DRAFT
DEPARTMENT OF HEALTH PROFESSIONS
BOARD OF HEALTH PROFESSIONS
REGULATORY RESEARCH COMMITTEE
June 20, 2011

TIME AND PLACE:	The meeting was called to order at 1:28 p.m. on Monday, June 20, 2011, Department of Health Professions, 9960 Mayland Drive, 2nd Floor, Board Room 2, Henrico, VA, 23233.
PRESIDING OFFICER:	Damien Howell, MS, PT, OCS
EMERGENCY EGRESS PROCEDURES:	Dr. Carter read the emergency egress procedures.
MEMBERS PRESENT:	Damien Howell, MS, PT, OCS, Chair Jonathan Noble, OD Yvonne Haynes
MEMBERS NOT PRESENT:	Fernando Martinez David Kozera
STAFF PRESENT:	Elizabeth A. Carter, Ph.D., Executive Director for the Board Justin Crow, Research Assistant Laura Chapman, Operations Manager Gloria Mitchell, BON
OTHERS PRESENT:	Samantha Soller, HDJN Randy Vandervander, VSCLS Bernie Bekken, VSCLS Teresa Nadder, VCU Becky Perdue, VSCLS Susan Ward, VHHA Paul Speidell, VHHA
QUORUM:	With three members present a quorum was established.
AGENDA:	No additions or changes were made to the agenda.
PUBLIC COMMENT:	There was no public comment.
APPROVAL OF MINUTES:	There were no prior meeting minutes to approve.
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 Genetic Counselors and Medical Laboratory Scientists /Technicians. **Medical Laboratory Scientists and Technicians** Attachment 1 provides a summary of the inspection findings. The Chair tabled consideration of recommendations until the full

Board can review the policy options at the August 2, 2011 meeting. The Chair cited that he wanted more time to consider all the potential policy options in light of the Board's September 10, 2010 vote that recommended regulation upon consideration of the actual complaints and deficiencies in Virginia. The study was delayed because CMS did not provide the CMS inspection results until late April 2011. The full array of policy options will be presented to the full Board at its meeting on August 2, 2011.

Genetic Counselors

The Committee discussed the legislative language developed by staff and approved the final report. (See Attachment 2). On properly seconded motion by Dr. Noble, the full final report incorporating suggested legislative proposal language was recommended for final approval by the full Board scheduled to meet August 2, 2011.

Nurse Practitioner Scope of Practice & Team Delivery Study

The Committee reviewed a draft workplan of the study into potential scope of practice barriers which may adversely affect team healthcare delivery in Virginia. (See Attachment 3). The workplan is in response to the Secretary's request for assistance for the Virginia Health Reform Initiative (VHRI). At the May 3, 2011 meeting, the full Board determined that it may best assist the VHRI Capacity Task Force in examining potential scope of practice barriers to the effective operations of team practice models. In keeping with the VHRI's findings reported in December as well as the extensive nature of existing research and other policy literature relative to Nurse Practitioners and Pharmacists, the Board directed the Committee to first focus on Nurse Practitioners and then Pharmacists. Subsequent professions will be determined by the Committee.

On properly seconded motion by Dr. Noble, the Committee adopted the workplan and directed that it be posted to the Board's website and made available to constituent groups and all other interested members via the Public Participation Guidelines list.

NEW BUSINESS:

Proposed Legislation

Dr. Carter presented as new business to the Committee draft proposed legislation designed to reduce the number of required full Board meetings from four times to once per year. This measure provides greater flexibility for the Board by permitting it to adjust meeting volumes and timeframes to meet its needs and ensure optimal efficiencies. The Board retains the option to meet more than once per year and in differing times of the year, but it would no longer be compelled to meet quarterly. (See Attachment 4).

On properly seconded motion by Ms. Haynes, the Committee approved the proposed legislation and will discuss its acceptance with the full Board in August.

There was no further new business.

ADJOURNMENT: With no other business to conduct, the meeting adjourned at 2:32 p.m.

______________________________	______________________________
Damien Howell, P.T., D.P.T., O.C.S	Elizabeth A. Carter, Ph.D.
Chair	Executive Director for the Board

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Clinical Laboratory Scientists/ Clinical Laboratory Technicians

CMS Complaint Information

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The Numbers

- In five years:
  - 32 Complaints
  - 37 Testing Personnel Citations
- In four years
  - 23 Immediate Jeopardy Citations
  - 4 related to Testing Personnel
- Includes Complaints to CMS only
  - Accrediting organizations may also receive complaints (Joint Commission)

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Testing Personnel Citation

- Related to Sufficient *Quantity* of Qualified Personnel
- Tests of Moderate Complexity
- May mean persons without an Associate/ Certificate are performing tests of moderate complexity.
- Citation may also indicate lack of evaluation or documentation by director

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Risk of Harm

- 3 Instances of Harm
  - Failed to inform physician when a received sample was lost/bad.
    - Texas patient had to repeat a painful, invasive biopsy procedure
    - Virginia patient delayed in receiving treatment for a resistant infection

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Risk of Harm

- Problem with a blood transfusion resulted in patient death
  - Multiple citations
  - Technical Supervisor cited
    - Failure to ensure staff competency
    - Failure to observe instrument maintenance tests
  - The technical supervisor may be a physician or a Bachelor or higher level scientist
    - Unknown in this case
  - No “Testing Personnel” Citation

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Summary

- Complaints/Citations identified by CMS only
- 32 Complaints for all Virginia labs over Five Years
- 37 citations for “Testing Personnel” over for 8,700 CLS/CLT over five years
- Most complaints related to communications and quality assurance procedures
- Three instances of harm
  - Not related to *qualifications* of testing personnel
  - One related to *competency* of testing personnel and technical supervisor

* Bureau of Labor Statistics, 2009

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Summary

- FOIA request supports literature
  - Low error rates
  - Errors mostly related to communication and quality assurance procedures

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Key Questions

Alternatives to Regulation

1. Does CLIA do an adequate job of protecting the public?
2. Would state regulation have an effect on error rates?
3. Should regulation effect waived tests
   1. If not, how will that effect the benefits of regulation?

Economic Impact

1. Would harm from increased cost of testing outweigh benefits?
2. Would regulation effect waived test availability?

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Genetic Counselors

Model Statute

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Key Points

- Restriction of Titles
  - Definition includes "coordination of diagnostic tests".
    - Does not explicitly include ordering tests
- Exceptions
  - Exception for PhD medical geneticists

VIRGINIA BOARD OF HEALTH PROFESSIONS
VIRGINIA DEPARTMENTOF HEALTH PROFESSIONS

STUDY WORKPLAN DRAFT

Review of Potential Nurse Practitioner Scope of Practice Barriers to the Development of Effective Team Approaches to Healthcare Delivery in Virginia

June 20, 2010

Background and Authority

At the February 15, 2011 meeting of the Virginia Board of Health Professions, the Secretary of Health and Human Resources requested the Board's assistance in addressing Virginia's health reform issues. The Secretary's request followed the publication in December 2010 of the Virginia Health Reform Initiative Advisory Council's (VHRI) latest findings and recommendations.

Led by Secretary Hazel and commissioned in August of 2010 by Governor Robert F. McDonnell, VHRI's charge is to develop recommendations for implementing health reform in Virginia and to search for innovative solutions to meet Virginia's needs in 2011 and beyond. To date, six VHRI task forces have been formed to address the following key interrelated issues: Medicaid Reform, Service Delivery and Payment Reform, Technology, Insurance Reform, Purchaser Perspectives, and, of greatest relevance to the Department and Board, Capacity.

The Capacity Task Force noted in the December VHRI report that health workforce capacity must be increased to ensure all Virginian's have access to affordable and high quality care. Even now before increased coverage from federal health reform takes effect, there are many medical, dental, and mental health underserved areas throughout across the state. And, looming shortages are predicted for most health service providers due to increases in Virginia's population size and age, alone. With increase coverage slated to go into effect in 2014, the gap between supply and demand can be expected to only worsen without help.

The Capacity Task Force viewed that effective capacity could be reached with increases in health professional supply, expanded use of technology to reach underserved areas, optimizing efforts to re-organize health care delivery through teams that effectively deploy non-physicians, and permitting health professionals to practice up to the evidence-based limits of their education and training in ways not currently possible with existing scope of practice and supervisory restrictions. To inform these approaches, the Task Force further recommended multi-dimensional studies which include reviews of promising team practice approaches and examination of how current scope of practice limits may needlessly restrict Virginia's ability to take full advantage of best practice team models of care delivery.

The Board of Health Professions is authorized by the General Assembly with a variety of powers and duties specified in §§54.1-2500, 54.1-2409.2, 54.1- 2410 *et seq.*, 54.1-2729 and 54.1-2730 *et seq.* of the *Code of Virginia.* Of greatest relevance here is §54.1-2510 (1), (7), and (12) enable the Board to evaluate the need for coordination among health regulatory boards, to advise on matters relating to the regulation or deregulation of health care professions and occupations, and

to examine scope of practice conflicts involving professions and advise on the nature and degree of such conflicts.

Thus, the Board determined at its May 3, 2010 meeting that it can most effectively assist VHRI and the Capacity Task Force by objectively examining the aforementioned current scope of practice limits in light of the latest evidence-based policy research and available data related to safety and effectiveness. With the assistance of member Boards and invited input from experts and public and private stakeholders, this review will identify barriers to safe healthcare access and effective team practice that may exist due to current scope of practice limits and will determine the changes, if any, that should be made to scope of practice and regulatory policies to best enable effective team approaches for the care of Virginia's patients. The aim is not to replace physicians with non-physicians but to lessen unnecessary restrictions to ease the burden on practitioners and better ensure access to healthcare through strengthened health professional teams.

The Board referred the project to the Regulatory Research Committee and directed that the first review focus on Nurse Practitioners' scope of practice in Virginia in the perspective of their potential role in team health care delivery models that have evidence of effectiveness in helping to address workforce shortage.

The Board also directed that the next review focus on similar potential scope of practice barriers for Pharmacists. The Committee, itself, will determine future professions to be highlighted based upon the evolving evidence related to effective team models and the workforce research findings for professions under review by the DHP Healthcare Workforce Data Center and Virginia Health Workforce Development Authority.

Methods

Throughout the review, it is understood that the Board will strive to work in concert with the efforts of its member Boards, the VHRI Capacity Task Force, the Department's Healthcare Workforce Data Center, the Health Care Workforce Development Authority, and others working to assist the Secretary in these matters.

In keeping with constitutional principles, Virginia statutes, and nationally recognized research standards, the Board has developed a standard methodology to address key issues of relevance in gauging the need for regulation of individual health professions. The specifics are fully described in the Board's *Policies and Procedures for the Evaluation of the Need to Regulate Health Occupations and Professions,* available from the Board's website: http://www.dhp.virginia.gov/bhp/bhp_guidelines.htm) under Guidance Document **75-2** Appropriate Criteria in Determining the Need for Regulation of Any Health Care Occupation or Professions, revised February 1998. (Hereinafter this is referred to as "the Policies and Procedures"). The Policies and Procedures will be employed in this study and modified as deemed appropriate by the Committee. It is understood that the Policies and Procedures' seven evaluative criteria apply most directly to determining *whether* a profession should be regulated and to what degree. But, they also provide a standard conceptual framework with proscribed questions and research methods that have been employed for over two decades to successfully address key policy issues related to health professional regulation The seven Criteria typically used in sunrise review studies are as follows:

1. **Risk of Harm to the Consumer**
2. **Specialized Skills and Training**

3. **Autonomous Practice**
4. **Scope of Practice**
5. **Economic Costs**
6. **Alternatives to Regulation**
7. **Least Restrictive Regulation**

Since Nurse Practitioners are already licensed, the first five Criteria will chiefly guide the study. This study will provide background information on the qualifications and scopes of practice of Nurse Practitioner in Virginia and elsewhere and on major existing and described emerging health delivery models, and, since Nurse Practitioners are already licensed, the study will answer questions regarding the first five Criteria.

The following provide the chief questions recommended to be addressed:

Background

1. What are the current qualifications that Virginia's Nurse Practitioners must demonstrate to become licensed? Do they differ from other states?
    a. What are the educational or training requirements for entry into this profession? (sample curricula) Which programs are acceptable? How are these programs accredited? By whom?
    b. What are the minimal competencies (knowledge, skills, and abilities) required for entry into the profession? As determined by whom?
    c. Which examinations are used to assess entry-level competency?
        i. Who develops and administers the examination?
        ii. What content domains are tested?
        iii. Are the examinations psychometrically sound – in keeping with *The Standards for Educational and Psychological Testing?*

2. How do Nurse Practitioners maintain continuing competency? Does it differ in other states?

3. What is the Nurse Practitioner Scope of Practice in Virginia? How does it differ from other states?

4. Describe existing team delivery models of care that utilize Nurse Practitioners in Virginia and elsewhere.

5. Based upon the emerging literature, describe existing and anticipated team delivery models that may evolve as a result of the federal health reform and the potential role(s) for Nurse Practitioners in those models.

Risk of Harm to the Consumer

1. What are the typical functions performed and services provided by Nurse Practitioners in Virginia and elsewhere?

2. Is there evidence of harm from Nurse Practitioners with expanded scopes of practice relative to that in Virginia? If any,
    a. To what can it be attributed (lack of knowledge, skills, characteristics of the patients, etc)?

   b. How is the evidence documented (Board discipline, malpractice cases, criminal cases, other administrative disciplinary actions)?
   c. Characterize the type of harm (physical, emotional, mental, social, or financial)
   d. How does this compare with other, similar health professions, generally?

3. Does a potential for fraud exist because of the inability of the public to make informed choice in selecting a competent practitioner?

4. Does a potential for fraud exist because of the inability for third party payors to determine competency?

5. Is the public seeking greater accountability of this group?

Specialized Skills and Training

NOTE: The following are in addition to the qualification-related questions previously posed for the "Background" section of the evaluation.

1. Are there currently recognized or emerging specialties/levels within this profession?
   a. If so what are they? How are they recognized? By whom and through what mechanism?
   b. Are they categorized according to function? Services performed? Characteristics of clients/patients? Combination? Other?
   c. How can the public differentiate among these specialties or levels?

Autonomous Practice

1. What is the nature of the judgments and decisions that Nurse Practitioners are currently entitled to make in practice in Virginia? Does this differ in states with more expanded scope of practice? If so, how?
   a. In rendering diagnoses?
   b. In determining or approving treatment plans?
   c. In directing or supervising others in patient care?

2. Which functions typically performed by Nurse Practitioners in Virginia are **unsupervised** (i.e., neither directly monitored nor routinely checked)?
   a. What proportion of the practitioner's time is spent in unsupervised activity?
   b. Who is legally accountable/liable for acts performed with no supervision?

3. Which functions are performed **only under supervision** in Virginia**?**
   a. Is the supervision *direct* (i.e., the supervisor is on the premises and responsible) or *general* (i.e., the supervisor is responsible but not necessarily on the premises?
   b. How frequently is supervision provided? Where? And for what purpose?
   c. Who is legally accountable/liable for acts performed under supervision?
   d. What is contained in a typical supervisory or collaborative arrangement protocol?

4. Do Nurse Practitioners typically supervise others? Describe the nature of this supervision?

5. Describe the typical work settings, including supervisory arrangements and interactions of the practitioner with other regulated and unregulated occupations and professions.

6. Are patients/clients **referred to** Nurse Practitioners for care or other services? By whom? Describe a typical referral mechanism.

7. Are patients/clients **referred from** Nurse Practitioners to other practitioners? Describe a typical referral mechanism. How and on what basis are decisions made to refer?

Scope of Practice

1. Which existing functions of this profession in Virginia are **similar to** those performed by other professions? Which profession(s)?

2. What additional functions, if any, are performed by Nurse Practitioners in other states?

3. Which functions of this profession are **distinct from** other similar health professions in Virginia? Which profession(s)? In other states?

Economic Costs

1. What are the range and average incomes of members of this profession in the Commonwealth? In adjoining states? Nationally?
2. If the data are available, what are the typical fees for service provided by this profession in Virginia? In adjoining states? Nationally?
3. Is there evidence that expanding the scope of Nurse Practitioners would
    a. Increase the cost for services?
    b. Increase salaries for Nurse Practitioners employed by health delivery organizations?
    c. Restrict other professions in providing care?
    d. Other deleterious economic effects?
4. Address issues related to supply and demand and distribution of resources
5. Are third-party payors in Virginia currently reimbursing services provided by Nurse Practitioners? Directly to the Nurse Practitioner? Employer?
6. Are similar services to those provided by Nurse Practitioner also provided by another non-physician profession? Which profession(s)? Are they reimbursed directly by third-party payors?

The following steps are recommended for this review

1. Conduct a comprehensive review of the pertinent policy and professional literature.

2. Review and summarize available relevant empirical data as may be available from pertinent research studies, malpractice insurance carriers, and other sources.

3. Review relevant federal and state laws, regulations and governmental policies.

4. Review other states' relevant experiences with scope and practice expansion and team approaches to care delivery.

5. Develop a report of research findings, to date, and solicit public comment on reports and other insights through hearing and written comment period.

6. Publish second draft of the report with summary of public comments. .

7. Committee to host a roundtable discussion with representatives from affected constituencies and other interested parties to clarify matters and resolve any conflicts if deemed needed.

8. Develop final report with recommendations, including proposed legislative language as deemed appropriate by the Committee.

9. Present final report and recommendations to the full Board for review and approval.

10. Forward to the Director for review and comment.

11. Upon approval from the Director forward to the Secretary for final review and comment.

12. Prepare the final report for publication and electronic posting and dissemination to interested parties.

Timetable and Resources

This initial study will be conducted with existing staff and within the budget for the remainder of FY2011 and half of FY2012. Subsequent professions' reviews will be incorporated into the review with their own over time as the Committee determines.

The following timeline is submitted for the Committee's consideration:

June 20, 2011	Committee Review of Workplan and Progress to Date
July 15, 2011	1st Draft Report Sent to Committee Members & Posted to the Website
July 29, 2011	Public Hearing/Committee Meeting on Draft Report
August 2, 2011	Full Board Meeting (Report from Committee – no decisions)
August 15, 2011	2nd Draft Report with Summary of Public Comment Sent to Committee Members
September 1, 2011	Report Posted to Website
September 29, 2011	Committee Meeting /Roundtable Discussion & Development of Final Recommendations
October 11, 2011	Committee Report and Recommendations to the Full Board
October 17, 2011	Report and Recommendations to Director
November 1, 2011	Final Report to Secretary

Virginia Department of Health Professions
2012 Session of the General Assembly

Draft Legislation

A bill to amend and reenact § 54.1-2508 of the Code of Virginia, relating to required meetings of the Board of Health Professions.

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-2508 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-2508. Chairman; meetings of Board; quorum.

The chairman of the Board of Health Professions shall be elected by the Board from its members. The Board shall meet at least ~~once quarterly~~ annually and may hold additional meetings as necessary to perform its duties. A majority of the Board shall constitute a quorum for the conduct of business.