

**DRAFT**  
**DEPARTMENT OF HEALTH PROFESSIONS**  
**BOARD OF HEALTH PROFESSIONS**  
**REGULATORY RESEARCH COMMITTEE**  
**February 15, 2011**

**TIME AND PLACE:** The meeting was called to order at 11:06 on Tuesday, February 15, 2011, Department of Health Professions, 9960 Mayland Drive, 2<sup>nd</sup> Floor, Board Room 2, Henrico, VA, 23233.

**PRESIDING OFFICER:** Damien Howell, MS, PT, OCS

**MEMBERS PRESENT:** Damien Howell, MS, PT, OCS, Chair  
Fernando Martinez  
John Wise, DVM  
Yvonne Haynes

**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

**OTHERS PRESENT:** Emy Harris, Medical Laboratory Scientists  
Kay Ballas, MT, Hendon, VA  
Sarah R. Hold, MT, Roanoke, VA  
Becky Perdue, Medical Laboratory Scientists

**QUORUM:** With four members present a quorum was established.

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

**PUBLIC COMMENT:** Emy Morris, Medical Laboratory Scientist  
Ms. Morris stated that as the Health Professions' Regulatory Research Committee, and ultimately, the Board of Health Professions make their final decisions related to the regulation of medical laboratory scientists and laboratory technicians, we would like to re-emphasize the following points: the CLIA regulations were developed more than 20 years ago and were considered minimal at the time. With today's more advanced testing and technology, the CLIA requirements do not provide the knowledge and background that the formal MSL and MLT designations provide. The designations of MLS and MLT acknowledge that these individuals have acquired a unique body of knowledge to meet the demands of today's clinical laboratories, and this will reduce the risk of harm to the consumer. While the board is tasked with providing the least restrictive means of regulation possible, we would encourage the Board to be consistent in the regulation of clinical laboratorians. Creating a different set of criteria within hospital laboratories and

laboratories outside the hospital could become problematic.

**APPROVAL OF MINUTES:** With four members in attendance a quorum was established and the meeting minutes from January 13, 2011 were approved.

**EMERGING PROFESSIONS UPDATE:** Research Assistant Justin Crow provided updates on the Board's current projects relating to emerging professions and their impact on the agency. These include Medical Laboratory Scientists /Technicians, Phlebotomists and Genetic Counselors. (Attachment)

#### **Medical Laboratory Scientists/Techs**

This is currently on hold until there is additional information available from the Centers for Medicare and Medicaid on Virginia's laboratory inspections. Staff will continue its research.

#### **Phlebotomists**

On properly seconded motion by Dr. Wise, the Committee requested that this profession be tabled until additional review can be completed.

#### **Genetic Counselors**

The Committee recommended the following options: title protection/voluntary certification or licensure. Staff was instructed to communicate with the Board of Medicine and request their input on these options. On properly seconded motion by Mr. Martinez, the Committee recommended regulation of this profession and noted that recommendation on the form of regulation requires further review. On properly seconded by Mr. Martinez the Committee also recommended the gathering of additional public comment on the two options.

#### **Community Health Workers**

Dr. Carter reported that there are no changes which would affect the Board's consideration for regulation at this time. Staff will continue to monitor the evolution of community health workers and report accordingly.

#### **Scope of Practice**

The Board has requested that Scope of Practice FAQ sheets be created for each profession to be used as a learning tool for the public as well as each respective Board. Scopes of Practice FAQ sheets will be created for one profession at a time and reviewed by the respective Board for accuracy. In addition to the scope of practice detailed in statute and regulation, this objective briefing on each profession will highlight education and training requirements, licensure examinations and other required credentialing as well as statistics on the number regulated in Virginia.

**NEW BUSINESS:** There was no new business.

**ADJOURNMENT:** The meeting adjourned at 12:06 p.m.

---

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

---

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



## Emerging Professions Review

Updates:

Medical Laboratory

Scientists/Technicians: Update

Phlebotomists: Preliminary Review

Genetic Counselors: Work plan



Medical Laboratory Scientists  
Medical Laboratory Technicians

Update

---



## Medical Laboratory Scientists/Technicians

- Still awaiting CMS survey results (FOIA Request)
  - Studies on laboratory errors
  - Error rates are low
  - Mostly in the pre- and post-analytic phases
- Regulation would have the most impact on waived tests
  - Would add continuing education requirement at all levels

	CLIA Minimum Personnel Requirements	Additional Personnel Requirements if impacted by licensure
Waived	None	Certificate/associate or military training and certification as MLT
Moderate Complexity	HS diploma and documented training	Certificate/associate or military training and certification as MLT
High Complexity	Associate degree and completion of either: 1) accredited or approved clinical laboratory training program 2) three months laboratory training in specialty	Certification as MLT



## Waived Tests

- Least Complex
- Lowest Risk of Harm
- Point of Care Tests
  - Ambulance
  - Pharmacy
  - School/Prison Health Service
  - Health Fair
  - Skilled Nursing Facility
  - Home Health Agency
  - Physician Offices

Waived Tests Performed by:

- Nurses
- Pharmacists/Pharmacy Techs
- EMTs
- Medical Assistants*



## Studies

	Plebani & Corrado (1997)	Nutting et al (1996)	Plebani & Corrado (2007)
Total Analyses	40490	160714	51,746
Number of errors	189	180	160
<b>Error Rate</b>	<b>0.47%</b>	<b>0.11%</b>	<b>0.31%</b>
Percentage of Errors that Effected Patient Outcomes	26%	27%	24%
Number of Errors that effected patient outcomes	49	49	39
<b>Patient Outcome Effecting Error Rate</b>	<b>0.12%</b>	<b>0.03%</b>	<b>0.075%</b>
Percent of Error occurring in Pre-analytical Phase	68%	56%	62 %
Percent of Error in Analytical Phase	13%	13%	15 %
Percent of Error in Post-analytical Phase	19%	27%	23%
Notes	Errors effecting patient care resulted in unnecessary investigation or inappropriate care. Reviewed hospital labs.	Figures based on patient visits to physicians, not analyses. Reviewed orders from primary care physicians-variety of lab types.	Replicating 2007 study



### Patient Outcome Effecting Errors, 2007

- 1 inappropriate intensive care unit admission
- 2 inappropriate transfusions
- 9 further inappropriate investigations
- 27 laboratory test repetition



## Preliminary Findings (Staff)

- Regulation would mostly affect waived tests, particularly those waived tests performed by medical assistants
  - Errors are rare
  - The greater majority of errors occur:
    - Outside of the laboratory
    - Due to organizational/communication problems
  - CLIA and related efforts by the CDC focus on organizational solutions. They have been effective in reducing errors over the past decade.
  - A minority of errors affect patients
    - Mostly through unnecessary/repetitive tests
- 



## Phlebotomists

---



## Phlebotomy

- Laboratory Specimen Collection/Blood donation collection
- One Billion annually
- High volume/low wage
  - High turnover
  - Minimal entry requirements
    - Often OJT, right out of HS
    - Certification eligibility
      - 1 yr work experience
      - Training—100 hrs/100 collections



### Risk of Harm

- To the Phlebotomists themselves
  - Sharps injuries & blood-borne pathogens
  - US Occupational Safety and Health Administration
  - Criteria require risk of harm to consumers
- Wrong/inadequate lab results
  - Patient misidentification
  - Wrong color-coded tube
- Patient Injury
  - Hematoma (bruising under the skin)
  - Blood Spurt
  - Multiple punctures
- Blood-borne Pathogens

### Training & Certification

#### Accredited Education:

- 100 hours applied experience,
- 100 unaided collections, and,
- Variety of techniques and patient types

#### Certification Eligibility

- Approved Education/Training,
- 1 year experience, or,
- Combination of training and experience





## Genetic Counselors

---



## Scope of Practice

- Diagnostic
    - Assist Physicians:
      - Determine if genetic test is appropriate
        - Family history
      - Select genetic test
      - Interpret Results
  - Counseling
    - Examine genetic risk
      - Family History
      - Refer for genetic testing
    - Ramifications/appropriateness of genetic tests
    - Understand results and risks
    - Options for addressing test results
    - Counseling
      - Referral to support groups/community resources
      - Referral to mental health professionals
-



## A Dynamic Field

- Rapid Growth of Knowledge & Testing
- Few clinically useful applications
- Slow integration of genetic knowledge
- Transformational potential

Prediction & Prevention  
Diagnosis & Treatment

### Genome Sequencing

2003-1<sup>st</sup> Genome Sequencing  
-13 years  
-\$3 billion  
2008-10 Genomes Sequenced to date  
2009-50 Genomes  
-Complete Genomics, Inc  
2010-Thousands  
-\$5,000  
2011-Tens of Thousands?  
-\$1,500?



*. . . Many experts believe [the likeliest] scenario is one in which geneticists play a larger role in educating PCPs, who will then incorporate more extensive genetic care into their daily practice.*

-Virginia GeneSEAN, 2006

*The future role of genetic counselors, and thus workforce needs, is also uncertain, although recent trends suggest that genetic counselors are increasingly working directly with other non-genetic medical specialists as part of health care delivery teams.*

-Virginia GeneSEAN, 2006



## Risk of Harm

### Risk Prediction/Diagnosis

- “False Positive” (false diagnosis or report of increased risk)
  - Prophylactic Actions (Breast, Ovary, Colon Removal)
  - Termination of Pregnancy
- “False Negative” (Undiagnosed condition or report of decreased risk)
  - Forego prophylactic actions/screening

### Psychological/Social Implications

- Difficult Practical Choices
- Difficult Ethical Choices
- Social Implications
  - Non-directive counseling
  - Heightened privacy needs

### Upon diagnoses of Downs Syndrome:\*

#### Overemphasize negative aspects to encourage termination

- Physicians: 13%
- Genetic Professionals: 13%

#### Overemphasize positive aspects to encourage continuation

- Physicians: 10%
- Genetic Professionals: 2%

#### Actively “urge” mothers to continue

- Physicians: 4%

\*1999 Study, 499 Physicians, 1084 genetics professionals in US. Wertz D C. Drawing lines: notes for policymakers. In: Parens E, Asch A, eds. Prenatal testing and disability rights. Washington, DC: Georgetown University Press, 2000: 261-87



## Sources of Harm

- Physicians and other Regulated Practitioners
  - Lack of training
  - Rapidly changing genetic test library
  - Underdeveloped/ underutilized clinical guidelines
  - Failure to refer
- Direct-to-consumer genetic tests
  - Includes “snapshot” of genetic disposition/gene risk
  - Many overseas companies
  - Different companies provide different results on the same DNA sample

*“You’d be in the high risk of pretty much getting it”*

Response from a customer service representative to a GAO investigator about an elevated risk of breast cancer

### Practice of Medicine?

**Yes**-Actions already violate statute and regulations

**No**-Health Professions regulation may have limited impact



## Sources of Harm

### Unregulated Practice

- Inherent Harm
- Reports of harm from inadequate genetic counseling/knowledge
- Genetic Testing companies advertising counseling
- Often provide limited or even wrong information

### Shortage

- Lack of genetic knowledge
- Lack of referrals
- Depend on GT companies for information/counseling
- Supply v. Demand
  - Supply: 60
  - Need: 106 (conservative)

The shortage of genetic professionals able to advise, educate and counsel physicians and patients appears to contribute to harm.



## Alternatives to Regulation

### FDA Classification of DTC Genetic Tests as Medical Devices

--FDA study of genetic test regulation is ongoing

### New York & California independently defined DTC genetic tests as medical devices

--Genetic Counselor legislation accompanied these efforts

--Genetic counselor licensure alone has not diminished access to DTC genetic tests

### Physician Education

--Continuing education requirements



**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.

---