

DRAFT
DEPARTMENT OF HEALTH PROFESSIONS
BOARD OF HEALTH PROFESSIONS
REGULATORY RESEARCH COMMITTEE
October 24, 2011

TIME AND PLACE: The meeting was called to order at 10:07 a.m. on Monday, October 24, 2011, Department of Health Professions, 9960 Mayland Drive, 2nd Floor, Board Room 2, Henrico, VA, 23233.

PRESIDING OFFICER: Jonathan Noble, OD

EMERGENCY EGRESS PROCEDURES: Dr. Carter read the emergency egress procedures.

MEMBERS PRESENT: Jonathan Noble, OD
Yvonne Haynes
Michael Stutts, Ph.D.

MEMBERS NOT PRESENT: All members were present

STAFF PRESENT: Elizabeth A. Carter, Ph.D., Executive Director for the Board
Justin Crow, Research Assistant
Laura Chapman, Operations Manager
Elaine Yeatts, Senior Policy Analyst
Arne Owens, Chief Deputy Director

OTHERS PRESENT: Teresa Nadder, VCU
Randy Vandevander, VSCLS
Emy Morris, VCU & VSCLS
Katherine Prentice, VCU
Nancy Barrow, AMT
Shannon Newman, AMT
Lynn Onesty, RRMC
Lisa Ballou, RMG
Scott Johnson, HDJN
Tyler Cox, HDJN
Susan Ward, VHHA
Michelle Satterlund, MACBUR
Becky Perdue, VSCLS
Brian Ball, VA Society of Anesthesiologists

QUORUM: A quorum was established with Dr. Noble and Ms. Haynes at the beginning of the meeting who were later joined by Dr. Stutts who served in an ex officio capacity as Acting Board President.

AGENDA: No additions or changes were made to the agenda.

PUBLIC COMMENT: 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. (Attachment 1)

Randy Vandevander, Chairman, Government Affairs, VSCLS
Mr. Vandevander stated that he would like the committee to continue with its original determination a year ago and present that recommendation to the full Board that clinical laboratory professionals need to be regulated in the Commonwealth of Virginia. (Attachment 2)

Emy, Morris, VCU & VSCLS

Ms. Morris stated that statutory certification of medical laboratory scientists and technicians is logical. It is no less necessary to the safety, health and well being of Virginia's healthcare consumer than regulation of the other professions that fall under the regulatory umbrella. (Attachment 3)

APPROVAL OF MINUTES: Meeting minutes for May 3, 2011; June 20, 2011 and July 29, 2011 were motioned for approval by Ms. Haynes and properly seconded by Dr. Noble.

EMERGING PROFESSIONS UPDATE: Research Assistant Justin Crow provided update on the Board's current sunrise review of Medical Laboratory Scientists and Technicians. Attachment 4 outlines the presentation.

On properly seconded motion by Ms. Haynes, the Committee voted to forward consideration of the matter to the full Board for further discussion. The significant turnover of Board members has resulted in two vacant seats for the Committee, and the full Board is in the midst of a turnover of twelve of its eighteen members. The significance of the issue merits a full understanding by all members of the Committee and Board of the existing findings and the opportunity to pose any additional questions deemed necessary to render a final recommendation.

Executive Director Elizabeth 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 application in keeping with the Policies and Procedures for the Evaluation of the Need for Regulation of Health Professions and Occupations. But it is anticipated in the future.

Dr. Carter also noted that an association representing Perfusionists had contacted the board office recently requesting information on making an application.

Nurse Practitioner Scope of Practice & Team Delivery Study

Dr. Carter discussed the need for a revised workplan for this study. She commented that due to the turnover of two-thirds of the entire Board and lack of a full complement of Regulatory Research Committee members at this time, a revised and longer

timeline would provide for additional opportunities for public comment and discussion by a fully informed Committee and Board. This is especially the case in light of the nascent, rapidly evolving, and diverse nature of effective health team delivery research.

PERIODIC REVIEW:

Ms. Yeatts discussed with the group the need for periodic review of the following current regulations; 18-VAC 75-20 Regulations Governing Practitioner Self Referral, 18-VAC 75-30 Regulations Governing Standards for Dietitians and Nutritionists, and 18-VAC 75-40 Regulations Governing Certification of Dialysis Technicians. The Board will consider whether the existing regulations are essential to protect the health, safety and welfare of the public in providing assurance that licensed practitioners are competent to practice. Alternatives to the current regulations or suggestions for clarification of the regulation will also be received and considered beginning November 21, 2011 and ending January 20, 2012.

NEW BUSINESS:

Dr. Carter briefly reported that pending the completion of the Scope of Practice review for Nurse Practitioners, that the Committee will be in a better position to develop the workplan for reviews for Pharmacists and Dentists next year.

ADJOURNMENT:

With no other business to conduct, the meeting adjourned at 11:03 a.m.

Jonathan Noble, OD
Chair

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

October 14, 2011

Elizabeth A. Carter, Ph.D.
Executive Director, BHP
9960 Mayland Drive
Suite 300
Richmond, Virginia 23233

To the Members of the Regulatory Research Committee:

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. In addition, I would like to address the inadequacy of the CMS data presented at the Regulatory Research Committee meeting in June 2011 as the basis of determining the level of regulation.

The work plan for the Review of MLS and Technicians was approved in May 2010 with a public hearing in July of the same year. Members of the Virginia Society for Clinical Laboratory Science (VSCLS) submitted documentation that described in detail our scope of practice and provided literature related to the potential risk for harm to the consumer. These materials, as well as the testimonies given in July 2010, were compelling such that the Board's Regulation Research Committee and subsequently the full board concluded at its September 29, 2010 meeting that: 1) "the current system of laboratory facility oversight was viewed as insufficient to ensure the public's health, safety, and welfare", 2) "MLTs and MLS should be held accountable as practitioners", and 3) Virginia should regulate MLS and MLTs.

Following the September 29, 2010 meeting, data was requested from CMS on activities occurring in Virginia's laboratories to ascertain the appropriate level of regulation. The CMS data which included the 5 most frequently cited conditional deficiencies and the number of times immediate jeopardy was called on laboratories in Virginia from December 2006 to the present is just the tip of the iceberg and may reflect only a small fraction of errors occurring in the laboratories. The information gleaned from this data is limited by the fact that laboratories performing moderate and/or high complexity testing have the option of being surveyed biennially by either CMS or an accrediting organization. CMS has approved 9 of these accrediting organizations many of which maintain their own separate database and does not require accrediting organizations to routinely submit data on serious deficiencies unless the deficiencies are classified as immediate jeopardy to the public. In addition, 60% of the 5,123 CLIA labs in Virginia that have Certificate of Waiver or PPM are not routinely inspected. It is also important to keep in mind, however, that labs 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.

Indeed, in 2006, the Government Accountability Office (GAO) was asked to examine the quality of lab testing, the effectiveness of surveys and complaint investigations in detecting and addressing laboratory problems and the adequacy of CMS's CLIA oversight. The GAO's report entitled *Clinical Lab Quality: CMS and Survey Organization Oversight Should Be Strengthened* stated that CMS's data does not provide an accurate assessment of lab quality nationwide and that CMS's oversight is not adequate to help ensure that labs meet CLIA requirements. Further, the report indicated that laboratory quality problems are masked by survey, complaint, and enforcement weaknesses due to: 1) announced visits, 2) lack of reporting as survey organizations do not cite *all* survey deficiencies, and 3) the failure of lab workers to file complaints because of concern about retaliation. The report also cited that weakness in the CMS oversight stems from the fact that CMS does not require labs to participate in key quality assurance testing as frequently as CLIA requires. Further, CMS rarely imposes sanctions and has more of an educational focus. The educational demand on surveyors would be less if personnel who perform laboratory testing had been appropriately educated and certified prior to employment.

COLA, an internationally respected clinical laboratory accreditation organization, issued a white paper on waived testing in January 2011 that substantiates the GAO report. The paper stated that evidence continues to grow showing that "significant quality problems exist in the largely unregulated labs relying on these tests" with the potential to contribute to errors and even patient harm. COLA called for increased education for Certificate of Waiver site personnel to ensure quality testing. Further, COLA has published (9/14/2010) a list of the 10 most frequently cited reasons for laboratory citations by its [COLA] surveyors. Included in the "top 10" are:

- #5: Manufacturer's instructions for the use of reagents, controls, and kits are not followed.
- #7: For each quantitative test performed, quality control data is not prepared and plotted with each testing event, or statistical indices are not calculated to permit the laboratory to assess continued accuracy and precision of the method.
- #8: Personnel Record does not contain documentation of person's education and experience to qualify them for the position they hold in the laboratory.

I would also like to comment on two statements made in the Regulatory Research Committee's June report. You indicated that the greater majority of errors occurred in the pre- and post-analytical phases and suggested that these phases are not under direct control of clinical laboratories. As pointed out in the testimonies given by our professionals last July, laboratory professionals are involved with each phase of testing and have the background and context to understand how these phases interrelate.

The June report also stated that "many laboratory tests are simple to perform, pose little or no risk to patients and are getting simpler." While waived tests are designed for ease of use at the patient bedside, the majority of testing is performed in clinical laboratories, which generate moderate and high complexity test results. Recent advances in technology have created increasingly complex testing that requires appropriate expertise to perform and accurately advise physicians of the results. Examples

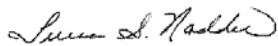
include the growing number of molecular assays or genetic testing that requires sophisticated complex instrumentation and to detect etiologic agents in clinical specimens that may be used in bioterrorism and toxins as chemical weapons.

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
Department of Clinical Laboratory Sciences
Virginia Commonwealth University

Comments to the Virginia Board of Health Professions Regulatory Research Committee
Monday, October 24, 2011

I would like to thank the members of the committee for allowing me the time to speak today. However, I must begin by saying that it is with disappointment that I feel that we are here once again to try to convince the committee of the need to regulate clinical laboratory professionals. A year ago, the committee made the recommendation to have some form of regulation and then this summer, it appeared that the committee was heading for a reversal of that decision. This is very disappointing, especially as we have tried to present what happens in the clinical laboratory when properly trained individuals are monitoring the processes and thereby prevent the very errors that the committee wants us to demonstrate.

While it appears that the committee believes that the CLIA regulations are sufficient for laboratory professionals, there are several problems with that line of thought. First, it is unfortunate that the personnel standards of the CLIA '88 regulations do not contain language necessary to protect our patient population through the personnel standards. CLIA had much input to these proposed standards at that time, and ultimately presented a set of standards, our current standards, that were much weaker than most laboratory professionals thought they should be. These standards were designed to meet only the minimal requirements for laboratory personnel in 1988, not to be inclusive enough to ensure that the individuals performing the testing are appropriately trained to evaluate the validity of the test results, especially for the testing that has evolved in these past 23 years.

Secondly, the CLIA regulations do nothing to protect the patients we serve from fraudulent activities such as identity theft. According to information presented at the most recent Washington G2 Conference by Judy Yost, Director of the Division of Laboratory Services at CMS, a large number of instances have been discovered where personnel qualifications were fraudulent and the ASCP's certification agency is having a problem with folks falsifying their

education. Without a formal registry of qualified laboratorians in the Commonwealth of Virginia, the possibility exists that self-acclaimed laboratory professionals may be able to enter our laboratories through fraudulent activities, again putting the safety of our patients at risk.

While some in this room may believe that the laboratory professionals are trying to achieve regulation by the Board of Health Professions to improve their financial standing or for professional protectionism, I believe that this committee has identified that regulation by itself does not lead to this outcome. Our reasons for being here are now, and consistently have been, to try to assure the safety to the patients we serve by providing the highest quality test results possible by the most qualified individuals available to perform that testing. If you look at the mission statement of most of the organizations representing health professionals and hospitals, they include some element of maintaining quality care or patient safety. The VHHA points this out in their mission statement, and I quote, "Our mission is to improve the health status of the communities we serve." Further, it acknowledges that while achieving reliability in health care is complex, a point that the laboratory professionals have commented upon many times at these meetings, and continuing, the VHHA is committed to making quality and patient safety a priority for Virginia's hospitals and health systems. This is my desire as well, to have a workforce in the clinical laboratory that can be counted upon to utilize its unique body of knowledge, a knowledge base unique to no other healthcare professional, so that it can reliably produce laboratory results that makes quality and patient safety a priority to those we serve in our hospitals and health systems.

With that said, I would once again ask this committee to continue with its original determination of a year ago and present that recommendation to the full Board, that clinical laboratory professionals need to be regulated in the Commonwealth of Virginia.

Randy Vandevander,
Laboratory Administrative Director, Augusta Health
Chairman, Government Affairs, VSCLS

October 24, 2011

To: Board Of Health Professions, Regulatory Research Committee
From: Emy Morris, MS, MT(ASCP)

I am speaking out of concern for the level of regulation that may be recommended by this committee. Specifically, my concern is the direction the recommended regulation may be going. I have been a participant on behalf of medical laboratory scientists and technicians since the beginning of this process. Over time, at these sessions, I have heard mention that maybe it's not the medical laboratory scientists/technicians on whom the regulation should be focused... but, perhaps elsewhere, maybe at the director level.

If this were to be the end result of this committee's work, then the logic is hidden to me, as I'm sure it would be to most healthcare consumers. In general, laboratory directors do not actually conduct laboratory tests themselves. In fact, few could actually step in to perform any but the most basic of tests. Physicians, in their education and training, receive very little education about laboratory practices and procedures. [note: clinical pathologists are the exception here]. Physicians, Physicians Assistants, and Nurse Practitioners make medical decisions—**diagnostic and treatment decisions including adjustment of drug dosages, antibiotics, IV fluids, and chemotherapy**-- on the basis of testing performed, not by the directors of labs in the vast majority of instances, but by the medical laboratory scientists and technicians.

If the same logic of "regulation at the director level" were applied to other healthcare professions, then:

Why are nurses regulated, if physicians bear the ultimate responsibility?

Why are pharmacy technicians regulated if pharmacists bear the ultimate responsibility?

Why are veterinary technicians regulated if doctors of veterinary medicine bear the ultimate responsibility?

Your answer could come back to say that some of those positions were regulated prior to the establishment of the current "criteria for regulation" in which evidence for harm is the #1 criterion. I don't know the timeline for regulation for the professions mentioned above, but that could be the answer in some cases. In various testimony and written communications to this Committee, we have explained why evidence for harm is hard to

come by—not because the potential isn't there, but because the vehicles for delivery of that information are somewhat lacking. Here I would ask you to remember the shortcomings of the CMS research documents previously commented on by Dr. Teresa Nadder earlier in this session.

So, the message I want to convey is that logic and common sense need to prevail here. When trying to find an analogy or metaphor that would be meaningful, the children's nursery rhyme about the "house that jack built" popped into my mind. The house that jack built is called a cumulative tale because it is not just the story of jack who built the house, but instead the "cumulative" verses show how the house is linked to numerous things and people and consequences there in.

What we're talking about here in this session is not Jack's house, but our collective Medical Outcomes house. If the test is performed incorrectly, then incorrect treatment or diagnostic outcomes certainly can result. The ownership belongs to the person doing the test, the person having the credentials and scope of knowledge to perform the test correctly. Just as the pharmacy technician is responsible for loading the right pills into the vial, just as the nurse is responsible for administering the prescribed dose, it logically follows that the laboratory professional performing the test would be responsible for generating accurate test results.

Statutory certification of medical laboratory scientists and technicians is logical. It is no less necessary to the safety, health and well being of Virginia's healthcare consumer than regulation of the other professions that fall under your umbrella.

Respectfully submitted.

Read during the public comment period of the 10/24/11 meeting of the Regulatory Research Committee [note: minor, non-substantive edits made for clarity of message in the written form]



Clinical Laboratory Personnel Policy Options

Regulatory Research Committee
Board of Health Professions

October 24, 2011
Perimeter Center
Henrico, Virginia



Key Findings

- 1. Laboratory tests pose an inherent risk of harm to patients.**
 - a) Diagnoses
 - b) Treatment
 - c) Drug regimen
 - d) Accurate and timely

- 2. Technological change affects tests.**
 - a) Some tests are simpler and easier to perform
 - i. Automated test performance & Quality Control
 - ii. Point of Care testing
 - b) New tests at the cutting edge of medicine
 - i. Genetic tests
 - ii. Molecular-level analysis



Key Findings

3. Clinical Laboratory Personnel Professional Roles.*

- a) Clinical Laboratory Scientists
 - i. Clinical/Medical Laboratory Scientists/Technologists
 - ii. The most complex tests
 - iii. Quality control, procedures and supervision
- b) Clinical Laboratory Technicians
 - i. Clinical/Medical Laboratory Technicians/Assistants
 - ii. Perform tests and prepare specimens
- c) Specialist Roles
 - i. Cytotechnologists, Histotechnologists, Blood Banking

*For this report, we use the terms “Laboratory Scientist” and “Laboratory Technician”.



Key Findings

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

- a) Classification of Laboratory Tests (by FDA)
 - i. Waived (from most CLIA requirements)
 - 1) So simple and accurate as to render the likelihood of erroneous results negligible
 - 2) Pose no reasonable risk of harm to the patient if the test is performed incorrectly
 - ii. Moderate Complexity
 - 1) Personnel must have a HS diploma and documented training
 - iii. High Complexity
 - a) Personnel must have an Associate degree and either completion of an accredited laboratory training program or three months of laboratory training in the specialty
 - iv. Provider-Performed Microscopy
 - a) Performed by a Physician, Dentist or Mid-level practitioner at the providers office.
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4. CLIA, continued
b) Certification of Laboratories

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



Key Findings

5. CLIA-defined Roles

a) Laboratory Director

- i. Responsible for overall operation
- ii. Qualifications
 - 1) Clinical Pathologist (Physician)
 - 2) Physician with training/experience in clinical laboratories
 - 3) Experienced PhD-Laboratory Sciences
 - 4) Masters w/ 2 years experience, 1 year supervisory
 - 5) Bachelors w/ 4 years experience, 2 years supervisory

b) Technical Consultant

- i. Technical Expert in Specialty or subspecialty
- ii. Qualifications
 - i. Equivalent to Laboratory Director, but in specialty area

c) Clinical consultant

- i. The laboratory director or a physician

d) Testing personnel

- i. Qualifications based on tests.



CLIA Advantages/Disadvantages

6. Advantages

- National market for laboratory tests
- Proficiency testing provides an objective measure of competency
- Classification system is flexible
- Errors tend to be process oriented
- 8. Education has improved quality by existing measures (deficiency citations, proficiency testing)

7. Disadvantages

- Over 80% of labs not subject to regular surveys
- Educational focus
- Fragmented survey process
- Quality data is unclear



Key Findings

9. State flexibility under CLIA

- a) May have more stringent requirements
- b) License Labs (Georgia, repealed in 2010)
- c) CLIA Equivalent (New York, Washington)

11. 2005-2010-CMS cited 37 Virginia labs for insufficient number of qualified testing personnel

- a) 4 Immediate jeopardy cases
- b) May be administrative/recordkeeping problems
- c) In at least one incident an unqualified person performed tests



Policy Options

All Options Nominally Exclude Waived/PPMP Tests and Laboratories

- a) Criterion One: Risk of Harm to the Consumer
 - i. The FDA has determined these tests do not pose a risk of harm
- b) Criterion Two: Specialized skills and training
 - a) The FDA has determined these tests to be simple and accurate

At its September 29, 2010 meeting, the RRC did recommend some type of regulation of laboratory personnel, but requested further information regarding the manner of regulation and the proper agency to perform regulation before making a final decision.



Policy Options

1. **No Professional Regulation, with recommendation to regulate facilities**
 - a) Department of Health, Office of Licensure and Certification
 - b) Flexible-can look at total laboratory quality
 - c) Personnel standards can be increased through this mechanism
 - d) Provides an alternative to professional regulation
 2. **Voluntary Certification/Title Protection**
 - a) Prohibits persons from using protected titles
 - b) Provide information to consumers about the qualifications of personnel performing tests or overseeing community laboratories—including waived tests and laboratories
 3. **License Laboratory Directors & Technical Supervisors/Consultants**
 - a) Focuses regulation at those responsible for total quality control
 - b) Require laboratory-specific continuing education for management, including physician management
 - c) Management is responsible for ensuring competency of staff
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Policy Options

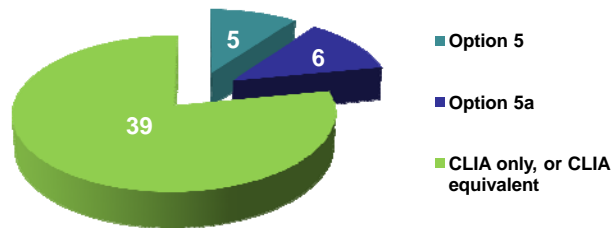
- 4. Licensure of Laboratory Scientists**
- a) Criteria require independent practice, autonomy and little direct supervision
 - b) Laboratory scientists:
 - a) Assist with development of processes and procedures
 - b) Assist with quality control
 - c) Supervise technicians
 - c) Would ensure non-physician management is licensed
- 5. Licensure for Laboratory Scientists and Laboratory Technicians**
- a) Technicians perform tests of moderate to high complexity that pose a risk of harm to patients
 - b) Would require formal training and certification of those performing these tests

Professional Level	Laboratory Management	Laboratory Scientist	Laboratory Technician
Option 1	Not Regulated	Not Regulated	Not Regulated
Option 2	Not regulated	Voluntary Certification	Voluntary Certification
Option 2a	Not regulated	Voluntary Certification	Not regulated
Option 2b	Licensure	Voluntary Certification	Not Regulated
Option 2c	Licensure	Voluntary Certification	Voluntary Certification
Option 2d	Licensure	Licensure	Voluntary Certification
Option 3	Licensure	Not Regulated	Not Regulated
Option 4	Not regulated	Licensure	Not regulated
Option 4a	Licensure	Licensure	Not regulated
Option 5	Not regulated	Licensure	Licensure
Option 5a	Licensure	Licensure	Licensure



Policy Options

10. State Regulation of Laboratory Personnel



VIRGINIA BOARD OF HEALTH PROFESSIONS
CRITERIA FOR EVALUATING THE NEED FOR REGULATION
Initially Adopted October, 1991
Readopted February, 1998



Criterion One: Risk for Harm to the Consumer

The unregulated practice of the health occupation will harm or endanger the public health, safety or welfare. The harm is recognizable and not remote or dependent on tenuous argument. The harm results from: (a) practices inherent in the occupation, (b) characteristics of the clients served, (c) the setting or supervisory arrangements for the delivery of health services, or (d) from any combination of these factors.

Criterion Two: Specialized Skills and Training

The practice of the health occupation requires specialized education and training, and the public needs to have benefits by assurance of initial and continuing occupational competence.

Criterion Three: Autonomous Practice

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

Criterion Four: Scope of Practice

The scope of practice is distinguishable from other licensed, certified and registered occupations, in spite of possible overlapping of professional duties, methods of examination, instrumentation, or therapeutic modalities.

Criterion Five: Economic Impact

The economic costs to the public of regulating the occupational group are justified. These costs result from restriction of the supply of practitioner, and the cost of operation of regulatory boards and agencies.

Criterion Six: Alternatives to Regulation

There are no alternatives to State regulation of the occupation which adequately protect the public. Inspections and injunctions, disclosure requirements, and the strengthening of consumer protection laws and regulations are examples of methods of addressing the risk for public harm that do not require regulation of the occupation or profession.

Criterion Seven: Least Restrictive Regulation

When it is determined that the State regulation of the occupation or profession is necessary, the least restrictive level of occupational regulation consistent with public protection will be recommended to the Governor, the General Assembly and the Director of the Department of Health Professions.