**
without amendment ☐	without amendment ☐
with amendment ☐	with amendment ☐
substitute ☐	substitute ☐
substitute w/amdt ☐	substitute w/amdt ☐
Date: _____	Date: _____
Clerk of the House of Delegates	Clerk of the Senate

1989 SESSION

VIRGINIA ACTS OF ASSEMBLY - CHAPTER 142

An Act to amend the Code of Virginia by adding a section numbered 18.2-502.2, relating to warning on certain medical tests; penalty.

[H 1621]

Approved MAR 6 1989

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered 18.2-502.2 as follows:

§ 18.2-502.2. Warning required for certain medical tests; penalty.—No commercial medical testing kit designed for consumer home use shall be sold in this Commonwealth unless a warning is provided to the consumer to the effect that such tests may produce erroneous results and that medical testing is more accurate when performed by professionals within the controlled conditions of a laboratory. The consumer shall be advised to seek professional medical consultation and, if recommended, another test for validation of such test results.

Any person who violates the provisions of this section shall be guilty of a Class 4 misdemeanor.

_____

President of the Senate

_____

Speaker of the House of Delegates

Approved:

_____

Governor

HOUSE BILL NO. 1622

House Amendments in [ ] - February 4, 1989

A BILL to amend and reenact § 11-45 of the Code of Virginia, relating to exceptions to requirements for competitive procurement.

Patrons--Cooper, Cunningham, J. W., Christian, Councill, Byrne, Keating, Munford, Marshall, Robinson, Moss, Stieffen, Tata, Ackerman, Grayson, Copeland, Crenshaw, Purkey, Crouch and Van Yahres; Senators: Miller, Y. B., Schewel and Saslaw

Referred to the Committee on General Laws

Be it enacted by the General Assembly of Virginia:

1. That § 11-45 of the Code of Virginia is amended and reenacted as follows:

§ 11-45. Exceptions to requirement for competitive procurement.--A. Any public body may enter into contracts without competition for the purchase of goods or services (i) which are performed or produced by persons, or in schools or workshops, under the supervision of the Virginia Department for the Visually Handicapped; or (ii) which are performed or produced by nonprofit sheltered workshops or other nonprofit organizations which offer transitional or supported employment services serving the handicapped.

B. Any public body may enter into contracts without competition for (i) legal services, provided that the pertinent provisions of Chapter 11 (§ 2.1-117 et seq.) of Title 2.1 remain applicable; or (ii) expert witnesses and other services associated with litigation or regulatory proceedings.

C. Any public body may extend the term of an existing contract for services to allow completion of any work undertaken but not completed during the original term of the contract.

D. An industrial development authority may enter into contracts without competition with respect to any item of cost of "authority facilities" for "facilities" as defined in § 15.1-1374 (d) and (e).

E. The Department of Alcoholic Beverage Control may procure alcoholic beverages without competitive sealed bidding or competitive negotiation.

F. Any public body administering public assistance programs as defined in § 63.1-87 or the fuel assistance program may procure goods or personal services for direct use by the recipients of such programs without competitive sealed bidding or competitive negotiations if the procurement is made for an individual recipient. Contracts for the bulk procurement of goods or services for the use of recipients shall not be exempted from the requirements of § 11-41.

G. Any public body may enter into contracts without competitive sealed bidding or competitive negotiation for insurance if purchased through an association of which it is a member if the association was formed and is maintained for the purpose of promoting the interest and welfare of and developing close relationships with similar public bodies, provided such association has procured the insurance by use of competitive principles and provided that the public body has made a determination in advance after reasonable notice to the public and set forth in writing that competitive sealed bidding and competitive negotiation are not fiscally advantageous to the public. The writing shall document the basis for this determination.

H. The Department of Health may enter into contracts with laboratories providing cytology and related services [~~*without competition*~~ *using competitive procedures prescribed by the Commissioner of Health*].

2. That this act shall become effective on July 1, 1990.

An Act to amend and reenact § 11-45 of the Code of Virginia, relating to exceptions to requirements for competitive procurement.

[H 1622]

Approved MAR 9 1989

Be it enacted by the General Assembly of Virginia:

1. That § 11-45 of the Code of Virginia is amended and reenacted as follows:

§ 11-45. Exceptions to requirement for competitive procurement.—A. Any public body may enter into contracts without competition for the purchase of goods or services (i) which are performed or produced by persons, or in schools or workshops, under the supervision of the Virginia Department for the Visually Handicapped; or (ii) which are performed or produced by nonprofit sheltered workshops or other nonprofit organizations which offer transitional or supported employment services serving the handicapped.

B. Any public body may enter into contracts without competition for (i) legal services, provided that the pertinent provisions of Chapter 11 (§ 2.1-117 et seq.) of Title 2.1 remain applicable; or (ii) expert witnesses and other services associated with litigation or regulatory proceedings.

C. Any public body may extend the term of an existing contract for services to allow completion of any work undertaken but not completed during the original term of the contract.

D. An industrial development authority may enter into contracts without competition with respect to any item of cost of "authority facilities" for "facilities" as defined in § 15.1-1374 (d) and (e).

E. The Department of Alcoholic Beverage Control may procure alcoholic beverages without competitive sealed bidding or competitive negotiation.

F. Any public body administering public assistance programs as defined in § 63.1-87 or the fuel assistance program may procure goods or personal services for direct use by the recipients of such programs without competitive sealed bidding or competitive negotiations if the procurement is made for an individual recipient. Contracts for the bulk procurement of goods or services for the use of recipients shall not be exempted from the requirements of § 11-41.

G. Any public body may enter into contracts without competitive sealed bidding or competitive negotiation for insurance if purchased through an association of which it is a member if the association was formed and is maintained for the purpose of promoting the interest and welfare of and developing close relationships with similar public bodies, provided such association has procured the insurance by use of competitive principles and provided that the public body has made a determination in advance after reasonable notice to the public and set forth in writing that competitive sealed bidding and competitive negotiation are not fiscally advantageous to the public. The writing shall document the basis for this determination.

H. The Department of Health may enter into contracts with laboratories providing cytology and related services without competitive sealed bidding or competitive negotiation if competitive sealed bidding and competitive negotiations are not fiscally advantageous to the public to provide quality control as prescribed in writing by the Commissioner of Health.

2. That this act shall become effective on July 1, 1990.

HOUSE JOINT RESOLUTION NO. 331

House Amendments in [ ] - February 6, 1989

Requesting Old Dominion University, in cooperation with the State Council of Higher Education and the Virginia Community College System, to study the feasibility of developing educational alternatives for medical technologists and cytotechnologists.

Patrons–Tata, Cunningham, J. W., Cooper and Ackerman; Senators: Miller, Y. B., Holland, C. A. and Schewel

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Referred to the Committee on Rules

WHEREAS, there is a nationwide shortage of medical technologists and cytotechnologists; and

WHEREAS, the programs for the education of these professionals have decreased dramatically in the United States and Virginia in the past decade; and

WHEREAS, medical technologists and cytotechnologists are essential health care professionals who conduct and analyze medical tests which are used in diagnosis and treatment of patients; and

WHEREAS, the Joint Subcommittee Studying Clinical Laboratory Testing has been made aware of the pending crisis in the delivery of health care being created by the growing shortage of medical technologists and cytotechnologists; and

WHEREAS, the joint subcommittee is convinced that educational alternatives are needed to provide opportunities for individuals to enter these professions; and

WHEREAS, Old Dominion University has established a program for the education of medical technologists and cytotechnologists which has only recently received any applications; and

WHEREAS, this program will award bachelors and masters degrees; and

WHEREAS, the Joint Subcommittee Studying Clinical Laboratory Testing believes that there may be merit in educational alternatives such as associate degrees which produce multi-skilled professionals; now, therefore be it

RESOLVED by the House of Delegates, the Senate concurring, That Old Dominion University [~~is~~ , Virginia Commonwealth University and Norfolk State University are] hereby requested to study, in cooperation with the State Council of Higher Education and the Virginia Community College System, the feasibilty of developing programs for medical technologists and cytotechnologists which are alternatives to the traditional bachelors and masters degrees. The University, the Council and the Community College System are further requested to evaluate the efficacy of programs which produce multi-skilled professionals and to report their recommendations to the Governor and the General Assembly by January 1, 1990, as provided in the procedures of the Division of Legislative Automated Systems for processing legislative documents.

Official Use By Clerks	
Agreed to By The House of Delegates	**Agreed to By The Senate**
without amendment ☐	without amendment ☐
with amendment ☐	with amendment ☐
substitute ☐	substitute ☐
substitute w/amdt ☐	substitute w/amdt ☐
Date: _____	Date: _____
Clerk of the House of Delegates	Clerk of the Senate

GENERAL ASSEMBLY OF VIRGINIA -- 1989 SESSION

HOUSE JOINT RESOLUTION NO. 331

Requesting Old Dominion University, Virginia Commonwealth University, University of Virginia and Norfolk State University, in cooperation with the State Council of Hig Education and the Virginia Community College System, to study the feasibility developing educational alternatives for medical technologists and cytotechnologists.

Agreed to by the House of Delegates, February 24, 1989
Agreed to by the Senate, February 23, 1989

WHEREAS, there is a nationwide shortage of medical technologists and cytotechnologists; and

WHEREAS, the programs for the education of these professionals have decreased dramatically in the United States and Virginia in the past decade; and

WHEREAS, medical technologists and cytotechnologists are essential health care professionals who conduct and analyze medical tests which are used in diagnosis and treatment of patients; and

WHEREAS, the Joint Subcommittee Studying Clinical Laboratory Testing has been made aware of the pending crisis in the delivery of health care being created by the growing shortage of medical technologists and cytotechnologists; and

WHEREAS, the joint subcommittee is convinced that educational alternatives are needed to provide opportunities for individuals to enter these professions; and

WHEREAS, Old Dominion University has established a program for the education of medical technologists and cytotechnologists which has only recently received any applications; and

WHEREAS, this program will award bachelors and masters degrees; and

WHEREAS, the Joint Subcommittee Studying Clinical Laboratory Testing believes that there may be merit in educational alternatives such as associate degrees which produce multi-skilled professionals; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That Old Dominion University, Virginia Commonwealth University, University of Virginia, and Norfolk State University are hereby requested to study, in cooperation with the State Council of High Education and the Virginia Community College System, the feasibility of developing programs for medical technologists and cytotechnologists which are alternatives to the traditional bachelors and masters degrees. The Universities, the Council and the Community College System are further requested to evaluate the efficacy of programs which produce multi-skilled professionals and to report their recommendations to the Governor and the General Assembly by January 1, 1990, as provided in the the procedures of the Division of Legislative Automated Systems for processing legislative documents.

LD6919441

HOUSE JOINT RESOLUTION NO. 352

Offered January 24, 1989

Requesting the State Council of Higher Education to assume a leadership role in developing certain programs.

Patrons--Cooper, Cunningham, J. W., Christian, Councill, Medico, Woods, Hamilton, Rollins, Byrne, Keating, Munford, Van Landingham, Martin, Moss, Marshall, Mayer, Robinson, Stieffen, Crouch, Tata, Ackerman, Grayson, Stambaugh, Copeland, Purkey, Crenshaw, Jones, J. C. and Van Yahres; Senators: Miller, Y. B., Schewel and Saslaw

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Referred to the Committee on Education

WHEREAS, § 23-9.3 of the Code of Virginia establishes the State Council of Higher Education and vests it with the responsibility "to promote the development and operation of an educationally and economically sound, vigorous, progressive, and coordinated system of higher education in the State of Virginia"; and

WHEREAS, pursuant to § 23-9.6:1, the Council has the duty to "review and approve or disapprove all new academic programs which any public institution of higher education proposes"; and

WHEREAS, the Council also has a statutorily established affirmative duty to "make recommendations, including those relating to financing, whereby adequate and coordinated educational programs may be provided to produce an appropriate supply of properly trained personnel" in all health professions and occupations pursuant to § 23-9.10:1; and

WHEREAS, § 23-9.10:1 also establishes the Board of Education for Health Professions and Occupations and vests this Board with the responsibility to "provide continuous in-depth study of educational needs of nursing and allied health professions and occupations; develop proposals for meeting changing needs; and offer such recommendations to the State Council as are deemed appropriate"; and

WHEREAS, there is currently a growing shortage of medical technologists and cytotechnologists in the Commonwealth and the nation; and

WHEREAS, the number of full-time equivalent students enrolled in medical technology programs has decreased in Virginia from 137 in 1982-83 to 85 in 1987-88; and

WHEREAS, nationwide, programs for cytotechnologists have decreased dramatically over a few short years and in Virginia, several cytotechnology programs have been closed since 1983, leaving the Commonwealth without an active program at this time; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the State Council of Higher Education is hereby requested to assume a leadership role in cooperation with the Board of Education of Health Professions and Occupations in developing educational programs for medical technology and cytotechnology in this Commonwealth. The Council and the Board are further requested to study this issue and to provide the Governor and the General Assembly with specific recommendations on how the shortage of medical technologists and cytotechnologists may be alleviated.

The Council shall complete its work in time to submit its findings and recommendations to the Governor and the General Assembly by December 1, 1989, as provided in the procedures of the Division of Legislative Automated Systems for processing legislative documents.

GENERAL ASSEMBLY OF VIRGINIA -- 1989 SESSION

HOUSE JOINT RESOLUTION NO. 352

Requesting the State Council of Higher Education to assume a leadership role i. developing certain programs.

Agreed to by the House of Delegates, February 6, 1989
Agreed to by the Senate, February 14, 1989

WHEREAS, § 23-9.3 of the Code of Virginia establishes the State Council of Higher Education and vests it with the responsibility "to promote the development and operation of an educationally and economically sound, vigorous, progressive, and coordinated system of higher education in the State of Virginia"; and

WHEREAS, pursuant to § 23-9.6:1, the Council has the duty to "review and approve or disapprove all new academic programs which any public institution of higher education proposes"; and

WHEREAS, the Council also has a statutorily established affirmative duty to "make recommendations, including those relating to financing, whereby adequate and coordinated educational programs may be provided to produce an appropriate supply of properly trained personnel" in all health professions and occupations pursuant to § 23-9.10:1; and

WHEREAS, § 23-9.10:1 also establishes the Board of Education for Health Professions and Occupations and vests this Board with the responsibility to "provide continuous in-depth study of educational needs of nursing and allied health professions and occupations; develop proposals for meeting changing needs; and offer such recommendations to the State Council as are deemed appropriate"; and

WHEREAS, there is currently a growing shortage of medical technologists and cytotechnologists in the Commonwealth and the nation; and

WHEREAS, the number of full-time equivalent students enrolled in medical technology programs has decreased in Virginia from 137 in 1982-83 to 85 in 1987-88; and

WHEREAS, nationwide, programs for cytotechnologists have decreased dramatically over a few short years and in Virginia, several cytotechnology programs have been closed since 1983, leaving the Commonwealth without an active program at this time; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the State Council of Higher Education is hereby requested to assume a leadership role in cooperation with the Board of Education of Health Professions and Occupations in developing educational programs for medical technology and cytotechnology in this Commonwealth. The Council and the Board are further requested to study this issue and to provide the Governor and the General Assembly with specific recommendations on how the shortage of medical technologists and cytotechnologists may be alleviated.

The Council shall complete its work in time to submit its findings and recommendations to the Governor and the General Assembly by December 1, 1989, as provided in the procedures of the Division of Legislative Automated Systems for processing legislative documents.

LD6922441

HOUSE JOINT RESOLUTION NO. 353

Offered January 24, 1989

Requesting the Medical Society of Virginia and the Board of Medicine to promote appropriate physician-patient communication concerning test results.

Patrons--Cooper, Cunningham, J. W., Christian, Councill, Martin, Orebaugh, Byrne, Keating, Munford, Van Landingham, Marshall, Robinson, Moss, Stieffen, Tata, Ackerman, Grayson, Stambaugh, Copeland, Crenshaw, Purkey, Crouch, Van Yahres and Jones, J. C.; Senators: Miller, Y. B., Schewel and Saslaw

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Referred to the Committee on Health, Welfare and Institutions

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WHEREAS, medical tests are essential tools for diagnosis and treatment; and

WHEREAS, in many instances, patients assume that if they are not notified of an adverse test result by the physician, there is no need to be concerned; and

WHEREAS, for example, many women never receive any formal notice of PAP smear results; and

WHEREAS, actual notice in the form of a copy of the test result may be an appropriate form of communication under certain circumstances; and

WHEREAS, however, many consumers of health care are not knowledgeable about medical terminology and its meaning and may need a careful explanation of test results from the treating physician; and

WHEREAS, in spite of this lack of sophistication, some patients would prefer to receive a copy of the results of medical tests for possible use in obtaining second opinions or as a record of the test; and

WHEREAS, if providing a copy of the test results to the patient would not be detrimental to the patient's condition then such action may provide the physician with protection from liability; and

WHEREAS, other patients may experience psychosocial problems from receiving a copy of the test results and may need counseling or require physician consultation with a family member; and

WHEREAS, consumers are becoming more conscious of their rights as the payors for health care; and

WHEREAS, although most physicians do appropriately communicate test results to their patients, a few physicians may need encouragement in this regard; now, therefore be it

RESOLVED by the House of Delegates, the Senate concurring, That the Medical Society of Virginia and the Board of Medicine are hereby requested to promote appropriate physician-patient communication concerning the results of the tests and to encourage treating physicians to initiate the critical involvement of the patient in the management of his own care; and, be it

RESOLVED FURTHER, That the Board is requested to publish this resolution in its newsletter and to use any other means available to it to focus attention on this issue; and, be it

RESOLVED FINALLY, That the Clerk of the House of Delegates is directed to prepare a copy of this resolution for presentation to the Medical Society of Virginia.

GENERAL ASSEMBLY OF VIRGINIA -- 1989 SESSION

HOUSE JOINT RESOLUTION NO. 353

Requesting the Medical Society of Virginia and the Board of Medicine to promote appropriate physician-patient communication concerning test results.

Agreed to by the House of Delegates, February 2, 1989
Agreed to by the Senate, February 14, 1989

WHEREAS, medical tests are essential tools for diagnosis and treatment; and

WHEREAS, in many instances, patients assume that if they are not notified of an adverse test result by the physician, there is no need to be concerned; and

WHEREAS, for example, many women never receive any formal notice of PAP smear results; and

WHEREAS, actual notice in the form of a copy of the test result may be an appropriate form of communication under certain circumstances; and

WHEREAS, however, many consumers of health care are not knowledgeable about medical terminology and its meaning and may need a careful explanation of test results from the treating physician; and

WHEREAS, in spite of this lack of sophistication, some patients would prefer to receive a copy of the results of medical tests for possible use in obtaining second opinions or as a record of the test; and

WHEREAS, if providing a copy of the test results to the patient would not be detrimental to the patient's condition then such action may provide the physician with protection from liability; and

WHEREAS, other patients may experience psychosocial problems from receiving a copy of the test results and may need counseling or require physician consultation with a family member; and

WHEREAS, consumers are becoming more conscious of their rights as the payors for health care; and

WHEREAS, although most physicians do appropriately communicate test results to their patients, a few physicians may need encouragement in this regard; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Medical Society of Virginia and the Board of Medicine are hereby requested to promote appropriate physician-patient communication concerning the results of the tests and to encourage treating physicians to initiate the critical involvement of the patient in the management of his own care; and, be it

RESOLVED FURTHER, That the Board is requested to publish this resolution in its newsletter and to use any other means available to it to focus attention on this issue; and, be it

RESOLVED FINALLY, That the Clerk of the House of Delegates transmit a copy of this resolution to the Medical Society of Virginia.

LD6923441

HOUSE JOINT RESOLUTION NO. 354

Offered January 24, 1989

Requesting the Virginia Hospital Association to encourage its members to subject medical testing conducted outside of central laboratories to quality assurance procedures.

Patrons--Cooper, Cunningham, J. W., Christian, Councill, Byrne, Keating, Munford, Van Landingham, Marshall, Robinson, Moss, Stieffen, Martin, Woods, Tata, Crouch, Ackerman, Grayson, Stambaugh, Copeland, Crenshaw, Purkey, Jones, J. C. and Van Yahres; Senators: Miller, Y. B., Schewel and Saslaw

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Referred to the Committee on Health, Welfare and Institutions

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WHEREAS, the joint subcommittee to Study Clinical Laboratory Testing has pondered the difficult and complex issues related to medical testing and the analyses of such tests; and

WHEREAS, the joint subcommittee does not recommend that Virginia initiate regulation of laboratories; and

WHEREAS, the joint subcommittee does, however, have a profound appreciation for the value of accurate medical testing in diagnosis and treatment; and

WHEREAS, many tests conducted in hospitals are performed outside the laboratory setting; and

WHEREAS, the joint subcommittee has become convinced of the efficacy of quality assurance programs for laboratories; and

WHEREAS, erroneous test results, even in the case of simple, dip stick tests, could create confusion, a false sense of security or panic; now, therefore be it

RESOLVED by the House of Delegates, the Senate concurring, That the Virginia Hospital Association is hereby requested to encourage its members to subject medical testing conducted outside of central laboratories to quality assurance procedures in order to ensure accuracy and to maintain the confidence of the public; and, be it

RESOLVED FURTHER, That the Clerk of the House of Delegates is directed to prepare a copy of this resolution to be presented to the Virginia Hospital Association.

Official Use By Clerks	
Agreed to By The House of Delegates	**Agreed to By The Senate**
without amendment ☐	without amendment ☐
with amendment ☐	with amendment ☐
substitute ☐	substitute ☐
substitute w/amdt ☐	substitute w/amdt ☐
Date: _____	Date: _____
Clerk of the House of Delegates	Clerk of the Senate

GENERAL ASSEMBLY OF VIRGINIA -- 1989 SESSION

HOUSE JOINT RESOLUTION NO. 354

Requesting the Virginia Hospital Association to encourage its members to subject medical testing conducted outside of central laboratories to quality assurance procedures.

Agreed to by the House of Delegates, February 2, 1989
Agreed to by the Senate, February 14, 1989

WHEREAS, the Joint Subcommittee to Study Clinical Laboratory Testing has pondered the difficult and complex issues related to medical testing and the analyses of such tests; and

WHEREAS, the joint subcommittee does not recommend that Virginia initiate regulation of laboratories; and

WHEREAS, the joint subcommittee does, however, have a profound appreciation for the value of accurate medical testing in diagnosis and treatment; and

WHEREAS, many tests conducted in hospitals are performed outside the laboratory setting; and

WHEREAS, the joint subcommittee has become convinced of the efficacy of quality assurance programs for laboratories; and

WHEREAS, erroneous test results, even in the case of simple, dip stick tests, could create confusion, a false sense of security or panic; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Virginia Hospital Association is hereby requested to encourage its members to subject medical testing conducted outside of central laboratories to quality assurance procedures in order to ensure accuracy and to maintain the confidence of the public; and, be it

RESOLVED FURTHER, That the Clerk of the House of Delegates transmit a copy of this resolution to the Virginia Hospital Association.

LD6920441

HOUSE JOINT RESOLUTION NO. 355

Offered January 24, 1989

Requesting the Medical Society of Virginia and the Board of Medicine to encourage physicians to participate in the voluntary accreditation program of the Commission on Office Laboratory Assessment.

Patrons--Cooper, Cunningham, J. W., Christian, Councill, Keating, Byrne, Munford, Van Landingham, Marshall, Robinson, Moss, Stieffen, Martin, Tata, Ackerman, Grayson, Stambaugh, Copeland, Jones, J. C., Crouch, Van Yahres and Woods; Senators: Miller, Y. B., Schewel and Saslaw

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Referred to the Committee on Health, Welfare and Institutions

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WHEREAS, many primary care physicians have established laboratories in their offices; and

WHEREAS, Medicare and Medicaid reimbursement is made directly to such physician office laboratories regardless of whether they are accredited or not; and

WHEREAS, H.R. 5471, the "Clinical Laboratory Improvement Amendments of 1988," was passed during the final days of the 100th Congress; and

WHEREAS, this federal act will require proficiency testing and other quality assurance standards of some physician office laboratories; and

WHEREAS, however, these laboratories are unregulated at this time and many do not utilize any method for assuring quality testing; and

WHEREAS, the Commission on Office Laboratory Assessment was recently incorporated and will begin a voluntary physician office laboratory accreditation program in 1989; and

WHEREAS, the Joint Subcommittee Studying Clinical Laboratory Testing has discussed many issues related to medical testing including questions concerning physician office laboratories; and

WHEREAS, the joint subcommittee has come to recognize the value of laboratory standards and quality assurance programs, but does not advocate state government regulation of physician office laboratories; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Medical Society of Virginia and the Board of Medicine are hereby requested to encourage physicians to participate in the voluntary accreditation program of the Commission on Office Laboratory Assessment in order to prepare for the implementation of the new federal regulatory requirements and to assure that accurate test results are used in the diagnosis and treatment of citizens of the Commonwealth; and be it

RESOLVED FURTHER, That the Board is requested to publish this resolution in its newsletter and to use any other means available to it to focus attention on this issue; and, be it

RESOLVED FINALLY, That the Clerk of the House of Delegates is directed to prepare a copy of this resolution for presentation to the Medical Society of Virginia.

GENERAL ASSEMBLY OF VIRGINIA -- 1989 SESSION

HOUSE JOINT RESOLUTION NO. 355

Requesting the Medical Society of Virginia and the Board of Medicine to encourage physicians to participate in the voluntary accreditation program of the Commission Office Laboratory Assessment.

Agreed to by the House of Delegates, February 6, 1989
Agreed to by the Senate, February 14, 1989

WHEREAS, many primary care physicians have established laboratories in their offices; and

WHEREAS, Medicare and Medicaid reimbursement is made directly to such physician office laboratories regardless of whether they are accredited or not; and

WHEREAS, H.R. 5471, the "Clinical Laboratory Improvement Amendments of 1988," was passed during the final days of the 100th Congress; and

WHEREAS, this federal act will require proficiency testing and other quality assurance standards of some physician office laboratories; and

WHEREAS, however, these laboratories are unregulated at this time and many do not utilize any method for assuring quality testing; and

WHEREAS, the Commission on Office Laboratory Assessment was recently incorporated and will begin a voluntary physician office laboratory accreditation program in 1989; and

WHEREAS, the Joint Subcommittee Studying Clinical Laboratory Testing has discussed many issues related to medical testing including questions concerning physician office laboratories; and

WHEREAS, the joint subcommittee has come to recognize the value of laboratory standards and quality assurance programs, but does not advocate state government regulation of physician office laboratories; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Medical Society of Virginia and the Board of Medicine are hereby requested to encourage physicians to participate in the voluntary accreditation program of the Commission on Office Laboratory Assessment in order to prepare for the implementation of the new federal regulatory requirements and to assure that accurate test results are used in the diagnosis & treatment of citizens of the Commonwealth; and, be it

RESOLVED FURTHER, That the Board is requested to publish this resolution in its newsletter and to use any other means available to it to focus attention on this issue; and, be it

RESOLVED FINALLY, That the Clerk of the House of Delegates transmit a copy of this resolution to the Medical Society of Virginia.

HOUSE JOINT RESOLUTION NO. 356

House Amendments in [ ] - February 6, 1989

Continuing the Joint Subcommittee Studying Clinical Laboratory Testing.

Patrons--Cooper, Cunningham, J. W., Christian, Councill, Van Landingham, Byrne, Keating, Munford, Marshall, Robinson, Martin, Moss, Stieffen, Tata, Ackerman, Grayson, Stambaugh, Copeland, Purkey, Jones, J. C., Crouch, Van Yahres and Woods; Senators: Miller, Y. B. and Saslaw

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Referred to the Committee on Rules

WHEREAS, the Joint Subcommittee Studying Clinical Laboratory Testing, established by Senate Joint Resolution No. 62 of the 1988 General Assembly, has met six times and has diligently worked to become knowledgeable about clinical laboratory testing and to develop an understanding of the many complex issues related to medical testing; and

WHEREAS, the joint subcommittee has developed a number of legislative proposals for introduction during the 1989 Session which represent significant progress toward resolving some of the difficult and technical problems that have developed in recent years in the field of medical testing; and

WHEREAS, the joint subcommittee believes that it has made substantial progress toward understanding the technical issues before it and in identifying alternative solutions; however, the joint subcommittee realizes that substantial work must be done to document and to determine the cost of some of the concepts it has endorsed; and

WHEREAS, the joint subcommittee is concerned about the shortage of cytotechnologists and medical technologists and is requesting the Council of Higher Education, the Board of Education for Health Professions and Occupations, the Community College System and Old Dominion University to study certain issues related to educational programs for these professionals; and

WHEREAS, the Board of Health Professions, which was charged by HJR 83 of 1988 with examining the need for regulation of cytotechnologists and medical technologists, has noted that "state regulations of laboratory personnel...is, at present, unwarranted" and has voiced its desire to cooperate with the joint subcommittee in order to arrive at viable, reasonable and consistent decisions; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Joint Subcommittee Studying Clinical Laboratory Testing is hereby continued. The current membership of the joint subcommittee shall continue to serve [, with additional members to be appointed as follows: one member of the Virginia Society of Internal Medicine and one member of the Virginia Society of Obstetrics and Gynecology to be appointed by the Governor to serve ex officio] . The joint subcommittee's deliberations shall include, but not be limited to:

1. Initiatives to attract and retain high quality individuals in the cytology and medical technology professions;

2. Ways to ensure accurate medical testing without imposing unnecessary or stringent regulation, such as proficiency testing programs;

3. Appropriate procedures for the reporting of test results to patients;

4. Ways to ensure the high quality of the cytology and related services provided to public health clients in the Commonwealth;

5. The monitoring of the regulatory effects of the new federal law known as the "Clinical Laboratory Improvement Amendments of 1988;"

6. Cooperating with the Board of Health Professions in examining issues related to cytotechnologists and medical technologists;

7. Assessment of the billing and charging issues related to clinical laboratory services; and

8. The monitoring of the studies requested of other state agencies.

All agencies of the Commonwealth shall provide assistance upon request as the joint subcommittee deems appropriate. The joint subcommittee shall complete its work in time to submit its findings and recommendations to the Governor and the 1990 Session of the General Assembly as provided in the procedures of the Division of Legislative Automated Systems for processing legislative documents.

The indirect costs of this study are estimated to be $14,580; the direct costs of this study shall not exceed $9,720.

Official Use By Clerks	
Agreed to By The House of Delegates	**Agreed to By The Senate**
without amendment ☐	without amendment ☐
with amendment ☐	with amendment ☐
substitute ☐	substitute ☐
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Date: _____	Date: _____
Clerk of the House of Delegates	Clerk of the Senate