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**Ad Hoc Ad Hoc Committee of the Boards of Pharmacy and Medicine  
to Amend the Regulations Governing Collaborative Practice Agreements**

Tuesday, August 20, 2013, 9:00 a.m.

9960 Mayland Drive, Suite 200, Henrico, VA 23233

Board Room 2

**Call to Order** – Kenneth Walker, MD

**Roll Call/Introductions** – Ms. Opher

**Emergency Egress Procedures** – Ms. Opher .....i

**Adoption of Agenda** – Ellen Shinaberry, RPh

**Public Comment on Agenda Items** – Kenneth Walker, MD

**NEW BUSINESS:**

1. Charge of the Committee – Ms. Yeatts ..... -----
2. Background Materials
  - a. Board of Health Professions Pharmacy Scope of Practice Study – Ms. Yeatts..... 1-7
  - b. Pharmacy Congress Response to BHP – Ms. Juran ..... 8-63
  - c. Summary of Public Comment from the July 23, 2013 Public Hearing – Ms. Yeatts..... 64-69
  - d. Minutes from the BHP Regulatory Research Committee, October 2, 2012 – Dr. Harp ..... 70-72
3. Review of HB1501 – Ms. Yeatts..... 73-74
4. Letter Regarding Advanced Pharmacy Practice from Regina Benjamin, MD, US Surgeon  
General – Dr. Harp ..... 75-76
5. Collaborative Practice Agreements—Pharmacist Initiation of Therapy – Dr. Harp ..... 77-138
6. Law Concerning Prescriptive Authority—Section 54.1-3303 of the Code of Virginia – Dr. Harp ..... 139-140
7. Definitions of Prescriber and Prescribing—Section 54.1-3401 of the Code of Virginia – Ms. Juran ..... 140-140
8. Current Regulations for Collaborative Practice Agreements – Ms. Yeatts ..... 141-145
9. Discussion of Amendments Necessary to Implement the New Law—Section 54.1-3300.1 – Ms. Yeatts -----
10. Next Steps – Ms. Yeatts
3. Adjournment - Co-Chairs

**PERIMETER CENTER CONFERENCE CENTER EMERGENCY  
EVACUATION OF BOARD AND TRAINING ROOMS** (Script to be  
read at the beginning of each meeting.)

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**Board Room 2**

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**VIRGINIA BOARD OF HEALTH PROFESSIONS  
VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS**

**STUDY WORKPLAN DRAFT**

**Review of Potential Pharmacist and Pharmacy Technician Scope of Practice Barriers  
to the Development of Effective Team Approaches to Healthcare Delivery in Virginia**

**May 8, 2012**

**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 Virginians 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 aim to 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 goal 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 address scope of practice issues in Virginia relating to Nurse Practitioners and this second study to focus on Pharmacists and Pharmacy Technicians. All reviews are to consider scope of practice issues in the perspective of their potential role in team health care delivery models that have evidence of effectiveness in helping to address workforce shortage. Subsequent to this review, the Committee 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](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 Pharmacists and Pharmacy Technicians 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 Pharmacists and Pharmacy Technicians in Virginia and elsewhere and on major existing and described emerging health delivery models.

The following provide the chief questions recommended to be addressed:

### **Background**

1. What are the current qualifications that Virginia's Pharmacists and Pharmacy Technicians must demonstrate to become licensed? Do they differ from other states?
  - a. What are the educational or training requirements for entry into each 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 Pharmacists and Pharmacy Technicians maintain continuing competency? Does it differ in other states?
3. What is the Scope of Practice in Virginia for Pharmacists? For Pharmacy Technicians? How does it differ from other states?
4. Describe existing team delivery models of care that utilize Pharmacists and Pharmacy Technicians 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 Pharmacists and Pharmacy Technicians in those models.

### **Risk of Harm to the Consumer**

1. What are the typical functions performed and services provided by Pharmacists and Pharmacy Technicians in Virginia and elsewhere?
2. Is there evidence of harm from either Pharmacists or Pharmacy Technicians 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 Pharmacists and Pharmacy Technicians currently entitled to make in practice in Virginia? Does this differ in states with more expanded scope of practice? If so, how?

2. Which functions typically performed by Pharmacists and, separately, Pharmacy Technicians 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 or civilly 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 or civilly liable for acts performed under supervision?
4. Describe the nature of 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** these professions for care or other services? By whom? Describe a typical referral mechanism.
7. Are patients/clients **referred from** these professions 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 these professions 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 each of these professions in the Commonwealth? In adjoining states? Nationally?

2. If the data are available, what are the typical fees for service provided by these professions in Virginia? In adjoining states? Nationally?
3. Is there evidence that expanding the scope of practice would
  - a. Increase the cost for services?
  - b. Increase salaries for those 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 including discussion of insurance reimbursement.

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. Develop final report with recommendations, including proposed legislative language as deemed appropriate by the Committee..
8. Present final report and recommendations to the full Board for review and approval.
9. Forward to the Director for review and comment.
10. Upon approval from the Director forward to the Secretary for final review and comment.
11. Prepare the final report for publication and electronic posting and dissemination to interested parties.

### **Timetable and Resources**

This study will be conducted with existing staff and within the budget for the remainder of FY2012 and half of FY2013.

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

|                    |                                                                           |
|--------------------|---------------------------------------------------------------------------|
| May 8, 2012        | Committee Review of Workplan and Progress to Date                         |
| July 13, 2012      | 1st Draft Report to Committee Members & Posted to the Website             |
| July 23, 2012      | Public Hearing/Committee Meeting                                          |
| August 17, 2012    | 2 <sup>nd</sup> Draft Report to Committee Members & Posted to the Website |
| September 17, 2012 | Committee Meeting/Recommendations                                         |
| October 2, 2012    | Committee Report to the Full Board/Final Recommendations                  |

**VIRGINIA PHARMACY CONGRESS  
STUDY WORKPLAN DRAFT**

for submission to

**VIRGINIA BOARD OF HEALTH PROFESSIONS  
VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS**

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

REVISED January 30, 2012

**Background**

- 1. What are the current qualifications that Virginia's Pharmacists must demonstrate to become licensed? Do they differ from other states?**

The **qualifications for licensure** as a pharmacist in the Commonwealth of Virginia are outlined in the Code of Virginia and further defined in the Regulations Governing the Practice of Pharmacy.<sup>1,2</sup> In order to be eligible for licensure, applicants must be at least 18 years and be in good moral character. A minimum of 1500 hours of practical experience in the practice of pharmacy is required for licensure. To gain pharmacy practical experience in Virginia, pharmacy students must first register with the board to become a pharmacy intern. On and after June 1, 1964, the applicant must have graduated from at least a five-year course of study with a Bachelor of Science degree in pharmacy or a Doctorate of Pharmacy degree awarded from a school that meets the standards of the Accreditation Council for Pharmaceutical Education. The applicant must achieve a passing score as determined by the board on the licensure examination which is approved by the board and which shall consist of an integrated examination of pharmacy practice, pharmacology, pharmacy mathematics, and such other subjects as are necessary to assure that the candidate possesses the necessary knowledge and skills to practice pharmacy. The approved licensing examination is The North American Pharmacist Licensure Examination™ (NAPLEX®).<sup>3</sup> An applicant must also achieve a passing score on a board-approved examination assessing the knowledge of the federal and state laws relevant to pharmacy practice. The board-approved law examination is the Virginia Federal and State Drug Law Examination.<sup>3</sup> Once these requirements are met, applicants may submit an application and fee to become licensed. Pharmacists must complete continuing pharmacy education in approved programs for each annual renewal of licensure.<sup>2</sup>

**The qualifications for licensure as a pharmacist vary among states.** For example, states have different requirements for practical experience prior to applying for licensure. While many states require a minimum of 1500 hours, certain states require more hours or have more stringent requirements for the experience. The practical experience

requirements for licensure in Pennsylvania include a maximum of 750 hours attained from school of pharmacy internship experience.<sup>4</sup> Differences exist in examination requirements for licensure among states. The specific examination assessing the applicants' law knowledge may be different. The Multistate Pharmacy Jurisprudence Examination (MPJE™) is utilized by 47 states, but Virginia uses a contracted administrator to administer its own psychometrically sound jurisprudence examination. Other states that do not utilize MPJE as part of licensure requirements are Arkansas and California.<sup>5</sup> Some states require examinations beyond the NAPLEX and law examination. For example, some states such as West Virginia require that pharmacists also pass The Errors and Omissions examination for licensure.<sup>6</sup> Requirements for continuing education and renewal of licenses also vary across states.

Pharmacists licensed in other states who wish to obtain licensure in Virginia must comply with the same minimal educational and practical experience requirements as pharmacists initially licensed in Virginia. Additionally, NABP serves as the clearinghouse for identifying any disciplinary action taken by another state for the Virginia board to take into consideration prior to issuance of the license.

Foreign graduates must also comply with obtaining the same number of years of educational experience from a school that is equivalent to an ACPE-approved school. In addition to obtaining the same number of hours of practical experience and passing the NAPLEX and Virginia Federal and State Drug Law Exam, this person must also pass the test of English as a foreign language and the Foreign Pharmacy Graduate Equivalency Examination.

In two states, New Mexico and North Carolina, licensed pharmacists can seek advanced-practice designations that broaden their scope of practice including and prescribing privileges. To gain these designations, licensed pharmacists must have additional qualifications and training. In order to be recognized as a Pharmacist Clinician in New Mexico, one must be a licensed pharmacist who meets one of the following criteria: 60 hours of physical assessment training with either 9 months of clinical experience or physician-supervised preceptorship of 150 hours and 300 patient contacts, plus passing of a Board-approved examination; OR certification by the Indian Health Service Pharmacist Practitioner Program with 600 patient contacts within the last 2 years and an affidavit from a supervising physician.<sup>7</sup> The state of North Carolina has its own requirements for the Clinical Pharmacist Practitioner designation. The pharmacist must be licensed to practice pharmacy, have a collaborative practice agreement with a physician, and meet one of the following criteria: a BS degree, five years experience, and completion of two approved Certificate Programs; OR a PharmD degree, three years experience, and completion of one approved Certificate Program; OR a Board of Pharmaceutical Specialties (BPS) Certification or Geriatric Certification or completion of an ASHP accredited residency program and two years clinical experience.<sup>8</sup>

- 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?**

The accreditation of colleges and schools of pharmacy are under the purview of the Accreditation Council for Pharmacy Education (ACPE). State boards of pharmacy require that licensure applicants from the United States have graduated from an accredited pharmacy degree program to be eligible to sit for the North American Pharmacist Licensure Examination™ (NAPLEX®). ACPE is the national agency for the accreditation of professional degree programs in pharmacy and providers of continuing pharmacy education. ACPE was established in 1932 and in 1975 its scope of activity was broadened to include accreditation of providers of continuing pharmacy education. ACPE is an autonomous and independent agency whose Board of Directors is derived through the American Association of Colleges of Pharmacy (AACP), the American Pharmacists Association (APhA), the National Association of Boards of Pharmacy (NABP) (three appointments each), and the American Council on Education (ACE) (one appointment).

After decades of debate, the transition to the Doctor of Pharmacy (PharmD) as the sole professional practice degree for pharmacy in the United States was initiated when ACPE adopted its *Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree* on June 14, 1997.<sup>9</sup> The implementation timeline for the new standards required transition for the entering professional classes in academic year 2000-2001, and the transition was completed in academic year 2004-2005 with the graduation of the last student from an ACPE-accredited baccalaureate in pharmacy program. Many pharmacy colleges and schools converted to the PharmD well in advance of the implementation deadline, and all programs met the implementation timetable. This dramatic action added an additional year to the entry-level curriculum and established clinical/direct patient care as a foundational element of the practice. Subsequently, the ACPE issued new standards in 2007 and 2011 that explicitly address the curricular content of educational programs.

A joint publication by the American Pharmacists Association and American Association of Colleges of Pharmacy highlights the strategies utilized by 18 schools and colleges of pharmacy to incorporate medication therapy management (MTM) into the curriculum. The goal of including MTM in the curriculum is to increase students' knowledge and experiences, therefore empowering graduates with the skills to develop and implement MTM services.<sup>10</sup>

**Sample curricula from the four pharmacy schools in Virginia can be found in Appendix A.**

A complete listing of all accredited colleges and schools of pharmacy can be found at [http://www.acpe-accredit.org/shared\\_info/programsSecure.asp](http://www.acpe-accredit.org/shared_info/programsSecure.asp). The pre-

requisites for acceptance into colleges and schools of pharmacy are variable however there is a strong trend toward requirement that students have previously earned an undergraduate degree.

**b. What are the minimal competencies (knowledge, skills, and abilities) required for entry into the profession? As determined by whom?**

The minimum competencies required for entry into the profession are set by ACPE. The ACPE standards and guidelines, taken together, ensure the development of students who can contribute to the care of patients and to the profession by practicing with competence and confidence in collaboration with other health care providers. The revision has placed greater emphasis on the desired scientific foundation and practice competencies, the manner in which programs need to assess students' achievement of the competencies, and the importance of the development of the student as a professional and lifelong learner. The standards focus on the development of students' professional knowledge, skills, attitudes, and values, as well as sound and reasoned judgment and the highest level of ethical behavior.

The AACP Center for the Advancement of Pharmaceutical Education (CAPE) published their CAPE Educational Outcomes in 1997 shortly after the ACPE established the new doctor of pharmacy accreditation standards. These outcomes were intended to be the target toward which the evolving pharmacy curriculum should be aimed. These outcomes, which were revised in 2004 and are articulated in points 1-3 below, now serve as the minimal competencies that student pharmacists must demonstrate in order to graduate from an ACPE accredited college or school of pharmacy. The revised CAPE *Educational Outcomes*<sup>11</sup> employ similar language to other competency/outcomes documents in the health professions (e.g., Institute of Medicine, Accreditation Council for Graduate Medical Education, Pharmacy's Framework for Drug Therapy Management, Medical School Objectives Project). The Outcomes include:

1. Provide pharmaceutical care in cooperation with patients, prescribers, and other members of an inter-professional health care team based upon sound therapeutic principles and evidence-based data, taking into account relevant legal, ethical, social, economic, and professional issues, emerging technologies, and evolving pharmaceutical, biomedical, sociobehavioral, and clinical sciences that may impact therapeutic outcomes.
  - a. Provide patient-centered care.
    - i. Design, implement, monitor, evaluate, and adjust pharmaceutical care plans that are patient-specific and evidence-based.
    - ii. Communicate and collaborate with prescribers, patients, care givers, and other involved health care providers to engender a team approach to patient care.

- iii. Retrieve, analyze, and interpret the professional, lay, and scientific literature to provide drug information to patients, their families, and other involved health care providers.
  - iv. Carry out duties in accordance with legal, ethical, social, economic, and professional guidelines.
  - v. Maintain professional competence by identifying and analyzing emerging issues, products, and services that may impact patient-specific therapeutic outcomes.
- b. Provide population-based care.
  - i. Develop and implement population-specific, evidence-based disease management programs and protocols based upon analysis of epidemiologic and pharmacoeconomic data, medication use criteria, medication use review, and risk reduction strategies.
  - ii. Communicate and collaborate with prescribers, population members, care givers, and other involved health care providers to engender a team approach to patient care.
  - iii. Retrieve, analyze, and interpret the professional, lay, and scientific literature to provide drug information to other health care providers and to the public.
  - iv. Carry out duties in accordance with legal, ethical, social, economic, and professional guidelines.
  - v. Maintain professional competence by identifying and analyzing emerging issues, products, and services that may impact population-based, therapeutic outcomes.
- 2. Manage and use resources of the health care system, in cooperation with patients, prescribers, other health care providers, and administrative and supportive personnel, to promote health; to provide, assess, and coordinate safe, accurate, and time-sensitive medication distribution; and to improve therapeutic outcomes of medication use.
  - a. Manage human, physical, medical, informational, and technological resources.
    - i. Apply relevant legal, ethical, social, economic, and professional principles/issues to assure efficient, cost-effective utilization of human, physical, medical, informational, and technological resources in the provision of patient care.
    - ii. Communicate and collaborate with patients, prescribers, other health care providers, and administrative and supportive personnel to engender a team approach to assure efficient, cost-effective utilization of human, physical, medical, informational, and technological resources in the provision of patient care.
    - iii. Carry out duties in accordance with legal, ethical, social, economic, and professional guidelines.

- iv. Maintain professional competence by identifying and analyzing emerging issues, products, and services that may impact management of human, physical, medical, informational, and technological resources in the provision of patient care.
- b. Manage medication use systems.
    - i. Apply patient and population-specific data, quality assurance strategies, and research processes to assure that medication use systems minimize drug misadventuring and optimize patient outcomes.
    - ii. Apply patient and population-specific data, quality assurance strategies, and research processes to develop drug use and health policy, and to design pharmacy benefits.
    - iii. Communicate and collaborate with prescribers, patients, caregivers, other involved health care providers and administrative and supportive personnel to identify and resolve medication use problems.
    - iv. Carry out duties in accordance with legal, ethical, social, economic, and professional guidelines.
    - v. Maintain professional competence by identifying and analyzing emerging issues, products, and services that may impact medication use systems, to develop use and health policy, and to design pharmacy benefits.
- 3. Promote health improvement, wellness, and disease prevention in cooperation with patients, communities, at-risk populations, and other members of an interprofessional team of health care providers.
    - a. Assure the availability of effective, quality health and disease prevention services.
      - i. Apply population-specific data, quality assurance strategies, and research processes to develop identify and resolve public health problems.
      - ii. Communicate and collaborate with prescribers, policy makers, members of the community and other involved health care providers and administrative and supportive personnel to identify and resolve public health problems.
      - iii. Carry out duties in accordance with legal, ethical, social, economic, and professional guidelines.
      - iv. Maintain professional competence by identifying and analyzing emerging issues, products, and services that may affect the efficacy or quality of disease prevention services to amend existing or develop additional services.

- b. Develop public health policy.
  - i. Apply population-specific data, quality assurance strategies, and research processes to develop public health policy.
  - ii. Communicate and collaborate with prescribers, policy makers, members of the community and other involved health care providers and administrative and supportive personnel to develop public policy.
  - iii. Carry out duties in accordance with legal, ethical, social, economic, and professional guidelines.
  - iv. Maintain professional competence by identifying and analyzing emerging issues, products, and services that may affect public health policy, to amend existing or develop additional policies.

**c. Which examinations are used to assess entry-level competency?**

**i. Who develops and administers the examination?**

The NAPLEX is issued by the National Association of Boards of Pharmacy (NABP) and is utilized by the state Boards of Pharmacy as part of their assessment of competence to practice pharmacy.<sup>12</sup> Each state requires applicants to pass the NAPLEX examination in order to obtain a license to practice as a registered pharmacist. The purpose of the NAPLEX is to determine whether or not it is safe for individuals to practice as an entry-level pharmacist. The examination is a computer-adaptive, competency-based examination. The examination is administered by Pearson VUE.

The Commonwealth of Virginia utilizes the Virginia Federal and State Drug Law Examination to test candidates' knowledge of Federal Drug Law and Virginia Pharmacy laws and regulations.<sup>13</sup> The examination is developed Virginia pharmacists under the direction of a contracted psychometrician and administered by Iso-Quality Testing. The test incorporates simulations of prescriptions, labels, and refill records to evaluate a candidates' ability to apply pharmacy laws in real-life situations.

**ii. What content domains are tested?**

The NAPLEX examination evaluates applicants' ability to apply knowledge learned in pharmacy school to real life situations. The NAPLEX competency statements are a blueprint of the areas covered.<sup>12</sup> These competencies include: assess pharmacotherapy to assure safe and effective therapeutic outcomes (56% of test), assess safe and accurate preparation and dispensing of medications (33% of test), and assess, recommend, and provide healthcare information that promotes public

health (11% of test). Further details on specific objectives are listed on the complete NAPLEX Blueprint.

The Virginia Federal and State Drug Law Examination evaluates applicants' knowledge of federal and state laws with more emphasis on state law.<sup>13</sup> The areas applicants must be competent in include the laws and regulations pertaining to licensing, registration, and inspection (24% of test), ordering, receiving, and managing drug inventory (21%), review of prescriptions (30% of test), and dispensing and distribution (25%). Further details including specific behavioral objectives are in the study guide posted on the Board of Pharmacy's website.

**iii. Are the examinations psychometrically sound – in keeping with *The Standards for Educational and Psychological Testing*?**

Yes, the examinations required for licensure are psychometrically sound.

**2. How do Pharmacists maintain continuing competency? Does it differ in other states?**

**Pharmacists complete continuing pharmacy education (CPE) to maintain competencies.** The Accreditation Council for Pharmacy Education defines CPE for the profession of pharmacy as a structured educational activity designed or intended to support the continuing development of pharmacists and/or pharmacy technicians to maintain and enhance their competence. CPE should promote problem-solving and critical thinking and be applicable to the practice of pharmacy.<sup>14</sup> The five core areas pharmacists should develop and maintain proficiency in are delivering patient care, working as part of interdisciplinary teams, practicing evidence-based medicine, focusing on quality improvement, and using information technology. Pharmacists may complete CPE sessions in three formats including live activities, home study, or activities that contain both live and home study.

**To be eligible for annual license renewal, pharmacists licensed in Virginia are required to complete at least 15 contact hours of continuing pharmacy education.<sup>2</sup>**

**The CPE requirements differ in other states.** States range from requiring 10 hours in a year (New Jersey and New Mexico) to 20 hours in a year (Ohio). The majority of states require 15 hours in a year, however 31 states require pharmacists to renew their license every 2 years and 2 (New York and Ohio) are every 3 years. Certain states place requirements on the number of live continuing pharmacy education courses whereas others may specify required topic areas.

**In the past, documenting and reporting of CPE has also varied across states.** In Virginia, pharmacists are required to attest to compliance with CPE requirements at the time of annual license renewal. The Board of Pharmacy has the authority to conduct audits to verify compliance. Pharmacists selected for an audit must submit original

documents of completion to the board for review. Since auditing all licensed pharmacists is not practical and the current self-reporting system is subject to fraud, boards of pharmacy needed an improved system for assessing CPE compliance. Recently, NABP and ACPE created the CPE Monitor, an electronic system for tracking CPE credits for pharmacists and technicians. This will improve CPE reporting and compliance verification.<sup>15</sup>

**CPE requirements also differ in states with advanced-practice designations for pharmacists, such as the Clinical Pharmacist Practitioner (CPP) in North Carolina and the Pharmacist Clinician in New Mexico.** Similar to the additional training and requirements to obtain these designations, additional continuing education is required. North Carolina's CPE requirement for licensed pharmacists is 15 hours of CPE annually, however the requirement for Clinical Pharmacist Practitioners is 35 hours annually.<sup>8,16</sup> Similarly, Pharmacist Clinicians must complete 20 additional hours of CPE beyond those required in New Mexico law.<sup>7</sup>

### **3. What is the Pharmacist Scope of Practice in Virginia? How does it differ from other states?**

The scope of pharmacy practice in Virginia and elsewhere encompasses functions that serve to improve public health through the safe and effective use of medications, and as such involves almost every aspect of the medication use process. Traditionally, pharmacist roles revolved mainly around the medication product: processing prescriptions or drug orders, preparing the pharmaceutical product, and dispensing or delivering the medication or device. Increasingly, pharmacist roles also encompass clinical and cognitive services that help promote safe and appropriate medication use. Pharmacists are responsible for assessing the appropriateness of prescribed therapies, ensuring patient understanding and adherence to treatment plans through counseling and education, monitoring and reporting patient outcomes, and preventing drug-related problems and adverse effects.<sup>17</sup>

In many settings across Virginia, including hospitals and health systems, pharmacists are responsible for managing medication use within the system, working with physicians and other health professionals to ensure optimal pharmacotherapy for patients, and delivering clinical services that promote wellness and disease prevention. These responsibilities are increasingly being performed within interdisciplinary team-based models that promote collaboration with other health care practitioners in acute care, primary care, and long-term care settings.<sup>17</sup>

Additionally, many state boards (including Virginia) have taken steps to incorporate expanded clinical services into the scope of practice for pharmacists by authorizing Collaborative Drug Therapy Management (CDTM) through collaborative practice arrangements with physicians, osteopaths, and podiatrists. In addition to the federal pharmacy sector, 44 states have enacted legislation to support some form of Collaborative Practice Agreements (CPAs) between physicians and pharmacists that

provide the opportunity for pharmacists to deliver high-level clinical services that extend beyond the usual scope of pharmacists practice.<sup>18</sup>

Although Virginia has established regulations for the creation of collaborative practice agreements, other states have been more progressive in expanding the scope of practice for pharmacists. Several state Medicaid programs, including Washington, Wisconsin, Mississippi, Iowa, Tennessee, Arizona, Minnesota, South Dakota, Missouri, New Mexico, and North Carolina had waivers approved to allow for contract pharmacist-related compensation for clinical services. Pharmacists in these states are recognized as providers and may be reimbursed for medication therapy management services.<sup>19</sup> The National Clinical Pharmacy Specialist (NCPS) program expanded the functions of Indian Health Service pharmacists by recognizing them as primary care providers with prescriptive authority.<sup>20</sup> Similar expanded functions exist for Veterans Affairs pharmacists.<sup>21</sup> Currently, in both North Carolina and New Mexico, pharmacists may seek advanced practice designations resulting in increased scope of practice including prescribing authority.<sup>7,8</sup> Since 1993, New Mexico pharmacists have the opportunity to pursue additional training and earn the designation Pharmacist Clinician. Pharmacist Clinicians may obtain personal DEA numbers and have prescriptive authority under a supervising physician. In North Carolina, the Clinical Pharmacist Practitioner Act of 2000 established the designation Clinical Pharmacist Practitioners (CPP).<sup>8</sup> A CPP provides disease therapy management and can initiate, modify, or substitute therapies under a broad collaborative practice agreements.

#### **4. Describe existing team delivery models of care that utilize Pharmacists in Virginia and elsewhere.**

In Virginia and other states, there are many avenues for pharmacists to practice within team delivery models. In institutional settings, pharmacists often round in treatment teams alongside physicians, nurses, dietitians, occupational therapists, and social workers in areas like acute care, cardiology, oncology, emergency department, pediatrics, psychiatry, critical care, and infectious disease. Pharmacists on these teams are responsible for assessing patients' medication regimens, evaluating laboratory values and diagnostic results, making recommendations regarding appropriate pharmacotherapy, and communicating information to other members of the team. Pharmacists in the acute setting also provide drug selection and dosing consultations, lead team-based antibiotic stewardship programs, manage anticoagulation therapy, and perform medication counseling services.<sup>22,23</sup> In the community setting, pharmacists provide care within the team delivery model by communicating with physicians (via phone or electronically) to discuss appropriate therapy, answer questions, and make recommendations as indicated. Pharmacists are also active in providing immunizations to patients for influenza, pneumococcal disease, meningococcal disease, hepatitis A and B, and herpes zoster (shingles).

Team-based patient care is also the cornerstone of collaborative practice agreements between physicians and pharmacists. Through this type of practice, pharmacists may engage in collaborative medication therapy management and chronic disease

management based on protocols agreed upon by the pharmacist and physician. Examples of disease states that can be managed using this team-based approach include hypertension, diabetes, hypercholesterolemia, asthma, anticoagulation, and pain.

There are numerous examples in the literature of collaborative practice arrangements and team-based care models that have been successfully implemented in various settings across the country. For example, in a study published in 2010, Carter, et al<sup>24</sup> evaluated the effect of a physician-pharmacist collaborative model in community-based medical offices on blood pressure (BP) control. The study demonstrated BP control in 63.9% of patients in the collaborative practice (intervention) group compared to 29.9% of patients in the control group ( $p < 0.001$ ), and a 55.4% increase in adherence to treatment guidelines in the intervention group.<sup>24</sup>

The effectiveness of group medical clinics (GMC) for managing patients with comorbid diabetes and hypertension was compared to usual care in a study conducted by Edelman and colleagues.<sup>25</sup> This study was conducted in two Veterans Affairs Medical centers in Durham, North Carolina and Richmond, Virginia. A “group medical clinic” included seven to eight patients managed by a care team that consisted of a primary care general internist, a pharmacist, and a nurse or other certified diabetes educator. The visits, conducted every two months, included various interactive educational sessions and the development of individualized plans for medication or lifestyle management created by the pharmacist and physician to improve diabetes control (reduction in HbA<sub>1c</sub>) and blood pressure. At the study conclusion, the mean systolic blood pressure decreased by 13.7 mm Hg in the GMC group and 6.4 mm Hg in the usual care group ( $P = 0.011$ ). Blood pressure control was achieved in 22% of patients in the GMC group and 12% in the usual care group [odds ratio [OR], 2.0 [CI, 1.0 to 4.2]. Diabetes control did not differ significantly between the groups.<sup>25</sup>

Examples of team-based patient care models in Virginia have been described both in the literature and through personal communication with participating pharmacists. In a study published in 2011, Moczygemba, et al<sup>26</sup> evaluated the effect of integrating a collaborative medication therapy management model into medical and mental health clinics serving homeless individuals. The study found that in the mental health clinic, pharmacists identified an average of 2 drug-related problems per patient, while in the medical clinic they identified an average of 5 per patient.<sup>26</sup> The study also found that up to 89% of pharmacist recommendations were accepted by providers and/or patients, indicating successful integration of pharmacist services into the patient care model.<sup>26</sup>

Another example of a team-based delivery model in Virginia can be found at Buford Road Pharmacy in Bon Air.<sup>27</sup> While the pharmacy does perform a dispensing and counseling role, there is a clinic located within the facility where pharmacists perform and evaluate point of care measurements, including cholesterol, glucose, bone density, blood pressure, and INR. Through protocols established as part of collaborative practice agreements with physicians, pharmacists at Buford Road Pharmacy communicate these measurements to the physicians and use them to make appropriate drug therapy recommendations.

As stated, there are many other studies that have evaluated these practice models and have shown improved clinical outcomes for patients as a result of team-based care with integration of pharmacists' clinical services. A summary of some of these studies can be found in Appendix B of the Report to the U.S. Surgeon General titled "Improving Patient and Health System Outcomes through Advanced Pharmacy Practice."<sup>28</sup>

**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 Pharmacists in those models. [Note: This section contains commentary]**

Pharmacists in progressive practices provide direct patient care in acute and chronic care settings by employing chronic disease state management and medication therapy management principles, which directly supports health reform by increasing patient access to high quality affordable care. One of the most pressing issues with the U.S. health system is that millions of patients do not have access to a healthcare provider, regardless of insurance coverage. The increasing number of uninsured Americans since the economic downturn of the last few years has added to this burden on the health system. Rural areas have fewer doctors and thus health provision is limited more so than in suburban and urban communities. Through the provision of chronic disease state management on collaboration with physicians, pharmacists can use their skills and expertise to expand patient access to care. In addition to improved health outcomes, the inclusion of a pharmacist as one of the primary care team members would help to ease the burden of too many patients and too few providers. A study in 2000 estimated that approximately 275 million people visited pharmacies each week and thus pharmacists are well posed to enhance patient access to care.<sup>29</sup> Primary care physicians are overburdened, and the aging of 'baby-boomer' generation will exacerbate this problem since it is projected that by 2030, one in five Americans will be over the age of 65.<sup>30,31</sup>

***Physician Shortages and Reduced physician burden.***

Several reports have identified an shortage in primary care physicians.<sup>32,33,34,35</sup> The American medical system is threatened by this severe shortage of primary care physicians, which could lead to restricted access to health care.<sup>35</sup> Implementation of the Affordable Care Act of 2010 will provide insurance to an additional 30 million Americans in 2014 will not solve the problem of access to services in and of itself if there are too few physicians. A recent and comprehensive report from the Association of American Medical Colleges Center for Workforce Studies projected a physician shortage of 85,000 to 200,000 by 2020,<sup>36</sup> and a 38% increase in demand for general internists is projected by the year 2020.<sup>31</sup> These data indicate that if current physician utilization patterns remain as they are, a physician shortage is imminent. If the relationship between economic growth and physician demand holds true – the demand for physicians will likely increase beyond what supply could possibly meet.

At least 12 states have already reported or projected physician shortages (AZ, CA, FL, GA, KY, MA, MI, MS, NC, TX, OR, and WI).<sup>34</sup> These findings suggest that physician workforce alone will not be able to provide primary care to the burgeoning population of

insured individuals in 2014 and beyond. Currently many health systems utilize non-physician providers, such as physician assistants (PA) and nurse practitioners (NP), to increase the productivity of physicians by assisting with patient care and directly providing patient care under collaborative agreements. If given similar primary care roles – and additional ones such as focused chronic disease state management – the health system can optimally utilize pharmacists to enhance access to care. Pharmacists who have demonstrated their competence in disease management, allows them to serve as a point of triage and referral to optimize the utilization of the health care system.<sup>37</sup>

There are other benefits of involving a pharmacist in the primary care setting. In the UK, it has been estimated that there are about 57 million primary care physician consultations per year. About 51.4 million out of those are for minor ailments, many of which could be handled by a pharmacist.<sup>38</sup> A model similar to the UK's has been in place in the Indian Health Service since the early 1970s and in Ontario, Canada for over 7 years. The Integrating Family Medicine and Pharmacy to Advance Primary Care Therapeutics (IMPACT) project involved the inclusion of a pharmacist into primary care office practices in seven sites in Ontario.<sup>39</sup> Pharmacists provided comprehensive medication assessments, and collaborated with the physician and other team members to resolve identified drug therapy problems. The IMPACT project paved the way for the development of multidisciplinary teams known as Family Health Teams that include a full-time pharmacist member. As illustrated, pharmacists are increasingly providing clinical services to supplement physician care through inter-professional practice arrangements, and therefore pharmacists can directly affect health determinants outlined in the Healthy People 2020 Action Model.<sup>40</sup>

### ***Support to Healthcare Reform.***

The US healthcare system is poised to include expanded health coverage for millions, and access to high quality primary care is paramount. Indeed there are many provisions in the Affordable Care Act of 2010 that clearly delineate expanded roles for pharmacists who are willing to enhance access to care as well as reduce the cost of care.<sup>41</sup> De Maeseneer et al.<sup>42</sup> argued that primary care contributes to public health by improving access; however they added that it also is through a contribution to social cohesion and empowerment of people, so that they become less vulnerable. This only occurs when quality of care is optimized. Accessibility without quality may even be dangerous. The pharmacy profession is uniquely situated to contribute to our healthcare system's changing needs. Pharmacists have the clinical and pharmacological education, training, scope and support from many providers of care and are in the best position of any health professional to effectively address the changing needs of the healthcare system. The cost to the system to implement this change is minimal as it is more a change in policy and perception than it is in fiscal resources.

Dramatic changes are needed to improve the U.S. health care system. The health reform that we are now in the midst of implementing will need to use existing providers and resources in order to achieve the goal of making health insurance more available, affordable, and accessible to all. Professional organizations, academia, the health care

industry, community and tertiary hospitals, and primary care practitioners must step to the plate if the implementation of these new initiatives is to be successful. The U.S. Surgeon General's endorsement of the PHS report "Improving Patient and Health System Outcomes through Advanced Pharmacy Practice" addresses the many attributes that pharmacists can contribute to health care reform and improve patient outcomes.<sup>43</sup> The Surgeon General specifically calls for the following:

1. Health leadership and policy makers should further explore ways to optimize the role of pharmacists to deliver a variety of patient-centered care and disease prevention, in collaboration with physicians or as part of the healthcare team. These collaborative pharmacy practice models can be implemented to manage and prevent disease, improve health care delivery and address some of the current demands on the health care system.
2. Utilization of pharmacists as an essential part of the healthcare team to prevent and manage disease in collaboration with other clinicians can improve quality, contain costs, and increase access to care.
3. Recognition of pharmacists as health care providers, clinicians and an essential part of the health care team is appropriate given the level of care they provide in many health care settings.
4. Compensation models, reflective of the range of care provided by pharmacists, are needed to sustain these patient oriented, quality improvement services. This may require further evolution of legislative or policy language and additional payment reform considerations.

Well in line with the Surgeon General's recommendations, a 2010 report of the Virginia Health Reform Initiative (VHRI) Advisory Council supports the "team" delivery model to improve access to care for patients in Virginia.<sup>44</sup> The report states that pharmacists are currently underutilized in the standard care model, despite their expertise in drug therapy. It recommends that state scope of practice laws be updated to permit more health care professionals, such as pharmacists, to practice to the evidence-based limit of their training. By reorganizing into multidisciplinary teams, increasing the scope of more health care professionals, utilizing information technology to extend care, and by increasing the supply of health professionals the Commonwealth of Virginia will be prepared to increase access to care for Virginians.

The recommendations of the VHRI report directly support the process outlined in the 2010 resource guide developed by the Patient-Centered Primary Care Collaborative (PCPCC) for the establishment of a patient-centered medical home.<sup>45</sup> The guide explicitly mentions that optimizing medication use is a critical component of achieving the vision of patient-centered medical homes. The report goes on to discuss in detail the specific procedures that should be incorporated into comprehensive medication management services, including:

1. An assessment of the patient's medication-related needs
2. Identification of the patient's medication-related problems

3. Development of a care plan with individualized therapy goals and personalized interventions
4. Follow-up evaluation to determine actual patient outcomes

Pharmacists have the expertise and training to perform each of these functions and be the key providers of medication management services. As outlined in the Surgeon General's letter, the VHRI report, and the PCPCC resource guide, pharmacists should be afforded the opportunity to practice at the top of their scope to more effectively provide those services and coordinate their efforts with all other members of the health care team.

The right thing to do now is to empower and compensate pharmacists providing the level of care described in this report, and integrate them into patient-centered medical homes and accountable care organizations to benefit this nation's health reform. This can only come to fruition if those in decision-making positions acknowledge the value of these services with appropriate policy and compensatory actions.

## Risk of Harm to the Consumer

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

Pharmacists in Virginia and elsewhere are charged with improving public health through the safe and effective use of medications, and as such are involved in almost every aspect of the medication use process. Traditionally, pharmacist roles revolved mainly around the medication product: processing prescriptions or drug orders, preparing the pharmaceutical product, and dispensing or delivering the medication or device.

Increasingly, pharmacist roles also encompass clinical and cognitive services that help promote safe and appropriate medication use. Pharmacists are responsible for assessing the appropriateness of prescribed therapies, ensuring patient understanding and adherence to treatment plans through counseling and education, monitoring and reporting patient outcomes, and preventing drug-related problems and adverse effects.<sup>17</sup>

The Code of Virginia specifies in §54.1-3320 those acts and functions that are restricted to and must be performed by a pharmacist.<sup>46</sup> They include:

1. The review of a prescription, in conformance with the chapter and Chapter 34 (§ 54.1-3400 et seq.) of this title and with current practices in pharmacy, for its completeness, validity, safety, and drug-therapy appropriateness, including, but not limited to, interactions, contraindications, adverse effects, incorrect dosage or duration of treatment, clinical misuse or abuse, and noncompliance and duplication of therapy;
2. The receipt of an oral prescription from a practitioner or his authorized agent;
3. The conduct of a prospective drug review and counseling as required by § 54.1-3319 prior to the dispensing or refilling of any prescription;
4. The provision of information to the public or to a practitioner concerning the therapeutic value and use of drugs in the treatment and prevention of disease;
5. The communication with the prescriber, or the prescriber's agent, involving any modification other than refill authorization of a prescription or of any drug therapy, resolution of any drug therapy problem, or the substitution of any drug prescribed;
6. The verification of the accuracy of a completed prescription prior to dispensing the prescription;
7. The supervision of pharmacy interns and pharmacy technicians; and
8. Any other activity required by regulation to be performed by a pharmacist.

In many settings across Virginia, including hospitals and health systems, pharmacists are also responsible for managing medication use within the system, working with physicians and other health professionals to ensure optimal pharmacotherapy for patients, and delivering clinical services that promote wellness and disease prevention. These responsibilities are increasingly being performed within interdisciplinary team-based models that promote collaboration with other health care practitioners in acute care, primary care, and long-term care settings.<sup>17</sup>

Additionally, many state boards (including Virginia) have taken steps to incorporate expanded clinical services into the scope of practice for pharmacists by authorizing Collaborative Drug Therapy Management (CDTM) through collaborative practice arrangements with physicians, osteopaths, and podiatrists. In addition to the federal pharmacy sector, 44 states have enacted legislation to support some form of Collaborative Practice Agreements (CPAs) between physicians and pharmacists that provide the opportunity for pharmacists to deliver high-level clinical services that extend beyond the usual scope of pharmacists practice.<sup>18</sup> [NOTE: Same findings in 2012 *Survey of Pharmacy Law*.]

**2. Is there evidence of harm from Pharmacists with expanded scopes of practice relative to that in Virginia?** [NOTE: Committee to determine if e-mail survey of all the states' boards of pharmacy is in order.]

No, there is not currently any evidence to suggest harm from pharmacists with expanded scopes of practice as compared to pharmacists with more traditional scopes of practice in Virginia or elsewhere.

One systematic review of 36 published studies evaluating interventions by clinical pharmacists in hospitalized adults found no interventions that led to worse clinical outcomes or increased risk of harm to patients.<sup>47</sup> Additionally, personal correspondence with a representative from Pharmacists Mutual Insurance Company revealed no documented claims over the last 15 years that were related to the initiation or modification of therapy by a pharmacist working under a collaborative practice agreement.<sup>48</sup>

**a. If any, to what can it be attributed (lack of knowledge, skills, characteristics of the patients, etc)?**

There is currently no evidence to suggest increased risk of harm from pharmacists with expanded scopes of practice relative to other pharmacists in Virginia. Therefore, there is no information to suggest potential contributing factors such as lack of knowledge or others.

**b. How is the evidence documented (Board discipline, malpractice cases, criminal cases, other administrative disciplinary actions)?**

While there is currently no evidence to suggest harm to patients, such evidence could potentially be obtained by contacting Boards of Pharmacy for information regarding complaints or disciplinary action taken against pharmacists with expanded scopes of practice. The National Practitioner Data Bank (NPDB) and Healthcare Integrity and Protection Data Bank (HIPDB) house information on all malpractice payments paid on behalf of practitioners in the US and could serve as additional sources of evidence for harm. The Institute for Safe Medication Practices (ISMP) does not currently have documented evidence of harm related to

expanded scopes of practice for pharmacists but may serve as a potential source if such evidence were documented in the future.

**c. Characterize the type of harm (physical, emotional, mental, social, or financial).**

As with any other field in health care, the scope of harm that a pharmacist could potentially inflict on a patient would encompass physical, emotional, mental, social, and/or financial harm. There is no evidence to suggest that the type of harm would be any different between pharmacists with expanded scopes of practice and pharmacists with traditional roles.

**d. How does this compare with other, similar health professions, generally?**

The potential for such harm from a pharmacist with an expanded scope of practice is not expected to be any different from that of physicians or other practitioners who provide clinical services in primary care and other settings.

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

There should be no potential for fraud in the ability of the public to choose a competent pharmacist who can perform the functions outlined within the scope of practice for a pharmacist. The licensing process of each state Board of Pharmacy ensures that all pharmacists have achieved a standard level of education and competence required for general practice. (Details of the licensure process are found in an earlier section of this document.)

Pharmacists who have entered into collaborative practice agreements and thereby expanded their scope of practice currently do not receive any state recognition/identification of the new responsibilities and activities involving direct patient care that they have taken on. Thus there may exist a potential for pharmacists who have not been authorized through their becoming a party to a collaborative practice agreement to represent themselves to the public fraudulently. In part to prevent this and to define through regulation pharmacists who have demonstrated competency in direct patient care, several states – namely, North Carolina and New Mexico – have taken progressive measures to ensure that there is an adequate credentialing process in place that may alert patients and other practitioners to the qualifications and competence of a pharmacist providing direct patient care clinical services.

In the mid-1990s, the State of New Mexico Board of Pharmacy and Medical Examiners pioneered a program that developed an advanced practice license designated as a Pharmacist Clinician (Ph.C).<sup>49</sup> In order to be recognized as a Pharmacist Clinician, one must be a licensed pharmacist who meets specifically outlined criteria, which are detailed in the Background section of this document. These specific requirements ensure that only pharmacists with adequate experience who have demonstrated their competency may be

designated with a Ph.C. license and may provide expanded clinical services. Since July 2000, a similar credentialing process has existed in North Carolina, where a pharmacist may apply to become a clinical pharmacist practitioner (CPP) so long as he/she meets the criteria specified by the state (also detailed in the Background section of this document).<sup>49</sup>

At the federal level, a pharmacist practicing within the Indian Health Service (IHS) or Bureau of Prisons (BOP) may be recognized by the National Clinical Pharmacy Specialist (NCPS) Program as someone who has met the qualifications necessary for the provision of high-level care.<sup>28</sup> This program, established in 1997, ensures uniform clinical competency and recognizes advanced scopes of practice for Public Health Service (PHS) pharmacists through the establishment of credentialing standards and adequate training and education programs for clinical pharmacists.

These certification and credentialing processes serve as a way to not only recognize pharmacists who practice in advanced clinical scopes, but also to ensure that the public has a means to identify those pharmacists who are authorized to provide clinical services. In this way, patients can feel confident in their ability to choose competent practitioners without the potential for fraud in that decision.

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

As stated above, there should be no potential for fraud in the ability of third party payors to determine competency of pharmacists practicing within a traditional scope due to the licensing process required by each State Board. In the determination of competency for pharmacists who practice within expanded scopes, some state Medicaid programs have specified credentials or qualifications necessary for pharmacists to be recognized as billable providers. In this way, the Centers for Medicare and Medicaid Services (CMS) and other third party payors who follow CMS payment structures can assure that only qualified pharmacists are compensated for clinical services, thus decreasing the potential for fraudulent reimbursement. For example, in New Mexico, Pharmacist Clinicians can apply to become Medicaid providers eligible for reimbursement based on the level of service provided.<sup>28</sup> Additional examples of Medicaid programs that provide compensation based on cognitive services by pharmacists exist in Washington, Wisconsin, Mississippi, Iowa, Tennessee, Arizona, Minnesota, South Dakota, Missouri, New Mexico, and North Carolina.<sup>19,28</sup> To date there is no evidence to suggest there have been problems with the ability of those Medicaid programs to determine competency of the pharmacists they choose to reimburse for clinical services.

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

In general, there is no evidence to suggest the public is seeking greater accountability of pharmacists with or without expanded scopes of practice compared to any other health professional group. Pharmacists have historically been and are consistently ranked among the most trusted professions in public opinion polls. In the most recent Gallup poll on the

honesty and ethics of various professions, pharmacists ranked 2<sup>nd</sup> behind nurses as the professionals with the highest level of honesty and ethical standards<sup>50</sup>

## Specialized Skills and Training

### 1. Are there currently recognized or emerging specialties/levels within this profession?

**Yes. There are many recognized specialties within the profession.**

[NOTE: DHP Healthcare Workforce Data Center's *Virginia's Licensed Pharmacist Workforce*: 2011 report provides information obtained directly from Virginia's on education, post-graduate credentials, post-graduate residency 1 and 2, specialty board certifications, and other non-board certifications. A copy of this report is being available on the Board of Health Professions' website ([www.dhp.virginia.gov/bhp](http://www.dhp.virginia.gov/bhp)) for reference for this study.]

In the 1960s clinical pharmacy began to emerge as a specialty within the profession. Several schools of pharmacy outside of the innovator programs in California began to offer two-year post-baccalaureate doctor of pharmacy degree programs in the 1970s. Over the subsequent 20 years these programs grew to represent career options for almost 30% of all graduating pharmacists. One of the goals of transitioning the entry level educational requirements of all schools and states in the 1990s from a bachelor's degree to the Doctor of Pharmacy degree as the sole entry-level degree was to increase clinical training for students to better prepare them for direct patient care practice.<sup>17</sup> The curriculum includes didactic and introductory and advanced experiential education in a variety of areas such as direct patient care, systems management, and public health.<sup>11,17</sup> The professional competencies and educational outcomes achieved through completion of a Doctor of Pharmacy degree prepares graduates to enter pharmacy practice in any setting.<sup>9</sup> Beyond the requirements for a degree and licensure, pharmacists can voluntarily pursue post-licensure experiences and certification to develop specialized skill sets and further knowledge. Since the practice of pharmacy occurs in different settings and pharmacists have differences in training and certification, many specialties have emerged within the profession.

The structure for the recognition of specialties within the profession has been in place for over 30 years. The Board of Pharmaceutical Specialties (BPS) was established in 1976 as an independent certification agency of the American Pharmacists Association.<sup>51</sup> The first specialty certifications developed by BPS were nuclear pharmacy (1978), nutrition support (1988), and pharmacotherapy (1988). There are also several independent multidisciplinary organizations that have recognized pharmacist as specialists as well.

Emerging specialties have been recognized by the ACCP with the creation of Practice and Research Networks (PRNs) of which there are currently 22 networks.<sup>52</sup> The formation of PRNs is predicated on the submission of endorsement by 50 plus individuals who practice within the given area. In several cases the creation of PRNs preceded the establishment of a BPS recognized specialty (Table 1). Several pharmacists have also been recognized as fellows in specialty medical societies such as American College of Clinical Pharmacology, American Society of Nephrology, and Society for Critical Care Medicine.

Table 1. ACCP Practice and Research Networks

| Practice and Research Networks (PRNs)              | Year Established | Members (No.) <sup>a</sup> |
|----------------------------------------------------|------------------|----------------------------|
| Adult Medicine                                     | 1999             | >750                       |
| Ambulatory Care                                    | 1992             | 1100                       |
| Cardiology                                         | 1993             | 796                        |
| Central Nervous System                             | 1993             | 171                        |
| Clinical Administration                            | 2001             | >200                       |
| Critical Care                                      | 1992             | 1034                       |
| Drug Information                                   | 2002             | 223                        |
| Education and Training                             | 2002             | 285                        |
| Emergency Medicine                                 | 2008             | 50                         |
| Endocrine and Metabolism                           | 2005             | 182                        |
| Geriatrics                                         | 1995             | 244                        |
| GI/Liver/Nutrition                                 | 2000             | 145                        |
| Health Outcomes                                    | 1994             | 142                        |
| Hematology/Oncology                                | 1994             | >500                       |
| Immunology/Transplantation                         | 1993             | 235                        |
| Infectious Disease                                 | 1998             | >1000                      |
| Nephrology                                         | 1993             | 180                        |
| Pain and Palliative Care                           | 2000             | 235                        |
| Pediatrics                                         | 1993             | 405                        |
| Pharmaceutical Industry                            | 1998             | 255                        |
| Pharmacokinetics/Pharmacodynamics/Pharmacogenomics | 1997             | ~130                       |
| Women's Health                                     | 1994             | ~140                       |

<sup>a</sup>Membership as of 2008 from accp.com individual PRN History document

**a. If so what are they? How are they recognized? By whom and through what mechanism?**

There are a variety of options for post-licensure education and training, which allows pharmacists to qualify for advanced practice positions or begin to specialize in specific practice areas. Pharmacists can obtain on-the-job training, opt to prepare for competency-based examinations, or partake in training programs.<sup>17</sup> There are certificate programs, specialty residency programs, certification programs, and finally board certification.

**Certificate programs** also known as practice-based continuing pharmacy education activities are available for pharmacists to gain additional competencies. These activities are a combination of didactic instruction and a practice

experience, which allows the pharmacist to evaluate the acquired skills.<sup>53</sup> Examples of certificate training programs for pharmacists include pharmacy-based immunization delivery, pharmaceutical care for patients with diabetes, pharmacy-based lipid management, and medication therapy management services developed by the American Pharmacists Association.<sup>54</sup>

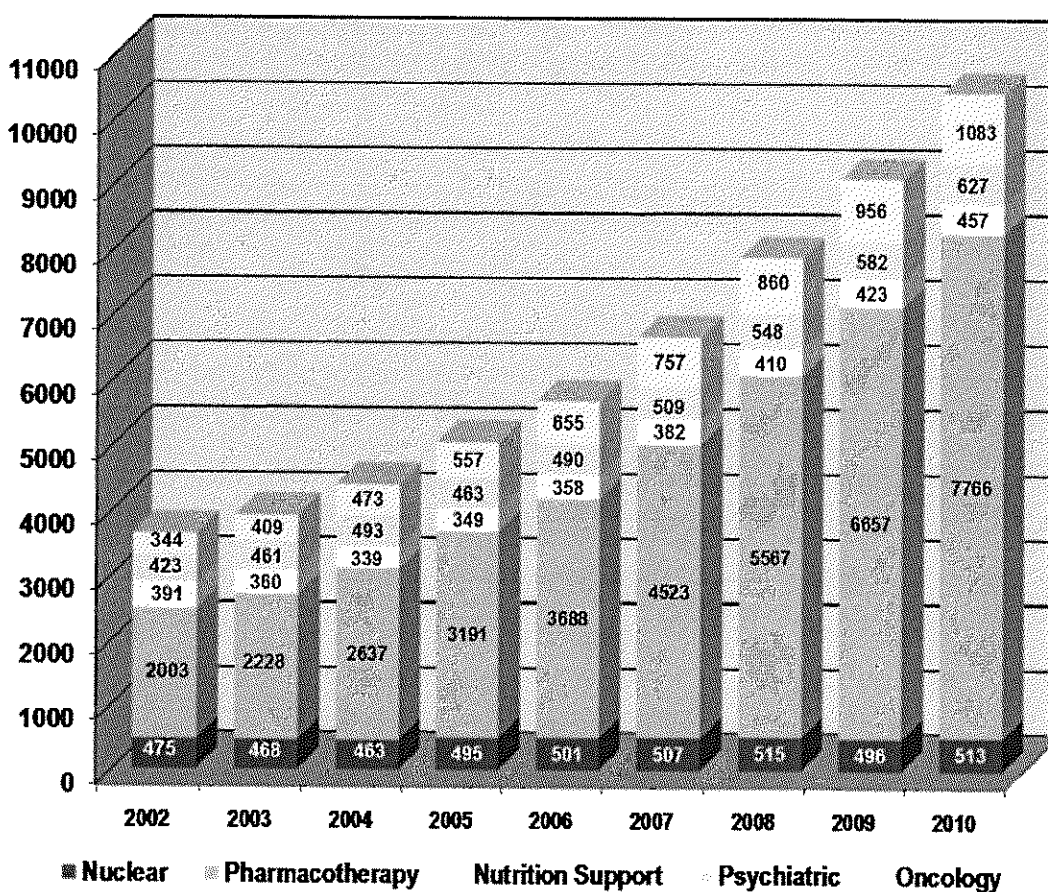
**Pharmacy residency programs** are post-licensure training programs designed for pharmacists to accelerate growth beyond entry-level competencies while remaining under the supervision of more experienced practitioners.<sup>55</sup> Specifically, a postgraduate year one pharmacy residency (PGY1) expands the general competencies in managing medication-use systems and supports optimal medication therapy outcomes in patients with a variety of disease states.<sup>55</sup> PGY1 residency experiences can occur in a variety of settings as long as residents meet the core required outcomes established by the American Society of Health-System Pharmacists (ASHP). Some pharmacists will choose to continue on to a postgraduate year two pharmacy residency program. PGY2 residency programs increase residents' depth of knowledge, skills, and level of expertise of medication management and clinical leadership in a specialized area of practice.<sup>55</sup> A PGY2 program prepares residents for board certification if available in the focused practice area. Some of the specialty areas where PGY2 residencies exist include critical care, oncology, health-system pharmacy administration, pediatrics, and other settings or patient populations. ASHP is responsible for accreditation of residency programs. The ASHP Commission on Credentialing develops the standards for residency programs. Completion of residency programs provides pharmacists with the training and experience to obtain advanced positions in direct patient care and team based care.

There are multiple pharmacist-specific certification opportunities. Certified Geriatric Pharmacists are pharmacists who have met the requirements and passed an examination demonstrating advanced competencies to provide care for the geriatric population.<sup>56</sup> Compounding pharmacy is another specialty area of pharmacy. Currently, compounding pharmacists can gain recognition by International Academy of Compounding Pharmacists.<sup>57</sup>

Pharmacists can pursue **board certification** and earn other credentials that designate increased competencies in specialty areas. These credentials may be specific to pharmacists or multidisciplinary. The Board of Pharmacy Specialties (BPS) was established in response to the expanding roles for pharmacists in specialized areas and need for a process to identify and evaluate the knowledge and skill sets.<sup>51</sup> Currently, BPS recognizes six specialties: ambulatory care pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pharmacotherapy, and psychiatric pharmacy. Board certification in these specialty areas occurs after passing a psychometrically sound examination. Each specialty area has its own eligibility requirements and examination content outlines describing the domains, tasks, and knowledge statements. Content outlines are validated and examinations are psychometrically sound and legally defensible.

Individual pharmacists who are board certified practitioners can attain board approved additional qualifications that designate advanced knowledge and skill in a focused area within the BPS recognized specialty. For example, a board certified pharmacotherapy specialist can obtain added qualifications in infectious disease or cardiology. Each specialty maintains its own recertification processes. The figure below depicts the number of pharmacists certified by BPS from 2002 to 2010.<sup>51</sup> The ambulatory care examination was first held in 2011, therefore, it is not represented in this figure.

### Pharmacists Certified by the Board of Pharmaceutical Specialties \*



\*As reported by BPS, February 2011

Beyond pharmacy-specific certification, pharmacists can participate in multidisciplinary certification programs.<sup>58</sup> Listed below are the credentials pharmacists may earn and the credentialing body in parentheses.

- Certified Anticoagulation Care Provider (National Certification Board for Anticoagulation Providers)
- Certified Asthma Educator (National Asthma Educator Certification Board)

- Accredited in Clinical Pharmacology (American Board of Clinical Pharmacology)
- Certified Diabetes Educator (National Certification Board for Diabetes Educators)
- Board Certified-Advanced Diabetes Management (American Nurses Credentialing Center)
- Clinical Lipid Specialist (Accreditation Council for Clinical Lipidology)
- Certified Nutrition Support Clinician (National Board of Nutrition Support Certification)
- Certified Pain Educator (American Society of Pain Educators)
- Credentialed Pain Practitioner (American Academy of Pain Management)
- Certified Specialist in Poison Information (American Association of Poison Control Centers)
- Diplomate of the American Board of Applied Toxicology (American Board of Applied Toxicology)
- Advanced Cardiac Life Support (American Heart Association)
- Pediatric Advanced Life support (American Heart Association)

**b. Are they categorized according to function? Services performed? Characteristics of clients/patients? Combination? Other?**

The pharmacy specialties can be categorized based on the functions or services provided, as well as the characteristics of the patient population. For example nuclear pharmacists are responsible for the preparation and dispensing of radioactive drugs for use in the diagnosis and treatment of diseases.<sup>17</sup> Another pharmacy specialty defined by its function is compounding pharmacy. Sometimes commercially manufactured medications are not acceptable for a specific patient or completely unavailable. Compounding pharmacists can prepare a product tailored to the specific needs of patients.

Some pharmacy specialties can be categorized by the service performed. For example, pharmacists provide medication therapy management services to optimize therapeutic outcomes for patients. Other specialty pharmacy areas defined by the services provided include drug information and immunizations.

The most common categories are specialty practice areas based on disease states or patient population. The pharmacists' role in all settings included ensuring safe and appropriate therapy and outcomes, but the differences occur in the practice areas. For example, pediatric pharmacists and geriatric pharmacists specialize in specific patient populations. Other pharmacists specialize in specific practice areas such as psychiatry or oncology.

**c. How can the public differentiate among these specialties or levels?**

Traditionally, the public is most familiar with the community pharmacist who evaluates, fills, dispenses, and counsels the patient on a drug product prescribed

by their doctor or dentist. The roles of community pharmacists are expanding to include providing immunizations, blood pressure assessment, hemoglobin A1c assessment, cholesterol assessment, and medication therapy management as well as disease state management services. The patient may realize those in the profession who have this specialty in part when they are referred by their doctor or through advertisements in the media. Thus the public may be able to differentiate pharmacists who have earned specialty status based on the functions and services provided as well as the specialty credentials they have earned. For example, patients may seek out a compounding pharmacist for the preparation of a specialized product specific to their needs.

The public does not routinely come in contact with pharmacists who practice in specialty settings such as family practice clinics or as members of interdisciplinary teams in health systems. However, in other health professions, the public has no problem differentiating among specialties. For example, a patient does not question a referral to physical therapists or endocrinologists. Therefore the public should not have difficulty differentiating among pharmacist specialties.

## Autonomous Practice

1. **What is the nature of the judgments and decisions that Pharmacists 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 assuring safe medication use?**

Pharmacists in Virginia and elsewhere must use their clinical judgment, expertise in pharmacotherapy, and evidence-based medicine to assure safe medication use for all patients. When receiving a prescription or medication order, a pharmacist must make an assessment regarding the validity of the prescription or order; the patient's need for the prescription and/or other therapies such as immunizations, over the counter medications, etc.; the appropriateness of the indication, dose, dosage form, frequency, and duration of therapy; and the potential for drug-drug, drug-disease, drug-food, or other interactions. The pharmacist must then make decisions regarding whether or not to fill the prescription or verify the order; what, if any, generic substitution can be made; the level of counseling the patient may need; what, if any, referrals may be indicated; and what parameters need to be monitored to assess for safety and efficacy.

Many of the functions that are specifically outlined in § 54.1-3320 of the Code of Virginia regarding acts to be performed by a pharmacist (refer to page 15) reflect the duty pharmacists have to ensure safe medication use, as well as the decisions they must make to do so.<sup>46</sup>

The general nature of judgments and decisions that pharmacists must make to assure safe medication use is similar across states, even in states with more expanded scopes of practice.

- b. **In determining or approving treatment plans?**

Pharmacists in Virginia and elsewhere must use clinical judgment, patient assessment skills, expertise in pharmacotherapy and pharmacokinetics, and primary and secondary literature in order to determine and approve treatment plans for individual patients. This is particularly true for community pharmacists that practice within a collaborative drug therapy management model, as discussed in earlier sections of this document. In general, pharmacists that work with physicians as part of a collaborative practice agreement do have greater responsibility and autonomy when it comes to determining appropriate pharmacotherapy options and treatment plans for their patients.

In institutional settings, clinical pharmacists are often tasked with developing protocols or nomograms for the use of certain (typically high-risk) medications or medication classes, which usually include drug selection recommendations, dosing recommendations, drug administration guidelines, and monitoring parameters that should be followed. In hospitals and health systems that utilize

computerized physician order entry (CPOE) systems, pharmacists are also often involved in the development of care sets, which group medications that are typically used together as part of a treatment plan.

The nature and scope of decisions that can be made regarding treatment plans are more extensive in states such as New Mexico and North Carolina that have expanded scopes of practice for pharmacists, as discussed in the Scope of Practice section.

**c. In directing or supervising others in patient care?**

While pharmacists do supervise others (pharmacy technicians, interns, and students) who perform functions related to the preparation and dispensing of medications, they do not typically direct or supervise other practitioners who are directly and immediately involved in patient care.

**2. Which functions typically performed by Pharmacists 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?**

The majority of pharmacists' time is spent on unsupervised activity that is not directly monitored or routinely checked, so long as it is within the scope of practice for pharmacists in Virginia. This is true for both dispensing and non-dispensing functions, which include, but are not limited to: assessing prescriptions and medication orders for accuracy; ensuring their appropriateness and safety with regards to indication, dose, frequency, etc.; checking for drug-drug, drug-food, drug-disease, and drug-allergy interactions; processing prescriptions and medication orders; preparing medications for dispensing and/or delivery; counseling patients on their medications; and helping patients with the selection of over-the-counter medications and herbals.<sup>17</sup>

Clinical functions that are performed independently and unsupervised by some pharmacists, particularly in primary care, long-term care, and/or acute care settings, include: patient assessment; medication profile review; drug level monitoring; immunization; obtaining and evaluating vital signs such as blood pressure, heart rate, and respiratory rate; and performing point of care tests such as blood glucose, cholesterol, INR, etc. that are waived by the Clinical Laboratory Improvement Amendments (CLIA).<sup>17</sup>

In institutional settings, pharmacists also independently perform tasks related to medication use and health systems management, such as: drug inventory control; monitoring of patient outcomes; reporting of medication errors and adverse events; and the development of protocols, nomograms, and guidelines for medication use within the system.

**b. Who is legally accountable/liable for acts performed with no supervision?**

As with other health care professionals, each individual pharmacist is responsible and legally accountable for duties 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)?**

Some pharmacists in the state of Virginia practice under the general supervision of other health care providers/prescribers. Pharmacists in Virginia who have entered into collaborative practice agreements with a physician, osteopath, or podiatrist are thereby authorized to perform additional functions under their general supervision. According to the Virginia Board of Pharmacy and Board of Medicine Regulations for Collaborative Practice Agreements, “‘Agreement’ means a collaborative practice agreement by which practitioners of medicine, osteopathy or podiatry and pharmacists enter into voluntary, written agreements to improve outcomes for their mutual patients using drug therapies, laboratory tests, and medical devices, pursuant to the provisions of §54.1-3300.1 of the Code of Virginia.”<sup>59</sup>

According to the Regulations, a practitioner of medicine, osteopathy, or podiatry authorizes the activities that a pharmacist can engage in as part of the agreement. However, the actions authorized as part of the treatment protocol are generally performed with a high degree of independence and autonomy. As such, the general supervision of the practitioner does not replace legal accountability and responsibility for the actions each individual pharmacist performs within the scope of the agreement.

**b. How frequently is supervision provided? Where? And for what purpose?**

The frequency with which supervision is provided is highly variable and dependent on the collaborative practice agreement between the practitioner and pharmacist. Factors that may influence the degree of supervision include the practice setting and the types of patients and disease states typically encountered by the pharmacist on behalf of the practitioner. This supervision is typically provided on-site if the pharmacist is integrated into the physician practice or via telephone or electronic correspondence with the practitioner if they are not integrated into the same practice. The purpose of such general supervision would be to allow for consultation with the practitioner if necessary and to ensure appropriate care for the patient if his/her needs extended beyond the scope of what the pharmacist could provide.

**c. Who is legally accountable/liable for acts performed under supervision?**

Each healthcare professional involved in a collaborative practice agreement is legally accountable/liable for actions performed within their scope of practice.

**d. What is contained in a typical supervisory or collaborative arrangement protocol?**

The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (NABP), most recently updated in August 2011, addresses the general content that should be included in a collaborative pharmacy practice agreement.<sup>60</sup>

A typical collaborative arrangement protocol should clearly identify the practitioner(s) and pharmacist(s) involved and the effective date of the agreement. It should outline the types of decisions the pharmacist is allowed to make, including: a detailed description of the types of diseases, drugs, or drug categories involved, and the activities allowed in each case; a detailed description of the methods, procedures, decision criteria, and plan the pharmacist should follow when conducting allowed activities; and a detailed description of the documentation procedures the pharmacist is to follow with regards to documenting, communicating, and reporting the specific decisions made. The protocol should outline a method for the practitioner to monitor compliance with the agreement and clinical outcomes, and a plan to intercede where necessary. It should also have a description of the continuous quality improvement program used to evaluate effectiveness of patient care and ensure positive patient outcomes. Finally, the agreement should include provisions for the practitioner to override decisions made by the pharmacist when he/she deems it necessary and/or appropriate, and provisions for either party to cancel the agreement by written notification.<sup>60</sup>

Activities that the pharmacist may be responsible for as part of such an agreement may include collecting and reviewing patient medication histories; measuring patient vital signs; ordering pertinent laboratory tests and interpreting the results; and the modification, continuation, or discontinuation of drug therapy per the protocol established as part of the agreement.

**4. Do Pharmacists typically supervise others? Describe the nature of this supervision?**

Pharmacists in Virginia and elsewhere typically supervise others as part of their practice. Pharmacists are required by Virginia law to directly supervise pharmacy technicians and pharmacy interns that practice under their responsibility. While pharmacy technicians and interns are responsible for a variety of functions such as computer data entry, medication preparation and compounding, inventory control, etc., the supervising pharmacist serves as the final check for many of these functions and is legally responsible for the care and safety of patients.

There is a Pharmacist-in-Charge (PIC) who is responsible for the general supervision of others who practice at any given practice location. In institutional and hospital settings, there are a number of managerial levels wherein pharmacy administrators and directors serve as general supervisors for other pharmacists and technicians employed by the department. This supervision is typically administrative in nature and not meant to be a direct supervision of the patient care activities of each individual pharmacist.

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

Pharmacists work in a number of different settings, each of which presents unique opportunities for interaction with different regulated and unregulated occupations. These settings include community pharmacies, hospitals and health systems, primary care clinics, long-term care facilities, nursing homes, assisted living facilities, hospice facilities, nuclear pharmacies, schools of pharmacy, federal health agencies, research facilities, managed care organizations (MCO's), pharmacy benefit managers (PBM's), and mail-order pharmacies. Some examples of regulated professions that pharmacists interact with in these settings include physicians, nurses and nurse practitioners, physician assistants, social workers, nutritionists, behavioral counselors, physical and occupational therapists, and dentists. In many of these settings, pharmacists also interact with pharmacy technicians, another regulated profession, in a supervisory capacity. Some examples of unregulated professions that pharmacists interact with in these settings include cashiers, secretaries, care partners, and volunteers.

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

Physicians and other practitioners often refer patients to community pharmacists for dispensing of prescriptions, compounding of unique drug formulations, counseling services, immunizations, management of minor ailments, and help with selection of over-the-counter medications and durable medical equipment. In Virginia and other states, primary care practitioners and specialists also refer patients to primary care clinics that have pharmacists integrated into their practice model. For example, the VA system and many academic medical centers have anticoagulation clinics, diabetes clinics, etc. which are primarily pharmacist-run. As part of collaborative practice agreements, some primary care physicians refer patients to a pharmacist for the management of chronic diseases like hypertension, diabetes, heart failure, asthma, etc. They may also refer patients with complicated medication regimens or issues with adherence for more focused medication management by a pharmacist.

In a September 2011 report, the Alliance for Patient Medication Safety (APMS) and the National Alliance of State Pharmacy Associations (NASPA) recently highlighted the work of Michelle Thomas, PharmD, CDE, who used the SuperioRx Care Adherence Discovery grant to establish a collaborative arrangement with a community primary care

physician office in rural Virginia.<sup>61</sup> The project allowed for the referral of certain patients to the pharmacist for cholesterol and diabetes management through education and medication management where appropriate. The pharmacist was available one day per week for referrals, which were made by two physicians at the site, nurse practitioners, and physician assistants. At the end of the six-month trial period, both the physicians and patients surveyed felt satisfied with the program and agreed that the pharmacist-provided services were making a significant impact in improving patient health and wellness.<sup>61</sup> This project provides just one example of a successfully implemented referral mechanism that allowed for the provision of pharmacist services to eligible patients who were identified by physicians and other providers in the community setting.

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

**As the most accessible health professionals in the community, pharmacists are frequently available to assess and triage patient care needs and thereby refer them to others for care.** Pharmacists refer patients to physicians and other practitioners for services that cannot be reasonably or safely provided by a pharmacist. For example, in the community setting, patients often come to pharmacists for counseling and recommendations regarding over-the-counter medications and herbals. The pharmacist may discover during the consultation or screening that the problem is not amenable to self-care and may refer the patient to a physician for a full assessment. In the primary care setting, a pharmacist may be assessing a patient during a visit for medication therapy management or chronic disease follow-up and notice physical symptoms that are suggestive of an acute process (infection, deep vein thrombosis, stroke, etc.) requiring physician assessment and care. The pharmacist would then refer the patient to a physician or other practitioner for evaluation.

According to one survey of over 500 pharmacist preceptors, students and faculty members at the Virginia Commonwealth University, 64% of respondents referred patients to another health care provider, usually a physician, at least daily. Less commonly reported referrals were to dietitians (38%), behavioral health clinicians (30%), specialty practice pharmacists (26%), physical therapists (20%), and chiropractors (13%).<sup>62</sup>

One example of a successful pharmacist referral mechanism in the community setting in the state of Virginia was described in Project ImPACT: Osteoporosis.<sup>63</sup> As a result of health-promotion and disease-prevention efforts at 22 Ukrop's pharmacies – a regional supermarket chain pharmacy in Richmond, VA – pharmacists screened a total of 532 patients for osteoporosis using bone mineral density (BMD) screening. Of 305 patients that were reached for follow-up, 37% were identified as having high risk for fracture, while 33% were identified as having moderate risk and 30% as having low risk. As a result of the pharmacists' screening and referral efforts, 37% of patients in the moderate- and high-risk categories subsequently completed a physician visit, 19% had a diagnostic scan, and 24% were initiated on osteoporosis therapy. In addition to the positive patient care outcomes that were reported, the study also confirmed that patients were willing to

pay for pharmacy-based osteoporosis screening and that third-party payers were willing to compensate pharmacists for collaborative community health management services.<sup>63</sup>

Decisions to refer patients are based on the clinical judgment of the pharmacist, the resources and time available to the pharmacist, and, in the case of collaborative practice agreements, the limitations of the protocol that specifies which activities are authorized to the pharmacist.

## Scope of Practice

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

Some of the functions of pharmacists are similar to those of other health care professionals.<sup>22,23</sup> In addition to nurses and physicians, pharmacists participate in taking medication histories and performing medication reconciliation. Physicians and other mid-level prescribers select the product and doses of medications for patients. In many settings pharmacists are actively involved in drug therapy selection and determining individualized dosing regimens based on pharmacokinetic and pharmacodynamic characteristics. Pharmacists often perform physical assessments similar to nurses and physicians. Pharmacists can assess blood pressure, perform point of care tests such as INR assessment for patients on warfarin therapy, and check blood sugar for diabetics to name but a few. Similar to nurses, pharmacists can administer vaccinations in accordance with state laws.<sup>54</sup> Pharmacists, similar to dietitians and nutrition specialists, can determine nutrition needs for patients and determine nutrition treatment plans. Often, pharmacists and nutrition specialists collaborate to continuously monitor patients especially those who need chronic nutritional support. Often there is overlap in the functions of health professionals due to utilization of team-based care models.

### 2. What additional functions, if any, are performed by Pharmacists in other states?

Although Virginia has established regulations for the creation of collaborative practice agreements, other states and countries have been more progressive in expanding the scope of practice for pharmacists. [Note: the phrase "more progressive" above constitutes commentary.]

Several state Medicaid programs, including Washington, Wisconsin, Mississippi, Iowa, Tennessee, Arizona, Minnesota, South Dakota, Missouri, New Mexico, and North Carolina had waivers approved to allow for contract pharmacist-related compensation for clinical services and more states are following.<sup>19</sup> Since being recognized as providers by Medicaid in 2005, pharmacists in Minnesota can be reimbursed for providing medication management services to eligible patients once enrolled with Minnesota Health Care Programs and after completion of an approved certification program on medication management. An ASHP document summarizes pharmacist provider status in 11 state health programs. It highlights the different paths taken to create and implement programs, the variety of patient populations served, and billing and reimbursement mechanisms. To attain pharmacist provider status in some of these state programs, pharmacists may need additional credentials such as additional training or certification. Most of the programs were state Medicaid programs, however, one program in Ohio was operated by the state Department of Health's Bureau for Children with Medical Handicaps.<sup>64</sup>

Nationally, the NCPS program expanded the functions of Indian Health Service pharmacists by recognizing them as primary care providers with prescriptive authority.<sup>20</sup> Similar expanded functions exist for Veterans Affairs pharmacists.<sup>21</sup> Currently, in both

North Carolina and New Mexico, pharmacists may seek advanced practice designations resulting in increased scope of practice including prescribing authority.<sup>7,8</sup> Since 1993, New Mexico pharmacists have the opportunity to pursue additional training and earn the designation Pharmacist Clinician. Pharmacist Clinicians may obtain personal DEA numbers and have prescriptive authority under a supervising physician. The Clinical Pharmacist Practitioner Act of 2000, established the designation Clinical Pharmacist Practitioners (CPP). A CPP provides disease therapy management and can initiate, modify, or substitute therapies under a broad collaborative practice agreements.

The DEA has also granted prescriber numbers to pharmacists working in institutions under collaborative practice agreements with physicians in five additional states (California, Massachusetts, Montana, North Dakota, and Washington).<sup>28</sup> In these states, DEA-registered pharmacists are recognized as mid-level practitioners and may prescribe controlled substances.

Prescribing authority has been expanded to pharmacists in both Canada and the United Kingdom.<sup>65,66</sup> Pharmacists in the United Kingdom can gain prescriptive privileges as Pharmacist Supplementary Prescribers. Supplementary prescribers establish an individualized, patient-specific clinical management plan (CMP) with an independent prescriber such as a doctor or dentist. Once the CMP is created, supplementary prescribers may treat the conditions diagnosed by the independent prescriber and prescribe both non-controlled and controlled medications. Canadian provinces are also expanding the scope of pharmacy practice. In Alberta, different prescribing categories exist for pharmacists after completing orientation and registration on the Alberta College of Pharmacist's clinical registry. Pharmacists may adapt prescriptions by modifying the dose or drug formulation based on organ function, availability, perform therapeutic substitution for patient-specific reasons, or issue a prescription for continuity of care until primary prescriber is contacted. Pharmacists may also prescribe during an emergency where immediate therapy is necessary and seeing another prescriber is unreasonable. Lastly, pharmacists may gain additional prescribing authority based on collaborative practice agreements.

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

The functions of the pharmacy profession that are distinct from other health professionals include: evaluation of prescriptions to assure compliance with state and federal statutes, the process of medication dispensing, monitoring the sale of over the counter controlled substances and pseudoephedrine, etc. The pharmacist dispensing process includes utilizing evidence-based literature and guidelines combined with patient-specific information to verify that the medication order is safe and effective for the patient.<sup>17</sup> Pharmacists conduct prospective drug utilization reviews in the medication dispensing process. By performing this review, pharmacists identify drug-related problems such as therapeutic duplication, drug-disease contraindications, incorrect dosage or duration of treatment, drug allergy and clinical misuse or abuse. If problems are identified, pharmacists utilize their drug knowledge expertise to collaborate with prescribers to

resolve the identified issues. The pharmacist then prepares, compounds, or repackages the medication to be dispensed to patients. In the community setting, pharmacists are responsible for counseling patients on the prescribed medication. Institutional pharmacists also provide counseling for patients being discharged with newly prescribed medications or medication regimen changes.

Pharmacists are also largely responsible for procuring and storing medications. Pharmacists may also enter into collaborative practice agreements with physicians resulting in a team approach for patient care. In both the ambulatory and inpatient settings, pharmacists are often called upon to determine an individualized dosage regimen for patients with renal or liver dysfunction or assisting in therapeutic drug monitoring. For example, pharmacists in anticoagulation clinics manage drug therapy by monitoring and making interventions such as dose modification as needed.

Pharmacists in specialty areas may have distinct functions unique to their practice. A distinct function of compounding pharmacists is preparing an individualized product specific to the needs of the patient. All patients in long-term care facilities or hospitals must have their drug regimens reviewed by a pharmacist at least once per month. Often, this is a function of consultant pharmacists.

## Economic Costs

### 1. What are the range and average incomes of members of this profession in the Commonwealth? In adjoining states? Nationally?

Below are average annual incomes and ranges for pharmacists in Virginia, adjoining states, and nationally, according to May 2010 data from the Bureau of Labor Statistics.<sup>67</sup> All ranges reported represent the 10<sup>th</sup> to 90<sup>th</sup> percentile of incomes.

Table 2. Annual Pharmacist Income (2010) – Average and Range

| State or Region      | Average Annual Income | Annual Income Range  |
|----------------------|-----------------------|----------------------|
| Virginia             | \$113,800             | \$91,210 - \$140,810 |
| North Carolina       | \$112,970             | \$88,170 - \$142,100 |
| West Virginia        | \$111,950             | \$80,430 - \$142,720 |
| Tennessee            | \$112,130             | \$86,840 - \$141,290 |
| Maryland             | \$104,880             | \$77,110 - \$132,750 |
| District of Columbia | \$114,340             | \$92,330 - \$144,490 |
| National             | \$109,380             | \$82,090 - \$138,620 |

The incomes in Virginia are comparable to the range and average incomes for pharmacists in adjoining states. Pharmacists in the mid-Atlantic states, including Virginia, have a slightly higher income overall than the national average.

### 2. If the data are available, what are the typical fees for service provided by this profession in Virginia? In adjoining states? Nationally?

Pharmacists' primary revenue for services provided are dispensing fees, which are added onto the cost of the medication product and are predominantly set by third party payors, including state Medicaid and Medicare Part D plans. Dispensing fees vary from one private insurance plan to another and from state to state. Typically, dispensing fees paid by Medicaid fall in the \$3 to \$5 range.<sup>68</sup>

Reimbursement for cognitive services provided by pharmacists is less common, so not much data is available regarding fees and payment for clinical services in Virginia. Some pharmacists in Virginia and elsewhere conduct point of care testing (blood glucose measurements, blood pressure, etc.) for which they charge a fee that is typically paid out of pocket by the patient. Fees charged by pharmacists for such services vary markedly among practice settings and geographic locations, so there is no reliable source for obtaining data on these values.

Currently, pharmacists are eligible to receive some compensation for medication therapy management (MTM) services provided once per year to Medicare Part D patients, as outlined in the Medicare Prescription Drug Improvement and Modernization Act of 2006. There are however a number of restrictions in place that have limited patient participation in and pharmacist reimbursement for these services. Additionally, some state Medicaid programs do recognize pharmacists as providers and compensate them for MTM services. The payment structures vary from state to state but typically depend on the acuity and

complexity of care provided. For example, under the Minnesota MTM program, pharmacists are able to bill Medicaid \$52 for the provision of level 1 (straightforward) care, and up to \$148 for level 5 (high complexity) care.<sup>69</sup>

In a 2005 review of existing MTM services and compensation models that are being used by both public and private sector programs, the Lewin Group was able to develop a model for payers to use in compensating pharmacists for MTM services.<sup>70</sup> The report found that the majority of payment systems currently in use are variants of fee-for-service (FFS), while in some settings, pharmacists are billing “incident to” the physician for clinical services provided by the pharmacist. Through interviews conducted with pharmacists, pharmacy benefit providers, health plans, and policy makers, the group also found that while payment amounts varied widely among the different programs, several interview respondents suggested a “rule of thumb” payment rate of \$2 to \$3 per minute for pharmacist-provided MTM services.<sup>70</sup>

### **3. Is there evidence that expanding the scope of Pharmacist would**

#### **a. Increase the cost for services?**

There are numerous examples in the literature that point to cost savings for institutions, CMS, and other third party payors secondary to expanding the scope of practice for pharmacists. To date, no study that has evaluated cost or return on investment as an outcome measure has presented evidence to suggest increased cost for services as a result of increasing patient care privileges for pharmacists. On the contrary, the literature has pointed to cost containment and overall cost savings secondary to reduced number of hospitalizations, emergency visits, outpatient visits, specialty visits, and drug-related morbidity and mortality.

Schumock, et al.<sup>71,72</sup> and Perez, et al.<sup>73</sup> conducted multiple studies from 1988-2005, including an extensive literature review by Schumock, et al.<sup>71</sup> of 104 articles, that evaluated the economic impact of clinical pharmacy services. These services included disease management, general pharmacotherapeutic monitoring, pharmacokinetic monitoring, targeted drug programs, and general patient education programs and cognitive services. The investigators found that over the period from 1988-2005, each dollar invested in clinical pharmacy services resulted in an overall average benefit gain of \$10.07 per \$1 of allocated funds. The benefit to cost ratio for this time period ranged from a low of \$1.02:\$1 to a high of \$75.84:\$1, illustrating that even at the ratio’s lowest level there was still an economic benefit to investing in clinical pharmacy services.

As another example, Brennan, et al.<sup>74</sup> published a study in early 2012 that estimated a \$3:\$1 return on investment for integrating pharmacy interventions aimed at improving medication adherence in patients with diabetes. The more than \$600,000 in health care cost avoidance resulted from improved adherence rates and increased initiation of appropriate therapies. This study was conducted in patients using CVS retail pharmacies or a Caremark mail order pharmacy to fill

their prescriptions, thereby illustrating the applicability of this cost-savings data to other large retail or mail order chains.

As stated, there is an extensive collection of peer-reviewed publications evaluating the cost-effectiveness of delivery of patient care services by pharmacists in a variety of settings. Many of the studies are summarized nicely in Appendix B (pp 66-77) of the 2011 Report to the U.S. Surgeon General.<sup>28</sup>

**b. Increase salaries for Pharmacist employed by health delivery organizations?**

There is currently no information available to determine how pharmacist salaries might be affected by expanding their scope of practice within different health delivery organizations. Any fluctuation in pharmacists' salaries would likely be affected by the specific setting and its current payment structure.

**c. Restrict other professions in providing care?**

[NOTE: Commentary]

There is no evidence to suggest that expanding the scope of practice for pharmacists would restrict other professions in providing care. The expertise and services brought by a clinical pharmacist to the primary, acute, or long-term care environment would be complementary to those of other professions, not competitive. When pharmacists take a more active role in providing medication therapy management, chronic disease management, and assessment of minor ailments, it frees up time for physicians and other practitioners to focus on more critically ill patients who may need more in-depth physician assessment.

In 2010, the NCPS Program developed a survey that sought input from IHS physicians on the clinical and administrative impact of primary care and disease management services by pharmacists. Of the 117 physicians that responded, 96% of providers reported some benefit in improved disease management outcomes, increased return on investment, increased patient access to care, or allowing the physician to shift their workload to more critical patients.<sup>28</sup>

Additionally, as outlined earlier in the Background section, the U.S. Surgeon General has endorsed the PHS report "Improving Patient and Health System Outcomes through Advanced Pharmacy Practice" and has called on health leadership to optimize the role of pharmacists and utilize collaborative practice models to improve health care delivery in all settings.<sup>43</sup> This endorsement gives further weight to the idea that pharmacist services will enhance, not restrict, the ability of all members of the health care team to deliver quality care while containing costs and increasing access to care.

The physician-pharmacist collaborative practice model has been in existence for decades, although not utilized to its full capacity, and so far there has not been reason to believe other professions are restricted in providing care because of this model.

**d. Have other deleterious economic effects?**

As stated previously, no study that has evaluated cost or return on investment as an outcome measure has suggested increased cost for services or other deleterious economic effects as a result of expanding the scope of practice for pharmacists. While there might be an initial increase in prescription drug spending secondary to initiation of therapies and increased adherence, total health care spending decreases over the long run due to more preventative services and less drug-related morbidity and mortality, costly hospitalizations, specialty referrals, etc. There is also an indirect cost savings related to decrease in the number of sick days from work and increased productivity secondary to improved health outcomes.

**4. Address issues related to supply and demand and distribution of resources.**

[NOTE: Commentary]

As discussed in the Background section, there is currently a primary care workforce shortage that is impacting patient access to care all over the United States. This shortage is only projected to get worse as more patients gain access to health insurance while less medical internists decide to practice in primary care, opting instead for more lucrative careers in specialty areas of medicine.

One solution for addressing the need for more primary care providers is to expand the scope of practice for pharmacists, who are in arguably the best position among all health care professionals to be able to fill the void left by decreasing numbers of primary care physicians. Pharmacists have the education, training, and expertise to be able to take a more active role in increasing access to primary care services, and the current supply of pharmacists into the workforce can support that role. The number of pharmacy school graduates in the U.S. has been climbing steadily over the last 10 years, partly in response to pharmacist shortages in the late 1990's, and now sits at about 10,500 graduates per year.<sup>75</sup> By expanding the scope of practice for pharmacists, creating pharmacy jobs that are integrated into primary care models, and pushing for proper reimbursement mechanisms for clinical services provided, many of these new pharmacy graduates could enter the primary care workforce and help respond to the growing demand for these services.

**5. Are third-party payors in Virginia currently reimbursing services provided by pharmacists? Directly to the Pharmacist? Employer?**

Third party payors in Virginia are not currently reimbursing pharmacists or their employers for clinical services provided by pharmacists. As discussed previously, Medicare, through various pharmacy benefits managers (PBMs), does compensate pharmacists directly for one MTM session per patient per year. However there are many restrictions regarding eligibility that limit patient participation in these sessions.

In comparison, some other states have third party payors and Medicaid programs that do recognize pharmacists as providers and compensate them for MTM services through PBMs. One example is Outcomes Pharmaceutical Health Care<sup>76</sup>, which contracts with PBMs to allow for the delivery, documentation, and billing of MTM services by pharmacists. As previously mentioned, the payment structures vary from state to state but typically depend on the acuity and complexity of care provided.

**6. Are similar services to those provided by pharmacists also provided by another non-physician profession? Which profession(s)? Are they reimbursed directly by third-party payors?**

Similar clinical services are provided by other non-physician professionals such as nurse practitioners and physician assistants (see section on Scope of Practice for additional information). These services are currently being reimbursed directly by third party payors, as most third party payors (including Medicaid) do recognize these non-physician practitioners as mid-level providers who may bill for clinical services.

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## Appendix A. PharmD Curricula (2011-2012) from Virginia Schools of Pharmacy

### Virginia Commonwealth University School of Pharmacy

#### P1 Fall Semester

| Department            | Course Number | Course Title                                                  | Course Credit |
|-----------------------|---------------|---------------------------------------------------------------|---------------|
| MEDC                  | 527           | Basic Pharmaceutical Principles for the Practicing Pharmacist | 3.0           |
| PCEU                  | 507           | Pharmaceutics & Biopharmaceutics I                            | 3.0           |
| PHAR                  | 509           | Evidence Based Pharmacy I (Drug Info)                         | 1.0           |
| PHAR                  | 510           | Medication Use Systems                                        | 1.0           |
| PHAR                  | 512           | Health Promotion & Disease Prevention                         | 2.5           |
| PHAR                  | 513           | Contemporary Pharmacy Practice                                | 2.5           |
| PHAR                  | 525           | Communications in Pharmacy Practice                           | 2.0           |
| MEDC                  | 550           | Scholarship I                                                 | Continues     |
| PHAR                  | 771           | Student Pharmacist Professionalism                            | Continues     |
| PHAR                  | 523           | Foundations I                                                 | 1.0           |
| PHAR                  | 530           | IPPE I: Community I                                           | 1.0           |
| <b>Semester Total</b> |               |                                                               | <b>17.0</b>   |

#### P1 Spring Semester

| Department | Course Number | Course Title                                                   | Course Credit |
|------------|---------------|----------------------------------------------------------------|---------------|
| PCEU       | 508           | Pharmacokinetics                                               | 2.0           |
| PCEU       | 509           | Pharmaceutics & Biopharmaceutics II                            | 2.5           |
| MEDC       | 533           | Pharmacognosy                                                  | 2.0           |
| MEDC       | 543           | Clinical Chemistry for the Pharmacist                          | 2.0           |
| MEDC       | 553           | Clinical Therapeutics Module I: Intro to Medicinal Chemistry   | 1.0           |
| PHTX       | 606           | Clinical Therapeutics Module II: Introduction to Pharmacology  | 1.0           |
| PHAR       | 529           | Clinical Therapeutics Module III: Intro to Special Populations | 1.0           |
| PHAR       | 540           | Self-care, Alternative and Complementary Treatments            | 3.0           |
| PHAR       | 545           | The U.S. Health Care System                                    | 2.5           |
| PHAR       | 547           | Managing Professional Patient-centered Practice                | 1.0           |
| MEDC       | 550           | Scholarship I                                                  | 1.0           |
| PHAR       | 771           | Student Pharmacist Professionalism                             | Continues     |
| PHAR       | 524           | Foundations II                                                 | 1.0           |
| PHAR       | 531           | IPPE II: Community II                                          | 1.0           |

**Semester Total 21.0**

**P2 Fall Semester**

| <b>Department</b>     | <b>Course Number</b> | <b>Course Title</b>                                       | <b>Course Credit</b> |
|-----------------------|----------------------|-----------------------------------------------------------|----------------------|
| PHAR                  | 565                  | Evidence Based Pharmacy II: Research Methods & Statistics | 2.5                  |
| PHAR                  | 566                  | Evidence Based Pharmacy III: Literature Evaluation        | 2.0                  |
| MEDC                  | 605                  | Biotechnology, Pharmacogenomics & Pharmacogenetics        | 2.0                  |
| PHAR                  | 567                  | Pharmacy Informatics                                      | 1.5                  |
| PHAR                  | 544                  | Clinical Therapeutics Module IV: Cardiovascular           | 4.5                  |
| PHAR                  | 555                  | Clinical Therapeutics Module V: Endocrinology             | 2.5                  |
| PHAR                  | 556                  | Clinical Therapeutics Module VI: Neurology I              | 3.0                  |
| PCEU                  | 550                  | Scholarship II                                            | Continues            |
| PHAR                  | 771                  | Student Pharmacist Professionalism                        | Continues            |
| PHAR                  | 534                  | Foundations III                                           | 1.0                  |
| PHAR                  | 532                  | IPPE III: Hospital                                        | Continues            |
| <b>Semester Total</b> |                      |                                                           | <b>19.0</b>          |

**P2 Spring Semester**

| <b>Department</b>     | <b>Course Number</b> | <b>Course Title</b>                                     | <b>Course Credit</b> |
|-----------------------|----------------------|---------------------------------------------------------|----------------------|
| PCEU                  | 615                  | Applied Pharmacokinetics                                | 2.0                  |
| PHAR                  | 621                  | Pharmacoeconomics                                       | 2.0                  |
| PHAR                  | 622                  | Epidemiology & Pharmacy Practice                        | 2.0                  |
| PHAR                  | 623                  | Patient Medication Safety                               | 2.0                  |
| PHAR                  | 601                  | Clinical Therapeutics Module VII: Neurology II          | 1.0                  |
| PHAR                  | 602                  | Clinical Therapeutics Module VIII: Psychiatry           | 3.0                  |
| PHAR                  | 603                  | Clinical Therapeutics Module IX: Respiratory/Immunology | 3.0                  |
|                       |                      | Electives                                               | 2.0                  |
| PCEU                  | 550                  | Scholarship II                                          | 2.0                  |
| PHAR                  | 771                  | Student Pharmacist Professionalism                      | Continues            |
| PHAR                  | 535                  | Foundations IV                                          | 1.0                  |
| PHAR                  | 532                  | IPPE III: Hospital                                      | 1.0                  |
| <b>Semester Total</b> |                      |                                                         | <b>21</b>            |

**P3 Fall Semester**

| Department | Course Number | Course Title                                         | Course Credit      |
|------------|---------------|------------------------------------------------------|--------------------|
| PHAR       | 660           | Pharmacy Practice Management I - Community Practice  | 4.0                |
| PHAR       | 604           | Clinical Therapeutics Module X: Infectious Diseases  | 4.5                |
| PHAR       | 605           | Clinical Therapeutics Module XI: Hematology/Oncology | 2.5                |
| PHAR       | 606           | Clinical Therapeutics Module XII: Nephrology/Urology | 2.5                |
| PHAR       | 607           | Clinical Therapeutics Module XIV: Dermatology/EENT   | 1.5                |
|            |               | Electives                                            | 2.0 - 3.0          |
| PHAR       | 550           | Scholarship III                                      | Continues          |
| PHAR       | 771           | Student Pharmacist Professionalism                   | Continues          |
| PHAR       | 640           | Foundations V                                        | 1.0                |
| PHAR       | 533           | IPPE IV: Clinical Patient Care                       | Continues          |
|            |               | <b>Semester Total</b>                                | <b>18.0 - 19.0</b> |

### P3 Spring Semester

| Department | Course Number | Course Title                                                  | Course Credit      |
|------------|---------------|---------------------------------------------------------------|--------------------|
| PHAR       | 661           | Pharmacy Practice Management II - Institutional Practice      | 2.0                |
| PHAR       | 618           | Clinical Therapeutics Module XIII: Gastrointestinal/Nutrition | 2.5                |
| PHAR       | 619           | Clinical Therapeutics Module XV: Women's Health/Bone, Joint   | 2.5                |
| PHAR       | 620           | Clinical Therapeutics Module XVI: Toxicology/Critical Care    | 2.0                |
| PHAR       | 721           | Clinical Therapeutics Module XVII: Special Populations        | 1.0                |
| PHAR       | 724           | Pharmacy Law                                                  | 3.0                |
|            |               | Electives                                                     | 2.0 - 3.0          |
| PHAR       | 550           | Scholarship III                                               | 2.0                |
| PHAR       | 771           | Student Pharmacist Professionalism                            | Continues          |
| PHAR       | 645           | Foundations VI                                                | 1.0                |
| PHAR       | 533           | IPPE IV: Clinical Patient Care                                | 1.0                |
|            |               | <b>Semester Total</b>                                         | <b>19.0 - 20.0</b> |

**P4 Year**

| <b>Department</b>   | <b>Course Number</b> | <b>Course Title</b>                  | <b>Course Credit</b> |
|---------------------|----------------------|--------------------------------------|----------------------|
| PHAR                | 760                  | Acute Care Pharmacy Practice I       | 5.0                  |
| PHAR                | 761                  | Advanced Hospital Pharmacy Practice  | 5.0                  |
| PHAR                | 762                  | Geriatrics Pharmacy Practice         | 5.0                  |
| PHAR                | 763                  | Ambulatory Care Pharmacy Practice    | 5.0                  |
| PHAR                | 765                  | Elective I                           | 5.0                  |
| PHAR                | 766                  | Elective II                          | 5.0                  |
| PHAR                | 768                  | Advanced Community Pharmacy Practice | 5.0                  |
| PHAR                | 771                  | Student Pharmacist Professionalism   | 1.0                  |
| PHAR                | 773                  | Acute Care Pharmacy Practice II      | 5.0                  |
| <b>Annual Total</b> |                      |                                      | <b>41.0</b>          |

**Hampton University School of Pharmacy****First Year Professional**

| <b>Fall Semester</b>      | <b>Credits</b> | <b>Spring Semester</b>         | <b>Credits</b> |
|---------------------------|----------------|--------------------------------|----------------|
| Pharmaceutics I           | 5              | Pharmaceutics II               | 4              |
| Pharmaceutics Lab I       |                | Pharmaceutics Lab II           | 1              |
| Anatomy & Physiology      | 4              | Medicinal Chemistry I          | 4              |
| Anatomy & Physiology Lab  | 1              | Biostats/Literature Evaluation | 3              |
| Pharmaceutical Care I     | 3              | Pharmaceutical Care II         | 3              |
| Physiological Chemistry   | 3              |                                |                |
| Profession of Pharmacy IV | 2              |                                |                |
| <b>Total:</b>             | <b>18</b>      | <b>Total:</b>                  | <b>15</b>      |

**Summer Session****Credits**

Community IPPE 1 (2 weeks - 80 hrs.)

**Total: 1**

**Second Year Professional**

| <b>Fall Semester</b>    | <b>Credits</b> | <b>Spring Semester</b> | <b>Credits</b> |
|-------------------------|----------------|------------------------|----------------|
| Pharmacokinetics        | 5              | Health Care Admin. II  | 3              |
| Medicinal Chemistry II  | 4              | Pharmaceutical Care IV | 3              |
| Microbiology/Immunology | 4              | Intro to Clerkships    | 2              |

|                         |           |               |           |
|-------------------------|-----------|---------------|-----------|
| Health Care Admin. I    | 2         | DDM I*        | 3         |
| Pharmaceutical Care III | 3         | DDM II*       | 3         |
|                         |           | DDM III*      | 4         |
| <b>Total:</b>           | <b>18</b> | <b>Total:</b> | <b>18</b> |

\*Drug and Disease Management

| <b>Summer Session</b> | <b>Credits</b> |                      |
|-----------------------|----------------|----------------------|
| Institutional IPPE    | 1              | (3 weeks - 120 hrs.) |
| <b>Total:</b>         | <b>1</b>       |                      |

**Third Year Professional**

| <b>Fall Semester</b>      | <b>Credits</b> | <b>Spring Semester</b>    | <b>Credits</b> |
|---------------------------|----------------|---------------------------|----------------|
| Pharmaceutical Care V     | 3              | Pharmacy Law & Ethics     | 2              |
| Patient Assessment        | 1              | Pharmacy Practice Lab     | 4              |
| Patient Assessment Lab    | 1              | DDM VII                   | 4              |
| DDM IV                    | 3              | DDM VIII                  | 4              |
| DDM V                     | 3              | Professional Elective (2) | 4              |
| DDM VI                    | 4              |                           |                |
| Research Methods          | 1              |                           |                |
| Professional Elective (1) | 2              |                           |                |
| <b>Total:</b>             | <b>18</b>      | <b>Total:</b>             | <b>18</b>      |

| <b>Summer Session</b> | <b>Credits</b> |                      |
|-----------------------|----------------|----------------------|
| Elective IPPE         | 1              | (3 weeks - 120 hrs.) |
| <b>Total:</b>         | <b>1</b>       |                      |

**Fourth Year Professional**

| <b>Three Semester Period</b>                                  | <b>Credits</b> |
|---------------------------------------------------------------|----------------|
| PHA 650 Seminar I                                             | 1              |
| PHA 651 Seminar II                                            | 1              |
| PHA 652 Seminar III                                           | 1              |
| PHA 670 Community Pharmacy Practice Experience*               | 5              |
| PHA 671 Institutional Pharmacy Practice Experience*           | 5              |
| PHA 672 Community/Institutional Pharmacy Practice Experience* | 5              |
| PHA 683 Geriatrics**                                          | 5              |
| PHA 685 Administration/Management**                           | 5              |
| PHA 690 Internal Medicine I                                   | 5              |

|                      |                      |                                                                 |
|----------------------|----------------------|-----------------------------------------------------------------|
| PHA 691              | Ambulatory Care I    | 5                                                               |
| PHA 692              | Ambulatory Care II   | 5                                                               |
| PHA 693              | Pediatrics**         | 5                                                               |
| PHA 694              | Psychiatry**         | 5                                                               |
| PHA 695              | Drug Information**   | 5                                                               |
| PHA 696              | Elective             | 5                                                               |
| PHA 699              | Internal Medicine II | 5                                                               |
| *Any (2) of the (3)  |                      | <b>Total 43.0 over 3 semesters (Summer, Fall, &amp; Spring)</b> |
| **Any (1) of the (5) |                      |                                                                 |

### Shenandoah University Bernard J. Dunn School of Pharmacy

#### First Professional Year (P1)

| FALL                                                  | Credit Hrs. | SPRING                                                 | Credit Hrs. |
|-------------------------------------------------------|-------------|--------------------------------------------------------|-------------|
| PHAR 501: Introduction to Pharmacy Practice           | 3           | PHAR 512: Pharmaceutics II                             | 4           |
| PHAR 508: Pharmaceutics I (Calculations)              | 2           | PHAR 513: Pharmaceutics II Lab                         | 1           |
| PHAR 516: Introductory Pharmacy Practice Experience I | 1           | PHAR 517: Introductory Pharmacy Practice Experience II | 2           |
| PHAR 518: Patient Counseling/Communications           | 2           | PHAR 527: IBHS IV: Cardiovascular                      | 2           |
| PHAR 523: IBHS I: Biocompounds and Biochemistry       | 2           | PHAR 528: IBHS V: Immunology, Respiration, Digestion   | 2           |
| PHAR 524: IBHS II: Endo, Skin, Bone, Muscle           | 2           | PHAR 529: IBHS VI: Renal, Reproduction, Development    | 2           |
| PHAR 525: IBHS III: Nervous System                    | 2           | PHAR 530: IBHS: Lab II                                 | 1           |
| PHAR 526: IBHS: Lab I                                 | 1           | PHAR 534: Essentials of Pharmacogenomics               | 3           |
| PHAR 531: Psychosocial Aspects of Disease             | 2           |                                                        |             |
| <b>Semester Total</b>                                 | <b>17</b>   | <b>Semester Total</b>                                  | <b>17</b>   |

#### Second Professional Year (P2)

| FALL                                                  | Credit Hrs. | SPRING                                                  | Credit Hrs. |
|-------------------------------------------------------|-------------|---------------------------------------------------------|-------------|
| PHAR 600: Pharmacokinetic Principles                  | 3           | PHAR 601: Drug Literature Evaluation                    | 2           |
| PHAR 603: Basic Principles of Pharmacology            | 3           | PHAR 602: Drug Literature Evaluation Lab                | 1           |
| PHAR 604: Nonprescription Products                    | 2           | PHAR 607: ICARE: Respiratory                            | 2           |
| PHAR 605: Outpatient Pharmacy Practice Lab            | 1           | PHAR 608: ICARE: Renal                                  | 2           |
| PHAR 617: Pharmacotherapy Outcomes                    | 1           | PHAR 619: ICARE: Cardiovascular                         | 4           |
| PHAR 627: Clinical Research Methods/Biostatistics     | 3           | PHAR 632: Applied Pk and PGx I                          | 1           |
| PHAR 628: Clinical Research Methods/Biostatistics Lab | 1           | PHAR 655: Introductory Pharmacy Practice Experience III | 2           |
| General Elective                                      | 3           | Professional Elective(s)                                | 3           |

|                                                           |                    |                                                          |                    |
|-----------------------------------------------------------|--------------------|----------------------------------------------------------|--------------------|
| <b>Semester Total</b>                                     | <b>17</b>          | <b>Semester Total</b>                                    | <b>17</b>          |
| <b>Third Professional Year (P3)</b>                       |                    |                                                          |                    |
| <b>FALL</b>                                               | <b>Credit Hrs.</b> | <b>SPRING</b>                                            | <b>Credit Hrs.</b> |
| PHAR 701: ICARE:<br>Endocrine/Reproduction                | 2                  | PHAR 700: ICARE: GI/Nutrition                            | 2                  |
| PHAR 704: Professional Practice<br>Management I           | 3                  | PHAR 708: ICARE: Musculoskeletal                         | 2                  |
| PHAR 709: ICARE:<br>Hematology/Oncology                   | 3                  | PHAR 712: Professional Practice<br>Management II         | 3                  |
| PHAR 718: ICARE: Infectious Disease                       | 3                  | PHAR 713: Sterile Compounding Lab                        | 1                  |
| PHAR 723: Patient Assessment I                            | 2                  | PHAR 717: Pharmacy Law                                   | 3                  |
| PHAR 725: Introductory Pharmacy<br>Practice Experience IV | 1                  | PHAR 720: ICARE: Neuro/Psychiatry                        | 3                  |
| PHAR 733: Applied Pk and PGx II                           | 1                  | PHAR 724: Patient Assessment II                          | 2                  |
| Professional Elective(s)                                  | 3                  | PHAR 734: Applied Pk and PGx III                         | 1                  |
|                                                           |                    | PHAR 735: Introductory Pharmacy<br>Practice Experience V | 1                  |
| <b>Semester Total</b>                                     | <b>18</b>          | <b>Semester Total</b>                                    | <b>18</b>          |
| <b>Fourth Professional Year (P4)</b>                      |                    |                                                          |                    |
| <b>FALL</b>                                               | <b>Credit Hrs.</b> | <b>SPRING</b>                                            | <b>Credit Hrs.</b> |
| PHAR 800: Ambulatory Care APPE                            | 5                  | PHAR 803: In-Patient Acute Care APPE                     | 5                  |
| PHAR 801: Community Clinical APPE                         | 5                  | PHAR 806: Selective APPE                                 | 5                  |
| PHAR 804: Institutional APPE                              | 5                  | PHAR 807B: Selective II APPE                             | 3                  |
| PHAR 807A: Selective I APPE                               | 2                  | PHAR 808: Advanced Pharmacy APPE                         | 5                  |
| PHAR 825: Pharmacy Practicum APPE                         | 1                  |                                                          |                    |
| <b>Semester Total</b>                                     | <b>18</b>          | <b>Semester Total</b>                                    | <b>18</b>          |
| <b>PROGRAM TOTAL</b>                                      |                    |                                                          | <b>140</b>         |

### **Appalachian College of Pharmacy**

#### **Fall Semester: P1 curriculum**

PHA 0100 Introduction to Pharmacy and Health Care Systems 3 Credits

PHA 0112 Cellular Biology and Biochemistry 6 Credits

PHA 0130 Principles of Immunology and Hematology 2 Credits

PHA 0120 Pharmaceutical Calculations 3 Credits

PHA 0125 Pharmaceuticals and Biopharmaceutics 4 Credits

PHA 0140 Communication and Professional Development 2 Credit

**Total Credits: 20 hours**

**Spring Semester: P1 curriculum**

PHA 0135 Introduction to Jurisprudence and Pharmacy Law 1 credit

PHA 0150 Autonomic Nervous System /Central Nervous: Medicinal Chemistry and Pharmacology 5 Credits

PHA 0155 Gastrointestinal Pharmacology and Medicinal Chemistry 2 Credits

PHA 0160 Cardiovascular, Renal, and Pulmonary: Pharmacology and Medicinal Chemistry 4 Credits

PHA 0200 Applied Clinical Pharmacokinetics 2 Credits

PHA 0175 Pharmaceutics Lab I 1 Credit

PHA 0180 OTC Products 2 Credits

PHA 1010 EPPE I 1 Credit

PHA 0195 P1 Pharmacy Milestone Examination 0 Credits (pass/fail)

**Credit hours: 18 hours**

**Summer Semester: P2 curriculum**

PHA 2010 CPPE I 3 Credits

PHA 2020 CPPE II 3 Credits

PHA 0145 Introduction to Anti-infective Agents 4 Credits

PHA 0165 Endocrine System: Pharmacology and Medicinal Chemistry 3 Credits

PHA 0170 Clinical Toxicology 1 Credits

PHA 0210 Drug Information, Clinical Research, and Biostatistics 3 Credits

**Total Credits: 17 hours**

**Fall Semester: P2 curriculum**

PHA 0220 Diseases of the Renal System and Fluid and Electrolyte Disorders 4 Credits

PHA 0225 Diseases of the Immune System, Skin and Connective Tissue Disorders 3 Credits

PHA 0282 Diseases of the Neurological System and Psychiatric Disorders 6 Credits

PHA 0242 Diseases of Cardiovascular and Respiratory Systems 6 Credits

PHA 0250 Patient Assessment and Case Studies I 1 Credit

PHA 0260 Pharmaceutics Lab II 1 Credit

PHA 2030 EPPE II 1 Credit

Elective 1 Credit

**Total Credits: 23 hours**

**Spring Semester: P2 curriculum**

PHA 0232 Infectious Disease 5 Credits

PHA 0275 Diseases of the Gastrointestinal System, Disorders of Nutrition and Metabolism and Bariatrics 4 Credits

PHA 0270 Diseases of the Hematological System and Oncological Disorders 5 Credits

PHA 0215 Pharmacy Administration 3 Credits

PHA 0251 Patient Assessment and Case Studies II 1 Credit

PHA 2040 EPPE II 1 Credit

PHA 0298 P2 Pharmacy Milestone Examination 0 Credits (pass/fail)

Elective 1 Credit

**Credit hours: 20 hours**

**Summer Semester: P3 curriculum**

PHA 0265 Disease of the Endocrine and Reproductive System 4 Credits

PHA 0290 Pharmacotherapeutic Considerations in Special Populations (Pediatrics, Geriatrics, Pregnancy/Lactation) 4 Credits

PHA 0300 Advanced Jurisprudence and Pharmacy Law 2 Credits

**Credit hours: 10 hours**

**PHA 3010-3080 APPE I through VIII, 5 Credits Each**

PHA 3010 Community Health and Wellness

PHA 3020 Hospital/Health System Pharmacy

PHA 3030 Community Patient Care

PHA 3040 Ambulatory Care

PHA 3050 Acute Care, Inpatient and General Medicine

PHA 3060 APPE Elective

PHA 3070 APPE Elective

PHA 3080 APPE Elective

PHA 0399 P3 Pharmacy Milestone Examination 0 Credits (pass/fail)

**Credit hours: 40 hours**

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

**SUMMARY OF PUBLIC COMMENT  
AS OF AUGUST 17, 2012**

Below is a summary of the comments received by the Board office between the Public Hearing held on July 23rd and August 17th in order of receipt.

**Oral Comment at the Public Hearing, July 23, 2012**

One speaker, who represented the Virginia Pharmacy Congress, presented oral comment during the Public Hearing. The following 21 points detail the comment as well as response to questions posed by the Regulatory Research Committee and staff.

**Janet A. Silvester, RPh, MBA, FASHP, Director of Pharmacy and Emergency Services, Martha Jefferson Hospital, Charlottesville, VA – speaking on behalf of the Virginia Pharmacy Congress**

1. Virginia Pharmacy Congress (VPC) had been in existence since 1998 and consists of the Virginia Society of Health System Pharmacists, Virginia Pharmacist Association, the Virginia Association of Chain Drug Stores, Virginia Commonwealth University School of Pharmacy, Appalachian College of Pharmacy, Hampton University School of Pharmacy, Shenandoah School of Pharmacy, and Epic Pharmacies.
2. Two representatives from the Virginia Board of Pharmacy serve as ex officio directors.
3. VPC's mission is to serve as a catalyst to advance the pharmacy profession in Virginia through discussion, understanding and action, regarding matters of common interest to Virginia pharmacists, pharmacy organizations and institutions, and constituencies served with respect to professional, education, ethical, technological, legislative, and regulatory issues.
4. VPC has reviewed the Virginia Health Reform Initiative Advisory Council's December 2010 report and is supportive of the report's statement related to changing scope of practice laws to permit more health professionals to practice up to the evidence based limit of their training. VPC agrees that Virginia is facing serious access to care issues and that pharmacists are uniquely positioned to be part of the solution due to their accessibility in the community and their education and training.
5. VPC's written response to the study workplan is intended to inform the work of the Committee
6. VPC believes that improving patient care and health system outcome can be realized through advanced pharmacy practice. VPC holds that pharmacists are significantly underutilized in the health care delivery system and that when pharmacists are integrated into direct patient care through collaborative practice with physicians or other members of the health care team, patient outcomes are improved. Evidence is cited from Chisholm and

Burns, et al. (2010),<sup>1</sup> an extensive systematic review and analysis of 298 research studies. This review demonstrates improved patient outcomes across health care settings and disease states, in inpatient settings, with reduced re-admissions, length of hospital stay, and mortality. Improved clinical markers were demonstrated in ambulatory care settings for patients with diabetes, heart failure, hypertension, and dyslipidemias, among other chronic diseases.

7. The 2011 report to the U.S. Surgeon General<sup>2</sup> describes the management of diseases following initial diagnosis, through a number of patient care services that pharmacists deliver in a variety of practice settings through collaborative practice agreements. Services discussed included performing or obtaining necessary health and functional status assessments, initiating or discontinuing treatment to manage disease according to therapeutic goals agreed upon by the primary provider and the patient. They also involved ordering, interpreting, and monitoring laboratory tests, formulating clinical assessments and developing therapeutic plans, documentation, and communication of essential information about the care delivered to other appropriate healthcare provider. Patient and caregiver education and training to enhance understanding and the appropriate use of medications and adherence with treatment regimens were also noted as were providing care, coordination, and services for wellness and disease prevention.
8. Ms. Silvester asked that a specific recommendation be made to revise the existing regulations for collaborative practice agreements in Virginia. She indicated that they want to work with the Medical Society of Virginia and Virginia Nurses Association in this process as they did when the original collaborative practice agreement language was introduced in 1998.
9. Ms. Silvester indicated that the 2011 report to the Surgeon General referenced earlier also indicates that medications are involved in 80 percent of all treatments and that drug-related morbidity and mortality are estimated to cost the U.S. \$200B per year. She further strongly suggested that expanded roles for pharmacists as part of a collaborative health care team could significantly improve the human and financial impact associated with adverse drug outcomes. She notes that pharmacist can help improve access to care and the quality and safety of medication use. She further indicates that the value of interdisciplinary collaboration must be enhanced to realize the best patient outcomes as a result of each team member providing their specific expertise to assure that quality care is delivered.
10. In follow-up, Ms. Silvester was specifically asked whether the VCA is seeking to be able to initiate and modify prescription. She replied that that would be part of the

<sup>1</sup> Chisholm-Burns, M. A., Kim Lee, J., Spivey, C.A., Slack, M., Herrier, R.N., Hall-Lipsy, E., Graff Zivin, J., Abraham, I., Palmer, J., Martin, J.R., Kramer, S. and Wunz, T. (2010). US pharmacists' effect as team members on patient care: Systematic review and meta-analyses. *Medical Care*, 48 (10), 923-933. Accessible through [http://journals.lww.com/lww-medicalcare/Fulltext/2010/10000/US\\_Pharmacists\\_Effect\\_as\\_Team\\_Members\\_on\\_Patient.10.aspx?WT.mc\\_id=HPxADx20100319xMP](http://journals.lww.com/lww-medicalcare/Fulltext/2010/10000/US_Pharmacists_Effect_as_Team_Members_on_Patient.10.aspx?WT.mc_id=HPxADx20100319xMP)

<sup>2</sup>Giberson, S., Yoder, S, Lee, M.P. (2011). Improving patient and health system outcomes through advanced pharmacy practice. U. S. Public Health Service, Dec. 2011. Accessible through [http://journals.lww.com/lww-medicalcare/Fulltext/2010/10000/US\\_Pharmacists\\_Effect\\_as\\_Team\\_Members\\_on\\_Patient.10.aspx?WT.mc\\_id=HPxADx20100319xMP](http://journals.lww.com/lww-medicalcare/Fulltext/2010/10000/US_Pharmacists_Effect_as_Team_Members_on_Patient.10.aspx?WT.mc_id=HPxADx20100319xMP)

recommendation sought, within the context of collaborative agreements based upon agreed upon protocols between the provider and pharmacist.

11. When followed-up further as to whether statutory change would be needed, Ms. Silvester indicated that VCA would expand on this further in written comment to be submitted after the hearing. However, the intent is to add initiation of therapy.
12. Ms. Silvester was asked whether VCA had information on any difference in the incidence of malpractice in North Carolina and New Mexico, states which permit initiation of therapy, in comparison with other states. She indicated that they did not. Neither did staff.
13. Ms. Silvester was asked about the training pharmacists receive in managing disease and order plans, and the criteria required such is the case for physician assistants or nurse practitioners. Ms. Silvester indicated that the written comments is to be provided subsequent to the public hearing that will articulate expectations about credentials and training in addition to the workplan response that previously provided the schools of pharmacy curricula. She noted that with regard to initiation of therapy, pharmacist training best prepares the practitioner. She further indicated that they comments would refer to how recent a pharmacist's training was and how it relates to the existing curriculum. It would speak to years of experience, residency training, board certifications, program accreditation and other means of assuring appropriate credentials.
14. Ms. Silvester was asked how the patient would be made aware of the coordination of their care, team membership, and who is making decisions. Ms. Silvester indicated that sharing information is essential and referred to previous personal experience of a pharmacist she knew how has worked with primary care physician practices under collaborative practice. Their patients were made aware that the pharmacist was part of the team and helping with management of disease states
15. Ms. Silvester was asked to expand on the pre-requisite coursework required prior to entering pharmacy school that would be of greatest relevance to initiating therapy, especially microbiology, physiology, anatomy. She reported that VCA would be sure to include this information in the written comments
16. When asked whether there were any concerns among the pharmacy community on the potential to require a separate certification similar to North Carolina's or New Mexico's provisions. Ms. Silvester indicated that there were differences of opinion. Practitioners who had been out of school for many years may have concern about how to demonstrate specific competencies. She noted that additional certification could help validate the knowledge and skill necessary for safe practice and reported that the written comment would articulate expectations related to education.
17. In response to a question concerning who bears ultimate responsibility for patient care, Ms. Silvester indicated that, in her view, the physician is a team leader, and there are delegated duties to the other team members, but they still share accountability for care. She noted that part of the protection for the physician is that there is an agreement in advance concerning treatment protocols. Unusual circumstances would prompt conversation between the team members.
18. When asked whether expanded practice authority would be limited to management of chronic diseases, Ms. Silvester responded that that VPC had not made a final determination.

Patients frequently present with multiple morbidities and some have complex issues that make their therapeutic regimens more challenging.

19. When asked whether pharmacists with advanced practice authority should be limited to Schedule VI (non-opioid medications), Ms. Silvester responded that they should also be permitted the full range of prescriptive medications.
20. When asked if pharmacists should be incorporated not only into primary and health systems patient care teams, but expanded practices at the local retail pharmacy, Ms. Silvester responded that the issue relates primarily to patient need and access and effective therapeutic management across settings as patients transition regardless of location. She noted that the ready accessibility of pharmacies for most patients make them a good portal for the underserved.
21. When asked if current collaborative practice agreements can be strengthened without consideration of prescriptive authority, Ms. Silvester responded that the current language requires a specific agreement between a pharmacist and a physician. If the pharmacist was going to support a primary care practice with multiple physicians, he would have to have a separate agreement with each rather than the practice as a whole. The original language was created in 1998, and the way that care is delivered today is very different than then.

#### **Written Comment**

##### **Janet Silvester - July 24, 2012**

Ms. Silvester wished to clarify that the Virginia Pharmacy Congress is seeking including “initiation of therapy” only within the context of a mutually agreed upon collaborative practice agreement that rests on protocols and treatment plans that have been agreed upon in advance.

They are not seeking independent prescriptive authority. Their desire is to work within a team based model of care that is best for the patient and healthcare system as a whole.

##### **Timothy S. Musselman, Pharm.D., Executive Director, Virginia Pharmacists Association - August 17, 2012**

Dr. Musselman supports the following changes to increase utilization of collaborative practice agreements:

1. Allow patients the choice of opting **out** of collaborative agreements rather than requiring them to “opt in,”
2. Add disease-state specific protocols rather than patient-specific ones,
3. Allow collaborative agreements to include all patients under the care of a physician or physician group. The medical director of a group practice could authorize practice-wide collaborative agreements which better reflect the growing culture of expanding group practices through evolving Accountable Care Organizations and Patient Centered Medical Home team models.
4. Include nurse practitioners and physician assistants to be specifically listed as authorizers of agreements in addition to physicians, and

5. Allow the use electronic protocols.

**Dawn Havrda, PharmD, FCCP, BCPS, Professor and Chair, Department of Pharmacy Practice, Shenandoah University, Dunn School of Pharmacy – August 17, 2012.**

Dr. Harva cites the increase in demand due to health care reform and the projected physician shortage, noting that pharmacists are academically prepared, ready, and able to work with physicians to help address the anticipated “health care void.”

Dr. Harva notes that current collaborative agreements may relate to treatment using drug therapy, laboratory tests, or medical devices to improve patient outcomes using a specific protocol. She echoes Dr. Musselman’s recommendations #1 through #5, above, and adds that “implementation” and/or “initiation” of drug therapy should be provided for as an option in collaborative agreements between the pharmacist and physician for post-diagnosis management of a medical condition. She notes that pharmacists are uniquely positioned to work in conjunction with physicians in managing drug therapy of a chronic disease state and indicates all options in managing a disease state should be available to the physician and pharmacist when they create a collaborative agreement and treatment protocol. She cites diabetes management in example.

**Rodney L. Stiltner, Pharm.D., Director, Pharmacy Services, VCU Health System, Medical College of Virginia Hospitals, Clinical Associate Professor, VCU School of Pharmacy, Department of Pharmacy Services representing the Virginia Society of Health-System Pharmacists and the Colleges of Pharmacy (Appalachian, Hampton, Shenandoah, and VCU) - August 17, 2012**

Dr. Stiltner provided the Committee with additional information concerning the curriculum and prerequisites for the training of pharmacists. A minimum of 95 semester hours as specified in the following listing of courses is required prior to admission for students entering in the Fall semester.<sup>3</sup>

|                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| General Biology (8 hrs. <sup>4</sup> : 6 lecture and 2 laboratory)<br>College Chemistry (8 hrs.: 6 lecture and 2 laboratory)<br>Organic Chemistry (8 hrs: 6 lecture and 2 laboratory)<br>Physics (4 hrs.: 3 lecture, 1 laboratory)<br>Human Anatomy (3 hrs. with 1 laboratory hr. preferred)<br>Human Physiology (3 hrs.)<br>Microbiology (3 hrs. with 1 laboratory hr. preferred)<br>Biochemistry (3 hrs.) | English (6 hrs.)<br>Calculus (3 hrs.)<br>Statistics (3 hrs.)<br>Public Speaking (3 hrs.)<br>Biomedical Science Foundation<br>and Elective Courses (35 hrs.) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|

<sup>3</sup> Neither College Board Advanced Placement Tests nor International Baccalaureate program courses in math or science are accepted as fulfilling requirements.

<sup>4</sup> Hours listed are semester hours.

Dr. Stiltner reports that 95% of entering classes for the past several years have previously earned a bachelor's degree.

As discussed at the public hearing, Dr. Stiltner holds that patient medication related outcomes are improvable and health system costs reducible by optimizing collaborative practice agreements that comport with the six recommendations noted in Dr. Musselman's and Dr. Havrda's comments, above. He cites the findings described in the Chisholm-Burns et al (2010) meta-analysis study and the 2011 report to the U.S. Surgeon General referenced earlier. He further notes the American Academy of Family Physicians (AAFP) position paper on pharmacists.<sup>5</sup>

Dr. Stiltner references the Vision for the Future of Pharmacy adopted by the Joint Commission of Pharmacy Practitioners<sup>6</sup> and notes that pharmacy educators have been preparing pharmacy students for years to fulfill responsibilities for the rational use of medications contingent upon their authority and autonomy to manage medication therapy and communicate and collaborate with patients, caregivers, other health professionals, and qualified support personnel.

He also references success across the country in integrating pharmacists care within community health teams and the development of comprehensive medical homes through the Patient Safety and Clinical Pharmacy Services Collaborative supported by the Health Resources and Services Administration, Centers for Medicare and Medicaid Services and State Quality Improvement Organizations.<sup>7</sup> He notes that his group believes that Congress envisioned in the *2010 Patient Protection and Affordable Care Act* a collaborative care model for Medicare recipients that incorporates medication management services to "manage chronic disease, reduce medical errors, and improve patient adherence to therapies while reducing costs and hospital readmissions" and that this management includes selection or initiation of therapy if authorized by the states.

Dr. Stiltner notes that the recommended changes will allow prescribers who wish to implement team-based care to enter into "more comprehensive collaborative practice agreements as a means to optimize the efficiency of their patient centered team care medical home practice." He further states that "these changes should make these agreements more effective and increase their use by pharmacists and physicians and improve access, health outcomes and reduce costs associated with the provision of care in Virginia."

<sup>5</sup> American Association of Family Practitioners. (December 2001 Board and 2003). Position paper: Pharmacists. Available at <http://www.aaafp.org/online/en/home/policy/policies/p/pharmacistspositionpaper.html>.

<sup>6</sup> Joint Commission of Pharmacy Practitioners (2004, November). *Vision statement*. Available from the American College of Clinical Pharmacy's website <http://www.accp.com/docs/positions/misc/JCPPVisionStatement.pdf>

<sup>7</sup> U.S. Department of Health and Human Services Health Resources and Services Administration Patient Safety and Clinical Pharmacy Services Collaborative website: <http://www.hrsa.gov/publichealth/clinical/patientsafety/index.html>.

**Department of Health Professions  
Board of Health Professions REGULATORY  
RESEARCH COMMITTEE October 2, 2012**

**TIME AND PLACE:** The meeting was called to order at 10:00 a.m. on Tuesday, October 2, 2012, Department of Health Professions, 9960 Mayland Drive, 2<sup>nd</sup> Floor, Board Room 2, Henrico, VA, 23233.

**PRESIDING OFFICER:** Jonathan Noble, OD

**MEMBERS PRESENT:** Jonathan Noble, OD  
Allison Gregory  
Charlotte Markva

**MEMBERS NOT PRESENT:** Yvonne Haynes  
Maureen Clancy

**STAFF PRESENT:** Elizabeth A. Carter, Ph.D., Executive Director for the Board  
Justin Crow, Research Assistant  
Laura Jackson, Operations Manager

**OTHERS PRESENT:** Susan Ward, VHHA  
James Pickral, Jr., Virginia Pharmacists Association

**QUORUM:** A quorum was established with three members in attendance.

**AGENDA:** There was one edit to the agenda. A heading of Pharmacy Scope of Practice Update was added by Dr. Carter.

**PUBLIC COMMENT:** There was no public comment.

**APPROVAL OF MINUTES:** A motion was made by Ms. Gregory and properly seconded to approve the minutes of the September 17, 2012 meeting. All committee members were in favor, none opposed.

**EXECUTIVE DIRECTOR:** **Pharmacy Scope of Practice & Team Delivery Study Update**  
Dr. Carter met with the Board of Pharmacy on October 1, 2012 and received their insights on the study report and comments received, to date, as well as their response to the questions posed at the Committee's last meeting concerning who bears ultimate responsibility for patient care and whether pharmacist practice in collaborative teams would be restricted to chronic care management.

The Board of Pharmacy comments were positive concerning the recommendations put forward by the Virginia Pharmacists Association (VPhA) in response to the Committee's review:

- Allow patients to opt out of a collaborative agreement rather than opt in.

- Allow disease-state specific protocols rather than only patient-specific protocols
- Allow collaborative agreements to include all patients under the care of a physician or a physician group rather than per-patient and per-physician only.
- Allow Nurse Practitioners and Physician Assistants to be listed as authorizers of collaborative agreements.
- Allow for electronic collaborative agreements and protocols rather than paper only.

Additionally, at the Board of Pharmacy meeting, on October 1", VPhA representative James Pickral, Jr. also advised that Board that the association would like to include two an additional recommendations, that implementation of therapy within team-based settings occur post-diagnosis and that they are not seeking a separate state certification for advanced practice pharmacists such as exists in New Mexico and North Carolina.

In response to, "Which party bears the ultimate responsibility for patient care?" the answer from the Board was "yes" implying that all practitioners bear responsibility for providing appropriate patient care, but the answer is also based on the specifics of each collaborative practice agreement. In response to "Is the expanded practice authority envisioned to be limited to management of chronic disease?" acute care would also be likely to be incorporated into collaborative practice.

Dr. Carter also advised that it her understanding there are negotiations underway between the Virginia Pharmacists Association and the Medical Society of Virginia that are planned to result in a legislative proposal in 2013.

Mr. Pickral was present and asked by the Chair if he had anything further to add. Mr. Pickral confirmed the information that Dr. Carter received from the Board of Pharmacy and emphasized the importance of collaborative agreements allowing for agreements with groups of practitioners to facilitate the emerging team model of care..

Due to the impending legislation, the Committee agreed that the Pharmacy Scope of Practice & Team Delivery study should continue after the General Assembly has had the opportunity to address the anticipated 2013 legislation. The Committee's report and all comments, to date, will remain available for reference on the website.

A motion was made by Ms. Markva and properly seconded to continue with the Pharmacy Scope of Practice & Team Delivery study. All committee members were in favor, none opposed.

**Pharmacy Technician Scope of Practice**

Staff will continue to prepare information on the pharmacy technician scope of practice for presentation at the next meeting scheduled for February 5, 2013.

**Lactation Consultants**

Dr. Carter informed the Committee that no additional information has been received from the Lactation Consultants.

**STUDIES:****Perfusionist Study Presentation**

A PowerPoint presentation regarding Perfusionists was presented by Mr. Crow. (Attachment 1) The Committee requested that a public hearing be held to receive public comment on the profession.

**NEW BUSINESS:**

There was no new business.

**ADJOURNMENT:**

With no other business to conduct, the meeting adjourned at 10:24 a.m.

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Jonathan Noble, OD  
Chair

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

**Attachment 1**

## VIRGINIA ACTS OF ASSEMBLY-- 2013 SESSION

## CHAPTER 192

*An Act to amend and reenact §§ 54.1-3300 and 54.1-3300.1 of the Code of Virginia, relating to pharmacy; collaborative agreements.*

[H 1501]

Approved March 12, 2013

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3300 and 54.1-3300.1 of the Code of Virginia are amended and reenacted as follows:

**§ 54.1-3300. Definitions.**

As used in this chapter, unless the context requires a different meaning:

"Board" means the Board of Pharmacy.

"Collaborative agreement" means a voluntary, written, or electronic arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a single physical location where patients receive services and a practitioner of medicine, osteopathy, or podiatry and his designated alternate practitioners (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided such collaborative agreement is signed by each physician participating in the collaborative practice agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working as part of a patient care team as defined in § 54.1-2900, involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility,

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for delivery.

"Pharmacist" means a person holding a license issued by the Board to practice pharmacy.

"Pharmacy" means every establishment or institution in which drugs, medicines, or medicinal chemicals are dispensed or offered for sale, or a sign is displayed bearing the word or words "pharmacist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "medicine store," "drug sundries," "prescriptions filled," or any similar words intended to indicate that the practice of pharmacy is being conducted.

"Pharmacy intern" means a student currently enrolled in or a graduate of an approved school of pharmacy who is registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

"Pharmacy technician" means a person registered with the Board to assist a pharmacist under the pharmacist's supervision.

"Practice of pharmacy" means the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging, and dispensing of drugs, medicines, and devices used in the diagnosis, treatment, or prevention of disease, whether compounded or dispensed on a prescription or otherwise legally dispensed or distributed, and shall include the proper and safe storage and distribution of drugs; the maintenance of proper records; the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; and the management of patient care under the terms of a collaborative agreement as defined in this section.

"Supervision" means the direction and control by a pharmacist of the activities of a pharmacy intern or a pharmacy technician whereby the supervising pharmacist is physically present in the pharmacy or in the facility in which the pharmacy is located when the intern or technician is performing duties restricted to a pharmacy intern or technician, respectively, and is available for immediate oral communication.

Other terms used in the context of this chapter shall be defined as provided in Chapter 34 (§ 54.1-3400 et seq.) of Title 54 unless the context requires a different meaning.

**§ 54.1-3300.1. Participation in collaborative agreements; regulations to be promulgated by the Boards of Medicine and Pharmacy.**

A pharmacist and his designated alternate pharmacists involved directly in patient care may

participate with a practitioner of medicine, osteopathy, or podiatry and his designated alternate practitioners (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided such collaborative agreement is signed by each physician participating in the collaborative practice agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working as part of a patient care team as defined in § 54.1-2900, involved directly in patient care in collaborative agreements which authorize cooperative procedures related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions and limitations, for the purpose of improving patient outcomes. However, no person licensed to practice medicine, osteopathy, or podiatry shall be required to participate in a collaborative agreement with a pharmacist and his designated alternate pharmacists, regardless of whether a professional business entity on behalf of which the person is authorized to act enters into a collaborative agreement with a pharmacist and his designated alternate pharmacists.

No patient shall be required to participate in a collaborative procedure without such patient's consent. A patient who chooses to not participate in a collaborative procedure shall notify the prescriber of his refusal to participate in such collaborative procedure. A prescriber may elect to have a patient not participate in a collaborative procedure by contacting the pharmacist or his designated alternative pharmacists or by documenting the same on the patient's prescription.

Collaborative agreements may include the implementation, modification, continuation, or discontinuation of drug therapy pursuant to written, patient specific or electronic protocols, provided implementation of drug therapy occurs following diagnosis by the prescriber; the ordering of laboratory tests; or other patient care management measures related to monitoring or improving the outcomes of drug or device therapy. No such collaborative agreement shall exceed the scope of practice of the respective parties. Any pharmacist who deviates from or practices in a manner inconsistent with the terms of a collaborative agreement shall be in violation of § 54.1-2902; such violation shall constitute grounds for disciplinary action pursuant to §§ 54.1-2400 and 54.1-3316.

Collaborative agreements may only be used for conditions which have protocols that are clinically accepted as the standard of care, or are approved by the Boards of Medicine and Pharmacy. The Boards of Medicine and Pharmacy shall jointly develop and promulgate regulations to implement the provisions of this section and to facilitate the development and implementation of safe and effective collaborative agreements between the appropriate practitioners and pharmacists. The regulations shall include guidelines concerning the use of protocols, and a procedure to allow for the approval or disapproval of specific protocols by the Boards of Medicine and Pharmacy if review is requested by a practitioner or pharmacist.

Nothing in this section shall be construed to supersede the provisions of § 54.1-3303.



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Office of the Surgeon General  
 Rockville, MD 20857  
 Dec 14, 2011

RADM Scott Giberson, R.Ph., Ph.C., NCPS-PP, M.P.H.  
 Chief Professional Officer, Pharmacy  
 U.S. Assistant Surgeon General

Dear RADM Giberson,

I wish to commend you and our Commissioned Corps colleagues, as well as publicly support *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General, 2011.*

The report provides a thorough discussion of the comprehensive patient care services that pharmacists are currently providing through collaborative practice agreements (CPAs) in 43 states and in federal health care settings (e.g. IHS, VA, DOD).

Under CPAs, pharmacists work in collaboration with physicians and primary care clinicians to help patients, particularly those with chronic conditions, manage their medication regimens by:

- Performing patient assessments and developing therapeutic plans;
- Utilizing authorities to initiate, adjust, or discontinue medications;
- Ordering, interpreting and monitoring appropriate laboratory tests;
- Providing care coordination and other healthcare services for wellness and prevention; and
- Developing partnerships with patients for ongoing and follow-up care.

The report demonstrates through evidence-based outcomes, that many expanded pharmacy practice models (implemented in collaboration with physicians or as part of a health team) improve patient and health system outcomes and optimize primary care access and delivery.

Specifically, the report supports the following case:

1. Health leadership and policy makers should further explore ways to optimize the role of pharmacists to deliver a variety of patient-centered care and disease prevention, in collaboration with physicians or as part of the healthcare team. These collaborative pharmacy practice models can be implemented to manage and prevent disease, improve health care delivery and address some of the current demands on the health care system.

2. Utilization of pharmacists as an essential part of the healthcare team to prevent and manage disease in collaboration with other clinicians can improve quality, contain costs, and increase access to care.
3. Recognition of pharmacists as health care providers, clinicians and an essential part of the health care team is appropriate given the level of care they provide in many health care settings.
4. Compensation models, reflective of the range of care provided by pharmacists, are needed to sustain these patient oriented, quality improvement services. This may require further evolution of legislative or policy language and additional payment reform considerations.

This report provides the evidence health leaders and policy makers need to support evidence-based models of cost effective patient care that utilizes the expertise and contributions of our nations' pharmacists as an essential part of the healthcare team.

I look forward to working with you and your team as you implement this report and take its findings to the wider professional pharmacy community.

Yours sincerely,

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Regina Benjamin, MD, MBA  
U.S. Surgeon General  
VADM USPHS

**"Collaborative Practice Agreements – Pharmacist Initiation of Therapy"**  
**NABPLaw®Search Results- August 12,2013**

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| Alaska .....               | 2  |
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## Alaska

NABPLAW Online/ALASKA/ALASKA Board of Pharmacy Regulations/AK BReg Title 12. Professional and Vocational Regulations/AK BReg Chapter 52. Board of Pharmacy Regulations /AK BReg ARTICLE 2. PERSONNEL./AK BReg 12 AAC 52.240. Pharmacist collaborative practice authority.

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### AK BReg 12 AAC 52.240.

#### Pharmacist collaborative practice authority.

- (a) A pharmacist planning to exercise collaborative practice authority in the pharmacist's practice by **initiating** or modifying drug therapy in accordance with a written protocol established and approved for the pharmacist's practice by a practitioner authorized to prescribe drugs under AS 08 must submit the completed written protocol to the board and be approved by the board before implementation.
- (b) A written protocol must include
  - (1) an agreement in which practitioners authorized to prescribe legend drugs in this state authorize pharmacists licensed in this state to administer or dispense in accordance with that written protocol;
  - (2) a statement identifying the practitioners authorized to prescribe and the pharmacists who are party to the agreement;
  - (3) the time period during which the written protocol will be in effect, not to exceed two years;
  - (4) the types of collaborative authority decisions that the pharmacists are authorized to make, including
    - (A) types of diseases, drugs, or drug categories involved and the type of collaborative authority authorized in each case; and
    - (B) procedures, decision criteria, or plans the pharmacists are to follow when making therapeutic decisions, particularly when modification or **initiation** of drug therapy is involved;
  - (5) activities the pharmacists are to follow in the course of exercising collaborative authority, including documentation of decisions made, and a plan for communication and feedback to the authorizing practitioners concerning specific decisions made;
  - (6) a list of the specific types of patients eligible to receive services under the written protocol;
  - (7) a plan for the authorizing practitioners to review the decisions made by the pharmacists at least once every three months; and
  - (8) a plan for providing the authorizing practitioners with each patient record created under the written protocol.

(c) To enter into a written protocol under this section, practitioners authorized to prescribe must be in active practice, and the authority granted must be within the scope of the practitioners' practice.

(d) Unless the board is satisfied that the pharmacist has been adequately trained in the procedures outlined in the written protocol, the board will specify and require completion of additional training that covers those procedures before issuing approval of the protocol.

(e) Documentation related to the written protocol must be maintained for at least two years.

(f) The written protocol may be terminated upon written notice by the authorizing practitioners or pharmacists. The pharmacists shall notify the board in writing within 30 days after a written protocol is terminated.

(g) Any modification to the written protocol must be approved by the board as required by this section for a new written protocol.

(h) This section does not apply to participation, by a pharmacist practicing in an institutional facility in drug therapy protocols and guidelines approved by the institutional facility's pharmacy and therapeutics committee or by another medical staff governing body of that institutional facility, if records related to the drug therapy protocols and guidelines are maintained and made available to the board upon request.

History: (Eff. 11/10/2001, Register 160; am 2/11/2004, Register 169)

NABPLAW06/2013

## California

**NABPLAW Online/CALIFORNIA/CALIFORNIA Pharmacy Practice Act/CA PracAct Business & Professions Code/CA PracAct Division 2. Healing Arts. Chapter 9. Pharmacy/CA PracAct Article 3. Scope of Practice and Exemptions/CA PracAct 4052.2. Allowed procedures if performed in accord with certain policies, procedures, or protocols.**

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### **CA PracAct 4052.2.**

**Allowed procedures if performed in accord with certain policies, procedures, or protocols.**

(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance with the policies, procedures, or protocols of that facility, home health agency, licensed clinic, health care service plan, or physician, and in accordance with subdivision (c):

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.

(4) **Initiating** or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen **initiated** pursuant to this paragraph within 24 hours.

(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(c) The policies, procedures, or protocols referred to in this subdivision shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and shall, at a minimum, do all of the following:

(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(4) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(d) Prior to performing any procedure authorized by this section, a pharmacist shall have done either of the following:

(1) Successfully completed clinical residency training.

(2) Demonstrated clinical experience in direct patient care delivery.

History: (Added by Stats.2006, c. 777 (A.B.2408), § 6.)

*NABPLAW03/2013*

## **Connecticut**

**NABPLAW Online/CONNECTICUT/CONNECTICUT Pharmacy Practice Act./CT PracAct Title 20. Professional and Occupational Licensing, Certification, Title Protection and Registration. Examining Boards/CT PracAct Chapter 400J. Pharmacy/CT PracAct Part III. Practice of Pharmacy/CT PracAct 20-631. Collaborative drug therapy management agreements between pharmacist and physicians. Scope. Pharmacist competency requirements. Regulations.**

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### **CT PracAct 20-631.**

**Collaborative drug therapy management agreements between pharmacist and physicians. Scope. Pharmacist competency requirements. Regulations.**

(a) Except as provided in section 20-631b, one or more pharmacists licensed under this chapter who are determined competent in accordance with regulations adopted pursuant to subsection (d) of this section may enter into a written protocol-based collaborative drug therapy management agreement with one or more physicians licensed under chapter 370 to manage the drug therapy of individual patients. In order to enter into a written protocol-based collaborative drug therapy management agreement, such physician shall have established a physician-patient relationship with the patient who will receive collaborative drug therapy. Each patient's collaborative drug therapy management shall be governed by a written protocol specific to that patient established by the treating physician in consultation with the pharmacist. For purposes of this subsection, a "physician-patient relationship" is a relationship based on (1) the patient making a medical complaint, (2) the patient providing a medical history, (3) the patient receiving a physical examination, and (4) a logical connection existing between the medical complaint, the medical history, the physical examination and any drug prescribed for the patient.

(b) A collaborative drug therapy management agreement may authorize a pharmacist to implement, modify or discontinue a drug therapy that has been prescribed for a patient, order associated laboratory tests and administer drugs, all in accordance with a patient-specific written protocol. In instances where drug therapy is discontinued, the pharmacist shall notify the treating physician of such discontinuance no later than twenty-four hours from the time of such discontinuance. Each protocol developed, pursuant to the collaborative drug therapy management agreement, shall contain detailed direction concerning the actions that the pharmacist may perform for that patient. The protocol shall include, but need not be limited to, (1) the specific drug or drugs to be managed by the pharmacist, (2) the terms and conditions under which drug therapy may be implemented, modified or discontinued, (3) the conditions and

events upon which the pharmacist is required to notify the physician, and (4) the laboratory tests that may be ordered. All activities performed by the pharmacist in conjunction with the protocol shall be documented in the patient's medical record. The pharmacist shall report at least every thirty days to the physician regarding the patient's drug therapy management. The collaborative drug therapy management agreement and protocols shall be available for inspection by the Departments of Public Health and Consumer Protection. A copy of the protocol shall be filed in the patient's medical record.

(c) A pharmacist shall be responsible for demonstrating, in accordance with regulations adopted pursuant to subsection (d) of this section, the competence necessary for participation in each drug therapy management agreement into which such pharmacist enters.

(d) The Commissioner of Consumer Protection, in consultation with the Commissioner of Public Health, shall adopt regulations, in accordance with chapter 54, concerning competency requirements for participation in a written protocol-based collaborative drug therapy management agreement described in subsection (a) of this section, the minimum content of the collaborative drug therapy management agreement and the written protocol and such other matters said commissioners deem necessary to carry out the purpose of this section.

History: (2002, P.A. 02-41, §I; 2003, P.A. 03-164, §I; 2003, June 30 Sp.Sess., P.A. 03-6, § 146, eff. July 1, 2004; 2004, P.A. 04-169, § 17, eff. June 1, 2004; 2004, P.A. 04-189, §I, eff. June 1, 2004; 2005, P.A. 05-217, § 1; 2010, P.A. 10-117, § 91.)

NABPLAWOS/2013

**NABPLAW Online/CONNECTICUT/CONNECTICUT Commission of Pharmacy Regulations./CT BReg Title 20 Professional Licenses. Dept of Consumer Protection (8)/CT BReg Collaborative Drug Therapy Management/CT BReg Sec. 20-631-2. Content of a collaborative drug therapy management agreement**

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**CT BReg Sec. 20-631-2.**

**Content of a collaborative drug therapy management agreement**

A collaborative drug therapy management agreement shall include:

- (1) The types of prescriptive authority decisions the pharmacist may make (e.g., **initiation**, continuation or modification);
- (2) Patients who are eligible for treatment;
- (3) The types of diseases, drugs, or drug categories involved (there are no limitations on disease states or conditions);
- (4) The procedures, decision criteria, plans, or guidelines the pharmacist is to follow when making therapeutic decisions, particularly when **initiating** or modifying drug therapy;
- (5) Required training;

- (6) A plan for periodic review, feedback and quality assurance; and
- (7) Procedures for documenting prescribing decisions.

History: (Added effective January 2, 2013.)

NABPLAWOS/2013

NABPLAW Online/CONNECTICUT/CONNECTICUT Commission of Pharmacy Regulations.ICT BReg Title 20 Professional Licenses. Dept of Consumer Protection (8)/CT BReg Collaborative Drug Therapy Management/CT BReg Sec. 20-631-3. Content of patient protocol

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CT BReg Sec. 20-631-3.  
Content of patient protocol

A written protocol for a specific patient established pursuant to a collaborative drug therapy management agreement shall include, but need not be limited to, the following:

- (1) The specific drug or drugs to be managed by the pharmacist;
- (2) The terms and conditions under which drug therapy may be implemented, modified or discontinued;
- (3) The conditions and events that the pharmacist is required to report to the physician;
- (4) The laboratory tests that may be ordered by the pharmacist; and
- (5) The drugs that may be administered by the pharmacist.

History: (Added effective January 2, 2013.)

NABPLAWOS/2013

#### District of Columbia

NABPLAW Online/DISTRICT OF COLUMBIA/DISTRICT OF COLUMBIA Pharmacy Practice Act/DC PracAct Division I. Government of District!DC PracAct Title 3. District of Columbia Boards and Commissions/De PracAct Subtitle I. General/De PracAct Chapter 12. Health Occupations Boards/DC PracAct Subchapter II. Establishment of Health Occupations Boards and Administrative Committees; Membership; Terms/DC PracAct 3-1202.08. Board of Pharmacy.

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DC PracAct 3-1202.08.  
Board of Pharmacy.

- (a) There is established a Board of Pharmacy to consist of 7 members appointed by the Mayor.
- (b)(1) The Board shall regulate the practice of pharmacy and the practice of pharmaceutical detailing.
- (2) The Board is authorized to:
  - (A) Establish a code of ethics for the practice of pharmaceutical detailing; and
  - (B) Collect information from licensed pharmaceutical detailers relating to their communications with licensed health professionals, or with employees or representatives of licensed health professionals, located in the District.
- (c) Of the members of the Board, 5 shall be pharmacists licensed in the District and 2 shall be consumer members.
- (d) Except as provided in subsection (e) of this section, members of the Board shall be appointed for terms of 3 years.
- (e) Of the members initially appointed under this section, 2 shall be appointed for a term of 1 year, 2 shall be appointed for a term of 2 years, and 3 shall be appointed for a term of 3 years.
- (f) An individual licensed to practice pharmacy pursuant to this chapter may administer immunizations and vaccinations only if certified to do so by the Board and only pursuant to a written protocol and valid prescription or standing order of a physician.
- (g) The Board and the Board of Medicine shall jointly develop and promulgate regulations to implement and regulate the administration of vaccinations and immunizations by pharmacists and to authorize pharmacists certified to administer vaccinations and immunizations to administer emergency anaphylactic reaction treatment pursuant to an approved physician-pharmacist protocol.
- (h)(1) A licensed pharmacist may **initiate**, modify, or discontinue a drug therapy regimen pursuant to a collaborative practice agreement with a licensed physician, or, pursuant to § 3-1204.12, other health practitioner.
- (2) The Board and the Board of Medicine shall jointly develop and issue regulations governing the implementation and use of collaborative practice agreements between a licensed pharmacist and a licensed physician. At minimum, the regulations shall:
  - (A) Require that all collaborative practice agreements include:
    - (i) Specification of the drug therapy to be provided and any tests that may be necessarily incident to its provision;
    - (ii) The conditions for **initiating**, modifying, or discontinuing a drug therapy; and

(iii) Directions concerning the monitoring of a drug therapy, including the conditions that would warrant a modification to the dose, dosage regime, or dosage form of the drug therapy; and

(B) Establish policies and procedures for approving, disapproving, and revoking collaborative practice agreements.

History: (Mar. 25, 1986, D.C. Law 6-99, § 208, 33 DCR 729; Mar. 26, 2008, D.C. Law 17-131, § 102(c), 55 DCR 1659; Mar. 20, 2009, D.C. Law 17-306, § 2(b), 56 DCR 23; Oct. 22, 2012, D.C. Law 19-185, § 2(b), 59 DCR 9454.)

*NABPLAW0412013*

## **Idaho**

**NABPLAW Online/IDAHO/IDAHO Board of Pharmacy Regulations/ID BReg Agency 27. Idaho State Board of Pharmacy/ID BReg Title 01./ID BReg Chapter 01. Rules of the Idaho State Board of Pharmacy/ID BReg 010. Definitions and Abbreviations (A-1).**

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### **ID BReg 010.**

#### **Definitions and Abbreviations (A - I).**

**13. Collaborative Pharmacy Practice.** A pharmacy practice whereby one (1) or more pharmacists jointly agree to work under a protocol authorized by one (1) or more prescribers to provide patient care and DTM services not otherwise permitted to be performed by a pharmacist under specified conditions or limitations. (3-21-12)

**14. Collaborative Pharmacy Practice Agreement.** A written agreement between one (1) or more pharmacists and one (1) or more prescribers that provides for collaborative pharmacy practice. (3-21-12)

**24. DTM - Drug Therapy Management.** Selecting, initiating, or modifying drug treatment pursuant to a collaborative practice agreement. (3-21-12)

*NABPLAW04/2013*

**NABPLAW Online/IDAHO/IDAHO Board of Pharmacy Regulations/ID BReg Agency 27. Idaho State Board of Pharmacy/ID BReg Title 01./ID BReg Chapter 01. Rules of the Idaho State Board of Pharmacy/ID BReg 310. Pharmacist Collaborative Pharmacy Practice.**

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### **ID BReg 310.**

#### **Pharmacist Collaborative Pharmacy Practice.**

Pharmacists and prescribers may enter into collaborative pharmacy practice through a written collaborative pharmacy practice agreement that defines the nature and scope of authorized DTM or other patient care services to be provided by a pharmacist. (3-21-12)

**01. Agreement Elements.** The collaborative pharmacy practice agreement must include: (3-21-12)

- a. Identification of the parties to the agreement; (3-21-12)
- b. The establishment of each pharmacist's scope of practice authorized by the agreement, including a description of the types of permitted activities and decisions; (3-21-12)
- c. The drug name, class, or category and protocol, formulary, or clinical guidelines that describe or limit a pharmacist's authority to perform DTM; (3-21-12)
- d. A described method for a prescriber to monitor compliance with the agreement and clinical outcomes of patients and to intercede where necessary; (3-21-12)
- e. A provision documenting a prescriber's right to override a collaborative practice decision made by a pharmacist whenever deemed necessary or appropriate; (3-21-12)
- f. A provision allowing any party to cancel the agreement by written notification; (3-21-12)
- g. An effective date; and (3-21-12)
- h. Signatures of the parties to the agreement and dates of signing. (3-21-12)
- i. Amendments to a collaborative pharmacy practice agreement must be documented, signed, and dated. (3-21-12)

**02. Board Review.** The original collaborative pharmacy practice agreement and any subsequent revisions must be made available to the Board upon request. (3-21-12)

**03. Agreement Review.** The collaborative pharmacy practice agreement must be reviewed and renewed annually and revised when necessary or appropriate. (3-21-12)

**04. Documentation of Pharmacist Activities.** The patient care provided pursuant to the agreement must be documented in the patient's permanent record in a manner that allows it to be readily available to other healthcare professionals providing care to the patient. (3-21-12)

*NABPLAW04/2013*

**NABPLAW Online/IOWA/IOWA Board of Pharmacy Examiners Regulations/fA BReg Agency 657. Pharmacy Board/IA BReg Chapter 8. Universal Practice Standards/fA BReg 657-8.34 (155A). Collaborative drug therapy management.**

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**IA BReg 657-8.34 (155A).**

**Collaborative drug therapy management.**

An authorized pharmacist may only perform collaborative drug therapy management pursuant to protocol with a physician pursuant to the requirements of this rule. The physician retains the ultimate responsibility for the care of the patient. The pharmacist is responsible for all aspects of drug therapy management performed by the pharmacist.

**8.34(1) Definitions.**

*"Authorized pharmacist"* means an Iowa-licensed pharmacist whose license is in good standing and who meets the drug therapy management criteria defined in this rule.

*"Board"* means the board of pharmacy.

*"Collaborative drug therapy management"* means participation by an authorized pharmacist and a physician in the management of drug therapy pursuant to a written community practice protocol or a written hospital practice protocol.

*"Collaborative practice"* means that a physician may delegate aspects of drug therapy management for the physician's patients to an authorized pharmacist through a community practice protocol. *"Collaborative practice"* also means that a P& T committee may authorize hospital pharmacists to perform drug therapy management for inpatients and hospital clinic patients through a hospital practice protocol.

*"Community practice protocol"* means a written, executed agreement entered into voluntarily between an authorized pharmacist and a physician establishing drug therapy management for one or more of the pharmacist's and physician's patients residing in a community setting. A community practice protocol shall comply with the requirements of subrule 8.34(2).

*"Community setting"* means a location outside a hospital inpatient, acute care setting or a hospital clinic setting. A community setting may include, but is not limited to, a home, group home, assisted living facility, correctional facility, hospice, or long-term care facility.

*"Drug therapy management criteria"* means one or more of the following:

1. Graduation from a recognized school or college of pharmacy with a doctor of pharmacy (Pharm.D.) degree;
2. Certification by the Board of Pharmaceutical Specialties (BPS);
3. Certification by the Commission for Certification in Geriatric Pharmacy (CCGP);
4. Successful completion of a National Institute for Standards in Pharmacist Credentialing (NISPC) disease state management examination and credentialing by the NISPC;
5. Successful completion of a pharmacy residency program accredited by the American Society of Health-System Pharmacists (ASHP); or
6. Approval by the board of pharmacy.

*"Hospital clinic"* means an outpatient care clinic operated and affiliated with a hospital and under the direct authority of the hospital's P& T committee.

*"Hospital pharmacist"* means an Iowa-licensed pharmacist who meets the requirements for participating in a hospital practice protocol as determined by the hospital's P& T committee.

*"Hospital practice protocol"* means a written plan, policy, procedure, or agreement that authorizes drug therapy management between hospital pharmacists and physicians within a hospital and the hospital's clinics as developed and determined by the hospital's P& T committee. Such a protocol may apply to all pharmacists and physicians at a hospital or the hospital's clinics or only to those pharmacists and physicians who are specifically recognized. A hospital practice protocol shall comply with the requirements of subrule 8.34(3).

*"IBM"* means the Iowa board of medicine.

*"P& T committee"* means a committee of the hospital composed of physicians, pharmacists, and other health professionals that evaluates the clinical use of drugs within the hospital, develops policies for managing drug use and administration in the hospital, and manages the hospital drug formulary system.

*"Physician"* means a person who is currently licensed in Iowa to practice medicine and surgery, osteopathic medicine and surgery, or osteopathy. A physician who executes a written protocol with an authorized pharmacist shall supervise the pharmacist's activities involved in the overall management of patients receiving medications or disease management services under the protocol. The physician may delegate only drug therapies that are in areas common to the physician's practice.

*"Therapeutic interchange"* means an authorized exchange of therapeutic alternate drug products in accordance with a previously established and approved written protocol.

#### **8.34(2) Community practice protocol.**

*a.* An authorized pharmacist shall engage in collaborative drug therapy management with a physician only under a written protocol that has been identified by topic and has been submitted to the board or a committee authorized by the board. A protocol executed after July 1, 2008, will no longer be required to be submitted to the board; however, written protocols executed or renewed after July 1, 2008, shall be made available upon request of the board or the IBM.

*b.* The community practice protocol shall include:

(1) The name, signature, date, and contact information for each authorized pharmacist who is a party to the protocol and is eligible to manage the drug therapy of a patient. If more than one authorized pharmacist is a party to the agreement, the pharmacists shall work for a single licensed pharmacy and a principal authorized pharmacist shall be designated in the protocol.

(2) The name, signature, date, and contact information for each physician who may prescribe drugs and is responsible for supervising a patient's drug therapy management. The physician who initiates a protocol shall be considered the main caregiver for the patient respective to that protocol and shall be noted in the protocol as the principal physician.

(3) The name and contact information of the principal physician and the principal authorized pharmacist who are responsible for development, training, administration, and quality assurance of the protocol.

(4) A detailed written protocol pursuant to which the authorized pharmacist will base drug therapy management decisions for patients. The protocol shall authorize one or more of the following:

1. Prescription drug orders. The protocol may authorize therapeutic interchange or modification of drug dosages based on symptoms or laboratory or physical findings defined in the protocol. The protocol shall include information specific to the dosage, frequency, duration, and route of administration of the drug authorized by the patient's physician. The protocol shall not authorize the pharmacist to change a Schedule II drug or to **initiate** a drug not included in the established protocol.

2. Laboratory tests. The protocol may authorize the pharmacist to obtain or to conduct specific laboratory tests as long as the tests relate directly to the drug therapy management.

3. Physical findings. The protocol may authorize the pharmacist to check certain physical findings, e.g., vital signs, oximetry, or peak flows, that enable the pharmacist to assess and adjust the drug therapy, detect adverse drug reactions, or determine if the patient should be referred back to the patient's physician for follow-up.

4. Patient activities. The protocol may authorize the pharmacist to monitor specific patient activities.

(5) Procedures for securing the patient's written consent. If the patient's consent is not secured by the physician, the authorized pharmacist shall secure such and notify the patient's physician within 24 hours.

(6) Circumstances that shall cause the authorized pharmacist to initiate communication with the physician including but not limited to the need for new prescription orders and reports of the patient's therapeutic response or adverse reaction.

(7) A detailed statement identifying the specific drugs, laboratory tests, and physical findings upon which the authorized pharmacist shall base drug therapy management decisions.

(8) A provision for the collaborative drug therapy management protocol to be reviewed, updated, and reexecuted or discontinued at least every two years.

(9) A description of the method the pharmacist shall use to document the pharmacist's decisions or recommendations for the physician.

(10) A description of the types of reports the authorized pharmacist is to provide to the physician and the schedule by which the pharmacist is to submit these reports. The schedule shall include a time frame within which a pharmacist shall report any adverse reaction to the physician.

(11) A statement of the medication categories and the type of **initiation** and modification of drug therapy that the physician authorizes the pharmacist to perform.

(12) A description of the procedures or plan that the pharmacist shall follow if the pharmacist modifies a drug therapy.

(13) Procedures for record keeping, record sharing, and long-term record storage.

(14) Procedures to follow in emergency situations.

(15) A statement that prohibits the authorized pharmacist from delegating drug therapy management to anyone other than another authorized pharmacist who has signed the applicable protocol.

(16) A statement that prohibits a physician from delegating collaborative drug therapy management to any unlicensed or licensed person other than another physician or an authorized pharmacist.

(17) A description of the mechanism for the pharmacist and the physician to communicate with each other and for documentation by the pharmacist of the implementation of collaborative drug therapy.

c. Collaborative drug therapy management is valid only when initiated by a written protocol executed by at least one authorized pharmacist and at least one physician.

d. The collaborative drug therapy protocol must be filed with the board, kept on file in the pharmacy, and be made available upon request of the board or the IBM. After July 1, 2008, protocols shall no longer be filed with the board but shall be maintained in the pharmacy and made available to the board and the IBM upon request.

e. A physician may terminate or amend the collaborative drug therapy management protocol with an authorized pharmacist if the physician notifies, in writing, the pharmacist and the board. Notification shall include the name of the authorized pharmacist, the desired change, and the proposed effective date of the change. After July 1, 2008, the physician shall no longer be required to notify the board of changes in a protocol but the written notification shall be maintained in the pharmacy and made available upon request of the board or the IBM.

**f** The physician or pharmacist who initiates a protocol with a patient is responsible for securing a patient's written consent to participate in drug therapy management and for transmitting a copy of the consent to the other party within 24 hours. The consent shall indicate which protocol is involved. Any variation in the protocol for a specific patient shall be communicated to the other party at the time of securing the patient's consent. The patient's physician shall maintain the patient consent in the patient's medical record.

### **8.34(3) *Hospital practice protocol.***

a. A hospital's P& T committee shall determine the scope and extent of collaborative drug therapy management practices that may be conducted by the hospital's pharmacists.

b. Collaborative drug therapy management within a hospital setting or the hospital's clinic setting is valid only when approved by the hospital's P& T committee.

c. The hospital practice protocol shall include:

- (1) The names or groups of pharmacists and physicians who are authorized by the P& T committee to participate in collaborative drug therapy management.
- (2) A plan for development, training, administration, and quality assurance of the protocol.
- (3) A detailed written protocol pursuant to which the hospital pharmacist shall base drug therapy management decisions for patients. The protocol shall authorize one or more of the following:
  1. Medication orders and prescription drug orders. The protocol may authorize therapeutic interchange or modification of drug dosages based on symptoms or laboratory or physical findings defined in the protocol. The protocol shall include information specific to the dosage, frequency, duration, and route of administration of the drug authorized by the physician. The protocol shall not authorize the hospital pharmacist to change a Schedule II drug or to **initiate** a drug not included in the established protocol.
  2. Laboratory tests. The protocol may authorize the hospital pharmacist to obtain or to conduct specific laboratory tests as long as the tests relate directly to the drug therapy management.
  3. Physical findings. The protocol may authorize the hospital pharmacist to check certain physical findings, e.g., vital signs, oximetry, or peak flows, that enable the pharmacist to assess and adjust the drug therapy, detect adverse drug reactions, or determine if the patient should be referred back to the physician for follow-up.
- (4) Circumstances that shall cause the hospital pharmacist to initiate communication with the patient's physician including but not limited to the need for new medication orders and prescription drug orders and reports of a patient's therapeutic response or adverse reaction.
- (5) A statement of the medication categories and the type of **initiation** and modification of drug therapy that the P& T committee authorizes the hospital pharmacist to perform.
- (6) A description of the procedures or plan that the hospital pharmacist shall follow if the hospital pharmacist modifies a drug therapy.
- (7) A description of the mechanism for the hospital pharmacist and the patient's physician to communicate and for the hospital pharmacist to document implementation of the collaborative drug therapy.

*NABPLAW0612013*

## **Kentucky**

**NABPLAW Online/KENTUCKY/KENTUCKY Board of Pharmacy Regulations/KY BReg Title 201. Chapter 2. Board of Pharmacy/KY BReg 201 KAR 2:220. Collaborative Care Agreements.**

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**KY BReg 201 KAR 2:220.**  
**Collaborative Care Agreements.**

Section 1. A collaborative care agreement shall:

- (1) Be in writing;
- (2) Be signed and dated by the:
  - (a) Individual practitioner;
  - (b) Individual pharmacist; and
  - (c) Patient or care giver;
- (3) Provide that upon termination of the agreement the individual practitioner or individual pharmacist shall notify the patient in writing;
- (4) State the method for termination of the agreement; and
- (5) Contain the information specified by Section 2 of this administrative regulation.

Section 2. A collaborative care agreement shall contain the following information:

- (1) Patient name;
- (2) Patient address and telephone number;
- (3) Protocol, criteria, standing orders, or other method by which services are authorized;
- (4) The method established for the assessment of patient outcomes, if appropriate; and
- (5) Lab tests that may be ordered.

Section 3. The following information relating to a collaborative care agreement shall be maintained by a pharmacist and shall be provided to the collaborating practitioner:

- (1) Emergency notification contact;
- (2) Date of birth, weight, height, and gender;
- (3) Prescription regimen;
- (4) Nonprescription regimen;
- (5) Medical history; including:
  - (a) Known diseases;

- (b) Known allergies; and
- (c) Reactions and conditions relating to;
  - 1. Prescription regimens; and
  - 2. Nonprescription regimens;
- (6) Lab tests ordered, including results of lab tests;
- (7) Assessments of patient outcomes;
- (8) Notes relating to contacts between the individual pharmacist and the individual practitioner concerning the care and course of therapy of the patient; and
- (9) Documentation of the specific counseling information provided to the patient or care giver.

Section 4. A collaborative care agreement, and information and records required by the provisions of this administrative regulation, shall be maintained:

- (1) At the pharmacist's practice site; and
- (2) For at least five (5) years after termination.

History: Adopted effective June 16, 1997; Amended effective August 1, 2008.

NABPLAW 05/2013

**NABPLAW Online/KENTUCKY/KENTUCKY Pharmacy Practice Act/KY PracAct Title XXVI. Occupations and Professions/KY PracAct Chapter 315. Pharmacists and Pharmacies/KY PracAct 315.010. Definitions for chapter.**

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**KY PracAct 315.010.  
Definitions for chapter.**

As used in this chapter, unless the context requires otherwise:

(4) "Collaborative care agreement" means a written agreement between a specifically identified individual practitioner and a pharmacist who is specifically identified, whereby the practitioner outlines a plan of cooperative management of a specifically identified individual patient's drug-related health care needs that fall within the practitioner's statutory scope of practice. The agreement shall be limited to specification of the drug-related regimen to be provided and any tests which may be necessarily incident to its provisions; stipulated conditions for **initiating**, continuing, or discontinuing drug therapy; directions concerning the monitoring of drug therapy

and stipulated conditions which warrant modifications to dose, dosage regimen, dosage form, or route of administration;

History: 2011 c 81, § 1, eff. 6-8-11; 2010 c 22, § 5, c 37, § 1, eff. 7-15-10; 2007 c 124, § 8, eff. 6-26-07; 2005 c 150, § 18, eff. 6-20-05; 2004 c 10, § 1, eff. 7-13-04; 1998 c 531, § 3, c 297, § 4, c 301, § 27, eff. 7-15-98; 1996 c 257, § 3, eff. 7-15-96; 1982 c 191, § 1, eff. 7-15-82; 1970 c 221, § 1; 1960 c 234, § 1; 1942 c 208, § 1

NABPLAW05/2013

## **Massachusetts**

**NABPLAW Online/MASSACHUSETTS/MASSACHUSETTS Board of Registration in Pharmacy Regulations/MA BReg Title 247. Board of Registration in Pharmacy/MA BReg Chapter 16.00. Collaborative Drug Therapy Management./MA BReg 16.01. Definitions.**

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### **MA BReg 16.01.**

#### **Definitions.**

Additional definitions applicable to the practice of CDTM in the Commonwealth appear in Board of Registration in Medicine regulations at 243 CMR 2.12 and Board of Registration in Pharmacy regulations at 247 CMR 2.00.

As used in 247 CMR 16.00, all references to "written" regarding collaborative practice agreement referrals, consents and any other documents related to a collaborative practice agreement shall be:

- (1) if paper-based, written in ink, indelible pencil or any other means; or
- (2) transmitted electronically in a format that maintains patient confidentiality and can be read and stored in a retrievable and readable form. Collaborative practice agreements and related referrals, consents and other documentation may be transmitted electronically with the electronic signature(s) without alteration of the information, provided the electronic transmission is in accordance with the requirements of M.G.L. c. 94C, § 23, subsection (g); 105 CMR 721.00, and 247 CMR 5.00, 9.01(19) and 9.07(1)(a).

As used in 247 CMR 16.01 and defined in M.G.L. c. 112, § 24B 112, subsection (a), the following words shall have the following meanings:

Authorized Pharmacist means a pharmacist who:

- (1) is currently registered by the Board and in good standing;
- (2) meets the requirements of 247 CMR 16.02; and

(3) is participating in drug therapy management with a supervising physician pursuant to a written CDTM agreement with written protocols.

Board means the Board of Registration in Pharmacy.

Collaborative Drug Therapy Management or CDTM means the **initiating**, monitoring, modifying and discontinuing of a patient's drug therapy by an authorized pharmacist under the supervision of a physician in accordance with a collaborative practice agreement. Collaborative drug therapy management may include: collecting and reviewing patient histories; obtaining and checking vital signs, including pulse, temperature, blood pressure and respiration; and, under the supervision of, or in direct consultation with, a physician, ordering and evaluating the results of laboratory tests directly related to drug therapy when performed in accordance with approved protocols applicable to the practice setting and when the evaluation shall not include a diagnostic component.

Collaborative Practice Agreement or CDTM Agreement means a written and signed agreement between an authorized pharmacist with training and experience relevant to the scope of the collaborative practice and a supervising physician that defines the collaborative practice in which the authorized pharmacist and supervising physician propose to engage. The collaborative practice must be within the scope of the supervising physician's practice. In the community pharmacy setting, the CDTM agreement shall include:

- (1) a written referral of a specific patient from the supervising physician to an authorized pharmacist; and
- (2) the written consent of the patient to the CDTM agreement.

Community Pharmacy means a pharmacy or pharmacy department, as defined in 247 CMR 2.00, in a "retail drug business" setting, as referenced in M.G.L. c. 112, § 24B 112, currently licensed by the Board pursuant to M.G.L. c. 112, §§ 38 and 39.

Patient means a person who is referred to an authorized pharmacist by a supervising physician for the purpose of receiving collaborative drug therapy management services from the pharmacist. In a community pharmacy setting:

- (1) the patient must be notified of, and provide written consent to, the collaborative drug therapy management services; and
- (2) in accordance with 243 CMR 2.12, the supervising physician must provide the patient with a copy of the referral to the authorized pharmacist and the written consent to the referral provided by the patient.

Referral means the individual patient referral by a supervising physician to an authorized pharmacist for the purpose of receiving CDTM services in a community pharmacy setting. In other practice settings, "referral" means the consultation of a supervising physician and an authorized pharmacist about a patient for the purpose of receiving CDTM services. In accordance with 243 CMR 2.12, the supervising physician shall execute a written CDTM referral which shall include, but not be limited to, the patient's name and address, the primary diagnosis

for which CDTM services are authorized, the diagnosis of any co-morbid conditions for which CDTM services are authorized, any known patient drug allergies, a statement that the patient has executed a written consent to CDTM services and any other specific instructions to the authorized pharmacist.

Supervising Physician, as defined in 243 CMR 2.12(1), means a physician who:

- (1) holds an active license in good standing to practice medicine in the Commonwealth of Massachusetts; and
- (2) may delegate specific CDTM services to an authorized pharmacist pursuant to the terms of the CDTM agreement with the authorized pharmacist.

NABPLAW04/2013

**NABPLAW Online/MASSACHUSETTS/MASSACHUSETTS Board of Registration in Pharmacy Regulations/MA BReg Title 247. Board of Registration in Pharmacy/MA BReg Chapter 16.00. Collaborative Drug Therapy Management/MA BReg 16.03. Practice Setting Requirements.**

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**MA BReg 16.03.  
Practice Setting Requirements.**

In accordance with M.G.L. c. 112, § 24B 1/2, subsection (c), collaborative drug therapy management may be performed in the following settings by pharmacists meeting the requirements of 247 CMR 16.02(1) and authorized by a supervising physician pursuant to a current collaborative practice agreement:

- (1) Hospitals licensed pursuant to M.G.L. c. 111, § 51, subject to approval by the hospital medical staff executive committee or designee;
- (2) Long-term Care Facilities licensed pursuant to M.G.L. c. 111, § 71, subject to approval by the long-term care facility medical director or designee;
- (3) Inpatient or Outpatient Hospice Settings licensed pursuant to M.G.L. c. 111, § 57D, subject to approval by the hospice medical director or designee;
- (4) Ambulatory Care Clinics licensed pursuant to M.G.L. c. 111, § 51, with on-site supervision by an attending physician affiliated with the ambulatory clinic and an authorized pharmacist, subject to approval by the ambulatory care clinic medical staff executive committee or designee, or medical director or designee;
- (5) Community Pharmacies (retail drug business settings) licensed by the Board pursuant to M.G.L. c. 112, § 39, subject to the restrictions listed below and pursuant to a current collaborative practice agreement that includes the following requirements:

(a) Patient Age. Patients must be 18 years of age or older.

(b) Vaccine Administration. Pharmacists, as authorized pursuant to a collaborative practice agreement, may administer vaccines.

(c) Patient Referral and Consent. In accordance with 243 CMR 2.12, the collaborative practice agreement must provide that the supervising physician will:

1. provide a written referral of the patient to the authorized pharmacist;
2. specify the primary diagnosis for the patient and any secondary diagnoses in the written referral or a subsequent referral;
3. provide a copy of the written referral of the patient to the authorized pharmacist for CDTM services to the patient; and
4. obtain the patient's written informed consent to the collaboration in the collaborative practice agreement and provide a copy of the consent to the patient.

(d) Record of Referral and Consent. The authorized pharmacist and supervising physician must maintain a written record of both the individual patient referral and the patient's written informed consent to the collaboration in the patient's records which are maintained by the authorized pharmacist and the supervising physician. In accordance with 243 CMR 2.12, the supervising physician shall:

1. maintain the original patient consent to the referral in the record in the custody of the supervising physician;
2. transmit a copy of the patient's consent to the authorized pharmacist within 24 hours; and
3. provide copies of the referral and consent to the patient in a timely manner.

(e) Limited Prescribing Authority.

1. An authorized pharmacist currently registered by the Department, pursuant to M.G.L. c. 94C, §§ 7 and 9 and 105 CMR 700.000, to prescribe and possess controlled substances, who practices in a community pharmacy pursuant to a collaborative practice agreement that includes individually developed prescriptive practice guidelines pursuant to which the supervising physician has authorized the pharmacist to prescribe, may:

- a. extend current drug therapy by 30 days for not more than two 30 day periods or as may otherwise be specifically authorized by the supervising physician in the referral of the patient and as provided in the CDTM agreement;
- b. **initiate**, modify or discontinue dosages of medications prescribed by the supervising physician for:
  - i. asthma;

- ii. chronic obstructive pulmonary disease;
  - iii. diabetes;
  - iv. hypertension;
  - v. hyperlipidemia;
  - vi. congestive heart failure;
  - vii. HIV or AIDS;
  - viii. osteoporosis; and
  - ix. co-morbidities listed in 247 CMR 16.03(5)(e)l.b.i. through viii. and identified by the supervising physician along with the primary diagnosis in the supervising physician's referral of the patient.
2. The authorized pharmacist must provide a copy of an initial prescription or a modification or discontinuation of a prescription to the supervising physician within 24 hours of issuance, unless more urgent notification is required under the circumstances and must note the action taken in the patient's medical record. A copy of all prescriptions must be included in the patient's medical record in the custody of the supervising physician.
3. No authorized pharmacist in a community pharmacy may prescribe or be authorized to prescribe Schedule II through V controlled substances, as defined in M.G.L. c. 94C, § 3, subsections (2) through (5).
4. An authorized pharmacist in a community pharmacy may be authorized by a supervising physician to issue prescriptions for Schedule VI controlled substances, as defined in M.G.L. c. 94C, § 3, subsection (6), for the diagnoses specified in the supervising physician's patient referral.

NABPLAW04/2013

**NABPLAW Online/MASSACHUSETTS/MASSACHUSETTS Board of Registration in Pharmacy Regulations/MA BReg Title 247. Board of Registration in Pharmacy/MA BReg Chapter 16.00. Collaborative Drug Therapy Management./MA BReg 16.04. Collaborative Practice Agreements - Required Agreement Terms for All Practice Settings; Duties; Biennial Renewal; Termination; Agreement to be Filed in Primary Practice Setting; and Employment Relationships.**

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**MA BReg 16.04.**

**Collaborative Practice Agreements - Required Agreement Terms for All Practice Settings;**

**Duties; Biennial Renewal; Termination; Agreement to be Filed in Primary Practice Setting; and Employment Relationships.**

(1) Required Agreement Terms for All Practice Settings. In addition to specific practice setting collaborative practice agreement requirements, pursuant to 247 CMR 16.03, and in accordance with M.G.L. c. 112, § 24B 3/4 and 243 CMR 2.12, all collaborative practice agreements must also include:

- (a) specific disease state(s) being co-managed, with each disease state identified as either primary or co-morbid;
  - (b) specific pharmacist prescribing authority pursuant to the CDTM agreement;
  - (c) detailed practice protocols;
  - (d) description of risk management activities;
  - (e) documentation of any **initiation**, modification or discontinuation of a patient's medication in the patient's permanent medical record;
  - (f) description of outcome measurements;
  - (g) detailed informed consent procedures appropriate to the practice setting;
  - (b) detailed procedures and periods by which time any test results, copies of initial prescriptions, modifications or discontinuances, copies of the patient consent and the CDTM agreement, and other patient information will be forwarded by the authorized pharmacist to the supervising physician, and a specific procedure for the authorized pharmacist to identify and transmit any urgent communications; description of the nature and form of the supervision of the authorized pharmacist by the supervising physician, and a description of the procedure to follow when either the authorized pharmacist or supervising physician is unavailable or absent;
  - (i) the authorized pharmacist's attestation of satisfaction of the qualifications listed in 247 CMR 16.02(1) for participating in collaborative drug therapy management; and
  - (j) the supervising physician's attestation of satisfaction of the qualifications listed in 243 CMR 2.12 for participating in collaborative drug therapy management.
- (2) Duties. A collaborative practice agreement shall specify those duties of the authorized pharmacist that may be delegated to other appropriately trained and authorized staff and those duties under the agreement that shall not be delegated. A collaborative practice agreement shall specify when and how an authorized pharmacist may delegate duties under the agreement, and the duration and scope of the delegation..Pharmacy interns and pharmacy technician duties providing support to an authorized pharmacist acting pursuant to a collaborative practice agreement must perform services in accordance with 247 CMR 8.01 (pharmacy interns) and 8.02 through 8.06 (pharmacy technicians).

(3) Biennial Renewal. A collaborative practice agreement must be reviewed and renewed by the authorized pharmacist and supervising physician(s) at least every two years.

(4) Termination. Prior to termination or non-renewal of a CDTM agreement, an authorized pharmacist and supervising physician shall arrange for an uninterrupted continuation of the patient's drug therapy, in accordance with the terms of the CDTM agreement. When a CDTM agreement is not renewed or CDTM is otherwise terminated, an authorized pharmacist and supervising physician shall inform the patient in writing of the termination and of the procedures in place for the continuation of the patient's drug therapy, in accordance with the terms of the CDTM agreement.

(5) Agreement to be Filed in Primary Practice Setting. An authorized pharmacist must maintain a copy of the current CDTM agreement, including copies of current patient referral and patient consent, in the primary practice setting, readily retrievable at the request of the Board of Registration in Pharmacy and Board of Registration in Medicine. In accordance with 243 CMR 2.12, the supervising physician must maintain the original of the current CDTM agreement, including the original current patient referral and patient consent, in the patient's medical record in the custody of the supervising physician.

(6) Employment Relationships. In accordance with M.G.L. c. 112, § 24B 112, subsection (e):

(a) A qualified pharmacist may be hired by a physician or group of physicians for the purpose of practicing collaborative drug therapy management under an agreement for the benefit of a patient of that physician or physician group;

(b) A community pharmacy may hire a physician or licensed medical practitioner to conduct quality assurance reviews of pharmacists engaged in collaborative drug therapy management; and

(c) No community pharmacy may employ a physician for the purpose of maintaining, establishing or entering into a collaborative practice agreement.

*NABPLAW04/2013*

**NABPLAW Online/MASSACHUSETTS/MASSACHUSETTS Board of Registration in Pharmacy Regulations/MA BReg Title 105. Department of Public Health/MA BReg Chapter 700.000. Implementation of M.G.L.C. 94C/MA BReg 700.003. Registration of Persons for a Specific Activity or Activities in Accordance with M.G.L. c. 94C, Section 7(g).**

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**MA BReg 700.003.**

**Registration of Persons for a Specific Activity or Activities in Accordance with M.G.L. c. 94C, Section 7(g).**

(I) A pharmacist may issue, modify or discontinue a written prescription, oral prescription or medication order as authorized in a collaborative practice agreement meeting the requirements of 247 CMR 16.00: *Collaborative Drug Therapy Management*, 243 CMR 2.12: *Collaborative Drug Therapy Management (CDTM) with Authorized Pharmacies* and M.G.L. c. 112, § 24B1/2, provided the following requirements are met:

- (1) the pharmacist meets all applicable requirements of the Board of Registration in Pharmacy established in accordance with M.G.L. c. 112, § 24 and 247 CMR 1.00 through 16.00;
- (2) the pharmacist registers with the Department of Public Health, in accordance with 105 CMR 700.004, and the Drug Enforcement Administration, if applicable, in accordance with 21 CFR 1300, for the purpose of prescribing under 105 CMR 700.000;
- (3) the pharmacist issues, modifies or discontinues a prescription or medication order in accordance with M.G.L. c. 112, § 24B1/2, 105 CMR 700.000, regulations of the Board of Registration in Pharmacy, 247 CMR 16.00, regulations of the Board of Registration in Medicine, 243 CMR 2.12, and the collaborative practice agreement between the pharmacist and supervising physician established in accordance with 247 CMR 16.00 and 243 CMR 2.12;
- (4) the pharmacist, if practicing in a retail setting, may issue a written prescription for a controlled substance in Schedule VI only, in accordance with 105 CMR 700.003(1)(3);
- (5) the pharmacist may dispense a controlled substance for immediate treatment in accordance with M.G.L. c. 94C, § 9, provided the pharmacist is authorized by 105 CMR 700.003(1) to prescribe such controlled substance;
- (6) the pharmacist may order from a drug wholesaler, manufacturer, laboratory or distributor, for purposes of dispensing for immediate treatment, those controlled substances in Schedule VI which the pharmacist is authorized by 105 CMR 700.003(1) and the collaborative practice agreement to prescribe. For the purposes of dispensing controlled substances in Schedules II through V for immediate treatment in accordance with 105 CMR 700.003(1)(5), the pharmacist may obtain such controlled substances only as supplied by the supervising physician or obtained through a written prescription or medication order for the patient;
- (7) the pharmacist may issue an oral prescription in accordance with M.G.L. c. 94C, § 20, provided that the prescribing pharmacist clearly identifies his or her name and professional designation to the dispensing pharmacist and provides his or her registration number, work address, phone number, and the name of the supervising physician. An oral prescription shall be followed up with a written prescription by the prescribing pharmacist to be provided to the dispensing pharmacist or postmarked within a period of not more than seven days or such shorter period as required by federal law, in accordance with M.G.L. c. 94C, § 20;
- (8) the pharmacist may prescribe a controlled substance for a patient in a licensed health facility, including a hospital, long term care facility, ambulatory care clinic or hospice, through the use of a written medication order entered on the patient's medical record maintained at the facility, provided that such a written order meets all applicable provisions of 105 CMR 700.000;

(9) the pharmacist maintains a record of any controlled substance maintained for the purpose of dispensing for immediate treatment or administering pursuant to 105 CMR 700.000 and any related Department guidelines;

(10) the pharmacist provides a copy of an initial prescription or a modification or discontinuation of a prescription to the supervising physician within 24 hours of its issuance, unless more urgent notification is required under the circumstances.

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**NABPLAW Online/MASSACHUSETTS/MASSACHUSETTS Pharmacy Practice Act/MA PracAct Part I. Administration of the Government/MA PracAct Title XVI. Public Health/MA PracAct Chapter 112. Registration of Certain Professions and Occupations/MA PracAct Registration of Pharmacists/MA PracAct 248 112. Pharmacist collaborative practice agreements; collaborative drug therapy management.**

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**MA PracAct 248 1/2 .**

**Pharmacist collaborative practice agreements; collaborative drug therapy management.**

(a) As used in this section and section 24B the following words shall, unless the context clearly requires otherwise, have the following meanings:--

"Collaborative drug therapy management", the **initiating**, monitoring, modifying and discontinuing of a patient's drug therapy by a pharmacist in accordance with a collaborative practice agreement; provided, however, that collaborative drug therapy management may include: collecting and reviewing patient histories; obtaining and checking vital signs, including pulse, temperature, blood pressure and respiration; and, under the supervision of, or in direct consultation with, a physician, ordering and evaluating the results of laboratory tests directly related to drug therapy when performed in accordance with approved protocols applicable to the practice setting and when the evaluation shall not include a diagnostic component.

"Collaborative practice agreement", a written and signed agreement between a pharmacist with training and experience relevant to the scope of the collaborative practice and a supervising physician that defines the collaborative practice in which the pharmacist and supervising physician propose to engage. The collaborative practice shall be within the scope of the supervising physician's practice. Each collaborative practice agreement shall be subject to review and renewal on a biennial basis. A collaborative practice agreement shall include individually developed guidelines for any prescriptive practice of the pharmacist.

"Commissioner", the commissioner of the department of public health.

"Department", the department of public health.

"Patient", a person who is referred to a pharmacist by his supervising physician for the purpose of receiving collaborative drug therapy management services from the pharmacist. The supervising physician shall assess the patient and include a diagnosis when referring the patient to the collaborating pharmacist. The patient shall be notified of, and shall consent to, the collaborative drug therapy management services in the retail drug business setting. Individual referral and consent shall be recorded by the pharmacist and the supervising physician in the patient's record.

(b) In order for a pharmacist to enter into a collaborative practice agreement, the pharmacist shall: (1) hold a current license to practice pharmacy in the commonwealth and currently be engaged in pharmacy practice in the commonwealth; (2) have at least \$1,000,000 of professional liability insurance; (3) have earned a doctor of pharmacy degree or have completed 5 years of experience as a licensed pharmacist or the equivalent; (4) agree to devote a portion of his practice to the defined drug therapy area that the pharmacist shall co-manage; and (5) agree to complete, in each year of the agreement, at least 5 additional contact hours or 0.5 continuing education units of board-approved continuing education that addresses areas of practice generally related to collaborative practice agreements.

(c) Collaborative drug therapy management shall only be allowed in the following settings: (1) hospitals licensed pursuant to section 51 of chapter 111, subject to approval by the medical staff executive committee at a licensed hospital or designee; (2) long-term care facilities licensed pursuant to section 71 of chapter 111, subject to approval by the long-term care facilities' medical director or designee; (3) inpatient or outpatient hospice settings licensed pursuant to section 57D of chapter 111, subject to approval by the hospice's medical director or designee; (4) ambulatory care clinics licensed pursuant to section 51 of chapter 111, with on-site supervision by the attending physician and a collaborating pharmacist, subject to approval by the ambulatory care clinic's medical staff executive committee or designee, or medical director or designee; (5) a collaborating pharmacist in a retail drug business, as registered in section 38 of chapter 112 and limited by this section, with supervision by a physician according to the terms of his collaborative practice agreement and limited to the following: patients 18 years of age or older; an extension by 30 days of current drug therapy prescribed by the supervising physician; and administration of vaccines or the modification of dosages of medications prescribed by the supervising physician for asthma, chronic obstructive pulmonary disease, diabetes, hypertension, hyperlipidemia, congestive heart failure, HIV or AIDS, osteoporosis and co-morbidities identified by the supervising physician for the individual patient along with the primary diagnosis. The collaborative practice agreement shall specifically reference each disease state being co-managed. A patient shall be referred by a supervising physician to that physician's collaborating pharmacist and shall be given notice of the collaboration and shall consent to the collaboration. No collaborative practice agreement in the retail drug business setting may permit the prescribing of schedule II through V controlled substances, as defined in section 3 of chapter 94C. A pharmacist in the retail setting, who has a collaborative practice agreement with a supervising physician which specifically allows initial prescriptions for referred patients of the supervising physician, may issue prescriptions for schedule VI controlled substances, as defined in clause 6 of section 3 of chapter 94C. Such prescriptions shall be for a patient diagnosis specified in the supervising physician's individual referral of that patient. A copy of the prescription shall be sent to the supervising physician within 24 hours.

(d) A retail drug business practicing in collaborative drug therapy management under this section shall not be required to register as a Health Facility under 105 CMR 700.004(A)(2)(d).

(e) A physician or a physician group may hire pharmacists for the purpose of practicing collaborative drug therapy management under a collaborative practice agreement, as defined in subsection (a), for the benefit of a patient of that physician or physician group. No retail pharmacy may employ a physician for the purpose of maintaining, establishing or entering into a collaborative practice agreement with a patient. Nothing shall prohibit a retail pharmacy from hiring a physician or licensed medical practitioner for the purpose of conducting quality assurance reviews of its pharmacists that are engaged in the practice of collaborative drug therapy.

History: Added by St.2008, c. 528, § 3, eff. April 15, 2009.

*NABPLAW04/2013*

## Mississippi

**NABPLAW Online/MISSISSIPPI/MISSISSIPPI State Board of Pharmacy Regulations/Title 30. Professions and Occupations/MS BReg Subtitle 20. Board of Pharmacy/Part 3001. Board Regulations/MS BReg 30-20-3001:XXIX. Regulations Governing Institutional Pharmacy.**

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### **MS BReg 30-20-3001:XXIX. Regulations Governing Institutional Pharmacy.**

1. **APPLICABILITY:** The following rules and regulations are applicable to all pharmacies classified and authorized by permit to operate as institutional pharmacies. All rules, regulations and laws which pertain to the practice of pharmacy in the retail setting shall be applied to those aspects of institutional practice which handle, prepare and dispense medications for use outside the confines of the institution, except that none shall be construed to prohibit the extension of a formulary system to outpatient dispensing.

2. **REGISTRATION:** No institutional pharmacy shall be operated before it has been registered with the Mississippi Board of Pharmacy and received an Institutional Permit in conformity with the requirements of ARTICLE VI of the regulations of the Mississippi Board of pharmacy.

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### **10. INITIATION OR MODIFICATION OF DRUG THERAPY**

Pharmacists may **initiate** or modify drug therapy after a written protocol indicating approval by a licensed practitioner has been placed on file at the institutions pharmacy. Such protocol must define the agreement by which the practitioner delegated prescriptive authority and the authority

granted must be within the scope of the practitioner's current practice. Any modification shall be treated as a new protocol.

A. Protocols shall include the following:

- (1) Identification of the practitioner and the scope of the practitioner's active practice;
- (2) Specifications of the type of prescriptive authority to be exercised which shall include a description of the types of medical conditions, drugs or drug categories, together with any special condition;
- (3) Mechanism for communication or feedback to the authorizing practitioner;
- (4) Documentation of the prescriptive activities performed;
- (5) Specification of the duration of the protocol agreement not to exceed two years;
- (6) Protocols must be signed by the authorizing practitioner.

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History: Amended Jan. 31, 2011; June 3, 2012; Jan. 1, 2013; April 26, 2013.

*NABPLAW07/2013*

**NABPLAW Online/MISSISSIPPI/MISSISSIPPI State Board of Pharmacy  
Regulationsffitle 30. Professions and Occupations/MS BReg Subtitle 20. Board of  
Pharmacy/Part 3001. Board Regulations/MS BReg 30-20-3001:XXXVI. Pharmaceutical  
Health Care/Initiation and/or Modification of Drug Therapy under Protocol.**

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**MS BReg 30-20-3001:XXXVI.**

**Pharmaceutical Health Care/Initiation and/or Modification of Drug Therapy under  
Protocol.**

1. Pharmacists may provide pharmaceutical health care to patients by **initiating** and/or modifying prescription drug therapy after a written protocol, indicating approval by a licensed practitioner who is authorized to prescribe prescription drugs, has been placed on file at the office of the Board. Any such protocol must define the agreement by which the practitioner delegates this authority and any such authority granted must be within the scope of the practitioner's prescribing authority and current practice. Any modification of the agreement must be treated as a new protocol.

For purposes of this ARTICLE "written protocol" shall mean an agreement in which any practitioner authorized to prescribe drugs delegates to a pharmacist authority to conduct specific **initiation** and/or modification of drug therapy functions in an institutional setting. In a

community phannacy out-patient setting, a specific protocol agreement shall be signed on each patient for whom a practitioner delegates any authority to **initiate** or modify drug therapy.

2. Unless specifically authorized by the Board, no person shall **initiate** or modify drug therapy under a protocol agreement unless he/she is certified and possesses the following qualifications; and

A. Have and maintain a license to practice phannacy issued by the Mississippi Board of Phannacy; and

B. Have attended and successfully completed at least sixteen (16) hours of continuing education consisting of basic phannaceutical care, development of patient care plans and the clinical practice of phannacy which has been approved by the Board; and in addition

C. Have attended and successfully completed a Board pre-approved study course consisting of not less than sixteen (16) hours of continuing education focusing on a specific disease state, patient care plans and protocol management.

Phannacists shall, on a biennial basis, obtain re-certification in each disease state by successfully completing a continuing education program consisting of not less than six (6) hours focusing on nationally recognized updates.

Phannacists who have successfully completed any study course(s) focusing on disease state management and protocols or re-certification, shall send to the Board office copies of any documents certifying such on request.

3. Protocol agreements shall meet the following requirements:

A. Identification of the practitioner who agrees to supervise the phannacist and the scope of the practitioner's active practice; and

B. Describe the specific responsibilities authorized by the supervising practitioner; and

C. Describe the method the phannacist shall use to document decisions or recommendations the phannacist makes to the supervising practitioner; and

D. Describe the patient activities the supervising practitioner requires the phannacist to monitor; and

E. Describe the types of reports the supervising practitioner requires the phannacist to report and the schedule by which the pharmacist is to submit these reports; and

F. Include a statement of the medication categories and the type of **initiation** and modification of drug therapy that the supervising practitioner authorizes the pharmacist to perform; and

G. Describe the procedures or plan that the pharmacist shall follow if the pharmacist exercises **initiation** and modification of drug therapy; and

H. Indicate the date the supervising practitioner's supervision ends. The duration of the protocol agreement shall not exceed one (1) year; and

I. Be dated and signed by the pharmacist(s) and the supervising practitioner, if more than one practitioner agrees to supervise the pharmacist(s), each practitioner and pharmacist(s) shall sign and date the protocol; and

J. Include a statement that stipulates that the patient has been notified by the pharmacist(s) and the supervising practitioner that a protocol agreement exists.

History: Amended Jan. 31, 2011; June 3, 2012; Jan. 1, 2013; April 26, 2013.

*NABPLAW02/2013*

## **Missouri**

**NABPLAW Online/MISSOURI/MISSOURI Board of Pharmacy Regulations/MO BReg  
Title 20. Dept. of Insurance, Financial Institutions and Professional Registration/MO BReg  
Div. 2220. Chapter 6. Pharmaceutical Care Standards/MO BReg 20 CSR 2220-6.060  
General provisions.**

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### **MO BReg 20 CSR 2220-6.060**

#### **General provisions.**

**PURPOSE:** This rule establishes definitions for 20 CSR 2220-6.060 to 20 CSR 2220-6.080 governing medication therapy services by pharmacists.

(1) Definitions. The following definitions shall apply for purposes of 20 CSR 2220-6.060 to 20 CSR 2220-6.080:

(A) Authorizing physician(s)--The physician identified in the written protocol as authorizing the pharmacist to provide medication therapy services;

(B) Health care entity--For purposes of this rule, a health care entity shall be defined as any entity or organization that is licensed or certified by the state or federal government as a hospital, hospice facility, ambulatory surgical center, nursing home, long-term care facility, residential care facility, assisted living facility, intermediate care facility, skilled nursing facility, or a habilitation center as defined by Chapter 630, RSMo, and that is required to maintain patient medical records by state or federal law;

(C) Medication therapy protocol-- A written agreement between a physician and a pharmacist for the provision of medication therapy services. A medication therapy protocol shall comply with the provisions of 20 CSR 2220-6.080;

(D) Medication therapy services--The designing, initiating, implementing, or monitoring of a plan to monitor the medication therapy or device usage of a specific patient, or to enhance medication therapeutic outcomes of a specific patient, by a pharmacist who has authority to **initiate** or implement a modification of the patient's medication therapy or device usage pursuant to a medication therapy protocol. For purposes of 20 CSR 2220-6.060 to 20 CSR 2220-6.080, modification shall include selecting a new, different, or additional medication or device, discontinuing a current medication or device, or selecting a new, different, or additional strength, dose, dosage form, dosage schedule, or route of administration for a current medication or device, and implementing such selection(s). Medication therapy services shall not include the sole act of dispensing a drug or device pursuant to a valid prescription for the product, generic substitutions made pursuant to section 338.056, RSMo, or medication therapy management that does not include the **initiation** or implementation of a modification of medication therapy, as provided herein;

(E) Pharmacy resident--A Missouri licensed pharmacist enrolled in a residency training program accredited by the American Society of Health-System Pharmacists or a residency training program with a valid application for accreditation pending with the American Society of Health-System Pharmacists;

(F) Prescription order for medication therapeutic plan --A lawful order that is issued by the authorizing physician within the scope of his/her professional practice for the provision of medication therapy services by a pharmacist for a specific patient, including, patients of a health care entity; and

(G) Protocol--A medication therapy protocol, as defined herein.

(2) The provisions of 20 CSR 2220-6.060 to 20 CSR 2220-6.080 and 20 CSR 2150-5.026 to 20 CSR 2150-5.028 shall only be deemed applicable to persons or entities under the jurisdiction of the Missouri State Board of Pharmacy and the Missouri State Board of Registration for the Healing Arts, as established by Chapter 338, RSMo, and Chapter 334, RSMo.

History: sections 338.010, 338.140.1., and 338.380, RSMo Supp. 2011." Original rule filed Jan. 13, 2012, effective Aug. 30, 2012.

*NABPLAW05/2013*

**NABPLAW Online/MISSOURI/MISSOURI Board of Pharmacy Regulations/MO BReg  
Title 20. Dept. of Insurance, Financial Institutions and Professional Registration/MO BReg  
Div. 2220. Chapter 6. Pharmaceutical Care Standards/MO BReg 20 CSR 2220-6.080  
Medication Therapy Services By Protocol.**

**MO BReg 20 CSR 2220-6.080****Medication Therapy Services By Protocol.**

*PURPOSE: This rule establishes procedures for the provision of medication therapy services by protocol, as authorized by section 338.010, RSMo.*

(1) Except as otherwise provided herein, a pharmacist who holds a certificate of medication therapeutic plan authority from the Missouri State Board of Pharmacy shall be authorized to provide medication therapy services in Missouri if the pharmacist--

(A) Holds a current Missouri pharmacist license that is not under discipline with the Missouri State Board of Pharmacy; and

(B) Has entered into a written protocol with a Missouri licensed physician that complies with the requirements of this rule.

(2) General Requirements. A pharmacist may provide medication therapy services only with current certification and as authorized by the protocol and the authorizing physician. A pharmacist providing medication therapy services pursuant to this rule shall comply with the following:

(A) Prior to providing medication therapy services, the pharmacist shall receive a prescription order for a medication therapeutic plan from the authorizing physician for a specific patient which authorizes the pharmacist to perform medication therapy services Except as otherwise provided in subsection (2)(B) of this rule, a prescription order for a medication therapeutic plan shall be valid for no more than one (1) year and shall include:

1. The patient's name, address, and date of birth;
2. The date the prescription order for a medication therapeutic plan is issued;
3. The clinical indication for medication therapy services;
4. The length of time for providing medication therapy services, if less than one (1) year; and
5. The authorizing physician's name and address;

(B) A prescription order for a medication therapeutic plan may be transmitted orally, electronically, or in writing. If an oral prescription order for a medication therapeutic plan is issued, all information required under subsection (2)(A) of this rule shall be documented by the pharmacist and maintained in the patient's record in accordance with section (7) of this rule;

(C) The pharmacist shall review relevant prescription records, patient profiles, patient medical records, or other medical information to determine the services to be rendered; and

(D) In lieu of compliance with 20 CSR 2220-2.018, prescription orders for medication therapy services shall comply with the provisions of this rule, provided the pharmacist shall maintain the

prescription order in the patient record required by section (7) of this rule and shall document any change or alteration made to the prescription ordered based on contact with the prescriber in the applicable patient record.

(3) Authorizing Physician Requirements.

(A) The authorizing physician shall be actively engaged in the practice of medicine in the state of Missouri and shall hold a current and unrestricted Missouri physician license pursuant to Chapter 334, RSMo.

(B) The authorizing physician shall be responsible for the oversight of the medication therapy services provided by the pharmacist that are authorized by protocol. The authorizing physician shall also consider the level of skill, education, training, and competence of the pharmacist and ensure that the activities authorized by the protocol are consistent with the pharmacist's level of skill, education, training, and competence.

(C) The written protocol shall be reviewed and signed by the pharmacist and the authorizing physician at least annually and revised as needed. The authorizing physician and pharmacist shall document the date of the annual review on the written protocol.

(D) The authorizing physician shall review the pharmacist's medication therapy service activities regularly, but not less than once every three (3) months. If the pharmacist is providing medication therapy services for, or on behalf of, a health care entity, the review requirements shall be satisfied if the pharmacist's work and services are reviewed every three (3) months by a clinical care committee, pharmacy and therapeutics committee, or a reviewing body/committee of the health care entity that includes a Missouri-licensed physician. The review required by this subsection may be accomplished in person or by electronic means.

(E) The practice location of the authorizing physician shall be no further than fifty (50) miles by road from the pharmacist identified in the written protocol.

(F) An authorizing physician shall notify the Missouri State Board of Registration for the Healing Arts of a written protocol for medication therapy services entered with a pharmacist at each renewal of the authorizing physician's license.

(4) Protocol Requirements.

(A) The medication therapy services performed by a pharmacist pursuant to the protocol shall be within the authorizing physician's scope of practice and within the skill, education, training, and competence of both the authorizing physician and the pharmacist.

(B) The written protocol between the authorizing physician and pharmacist shall, at a minimum, include the following:

1. The identity and signatures of the authorizing physician and pharmacist;

2. The effective dates of the protocol;
3. A statement of clinical conditions, diagnoses, diseases, and specific drugs, or drug categories included in the written protocol and the type of medication therapy services allowed in each case;
4. A statement of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting medication therapy services;
5. Procedures for documenting medication therapy decisions made by the pharmacist and a plan for communication, feedback, and reporting to the authorizing physician concerning specific decisions made;
6. A mechanism and procedure that allows the authorizing physician to override, rescind, modify, or otherwise amend the protocol. All modifications or amendments to the protocol shall be documented in writing, signed, and dated by all involved parties prior to the implementation of such modification or amendment. The protocol may be immediately rescinded by the authorizing physician or the pharmacist with or without cause, provided the rescission is documented in writing. If any conflict arises regarding the professional judgment of the pharmacist and physician with regard to the subject of the medication therapy services, the physician has ultimate authority;
7. A statement that the pharmacist shall not delegate the responsibility of medication therapy services to another person;
8. A description of any authority granted to the pharmacist to administer any drug or medication including the identification of any such drug, medication, or device;
9. A description of drug therapy related patient assessment procedures or testing that may be ordered or performed by the pharmacist, including any authority to order or perform routine or other laboratory testing;
10. Provisions for allowing the pharmacist to access the patient's medical records for purposes of providing medication therapy services;
11. A provision for providing the authorizing physician access to patient records for medication therapy services provided by the pharmacist for patients of the authorizing physician;
12. Provisions establishing a course of action the pharmacist is authorized to follow to address emergency situations, including, but not limited to, anaphylactic or other adverse medication reactions, adverse needle sticks, or other adverse events;
13. Criteria for timely communication from the authorizing physician to the pharmacist and from the pharmacist to the authorizing physician, not inconsistent with the provisions of this rule;
14. The notification requirements required by section (5) of this rule; and

15. The method for reviewing the pharmacist's medication therapy work or services by the authorizing physician, as required by subsection (3)(D) of this rule.

(C) The written protocol shall include a description of medication therapy services the pharmacist is authorized to render or provide. Such services may include:

- I. Assessing patient-specific data and issues;
2. Establishing medication therapeutic goals or medication related action plans for identified medical conditions and medication related concerns;
3. Assessing and addressing adverse reactions and adverse drug events;
4. Modifying and monitoring medication regimens;
5. Evaluating treatment progress;
6. Assessing and monitoring pharmacokinetic and pharmacodynamic changes in medication regimen reviews;
7. Medication reconciliation;
8. Drug utilization review;
9. Formulating and documenting personal medication records;
10. Documenting clinical outcomes;
- II. Interpreting, monitoring, and assessing patient test results;
12. **Initiation** of drug therapy, as authorized by protocol; and
13. Patient education and counseling.

(D) The protocol required by this section shall be signed and dated by the authorizing physician and the pharmacist. If the protocol includes multiple authorizing physicians or participating pharmacists, a separate protocol shall not be required for each physician or pharmacist if all authorizing physicians and pharmacists have signed and dated a statement agreeing to be governed by the terms of the written protocol.

(E) Any revisions, modifications, or amendments to the protocol must be in writing. The authorizing physician shall promptly notify the pharmacist of any such revision, modification, or amendment and shall maintain documentation of the notification, including the date such notification was made. The authorizing physician may delegate the notification requirements of this subsection to an authorized designee, provided the physician shall be ultimately responsible for compliance with the notification requirements.

(F) A pharmacist shall not be authorized to adjust, change, or modify any controlled substance prescribed for a patient, except as authorized by state or federal law.

(G) The protocol shall be maintained by the authorizing physician and the pharmacist for a minimum of eight (8) years after termination of the protocol. The protocol may be maintained electronically.

(H) A protocol shall automatically and immediately terminate if the pharmacist ceases to maintain an active Missouri pharmacist license, the authorizing physician is deceased, or if the authorizing physician fails to maintain an active, unrestricted Missouri physician license.

(I) Pharmacy Residents. If specifically authorized by the protocol, a pharmacy resident shall be authorized to perform medication therapy services under the written protocol of a Missouri pharmacist in lieu of an individual protocol, if--

1. The resident holds a certificate of medication therapeutic plan authority from the Missouri State Board of Pharmacy;
2. The resident is enrolled in a residency training program accredited by the American Society of Health-System Pharmacists or a residency training program with a valid application for accreditation pending with the American Society of Health-System Pharmacists; and
3. The resident is providing medication therapy services under the supervision of a Missouri pharmacist certified by the Missouri State Board of Pharmacy to perform medication therapy services.

(J) The provisions of subsection (4)(!) shall only apply to medication therapy services provided by a pharmacist as part of his/her residency training.

(5) Notification Requirements. A pharmacist shall comply with the following notification requirements:

(A) Within twenty-four (24) hours after learning of an anaphylactic or other adverse medication reaction, adverse needle stick, or other adverse event experienced by a patient, the pharmacist shall notify the patient's authorizing physician or an authorized designee of the authorizing physician;

(B) The pharmacist shall notify the authorizing physician or an authorized designee of the authorizing physician in the written protocol of any modification of therapy, within twenty-four (24) hours, provided the protocol may include more stringent notification requirements;

(C) A pharmacist shall be deemed in compliance with the notification requirements of this rule if the pharmacist is providing medication therapy services for, or on behalf of, a health care entity, as defined by this rule, and documentation of the notifications required by this section is

recorded in a patient medical record that is required to be maintained by the health care entity pursuant to state or federal law; and

(D) Notifications required by this section shall be in writing unless otherwise authorized by the authorizing physician.

(6) Modifying Drug Therapy.

(A) A pharmacist may be authorized by protocol to modify a patient's non-controlled substance medication therapy, subject to the following:

1. If the pharmacist modifies medication therapy and a medication or device is to be dispensed, the pharmacist shall create a prescription for the medication or device modified under the authorizing physician's name. Such prescription may be dispensed by a licensed pharmacy and shall be maintained in the prescription records of the dispensing pharmacy as provided by the rules of the Missouri State Board of Pharmacy; and
2. If the pharmacist modifies medication therapy or a device, the pharmacist shall document such modification according to section (7) of this rule. Pharmacists providing medication therapy services for patients of a health care entity shall be deemed in compliance with the provisions of this subsection if the modification is documented in a patient medical record that the health care entity is required to maintain under state or federal law.

(B) The pharmacist shall not modify any controlled substance prescription. A prescription from the authorizing physician shall be required to modify a controlled substance.

(C) For purposes of 20 CSR 2220-6.060, 20 CSR 2220-6.070, and 20 CSR 2220-6.080, modification of medication therapy shall include selecting a new, different, or additional medication or device, discontinuing a current medication or device, or selecting a new, different, or additional strength, dose, dosage form, dosage schedule, or route of administration for a current medication or device, and implementing such selection(s). Medication therapy services shall not include the sole act of dispensing a drug or device pursuant to a valid prescription for the product or generic substitutions made pursuant to section 338.056, RSMo.

(7) Record Keeping.

(A) A pharmacist shall document and maintain an adequate patient record of medication therapy services provided to each patient. The records may be maintained in electronic format provided the records are capable of being printed for review by the Missouri State Board of Registration for the Healing Arts and the Missouri State Board of Pharmacy. An adequate and complete patient record shall include documentation of the following:

1. The identification of the patient, including, name, birthdate, address, and telephone number;
2. The date(s) of any patient visit or consultation, including the reason for any such visit/consultation;

3. Any pertinent assessments, observations, or findings;
4. Any diagnostic testing recommended or performed;
5. The name of any medication or device modified and the strength, dose, dosage schedule, dosage form, and route of administration of any medication modified or administered;
6. Referrals to the authorizing physician;
7. Referrals for emergency care;
8. Any contact with the authorizing physician concerning the patient's treatment or medication therapy services plan;
9. Any informed consent for procedures, medications, or devices; and
10. Any consultation with any other treatment provider for the patient and the results of such consultation.

(B) Pharmacist Record Retention. Except as otherwise provided herein, records required to be maintained by a pharmacist pursuant to this rule shall be maintained securely and confidentially for a minimum of seven (7) years after termination of the protocol unless more stringent requirements are established for record keeping under state or federal law. All records required to be maintained by the pharmacist by this rule shall be maintained by the pharmacist at an address that shall be identified in the written protocol.

(C) Physician Record Retention. Except as otherwise provided herein, records required to be maintained by the authorizing physician pursuant to this rule shall be maintained securely and confidentially for a minimum of seven (7) years after termination of the protocol unless more stringent requirements are established for record keeping pursuant to state or federal law.

(8) Production of Records. Records maintained at a pharmacy must be produced during an inspection or investigation by the Missouri State Board of Pharmacy, Missouri State Board of Registration for the Healing Arts, or their authorized representatives, as requested by the respective board or the board's designee. Records not maintained at a pharmacy shall be produced within three (3) business days after a request from the Missouri State Board of Pharmacy, Missouri State Board of Registration for the Healing Arts, and/or its authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.

(9) Nothing in this rule shall be construed to permit medical diagnosis of any condition by a pharmacist or the independent issuing of a prescription by a pharmacist.

(10) A pharmacist shall not violate or practice in a manner inconsistent with the provisions of this rule or a written protocol. A pharmacist's failure to abide by the requirements of this rule or

the provisions of a written protocol shall be subject to disciplinary action pursuant to the provisions of Chapter 338, RSMo.

(11) The requirements of this rule shall not apply to the administration of vaccines pursuant to protocol as governed by 20 CSR 2220-6.050 or the administration of medication by protocol as governed by 20 CSR 2220-6.040.

(12) The Missouri State Board of Registration for the Healing Arts and the Missouri State Board of Pharmacy separately retain the right and duty to discipline their respective licensees for violations of any state or federal statutes, rules, or regulations regardless of the licensee's participation in a protocol agreement.

(13) The provisions of 20 CSR 2220-6.060 to 20 CSR 2220-6.080 and 20 CSR 2150-5.026 to 20 CSR 2150-5.028 shall only be deemed applicable to persons or entities under the jurisdiction of the Missouri State Board of Pharmacy and the Missouri State Board of Registration for the Healing Arts, as established by Chapter 338, RSMo, and Chapter 334, RSMo.

History: sections 338.010, 338.140.1., and 338.380, RSMo Supp. 2011 a Original rule filed Jan. 13, 2012, effective Aug. 30, 2012.

NABPLAWOS/2013

## Montana

**NABPLAW Online/MONTANA/MONTANA Board of Pharmacy Regulations /MT BReg Title 24. Department of Labor and Industry/MT BReg Chapter 174. Board of Pharmacy/MT BReg Subchapter 5. Licensing/MT BReg 24.174.524. Collaborative practice agreement requirements.**

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### **MT BReg 24.174.524.**

#### **Collaborative practice agreement requirements.**

(1) Prior to initially engaging in collaborative practice, a pharmacist must provide the board with an executed written and electronic copy of the collaborative practice agreement.

(2) The collaborative practice agreement must include:

(a) the identification and signature of individual practitioner(s) authorized to prescribe drugs and responsible for the delegation of drug therapy management;

(i) the practitioner as defined in 37-2-101, MCA, must be licensed in good standing in Montana; and

(ii) the practitioner must be in active practice in the community in which the collaborating pharmacist practices. A request for an exception to this provision must be in writing and will be decided by the board.

(b) the identification and signature of individual pharmacist(s) authorized to dispense drugs and engage in drug therapy management;

(c) the types of drug therapy management decisions that the pharmacist is allowed to make which may include:

(i) a specific description of the types of diseases and drugs involved, and the type of drug therapy management allowed in each case; and

(ii) a specific description of the procedures and methods, decision criteria and plan the pharmacist is to follow.

(d) a detailed description of the procedures and patient activities the pharmacist is to follow in the course of the protocol, including the method for documenting decisions made and a plan or mechanism for communication, feedback and reporting to the practitioner concerning specific decisions made. Documentation shall be recorded within 24 hours following each intervention and may be recorded on the patient medication record, patient medical chart, or a separate log book. Documentation of drug therapy management must be kept as part of the patient's permanent record and shall be considered confidential information;

(e) a method by which adverse events shall be reported to the practitioner;

(f) a method for the practitioner to monitor clinical outcomes and intercede when necessary;

(g) a provision that allows the practitioner to override protocol agreements when necessary;

(h) a provision that allows either party to cancel the agreement by written notification;

(i) the effective date of the protocol. The duration of each protocol shall not exceed one year;

(j) the annual date by which review, renewal, and revision, if necessary, will be accomplished;

(k) the addresses where records of collaborative practice are maintained; and

(l) the process for obtaining the patient's written consent to the collaborative practice agreement.

(3) Patient records shall be maintained by the pharmacist for a minimum of seven years and may be maintained in an automated system pursuant to ARM 24.174.817.

(4) Collaborative practice agreements approved by an institutional committee such as the pharmacy and therapeutics committee and that will be used solely for inpatients are exempt.

History: 37-7-201, MCA; IMP, 37-7-101, 37-7-201, MCA; NEW, 2002 MAR p. 794, Eff. 211/02; AMD, 2006 MAR p. 1615, Eff. 6/23/06; AMD, 2007 MAR p. 1936, Eff. 11/22/07.

NABPLAW06/2013

**NABPLAW Online/MONTANA/MONTANA Pharmacy Practice Act/Montana Code Annotated /MT PracAct Title 37: Professions and Occupations/MT PracAct Chapter 7. Pharmacy/MT PracAct Part 1. General/MT PracAct 37-7-101. Definitions.**

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**MT PracAct 37-7-101.  
Definitions.**

As used in this chapter, the following definitions apply:

(5) "Clinical pharmacist practitioner" means a licensed pharmacist in good standing who meets the requirements specified in 37-7-306.

(6) "Collaborative pharmacy practice" means the practice of pharmacy by a pharmacist who has agreed to work in conjunction with one or more prescribers, on a voluntary basis and under protocol, and who may perform certain patient care functions under certain specified conditions or limitations authorized by the prescriber.

(7) "Collaborative pharmacy practice agreement" means a written and signed agreement between one or more pharmacists and one or more prescribers that provides for collaborative pharmacy practice for the purpose of drug therapy management of patients.

(34) "Practice of pharmacy" means:

(a) interpreting, evaluating, and implementing prescriber orders;

(b) administering drugs and devices pursuant to a collaborative practice agreement and compounding, labeling, dispensing, and distributing drugs and devices, including patient counseling;

(c) properly and safely procuring, storing, distributing, and disposing of drugs and devices and maintaining proper records;

(d) monitoring drug therapy and use;

(e) **initiating** or modifying drug therapy in accordance with collaborative pharmacy practice agreements established and approved by health care facilities or voluntary agreements with prescribers;

(f) participating in quality assurance and performance improvement activities;

(g) providing information on drugs, dietary supplements, and devices to patients, the public, and other health care providers; and

(h) participating in scientific or clinical research as an investigator or in collaboration with other investigators.

History: Enacted by Laws 1939, ch. 175, § 2. Amended by Laws 1951, ch. 33, § I; amended by Laws 1971, ch. 241, § 2; amended by Laws 1974, ch. 350, § 148; amended by Laws 1977, ch. 439, § 1; Revised Code of Montana 1947, 66-1502; amended by Laws 1979, ch. 22, § 7; amended by Laws 1981, ch. 379, § 3; amended by Laws 1983, ch. 247, § 1; amended by Laws 1991, ch. 219, § I; amended by Laws 1995, ch. 429, § 36; amended by Laws 2001, ch. 388, § 3; amended by Laws 2001, ch. 483, § 116; amended by Laws 2009, ch. 293, § 1, eff. Oct. 1, 2009; amended by Laws 2009, ch. 299, § 4, eff. Oct. 1, 2009; amended by Laws 2011, ch. 119, § 1, eff. Oct. 1, 2011; amended by Laws 2011, ch. 241, § 2, eff. July 1, 2011.

*NABPLAW06/2013*

### **New Hampshire**

**NABPLAW Online/NEW HAMPSHIRE/NEW HAMPSHIRE Board of Pharmacy Regulations/NH BReg Chapter Ph 1100. Collaborative Pharmacy Practice/NH BReg Part Ph 1102. Definitions/NH BReg Ph 1102.02 'Collaborative pharmacy practice'.**

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#### **NH BReg Ph 1102.02**

#### **'Collaborative pharmacy practice'.**

'Collaborative pharmacy practice' means 'collaborative pharmacy practice' as defined in RSA 318:1, XXV, namely, 'the practice of pharmacy whereby one or more pharmacists jointly agree, on a voluntary basis, to work in conjunction with one or more attending practitioners under written protocol whereby the collaborating pharmacist or pharmacists may perform medication therapy management authorized by the attending practitioner or practitioners under certain specified conditions and limitations.'

*NABPLAW 08/2013*

**NABPLAW Online/NEW HAMPSHIRE/NEW HAMPSHIRE Board of Pharmacy Regulations/NH BReg Chapter Ph 1100. Collaborative Pharmacy Practice/NH BReg Part Ph 1102. Definitions/NH BReg Ph 1102.03 'Collaborative pharmacy practice agreement' means**

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**NH BReg Ph 1102.03****'Collaborative pharmacy practice agreement' means**

'Collaborative pharmacy practice agreement' means 'collaborative pharmacy practice agreement' as defined in RSA 318:1, XXVII, namely, 'a written and signed specific agreement between a pharmacist, an attending practitioner, and the patient or patient's authorized representative who has granted his or her informed consent, that provides for collaborative pharmacy practice for the purpose of medication therapy management for the patient.' For purposes of these rules, the term includes each protocol developed pursuant to RSA 318:16-a, II(a).

NABPLAW08/2013

**NABPLAW Online/NEW HAMPSHIRE/NEW HAMPSHIRE Board of Pharmacy Regulations/NH BReg Chapter Ph 1100. Collaborative Pharmacy Practice/NH BReg Part Ph 1102. Definitions/NH BReg Ph 1102.04 'Medication therapy management' means.**

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**NH BReg Ph 1102.04****'Medication therapy management' means.**

"Medication therapy management" means "medication therapy management" as defined in RSA 318:1, XXVIII, namely, "the review of medication therapy regimens of patients by a pharmacist for the purpose of evaluating and rendering advice to a practitioner, or evaluating and modifying the medication regimen in accordance with the collaborative pharmacy practice agreement" and is limited to:

- (a) Implementing, modifying, and managing medication therapy according to the terms of the collaborative pharmacy practice agreement;
- (b) Collecting and reviewing patient histories within the context of needs for pharmacy practice;
- (c) Obtaining and checking vital signs, such as pulse, temperature, blood pressure, and respiration;
- (d) Ordering laboratory tests as specifically set out in the collaborative pharmacy practice agreement between the pharmacist and the attending practitioner that are specific to the medication or protocol-driven;
- (e) Formulating a medication treatment plan that will be shared with the patient's attending practitioner;
- (f) Monitoring and evaluating the patient's response to therapy, including safety and effectiveness;
- (g) Performing a comprehensive medication review, in conjunction with the attending practitioner, to identify, resolve, and prevent medication-related problems, including adverse drug events;
- (h) Documenting the care delivered and, if applicable, communicating essential information to the patient's other health care providers; and
- (i) Providing education and training designed to enhance patient understanding and the appropriate use of his or her medications.

NABPLAWOS/2013

**NABPLAW Online/NEW HAMPSHIRE/NEW HAMPSHIRE Board of Pharmacy Regulations/NH BReg Chapter Ph 1100. Collaborative Pharmacy Practice/NH BReg Part Ph 1104. Collaborative Practice Agreements and Practice Thereunder/NH BReg Ph 1104.03 Practice Under a Collaborative Practice Agreement.**

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**NH BReg Ph 1104.03**

**Practice Under a Collaborative Practice Agreement.**

- (a) Practice by a pharmacist under a collaborative practice agreement shall not be delegable but shall be performed only by the pharmacist who is a party to the agreement.
- (b) Prior to **initiation** of medication therapy management for a patient, the pharmacist shall review and confirm the patient's:
  - (1) Name;
  - (2) Gender, and if female, pregnancy and lactation status;
  - (3) Date of birth;
  - (4) Height and weight;
  - (5) Diagnosis, through consultation with the attending practitioner;
  - (6) Medication history;
  - (7) Prior lab values;
  - (8) Known allergies; and
  - (9) Emergency contact information.
- (c) The pharmacist shall review the collaborative practice agreement and each protocol developed pursuant thereto so as to determine whether changes should be made to reflect the standard of care. If such a review reveals that a change should be made, the pharmacist shall inform the attending practitioner and the patient or the patient's authorized representative.
- (d) Nothing in this chapter shall be construed to prohibit an authorized pharmacist from participating in medication therapy management by protocol or policy approved by the medical staff of the hospital.

NABPLAWOS/2013

**NABPLAW Online/NEW HAMPSHIRE/NEW HAMPSHIRE Pharmacy Practice Act/NH PracAct Title XXX. Chapter 318. Pharmacists & Pharmacies/NH PracAct 318:16a. Standards for Collaborative Pharmacy Practice.**

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**NH PracAct 318:16a.**

**Standards for Collaborative Pharmacy Practice.**

I. For a pharmacist to participate in a collaborative pharmacy practice agreement, the pharmacist shall:

- (a) Hold an unrestricted and current license to practice as a pharmacist in New Hampshire.
- (b) Have at least \$1,000,000 of professional liability insurance coverage.
- (c) Have earned a Pharm.D. degree or completed 3 years of institutional clinical experience as a licensed pharmacist.
- (d) Complete at least 5 contact hours or 0.5 continuing education units of board-approved continuing education each year. Such continuing education shall address the area or areas of practice generally related to the collaborative pharmacy practice agreement or agreements. The continuing education hours may be applied to the requirements for licensure as a pharmacist in this state.
- (e) In order to administer drugs by injection, have completed training that includes programs approved by the Accreditation Council for Pharmacy Education (ACPE) or curriculum-based programs from an ACPE-accredited college of pharmacy or state or local health department programs or programs recognized by the board.

II. Collaborative pharmacy practice agreements shall meet the following general requirements:

- (a) Each protocol developed, pursuant to the collaborative pharmacy practice agreement, shall contain detailed direction concerning the services that the pharmacist may perform for that patient. The protocol shall include, but not be limited to:
  - (1) The specific drug or drugs to be managed by the pharmacist.
  - (2) The terms and conditions under which drug therapy may be implemented, modified, or discontinued.
  - (3) The conditions and events upon which the pharmacist is required to notify the collaborating practitioner.
  - (4) The laboratory tests that may be ordered in accordance with medication therapy management.
  - (5) In instances where drug therapy is discontinued, the pharmacist shall notify the collaborating practitioner of such discontinuance in the time-frame and manner established by the collaborative pharmacy practice agreement.
  - (6) All activities performed by the pharmacist in conjunction with the protocol shall be documented as specified in the protocol.
- (b) The collaborative pharmacy practice agreement and protocols shall be on file at the pharmacist's place of practice. The collaborative pharmacy practice agreement and protocols shall be available to the appropriate licensing board for review upon request.
- (c) Collaborative pharmacy practice agreements shall be reviewed, at least every 2 years, by both the pharmacist and the practitioner, and may be terminated, in writing, by either party. When collaborative pharmacy practice agreements are terminated, the patient shall be informed and provided with details to allow for the uninterrupted continuation of his or her medication therapy management regimen.
- (d) Neither the attending practitioner nor the pharmacist in a collaborative practice agreement may seek to gain personal financial benefit by participating in any incentive-based program that influences or encourages therapeutic or product changes or the ordering of tests or services.

III. A collaborative pharmacy practice agreement that complies with all the requirements of this section shall only be allowed in the following settings:

- (a) Hospitals.
- (b) Long-term care facilities.
- (c) Licensed inpatient or outpatient hospice settings.

(d) Ambulatory care clinics with onsite supervision by the attending practitioner and with a collaborating pharmacist who has no connection to any onsite retail pharmacy.

· NABPLAW07/2013

### **New Mexico**

**NABPLAW Online/NEW MEXICO/NEW MEXICO Board of Pharmacy Regulations/NM BReg Title 16. Occupational and Professional Licensing!NM BReg Chapter 19. Pharmacists/NM BReg Part 4. Pharmacist!NM BReg 16.19.4.17. Pharmacist clinician.**

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#### **NM BReg 16.19.4.17. Pharmacist clinician.**

**A. Purpose:** The purpose of these regulations is to implement the Pharmacist Prescriptive Authority Act, Sections 61-11B-1 through 61-11B-3 NMSA 1978 by providing minimum standards, terms and conditions for the certification, registration, practice, and supervision of pharmacist clinicians. These regulations are adopted pursuant to Section 61-11B-3 of the Pharmacist Prescriptive Authority Act.

**B. Initial certification and registrants:**

- (1) The board may certify and register a pharmacist as a pharmacist clinician upon completion of an application for certification and satisfaction of the requirements set forth in these regulations.
- (2) A pharmacist who applies for certification and registration as a pharmacist clinician shall complete application forms as required by the board and shall pay a fee. The fee shall be set by the board to defray the cost of processing the application, which fee is not returnable.
- (3) To obtain initial certification and registration as a pharmacist clinician, she/he must submit the following:
  - (a) proof of completion of sixty (60) hour board approved physical assessment course, followed by a 150 hour, 300 patient contact preceptorship supervised by a physician or other practitioner with prescriptive authority, with hours counted only during direct patient interactions;
  - (b) the applicant will submit a log of patient encounters as part of the application;
  - (c) patient encounters must be initiated and completed within 2 years of the application.
- (4) The board shall register each pharmacist certified as a pharmacist clinician.
- (5) Upon certification and registration by the board, the name and address of the pharmacist clinician, (name of the supervising physician if applicable), and other pertinent information shall be enrolled by the board on a roster of pharmacist clinicians.

**C. Biennial renewal of registration:**

- (1) Renewal applications shall be submitted prior to the license expiration.
- (2) Applications for renewal must include:
  - (a) After January 1, 2013, documentation of continuing education hours, including proof of completion of 2.0 CEU twenty (20) contact hours of live CPE or continuing medical education (CME) approved by (ACPE) or AACME (live programs provided by other continuing education providers may be submitted for review and approval to the board), beyond the required hours in 16.19.4.10 NMAC (as amended), as required by the board; and

- (b) a current protocol of collaborative practice signed by the supervising physician (if prescriptive authority is sought); and
- (c) a copy of the pharmacist clinicians registration with the supervising physicians board (if prescriptive authority is sought); and
- (d) other additional information as requested by the board.

**D. Prescriptive authority, guidelines or protocol:**

- (1) Only a registered pharmacist clinician with current protocols, registered with the New Mexico medical board or the New Mexico board of osteopathic medical examiners, may exercise prescriptive authority.
- (2) A pharmacist clinician seeking to exercise prescriptive authority shall submit an application to the board. The application must include the supervising physicians' name and current medical license, protocol of collaborative practice and other information requested by the board. A pharmacist may submit the application with the initial application for certification or as a separate application after becoming certified and registered as a pharmacist clinician.
- (3) The protocol will be established and approved by the supervising physician as set forth in these regulations and will be kept on file at each practice site of the pharmacist clinician and with the board.
- (4) The protocol must include:
  - (a) name of the physician(s) authorized to prescribe dangerous drugs and name of the pharmacist clinician;
  - (b) statement of the types of prescriptive authority decisions the pharmacist clinician is authorized to make, including, but not limited to:
    - (i) types of diseases, dangerous drugs or dangerous drug categories involved and the **type of prescriptive authority authorized in each case;**
    - (ii) ordering lab tests and other tests appropriate for monitoring of drug therapy;
    - (iii) procedures, decision criteria or plan the pharmacist clinician is to follow when exercising prescriptive authority;
  - (c) activities to be followed by the pharmacist clinician while exercising prescriptive authority, including documentation of feedback to the authorizing physician concerning specific decisions made; documentation may be made on the prescriptive record, patient profile, patient medical chart or in a separate log book;
  - (d) description of appropriate mechanisms for consulting with the supervising physician, including a quality assurance program for review of medical services provided by the pharmacist clinician, (this quality assurance program will be available for board review); and
  - (e) description of the scope of practice of the pharmacist clinician.

**E. Scope of practice:**

- (1) A pharmacist clinician shall perform only those services that are delineated in the protocol and are within the scope of practice of the supervising physician and/or alternate supervising physician(s).
- (2) A pharmacist clinician may practice in a health care institution within the policies of that institution.
- (3) A pharmacist clinician may prescribe controlled substances provided that the pharmacist clinician:
  - (a) has obtained a New Mexico controlled substances registration and a drug enforcement agency registration, and

(b) prescribes controlled substances within the parameters of written guidelines or protocols established under these regulations and Section 3, A. of the Pharmacist Prescriptive Authority Act.

(4) The board may, in its discretion after investigation and evaluation, place limitations on the tasks a pharmacist clinician may perform under the authority and direction of a supervising physician and/or alternate supervising physician(s).

**F. Collaborative professional relationship between pharmacist clinicians and supervising physician(s):**

(1) The direction and supervision of pharmacist clinicians may be rendered by approved supervising physician/designated alternate supervising physician(s).

(2) This direction may be done by written protocol or by oral consultation. It is the responsibility of the supervising physician to assure that the appropriate directions are given and understood. (3) The pharmacist clinician must have prompt access to consultation with the physician for advice and direction.

(4) Upon any change in supervising physician between registration renewals, a pharmacist clinician shall submit to the board, within ten (10) working days, the new supervising physician's name, current medical license, and protocol; notification to and completion of requirements for the supervising physicians' board shall be completed per that board's requirements. This notice requirement does not apply to an alternate supervising physician who is designated to cover during the absence of the supervising physician.

**G. Complaints and appeals:**

(1) The chair of the board will appoint two (2) members of the board, and the president of the supervising physician respective board will appoint (2) members of the respective board to the oversight committee; the oversight committee will review complaints concerning the pharmacist clinician practice; the oversight committee will make a report that may include non-binding recommendations to both the board and respective board(s) regarding disciplinary action. Each board can accept or reject the recommendations.

(2) Any applicant for certification or any pharmacist clinician may appeal a decision of the board in accordance with the provisions of the Uniform Licensing Act, Sections 61-1-1 to 61-1-33 NMSA 1978.

NABPLAWOS/2013

## **Nevada**

**NABPLAW Online/NEVADA/NEVADA Pharmacy Practice Act /NV PracAct Title 54 Chapter 639. Pharmacists and Pharmacy/NV PracAct Regulation of Trade Practices/NV PracAct Miscellaneous Provisions/NV PracAct 639.2809. Implementation, monitoring and modification of drug therapy by pharmacist: Restrictions; notice; regulations**

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**NV PracAct 639.2809. Implementation, monitoring and modification of drug therapy by pharmacist: Restrictions; notice; regulations**

1. Written guidelines and protocols developed by a registered pharmacist in collaboration with a practitioner which authorize the **implementation**, monitoring and modification of drug therapy:

- (a) May authorize a pharmacist to order and use the findings of laboratory tests and examinations.
  - (b) May provide for **implementation**, monitoring and modification of drug therapy for a patient receiving care:
    - (1) In a licensed medical facility; or
    - (2) If developed to ensure continuity of care for a patient, in any setting that is affiliated with a medical facility where the patient is receiving care. A pharmacist who modifies a drug therapy of a patient receiving care in a setting that is affiliated with a medical facility shall, within 72 hours after implementing or modifying the drug therapy, provide written notice of the implementation or modification of the drug therapy to the collaborating practitioner or enter the appropriate information concerning the drug therapy in an electronic patient record system shared by the pharmacist and the collaborating practitioner.
  - (c) Must state the conditions under which a prescription of a practitioner relating to the drug therapy of a patient may be changed by the pharmacist without a subsequent prescription from the practitioner.
  - (d) Must be approved by the Board.
2. The Board may adopt regulations which:
- (a) Prescribe additional requirements for written guidelines and protocols developed pursuant to this section; and
  - (b) Set forth the process for obtaining the approval of the Board of such written guidelines and protocols.
- History: Added by Laws 2011, c. 486, § 1.

NABPLAW04/2013

### North Carolina

**NABPLAW Online/NORTH CAROLINA/NORTH CAROLINA Board of Pharmacy Regulations/NC BReg Title 21: Occupational Licensing Boards/NC BReg Chapter 46: Board of Pharmacy/NC BReg Section .3100. Clinical Pharmacist Practitioner/NC BReg .3101. Clinical pharmacist practitioner.**

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#### **NC BReg .3101.**

#### **Clinical pharmacist practitioner.**

- (a) Definitions. As used in this Rule:
  - (1) "Medical Board" means the North Carolina Medical Board.
  - (2) "Pharmacy Board" means the North Carolina Board of Pharmacy.
  - (3) "Joint Subcommittee" means the subcommittee composed of four members of the Pharmacy Board and four members of the Medical Board to whom responsibility is given by G.S. 90-6(c) to develop rules to govern the provision of drug therapy management by the Clinical Pharmacist Practitioner in North Carolina.

(4) "Clinical Pharmacist Practitioner or CPP" means a licensed pharmacist who is approved to provide drug therapy management, including controlled substances, under the direction of, or under the supervision of a licensed physician who has provided written instructions for a patient and disease specific drug therapy which may include **ordering**, changing, substituting therapies or ordering tests. Only a pharmacist approved by the Pharmacy Board and the Medical Board may legally identify himself as a CPP.

(5) "Supervising Physician" means a licensed physician who, by signing the CPP agreement, is held accountable for the on-going supervision and evaluation of the drug therapy management performed by the CPP as defined in the physician, patient, pharmacist and disease specific written agreement.

(6) "Approval" means authorization by the Medical Board and the Pharmacy Board for a pharmacist to practice as a CPP in accordance with this Rule.

(7) "Continuing Education or CE" is defined as courses or materials which have been approved for credit by the American Council on Pharmaceutical Education.

(8) "Clinical Experience approved by the Boards" means work in a clinical pharmacy practice setting which includes experience consistent with the components listed in Parts (b)(2)(A), (B), (C), (D), (E), (H), (I), (J), (N), (O), and (P) of this Rule. \_ Clinical experience requirements must be met only through activities separate from the certificate programs referred to in Parts (b)(1)(B) of this Rule.

(b) CPP application for approval.

(1) The requirements for application for CPP approval include that the pharmacist:

(A) has an unrestricted and current license to practice as a pharmacist in North Carolina;

(B) meets one of the following qualifications:

(i) has earned Certification from the Board of Pharmaceutical Specialties, is a Certified Geriatric Pharmacist as certified by the Commission for Certification in Geriatric Pharmacy or has completed an American Society of Health System Pharmacists (ASHP) accredited residency program, which includes two years of clinical experience approved by the Boards; or

(ii) has successfully completed the course of study and holds the academic degree of Doctor of Pharmacy and has three years of clinical experience approved by the Boards and has completed a North Carolina Center for Pharmaceutical Care (NCCPC) or American Council on Pharmaceutical Education (ACPE) approved certificate program in the area of practice covered by the CPP agreement; or

(iii) has successfully completed the course of study and holds the academic degree of Bachelor of Science in Pharmacy and has five years of clinical experience approved by the Boards and has completed two NCCPC or ACPE approved certificate programs with at least one program in the area of practice covered by the CPP agreement;

(C) submits the required application and the fee to the Medical Board;

(D) submits any information deemed necessary by the Medical Board in order to evaluate the application; and

(E) has a signed supervising physician agreement.

If for any reason a CPP discontinues working in the approved physician arrangement, the CPP shall notify both Boards in writing within 10 days and the CPP's approval shall automatically terminate or be placed on an inactive status until such time as a new application is approved in accordance with this Subchapter.

(2) All certificate programs referred to in Subpart (b)(1)(B)(i) of this Rule must contain a core curriculum including the following components:

(A) communicating with healthcare professionals and patients regarding drug therapy, wellness, and health promotion;

(B) **designing, implementing,** monitoring, evaluating, and modifying or recommending modifications in drug therapy to insure effective, safe, and economical patient care;

(C) identifying, assessing and solving medication-related problems and providing a clinical judgment as to the continuing effectiveness of individualized therapeutic plans and intended therapeutic outcomes;

(D) conducting physical assessments, evaluating patient problems, ordering and monitoring medications and laboratory tests;

(E) referring patients to other health professionals as appropriate;

(F) administering medications;

(G) monitoring patients and patient populations regarding the purposes, uses, effects and pharmacoeconomics of their medication and related therapy;

(H) counseling patients regarding the purposes, uses, and effects of their medication and related therapy;

(I) integrating relevant diet, nutritional and non-drug therapy with pharmaceutical care;

(J) recommending, counseling, and monitoring patient use of non-prescription drugs, herbal remedies and alternative medicine practices;

(K) using, ordering, and instructing on the use of devices, and durable medical equipment;

(L) providing emergency first care;

(M) retrieving, evaluating, utilizing, and managing data and professional resources;

- (N) using clinical data to optimize therapeutic drug regimens;
- (O) collaborating with other health professionals;
- (P) documenting interventions and evaluating pharmaceutical care outcomes;
- (Q) integrating pharmacy practice within healthcare environments;
- (R) integrating national standards for the quality of healthcare; and
- (S) conducting outcomes and other research.

(3) The completed application for approval to practice as a CPP shall be reviewed by the Medical Board upon verification of a full and unrestricted license to practice as a pharmacist in North Carolina.

(A) The application shall be approved and at the time of approval the Medical Board shall issue a number which shall be printed on each prescription written by the CPP; or

(B) The application shall be denied; or

(C) The application shall be approved with restrictions.

(c) Annual Renewal.

(1) Each CPP shall register annually on the anniversary of his or her birth date by:

(A) verifying a current Pharmacist license;

(B) submitting the renewal fee as specified in Subparagraph G)(2) of this Rule;

(C) completing the Medical Board's renewal form; and

(D) reporting continuing education credits as specified by the Medical Board.

(2) If the CPP has not renewed within 30 days of the anniversary of the CPP's birth date, the approval to practice as a CPP shall lapse.

(d) Continuing Education.

(1) Each CPP shall earn 35 hours of practice relevant CE each year approved by the Pharmacy Board.

(2) Documentation of these hours shall be kept at the CPP practice site and made available for inspection by agents of the Medical Board or Pharmacy Board.

(e) The supervising physician who has a signed agreement with the CPP shall be readily available for consultation with the CPP and shall review and countersign each order written by the CPP within seven days.

(f) The written CPP agreement shall:

- (1) be approved and signed by both the supervising physician and the CPP and a copy shall be maintained in each practice site for inspection by agents of either Board upon request;
- (2) be specific in regard to the physician, the pharmacist, the patient and the disease;
- (3) specify the predetermined drug therapy which shall include the diagnosis and product selection by the patient's physician; any modifications which may be permitted, dosage forms, dosage schedules and tests which may be ordered;
- (4) prohibit the substitution of a chemically dissimilar drug product by the CPP for the product prescribed by the physician without first obtaining written consent of the physician;
- (5) include a pre-determined plan for emergency services;
- (6) include a plan and schedule for weekly quality control, review and countersignature of all orders written by the CPP in a face-to-face conference between the physician and CPP;
- (7) require that the patient be notified of the collaborative relationship; and
- (8) be terminated when patient care is transferred to another physician and new orders shall be written by the succeeding physician.

(g) The supervising physician of the CPP shall:

- (1) be fully licensed with the Medical Board and engaged in clinical practice;
- (2) not be serving in a postgraduate medical training program;
- (3) be approved in accordance with this Subchapter before the CPP supervision occurs; and
- (4) supervise no more than three pharmacists.

(h) The CPP shall wear a nametag spelling out the words "Clinical Pharmacist Practitioner".

(i) A CPP may be censured or reprimanded, and his or her approval may be restricted, suspended, revoked, annulled, denied or terminated by the Medical Board or the Pharmacy Board. The pharmacist may be censured or reprimanded, and the pharmacist's license may be restricted, suspended, revoked, annulled, denied, or terminated by the Pharmacy Board, in accordance with provisions of G.S. 130B if either Board finds one or more of the following:

- (1) the CPP has held himself or herself out, or permitted another, to represent the CPP as a licensed physician;
- (2) the CPP has engaged, or attempted to engage, in the provision of drug therapy management other than at the direction of, or under the supervision of, a physician licensed and approved by the Medical Board to be that CPP's supervising physician;

(3) the CPP has performed, or attempted to provide, medical management outside the approved drug therapy agreement or for which the CPP is not qualified by education and training to perform;

(4) the CPP commits any act prohibited by G.S. 90-85.38 as determined by the Pharmacy Board or G.S. 90-14(a)(1), (a)(3) through (a)(14) and (c) as determined by the Medical Board; or

(5) the CPP has failed to comply with any of the provisions of this Rule.

Any modification of treatment for financial gain on the part of the supervising physician or CPP shall be grounds for denial of Board approval of the agreement.

(j) Fees:

(1) An application fee of one hundred dollars (\$100.00) shall be paid at the time of initial application for approval and each subsequent application for approval to practice.

(2) The fee for annual renewal of approval, due on the CPP's anniversary of birth date is fifty dollars (\$50.00).

(3) No portion of any fee in this Rule is refundable.

*NABPLAW06/2013*

## **North Dakota**

**NABPLAW Online/NORTH DAKOTA/NORTH DAKOTA State Board of Pharmacy Regulations/ND BReg Title 61. State Board of Pharmacy/ND BReg Article 61-04. Professional Practice/ND BReg Chapter 61-04-08. Limited Prescription Practices/ND BReg 61-04-08-02. Definitions.**

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### **ND BReg 61-04-08-02. Definitions.**

For purposes of this chapter:

1. "Collaborative agreement" means the written document signed by a physician and a pharmacist which describes the limited prescribing authority granted the pharmacist under North Dakota Century Code section 43-15-31.4.

2. "Immediate notification" means interactive two-way communication between the pharmacist and physician within twenty-four hours of the **initiation** or modification of drug therapy, unless specific reference is made in the collaborative agreement to situations in which a notification time limit of up to seventy-two hours is appropriate.

3. **"Initiate drug therapy"** means to begin administering for the first time a prescribed drug therapy for treating a patient with an existing diagnosis. A licensed physician shall make any diagnosis required.

4. **"Medical record"** means a written record of clinical care developed and maintained by a patient's physician which contains information and data about a patient's condition sufficient to justify the diagnosis and subsequent treatment. The record must contain further appropriate information as described in section 33-07-01.1-20.

5. **"Modify drug therapy"** means to change, within the same therapeutic class of drugs, a specific drug, the dosage, or route of delivery of a drug currently being administered for an existing diagnosis.

6. **"Pharmacist in an institutional setting"** means a pharmacist who:

- a. Has a written agreement to provide daily or regular pharmaceutical services within a hospital, physician clinic, skilled nursing facility, swing-bed facility, or long-term care facility; and
- b. Is physically present in the facility when exercising prescriptive practices under the terms of a collaborative agreement.

7. **"Supervision"** means the active role taken by the physician to oversee the pharmacist throughout the provision of drug therapy to patients under the terms of a collaborative agreement.

History: Effective December 1, 1996; amended effective December 1, 2003.

*NABPLAW06/2013*

- **NABPLAW Online/NORTH DAKOTA/NORTH DAKOTA State Board of Pharmacy Regulations/ND BReg Title 61. State Board of Pharmacy/ND BReg Article 61-04. Professional Practice/ND BReg Chapter 61-04-08. Limited Prescription Practices/ND BReg 61-04-08-03. Eligibility and approval.**

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**ND BReg 61-04-08-03.  
Eligibility and approval.**

1. A physician and a pharmacist who are licensed and practicing their respective professions in this state are eligible, provided the conditions of this section and any applicable statutes are met, to enter into the collaborative agreement allowing the pharmacist to provide prescription drug therapy to patients in an institutional setting on a limited basis.

2. A physician may have a collaborative agreement with no more than three eligible pharmacists unless the physician's licensing board specifies otherwise based on individual circumstances. A

pharmacist may have a collaborative agreement with one or more physicians, the number of which may be limited by the board based on individual circumstances.

3. The collaborative agreement serves as a formal arrangement between an individual pharmacist and an individual collaborative supervising physician and is operative only within the institutional setting identified on the collaborative agreement form.

4. Each individual collaborative agreement must be reviewed by the board of medical examiners and the board of pharmacy, and will not become effective until both boards grant approval and notify the parties. Each agreement must be reviewed at least every two years or when modifications are proposed by the parties, and must receive continued approval from both boards in order to remain in effect.

5. A collaborative agreement may be terminated by either board for good cause, including adverse action taken against either licensee. Noncompliance with the terms of these rules or of a collaborative agreement may be considered evidence of unprofessional conduct by either board.

6. Either party of a collaborative agreement may terminate the agreement at will by notifying either board of their desire to do so.

7. Neither party to a collaborative agreement may seek to gain personal financial benefit by participating in any incentive-based program that influences or encourages therapeutic or product changes.

History: Effective December 1, 1996.

*NABPLAW06/2013*

**NABPLAW Online/NORTH DAKOTA/NORTH DAKOTA State Board of Pharmacy  
Regnlations/ND BReg Title 61. State Board of Pharmacy/ND BReg Article 61-04.  
Professional Practice/ND BReg Chapter 61-04-08. Limited Prescription Practices/ND BReg  
61-04-08-04. Procednres.**

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**ND BReg 61-04-08-04.  
Procednres.**

A physician who has signed an approved collaborative agreement with a pharmacist shall remain responsible for the care of the patient following initial diagnosis and assessment, and for the supervision of the pharmacist as prescriptive authority is exercised. The physician shall remain available to receive immediate notification from the pharmacist regarding prescriptive drug therapy being provided. The parties may modify as necessary, within the practice guidelines described in the collaborative agreement, their relationship in the joint provision of care to each patient as the requirements of the patient or drug therapy change.

History: Effective December 1, 1996.

*NABPLAW06/2013*

**NABPLAW Online/NORTH DAKOTA/NORTH DAKOTA State Board of Pharmacy Regulations/ND BReg Title 61. State Board of Pharmacy/ND BReg Article 61-04. Professional Practice/ND BReg Chapter 61-04-08. Limited Prescription Practices/ND BReg 61-04.08-05. Initiation of drug therapy.**

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**ND BReg 61-04.08-05.  
Initiation of drug therapy.**

To **initiate** drug therapy, a pharmacist must hold a valid North Dakota pharmacist license and have a collaborative agreement with the treating physician. A pharmacist may **initiate** drug therapy only if the pharmacist has obtained a doctor of science, doctor of philosophy in clinical pharmacy, master of science, or doctor of pharmacy degree, has been certified a fellow by the board of pharmaceutical specialties, or has completed an accredited pharmacy fellowship or residency, and has been authorized to do so within the collaborative agreement. Verification of these credentials must be provided by the pharmacist. The pharmacist must provide immediate notification to the physician when the pharmacist **initiates** drug therapy.

History: Effective December 1, 1996.

*NABPLAW06/2013*

**NABPLAW Online/NORTH DAKOTA/NORTH DAKOTA State Board of Pharmacy Regulations/ND BReg Title 61. State Board of Pharmacy/ND BReg Article 61-04. Professional Practice/ND BReg Chapter 61-04-08. Limited Prescription Practices/ND BReg Appendix Collaborative Agreement Form.**

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**NDBReg  
Appendix Collaborative Agreement Form.**

The pharmacist and physician listed below are parties to this collaborative agreement, through which the pharmacist receives limited prescriptive authority under the supervision of the physician in accordance with North Dakota Century Code section 43-15-31.4 and administrative rules.

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Institution

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 Pharmacist Name

---

 Physician Name

---

 Address

---

 Address

---

 Phone

---

 License Number

---

 Phone

---

 License Number

[Please review the administrative rules governing collaborative agreements which accompany this form before proceeding.]

1. Describe the scope and authority to be exercised by the pharmacist. (If requesting authority to **initiate** drug therapy, pharmacist must include credential verification.)
2. Indicate any restrictions placed on the use of certain types or classes of drugs or drug therapies under this agreement. (Note: Schedule II drugs are excluded by these rules.)
3. If appropriate, indicate any diagnoses which are specifically included or excluded under this agreement.
4. Attach any protocols or guidelines to be used in decision making or other activities contemplated under this agreement. This must include a protocol for treating acute allergic or other adverse reactions related to drug therapy.
5. Describe approved situations, if any, in which the notification time limit may be extended beyond twenty-four hours (not to exceed seventy-two hours).

Attach additional sheets if necessary.

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 Pharmacist Signature

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 Date

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 Physician Signature

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 Date

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State Board of Pharmacy Approval Date

Board of Medical Examiners

Approval Date

*NABPLAW06/2013*

**NABPLAW Online/NORTH DAKOTA/NORTH DAKOTA Pharmacy Practice Act!ND  
.PracAct Title 43. Occupations And Professions/NO PracAct Chapter 43-15.  
Pharmacists/NO PracAct 43-15-31.4. Limited prescriptive practices.**

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**ND PracAct 43-15-31.4.  
Limited prescriptive practices.**

1. A licensed pharmacist in an institutional setting has limited prescriptive practices to **initiate** or modify drug therapy following diagnosis and initial patient assessment by a licensed physician, under the supervision of the same licensed physician, in accordance with this section. An institutional setting, for the purpose of this section, is a hospital, a physician clinic, a skilled nursing facility, or a swing-bed facility in which a patient's medical records are readily available to the licensed physician and the licensed pharmacist.
2. The licensed physician and the licensed pharmacist shall prepare a collaborative agreement concerning the scope of the pharmacist's prescriptive practices and shall update the agreement at least every two years or when they modify the scope of the pharmacist's prescriptive practices. The collaborative agreement, or an amendment to the agreement, is effective when approved by the board of medical examiners and the board of pharmacy.
3. The agreement must include a provision that requires the licensed pharmacist to immediately notify the licensed physician when the licensed pharmacist **initiates** or modifies a drug therapy.
4. The board of medical examiners and the board of pharmacy shall jointly establish a prescriptive practices committee consisting of two physicians appointed by the board of medical examiners, one physician appointed by the North Dakota medical association, one pharmacist appointed by the board of pharmacy, and one pharmacist appointed by the North Dakota pharmaceutical association. The prescriptive practices committee shall develop and submit proposed rules concerning the implementation of this section to the board of medical examiners and the board of pharmacy. Any rules to implement this section must be jointly adopted by the board of medical examiners and the board of pharmacy.

History: S.L. 1995, ch. 408, §1; S.L. 2001, ch. 376, §1.

*NABPLAW06/2013*

## South Dakota

**NABPLAW Online/SOUTH DAKOTA/SOUTH DAKOTA Pharmacy Practice Act/SD PracAct Title 36. Professions and Occupations/SD PracAct Chapter 36-11. Pharmacies and Pharmacists/SD PracAct 36-11-19.1. Authority of registered pharmacists.**

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### **SD PracAct 36-11-19.1.**

#### **Authority of registered pharmacists.**

Registered pharmacists may:

- (1) Perform drug administration pursuant to a prescription drug order. The Board of Pharmacy shall establish standards for drug administration pursuant to chapter 1-26 with the approval of a committee composed of two persons appointed by the Board of Pharmacy, two persons appointed by the Board of Nursing and two persons appointed by the Board of Medical and Osteopathic Examiners;
- (2) Perform drug reviews;
- (3) Perform or participate in scientific or clinical drug or drug-related research as an investigator or in collaboration with other investigators;
- (4) Interpret and apply pharmacokinetic data and other pertinent laboratory data to design safe and effective drug dosage regimens;
- (5) Participate in drug and drug device selection pursuant to a prescription drug order;
- (6) **Initiate** or modify drug therapy by protocol or other legal authority established and approved within a licensed health care facility or by a practitioner authorized to prescribe drugs; and
- (7) Provide information on prescription drugs, which may include advising, consulting, and educating, as necessary or as required, patients, the public, and other health care providers on the rational, safe and cost-effective use of drugs, including therapeutic values, content, hazards and appropriate use.

History: SL 1993, ch 278, § 2.

NABPLAWOS/2013

**NABPLAW Online/UTAH/UTAH Board of Pharmacy Rules/UT BReg R156. Commerce. Occupational and Professional Licensing/UT BReg R156-17b. Pharmacy Practice Act Rule /UT BReg R156-17b-611. Operating Standards--Drug Therapy Management.**

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**UT BReg R156-17b-611.****Operating Standards--Drug Therapy Management.**

(1) In accordance with Subsections 58-17b-102(17) and 58-17b-601(1), decisions involving drug therapy management shall be made in the best interest of the patient. Drug therapy management may include:

(a) **implementing**, modifying and managing drug therapy according to the terms of the Collaborative Pharmacy Practice Agreement;

(b) collecting and reviewing patient histories;

(c) obtaining and checking vital signs, including pulse, temperature, blood pressure and respiration;

(d) ordering and evaluating the results of laboratory tests directly applicable to the drug therapy, when performed in accordance with approved protocols applicable to the practice setting; and

(e) such other patient care services as may be allowed by rule.

(2) For the purpose of promoting therapeutic appropriateness, a pharmacist shall at the time of dispensing a prescription, or a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant conditions, situations or items, such as:

(a) inappropriate drug utilization;

(b) therapeutic duplication;

(c) drug-disease contraindications;

(d) drug-drug interactions;

(e) incorrect drug dosage or duration of drug treatment;

(f) drug-allergy interactions; and

(g) clinical abuse or misuse.

(3) Upon identifying any clinically significant conditions, situations or items listed in Subsection (2) above, the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner.

*NABPLAW0312013*

**§ 54.1-3303. Prescriptions to be issued and drugs to be dispensed for medical or therapeutic purposes only.**

A. A prescription for a controlled substance may be issued only by a practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine who is authorized to prescribe controlled substances, or by a licensed nurse practitioner pursuant to § 54.1-2957.01, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32. The prescription shall be issued for a medicinal or therapeutic purpose and may be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship.

For purposes of this section, a bona fide practitioner-patient-pharmacist relationship is one in which a practitioner prescribes, and a pharmacist dispenses, controlled substances in good faith to his patient for a medicinal or therapeutic purpose within the course of his professional practice. In addition, a bona fide practitioner-patient relationship means that the practitioner shall (i) ensure that a medical or drug history is obtained; (ii) provide information to the patient about the benefits and risks of the drug being prescribed; (iii) perform or have performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; except for medical emergencies, the examination of the patient shall have been performed by the practitioner himself, within the group in which he practices, or by a consulting practitioner prior to issuing a prescription; and (iv) initiate additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects. Any practitioner who prescribes any controlled substance with the knowledge that the controlled substance will be used otherwise than medicinally or for therapeutic purposes shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the distribution or possession of controlled substances.

B. In order to determine whether a prescription that appears questionable to the pharmacist results from a bona fide practitioner-patient relationship, the pharmacist shall contact the prescribing practitioner or his agent and verify the identity of the patient and name and quantity of the drug prescribed. The person knowingly filling an invalid prescription shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the sale, distribution or possession of controlled substances.

No prescription shall be filled unless there is a bona fide practitioner-patient-pharmacist relationship. A prescription not issued in the usual course of treatment or for authorized research is not a valid prescription.

C. Notwithstanding any provision of law to the contrary and consistent with recommendations of the Centers for Disease Control and Prevention or the Department of Health, a practitioner may prescribe Schedule VI antibiotics and antiviral agents to other persons in close contact with a diagnosed patient when (i) the practitioner meets all requirements of a bona fide practitioner-patient relationship, as defined in subsection A, with the diagnosed patient; (ii) in the practitioner's professional judgment, the practitioner deems there is urgency to begin treatment to prevent the transmission of a communicable disease; (iii) the practitioner has met all requirements of a bona fide practitioner-patient relationship, as defined in subsection A, for the close contact except for the physical examination required in clause (iii) of subsection A; and (iv) when such emergency treatment is necessary to prevent imminent risk of death, life-threatening illness, or serious disability.

D. A pharmacist may dispense a controlled substance pursuant to a prescription of an out-of-state practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine authorized to issue such

prescription if the prescription complies with the requirements of this chapter and Chapter 34 (§ 54.1-3400 et seq.), known as the "Drug Control Act."

E. A licensed nurse practitioner who is authorized to prescribe controlled substances pursuant to § 54.1-2957.01 may issue prescriptions or provide manufacturers' professional samples for controlled substances and devices as set forth in Chapter 34 (§ 54.1-3400 et seq.) in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.

F. A licensed physician assistant who is authorized to prescribe controlled substances pursuant to § 54.1-2952.1 may issue prescriptions or provide manufacturers' professional samples for controlled substances and devices as set forth in Chapter 34 (§ 54.1-3400 et seq.) in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.

G. A TPA-certified optometrist who is authorized to prescribe controlled substances pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 may issue prescriptions in good faith or provide manufacturers' professional samples to his patients for medicinal or therapeutic purposes within the scope of his professional practice for the drugs specified on the TPA-Formulary, established pursuant to § 54.1-3223, which shall be limited to (i) oral analgesics included in Schedules III through VI, as defined in §§ 54.1-3450 and 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.), which are appropriate to relieve ocular pain, (ii) other oral Schedule VI controlled substances, as defined in § 54.1-3455 of the Drug Control Act, appropriate to treat diseases and abnormal conditions of the human eye and its adnexa, (iii) topically applied Schedule VI drugs, as defined in § 54.1-3455 of the Drug Control Act, and (iv) intramuscular administration of epinephrine for treatment of emergency cases of anaphylactic shock.

H. The requirement for a bona fide practitioner-patient relationship shall be deemed to be satisfied by a member or committee of a hospital's medical staff when approving a standing order or protocol for the administration of influenza vaccinations and pneumococcal vaccinations in a hospital in compliance with § 32.1-126.4.

(1983, c. 528, § 54-524.50:1; 1985, c. 336; 1988, c. 765; 1991, cc. 519, 524; 1992, c. 793; 1996, cc. 152, 158, 408; 1997, c. 806; 1998, c. 101; 1999, c. 745; 2000, cc. 882, 924; 2001, c. 465; 2003, c. 639; 2004, c. 744; 2006, c. 432; 2010, c. 74.)

#### **§ 54.1-3401. Definitions.**

As used in this chapter, unless the context requires a different meaning:

"Prescriber" means a practitioner who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription.

"Prescription" means an order for drugs or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph, or other means of communication to a pharmacist by a duly licensed physician, dentist, veterinarian, or other practitioner authorized by law to prescribe and administer such drugs or medical supplies.

*Commonwealth of Virginia*



Virginia Board of Pharmacy  
Virginia Board of Medicine

**REGULATIONS**  
FOR COLLABORATIVE  
PRACTICE AGREEMENTS

Title of Regulations: 18 VAC 110-40-10 et seq. Statutory

Authority: § 54.1-2400 and Chapters 33 and 34  
of Title 54.1 of the *Code of Virginia*

Effective Date: November 14, 2007

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**18VAC110-40-10. Definitions.**

The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"Agreement" means a collaborative practice agreement by which practitioners of medicine, osteopathy or podiatry and pharmacists enter into voluntary, written agreements to improve outcomes for their mutual patients using drug therapies, laboratory tests, and medical devices, pursuant to the provisions of §54.1-3300.1 of the Code of Virginia.

"Committee" means an Informal Conference Committee, comprised of two members of the Board of Pharmacy and two members of the Board of Medicine.

"Pharmacist" means a pharmacist who holds an active license to practice pharmacy from the Virginia Board of Pharmacy.

"Practitioner" means, notwithstanding the definition in §54.1-3401 of the Code of Virginia, a doctor of medicine, osteopathy, or podiatry who writes the order and is directly and ultimately responsible for the care of a patient being treated under an agreement and who holds an active license to practice from the Virginia Board of Medicine.

**18VAC110-40-20. Signed authorization for an agreement.**

A. The signatories to an agreement shall be a practitioner of medicine, osteopathy, or podiatry involved directly in patient care and a pharmacist involved directly in patient care. The practitioner may designate alternate practitioners, and the pharmacist may designate alternate pharmacists, provided the alternates are involved directly in patient care at a location where patients receive services.

B. An agreement shall only be implemented for an individual patient pursuant to an order from the practitioner for that patient. Documented informed consent from the patient shall be obtained by the practitioner who authorizes the patient to participate in the agreement or by the pharmacist who is also a party to the agreement.

1. The patient may decline to participate or withdraw from participation at any time.
2. Prior to giving consent to participate, the patient shall be informed by the practitioner or the pharmacist of the cooperative procedures that will be used pursuant to an agreement, and such discussion shall be documented in the patient record.
3. As part of the informed consent, the practitioner and the pharmacist shall provide written disclosure to the patient of any contractual arrangement with any other party or any financial incentive that may impact one of the party's decisions to participate in the agreement.

**18VAC110-40-30. Approval of protocols outside the standard of care.**

A. If a practitioner and a pharmacist intend to manage or treat a condition or disease state for which there is not a protocol that is clinically accepted as the standard of care, the practitioner and pharmacist shall apply for approval. The committee shall, in accordance with §2.2-4019 of the Code of Virginia, receive and review the proposed treatment protocol and recommend approval or disapproval to the boards.

B. Application and approval are not needed for treatment of conditions for which there is an accepted standard of care, but for which the practitioner wants to increase the monitoring and oversight of the condition over what the protocol recommends.

C. In order to apply for approval of a protocol outside the standard of care, the practitioner and the pharmacist shall submit:

1. An application and required fee of \$750;
2. A copy of the proposed protocol; and
3. Supporting documentation that the protocol is safe and effective for the particular condition or disease state for which the practitioner and the pharmacist intend to manage or treat through an agreement.

**ISVAC110-40-40. Content of an agreement and treatment protocol.**

A. An agreement shall contain treatment protocols that are clinically accepted as the standard of care within the medical and pharmaceutical professions.

B. The treatment protocol shall describe the disease state or condition, drugs or drug categories, drug therapies, laboratory tests, medical devices, and substitutions authorized by the practitioner.

C. The treatment protocol shall contain a statement by the practitioner that describes the activities the pharmacist is authorized to engage in, including:

1. The procedures, decision criteria, or plan the pharmacist shall follow when providing drug therapy management;
2. The procedures the pharmacist shall follow for documentation; and
3. The procedures the pharmacist shall follow for reporting activities and results to the practitioner.

D. The signatories shall implement a procedure for periodically reviewing and, if necessary, revising the procedures and protocols of a collaborative agreement.

E. If either the practitioner or the pharmacist who is a party to the agreement has a change of location or change of ownership, that person shall notify the other party and all patients who are participants in the collaborative agreement.

**18VAC110-40-50. Record retention.**

A. Signatories to an agreement shall keep a copy of the agreement on file at their primary places of practice.

B. An order for a specific patient from the prescribing practitioner authorizing the implementation of drug therapy management pursuant to the agreement shall be noted in the patient's medical record and kept on file by the pharmacist.

C. The patient's documented informed consent shall be retained by the practitioner in the patient record.

**18VACU0-40-60. Rescindment or alteration of the agreement.**

- A. A signatory may rescind or a patient may withdraw from an agreement at any time.
- B. A practitioner may override the collaborative agreement whenever he deems such action necessary or appropriate for a specific patient.

**ISVACII0-40-70. Compliance with statutes and regulations.**

Any collaborative agreement or referral under an agreement governed by this chapter shall be in compliance with the requirements of the Practitioner Self-Referral Act (§ 54.1-2410 et seq. of the Code of Virginia) and with Chapters 29 (§ 54.1-2900 et seq.), 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia and regulations promulgated pursuant thereto.