DRAFT

DEPARTMENT OF HEALTH PROFESSIONS
BOARD OF HEALTH PROFESSIONS
REGULATORY RESEARCH COMMITTEE
September 29, 2010

TIME AND PLACE:	The meeting was called to order at 11:05 a.m. on Wednesday, September 29, 2010, Department of Health Professions, 9960 Mayland Drive, 2nd Floor, Board Room 2, Henrico, VA, 23233.
PRESIDING OFFICER:	Damien Howell, P.T., D.P.T., O.C.S, Chair
MEMBERS PRESENT:	Damien Howell, P.T., D.P.T., O.C.S David Boehm, L.C.S.W. Mary Lou Argow, LPC, LMFT, LSATP John Wise, DVM Billie Watson Hughes, FSL Fernando Martinez
MEMBERS NOT PRESENT:	Susan Chadwick, AU.D. Vilma Seymour
STAFF PRESENT:	Elizabeth A. Carter, Ph.D., Executive Director for the Board Justin Crow, Research Assistant Laura Chapman, Operations Manager Elaine Yeatts, DHP Senior Policy Analyst Eric Gregory, Assistant Attorney General
OTHERS PRESENT:	Nancy Barrow, Virginia State & National American Medical Technologists Beverley Soble, VHCA Susan Ward, VHHA Carter Harrison, Alzheimer's Association Cal Whitehead, Virginia Orthopedic Society Gary Bolden, Kinesiotherapy Henry Jackson, Kinesiotherapy Aimee Penn Seibert, NASW-VA Teresa Nadder, VSCLS Nancy Barrow, VSCLS Katherine Prentice, VSCLS Emy Morris, VSCLS Rebecca T. Perdue, VSCLS
QUORUM:	With six members present a quorum was established.
AGENDA:	No additions or changes were made to the agenda.
PUBLIC COMMENT:	Dr. Carter advised the committee that additional public comment was received from JoAnne Gisson.

Nancy Barrow of the Virginia State & National American Medical Technologists was present at the meeting, but had no comment.

APPROVAL OF MINUTES: With six members in attendance a quorum was established and meeting minutes from May 4, 2010, May 26, 2010, July 16, 2010, July 30, 2010, August 16, 2010 and September 17, 2010 were approved.

EMERGING PROFESSIONS UPDATE: Research Assistant Justin Crow and Executive Director Elizabeth Carter provided updates on the Board's current sunrise review research projects relating to emerging professions and their impact on the agency. Three of these studies involve legislative requests: Kinesiotherapy, Expansion of Medication Aides into Nursing Homes, and Medical Laboratory Scientists and Technicians. The remaining studies involve a new request from Phlebotomists for evaluation, a request to remove Grand Aides from the review of Community Health Workers, and an evaluation into the need for a new Allied Health Board.

Kinesiotherapy

The primary focus of this study is to determine the need to regulate kinesiotherapists in the Commonwealth of Virginia pursuant to Senate Bills 573 and 727 (2010). Kinesiotherapy provides therapeutic exercise to rehabilitative patients. Kinesiotherapists began practice during WWII. They currently work to the full scope of practice in Veteran's Health Administration & Military Health Systems. They are currently limited outside of the Federal Health System due to difficulty in obtaining third-party reimbursement. Attachment 1 provides a presentation summarizing the findings and the policy options considered.

On properly seconded motion by Mr. Boehm, the Committee voted to not recommend regulation of kinesiotherapists.

Medication Aides in Nursing Homes

This study was requested by the General Assembly to review the advisability of allowing medication aides in nursing homes pursuant to House Joint Resolution No. 90 (2010). Attachment 1 provides a presentation summarizing the findings and the policy options considered.

Citing the research, public hearing and focus group, on properly seconded motion by Ms. Argow, the Committee voted that it was not advisable for Virginia to expand medication aides into nursing homes at this time.

Medical Laboratory Scientists / Medical Laboratory Technicians
Delegate O'Bannon proposed House Bill 601 during the 2010 Session of the General Assembly. The general scope of the study provides an evaluative review of the policy literature, pertinent state and federal laws, malpractice and disciplinary data, potential economic impact, and public comment concerning the regulation of medical laboratory scientists and medical laboratory technicians in Virginia. The aim is to better understand the scopes of practice of these practitioners and issues relating to the need for adequate safeguards for the public's protection. Attachment 2 provides a presentation prepared by research consultant Sherri Johnson summarizing findings and policy options.

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.

Phlebotomists
Dr. Carter stated that a telephonic request has been made to study Phlebotomists although a formal letter making the request has not yet been received.
On properly seconded motion by Mr. Boehm, the Committee requested staff to develop background information for presentation at the next meeting.

Community Health Workers
The request originally made by Dr. Arthur Garson to evaluate the need for regulation of Grand-Aides has been withdrawn citing conflicts with Virginia's scope of nursing practice and delegation statutes. On properly seconded motion by Ms. Argow, the Committee agreed with the request but also directed staff to continue to monitor pertinent developments with Community Health Workers that may warrant professional regulation in time.

Allied Health Board
The Committee deemed that its review into the need for an allied health board addresses issues that could directly affect the operation of existing boards and the overall Department. The Committee was advised by Dr. Carter that an internal senior staff committee reviewed the governing structures for all allied health professions across the United States and Canada, including Ontario, with its model of regulating controlled acts rather than professions. None of the existing systems could be said to offer a "best practice" model from the Board of Medicine's existing advisory board and committee structure. At the request of Dr. Cane, Dr. Harp, Executive Director of the Board of Medicine is

conducting a staffing and organizational review to determine what measures are needed to help the Board of Medicine accommodate the allied health profession workload. The Committee will be kept abreast of developments at its next scheduled meeting.

ADDITIONAL PUBLIC COMMENT: There was no additional public comment.

NEW BUSINESS: No new business was presented.

ADJOURNMENT: The meeting adjourned at 12:22 p.m.

Damien Howell, P.T., D.P.T., O.C.S
Chair

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

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Studies into the Need to Regulate Kinesiotherapists & Advisability of Expanding Medication Aides into Nursing Homes

Presentation to the Virginia Board of Health Professions
Regulatory Research Committee
September 29, 2010

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Kinesiotherapy

- Background
  - Provide post-acute therapeutic exercise to rehabilitative patients
  - Began during WWII
  - Work to full scope of practice in Veteran's Health Administration & Military Health System
  - Limited outside of Federal health systems

Scope of Practice

- Crowded Rehabilitation Field
- Evolved from Physical Therapy
- Focus on therapeutic exercise
- Patient Population
  - Rehabilitation patients
  - Disabled
  - Spinal Injury
  - Polytraumatic Brain Injury

Kinesiotherapy	Physical Therapy	Occupational Therapy	Athletic Trainers
Reconditioning following illness or injury, or to cope with ongoing conditions	Rehabilitation of specific acute injuries	Increased functionality in daily life and work	Conditioning and training to prevent injuries and first aid for acute injuries

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Credentials

- COPS-KT
  - Arms Length from AKTA
  - Accreditation
  - Certification
  - Continuing Education
- Bachelor's Degree
  - CAAHEP Accredited
- Registered Kinesiotherapist (RKT)
  - Job Analysis in 1986
  - Not independently accredited
  - Not required for VHA employment

No state licenses, certifies, registers or otherwise regulates kinesiotherapists

*Council on Professional Standards-KT

Economic Impact

- Different situation from other professions
  - Existing Profession, not practicing in non-Federal sector
- Barriers to Practice?
  - Strict CMS restrictions
    - Providers may only use PT/OT or PTA/OTA
  - PT/OT Regulations
    - Real or perceived Scope of Practice barriers
    - Restrictions on collaboration with unlicensed therapists
    - Restrictions on using unlicensed support personnel
  - Crowded Rehabilitation Field

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Economic Impact

Occupational Category	Projected Employment Change, 2008-2018
All Occupations	10.12%
Health Practitioners & Technical Occupations	21.35%
Physical Therapists	30.27%
Physical Therapist Assistants & Aides	34.54%
Occupational Therapists	25.60%
Occupational Therapist Assistants and Aides	29.99%
Chiropractors	19.50%
Athletic Trainers	36.95%
Orthotists & Prosthetists	15.48%
Recreational Therapists	14.60%
Recreation & Fitness Workers	29.41%

Projected Employment Growth of Select Occupations, 2008-2018.
Source: Bureau of Labor Statistics

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Cost of Regulation

- 37 RKTs in Virginia
  - Virginia schools have conferred 250 KT degrees since 1989
  - AKTA estimates only 20% of KT graduates pursue KT credentials/employment
  - Employed largely in Federal service
- Independent Board is cost prohibitive
- Advisory Board w/ Medicine or PT
  - ≈$12,300 for 500 licensees

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Criterion #1: Risk of Harm

- No cases of harm
- Potential for harm
  - Practices inherent to the occupation
  - Patient characteristics
- PT/OT Scope of Practice
  - Overlapping modalities
  - BHP never recommended regulation of PTs/OTs
  - Professions have evolved since regulation
- AT—BHP recommended regulation
  - In part based on risk of harm from "Rehabilitation & Reconditioning of Athletic Injuries" domain.
  - Also injury prevention, recognition & immediate care tasks

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Criterion #4: 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

Licensure: Scope of Practice is definable in enforceable legal terms.

Statutory Certification: Scope of Practice is definable, but not stipulated in law

Registration:

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Medication Administration

- Medication administration is a regulated nursing task
  - Performed by Registered Medication Aides (RMAs) in ALFs
  - Performed by RNs & LPNs in medical settings
- Assisted Living Facility (ALF)
  - Semi-independent residents
    - Resident monitoring
    - Activities of Daily Living assistance
    - Coordinate medical care—do not provide it
    - Medication otherwise self-administered
  - Regulated by the Virginia Department of Social Services (VDSS)
- Nursing Homes
  - Patients requiring skilled nursing care
    - Significant cognitive or physical limitations
    - Both post-acute & chronic patients
    - Often cannot participate in the medication administration process
  - Regulated by the Virginia Department of Health (VDH)

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Registered Medication Aides

- Ad Hoc program for ALFs
- Response to unregulated personnel administering in ALFs
- Alternative to requiring nurses
- Ongoing Concerns
  - No requirement for clinical supervision
  - High discipline rate
  - Limited response staff in ALFs

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Medication Aides in Nursing Homes

- Differences
  - Already regulated
    - Lower Qualifications?
  - Patient characteristics
    - Participation
    - Communication
    - Consequences
  - Complexity of Medication Regimens
  - RN/LPN on staff
  - CMS Surveys & VDH Inspections

Twenty states allow "medication aides" to administer medications in nursing homes

Type and Route

- Type
  - PRN (as needed) medications
    - May require basic assessment to administer
  - Narcotics/Schedule II Drugs
    - Drug Diversion
    - Risk to patients
- Route
  - Injection
  - IV
  - Tube
- Varies by state
  - Most states allow PRN medications, some limit schedule II or narcotics
  - Many states do not allow administration by injection, IV, or tube

NH Medication Aides in Other States

Nurse Delegation

- Nurses responsible for medication administration
- Fundamental aspect of programs in other states
- Limits substitution

Eligibility of NH Medication Aides in other states:*

- Certified Nursing Assistants
- Experience as CNA
- Employment in Nursing Home
- Nurse or facility recommendation
- 16-140 hours of medication aide specific training

*All states exhibit one or more of these characteristics. A few exhibit all.

Medication Errors

- Institute of Medicine (2007)
  - "Unacceptable" nursing home error rates
  - 6 to 20% of **doses** involve non-wrong time errors
  - Wrong-time errors "predictably high" due to length of medication passes
  - 800,000 **preventable** Adverse Drug Events (ADEs) annually
- Causes
  - Organizational
    - Communication
    - Fragmentation in care/medication process
    - Lack of staffing
  - Professional
    - Limited assessment skills of LPNs/medication aides
    - Not often mentioned
    - Literature provides little meaningful evidence concerning medication aides and error rates

Year	Author	Administration errors per 100 opportunities/doses
1982	Barker, et al.	12.2
1992	Baldwin	20
1994	Cooper	6
2002	Barker, et al.	14.7

Source: Institute of Medicine, Preventing Medication Errors: Quality Chasm Series. *2007.*

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Characteristics of Nursing Homes employing medication technicians

- Study not looking at use of labor extensive anti-osteoporosis medications
  - Found no increase in use w/ medication technicians
- Examined characteristics of nursing homes employing medication technicians
- Nursing homes employing medication technicians are:
  - More likely to:
    - Have CMS citations for significant medication errors
    - Have medication error rates higher than 5%
  - Less likely to:
    - Have a physician/medical director on staff
    - Have an in-house pharmacy
  - Tend to have lower staffing levels per 100 beds
    - Nurses
    - CNAs
- Does not indicate that medication aides cause higher error rates
- Does indicate that nursing homes with higher error rates tend to hire medication aides
  - Possible causes
    - Medication aides themselves
    - Lowered staffing levels/quality
    - Fragmented medication delivery system

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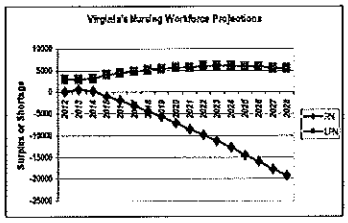
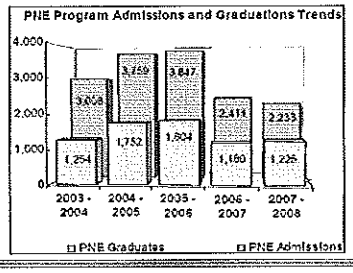
Economic Impact

- LPN Surplus projected
  - May be local/rural shortages
  - *Nursing* shortage
- Direct care
  - High-employment growth, 2008-2018
- ALF RMA-training
  - Difficulty capturing investment in training
  - Recently built-up RMA workforce
  - 50%+ are also CNAs





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Policy Options

1. No Change
   - High medication error rates
   - LPNs available
   - RMA experience/workforce underdeveloped
2. Statewide expansion
   - Evidence suggests medication aides can be successfully employed
   - Nursing/rural LPN shortage
   - Increased labor flexibility could decrease interruptions/pass times
   - Note: Virginia does not have mandated staffing ratios
3. Limited Expansion
   - "Pilot Program" model
   - Apply for medication aide approval based on staffing mix and/or medication error citations
   - Provide an incentive to invest in organizational/staffing improvements

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Study of the Need to Regulate Medical Laboratory Scientists and Medical Laboratory Technicians

Presentation to the Virginia Board of Health Professions

Regulatory Research Committee
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Medical Laboratory Scientists
a.k.a.
Medical Laboratory Technologists
Clinical Laboratory Scientists
Clinical Laboratory Technologists

Medical Laboratory Technicians
a.k.a.
Medical Technicians
Clinical Laboratory Technicians

Income (national median) (BLS, 2008)

MLS: $53,500

MLT: $35,800

Projected growth in these professions (BLS, 2008)

MLS: +12%

MLT: +16%

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Education and Training

MLS: Bachelor's degree

MLT: Associate's degree, certificate/diploma

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Accrediting agencies for MLS/MLT programs

NAACLS
CAAHEP
ABHES

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In Virginia,

NAACLS 7 MLS programs and 4 MLT programs

CAAHEP 0 MLS programs and 1 MLT program

ABHES none

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Current National Totals and Expected Growth from 2008 - 2018 (BLS, 2008)

Professional level	Number	Est. Change
MLS	172,400	+12%
MLT	155,600	+16%
Medical Assistant	483,600	+34%

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Certification/Regulation

- Voluntary certification
- State licensure and laws
- Federal regulation of laboratories
- Laboratory accreditation

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Voluntary certification

Certification for MLS/MLT granted by:

AAB	American Association of Bioanalysts
AMT	American Medical Technologists
ASCP-BOC	American Society for Clinical Pathology-Board of Certification

~~ASCLS — American Society for Clinical Laboratory Science~~
~~NCA — National Credentialing Agency for Laboratory Personnel~~

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State licensure

States/Territory that currently require licensure for MLS and MLT personnel

- California
- Florida
- Georgia
- Hawaii
- Louisiana
- Montana
- Nevada
- New York
- North Dakota
- Rhode Island
- Tennessee
- West Virginia
- Puerto Rico

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Average licensure fees

Annual/initial fees: MLS = $90, MLT = $77

Renewal fees: MLS = $50, MLT = $45

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Federal Regulation of Laboratories

Clinical Laboratory Improvement Amendments (CLIA)

Test Complexity

- waived complexity,
- moderate complexity*
- high complexity.

[*Moderate complexity also includes a subcategory of provider-performed microscopy (PPM)].

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Types of CLIA Laboratories in Virginia

Certificate Type	Percent of Labs
Waiver	59%
PPM	21%
Accredited	9%
Compliance	9%
Registration	1%

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CLIA: Test Complexity and Minimum Personnel Requirements

Waived

None

Moderate Complexity

HS diploma or (equivalent) and documented training for the testing performed

High Complexity

Associate's degree (including 24 semester hours in science) and completion of either:

(1) accredited or approved clinical laboratory training program

(2) three months laboratory training in the specialty(ies) in which the individual performs high complexity testing

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Laboratory Accreditation

CMS Approved Accrediting Organizations

- AAB
- American Osteopathic Association
- American Society for Histocompatibility and Immunogenetics
- College of American Pathologists
- COLA
- Joint Commission

(CMS/CLIA/Accreditation Organizations, n.d.)

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Literature Review

Laboratory error and its relationship to testing phase

- Pre-analytic
- Analytic
- Post-analytic

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Summary of July 2010 Public Hearing

In support of regulation:

- Increased automation and volume of testing requires professionals with full understanding of the scientific processes as they relate to medical laboratory science.

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- Scope of practice requires integration of day-to-day processes into the phases of laboratory testing.
- Documented examples of harm can be difficult to obtain but that doesn't mean that harm does not occur.
- CLIA regulations are not ideal professional standards.

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- Importance of education and training, and how it might help reduce the profession's current shortage of personnel.
- Concerns about point-of-care testing by non-laboratory personnel

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- Specific suggestions about/benefits of regulating MLS/MLTs in Virginia

In opposition to regulation:

- Current regulations may be sufficient and federal health care reform will bring significant changes system-wide including emerging regulations.

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Review of the Criteria

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.

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(Criterion 1)

- CLIA regulations on the minimum qualifications of laboratory staff
- Increase of waived tests/waived testing facilities
- CMS study findings

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(Criterion 1, continued)

- Point-of-Care testing by non-laboratory personnel
- Difficult to detect harm

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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.

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(Criterion 2)

- Bureau of Labor Statistics (BLS) information
- CLIA requirements
- Educational background and continuing education

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Criterion Three: Autonomous Practice

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

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(Criterion 3)

- CLIA requires supervision
- Effectiveness of supervision may be mitigated by high volumes of testing

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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.

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(Criterion 4)

- Scope of practice for MLT/MLSs distinguishable from physicians, nurses, and laboratory directors

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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.

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(Criterion 5)

- Regulation may increase costs for MLS/MLTs and their employers

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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.

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(Criteria 6)

- Establish minimum education requirement and/or minimum work experience (stronger than CLIA requires)
- Continuing education requirement
- Disclosure requirement

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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.

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(Criterion 7)

- Registration
- Certification

Thank you