VIRGINIA PHARMACY CONGRESS
STUDY WORKPLAN DRAFT

for submission to

VIRGINIA BOARD OF HEALTH PROFESSIONS
VIRGINIA DEPARTMENTOF HEALTH PROFESSIONS

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

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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 in the Code of Virginia and further defined in the Regulations Governing the Practice of Pharmacy.[1,2] 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®).[3] 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.[3] 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.[2]

   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.[4] 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.[5] 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.[6] 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.[7] 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.[8]

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.[9] 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.[10]

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. 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*[11] 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.[12] 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.[13] 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.[12] 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.[13] 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.[14] 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.[2]

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.[15]

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.[8,16] Similarly, Pharmacist Clinicians must complete 20 additional hours of CPE beyond those required in New Mexico law.[7]

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.[17]

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.[17]

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.[18]

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.[19] 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.[20] Similar expanded functions exist for Veterans Affairs pharmacists.[21] Currently, in both North Carolina and New Mexico, pharmacists may seek advanced practice designations resulting in increased scope of practice including prescribing authority.[7,8] 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).[8] 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, dieticians, 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.[22,23] 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[24] 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.[24]

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.[25] 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_{1C}) 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.[25]

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[26] 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.[26] 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.[26]

Another example of a team-based delivery model in Virginia can be found at Buford Road Pharmacy in Bon Air.[27] 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."[28]

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.[29] 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.[30,31]

Physician Shortages and Reduced physician burden.

Several reports have identified an shortage in primary care physicians.[32,33,34,35] The American medical system is threatened by this severe shortage of primary care physicians, which could lead to restricted access to health care.[35] 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,[36] and a 38% increase in demand for general internists is projected by the year 2020.[31] 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).[34] 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.[37]

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.[38] 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.[39] 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.[40]

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.[41] De Maeseneer et al.[42] 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 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.[43] 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.[44] 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.[45] 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.[17]

   The Code of Virginia specifies in §54.1-3320 those acts and functions that are restricted to and must be performed by a pharmacist.[46] 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.[17]

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.[18] [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.[47] 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.[48]

   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).[49] 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).[49]

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.[28] 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.[28] 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.[19,28] 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 2nd behind nurses as the professionals with the highest level of honesty and ethical standards.[50]

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 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.[17] 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.[11,17] The professional competencies and educational outcomes achieved through completion of a Doctor of Pharmacy degree prepares graduates to enter pharmacy practice in any setting.[9] 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.[51] 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.[52] 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.)[a]
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

[a]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.[17] 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.[53] 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.[54]

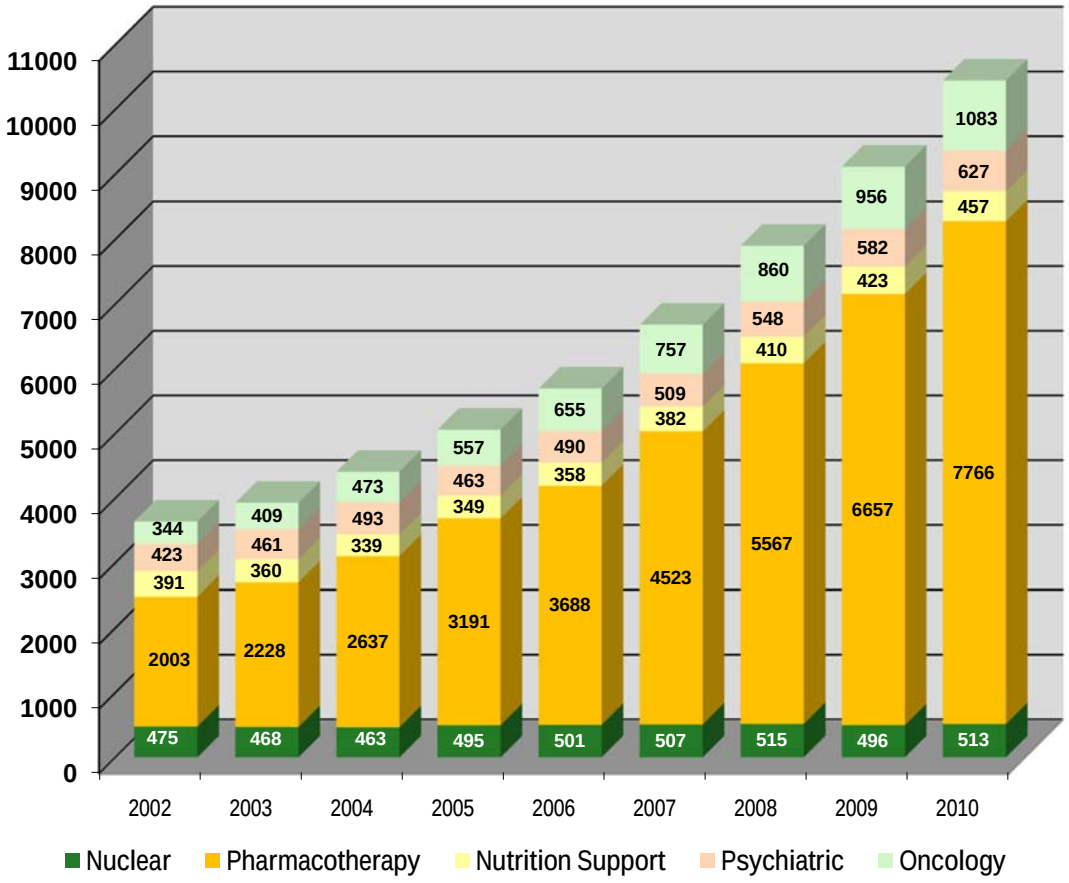
Pharmacy residency programs are post-licensure training programs designed for pharmacists to accelerate growth beyond entry-level competencies while remaining under the supervision of more experienced practitioners.[55] Specifically, a postgraduate year one pharmacy residency (PGY1) expands the general competencies in managing medication-use systems and supports optimal medication therapy outcomes in patients with a variety of disease states.[55] 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.[55] 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.[56] Compounding pharmacy is another specialty area of pharmacy. Currently, compounding pharmacists can gain recognition by International Academy of Compounding Pharmacists.[57]

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.[51] 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.[51] 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.[58] 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)
- Diplomat 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.[17] 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.[46]

    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.[17]

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).[17]

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."[59]

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.[60]

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.[60]

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.[61] 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.[61] 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 dieticians (38%), behavioral health clinicians (30%), specialty practice pharmacists (26%), physical therapists (20%), and chiropractors (13%).[62]

One example of a successful pharmacist referral mechanism in the community setting in the state of Virginia was described in Project ImPACT: Osteoporosis.[63] 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.[63]

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.[22,23] 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.[54] Pharmacists, similar to dieticians 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.[19] 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.[64]

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

North Carolina and New Mexico, pharmacists may seek advanced practice designations resulting in increased scope of practice including prescribing authority.[7,8] 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).[28] 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.[65,66] 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.[17] 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.[67] All ranges reported represent the 10th to 90th 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.[68]

   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.[69]

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.[70] 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.[70]

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.[71,72] and Perez, et al.[73] conducted multiple studies from 1988-2005, including an extensive literature review by Schumock, et al.[71] 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.[74] 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.[28]

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.[28]

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.[43] 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.[75] 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[76], 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
		Semester Total	**17.0**

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

Department	Course Number	Course Title	Course Credit
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
		Semester Total	**19.0**

P2 Spring Semester

Department	Course Number	Course Title	Course Credit
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
		Semester Total	**21**

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
		Semester Total	**18.0 - 19.0**

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
		Semester Total	**19.0 - 20.0**

P4 Year

Department	Course Number	Course Title	Course Credit
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
		Annual Total	**41.0**

Hampton University School of Pharmacy

First Year Professional

Fall Semester	**Credits**	**Spring Semester**	**Credits**
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		
Total:	**18**	**Total:**	**15**

Summer Session	**Credits**	
Community IPPE	1	(2 weeks - 80 hrs.)
Total:	**1**	

Second Year Professional

Fall Semester	**Credits**	**Spring Semester**	**Credits**
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
Total:	**18**	**Total:**	**18**

*Drug and Disease Management

Summer Session	**Credits**	
Institutional IPPE	1	(3 weeks - 120 hrs.)
Total:	**1**	

Third Year Professional

Fall Semester	**Credits**	**Spring Semester**	**Credits**
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		
Total:	**18**	**Total:**	**18**

Summer Session	**Credits**	
Elective IPPE	1	(3 weeks - 120 hrs.)
Total:	**1**	

Fourth Year Professional

Three Semester Period		**Credits**
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)
**Any (1) of the (5)

Total 43.0 over 3 semesters (Summer, Fall, & Spring)

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		
Semester Total	**17**	**Semester Total**	**17**

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

Semester Total	**17**	**Semester Total**	**17**

Third Professional Year (P3)

FALL	**Credit Hrs.**	**SPRING**	**Credit Hrs.**
PHAR 701: ICARE: Endocrine/Reproduction	2	PHAR 700: ICARE: GI/Nutrition	2
PHAR 704: Professional Practice Management I	3	PHAR 708: ICARE: Musculoskeletal	2
PHAR 709: ICARE: Hematology/Oncology	3	PHAR 712: Professional Practice 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 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 Practice Experience V	1
Semester Total	**18**	**Semester Total**	**18**

Fourth Professional Year (P4)

FALL	**Credit Hrs.**	**SPRING**	**Credit Hrs.**
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		
Semester Total	**18**	**Semester Total**	**18**
		PROGRAM TOTAL	**140**

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 Pharmaceutics 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