DRAFT

Department of Health Professions
Board of Health Professions
REGULATORY RESEARCH COMMITTEE
February 14, 2012

TIME AND PLACE:	The meeting was called to order at 11:00 a.m. on Tuesday, February 14, 2012, Department of Health Professions, 9960 Mayland Drive, 2nd Floor, Board Room 2, Henrico, VA, 23233.
PRESIDING OFFICER:	Jonathan Noble, OD
MEMBERS PRESENT:	Jonathan Noble, OD Yvonne Haynes Allison Gregory Charlotte Markva Michael Stutts, Ph.D. - Ex Officio
MEMBERS NOT PRESENT:	All members were present
STAFF PRESENT:	Elizabeth A. Carter, Ph.D., Executive Director for the Board Justin Crow, Research Assistant Laura Jackson, Operations Manager Elaine Yeatts, Senior Policy Analyst
OTHERS PRESENT:	Teresa Nadder, VCU Bill Korzun, VCU Lisa Ballou Nancy Barrow, MT (AMT) Susan Ward, VHHA Chevonne Logan Emy Morris, VCU & VSCLS Shelby Wilber, Sentara Health Kim Beazley, OLC Becky Perdue, VSCLS Ann Hughes, MSV
QUORUM:	A quorum was established with all members in attendance.
AGENDA:	No additions or changes were made to the agenda.
PUBLIC COMMENT:	Dr. Teresa Nadder, VCU As Chairman of the Department of Clinical Laboratory Sciences and a member of the Virginia Society for Clinical Laboratory Sciences, I appreciate the opportunity to reaffirm our support for the regulation of MLS/MLT professionals. We ask you to approve regulation of MLS/MLT that would specify education and training requirements and require certification by a nationally recognized certification agency. (Attachment 1)

Dr. Bill Korzun, VCU Lab Director
Dr. Korzun is an Associate Professor/Clinical Chemistry at VCU. He has helped shape CLIA criteria for Clinical Laboratory Scientists and Technologists. Dr. Korzun stated that approximately 30% of all lab tests fail auto verification for a number of reasons. It is the responsibility of the lab personnel to verify the reason for failure. With this in mind, it is essential to have assurances of the competencies of persons acting as Medical Laboratory Scientists and Technicians.

Lisa Ballou, MS, MLS(ASCP)DLM
Laboratory Technical Services Manager
Riverside Regional Medical Center
Ms. Ballou would like the focus of certification to be on non-hospital based laboratories. Ms. Ballou stated that 8.7% of Virginia labs do moderate testing with a minimum education level of the technician at the high school level. She stated that harm is recognizable but not always easy to prove. She encourages mandatory certification.

Nancy Barrow, AMT
Memorial Hospital Martinsville
Ms. Barrow works in a hospital lab, she is certified and registered. Ms. Barrows stated that Outpatient and Urgent Care centers are the issue. She stated that they do not hire qualified or properly educated staff. Ms. Barrow is in agreement with regulation, supports licensure and would like a "grandfather" clause added.

APPROVAL OF MINUTES: On properly seconded motion by Ms. Haynes, the Committee approved the meeting minutes for October 24, 2011 as presented.

EMERGING PROFESSIONS UPDATE: Research Assistant Justin Crow provided an update on the Board's current sunrise review of Medical Laboratory Scientists and Technicians. (Attachment 2)

On properly seconded motion by Ms. Haynes, the Committee recommended that licensure is the appropriate level of regulation for Medical Laboratory Scientists and Medical Laboratory Technicians. On properly seconded motion by Ms. Markva, the Committee voted to forward the recommendation to the full Board. All committee members were in favor, none opposed.

Dr. Carter discussed the implications of the changes to the practice authority, supervision, and team delivery aspect of House Bill 346 (Attachment 3) and the impact on the Nurse Practitioner Scope of Practice Barriers to Effective Team Delivery study's approach. The Committee directed that future reporting reflect the resulting changes brought about by the new legislation and that it would continue to monitor major developments relating to team delivery.

Dr. Carter further reported that the Nurse Practitioner research has provided useful insight into the meaningful differences between scope of practice and practice authority as well as just how complex and evolving multidisciplinary team delivery approaches have become in recent years. She stated that this knowledge will be helpful to shaping the upcoming Pharmacy and Dentistry reviews She further recommended that the Committee move forward with developing the Pharmacy study workplan with staff reporting on progress at the next Committee meeting in May.

Dr. Carter noted that the earlier verbal inquiry from Lactation Consultants requesting the Board to conduct a sunrise review has not yet been followed-up with their formal written application in keeping with the Policies and Procedures for the Evaluation of the Need for Regulation of Health Professions and Occupations.

Dr. Carter also noted that the Virginia Perfusion Society provided a written request on January 17, 2012 asking the Board to initiate a study into the need to regulate Perfusionists. This request will be reviewed by the Full Board for further discussion at the meeting today. (Attachment 4)

LEGISLATIVE STUDIES: Delegate Dr. Christopher Stolle is expected to request the Department to conduct a study of options for accepting military training and experience as satisfying requirements for licensure, certification, or registration as a health care provider. Dr. Carter noted that she will be attending a summit being held by the American Legion February 21-23, 2012 on this very subject in anticipation to identify the chief issues and relevant organizations. (Attachment 5)

NEW BUSINESS: There was no new business.

ADJOURNMENT: With no other business to conduct, the meeting adjourned at 12:26 p.m.

_____ _____

Jonathan Noble, OD
Chair

Elizabeth A. Carter, Ph.D.
Executive Director for the Board

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February 14, 2012

Elizabeth A. Carter, Ph.D.
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To the Members of the Regulatory Research Committee:

As Chairman of the Department of Clinical Laboratory Sciences, Virginia Commonwealth University and a member of the Virginia Society for Clinical Laboratory Sciences, I appreciate the opportunity to reaffirm our support for the regulation of MLS/MLT professionals. In addition, I would like to address information presented by the Regulatory Research Committee during the October 2011 meeting, which may assist you in your decision for determining the appropriate level of regulation for medical laboratorians.

Information in your October report that focused on technological changes rendering laboratory testing and quality control easy to perform applies to point-of-care testing (POC), which differs greatly from the moderate and complex laboratory testing performed in central clinical laboratories with regards to scope of testing menu, instrumentation, and rigor of testing practices including regulations applied to personnel and quality assurance programs. A difference must be noted between "clinical laboratories" whose mission is to provide a variety of laboratory testing services in the areas of hematology, microbiology, chemistry, transfusion medicine, and molecular diagnostics and "facilities" that perform point-of-care (POC) testing, " whose primary focus is not laboratory testing but providing direct patient care. Clinical laboratories vary in provided services from small physician office labs that may conduct fewer than 2,000 tests annually to hospital laboratories conducting millions of tests each year. Instrumentation contained in a central hospital laboratory includes large bench-top or floor models and designed to conduct moderate and high complexity testing.

The performance of moderately and highly complex tests requires the interpretation of patient results by a medical laboratory technician or scientist with respect to patient information such as the diagnosis and/or patient history. This is necessary to identify results that are physiologically implausible due to analytical error, and to identify the majority of pre-analytical errors such as mislabeled specimens and

specimens collected from the wrong patient. It is also necessary to catch analytical errors due to system failures in between quality control events. Moderate and high complexity testing mandates intricate quality control programs and proficiency assessment for those performing the testing and reporting results.

Alternatively, instrumentation for POC testing is usually small or comprised of hand-held devices. Ease of testing and short turnaround time associated with POC allows the healthcare provider to address the acute needs of the patient. Outside of the clinical laboratory, POC testing is utilized in a variety of settings including health fairs, health maintenance organizations, school health clinics, and nursing home facilities. Within a hospital, POC testing occurs in locations outside the central laboratory including emergency departments, operating suites, and on patient floors; however, laboratory oversight is required. Quality control is often simplified for POC testing. However, manufacturers' directions must be strictly followed, and calibrations and quality control samples must be run at regular intervals. Further, POC testing results must correlate with methods used in the central laboratory that measure the same analyte. Unfortunately, a well-publicized incident occurred this past year where a Pennsylvania Hospital patient died from improper administration of insulin due to reliance on bedside blood sugar test strips instead of more accurate blood serum test results from the central hospital laboratory. If controls are not within a specified range or patient test results are abnormal or significantly different from a previous occasion, the laboratorian must take appropriate steps to ensure the accuracy of the results before reporting them.

Your summary of the CMS data presented at the October meeting included that many of the complaints were related to quality assurance procedures. For testing results to be reported, a quality control process must be conducted to ensure that the accuracy and precision of the measurement procedure is appropriate. Most instruments and test systems only *require* quality control to be performed once every 24 hours. Without the knowledge of how to clinically correlate a patient's test results with each other and with other available patient information, dozens, if not hundreds of erroneous patient results may be reported to the medical record in the time between an acceptable quality control event and a subsequent quality control failure. This not only puts patients at risk, but increases the cost to provide laboratory services, as many "repeat" testing has to be performed to correct the errors in the medical record. These tests consume resources but are not reimbursable. Interpretation of the quality control results, trouble-shooting, implementing a system to track systematic errors and for corrective actions across time require skills obtained through appropriate education and training.

Your September 2010 report summarizes the risk of harm to the consumer if this profession remains unregulated:

> "Due to the nature of proper test selection and laboratory testing generally, it can often be difficult to detect harm with certainty. When the wrong test is administered a correct diagnosis may be missed, if a test conducted without adherence to best laboratory practice, results of that test may not relay the most accurate results. These sorts of missteps could result in a patient receiving the wrong treatment, receiving treatment that is too aggressive or not aggressive

enough, having to ensure further or unnecessary testing, or in not receiving any treatment at all. Not all laboratory error results in obvious and immediately recognizable harm."

We ask you to approve regulation of MLS/MLTs that would specify education and training requirements and require certification by a nationally recognized certification agency.

Sincerely,

Teresa S. Nadder, Ph.D., MLS(ASCP)^{CM}
Chair and Associate Professor
Virginia Commonwealth University

LABORATORY SCIENTISTS AND LABORATORY TECHNICIANS: POLICY OPTIONS

AUTHORITY

Delegate John M. O'Bannon introduced House Bill No. 601 during the 2010 Session of the Virginia General Assembly. The bill proposed registration of medical laboratory scientists and medical laboratory technicians. By virtue of its statutory authority in §54.1-2510 of the Code of Virginia to advise the Governor, the General Assembly, and the Department Director on matters related to the regulation and level of regulation of health care occupations and professions, the Board of Health Professions is reviewing the need for regulation of laboratory scientists and technicians pursuant to the request from Delegate John M. O'Bannon.

The review was initially undertaken in summer of 2010 by an independent contractor, and the Board of Health Professions' Regulatory Research Committee (RRC) held a public hearing on July 16, 2010. The contractor submitted a document entitled *Study of the Need to Regulate Medical Laboratory Scientists and Laboratory Technicians* in September of 2010. At its September 29, 2010 meeting, the RRC recommended that some regulation of medical laboratory scientists and technicians was warranted. However, action was tabled pending further research on the proper form of regulation. Completion of the study was undertaken by Board of Health Professions staff.

On April 14, 2011, staff received documents from the Centers for Medicare & Medicaid Services (CMS) pertaining to a Freedom of Information Act (FOIA) request submitted by the independent contractor for documents related to complaints and deficiency citations in Virginia's clinical laboratories. The RRC reviewed these documents at its June 20, 2011 meeting and requested staff to prepare a description of policy options. Since the Board has experienced turnover, we have also included a summary of staff findings in this document.

SUMMARY OF FINDINGS

1. Laboratory tests are an essential part of modern medical practice, and their quality directly influences patient health.

Health and laboratory workers perform over 10 billion laboratory tests every year. Up to 80 percent of medical diagnoses are based on laboratory test results. Laboratory tests are often essential for developing treatment plans, including drug regimens and transfusions. Inaccurate laboratory results, or delays in providing results, can result in significant harm to patients, including death.

2. Clinical laboratories and tests are changing rapidly due to technological advances. Technological change is affecting clinical laboratories and tests in two ways. First, new tests are being developed at the vanguard of medical practice in areas such as genetics and molecular medicine. Performing and understanding these tests often requires new skills and updated education in these areas. Meanwhile, technological advances are making existing tests easier and more routine to perform. Tests which previously required skilled professional judgment and expensive laboratory equipment are now provided at the point of care, in nursing homes, ambulances, pharmacies or in patient's homes. They are performed by nurses, pharmacy technicians, family caregivers or patients themselves. Most labs are not centralized independent or hospital labs, but are point of care labs. (See Table, next page).

4. The 1988 Federal Clinical Laboratory Improvement Amendments (CLIA) are the main regulatory apparatus ensuring the quality of clinical laboratory services.

The Centers for Medicare & Medicaid Services administers CLIA in conjunction with the Food and Drug Administration and the Centers for Disease Control and Prevention. All clinical laboratories (not just those receiving CMS reimbursement) are required to be certified through CLIA. CLIA's regulatory approach involves certifying clinical laboratories based on the type of laboratory tests performed. Certified laboratories must meet standards, including personnel standards, based on the complexity and the risk of harm of the tests performed, and their potential risk of harm. CLIA uses a combination of lab surveys, complaint investigations and proficiency testing to enforce standards. In Virginia, surveys and investigations are conducted by either the Virginia Department of Health, or a private accreditation agency "deemed" by CMS to have equivalent standards to CLIA. Proficiency testing is performed by private proficiency testing companies on behalf of CMS. Proficiency testing tests lab personnel individually as well as lab quality control measures in general. An outline of test categories, lab categories and their related standards and enforcement procedures appears below:

Test Type	Definition	CLIA Personnel Requirements
Waived	Low complexity and low risk of harm. These tests are often performed by providers at the point of care.	None
Moderate Complexity	Moderate Complexity and/or risk of harm	HS diploma and documented training
High Complexity	High complexity and/or risk of harm	Associate degree and completion of either: 1) accredited or approved clinical laboratory training program 2) three months laboratory training in specialty
Provider-Performed Microscopy Procedures (PPMP)	Moderate or High Complexity tests that must be performed at the point of care by a health care provider.	Physician, Dentist or Mid-level health care provider

CMS issues four types of certificates to labs (Figures from June, 2011):

Certificate	Definition	Requirements	National	In Virginia
Certificate of Waiver	Waived tests only	Must be certified. Subject to random, on-site inspections- about 2% of labs per year.	146,071 (66.7 %)	3,158 (60.8%)
Certificate of Compliance	Perform all tests Surveyed by State agency	Surveyed biennially. Proficiency testing quarterly.	19,319 (8.8%)	482 (8.7%)
Certificate of Accreditation	Perform all tests Surveyed by accrediting organization	Surveyed biennially. Proficiency testing quarterly.	15,787 (7.2%)	469 (9.0 %)
Certificate for Provider Performed Microscopy Procedures	Perform PPMP and waived tests only.	Subject to random, on-site inspections— about 2% of labs per year.	37,767 (17.2%)	1,086 (20.9%)
		Total	**218,944**	**5,195**

5. CLIA defines roles for clinical laboratory management.

CLIA identifies certain roles that must be filled within each laboratory. In the case of small labs performing a limited number of tests, these roles may be filled by one person. In larger labs, a qualified person may fill one or

quality control, communication and other management issues that improve lab quality as well as the quality of staff.

7. There are some notable criticisms of CLIA.

A. Over 80% of labs are not subject to enforcement measures: Waived labs and PMPP labs are not subject to surveys or proficiency testing. Additionally, a greater number and breadth of tests are being categorized as waived tests. In 2002, CMS initiated random on-site surveys of waived and PMPP labs after finding deficiencies in over 50 percent of these labs during a review. CMS is currently reviewing its process for regulating waived tests and laboratories.

B. Sanctions are rare: CLIA's goal is to improve quality in labs. Regulators view the survey process as educational as well as regulatory, and often allow labs to correct deficiencies before imposing sanctions unless there is a risk to patients or there are repeated deficiencies.

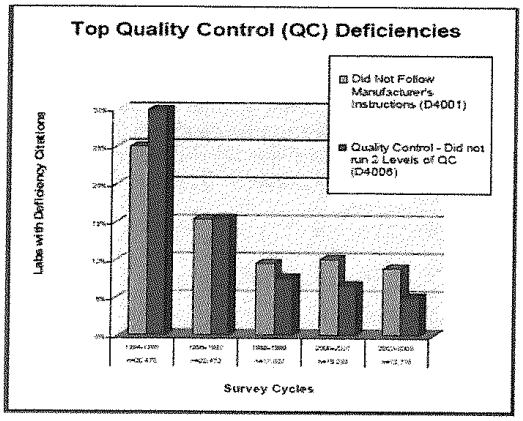
C. Survey process is fragmented: Survey and complaint investigations are conducted by agencies in each state and by six deemed accrediting organizations. Although all labs must meet CLIA or CLIA-equivalent standards, the ability of the survey organizations and their processes to identify deficiencies varies.

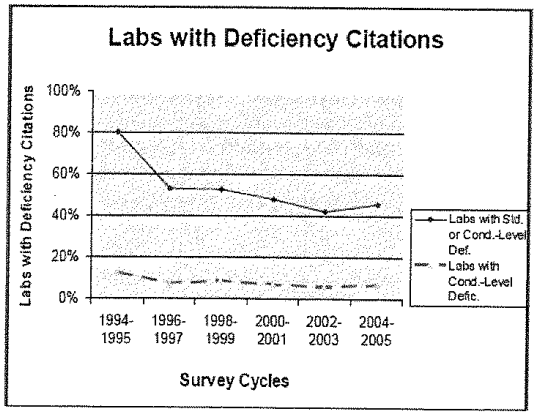
D. It is unclear if CLIA has improved lab quality: The lack of standardization of enforcement and data reporting makes it difficult to assess the efficacy of CLIA regulations at improving lab quality. Additionally, improvements in existing quality measures may be due to the growth of waived labs, which are not subject to CLIA surveys or proficiency tests, rather than real improvements in lab quality.

8. CMS measures show an increase in lab quality since CLIA was enacted.

CMS reports that on key measures, lab quality has improved since the introduction of CLIA. The following charts are from a presentation by Judith A. Yost, Director of CMS Laboratory Services, to the Clinical Laboratory Improvement Amendments Advisory Committee (CLIAC), a part of the CDC, in September 2006, available in the CLIAC minutes of the same date as Addendum E: http://wwwn.cdc.gov/cliac/cliac0906.aspx.

Deficiency citations for labs that did not have at least two levels of quality control and that did not follow manufacturer's instructions in lab procedures declined from about 20 percent and 30percent, respectively, from the mid-90's to about five percent and eight percent in 2003. The proportion of non-waived labs with minor and major deficiencies has declined as well. Proficiency test pass rates for all tests increased from about 70 percent in 1996 to over 90 percent in 2006.





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12. Staff received comment from clinical laboratory personnel, their professional organizations and the American Society of Clinical Pathologists supporting regulation. No patients, providers, facilities or other consumers of laboratory services provided comment supporting regulation. The Virginia Hospital and Healthcare Association provided comment opposing regulation.

13. The Regulatory Research Committee has previously recommended regulation of clinical laboratory personnel: From the minutes of the Sept. 29, 2010 Regulatory Research Committee meeting: "On properly seconded motion by Mr. Boehm, the Committee recommended that regulation of medical laboratory scientists and technicians was warranted. They further recommended continuance of the study to enable them to determine the appropriate form of regulation and under which agency or board that regulation should be overseen."

POLICY OPTIONS

Several policy options are presented here with a bullet point list outlining the rationale for each. Waived tests and waived laboratories are exempt in all options.

1. No professional regulation, with recommendation to license or certify laboratory facilities: The committee examined the need to regulate laboratory personnel as a regulated health profession, and the licensure provisions in H.B. 601 in particular. We did not, however, look into regulation of clinical laboratories or clinical testing in general. However, if the Committee believes that CLIA regulations are not sufficient to ensure quality in clinical laboratories, the committee may recommend facility regulation as an alternative to professional regulation. The Office of Licensure and Certification (OLC) of the Virginia Department of Health licenses, regulates and inspects healthcare facilities and the Virginia Board of Health provides oversight and regulatory guidance in this area.

- Evidence of harm related to substandard regulation of testing personnel was not found.
- Clinical laboratories and laboratory personnel are already regulated through CLIA. CLIA has improved lab quality and proficiency test pass rates of non-waived labs.
- Deficiencies related to personnel were cited, indicating that CLIA enforces personnel standards.
- The Board's criteria for regulating a new profession require that there be no alternatives to professional regulation that adequately protect the public, including strengthening existing consumer protection laws and regulations.
- While states must meet CLIA requirements, they may set additional requirements above CLIA's requirements.
- If Virginia's laboratories require additional regulation, regulating laboratory facilities provides an avenue of regulation that does not create an additional regulatory structure. VDH already surveys laboratories under CLIA.
- About 7.2 percent of Virginia's CLIA registered labs are accredited and surveyed by private "deemed" organizations. Laboratory regulation would provide additional state oversight of these laboratories.
- Facility regulation may provide more flexibility in addressing quality issues, including raising personnel standards.
- Most errors occur in the pre- and post-analytical phases of the testing process, related to communication, data and specimen management and other administrative processes. Regulation of workers may pull resources from investments that may have a greater impact on lab and testing quality.
- Proficiency testing and laboratory inspections may provide a better means of ensuring quality, since outputs may be measured objectively and laboratory personnel do not provide direct patient care.
- Consumers of laboratory services are not seeking additional regulation of clinical laboratory personnel.

2: Voluntary certification for testing personnel: Creates title protection for laboratory scientists and laboratory technicians certified by national certification organizations. This would prevent uncertified persons

5. Licensure for all testing personnel: Requires licensure for laboratory technicians as well as laboratory scientists.

- There is an inherent risk of harm related to laboratory testing that justifies regulation.
- Although laboratory technicians do not perform tests that require independent judgment or responsibility, they perform tests of moderate to high complexity that can pose a risk of harm to patients.
- CLIA allows those with high school and on-the job training to perform these tests. Licensure as a laboratory technician would require formal certification and a post-secondary certificate or associate degree.
- Licensure for testing personnel ensures that non-physician laboratory management personnel are licensed as well.

POLICY OPTIONS IN COMBINATION

The previous policy options may be used alone or in combination. The following chart provides an overview of all the options available.

Professional Level	Laboratory Management	Laboratory Scientist	Laboratory Technician	Rationale
Option 1	Not Regulated	Not Regulated	Not Regulated	• See Option 1
Option 2	Not regulated	Voluntary Certification	Voluntary Certification	• CLIA is effectively regulating laboratories • Patients at community-based labs may benefit from information on the qualifications of laboratory personnel
Option 2a	Not regulated	Voluntary Certification	Not regulated	• CLIA is effectively regulating laboratories • Patients at community-based labs may benefit from information on the qualifications of those supervising lab personnel
Option 2b	Licensure	Voluntary Certification	Not Regulated	• The Board determines management requires licensure • Patients at community-based labs may benefit from information on the qualifications of those supervising lab personnel
Option 2c	Licensure	Voluntary Certification	Voluntary Certification	• The Board determines management requires licensure • Patients at community-based labs may benefit from information on the qualifications of laboratory personnel
Option 2d	Licensure	Licensure	Voluntary Certification	• The Board determines management and laboratory scientists require licensure. • Patients at community-based labs may benefit from information on the qualifications of laboratory personnel.
Option 3	Licensure	Not Regulated	Not Regulated	• See Option 3
Option 4	Not regulated	Licensure	Not regulated	• See Option 4
Option 4a	Licensure	Licensure	Not regulated	• Option 4 and • All those using independent judgment and providing supervision of laboratory workers require licensure • Laboratory management, including physicians, require licensure specific to their management role beyond that of laboratory scientists
Option 5	Not regulated	Licensure	Licensure	• See Option 5
Option 5a	Licensure	Licensure	Licensure	• Option 5 and • All those performing non-waived tests require licensure • Laboratory management, including physicians, require licensure specific to their management role beyond that of laboratory scientists

Rhode Island: Rhode Island regulates Clinical Laboratory Scientists, Clinical Laboratory Technicians, Cytotechnologists, Histologic Technicians and MOHS (micrographic surgery) Technicians. Laboratory scientists may be licensed as generalists, or in one of eight specialties. Scientists may perform all tests within their license area. Technicians may perform tests which do not require independent judgment under supervision of a laboratory scientist, supervisor or director.

Tennessee: Tennessee licenses Laboratory Directors, Supervisors, Technologists (scientist), Technicians and special analysts. Laboratory supervisors fulfill roles similar to the technical supervisor role; technologists may perform any test laboratory. Special analysts may perform tests within a specific specialty. Technicians may only perform tests which require limited skill, responsibility or independent judgment under the supervision of a technologist, supervisor or director.

West Virginia: West Virginia requires licenses for laboratory directors, consultants, scientists, and technicians and point of care technicians in eleven specialties based on positions and functions held in a laboratory. Scientists perform all tests within approved specialty areas, while technicians may only perform tests requiring limited exercise of independent judgment under supervision of a laboratory director or supervisor. Point of Care Technicians may only perform point of care tests of moderate complexity when reporting directly to a physician and under the supervision of a laboratory director and supervisor. The consultants and directors fulfill roles equivalent to those in CLIA, and must meet the same requirements.

Clinical Laboratory Workforce: Economic Impacts

BACKGROUND & AUTHORITY

At its October 24th, 2011 meeting, the Regulatory Research Committee considered an ongoing study to regulate clinical laboratory scientists (hereafter "scientists") and clinical laboratory technicians (hereafter "technicians").[1] Since most members of the RRC and the Board of Health Professions were new at the time of this meeting, the RRC and Board requested more time to review the issue. Members of the RRC also expressed a desire for more information about the potential economic impacts of regulation.

WORKFORCE SHORTAGE

The literature on clinical laboratories abounds with articles and journals about a national workforce shortage in clinical laboratories (see bibliography). Shortages are widespread, including shortages of qualified scientists, technicians and their various specialties. The US Bureau of Labor Statistics projects clinical laboratories will add an additional 42,900 scientist and technician jobs by 2020, on top of the current workforce of 330,600. Over this period, the US will need an additional 107,300 new scientists and technicians to fill new positions and to replace retirees. Estimates of the number of current vacancies range up to 100,000.[2]

These shortages trace their roots to lab consolidations over the last few decades. Large, consolidated labs achieved economies of scale and needed fewer workers than smaller local or hospital laboratories. While some workers left the profession, the most dramatic outcome was the shrinking number of educational programs. From 1975 to 2005, the number of accredited technician programs declined from 709 to 232, and the number of graduates declined from 6,121 per year to 2,070.[3] Scientist programs saw similar declines. As of 2010, the average age of the laboratory workforce was 50 years old, compared to 42 years old for the entire civilian labor force.[4]

The American Society for Clinical Pathology concluded a summary of its 2008 Wage and Vacancy Survey by warning that "demand for all laboratory professionals far outstrips supply." The survey found that 43 percent of labs reported difficulties hiring personnel, including 65 percent of hospital labs and 42 percent of labs located in the South Central Atlantic region. The vacancy rate for staff level scientists was 10.4 percent, while the rate for staff level technicians was 6.4 percent. Two-thirds of labs reported increased competition for qualified staff as their chief hiring challenge.[5]

RESPONSE TO THE WORKFORCE SHORTAGE

Professional associations, educational institutions and laboratories have many tools at their disposal to deal with the shortage of professionals. The first and most basic is the simple economics of supply and demand. As competition for a diminished number of professionals heats up, laboratories will have to raise wages to attract qualified professionals. Over time, raised wages should draw more persons into the profession. Raising wages, however, may be difficult in a health industry marked by regulated reimbursement rates and increasing pressure to lower costs.

1Clinical Laboratory Scientists and Technicians use a variety of terms to describe themselves and may practice in a variety of specialties. For our purposes, we use "scientist" to describe laboratory scientists and technologists, regardless of specialty, that usually have bachelor level education but may have an equivalent amount of education, training and experience and "technician" to describe technicians and assistants with less education and qualifications. "Clinical/Medical" and "Laboratory" descriptors are implied.

2See Maddox, 2011 & Medical Laboratory Observer, 2011.

3Kaplan & Burgess, 2010. Pg. 141.

4Ibid.

5Bennett, et al. 2009.

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Coordinating Council on the Clinical Laboratory Workforce. www.ccclw.org.
The CCCLW is a coalition of laboratory organizations collaborating on workforce issues.

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2012 SESSION

HB 346 Nurse practitioners; practice as part of patient care teams.

Introduced by: John M. O'Bannon, III | all patrons ... notes | add **to my profiles** | history

SUMMARY AS PASSED HOUSE:

Practice of nurse practitioners; patient care teams. Amends provisions governing the practice of nurse practitioners. The bill provides that nurse practitioners shall only practice as part of a patient care team and shall maintain appropriate collaboration and consultation, as evidenced in a written or electronic practice agreement, with at least one patient care team physician licensed to practice medicine in the Commonwealth. The bill also establishes requirements for written or electronic practice agreements for nurse practitioners, provides that physicians practicing as part of a patient care team may require nurse practitioners practicing as part of that patient care team to be covered by professional malpractice insurance, and amends requirements related to the prescriptive authority of nurse practitioners practicing as part of a patient care team.

SUMMARY AS INTRODUCED:

Practice of nurse practitioners; patient care teams. Amends provisions governing the practice of nurse practitioners. The bill provides that nurse practitioners shall only practice as part of a patient care team, which shall include at least one patient care team physician licensed to practice medicine in the Commonwealth who provides management of and leadership in the care of a patient or patients. The bill also establishes requirements for written or electronic practice agreements for nurse practitioners, provides that physicians practicing as part of a patient care team may require nurse practitioners practicing as part of that patient care team to be covered by professional malpractice insurance, and amends requirements related to the prescriptive authority of nurse practitioners practicing as part of a patient care team.

Virginia Perfusion Society
Inova Fairfax Hospital, Cardiovascular Perfusion
3300 Gallows Road, Falls Church, VA 22042

Elizabeth Carter, Ph.D.
Executive Director
Virginia Department Of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463

Dear Dr. Carter:

The Virginia Perfusion Society (VPS) respectively requests that the Department of Health Professions initiate a study that assesses the need for licensure of perfusionists. With filing of this Sunrise Proposal, we are aware of the criteria underlying this application and have included quantitative and qualitative evidence-based information to assist with the study and recommendation to the General Assembly of the Commonwealth.

The VPS and its elected and voluntary leadership, as governed by the members of the Society, and perfusionists who are not members, believe that licensure is the only level of regulation for adequately protecting the public. There are currently 90 practicing perfusionists in the Commonwealth. Between 2003 and 2010, approximately 48,000 residents of the state have received open heart surgeries or relevant organ transplants. Approximately 6,000 persons of all ages each year require the services of a perfusionist. Reliable statistical evidence supports the potential for 5 to 6 persons each year suffering a serious long-term adverse surgical outcome or possible death attributable to device malfunctions and incompetent practice.

Perfusionists are not now regulated by the State. There are no mandated educational or training standards, national professional certification standards for entry to practice, and no educational competency standards. For these and other reasons, the VPS believes that licensure will ensure the public health and safety for thousands of Virginians each year that require cardiovascular and cardiothoracic surgical procedures. Please refer to the attached documents that we believe provide support for our claim that perfusionists meet the Virginia Department of Health Professions' criteria for regulation by licensure.

Sincerely,

Mike Brown, CCP
VPS Board Member
Chief of Perfusion
Cardiovascular and Thoracic Surgery
Virginia Heart & Vascular Institute
Mary Washington Hospital
Fredericksburg, Virginia 22401

David Fitzgerald, CCP
VPS Board Member
Chief of Perfusion
INOVA Fairfax Hospital
Falls Church, Virginia 22030

2012 SESSION

INTRODUCED

12101611D

HOUSE JOINT RESOLUTION NO. 51

Offered January 11, 2012

Prefiled January 10, 2012

Requesting the Department of Health Professions to study options for accepting military training and experience as satisfying requirements for licensure, certification, or registration as a health care provider. Report.

Patrons—Stolle, Anderson, Bell, Richard P., Brink, Cole, Cosgrove, Iaquinto, Ingram, Keam, Purkey, Putney and Villanueva

Referred to Committee on Rules

WHEREAS, the Commonwealth, like the rest of the United States, is currently facing shortages in health care services and the health care work force; and

WHEREAS, veterans of the United States armed forces and the Virginia National Guard often gain valuable training and experience in health care services and the healing arts during their military training and experience; and

WHEREAS, such training and experience often parallels training and experience requirements for licensure, certification, or registration as a health care provider, but is not always recognized by the Commonwealth as satisfying educational and experiential requirements for licensure, certification, or registration as a health care provider in the Commonwealth; and

WHEREAS, recognizing training and experience gained by veterans during the course of their military service and accepting evidence of such training and experience as satisfaction of educational and experiential requirements for licensure, certification, or registration as a health care provider can lead to an increase in the availability of qualified health care providers while also providing employment for veterans; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Department of Health Professions be requested to study options for accepting military training and experience as satisfying requirements for licensure, certification, or registration as a health care provider. In conducting its study, the Department of Health Professions shall review existing state laws governing licensure, certification, or registration of health care providers regulated by the various health regulatory boards, compare these requirements to similar Military Occupational Specialties in health care, and develop recommendations for statutory and regulatory changes to allow the Department of Health Professions to accept evidence of military training and experience as satisfying educational and experiential requirements for licensure, certification, or registration as a health care provider. The Department of Health Professions shall also develop recommendations related to options for increasing awareness among veterans and citizens of the Commonwealth for submitting evidence of military training and experience to satisfy educational and experiential requirements for licensure, certification, or registration as a health care provider.

All agencies of the Commonwealth shall provide assistance to the Department of Health Professions for this study, upon request.

The Department of Health Professions shall complete its meetings by November 30, 2012, and shall submit to the Governor and the General Assembly an executive summary and a report of its findings and recommendations for publication as a House or Senate document. The executive summary and report shall be submitted as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports no later than the first day of the 2013 Regular Session of the General Assembly and shall be posted on the General Assembly's website.

INTRODUCED

HJ51

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