

**A Petition to the  
Board of Pharmaceutical Specialties  
Requesting Recognition of  
Ambulatory Care Pharmacy Practice  
as a Specialty**

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**Sponsored by:**

**The American College of Clinical Pharmacy**

**The American Pharmacists Association**

**The American Society of Health-System Pharmacists**

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***Definition of Ambulatory Care Pharmacy Practice—  
A Specialty in Medication Use for Preventive and Chronic Care***

*Ambulatory care pharmacy practice is the provision of integrated, accessible healthcare services by pharmacists who are accountable for addressing medication needs, developing sustained partnerships with patients, and practicing in the context of family and community.*

*This is accomplished through direct patient care and medication management for ambulatory patients, long-term relationships, coordination of care, patient advocacy, wellness and health promotion, triage and referral, and patient education and self-management.*

*American College of Clinical Pharmacy  
American Pharmacists Association  
American Society of Health-System Pharmacists*

***A Petition to the Board of Pharmaceutical Specialties  
Requesting Recognition of  
Ambulatory Care Pharmacy Practice as a Specialty***

***Executive Summary***

**Ambulatory Care Pharmacy Practice—  
A Specialty in Medication Use for Preventive and Chronic Care**

*Ambulatory care pharmacy practice is the provision of integrated, accessible healthcare services by pharmacists who are accountable for addressing medication needs, developing sustained partnerships with patients, and practicing in the context of family and community. This is accomplished through direct patient care and medication management for ambulatory patients, long-term relationships, coordination of care, patient advocacy, wellness and health promotion, triage and referral, and patient education and self-management.*

—ACCP/APhA/ASHP Joint Working Group

***Background***

By acquiring specialized knowledge and skills and creating a unique practice beyond the scope of pharmacy practice defined by licensure examination, an increasing number of pharmacists have distinguished themselves through the care of complex ambulatory patients according to the above definition.

In recognition of these efforts, the American College of Clinical Pharmacy (ACCP), the American Pharmacists Association (APhA), and the American Society of Health-System Pharmacists (ASHP) have partnered to develop a petition to the Board of Pharmaceutical Specialties (BPS) to recognize ambulatory care pharmacy practice as a specialty. The partnering associations believe there is tremendous value in recognizing and credentialing pharmacists who:

- maintain access to patients and foster ongoing, long-term relationships
- manage complex medication regimens in ambulatory patients
- integrate care of acute illnesses and exacerbations in the context of chronic conditions
- capably coordinate care among members of the healthcare team and through transitions among venues of care
- educate patients and engage in health promotion, wellness, and self-management
- advocate for patients

## ***Petition Overview***

Chronic diseases are the leading cause of death and disability in the United States. The incidence of major chronic diseases such as diabetes, asthma, heart disease, preventable cancers, and obesity, and their corresponding complications, is rising, despite advances in health science and technology. By 2025, an estimated 164 million Americans, nearly half the current population, will be affected by at least one chronic disease. In October 2007, the Milken Institute released a report indicating that the seven most common chronic diseases in the nation create a \$1.3 trillion annual additional cost for the U.S. economy. The report estimates that these costs could approach \$6 trillion by the middle of the century. In addition, poor medication adherence has been estimated to cost our nation approximately \$177 billion annually in total direct and indirect health care costs.

Medications play a significant role in the treatment, management, and prevention of chronic diseases, and they are being taken by a greater proportion of the population than ever before. With increased use of medications comes a heightened potential for medication errors, adverse drug events, drug misuse, and consequences of nonadherence. Within the current healthcare system, there are serious shortcomings in the safe and effective management of medications taken by patients with multiple, often interrelated, chronic diseases. The complexity of treatment regimens requires that patients have access to knowledgeable health professionals who can help manage their medication therapy. Another national health reform effort is pending, and health policy leaders will be looking for solutions, especially in the areas of chronic disease, wellness, prevention, and optimization of medication use.

Numerous scientific publications have conclusively demonstrated the dramatic reductions in morbidity and mortality among patients with chronic diseases who have had access to the professional services of an ambulatory care pharmacist. Such benefits have been documented, for example, in patients with asthma, diabetes, hepatitis C, hyperlipidemia, hypertension, chronic kidney disease, and HIV infection, among others. Fostering the expansion of specialty pharmacy practice in ambulatory care is one mechanism through which to address the substantial impact of chronic disease from a public health, humanistic, and financial perspective.

Ambulatory care pharmacist specialists practicing in a variety of patient care settings are well positioned to be part of the solution to the current public health crisis in chronic care. Ambulatory care pharmacist specialists screen and monitor patients for chronic diseases, complications, and exacerbations; collaboratively manage complex medication regimens; and support patients in their efforts to engage in positive health behaviors. Such pharmacists are already demonstrating improved outcomes of medication therapy, reduced complications, and improvement in health status.

As the complexity of a patient's health needs vary, so, too, does the level of knowledge and experience of the pharmacist serving that patient. Patients with complex diseases, problems, and medication regimens require care by pharmacists with specialized training, knowledge, and experience to help them achieve positive therapeutic outcomes. Health policy makers and society need a mechanism for identifying, recognizing, and providing access to pharmacists who can meet patient needs for specialized medication management. Specialty recognition of ambulatory care pharmacy practice by BPS would meet this need and provide a mechanism through which pharmacists could attain voluntary certification that recognizes achievement of

distinct knowledge, experience, and skill in meeting the unique needs of complex ambulatory patients with multiple chronic diseases.

## ***BPS Petition Process***

The *BPS Petitioner's Guide for Recognition of a Pharmacy Practice Specialty* outlines seven criteria, each with a list of supporting guidelines, to be addressed in each section of a petition. The petitioning organizations conducted a comprehensive literature review, examined in detail the 2007 *BPS Report of the Role Delineation Study of Ambulatory Care Pharmacists*, and obtained follow-up analyses of data gathered through the role delineation study to amass evidence to support the development of this petition. We also conducted web-based surveys of ambulatory care pharmacists and their employers to provide additional, more timely data for the petition. The evidence presented in our petition for each of the BPS criteria is summarized below.

### ***Criterion A: Need***

*This Criterion identifies the public health and patient care needs that are currently unmet by pharmacists in generalized practice, other pharmacist specialists, or other health professionals. The petition establishes how pharmacists in specialized ambulatory care practice can effectively meet these needs.*

Society has significant and growing patient-care and medication-management needs related to chronic and preventive care. Medication therapy is essential in the care and prevention of chronic diseases; with increasing numbers of ambulatory patients who have multiple coexisting conditions, regimens are often complex and associated monitoring needs, high. Unfortunately, a significant incidence of morbidity and mortality is associated with the misuse or inappropriate use of medications; risks are heightened in complex patients on multiple chronic medications. By virtue of their education, training, and experience, pharmacists are better prepared than any other healthcare professionals to meet patients' medication-management needs. Ambulatory care pharmacist specialists have the specialized knowledge and skills to meet the needs of complex ambulatory care patients with chronic diseases and to take responsibility for helping them achieve desired medication therapy outcomes and to detect and prevent complications more effectively and adeptly than generalist pharmacists or those certified in other specialties.

Ambulatory care pharmacist specialists serve as leaders in chronic and preventive care among the profession. They often implement patient care programs; educate and train pharmacists to deliver innovative clinical services (e.g., diabetes care, immunizations, health screening and point-of-care testing) in outpatient settings; and conduct practice-based research. In addition, they serve as practice-based educators within pharmacy, often serving as preceptors for the required undergraduate advanced pharmacy practice experiences and the growing number of post-graduate community and ambulatory care residency programs.

Similar to the overlap seen among medical specialties (e.g., family medicine, internal medicine, public health/preventive care), some similarities in domains exist between the proposed ambulatory care specialty and other BPS-recognized specialties, particularly pharmacotherapy. The differences, however, are significant. For example, ambulatory care pharmacist specialists, who develop long-term relationships with their patients and

families, often perform focused physical examinations and are unique in their ability to help patients make the behavioral changes often needed to achieve optimum health outcomes. They are also experts in preventive care. Another significant difference is practice setting. More than 70 percent of BPS-certified pharmacists in pharmacotherapy practice in institutional settings. In 2007, only 10 percent of those who passed the pharmacotherapy certification examination or who were recertified in that specialty practiced in an ambulatory setting.

### **Criterion B: Demand**

*The Criterion establishes that there exists a significant and clear health demand to provide the necessary public reason for certification. This is demonstrated through employer survey data, assessment of employment opportunities for ambulatory care pharmacist specialists, and letters and statements by individuals in specific areas within the healthcare system. Demand is viewed as a willingness and ability to purchase a commodity or service.*

With the growth in patient demand for management of complex medication therapy comes a concomitant rise in demand for all types of pharmacist services. The demand for ambulatory care pharmacist specialists is increasing, as is the demand for generalist pharmacist practitioners. Caring for patients in an effective and efficient manner will continue to require the coordinated efforts of both specialists and generalists.

The demand for ambulatory care pharmacist specialists has been demonstrated both by physicians, through the expansion of collaborative drug therapy management to 45 states, and by patients and third-party payers, who increasingly pay for specialized services. David A. Knapp, a recognized researcher in the area of pharmacist demand, estimated the quantity of pharmaceutical services that would best serve the healthcare needs of society in 2020. His research determined that one pharmacist would be required to meet the needs of every 1,000 such patients. On the basis of this projection, the United States will need about 130,000 primary (ambulatory) care pharmacists by 2020. Another estimate of demand has been created on the basis of the experience of Kaiser Permanente/Denver, which operates a closed system that provides its 350,000 patients with highly managed medication therapy. Kaiser estimates its needs for primary (ambulatory) care pharmacists for its patients at 1.1 per 1,000. If this ratio were extended to the U.S. population in 2020, more than 300,000 such pharmacists would be needed. (These estimates do not include pharmacists performing order- fulfillment functions in community pharmacies.)

### **Criterion C: Number and Time**

*This Criterion quantifies that there are a reasonable number of individuals who devote most of the time of their practice to ambulatory care pharmacy practice.*

To accurately determine the number of practitioners and the time spent in ambulatory care practice, the petitioners developed a web-based survey and fielded it to 5,434 pharmacists in ambulatory care practice. Names were identified through membership records within ACCP, APhA, and ASHP. Of the 772 responding pharmacists, over 87 percent indicated that they are practicing at a specialty level. Based on these survey results, we estimate that 4,728 pharmacists are currently engaged in specialized ambulatory care practice. Clearly this number is underestimated because not all pharmacists practicing in ambulatory care specialty practice are members of the three partnering professional organizations; however, we believe



that pharmacists who are professionally engaged as members of associations are more likely than others to pursue specialty recognition.

The survey also asked pharmacists to quantify the percentage of time in an average week that they spent engaged in direct patient-care activities such as the following:

- managing medication use
- developing and implementing individualized treatment goals and plans
- gathering information from and assessing patients
- integrating care of acute illnesses in the context of patients' underlying chronic diseases and health status
- performing roles in patient education, health promotion, wellness, and self-management
- coordinating care among members of the healthcare team
- advocating for patients

Results showed that more than 55 percent of survey respondents spent at least 50 percent of their time engaged in direct patient-care activities.

The growth in specialized ambulatory care practice is reflected in the growth of the number of postgraduate year (PGY) 2 ("specialty") residency programs in ambulatory care. Ten years ago, there were 33 ASHP-accredited specialty residency programs in ambulatory care (previously called "primary care"). Today, these programs number 45—an increase of 36 percent. In comparison, there are currently 47 PGY2 residency programs in oncology. Specialty residencies in ambulatory care graduate about 48 ambulatory care pharmacist specialists each year, fully 19 percent of all PGY2 residency graduates. Community pharmacy residency programs were in their infancy 10 years ago; today, there are 54 accredited programs with 80 positions.

The survey indicated that 56 percent of responding pharmacists would be interested in obtaining ambulatory care pharmacist specialist certification if one were made available. An additional 20 percent indicated they would be "somewhat likely" to pursue the credential. Pharmacy employers predicted an increased need for pharmacists at the specialist level.

**Criterion D: Specialized Knowledge**

**Criterion E: Specialized Functions**

*These Criteria outline the specialized knowledge of one or more of the pharmaceutical sciences and the biological, physical, behavioral, and administrative sciences which underlie them required by ambulatory care pharmacist specialists and defines the specialized functioning of the ambulatory care pharmacist specialist, which is distinct from other BPS-recognized pharmacy specialties.*

Ambulatory care pharmacist specialists possess a unique body of knowledge and skills that enable them to perform specialized functions that fulfill unmet patient-care needs. Services provided by ambulatory care pharmacist specialists, and the specialized knowledge that support these functions, are qualitatively different from those provided by generalist pharmacist practitioners. While ambulatory care pharmacist specialists may perform some of the same functions as generalist pharmacist practitioners do, certain functions performed by the specialist are distinctly different. Likewise, the generalist pharmacist practitioner may at

times perform functions that could be identified as specialist ambulatory care functions. However, compared with generalist pharmacists, pharmacists in ambulatory care routinely perform many unique functions and additional functions at greater depth or with greater emphasis.

BPS analyzed these functions in 2006 in the afore-mentioned role delineation study, which describes and empirically validates the domains, tasks, and knowledge that comprise ambulatory care pharmacy practice. According to the task analysis performed for that study, the following are the domains of ambulatory care pharmacy specialty practice that are performed regardless of practice site:

- direct patient care
- practice management
- public health functions
- medical informatics and professional development
- patient advocacy

The functions that were determined to be unique to specialized ambulatory care practice, or performed at a greater depth or with a different emphasis in ambulatory care practice, were within direct patient care, practice management, and public health functions. Performance of these specialized tasks was further supported through a supplemental survey of ambulatory care pharmacists conducted by the petitioners.

The specialized skills required to perform these functions are as follows:

- analyze, synthesize, evaluate, and manage complex drug regimens by monitoring and assessing the patient and/or patient information, developing individualized care plans, collaborating with other healthcare professionals, and providing patient education
- communicate in ways that foster the development of effective, collaborative, long-term relationships with patients and their caregivers, peers, and other healthcare professionals; motivate patients to adhere to medication therapy and engage in healthy behaviors (e.g., lifestyle and behavior changes)
- conduct physical assessments, administer medications and immunizations, and perform point-of-care testing for patients at risk for disease and for the purpose of monitoring and adjusting drug therapy; engage in preventive care activities and health promotion
- design and implement clinical services and take responsibility for the planning for and management of those services
- retrieve and assess relevant medical and patient information to practice evidence-based medicine, conduct practice-based research, and contribute to the body of knowledge regarding medication management for chronic and preventive care
- model ambulatory practice leadership

The petition also compares and contrasts the differences between the recognized domains and functional areas for ambulatory care pharmacist specialists and pharmacotherapy specialists. The ambulatory care pharmacist specialist performs a significant breadth and depth of direct patient-care functions, such as interviewing and assessing patients, employing point-of-care and self-testing devices, and implementing practices and systems. These functions are centered around long-term relationships with patients and caregivers, ongoing

communication and support, and activities that support patient behavioral changes and improvement of health outcomes.

### **Criterion F: Education and Training**

*Criterion F describes the education, training, and experience required to acquire specialized knowledge and skills to perform the specialized functions and distinguishes from the generalist practitioner and the requirements of initial licensure.*

According to the *Accreditation Council for Pharmacy Education Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy (PharmD) Degree Program*, the pharmacy curriculum provides a thorough foundation in the biomedical, pharmaceutical, social/behavioral/administrative, and clinical sciences. The curriculum provides graduates with the competencies needed to enter pharmacy practice in any setting and to contribute to the profession of pharmacy throughout their careers. The PharmD degree alone, however, does not provide sufficient educational depth and breadth for an ambulatory care pharmacist specialist; additional training, clinical work experience, and study are necessary to prepare a specialist in ambulatory care. Because ambulatory care is an evolving specialty, many ambulatory care pharmacist specialists have obtained the knowledge, skills, and abilities to provide specialized care through mechanisms other than structured training programs.

The state licensure examination sets a minimum standard for practicing pharmacy. Following licensure, pharmacists have acquired the differentiated knowledge and skills required for specialized ambulatory care pharmacy practice by a variety of methods. These methods include:

- PharmD degree education, clinical work experience, and self-study
- PharmD degree education, PGY1 residency training, clinical work experience, and self-study
- PharmD degree education, PGY1 residency training followed by PGY2 ambulatory care residency training, clinical work experience, and self-study

The most effective process by which to prepare a pharmacist for a career as an ambulatory care pharmacist specialist is the completion of a PGY1 residency in pharmacy practice, with or without an emphasis in community practice, followed by completion of a PGY2 residency in ambulatory care. Residency programs provide the most effective structured experiential learning opportunities in ambulatory care and have been increasingly utilized as programs become more readily available. BPS will determine the education and training requirements for specialist eligibility.

### **Criterion G: Transmission of Knowledge**

*Criterion G establishes that there is adequate transmission of specialized knowledge through professional, scientific, and technical literature immediately related to specialized ambulatory care practice.*

Because issues related to medication use for chronic and preventive care are of interest to a broad array of pharmacists, dissemination of knowledge occurs through mainstream peer-reviewed pharmacy and medical journals, newsletters, and other publications. Each year, hundreds of hours of live and web-based programming related to specialized ambulatory care are offered through pharmacy practice organizations, thereby fostering the sharing and dissemination of knowledge and practice excellence. In addition, certificate training programs and traineeships provide a mechanism by which pharmacists can acquire the knowledge and skills they need to perform specialized ambulatory care functions within a variety of focused disease states. Enduring resources are also made available through a variety of means. The number of articles relating to ambulatory care pharmacy published in peer-reviewed journals has nearly doubled in the past three years, demonstrating an interest in and need for information on medication therapy management and improved outcomes for ambulatory patients with complex chronic and preventive care needs.

## ***Conclusion***

The preventive and chronic care needs of ambulatory patients are complex. These needs are dictated by the patient's health status and expectations and are not a function of a particular practice setting. The fact that patients are ambulatory is significant, as societal influences and trends have a strong impact on patients' adherence to medication regimens, self-care, and self-monitoring of their chronic diseases. While there is some overlap among specialty areas, the needs of complex ambulatory patients with and at risk for chronic disease are significant and growing. They are sufficiently unique to support recognition of ambulatory care pharmacy practice as a distinct specialty. Given the predicted increase in needs and acuity in ambulatory care patients with chronic diseases, it is clear that high-quality care for these patients will require the full application of specialized knowledge and skills of today's ambulatory care pharmacist specialists and those who would seek specialty recognition in ambulatory care.

## CRITERION A: Need

The area of specialization shall be one for which specifically trained practitioners are needed to fulfill the responsibilities of the profession of pharmacy in improving the health and welfare of the public, which responsibilities may not otherwise be *effectively* fulfilled. ***This criterion addresses NEED.*** BPS defines NEED as a condition of requiring supply.

### ***Introduction***

In recent decades, improvements in medical science and technology have provided opportunities for people to live longer, healthier lives. New medications and technologies are discovered and employed with increasing frequency. Nonetheless, the United States is faced with the paradox of increasing life expectancy at the same time that chronic disease morbidity and mortality are also on the rise. Compounding the situation are escalating health expenditures that are not translating into better overall healthcare or health status.

#### *Chronic Diseases and Complex Medication Therapy*

Chronic diseases are the leading cause of death and disability in the United States. Seventy percent of all deaths (1.7 million Americans annually) are a result of chronic diseases and their complications. The incidence of major chronic diseases such as diabetes, asthma, heart disease, preventable cancers, and obesity—and their corresponding complications—is rising, despite advances in health information and technology. **Nearly half of all Americans live with at least one chronic condition.**<sup>1</sup> Chronic diseases and their complications impose major limitations on daily living for 25 million Americans. While these diseases are common and costly, many are also preventable—through strategies such as eating a nutritious diet, being physically active, using medications safely and appropriately, and avoiding tobacco use.

The lag time between discovery of new evidence and implementation into practice contributes to this problem. It takes an average of 17 years following the completion of original research for new evidence to be widely integrated as a standard of care within the healthcare system.<sup>2</sup> In the interim, the opportunities to help patients lead healthier lives and attain better outcomes while reducing the costs of suboptimal care are lost. **The medical costs for people with chronic diseases account for more than 75 percent of the nation's \$2 trillion annual healthcare expenditures.**

Medications play a significant role in the treatment, management, and prevention of chronic diseases, and they are being taken by a greater proportion of the population than ever before. It comes as no surprise that medication use is highest among the senior population, which accounts for approximately 34 percent of all prescriptions. Among adults over 65 years of age, 28 percent use five or more chronic medications each month, and more than

75 percent have at least one chronic health condition that requires ongoing care and management.<sup>3</sup>

A recent study evaluating prescription data of 2.5 million Americans that was conducted by Medco Health Solutions shows that more than half of all insured Americans take at least one chronic medication.<sup>4</sup> Moreover, increased medication use is growing faster in young adults than in other segments of the population. Thirty percent of children under age 19 take at least one chronic medication for conditions such as asthma, allergies, attention-deficit hyperactivity disorder, diabetes, or depression.<sup>4</sup> Seventy percent of walk-in physician visits and outpatient clinic visits result in at least one prescription medication.<sup>5</sup> The complexity of treatment regimens requires patients to have access to knowledgeable health professionals who can help manage their medication therapy.

#### *Medication Errors, Misuse, and Adherence Challenges*

With this increased use of chronic medications comes a heightened potential for errors and misuse, underscoring the need for well-coordinated medication therapy management (MTM). Within the current healthcare system, there are serious shortcomings in the provision of safe and effective medication management. In 2000, the costs of drug-related illness and death in ambulatory care settings alone were estimated at more than \$177 billion.<sup>6</sup> These data are eight years old, and the costs continue to rise steadily. A 2007 Call to Action by the Institute for Safe Medication Practices (ISMP)<sup>7</sup> and the 2006 Institute of Medicine (IOM) Quality Chasm Series report *Preventing Medication Errors* demonstrate the critical need for ambulatory care pharmacist specialists to help patients use medications safely and appropriately. In addition to helping ensure appropriate medication use and preventing errors, pharmacists are needed to coordinate, manage, and integrate ambulatory patients' chronic disease care, and the acute episodes that surface in association with chronic diseases, in order to prevent disease progression and to optimize outcomes.

Knapp has projected that by 2020, nearly 300,000 pharmacists will be needed to perform patient-care functions beyond provision of medication—165,000 of these in primary care.<sup>5</sup> This figure is based upon the services that the population will require for medication management in 2020 given projections of medication utilization, characteristics of the population, and the unmet need of today. This projected need is 50 percent higher than the entire population of practicing pharmacists today. Importantly, this figure is independent of the service needs associated with dispensing of medications.

Compounding each of these issues is the fact that today's ambulatory patients are sicker than ever before. Technology now enables many procedures and surgeries to be performed on an outpatient, rather than inpatient, basis. Cost-containment efforts to shorten hospital stays result in the discharge of patients earlier in the course of treatment, recovery, and postsurgical procedures, thus resulting in greater acuity of patients in ambulatory settings. In addition, because new medication therapy is often initiated during inpatient care, early discharge increases the likelihood that adverse drug-related effects (ADEs) might occur in the ambulatory setting and may go undetected. Continuity of care related to the exchange of information and to management of medication therapy throughout the continuum of pharmacy services delivery remains a challenge.

### *Pending Healthcare Reform*

The nation is frequently described as “facing a healthcare crisis,” and another national health reform effort is pending. Both candidates in the 2008 presidential election campaign included health care as a top priority for their administrations. In June 2008, Senate Finance Committee leaders Max Baucus (D–Montana), chair, and Charles Grassley (R–Iowa), ranking member, held *Prepare for Launch—Health Reform Summit* to initiate a process to gain knowledge and begin discussions for reforming the U.S. healthcare system. Healthcare costs make up more than 15 percent of the gross domestic product (GDP) and are growing 2.5 percent faster than the GDP. Should this rate of growth continue, healthcare spending will exceed 22 percent of GDP by 2020 and reach almost 30 percent of GDP by 2030.<sup>8</sup> According to the Congressional Budget Office, this exceeds our country’s spending on food or housing—a level viewed by many as unsustainable. These senate leaders concluded that our healthcare system is “broken (and) endangering families and sapping this country’s ability to compete economically.” Health policy leaders will be looking for solutions, especially in the areas of chronic disease, wellness, prevention, and optimization of medication use.

### *Ambulatory Care Pharmacist Specialists*

Many pharmacists who practice in ambulatory care settings have distinguished themselves by gaining in-depth knowledge, advanced training, and expertise to provide optimal care to patients who are at risk for chronic diseases. These ambulatory care pharmacist specialists are in a position to be part of the solution to our nation’s healthcare crisis. In specialized practices that span a variety of outpatient environments, they assist patients in screening and monitoring their conditions, collaboratively manage their medications, and support them in their efforts to engage in positive health behaviors aimed at improving their overall health, preventing diseases and disease progression, and minimizing avoidable complications of their disease. Ambulatory care pharmacist specialists are already demonstrating improved outcomes of medication therapy, reduced complications, and improvement in health status.<sup>9,10,11</sup>

Patients with complex diseases, problems, and medication regimens require care by pharmacists with specialized training, knowledge, and experience to help them achieve positive therapeutic outcomes. Health policy makers and society need a mechanism for identifying, recognizing, and providing access to pharmacists who can meet patient needs for specialized medication management, including recognizing individuals who have obtained specialist recognition and have attained the additional training, experience, and expertise to lead patients, the profession, other healthcare providers, and society to better health by managing their disease and reducing preventable conditions, complications, and sequelae. Specialty recognition of ambulatory care pharmacy practice by the Board of Pharmaceutical Specialties (BPS) would provide a mechanism through which pharmacists could attain voluntary certification that recognizes achievement of a focused and distinct level of knowledge, experience, and skill in serving the unique needs of ambulatory patients.

**Guideline 1. Identify specific public health and/or patient care needs which are not being met currently and which pharmacists in the proposed specialty can meet effectively.**

Seriously unmet needs exist in the areas of chronic diseases, medication adherence, medication therapy management of the underserved, preventive care, and wellness. Among the chronic conditions in which the need is greatest are asthma, diabetes, cardiovascular disease and stroke, cancer, obesity and inactivity, and chronic renal disease. Many of these chronic diseases are interrelated and coexist in patients, complicating their health status and requiring complex treatment regimens.

#### *Unmet Needs in Medication Adherence and Medication Error Prevention*

Medication errors occur frequently in the U.S. healthcare system—both in inpatient and ambulatory care settings. Many of these errors are preventable and often result in patient injury and added costs to the healthcare system. In recent years, national initiatives aimed at researching, raising awareness of, and preventing problems with medication use have been launched by the IOM, the National Council for Patient Information and Education (NCPIE), and the Institute for Safe Medication Practices, as well as independent researchers. IOM has estimated national annual costs associated with preventable ADEs events in the ambulatory care setting at \$887 million, equating roughly to \$1,983 per ADE.<sup>12</sup> Authors of the IOM report suggest this figure is underestimated, as it does not include costs of nonadherence to prescribed regimens, use of drugs without an appropriate indication, or lack of use (i.e., a patient did not receive medications that should have been prescribed based on medical evidence). This figure also does not account for lost earnings or lost productivity.

Gandhi et al. reported the prevalence and impact of preventable ADEs in the ambulatory care setting in a 2007 article published in the *New England Journal of Medicine*.<sup>13</sup> This prospective study, which involved direct patient interviews and three-month follow-up, demonstrated a 27 percent occurrence of ADEs in the ambulatory setting—four times higher than that estimated for inpatients (accounted for in part by the longer duration of therapy in the ambulatory setting and the fact that this study's methods involved patient interviews in addition to chart reviews). Thirty-nine percent of these ADEs were determined to be preventable or ameliorable. Notably, in 63 percent of the ameliorable ADEs, patients reported ADE-related symptoms to physicians; however, the ADEs went undetected and no change in therapy was made during the three-month study period. (In the other 37 percent, patients did not report symptoms to their physicians.) Interestingly, three times as many ADEs were detected through patient interviews as from chart reviews—underscoring the importance of direct communication with patients and long-term patient/provider relationships.

In August 2007, NCPIE released a national action plan for improving prescription medication adherence. This initiative was aimed at addressing “America’s ‘other’ drug problem” that leads to disease progression, unnecessary complications, reduced functional abilities, and lower quality of life. The total direct and indirect health care costs associated with consequences of medication nonadherence are estimated to be \$177 billion annually.<sup>14</sup>

As more and more Americans of all ages use medications to manage chronic conditions, the need for coordinated, integrated medication therapy management increases. Over the next 22 years, the number of Americans over age 65 years is expected to reach an all-time high of 71.5 million—roughly 20 percent of the population and nearly double the total in 2003. Older adults are prescribed multiple medications; roughly 28 percent take five or



more chronic medications. Polypharmacy and the potential for ADEs and medication errors, as well as associated problems, will be even more prevalent.

MTM is an important component of the Medicare Part D drug benefit, and one for which pharmacists are being compensated as drug therapy managers. An estimated 11 percent of Medicare beneficiaries qualify for MTM services, and the demand for these services will increase with the aging population. The need for MTM extends well beyond the Medicare population to all patients with chronic diseases and conditions, including diabetes, hypertension, dyslipidemias, asthma, and thromboembolic disease. Ambulatory care pharmacist specialists manage complex medication regimens for patients with chronic disease, help prevent complications, identify ADEs, and intervene as needed, while motivating patients to adhere to medication therapy and care plans.

The need for expanded preventive care and wellness efforts aimed at preventing chronic diseases and their associated complications is well documented. For example, national public health efforts like Healthy People 2010, Healthy People 2020, and Steps to a *HealthierUS* encourage healthy choices that may prevent development of diabetes, heart disease, and other chronic conditions. Ambulatory care pharmacist specialists are actively engaged in specialty practices to meet the chronic and preventive care needs of patients.

#### *Unmet Need of Patients with Diabetes*

An estimated 18 million patients of all ages have been diagnosed with diabetes.<sup>15</sup> The incidence of diabetes and related complications is increasing. The rate of diabetes among people between the ages 30 and 39 has risen by 70 percent in recent years; among children, the incidence of type 2 diabetes is dramatically increasing. Societal trends of eating diets higher in fat and sugar, consuming larger serving sizes, and living less active, more sedentary lifestyles are introducing diabetes complications, including heart disease, at much earlier ages than seen in previous generations. In addition, of the 23.6 million people estimated to have diabetes, 5.7 million are unaware that they have the disease.<sup>15</sup>

Undiagnosed or inadequately managed diabetes may lead to complications such as cardiovascular disease, retinopathy, blindness, renal failure, neuropathies, dental and periodontal disease, foot ulcers, and dermatologic problems. These complications are also increasingly prevalent, demonstrating that the needs of many patients with diabetes are not being met. Patient outcomes in the short and long term are highly dependent on the effective use of medications, integration of diet and exercise, self-monitoring of blood glucose, self-care, and patient understanding of their care plans. A related unmet need is the integration of diabetes care and treatment for other acute problems (e.g., influenza, gastrointestinal viral infections) that have the potential to significantly influence hydration status and blood glucose levels in patients with diabetes.

The total cost of diabetes and related complication in the United States in 2007 was \$174 billion.<sup>15</sup> Nearly one-third of patients with diabetes experience severe complications that result in two or more hospitalizations per year. An estimated \$2.5 billion could be saved annually through better management of patients with diabetes and complications in ambulatory care and through prevention of complications that require hospitalization.<sup>16</sup> Ambulatory care pharmacist specialists educate these patients in the use of medications and devices for treating and monitoring their disease. They also develop and refine care

plans to ensure patients are prepared to manage hyper- and hypoglycemic episodes and prevent complications.

#### *Unmet Need of Patients with Asthma*

Asthma affects an estimated 22.2 million people in the United States.<sup>17</sup> In 2004, there were 14.7 million outpatient asthma-related visits to physicians' offices and hospital outpatient departments and 1.8 million visits to emergency departments (EDs). There also were 497,000 asthma-related hospitalizations and 4,055 deaths. Children aged four years and younger had the highest incidence of ED visits and hospitalizations associated with asthma.

When asthma is not effectively managed, acute exacerbations are more frequent. Such episodes require emergent treatment and result in 12.8 million missed days of school and 10.1 million missed days of work each year.<sup>17</sup> Better understanding of the pathophysiology and pathogenesis of asthma has led to improved treatment approaches and higher-quality evidence for preventing exacerbations, improving quality of life, and reducing asthma-related morbidity and mortality. Prescription medications, self-monitoring, and self-treatment are integral to improved asthma management. Patient education, follow-up, and adherence are critical to maintaining control of the disease and preventing or adequately managing exacerbations. In addition, evidence now suggests that early anti-inflammatory intervention may prevent airway remodeling—providing additional opportunities for long-term outcome improvement. An estimated 80 percent of costs associated with asthma are generated by the 20 percent of patients whose asthma is not well managed in the ambulatory care setting.<sup>18</sup> Ambulatory care pharmacist specialists educate patients in the use of medications and devices. They also create and adjust action plans to help patients with asthma maintain control and prevent exacerbations.

#### *Unmet Need of Patients with Cardiovascular Disease*

Heart disease is the leading cause of death in the United States and a major cause of disability. Almost 700,000 people die of heart disease in the United States each year. Medications are the mainstay of treatment for hypertension, dyslipidemias, arrhythmias, angina, and congestive heart failure, as well as for primary or secondary prevention of cardiovascular disease, coronary artery disease, myocardial infarction, and stroke.

With advances in medical technology and the coexistence of many of these problems with other chronic diseases, medication therapy for patients with cardiovascular diseases has become increasingly complex. Ambulatory care pharmacist specialists manage these complex medications, provide individualized clinical pharmacokinetic dosing when needed, and help patients adhere to therapy and achieve desired medication and health outcomes.

#### *Unmet Need in Preventing and Managing Renal Disease*

The primary causes of chronic renal disease are hypertension and diabetes. Twenty-six million Americans have chronic renal disease, and 20 million more are at increased risk for the disease. Optimal disease management of hypertension and diabetes and early detection can help prevent the progression of renal disease. Adherence with medication regimens is crucial to keeping these diseases in check and preventing the development, or slowing the progression, of renal disease. Ambulatory care pharmacist specialists contribute significantly to prevention and management of chronic renal disease.

### *Unmet Needs in Preventive Care—Helping Patients to Make Healthy Behavior Choices*

Preventive interventions focusing on such areas as adult immunizations, smoking cessation, weight loss, healthy diet, and physical activity are known to improve health, prevent disease, and slow disease progression. Despite the data supporting these activities, they are not routinely sought or embraced by most Americans. Pharmacists who develop long-standing relationships with their patients and interact with them at regular intervals are well positioned to influence healthy lifestyle choices and encourage behavior change. With the required knowledge and skills, pharmacists can significantly contribute to improved health of their patients. Ambulatory care pharmacist specialists often provide leadership within the profession by establishing preventive care programs, implementing innovative services, and educating and training pharmacists to engage in preventive care activities.

**Immunization.** Among the objectives of Healthy People 2010 is to “prevent disease, disability, and death from infectious diseases, including vaccine-preventable diseases.” Immunizations are now available to address many diseases. However, patients are still suffering from the morbidity and mortality associated with these diseases because they are unaware of, or do not have access to, these vaccines. Pharmacists are acquiring specialized knowledge, training, and legal authority to screen patients and administer these vaccines in nearly all states. Ambulatory care pharmacist specialists often lead efforts to provide pharmacist training and implement immunization programs.

**Smoking Cessation and Prevention.** Some 46.5 million adults in the United States smoke cigarettes; this single behavior will result in disability and premature death for half of them. For individuals who quit smoking, the risk of smoking-related morbidity declines and eventually is similar to that of a nonsmoker. These statistics underscore the importance of efforts aimed at smoking cessation for any patients who smoke and for smoking prevention among teens and young adults.

**Healthy Diet and Weight Loss.** Another objective of Healthy People 2010 is to reduce the prevalence of obesity among adults to less than 15 percent. Despite this goal, current data indicate that the situation is worsening rather than improving. Since the 1970s, the prevalence of overweight and obesity has increased sharply, from 15 percent to 32.9 percent in adults aged 20–74 years. During that same period, the prevalence of overweight increased from 5 percent to 13.9 percent in children aged 2 to 5 years; for those aged 6 to 11 years, prevalence increased from 6.5 percent to 18.8 percent; and for those between the ages of 12 and 19, prevalence increased from 5.0 percent to 17.4 percent.<sup>19</sup> An increasing number of pharmacists are successfully helping patients achieve a healthier weight.

**Exercise/Inactivity.** More than 60 percent of American adults do not get enough physical activity, and more than one-fourth are not active at all. Exercise, along with a healthy diet, is important in optimizing outcomes in diabetes, cardiovascular wellness, and weight control. In addition, poor dietary choices and inactivity lead to obesity, type 2 diabetes, and cardiovascular diseases, especially in patients at risk for such diseases because of family history or other factors.

Many diseases and conditions, such as hypertension, osteoarthritis, dyslipidemias, type 2 diabetes, coronary heart disease, stroke, gallbladder disease, sleep apnea, respiratory problems, and certain types of cancer (e.g., endometrial, breast, colon), are associated with or worsened by obesity and inactivity.

### *Unmet Needs in Cancer Prevention and Early Detection*

The association between unhealthy behaviors and certain types of cancer is well documented. For example smoking and tobacco use are associated with development of lung, oral, esophageal, and pancreatic cancer. Unprotected sexual activity with multiple partners is associated with cervical cancer caused by the human papilloma virus. Certain cancers, such as colorectal, breast, prostate, and cervical, have much better outcomes when detected and treated early. Through ongoing trusting relationships with their patients, pharmacists can encourage screening and other wellness activities aimed at cancer detection and prevention.

The unmet public health needs of patients with or at risk for chronic diseases and their complications are significant, especially among complex patients with multiple diseases on multiple medications. Ambulatory care pharmacist specialists provide particular value to patients and the healthcare system in managing medications, chronic and preventive care, and transitions between settings of care for these complex patients. Specialized functions performed by ambulatory care pharmacist specialists to actively and effectively help these patients manage their diseases are described and documented in Guideline 2.

### **Guideline 2. Specify how the functions performed by pharmacists in the proposed specialty address these specific needs of the public's health and well-being.**

Many ambulatory care pharmacist specialists have distinguished themselves by gaining in-depth knowledge, advanced training through residencies and certificate training programs, and expertise to provide advanced care to patients. Ambulatory care pharmacist specialists practice in many different settings—including community pharmacies, ambulatory clinics, physicians' offices, hospital outpatient departments, HMOs, and managed care organizations. In their specialized practices, these pharmacists establish long-term relationships with patients, caregivers, and providers that form a foundation of trust, education, motivation, and support. Ambulatory care pharmacist specialists assist patients in screening and monitoring their conditions, collaboratively managing their medications, and supporting them in their efforts to engage in positive health behaviors aimed at improving their overall health, preventing diseases and disease progression, and minimizing avoidable complications of their disease. Many pharmacists providing this specialized care are demonstrating improved outcomes of medication therapy, reduced complications, and improvement in health status.<sup>20,21,22,23</sup> They publish their work in peer-reviewed journals, and many also engage in practice-based research.

Ambulatory care pharmacist specialists work directly with complex patients in collaboration with other members of the healthcare team to develop and refine individualized care plans and educate patients about self-monitoring and self-management of their disease including symptoms of exacerbation. When their patients experience other health issues, with or without transitioning between care settings, these pharmacists work with them to ensure that management of their acute condition is correlated with ongoing care of their chronic conditions, and that patients know what to look for and what to do if problems occur.

Ambulatory care pharmacist specialists routinely provide continuity of care for ambulatory patients who are under the care of multiple physicians in various settings. Following patient discharge from hospitalization for an acute problem, the ambulatory pharmacist specialist

ensures that their patient transitions smoothly back to daily living, and that any new regimens are well coordinated with existing regimens and pre-existing diseases. These pharmacists identify and prevent possible drug therapy problems, and proactively manage problems when they do occur.

Ambulatory care pharmacist specialists provide specialized care to patients with diabetes, cardiovascular disease, asthma, renal disease, and other chronic diseases. They provide individualized dosing of anticoagulation therapy for patients with thromboembolic disease and educate patients with asthma in the use of peak flow meters, inhalers, spacers, and nebulizers. They also create and adjust asthma action plans. They educate patients with diabetes in the use of medications, blood glucose monitors, insulin measurement and injection techniques, pumps, carbohydrate counting, and care plans—including how to manage hyper- and hypoglycemic episodes and what to do when they become sick with viral illnesses and other problems that influence control of their diabetes. Ambulatory care pharmacist specialists also work with their patients to monitor and prevent cardiovascular and common infectious diseases. Ambulatory care specialists build relationships with patients and caregivers. They perform periodic assessments to monitor their patients' conditions and prevent exacerbations and to ensure new medications or changes in therapy are well tolerated and effective. They actively and adeptly manage medication therapy for their patients in the context of current and ongoing therapy, prevent and detect drug therapy problems, and skillfully work with patients to motivate behaviors (and when necessary behavior changes) that improve their health.

Many ambulatory care pharmacist specialists are engaged in collaborative practice arrangements. They review laboratory data and adjust therapy as indicated, in collaboration with other care providers. They assume responsibility for managing complex regimens and work to ensure that desired medication-related outcomes are met. They advocate for their patients and provide public health education and screenings.

In August 2008, the petitioning organizations conducted a survey of ambulatory care pharmacist specialists. The survey was fielded to 5,434 pharmacists in ambulatory care practice identified through membership records within ACCP, APhA, and ASHP. The response rate was 14 percent. A copy of the survey instrument is attached as Appendix A-1. A majority of respondents (55.2 percent) reported that in an average week, they devote more than 70 percent of their time performing specialized functions.

**Guideline 3. Describe and document with references how the public's health and well being may be at risk if the services of practitioners in the proposed specialty are not provided.**

#### *Public Health Risks of Medication-Related Problems*

One and a half million preventable ADEs, including errors resulting in drug mix-ups and unintentional overdoses, occur in the United States each year.<sup>7,12-14</sup> Between 1995 and 2005, the number of prescriptions per year increased 60 percent, to 3.4 billion prescriptions. According to ISMP, half of the outpatient prescriptions taken each year in the United States are used improperly. Only 4 percent of patients ask questions to ensure they understand how to appropriately use their medications. The risk of inappropriate medication use is high

and increasing in prevalence; in 2000, costs associated with medication-related injury and death totaled \$177 billion.<sup>7,12–14</sup>

One-third of patients who experience ameliorable ADEs following an outpatient visit do not report symptoms to their prescribers. In a prospective study evaluating ADEs in ambulatory patients, more than 60 percent of patients who experienced symptoms of ADEs that could be resolved with intervention and reported the symptoms to their physician were left to endure the symptoms; the ADE was not detected as a source of their problem.<sup>13</sup> The same study revealed that three times as many ADEs were detected via direct patient interviews as opposed to chart reviews by trained professionals. With increases in the use of chronic medications in ambulatory patients—especially in children and young adults—the potential for medication errors and ADEs is likely to increase.

Ambulatory care pharmacist specialists are adept at managing the complex drug regimens of patients with chronic diseases, as well as in detecting and addressing drug therapy problems, including errors and ADEs. With a solid relationship of trust as a foundation, these pharmacists motivate their patients to adhere to their treatment regimens and to actively and accurately monitor their disease. These relationships provide the foundation for prompt detection and resolution of medication- and disease-related problems experienced by ambulatory patients. Without a sufficient supply of pharmacist specialists who devote the majority of their time to direct, specialized patient care activities, medication-related problems will continue to rise and persist undetected by other health professionals or pharmacists who interface with these patients episodically, or who spend the majority of their time engaged in administrative, dispensing, or general patient-care functions. Undetected preventable or ameliorable drug therapy problems lead to nonadherence, disease progression, morbidity, or reduced quality of life for patients.<sup>6</sup>

#### *Public Health Risks of Chronic Diseases*

Ambulatory care pharmacist specialists are needed to mitigate public health risks associated with chronic diseases, unhealthy behavior choices, and preventable chronic and infectious diseases through skillful management of increasingly complex medications, immunizations, collaborative care, and motivation of positive health choices.

Diabetes poses significant public health risks to Americans. If not well managed, it may lead to heart disease and stroke, hypertension, blindness, renal disease, diabetic neuropathy, amputation, periodontal disease, pregnancy complications, and sexual dysfunction. The total cost of diabetes in 2007 was estimated to be \$174 billion—a cost that has been increasing at a rate of \$8 billion per year since 2002 as a result of inadequate management, increases in preventable complications, and greater prevalence of the disease.<sup>16</sup>

The public health is at risk from cardiovascular disease and related complications and from misuse and nonadherence of medications for the treatment of cardiovascular disease. Uncontrolled cardiovascular disease progresses to coronary heart disease, acute myocardial infarction, heart failure, stroke, and renal disease. Ambulatory care pharmacist specialists manage complex cardiovascular medication regimens and provide risk assessment, patient education, individualized monitoring, and adherence support. They also encourage their patients to engage in behaviors that promote wellness. Patients with poorly managed hypertension, dyslipidemias, and high risk factors are at serious risk for complications, morbidity, and mortality. Medication technologies offer significantly improved

options for controlling, and preventing, cardiovascular disease; however, the regimens are increasingly complex and require careful, knowledgeable management to achieve desired results.

The public health is also at risk from the effects of smoking and obesity and certain types of cancer that are preventable through healthy choices or more easily treatable through early detection. Cigarette smoking causes 87 percent of lung cancer deaths. Lung cancer is the leading cause of cancer death in both men and women. Smoking is also responsible for most cancers of the larynx, oral cavity and pharynx, esophagus, and bladder. In addition, smoking is a cause of kidney, pancreatic, cervical, and stomach cancers, as well as acute myeloid leukemia. Smoking contributes to significant morbidity such as chronic lung disease (emphysema and chronic bronchitis), cardiovascular disease, stroke, and cataracts. Smoking during pregnancy can cause stillbirth, low birth weight, sudden infant death syndrome, and other serious pregnancy complications. Obesity contributes to the development, progression, and exacerbation of cardiovascular disease, diabetes, chronic gastrointestinal disorders, and arthritis, and may be associated with certain cancers.

Quitting smoking greatly reduces a person's risk of developing these diseases. Quitting during pregnancy can limit adverse health effects on the developing fetus. Healthy diet and weight loss in overweight/obese patients have been shown to improve disease control, slow progression, and reduce medication needs, particularly in patients with type 2 diabetes.

Through strong patient relationships, coupled with skills in motivational interviewing and other techniques, ambulatory care pharmacist specialists optimize complex medication regimens and support patients over time in transitioning to positive health behaviors such as smoking cessation, healthy diet, and weight loss.

Each year 60,000 or more people die from vaccine-preventable diseases, and more suffer from related complications. Pharmacists' recommendations to patients regarding immunizations are highly regarded and followed up on in one-half to 94 percent of cases.<sup>24</sup> Chronic diseases and their negative health consequences are rising, despite the introduction of new medications and treatment technologies. Increases in medication use are leading to higher incidence of errors, ADEs, misuse, and inefficient, ineffective medication management, particularly among ambulatory patients with chronic diseases. As the health of our younger population (including children under age 19 and younger adults) continues to decline, more Americans of all ages will rely on chronic medications and increasingly complex regimens. The risks of harm from errors, ADEs, and nonadherence will rise unless more pharmacists gain specialized knowledge and training to effectively manage and monitor these patients in collaboration with other members of the healthcare team and are positioned to devote the majority of their professional time to performing these critical functions.

**Guideline 4. Describe how functions provided by the practitioners in the proposed specialty will fulfill the responsibility of the profession of pharmacy in improving the public's health.**

*The mission of pharmacy is to serve society as the profession responsible for the appropriate use of medications, devices, and services to achieve optimal therapeutic outcomes.*

*The vision of pharmacy states that by 2015, pharmacists "... will be the patient care providers that healthcare system and payers recognize as being responsible for ensuring desired medication use outcomes." [Joint Commission of Pharmacy Practitioners (JCPP)]<sup>25</sup>*

Pharmacists have a responsibility to the American public to ensure that medications are used appropriately and desired medication outcomes are achieved. Achieving the JCCP vision will require expansion in the number of specialized pharmacists with the knowledge, skills, and abilities to care for the growing population of patients with complex medication therapy regimens for treating their multiple chronic diseases. Ambulatory care pharmacist specialists adeptly manage complex medication regimens, develop and refine individualized patient care plans, work collaboratively as members of the healthcare team, conduct and publish research, and maintain long-term relationships with even the most complex of patients—becoming their medication-use coaches and motivating them to adhere to care plans and engage in healthful behaviors.

Ambulatory care pharmacist specialists also serve as leaders in chronic and preventive care within the profession. They often implement patient care programs; educate and train pharmacists to deliver innovative clinical services (e.g., diabetes care, immunizations, health screening and point-of-care testing) in outpatient settings; and conduct practice-based research. In addition, they serve as practice-based educators within pharmacy, often serving as preceptors for the required undergraduate advanced pharmacy practice experiences and the growing number of post-graduate community and ambulatory care residency programs.

A new specialty in preventive and chronic care for ambulatory patients would be consistent with the mission of the Board of Pharmaceutical Specialties: "to improve patient care through recognition and promotion of high-level training, knowledge, and skills in pharmacy through board certification of pharmacists."<sup>26</sup> BPS specialty certification is not only the pharmacist's path to advancement in contemporary medicine but also a roadmap for pharmacists who desire to gain additional training and knowledge to differentiate themselves by achieving certification. The complexities of care for ambulatory patients continue to multiply. Advances in medication technology, increased acuity, and chronic diseases are driving a need for specialty-trained pharmacists to expand their scope of practice to integrate and manage highly complex medication therapy for patients with multiple chronic diseases.

As the profession moves forward to achieve the JCPP 2015 Vision for Pharmacy Practice, there will be an increasing emphasis on pharmacist provision of more sophisticated and specialized direct patient care services in ambulatory care settings.



**Guideline 5. Describe the reasons why the needs as described above are not or cannot be met by pharmacists who do not have specialized education and training.**

Regrettably, neither the general practice of pharmacy nor of medicine is currently meeting patients' and society's preventive and chronic care medication management needs. As a result, the nation is facing significant public health problems, including preventable morbidity and mortality from chronic diseases, medication nonadherence, medication errors, and reduced cost effectiveness of care. Today's patients have complicated health conditions and comorbidities with complex medication regimens. There are pockets of excellence throughout the country, where individual pharmacists practicing in community pharmacies, ambulatory clinics, managed care organizations, hospital outpatient clinics, and physicians' offices have distinguished themselves in the care of ambulatory patients through a variety of avenues. These pharmacists should be recognized for the additional knowledge, experience, and training they have acquired and for the work they are doing to improve the health and medication outcomes of their patients.

Public health data over the past 10 years demonstrate increasing prevalence of chronic diseases and use of chronic medications in much younger Americans, including children and young adults. This trend, coupled with the projected doubling of the population aged 65 and older by 2030, will likely result in an exponential increase in the specialized needs of ambulatory patients. The pharmacy profession is not fully meeting the growing medication needs of these complex patients in the current healthcare paradigm, and there are no signs that it will be prepared to meet projected needs. In order to realize its potential as a health profession, pharmacy needs mechanisms through which employers, payers, and patients will be able to discern who can provide these needed specialized services.

Lists of healthcare settings where complex medication management and preventive and chronic care needs of ambulatory patients are being met with tremendous success often include examples like the Veterans Health Administration, Kaiser Permanente, and others where concerted efforts are undertaken to employ pharmacists with specialized experience and where pharmacists' time is purposefully devoted to medication management and patient assessment functions.

Licensure examinations by state boards of pharmacy evaluate some of the core functions performed by ambulatory care pharmacist specialists, but do so at a generalist level that does not evaluate abilities to manage complex needs.<sup>27</sup> Pharmacists in general practice perform important medication management, screening, and patient education functions. However, management of complex ambulatory patients frequently requires the advanced knowledge and skills of the specialized practitioner.

Data gathered from ambulatory care pharmacist specialists about their practice functions and knowledge that they apply in patient care illustrate the implications of additional training and credentials. Based on follow-up analyses of data gathered through the Report of the Role Delineation Study of Ambulatory Care Pharmacists,<sup>28</sup> pharmacists who have completed residency training or who have acquired additional credentials beyond licensure (e.g., certified diabetes educator [CDE], certified disease manager [CDM], certified geriatric pharmacist [CGP], BCPS) more frequently apply specialized knowledge and perform specialized care functions than do pharmacists who have not acquired these advanced credentials. For example, pharmacists with advanced training or credentials more

frequently developed individualized care plans, coordinated care among health professionals, and used laboratory data to adjust medication therapy. Pharmacists without additional training or credentials were more likely to engage in functions related to work flow, drug procurement, and important, yet less specialized, care functions such as general health screenings. The petitioners acknowledge there are other mechanisms for acquiring necessary training and education to perform specialized functions. Nevertheless, the data linking specialized care to known types of advanced training and knowledge show a clear distinction between functions performed in the specialized care of ambulatory patients and functions performed by a generalist pharmacist with training and knowledge demonstrated by licensure examination.

A similar trend was seen in the survey of ambulatory care pharmacists conducted by the petitioners ( $N = 772$ ). Pharmacists who report spending 60 percent or more of their time in specialized direct patient care functions were more than three times as likely to have completed a residency as were those who spent less time providing specialized care (76.6 percent versus 23.4 percent). Conversely, while the percentage of ambulatory care pharmacists surveyed overall who spent the majority of their time in nonspecialized, administrative, or dispensing functions was low (15 percent), 59 percent of respondents who spent 60 percent or more of their time in these nonspecialized functions had not completed a residency, compared with 41 percent who were residency trained.

Pharmacists whose practices are centered primarily on generalized dispensing or administrative functions generally do not perform specialized ambulatory care functions.

Several thousand pharmacists have prepared themselves to meet public health needs by providing specialized care for ambulatory patients that involves managing complex medication regimens, improving outcomes in collaboration with other healthcare providers, providing health-promotion and disease-prevention services, and addressing a broad range of other health-related needs for their ambulatory patients. In addition, these ambulatory care pharmacist specialists provide leadership among the profession in establishing patient care services, precepting student pharmacists in required advanced pharmacy practice experiences in ambulatory care, and training other pharmacists through residencies, certificate training programs, and continuing professional development programs.

By any measure, the health challenges facing today's ambulatory patients—increased acuity of disease; declining health status of children and young adults; an expanding elderly population; increasing prevalence, morbidity, and mortality associated with chronic diseases and medication use; and the costs of medications and medication-related problems—are not being adequately addressed by pharmacists in general practice or by other types of pharmacist specialists. BPS certification of ambulatory care pharmacist specialists will lay the groundwork for other committed and interested pharmacists to focus their professional development, training, and educational efforts on preparing themselves to fully meet this public health need.

**Guideline 6. Describe in detail how the needs as described above are not or cannot be met by pharmacists in those pharmacy specialties already recognized by BPS.**

The health and medication management needs of ambulatory patients with chronic diseases are complex, and effective management requires long-term relationships and distinct knowledge, training, and skills. Ambulatory patients have specialized needs that are unlike those of patients cared for in inpatient or institutionalized settings.

While there is some overlap between specialized ambulatory care and the existing BPS pharmacotherapy specialty, the knowledge and functions of ambulatory care pharmacist specialists are distinct. The petitioners acknowledge the existence of a mechanism for added emphasis in certain areas of “added qualifications” within BPS (e.g., infectious diseases and cardiology within the Board-certified specialty in pharmacotherapy (BCPS)); however, there are important differences between the specialized practices of ambulatory care and pharmacotherapy that make it important to recognize the ambulatory care specialty independently. Precedent for such separate recognition can be found by looking to medicine’s specialization structure.

*A Comparison with Specialization in Medicine*

It has long been recognized for decades that the base of knowledge and skills in medicine far exceeds an individual’s ability to master every facet of medicine. Currently physicians may become certified in any of 145 medical specialties or subspecialties.<sup>29</sup>

Among the specialties in medicine, overlap is apparent in many areas. This overlap is unavoidable given the complexities and commonalities within patient care. In comparison with ambulatory care pharmacy and pharmacotherapy specialties, separate and distinct medical specialties (i.e., not subspecialties) exist in family medicine, internal medicine, and public health/preventive care.

Other specialized areas, such as cardiology and infectious diseases, are defined as subspecialties of the specialty of internal medicine. Despite significant overlap, practice in family medicine and internal medicine is recognized separately; distinct areas of focus set them apart from each other and from the area of preventive care and public health. A case could be made that internal medicine is the adult subspecialty of family medicine, or that preventive care/public health is a subspecialty of either; nonetheless, the emphasis of each is sufficiently distinctive to require separate recognition.

Likewise, in pharmacy, the breadth and depth of knowledge exceed an individual’s ability to master content and skills at an advanced level in all areas of practice and pharmacotherapy. Specialty ambulatory care pharmacy practice is distinct from other BPS specialties in its emphasis in chronic disease prevention and management and its focus on monitoring and medication therapy management through long-standing relationships with patients and other providers longitudinally. These relationships are aimed at minimizing complications and improving outcomes through education, adherence, motivation, and monitoring.

While certain elements of practice in the recognized specialty of pharmacotherapy do overlap with those of specialized ambulatory care pharmacy practice (e.g., individualized pharmacokinetic dosing for patients receiving anticoagulation therapy, and interpretation of

associated laboratory values), there are functions important to each specialty that are less relevant, or even nonapplicable, to the other specialty. The long-term patient relationships that must be established for longitudinal management of medication therapy in specialized ambulatory care practice are rarely, if ever, achieved with patients in secondary or tertiary care institutional practice; outcomes for patients are defined and measured in shorter segments of time. In addition, skills associated with physical assessment and motivating patients to adhere to drug regimens, to actively monitor their disease, and to engage in long-term healthy behaviors and choices are central functions performed by ambulatory care pharmacist specialists that receive little emphasis by specialists in pharmacotherapy.

In addition, while ambulatory care includes acute and chronic disease management, the functions related to managing inpatient acute care problems within a controlled institutional setting are not performed at all by pharmacists specializing in ambulatory care. In the ambulatory care pharmacist survey conducted by the petitioners, a number of responding pharmacists chose to use the “write-in” comment function to share their perspective that the current BCPS specialty does not meet their needs, and that the BCPS requirements for advanced knowledge and skills related to inpatient care prevent them from pursuing specialization in pharmacotherapy.

*Demographics of BCPS Pharmacists*

Opponents of a specialty in ambulatory care claim that close to 50 percent of the pharmacotherapy examination is reflective of ambulatory care and thus prepares BCPS pharmacists for specialized ambulatory care practice. In fact, according to BPS demographic data collected during certification examinations, most Board-certified pharmacotherapy specialists do not practice in ambulatory care. The specialized knowledge and functions they possess are often viewed as better suited to hospital-based practice or academia. BPS data reveal that more than 70 percent of pharmacists who were certified or recertified in pharmacotherapy practice in hospitals or institutions (see Table A-1). Only 10 percent of those certified in 2007 indicated they practiced in a community or ambulatory care setting.

**Table A-1: Demographics of Board-Certified Pharmacotherapy Specialists**

<b><i>Number Who Passed BCPS Certification/ Recertification</i></b>	<b><i>Ambulatory- /Community-Based Practice</i></b>	<b><i>Institutional Practice and Academia</i></b>
<i>2007 (of 868 who passed)</i>	<i>89 pharmacists (10%)</i> <ul style="list-style-type: none"> <li>• <i>79 ambulatory care clinic</i></li> <li>• <i>3 chain</i></li> <li>• <i>7 independent</i></li> </ul>	<i>665 (77%)</i> <ul style="list-style-type: none"> <li>• <i>612 institutional (71%)</i></li> <li>• <i>53 academia (6%)</i></li> </ul>
<i>Cumulative—All Years (4,887 who passed)</i>	<i>522 out of 4,887 (11%)</i>	<i>3,623 out of 4,887 (74%)</i> <ul style="list-style-type: none"> <li>• <i>3,195 institutional (65%)</i></li> <li>• <i>428 academia (9%)</i></li> </ul>

In addition to pharmacotherapy specialists, pharmacists who specialize in psychiatric, oncology, nutritional support, and nuclear pharmacy possess highly specialized knowledge

and skills that are suitable to their specialties but are not adequate to prepare them for specialized practice in ambulatory care pharmacy.

**Guideline 7. Describe the reasons why the needs as described above are not or cannot be met by other health professionals.**

Many of the chronic diseases and conditions common in ambulatory patients are managed primarily through complex medication therapy, requiring a health professional with expertise in medication use and management, along with specialized knowledge and skills, to achieve optimal outcomes. Pharmacists are uniquely qualified among all health professionals as the medication-use experts on the healthcare team. Physicians, nurses, physician assistants, nurse practitioners, and others do not have the pharmacologic and therapeutic expertise to identify drug therapy problems and manage nuances of medication use with the perspective and understanding of the pharmacist. Pharmacists with specialized knowledge, skills, and practices in ambulatory care are best positioned to meet the complex medication management and chronic and preventive care needs of ambulatory patients,

The unmet medication management and chronic and preventive care needs of ambulatory patients are significant, increasing, and growing in complexity. Current public health data and epidemiologic trends show these needs are not adequately being met—nor can they be met—by health professionals who lack the specialized expertise of ambulatory care pharmacist specialists. Physicians and other health professionals look to pharmacists who specialize in ambulatory care to partner with them and guide complex medication use in ambulatory patients with chronic diseases. This reliance is commonly seen in Veterans Health Administration clinics and health organizations like Kaiser Permanente where health professionals are aware of and seek out the expertise brought by these pharmacists.

The “Joint Principles of the Patient-Centered Medical Home,” issued in March 2007 by the American College of Physicians, American Academy of Family Physicians, and the American Osteopathic Association, identifies the need for a team of health professionals at the practice level who collectively take responsibility for the ongoing care of patients at all stages of life, including chronic and preventive care.<sup>30</sup> The petitioners believe pharmacists, and especially ambulatory care pharmacy specialists, are and will increasingly play an important role on these teams.

**Guideline 8. If these needs are currently being met by other areas of pharmacy practice, or by other health professionals, describe how these needs can be met more effectively by pharmacists in the proposed specialty.**

Pharmacists in community pharmacies, ambulatory care clinics, managed care organizations, and other ambulatory settings where ambulatory patients receive care are providing medication management, providing screening and monitoring, and performing important functions to optimize medication use. There are pockets of excellence with regional variation throughout the United States. Patients with less complicated needs are being served more effectively than are the increasing numbers of patients with complicated needs. The successes contribute to some of the emerging, impressive data being gathered in demonstrations of the value of pharmacists’ services.

The demands on pharmacists' time and focus in some ambulatory practice environments influence the amount of time and emphasis they choose to spend on integrated, complex medication therapy management and interdisciplinary collaboration. Furthermore, pharmacists with general training and knowledge perform generalized patient care functions. Pharmacists with additional training, knowledge, and experience in the management of complex patients with and at risk for chronic diseases and associated complications provide care at a specialized level and can detect, manage, and motivate necessary changes to an extent that other pharmacists are not equipped to perform, in the absence of additional training or experience. As reported under Guideline 3 of this criterion, pharmacists with specialized skills and knowledge perform important specialized ambulatory care functions more frequently, and with greater emphasis, than do pharmacists with generalized knowledge, training, and skills.

All pharmacists perform important patient care functions in serving the public health needs of the people in our country. By definition, pharmacists who voluntarily choose to earn BPS certification are prepared to meet the needs of patients within their respective specialty areas more effectively than pharmacists without specialized knowledge and training. In all areas, collaboration with other members of the healthcare team is critical in partnering with patients to prevent medication errors, ensure appropriate medication use, and ensure that desired therapeutic outcomes are achieved.

Ambulatory patients have complex preventive and chronic care needs. The needs are dictated by the patient's condition and expectations; they are not a function of a particular practice setting. The fact that the patients are ambulatory, and not inpatient or institutionalized, is significant, as societal influences and trends have a strong impact on patients' adherence, self-care, and self-monitoring of their chronic diseases. While there is some overlap among specialty areas, the needs of ambulatory patients with and at risk for chronic disease are significant and growing, and are sufficiently unique to support recognition of ambulatory care pharmacy practice as a distinct specialty. Effective, successful, high-quality care for these patients will require the full application of specialized knowledge and skills of today's ambulatory care pharmacist specialists and those who would seek to achieve specialty recognition in ambulatory care.

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## **CRITERION B: Demand**

The area of specialization shall be one in which there exists a significant and clear health demand to provide the necessary public reason for certification. ***This criterion emphasizes DEMAND.*** BPS defines DEMAND as a willingness and ability to purchase a commodity or service.

The demand for ambulatory care pharmacist specialists can be expressed in terms of requests for services from patients and other health professionals. It can also be reflected in employment trends and surveys that document increased demand for pharmacists who provide specialized ambulatory care services. Direct payment for services from both patients and third-party payers also provides an indicator of demand for the specialized services of pharmacists with unique skills and knowledge in ambulatory care practice.

### ***Demand for Ambulatory Care Pharmacist Services***

By 2025, an estimated 164 million Americans, nearly half the current population, will be affected by chronic disease.<sup>1</sup> In October 2007, the Milken Institute released a report that indicated the seven most common chronic diseases in the nation create a \$1.3 trillion annual additional cost for the economy. The report estimated that these costs could reach nearly \$6 trillion by the middle of the century. In addition, poor medication adherence has been estimated to cost approximately \$177 billion annually in total direct and indirect health care costs.

**Numerous scientific publications have conclusively demonstrated the dramatic reductions in morbidity and mortality that ambulatory care pharmacists can have on patient populations afflicted with chronic diseases such as asthma, diabetes, hepatitis C, hyperlipidemia, hypertension, chronic kidney disease, and HIV, among others.**<sup>2,3,4,5,6,7,8,9</sup> Fostering the expansion of specialty pharmacy practice in ambulatory care is one mechanism to address the substantial impact of chronic disease from both a humanistic and financial perspective.

State boards of pharmacy and medicine have also recognized the importance of fostering clinical relationships between pharmacists and physicians to provide specialized care to patients. Physician demand for the services of ambulatory care pharmacist specialists is especially relevant to the topic of specialty recognition since it reflects many of the types of patient services that may be required or desired. Consistent with this demand for specialized care, 45 states and the territory of Guam have authorized collaborative drug therapy management (CDTM) between pharmacists and physicians. CDTM is a team approach to healthcare delivery that seeks to maximize the expertise of the pharmacist and the physician in order to achieve optimal outcomes through appropriate medication use and enhanced patient-care services.



CDTM is most commonly provided under mutually agreed upon practice protocols and guidelines. CDTM activities include, but are not limited to, the following pharmacist activities:

- initiating, modifying, and monitoring a patient's drug therapy
- ordering and performing laboratory and related tests
- assessing patient response to therapy
- counseling and educating patients about their medications
- administering medications

### ***Demand for Generalist Pharmacist Services***

Medication therapy is becoming more complex, and increasing numbers of patients receive care in ambulatory settings. With this growth in patient need for pharmacist services comes an increased demand for all types of pharmacists. Currently, the demand for ambulatory care pharmacist specialists is increasing, as is the demand for generalist pharmacist practitioners. Caring for patients in an effective and efficient manner will continue to require the coordinated efforts of both specialists and generalists.

In December 2000, the Bureau of Health Professions of the U.S. Department of Health and Human Services (DHHS) released a report to Congress on the pharmacist workforce. This report provided an overview of the anticipated supply and demand for pharmacists and the factors that could affect it.<sup>10</sup> Most of the factors driving the demand for pharmacists at the time the report was issued (i.e., increased demand for pharmaceutical care services, insufficient numbers of new pharmacists graduating from the nation's schools and colleges of pharmacy, and expansion of the professional roles of pharmacists) remain relevant.

The increase in demand for pharmacists in community pharmacy settings is particularly acute. Factors influencing the increase in demand in this practice area include the size of the "baby boomers" cohort, increased number of community pharmacy locations, increased patient participation in Medicare Part D, and increases in the development of clinical services in community pharmacies. According to the Pharmacy Manpower Project aggregate demand index, demand for pharmacists has remained fairly steady over the past three years.

### ***Demand for Ambulatory Care Pharmacist Specialists***

Data released in August 2008 by the National Center for Health Statistics (NCHS)<sup>11</sup> show that an estimated 1.1 billion visits to physicians' offices, hospital outpatient departments (OPDs) and emergency departments (EDs) were made in 2006. This is a rate of 381.9 visits per 100 persons annually. Between 1996 and 2006, the number of visits increased by 26 percent, faster than the growth of the U.S. population, which grew by 11 percent. OPD visits increased by 52 percent, and ED visits by 32 percent, during that period. NCHS attributes the disproportionate growth to the aging of the population and to higher utilization by older persons. Since the leading edge of the baby boom generation is only reaching 65, utilization of specialized ambulatory care pharmacist services is likely to continue to grow

for another 20 to 30 years. Data from Medco Health Solutions also demonstrate increasing health needs and medication use among children and young adults.<sup>12</sup>

NCHS noted that 71.6 percent of all ambulatory care visits in 2006 involved medication therapy: “An estimated 2.6 billion medications [of all types] ... were provided, prescribed or continued at ambulatory care visits.”<sup>11</sup> The demand for specialized medication services is certain to grow among ambulatory care patients as the volume of visits continues its steady rise.

The Medicare Part D drug benefit program has acknowledged the demand for differentiated medication management services for beneficiaries with complex medical conditions through its Medication Therapy Management program (MTMP) requirement. Roughly 11 percent of the beneficiaries enrolled in a Medicare plan with a MTMP met the high-risk criteria in 2008.<sup>13</sup> The Centers for Medicare & Medicaid Services (CMS) recognize pharmacists as the principal providers of this type of service and have issued broad guidelines to Medicare prescription drug plans regarding payment mechanisms for such services.

According to Medco Health Solutions, while seniors show the highest prevalence of chronic medication use, younger adults are quickly catching up.<sup>12</sup> Nearly half (48 percent) of women ages 20-44 are being treated for a chronic condition, as compared to one-third of men their age. Antidepressants are the most commonly used medication among this group, with 16 percent of 20- to 44-year-old women taking them. Women in this age group also claimed the sharpest increases in the number of patients on chronic medications, rising more than 20 percent between 2001 and 2007.

This information on demand for ambulatory care pharmacist specialists is supplemented by conclusions from a conference convened by the Pharmacy Manpower Project in the fall of 2001.<sup>14</sup> The intent of the conference was to delineate and project the need for pharmacy services in the United States over the next 20 years. Conference participants concluded that pharmacists can take responsibility for major improvements in patient care stemming from better drug therapy management in ways that the members of no other health profession can. They also made the following conclusions:

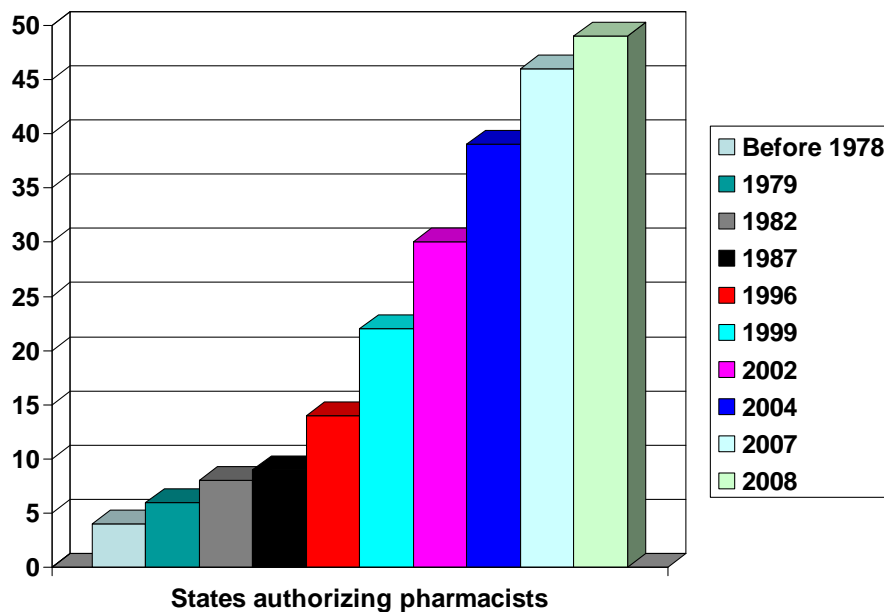
- The healthcare of the public would be improved if the amount of high-quality pharmaceutical care services provided to patients was increased significantly, either by pharmacists or some other means.
- The total amount of such services needed over the next 20 years will exceed the supply of pharmacists, even if the maximum redeployment of pharmacists from order fulfillment to patient care is accomplished.<sup>14</sup>

### ***Examples of Demand for Ambulatory Care Pharmacist Specialists***

One of the most dramatic examples of the demand for ambulatory care pharmacist services has been showcased by the important leadership role that ambulatory care pharmacist specialists have played in the development, implementation, and management of immunization services. Over the past 12 years, more than 40,000 pharmacists have received formal training and recognition as providers of a wide range of immunization services. The practice of pharmacist-administered immunizations has led the movement

toward expanded services for complex ambulatory patients. Among the key drivers for the involvement of pharmacists in patient immunization has been the increased willingness of both patients and third-party payers to reimburse pharmacists for these services. The increase in the number of states that permit pharmacists to administer vaccines has also risen rapidly (see Figure B-1), reflecting the growing demand for this type of service for ambulatory care patients.

**Figure B-1: States Granting Pharmacist Authority to Administer Immunizations**



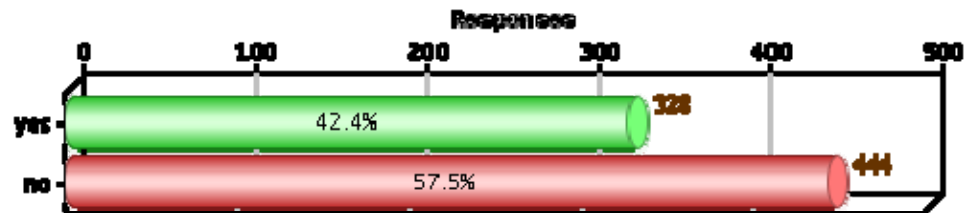
In a recent example of employer demand, more than 90 employer groups in communities across the country have established a voluntary health benefit for their employees and dependents through programs offered by the APhA Foundation and other entities. Using incentives, employers encourage their employees to manage chronic conditions such as diabetes with the help of pharmacist coaches, physicians, and community health resources. This collaborative approach resulted in:

- a savings of approximately \$918 per employee in total health care costs for the initial year, with an even greater savings in subsequent years
- return on investment of at least 4:1 beginning in the second year
- a 50 percent reduction in absenteeism and fewer worker's compensation claims
- high employee satisfaction (95 percent approval for pharmacist care) and improved quality of life
- employee savings averaging \$400 to \$600 per year with incentives such as waived copayments

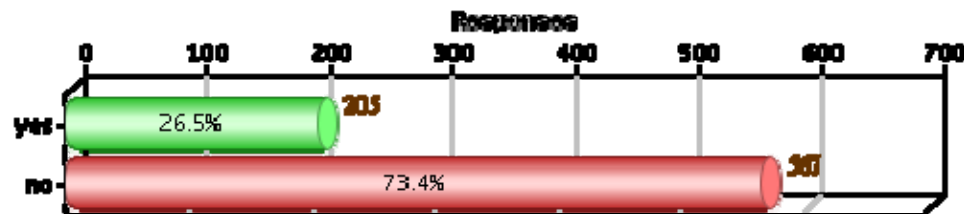
Programs such as these, coupled with the availability of pharmacists focused on ambulatory patient care, provide employers and employees with an enormous incentive that results not only in improved health outcomes but also reduced overall medical costs.

Willingness to pay for services is another indicator of demand. To assess this indicator, the sponsors of this petition surveyed pharmacists who have expressed an interest in ambulatory care practice, asking respondents to indicate if they currently bill third parties or collect cash payments for the provision of specialized clinical services. Over forty-two percent of respondents indicated that they bill third parties for clinical services and 26.5 percent collect cash from patients for these services (see Figures B-2 and B-3).

**Figure B-2: Practices That Currently Bill Third Parties for Clinical Services**



**Figure B-3: Practices That Currently Collect Cash Payments from Patients Who Receive Clinical Services**



In addition, in January 2008 the American Medical Association (AMA) adopted permanent CPT codes that include pharmacist-provided medication therapy management codes. The evidence to support this new standard was derived from ambulatory care practices and makes the case that Medication Therapy Management by pharmacists is a viable practice model.

## ***Future Demand for Ambulatory Care Specialists in Pharmacy Practice***

In 2004, the JCPP developed and accepted a vision statement that summarizes members' consensus on the future of pharmacy practice for 2015.<sup>15</sup> JCPP members include the Academy of Managed Care Pharmacy (AMCP), the American College of Apothecaries (ACA), ACCP, APhA, the American Society of Consultant Pharmacists (ASCP), ASHP, and the National Community Pharmacists Association (NCPA). The vision statement states that "pharmacists will be the health care professionals responsible for providing patient care that ensures optimal medication therapy outcomes."

The statement describes the foundations of pharmacy, how pharmacists will practice, and how pharmacy will benefit society. Patient care is described as both patient centered and population based. The vision stresses that pharmacists are the medication experts and that they will be accountable for therapeutic outcomes, will work collaboratively with other healthcare professionals, and will be recognized by the public for embracing this enhanced role. It is clear from this vision that by the year 2015, pharmacists are expected to practice clinical pharmacy as a generalist practitioner. The complete vision statement is attached at Appendix B-1.

Similarly, Project Destiny, a collaborative effort by APhA, NCPA, and the National Association of Chain Drug Stores (NACDS) seeks to advance the level of care provided to patients by pharmacists. This project supports progress toward the JCPP Vision for Pharmacy Practice within the largest segment of the profession—community pharmacy. Project Destiny has developed the following proposed vision for community pharmacy:<sup>16</sup>

*Community pharmacists will fulfill the role of a primary care pharmacist, serving as a trusted and effective resource that is valued by consumers, prescribers, healthcare funders and payers for their clinical and medical management expertise.*

*The primary care pharmacist will demonstrate their value working with consumers to navigate throughout the healthcare delivery system and improve health outcomes through better medication and condition management.*

*Working collaboratively with the healthcare delivery and financing systems, the primary care community pharmacist will focus on managing medications, positively impacting health outcomes, reducing overall healthcare system costs and empowering consumers to actively manage their health.*

Based on research, analyses, and stakeholder feedback, the initial key findings of Project Destiny provide insight to community pharmacy relative to a new model for the future. These findings show that a significant unmet consumer need to manage medication therapy exists in the market, as exemplified by increases in chronic conditions and avoidable healthcare costs. The findings also note that pharmacists are well positioned to address unmet needs as medication experts and trusted professionals.

ACCP's *Vision of Pharmacy's Future Roles, Responsibilities, and Manpower Needs in the United States* outlines steps that should be considered to facilitate a shift toward a profession-wide, patient-centered practice model that supports a level of patient care that has a positive impact on health outcomes. ACCP's vision predicts that in 20 to 30 years,

most clinical pharmacy practitioners will be Board-certified specialists, and that practice systems will evolve to a patient-centered model that provides specialized patient-care services that have a genuine impact on health outcomes.<sup>17</sup>

ASHP has published a *Long-Range Vision for the Pharmacy Work Force in Hospitals and Health Systems*. This document envisions the following vision for pharmacist responsibilities:

*Increasingly, pharmacists will apply their time to direct, interdisciplinary patient care to ensure the best use of medicines by individual patients. A growing number of pharmacists will work in highly specialized therapeutic areas. The expanded use of uniformly educated and certified pharmacy technicians will permit a larger portion of a pharmacy department's pharmacist staff to focus on direct patient care activities.*

This vision recognizes that licensure alone will be insufficient for pharmacy practice in hospitals and health systems, and that credentials such as residency training and specialty certification will be required to provide ambulatory care at the specialty level.<sup>18</sup>

The four documents just cited have a common purpose: to improve medication use and position the pharmacist in a central role in the care of ambulatory patients who are suffering from chronic disease or seeking to maintain health and wellness. Many pharmacists, practicing in many different practice settings, will want the opportunity to earn specialty recognition that rewards and acknowledges the specialized care that they provide.

The information and data that follow provides additional support from a variety of perspectives recognizing the demand for establishing a specialty in ambulatory care pharmacy practice and a mechanism to certify specialists in this area of practice.

**Guideline 1. Include statements by at least two individuals in each of the categories listed below regarding the demand for pharmacists with specialized training and knowledge to provide specialized services in the proposed specialty.**

Appendix B-2 provides statements from the following nonpharmacist health professional leaders, planners, and administrators:

- David Schulke, The American Health Quality Association
- Diane Reynolds-Cane, Daily Planet Health Care for the Homeless Clinic

David Schulke, Executive Vice President of the American Health Quality Association (AHQA), represents thousands of physicians, nurses, pharmacists and other health professionals who are improving health care outcomes and patient safety in communities across America. He states that “pharmacists who can satisfy the requirements for the proposed specialty will be a valuable resource to individuals and organizations working to improve the value of drug therapy and the quality of health care. As AHQA’s member Quality Improvement Organizations (QIOs) expand their work with prescription drug plans and health professionals to improve the safety and effectiveness of pharmacotherapy, I am confident they will seek out pharmacist specialists who are skilled in working with patients,

identifying and reducing clinically significant adverse events, and preventing the costly consequences of poorly coordinated treatment.

Ambulatory care pharmacist specialists also provide valuable services to patient populations at extreme risk. Diane Reynolds-Cane, Medical Director of Daily Planet Health Care for the Homeless, recognizes that “pharmacists with specialized skills in ambulatory care practice are invaluable to the care of her patients”. These pharmacists engage in preventive strategies for improving outcomes, manage medication use in complex patients and partner with other members of the clinic to coordinate and integrate care. Dr. Reynolds Cane indicates that “recognizing ambulatory care pharmacist specialists will help improve the care of patients in multiple settings”.

Appendix B-3 includes the statements of pharmacists who are not practicing in ambulatory care pharmacy practice, yet recognize the demand for ambulatory care pharmacists who are practicing at the specialty level. These pharmacists include

- Roger Anderson, Medco Health Solutions
- Lyle Bootman, University of Arizona
- Mike Flagstead, Visante
- Dennis Helling, Kaiser Colorado
- Dave Knapp, University of Maryland, School of Pharmacy
- Jimmy Mitchell, Health Resources and Services Administration
- David Nau, University of Kentucky College of Pharmacy
- Bob Pitman, U.S. Public Health Service

These letters are from large employers of pharmacists, administrators of schools and colleges of pharmacy, government organizations that employ ambulatory care pharmacists and researchers who have studied the need for ambulatory care pharmacist specialists. These individuals have significant experience and insights, and their statements clearly demonstrate the demand for pharmacists with specialized training in ambulatory care.

According to Dennis Helling, Executive Director of Pharmacy Operations and Therapeutics at Kaiser Permanente, Colorado Region, demand for BPS-credentialed pharmacists increased by more than 1,600 percent at his organization during the past 15 years. The department currently employs 82 BPS-certified pharmacists practicing at the specialty level of ambulatory care practice. Most of these pharmacists hold BCPS credentials, and 25 percent of these pharmacists indicate that they would seek certification in ambulatory care *in addition to* their current BCPS status.

A long-term supporter of recognition of ambulatory care pharmacy as a specialty, Roger W. Anderson, Senior Vice President and Chief Pharmacist for Medco Health Solutions, writes that Medco’s 2,500 pharmacists have responsibility for caring for over 65 million patients who are on chronic medication therapies. He notes that Medco has a need to further elevate the level of practice for their pharmacists. Dr. Anderson indicates that certification of ambulatory care pharmacist specialists fits perfectly with Medco’s vision and strategy, which seeks to provide additional practice opportunities and enhanced compensation for those pharmacists with BPS certification.

David A. Knapp, a well-known researcher in the area of pharmacist demand, writes in support of the recognition of ambulatory care pharmacy practice as a specialty. In 2001, Dr. Knapp convened and facilitated a conference of two dozen experts from around the country. At the meeting, participants discussed the quantity of pharmaceutical services that they believed would best serve the healthcare needs of society in 2020.<sup>14</sup> Participants estimated the needs of ambulatory patients receiving four or more prescriptions, a group defined as requiring complex primary care pharmaceutical services. According to Dr. Knapp's letter, the experts assumed that one pharmacist would be required to meet the needs of 1,000 such patients, or about 130,000 primary (ambulatory) care pharmacists by 2020.

An alternative estimate of demand is based on the experience of Kaiser Permanente/Denver, which provides 350,000 patients with highly managed medication therapy. Kaiser estimates its needs for primary (ambulatory) care pharmacists for its complex patients at 1.1 to 1,000. If this ratio were extended to the U.S. population in 2020, more than 300,000 such pharmacists would be needed. (These estimates *exclude* pharmacists performing order-fulfillment functions in community pharmacies.)

Jimmy R. Mitchell, Director of the Office of Pharmacy Affairs for the Health Resources and Services Administration (HRSA), DHHS, reinforces the value of ambulatory care pharmacist specialists in a letter stating that "clinical pharmacy services in the outpatient/ambulatory setting have proven benefits to patients, health centers and to colleges and schools of pharmacy. The integration of clinical pharmacy services into primary health care improves patient health outcomes, increases patient safety and reduces cost to the health care system. In recognition of these proven benefits, HRSA has initiated a Patient Safety and Clinical Pharmacy Services Collaborative. The primary emphasis of the Collaborative is the improvement of healthcare delivery systems which integrate use of clinical pharmacy services and safe medication practices. These practices will ultimately result in improved patient outcomes. HRSA believes that the outcomes/demonstrated improvements of the Collaborative will generate broader interest and demand for ambulatory clinical pharmacy services."

David P. Nau, a pharmacist, researcher, and former Director of Practice Improvement for the Pharmacy Quality Alliance, indicates that "employers have begun to recognize that ambulatory pharmacists can have a profound effect on health outcomes for employed patients with chronic diseases and have started to demand medication-therapy management services for the commercially-insured population." In reflecting on currently available certification options, he concluded that "the current pharmacotherapy recognition program is useful but fails to provide the necessary focus on disease prevention, health promotion and patient counseling that are cornerstones of ambulatory care. Given that the majority of healthcare is delivered in an ambulatory setting and since the appropriate treatment of chronic disease is largely shaped in the ambulatory setting, there is a need to identify pharmacists who have the knowledge and skills to help physicians select appropriate treatment and therapeutic monitoring for ambulatory patients and to help patients use and self-monitor their chronic medications. An exam and recognition criteria that are tailored to the ambulatory role of clinicians is needed."

According to J. Lyle Bootman, Founding and Executive Director of the University of Arizona Center for Health Outcomes and PharmacoEconomic Research and Co-Chair of the IOM's Committee on Identifying and Preventing Medication Errors, indicated that supporting a



specialty level for ambulatory care pharmacy practice is important to reinforce advanced pharmacy practice for optimal, cost-effective patient care. “At least 1.5 million preventable adverse drug events (ADEs) occur each year and current estimates as to the cost of drug related morbidity in the US may be in excess of 200 billion dollars annually with estimates that more than 60 percent can be prevented. Pharmacists need to participate actively and effectively as a multidisciplinary health team within the ambulatory care setting to provide improved therapeutic planning and achievement of patient outcomes.”

These statements are representative of the support and acceptance ambulatory care pharmacist specialists have achieved across the country. They are further supportive of the widespread and growing demand for the professional services of these specialized practitioners.

Appendix B-4 includes statements from members of the public that recognize the demand for ambulatory care pharmacists who are practicing at the specialty level. These individuals include

- John Paul Berry, patient
- Frank Daniels, patient
- Nancy Puckett, patient
- Richard Taylor, patient
- Jane Thurman, patient

Probably the most powerful indicator of the demand for pharmacists who are ambulatory care specialists comes from patients whose health and well-being have been directly affected by these pharmacists. The statement of Richard Taylor, a patient of Stuart Haines, PharmD, BCPS, CDE, an ambulatory care pharmacist specialist at the Veterans Administration Medical Center in Baltimore, Maryland, is particularly powerful. Taylor states:

*From 1968 through 1993, I saw a different doctor at nearly every VA clinic appointment. For 25 years I felt I was just a folder, a number. In 1993 I was placed under the care of Dr. Haines. Dr. Haines educated me in what I needed to do to get control of my diabetes. Specifically, Dr. Haines' patience and persistence with me has enabled me to improve my A1C readings from a poorly controlled A1C9 to a current and consistent range of A1C5.9 to A1C6.4. Dr. Haines was instrumental in my decision to go on an insulin pump in 2000. He told me I would be a good candidate and that it would benefit me tremendously. Once the decision was made Dr. Haines had to make a special request on my behalf for the pump. Once the pump became a reality, Dr. Haines and I were in constant contact day and night for weeks, while he walked me through the adjustments, intricacies and interpretation of my results. Over time when some adjustments were needed, Dr. Haines would review the pump results and advise some changes. He was instrumental in giving me additional control over my life. This would not have been possible without his ongoing support over the years.*

John Paul Berry, another patient of Dr. Haines, describes the impact of having an ambulatory care pharmacist specialist on his medical team.

*I currently take 10 different medications that are prescribed by eight different doctors. Not only do the health conditions interact with one another, so do the prescribed medications. Often medical doctors do not have an appreciation for these interactions or the effects of a given medication on what I will call quality of life. Dr. Haines helped me sort out my medications during the last three years. He made two of his graduate students at the University of Maryland available to help me devise a procedure to properly take my insulin with a syringe when I have an insulin pump failure. I now consider the pharmacist a vital member of my health care team. I endorse having a specialty that will make this aspect of patient care an every day standard.*

All the statements received demonstrate a substantial demand for ambulatory care pharmacy specialists and definitively support recognition of ambulatory care pharmacy practice as a specialty.

**Guideline 2. Include estimates of positions for pharmacists with specialized training and knowledge in the proposed specialty that are currently filled and those that are currently unfilled. Identify these positions by practice settings. Describe the sources and methods used to determine these estimates.**

In an effort to estimate the number of positions for pharmacists with specialized training and knowledge in ambulatory care practice, the Task Group developed an employer survey that was fielded to 271 employers from the following groups:

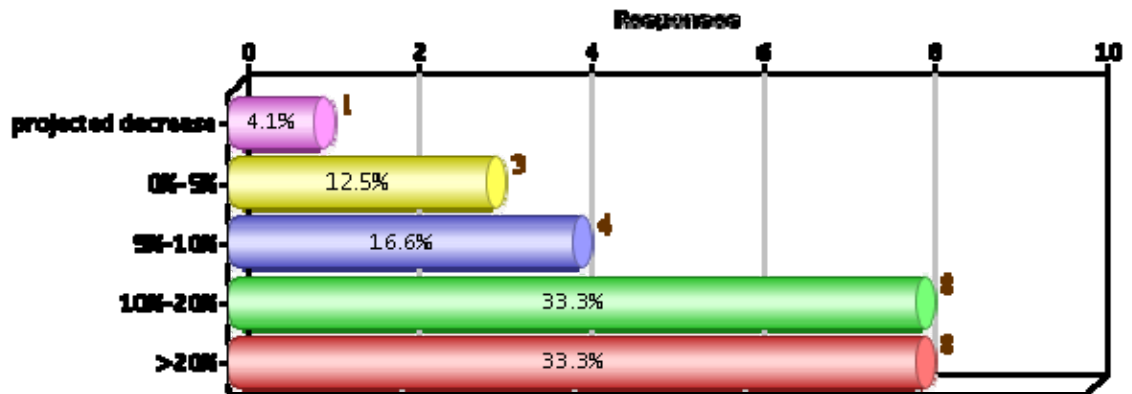
- directors of PGY2 ambulatory care specialty practice residencies
- directors of PGY1 community pharmacy practice residencies
- deans of schools and colleges of pharmacy
- clinical contacts within chain pharmacies
- organizations that had placed an advertisement in professional pharmacy association vehicles in the past three years

The survey response rate was 9 percent. The respondents currently employ 892 pharmacists, 213 (24 percent) of whom provide specialized ambulatory care services. The survey instrument is included as Appendix B-5.

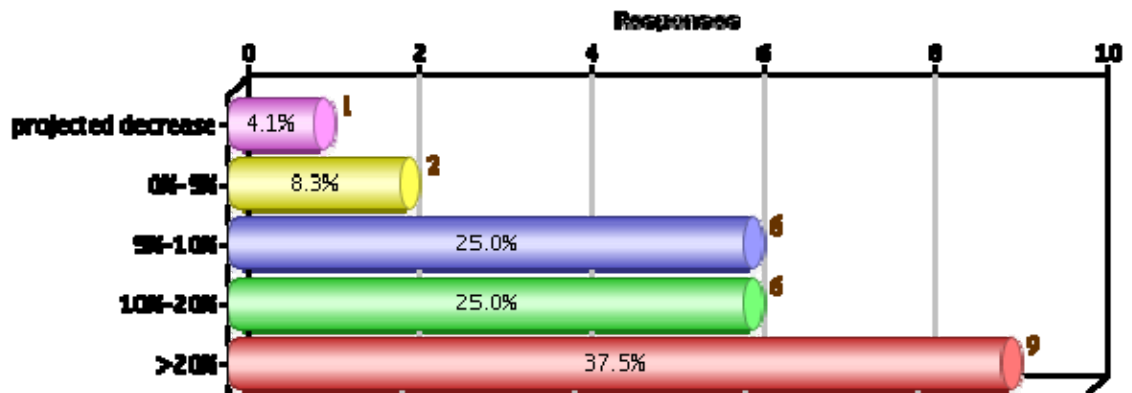
Employers indicated that they had recruited for 99 ambulatory care pharmacist specialists over the past three years and had filled more than 81 percent of these positions. These employers estimate that they will fill an additional 114 positions over the next three years. More than 37 percent of employers estimated a growth of over 20 percent within their organizations for ambulatory care specialists.

As shown in Figures B-4 and B-5, over 66 percent of employers anticipate that their total pharmacist staff will grow 10 percent or more within the next five years. More than 62 percent of these same employers indicated that their ambulatory care pharmacist specialist staff would increase by 10 percent in that period.

**Figure B-4: Anticipated Growth in Total Pharmacist Staff over the Next Five Years**



**Figure B-5: Anticipated Growth in Ambulatory Care Pharmacist Specialists over the Next Five Years**



Employers surveyed also estimated that over 25 percent of their total pharmacist staff will be practicing at a specialty level of ambulatory care within the next five years. These survey results demonstrate a consistent and growing market for ambulatory care specialists.

**Guideline 3. Include estimates of filled and unfilled positions in each of the past three (3) years in order to demonstrate a sustained or increased demand for pharmacists with specialized knowledge and training. Describe the sources and methods used to determine these estimates.**

Employer demand for specialized ambulatory care pharmacy services can be documented by tabulating employment opportunities for pharmacists that appear in ambulatory care in selected pharmacy journals and in online employment sites for pharmacists. We reviewed

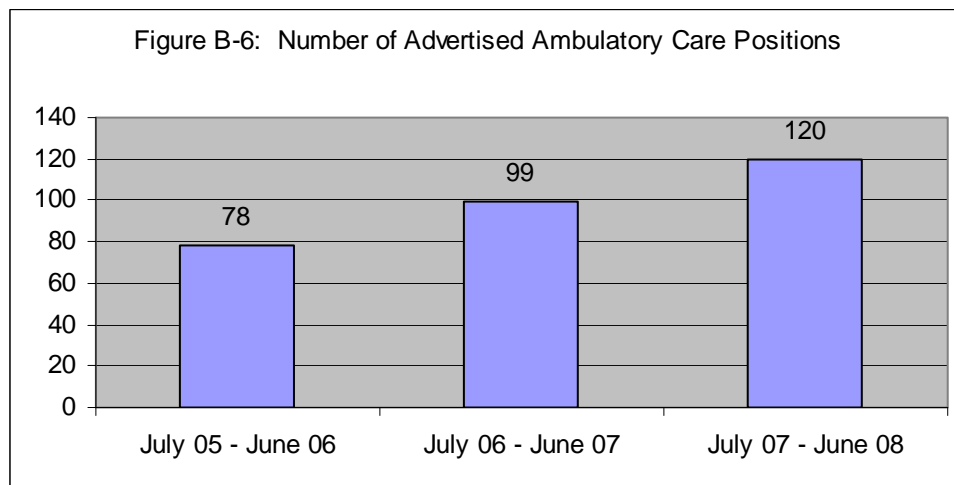
the following sources for ambulatory care employment advertisements published from July 1, 2005, through June 30, 2008:

- *American Association of Colleges of Pharmacy News*
- *ACCP Report*
- *ASHP Career Pharm*
- *APhA Pharmacy Today*

We made no attempt to differentiate practice functions requested by the employer in these advertisements; however, all advertisements specifically called for a clinical pharmacist in ambulatory care. Positions were offered primarily within schools and colleges of pharmacy, health systems, and managed care organizations. A total of 297 positions were listed during the three-year period, with an increase in demand of 180 percent over those three years.

The number of positions is likely underestimated for two reasons. First, we cannot estimate or make accurate assumptions concerning other methods employed to recruit ambulatory care pharmacy specialists, such as internal placements, word-of-mouth advertising, networking, or use of professional search firms. Second, professional recruiting efforts have shifted from published media (e.g., journals and newsletters) to electronic communication vehicles (online recruiting), where historical records are not maintained when these positions have been filled. It is highly likely that positions advertised in the past 12 months have been increasingly electronic, and have not been adequately captured.

Figure B-6 demonstrates the increase in advertised positions for ambulatory care pharmacists from July 2005 to June 2008.



<sup>1</sup>Partnership for Solutions. Chronic Conditions: Making the Case for Ongoing Care. September 2004 Update. Available at: <http://www.rwjf.org/files/research/chronicbook2002.pdf>. Accessed August 30, 2008.

<sup>2</sup>Witt A, Sadler M, Shanahan R, Mazzoli G, and Tillman D. Effect of a centralized clinical pharmacy anticoagulation service on the outcomes of anticoagulation therapy. *CHEST* 2005;127:1515–22.

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- <sup>3</sup> Wubben D, and Vivian E. Effects of pharmacist outpatient interventions on adults with diabetes mellitus: A systematic review. *Pharmacotherapy* 2008;28(4):421-36.
- <sup>4</sup> Gilmartin C. Pharmacist's role in managing anemia in patients with chronic kidney disease: Potential clinical and economic benefits. *Am J Health-Syst Pharm* 2007;64(Suppl 8):S15-22.
- <sup>5</sup> March K, Mak M, and Louie S. Effects of pharmacists' interventions on patient outcomes in an HIV primary care clinic. *Am J Health-Syst Pharm* 2007;64:2574-8.
- <sup>6</sup> Nkansah N, Brewer J, Connors R, and Shermock K. Clinical outcomes of patients with diabetes mellitus receiving medication management by pharmacists in an urban private physician practice. *Am J Health-Syst Pharm* 2008;65:145-9.
- <sup>7</sup> Loughlin S, Mortazavi A, Garey K, Rice G, and Birtcher K. Pharmacist-managed vaccination program increased influenza vaccination rates in cardiovascular patients enrolled in a secondary prevention lipid clinic. *Pharmacotherapy* 2007;27(5):729-33.
- <sup>8</sup> Smith J, Dong M, and Kaunitz J. Evaluation of a pharmacist-managed hepatitis C care clinic. *Am J Health-Syst Pharm* 2007;64:632-6.
- <sup>9</sup> Choe H, Townsend K, Blout G, Lo C, Sadowski L, and Standiford C. Treatment and control of blood pressure in patients with diabetes mellitus. *Am J Health-Syst Pharm* 2007;64:97-103.
- <sup>10</sup> US Department of Health and Human Services, Health Resources and Services Administration, Bureau of Health Professions. Report to Congress. The Pharmacist Workforce: A Study of the Supply and Demand of Pharmacists, 2000.
- <sup>11</sup> Schappert SM, and Rechsteiner EA. Ambulatory medical care utilization estimates for 2006. National health statistics reports: no 8. Hyattsville, MD: National Center for Health Statistics. August 2008.
- <sup>12</sup> PRNewswire. Franklin Lakes, NJ. Chronic Medication Nation: Research Finds Chronic Health Problems Now Afflict More Than Half of All Americans. May 14, 2008. Available at: <http://medco.mediaroom.com/index.php?s=43&item=317>. Accessed September 1, 2008.
- <sup>13</sup> Medicare Part D Medication Therapy Management (MTM) Programs: 2008 Fact Sheet. Baltimore, MD: Centers for Medicare & Medicaid Services. March 19, 2008
- <sup>14</sup> Knapp D. Professionally determined need for pharmacy services in 2020. *Am J Pharm Educ* Winter 2002;66:421-9.
- <sup>15</sup> American Association of Colleges of Pharmacy. JCPP future vision of pharmacy practice. Available from [http://aacp.org/Docs/MainNavigation/Resources/8597\\_JCPPVisionStatement.pdf](http://aacp.org/Docs/MainNavigation/Resources/8597_JCPPVisionStatement.pdf). Accessed June 15, 2008.
- <sup>16</sup> Project Destiny Executive Summary. February 2008. Available at: [www.pharmacist.com](http://www.pharmacist.com). July 12, 2008
- <sup>17</sup> American College of Clinical Pharmacy. A vision of pharmacy's future roles, responsibilities, and manpower needs in the United States. *Pharmacotherapy* 2000;20(8):991-1022.
- <sup>18</sup> American Society of Health-System Pharmacists. ASHP long-range vision for the pharmacy work force in hospitals and health systems. *Am J Health-Syst Pharm* 2007;64:1320-30.

## **CRITERION C: Number and Time**

The area of specialization shall include a reasonable number of individuals who devote most of the time of their practice to the specialty area. ***This criterion relates to the NUMBER of practitioners and the amount of TIME spent in the practice of the specialty.***

To determine the number of practitioners and the time spent in ambulatory care practice, we developed a web-based survey and fielded it to pharmacists in ambulatory care practice identified through membership records of ACCP, APhA, and ASHP. After removing duplicate entries and undeliverable e-mail addresses, we defined 5,434 individuals as currently working in an ambulatory care setting, having an expressed interest in ambulatory care practice, or having completed a PGY2 ambulatory care practice residency. Clearly this number is underestimated because not all pharmacists practicing in ambulatory care are members of the three organizations from whose records names were drawn; however, we believe that those pharmacists who are more professionally engaged are more likely to pursue specialty recognition.

The survey was fielded in mid-August 2008, and the response rate was 14 percent. Over 40 percent of respondents took the initiative to sign the online petition in support of specialty recognition for ambulatory care pharmacists. A copy of the survey instrument is attached as Appendix A-1.

***Guideline 1: Estimate the number of pharmacists currently practicing in the proposed specialty. Identify the types of practice settings for these pharmacists (e.g., academic, hospital, managed health care, community). Describe the sources and methods used to determine these estimates.***

Specialty practice in ambulatory care has experienced significant growth over the past 10 years in multiple pharmacy practice settings. One indicator of this is the growing number of PGY2 (specialty) residency programs in ambulatory care. Ten years ago, there were 33 ASHP-accredited specialty residency programs in ambulatory care (previously called primary care); today, these programs number 45—an increase of 36 percent. In comparison, there are currently 47 PGY2 residency programs in oncology. Specialty residencies in ambulatory care graduate about 48 ambulatory care specialists each year, fully 19 percent of all PGY2 residency graduates.

Community pharmacy residency programs were in their infancy 10 years ago; today, there are 54 accredited programs with 80 positions. Individuals completing community pharmacy residency programs assume patient care practice roles at the level described within the proposed specialty definition. As described in the JCPP 2015 vision statement, the shift

toward greater patient-care roles will continue, and the number of these pharmacists practicing at the specialty level will likewise increase.

Of the pharmacists surveyed, over 87 percent indicated that they are practicing at a specialty level according to the following definition, which was developed jointly by ACCP, APhA, and ASHP, the three organizations that partnered to develop this petition.

**Definition of Ambulatory Care Pharmacy Practice—  
A Specialty in Medication Use for Preventive and Chronic Care**

*Ambulatory care pharmacy practice is the provision of integrated, accessible healthcare services by pharmacists who are accountable for addressing medication needs, developing sustained partnerships with patients, and practicing in the context of family and community.*

*This is accomplished through direct patient care and medication management for ambulatory patients, long-term relationships, coordination of care, patient advocacy, wellness and health promotion, triage and referral, and patient education and self-management.*

**Based upon survey results, we estimate that 4,728 pharmacists are currently engaged in specialized ambulatory care practice.**

The survey revealed that ambulatory care pharmacist specialists practice in a variety of settings, as shown in Figure C-1.

**Figure C-1: Practice Settings for Ambulatory Care Pharmacist Specialists**

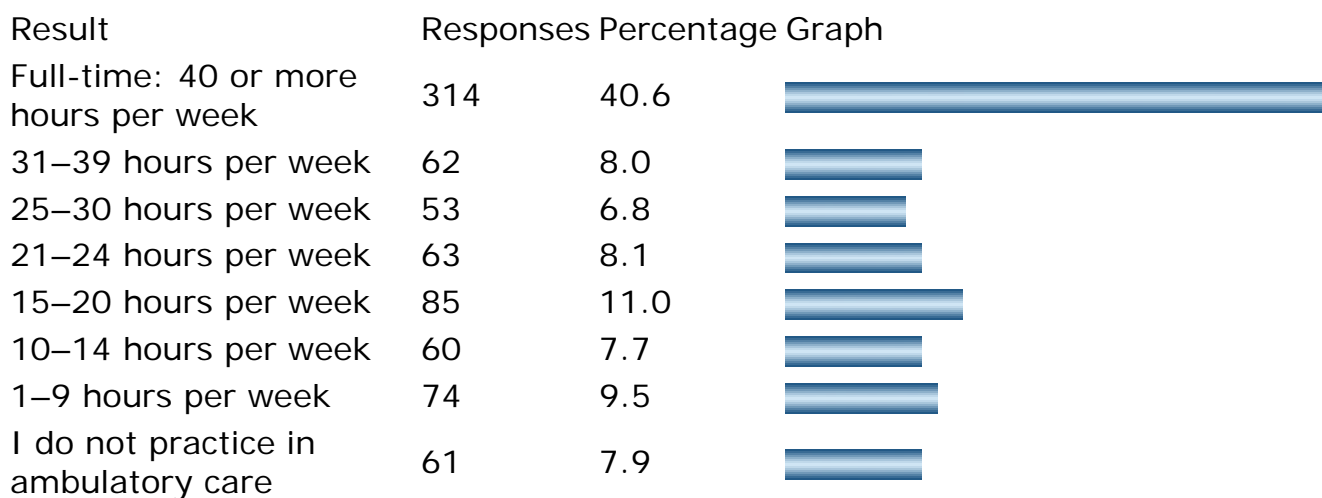
Result	# Responses	Percentage	Graph
Academic—teaching and practice (ambulatory care clinic)	265	34.3	
Ambulatory care clinic	108	13.9	
Community pharmacy practice	108	13.9	
Academic—teaching and practice (physicians' office-based)	69	8.9	
Other	55	7.1	
I do not have an ambulatory care practice	50	6.4	
Managed care practice	47	6.0	
Academic—teaching and practice (community pharmacy)	32	4.1	
Physicians' office	30	3.8	
Academic—teaching and practice (managed care)	8	1.0	

***Guideline 2: For the pharmacists identified in Guideline 1 (immediately above), estimate the percentage of time they devote exclusively to the practice of the***

**proposed specialty. Describe the sources and methods used to determine these estimates.**

As part of the survey, we asked pharmacists to quantify the amount of time that they spend in specialized ambulatory care practice and the types of functions that they perform in their ambulatory care practice. Results indicate that over 40 percent of pharmacists work at least 40 hours per week in their ambulatory care practice site. The average number of hours that responding pharmacists spend in ambulatory care practice per week is shown in Figure C-2.

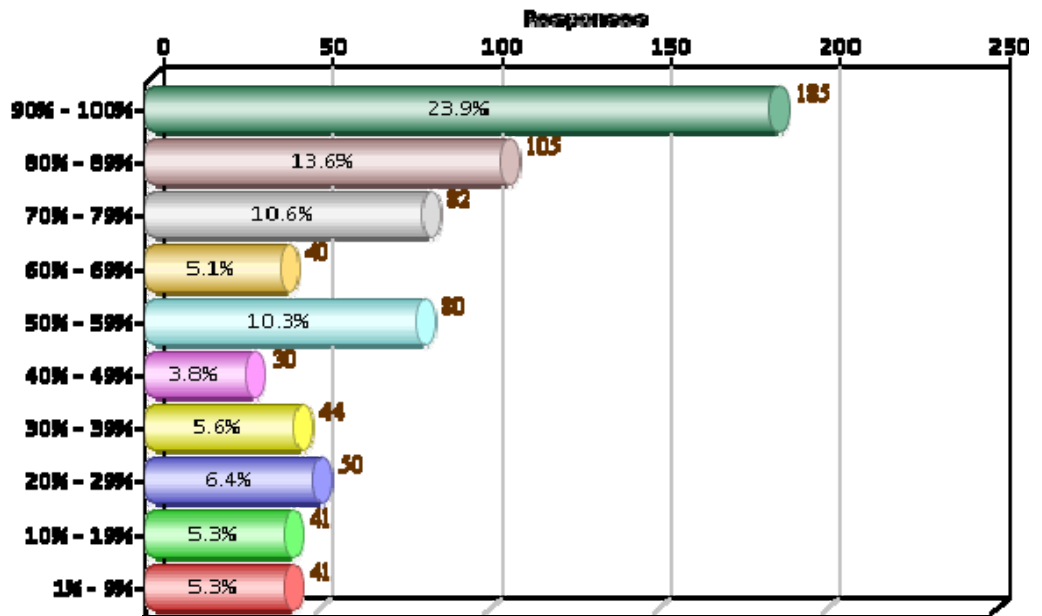
**Figure C-2: Average Number of Hours per Week Spent Practicing in an Ambulatory Care Practice Site (N = 772)**



Almost 64 percent of the pharmacists who indicated that they are practicing at a specialty level spent over 50 percent of their time spent engaged in patient-care functions of specialized ambulatory care practice. Almost one-quarter of respondents indicated that they spent 90 to 100 percent of their time performing specialized ambulatory care functions (see Figure C-3).



**Figure C-3: Percentage of Time Devoted Exclusively to Practicing Specialized Ambulatory Care Pharmacy Practice**

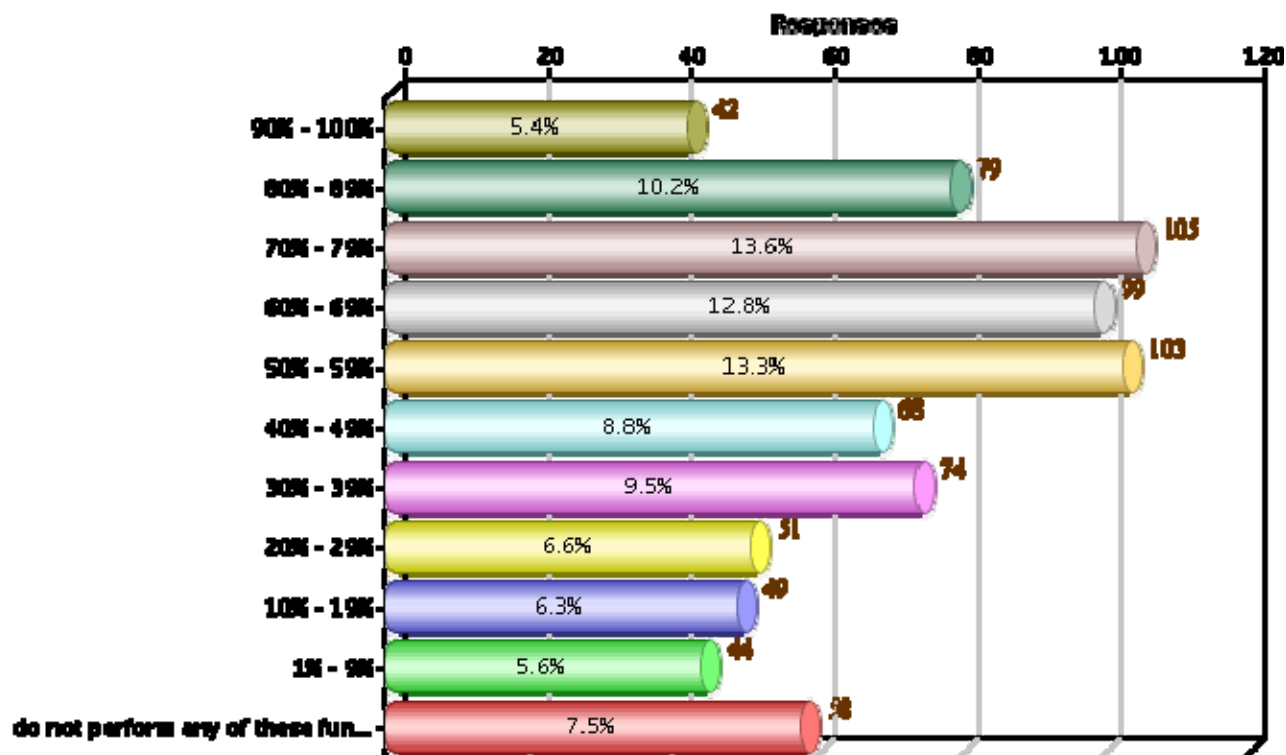


Pharmacists were also asked to quantify the percentage of time in an average week that they spend engaged in direct patient care activities such as the following:

- managing medication use
- developing/implementing individualized treatment goals and plans
- gathering information from and assessing patients
- integrating care of acute illnesses in the context of patients' underlying chronic disease(s) and health status
- performing roles in patient education, health promotion, wellness, and/or self-management
- coordinating care among members of the health team
- advocating for patients

These results, highlighted in Figure C-4, show that over 55 percent of survey respondents spent at least half of their time engaged in direct-care activities.

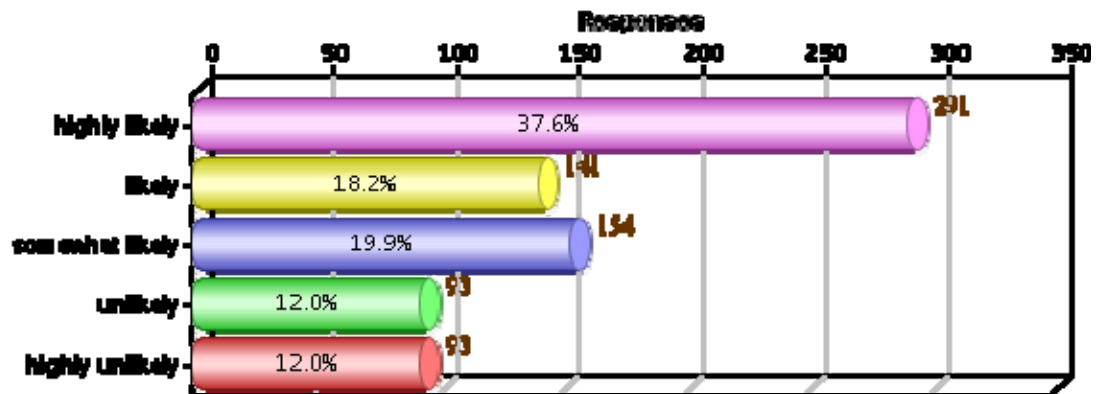
Figure C-4: Percentage of Time Spent in Direct Patient Care Activities



***Guideline 3: Estimate the number of pharmacists who would likely seek board certification in the proposed specialty during the first five years in which board certification would be available. Describe the sources and methods used to determine these estimates.***

Our survey asked respondents to indicate whether, if the petition to recognize ambulatory care pharmacy practice as a specialty is approved, how likely they would be to pursue this specialty recognition within the next five years. Almost 56 percent of respondents, or 432 pharmacists, indicated that they would be “highly likely” or “somewhat likely” to pursue specialty recognition in ambulatory care (see Figure C-5).

**Figure C-5: Likelihood of Pursuing Specialty Recognition within the Next Five Years**



Since this survey sampled only a small proportion of the individuals who may be practicing as ambulatory care pharmacist specialists, it is likely that the number of individuals who would seek certification is underrepresented. The growth and number of residency programs and the number of individuals who have indicated that they would be interested in certification are comparable to those of specialties currently recognized by BPS. Recognition of an ambulatory care specialty that has broad acceptance across many practice settings will certainly increase the numbers of individuals who are likely to seek certification.

## **CRITERION D: Specialized Knowledge**

The area of specialization shall be based on specialized knowledge of one or more of the pharmaceutical sciences and the biological, physical, behavioral, and administrative sciences which underlie them. Procedural or technical services and the specific environment in which pharmacy is practiced are not applicable to this criterion.

***This criterion relates to specialized knowledge.***

Specialized pharmacy practice in ambulatory care requires the acquisition and application of specialized knowledge to meet the complex medication management needs of patients with chronic diseases and to perform the specialized functions detailed in Criterion E. Ambulatory care pharmacist specialists obtain this knowledge through a variety of means, which are discussed in detail under Criterion F (Education and Training) and Criterion G (Transmission of Knowledge).

The specialized pharmaceutical sciences knowledge required to practice in this specialty is outlined in Guideline 1 below. Guideline 2 associates this knowledge with the biological, physical, and behavioral sciences. Guidelines 3 and 4 explain how the specialized knowledge applied by the ambulatory care pharmacist specialist differs from that of the generalist pharmacist and of pharmacist specialists in other recognized specialty areas of pharmacy practice.

In 2006, a role delineation study was conducted to describe and empirically validate the domains, tasks, and knowledge that comprise specialty practice in ambulatory care.<sup>1</sup> (The complete study is attached as Appendix D-1: Report of the Role Delineation Study of Ambulatory Care Pharmacists.)

The role delineation study identified and validated five domains of specialty practice in ambulatory care and the knowledge areas associated with each domain. The domains are

- direct patient care
- practice management
- public health
- medical informatics and professional development
- patient advocacy

This criterion documents the specialized knowledge required for professional practice in the role of ambulatory care pharmacist specialist. In order to perform functions of specialized ambulatory care practice, pharmacists must attain specialized knowledge in each of the five domains. This knowledge is unique, or required at a deeper level, in comparison with the knowledge required by individuals in general practice or in other BPS-recognized specialties.

Exhibit 3 in the Role Delineation Study lists 102 areas of knowledge identified within the five domains of ambulatory care practice. In May 2007, a joint task force of ambulatory care pharmacist specialists convened by the petitioning organizations reviewed the role delineation study results and further segmented these areas of knowledge into those that are unique to specialty practice or that are required with greater depth or emphasis in ambulatory care pharmacist specialists' practice. The determinations of this joint task force are summarized in Table D-1.

**Table D-1: Specialized Knowledge Unique to or Applied with Greater Emphasis and/or Depth by Ambulatory Care Pharmacist Specialists**

Domain	Knowledge Unique or Required with Greater Emphasis/Depth by Ambulatory Care Pharmacist Specialists
<b>Domain 1: Direct Patient Care</b>	<ul style="list-style-type: none"> <li>5 Knowledge of physical assessment techniques</li> <li>13 Knowledge of common immunizations</li> <li>16 Knowledge of recent advances related to pharmacotherapy in ambulatory practice</li> <li>17 Knowledge of factors affecting medication and treatment adherence</li> <li>18 Knowledge of effective interventions to address medication and treatment nonadherence</li> <li>19 Knowledge of the techniques for use of point-of-care testing (for example, blood glucose, cholesterol, INR)</li> <li>21 Knowledge of patient interviewing skills</li> <li>22 Knowledge of motivational interviewing techniques</li> <li>23 Knowledge of how to assess the patient's readiness and/or willingness to participate in their own care</li> <li>32 Knowledge of how to prioritize patient needs and/or drug-related problems</li> <li>36 Knowledge of how to implement an effective individualized treatment plan,</li> <li>38 Knowledge of the format for documentation of patient-care activities, plans and recommendations (for example, SOAP notes)</li> <li>39 Knowledge of the types, indications, and uses of health-related screening tests (for example, home pregnancy tests, hemocult tests)</li> <li>40 Knowledge of the types, indications, and uses of self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors)</li> <li>43 Knowledge of how to effectively communicate with the patient</li> <li>44 Knowledge of the principles and practices of wellness and prevention</li> </ul>
<b>Domain 2: Practice Management</b>	<ul style="list-style-type: none"> <li>1 Knowledge of the collaborative care relationships necessary in fulfillment of the pharmacist's role in a successful ambulatory care practice</li> <li>3 Knowledge of the regulations surrounding collaborative drug therapy agreements</li> <li>4 Knowledge of the strategies and resources necessary for establishing a collaborative care agreement and referral process</li> <li>6 Knowledge of implementation strategies for ambulatory care pharmacy services</li> <li>9 Knowledge of procedures for coding and billing as relevant to pharmacy practice</li> <li>10 Knowledge of tasks involved in managing the implementation of a new service or program</li> <li>11 Knowledge of effective marketing strategies for initiating or expanding ambulatory pharmacy services</li> <li>12 Knowledge of systems for patient referral and follow up</li> <li>14 Knowledge of regulations with regard to point-of-care testing (for example, OSHA, CLIA, state board of pharmacy, other state laws)</li> </ul>

	<p>18 Knowledge of cost-effective alternative and therapeutic interchange options</p> <p>20 Knowledge of service development process (for example, needs assessment, business plan, SWOT [strengths, weaknesses, opportunities, and threats] analysis)</p> <p>22 Knowledge of process necessary for evaluation, analysis, and justification of services</p>
<p><b>Domain 3: Public Health</b></p>	<p>2 Knowledge of resources available through relevant groups, organizations, and agencies (for example, ADA, AHA, NIH, CDC, AAAAI)</p> <p>3 Knowledge of disease prevention strategies</p> <p>4 Knowledge of disease screening guidelines</p>
<p><b>Domain 4: Medical Informatics and Professional Development</b></p>	<p>2 Knowledge of common resources of biomedical literature applicable to ambulatory pharmacy practice</p> <p>13 Knowledge of the ethical principles surrounding research on human subjects</p> <p>14 Knowledge of elements of informed consent</p>
<p><b>Domain 5: Patient Advocacy</b></p>	<p>2 Knowledge of patient-specific factors that may have an impact on access to medications (for example, socioeconomic)</p> <p>3 Knowledge of the structure, guidelines, and process of patient and/or medication assistance programs</p> <p>7 Knowledge of the healthcare resources and services available to ambulatory care patients (for example, disease-specific websites, medication assistance programs, social services).</p> <p>8 Knowledge of collaborative relationships necessary to enable case management of ambulatory care patients</p> <p>9 Knowledge of the scope and limitations of ambulatory care pharmacy practice</p>

**Guideline 1. Describe in detail the specialized knowledge of pharmaceutical sciences required for the proposed specialty.**

Patients with a broad range of diseases and conditions are managed in ambulatory settings. Many of these conditions coexist and thus require complicated medication therapy and other interventions. To effectively care for these complex patients and take responsibility for achieving intended therapeutic outcomes, ambulatory care pharmacist specialists rely on a specialized body of knowledge that is distinct in both breadth and depth.

Related to pharmaceutical sciences, in-depth knowledge of drugs used in cardiovascular, endocrine, respiratory, allergy/immunology, musculoskeletal, gastrointestinal, infectious disease, and mental health, and other diseases prevalent in ambulatory care is required. Knowledge of integrated pharmacotherapeutic principles associated with medications and diseases managed in ambulatory care—and the interplay of each—is also required in specialty ambulatory care pharmacy practice. Specialized knowledge of pharmaceutical sciences in ambulatory care requires a solid foundation of knowledge, such as that acquired through entry-level doctor of pharmacy programs and defined in the *Accreditation Council for Pharmacy Education (ACPE) Standards 2007*.<sup>2</sup> Ambulatory care pharmacist specialists build on a foundation of knowledge in medicinal chemistry, including the chemical basis of pharmacology and therapeutics and structural activity relationships that lead to drug-target

interactions, and chemical pathways of drug metabolism, coupled with a broad understanding of pharmacology. Pharmacologic principles of medications used in ambulatory care, including mechanism of action, pharmacodynamics, pharmacokinetics, bioavailability, bioequivalence, potential ADEs and side effects, and interactions between drug-target, drug-drug, drug-food, and drug-lab tests underpin these pharmacists' ability to analyze individual patient situations and make determinations regarding drug treatment. In addition, knowledge of natural products and supplements allow pharmacists to prevent and detect safety problems and interactions of medications with complementary and alternative treatments and to advise patients in self-management of their disease and symptoms. Knowledge of pharmaceuticals and biopharmaceuticals provides important insights into drug delivery through varying dosage forms and their associated physical-chemical properties, which may influence adherence and product selection for patients. A knowledge of toxicology, exposure, and poison control, and a baseline understanding of pharmacogenomics, extemporaneous compounding, and enteral nutrition adds to this foundation.

Bloom's taxonomy of learning states that acquiring knowledge and understanding is only the first step in the hierarchy of cognitive learning that enables critical thinking, synthesis, and problem solving.<sup>3</sup> Specialized knowledge provides the foundation—the means to the desired end that enables pharmacist specialists to perform the specialized tasks and functions required to identify and solve drug therapy problems.<sup>3,4</sup>

Ambulatory care pharmacist specialists have expanded their knowledge in the pharmaceutical sciences to encompass the depth of understanding required for synthesis of individualized dosing and care plans for patients with coexisting, overlapping, and sometimes interacting drug therapy regimens. Their specialized knowledge enables them to develop expertise in the comparative use of alternative therapies in subsets of ambulatory patients with chronic diseases, as well as their concomitant use in patients with multiple and overlapping disease states. A specialized knowledge of clinical pharmacokinetics, and of its interface with pharmacodynamics, is important to the ambulatory care pharmacist specialist. In providing care of patients with anticoagulation needs, these pharmacists must understand the principles associated with individualizing therapy (e.g., warfarin) and interpret and act on patients' laboratory results by adjusting therapy, often in the context of multiple conflicting problems. The fundamentals of laboratory medicine and their application in screening and monitoring patients with and at risk for chronic diseases and in managing their medication therapy are another specialized area of knowledge in ambulatory care.

Ambulatory care pharmacist specialists enhance their ability to prevent, detect, or ameliorate ADEs, which reportedly occur at a rate of 27 percent in ambulatory patients,<sup>5</sup> through acquiring and maintaining specialized knowledge of potential ADEs associated with medications and of combinations of medications used in the management of ambulatory patients with complex chronic conditions. In addition, because patients in ambulatory care have control over decisions related to their diets, in-depth knowledge of dietary influences on absorption, distribution, metabolism, and excretion are essential in ambulatory care practice. Specialized knowledge of immunizations from a pharmacologic, patient screening, and drug administration standpoint is required to enable ambulatory care pharmacist specialists to advise patients and help prevent illness, as well as to train other pharmacists to participate in patient immunization programs. Ambulatory care pharmacist specialists often provide care for patients with diseases or problems where drug metabolism and

elimination are altered and where therapy for one chronic disease complicates treatment for another.

Much of the specialized pharmaceutical sciences knowledge required for specialized practice in ambulatory care therefore lies in the **depth and breadth** of the combined use of medications relative to others in treating a variety of chronic diseases (e.g., diabetes, asthma, cardiovascular disease) and associated complications concurrently. Rarely do ambulatory patients with chronic diseases present with a single problem; as such the specialists providing care must be able to draw upon a strong knowledge base that enables them to integrate the care for one problem within the context of the whole patient and to coordinate care with multiple caregivers.

**Guideline 2. Explain fully the relationship of this specialized knowledge to the biological, physical and behavioral sciences.**

A broad-based, in-depth, specialized knowledge of the pharmaceutical sciences provides the critical underpinning of the complex knowledge in the biological, physical, and behavioral and social sciences required to manage the chronic and preventive care needs of ambulatory patients. Increasing attention is being given to the importance of knowledge acquisition and maintenance and its influence on healthcare quality in the United States.<sup>6</sup>

Ambulatory care pharmacist specialists must possess specialized knowledge in anatomy and physiology, pathophysiology, and pathogenesis of chronic diseases and conditions commonly experienced by patients in ambulatory care, along with knowledge of physical and clinical assessment techniques. They must keep abreast of changes in technology associated with detecting, diagnosing, and managing patients, and integrate knowledge of laboratory analyses and their relation to health status and drug therapy. They must also gain specialized knowledge of the coexistence of chronic diseases and the interplay of medication therapy in treating them. To ensure quality, ambulatory care pharmacist specialists must maintain specialized and up-to-date knowledge of evidence-based medicine, clinical practice guidelines, and clinical research; they must also understand systems and processes in practice-based research. The ability to interpret the published literature to determine the validity of the research methods, results, and outcomes and to make judgments regarding the relative merits of conflicting information is a foundational skill used by the ambulatory care pharmacist specialist.

In the behavioral sciences, ambulatory care pharmacist specialists must understand theory and strategies of motivational interviewing, interpersonal communication, listening, negotiation, cultural competence, and health literacy. This knowledge is essential for developing the long-standing, trusting relationships required in ambulatory care. This knowledge also underpins skills required to motivate patients to adhere to prescribed therapies, to make choices that have a positive influence on their health, and to detect ADEs or other medication problems. Ambulatory care pharmacist specialists need to understand the costs of various therapeutic options, particularly the out-of-pocket costs borne by patients, and methods for sensitively discussing these issues with their patients. In this regard, specialized knowledge in bioequivalence of alternative treatments is important to ensure that cost-reducing strategies result in positive or equivalent effects on the patients' health status.



Biological and social sciences knowledge also includes the impact of behavior and lifestyle choices on chronic diseases and their complications. Knowledge of technology for screening and monitoring diseases is also required in specialized ambulatory care, as is knowledge of disease prevention and screening guidelines. Moreover, the ambulatory care pharmacist specialist must be adept at using information resources produced and disseminated by national health organizations and agencies, such as the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, and National Heart, Lung and Blood Institute. Familiarity with medical and medication assistance programs and services is required, as is knowledge of program qualifications and structure.

Collaboration with prescribers and other members of the healthcare team in managing complex ambulatory patients with chronic diseases requires specialized knowledge in communication and negotiation strategies with peers, subordinates, or superiors, as well as understanding of legal and practical requirements for establishing a collaborative practice. In addition, the ambulatory care pharmacist specialist must be knowledgeable regarding the methods and systems for documenting patient-care activities and plans (e.g., through SOAP notes, electronic communication systems).

### ***Discussion***

The body of specialized knowledge described in Guidelines 1 and 2 provides the required foundation for the development of the analysis, synthesis, and problem-solving skills required by ambulatory care pharmacist specialists. As Bloom<sup>3</sup> suggests, learning is hierarchical. Learning and performance at high levels, such as that required for the management of complex chronic diseases and associated drug therapy follows a process that begins with obtaining knowledge (i.e., learning facts) and comprehending that knowledge. Applying the knowledge is an interim step, leading ultimately to the ability to fully use the knowledge in analysis, synthesis, and evaluation. The skills and functions performed by ambulatory care pharmacist specialists that demonstrate the highest levels of specialized knowledge acquisition that are needed to make determinations regarding drug choice, treatment of complex diseases, and synthesis of care plans are described in Criterion E.

A subanalysis of the role delineation study data (Appendix D-2) revealed greater emphasis on core sets of knowledge by ambulatory care pharmacists who had acquired additional training and/or credentials through various mechanisms (e.g., residency). These individuals relied more heavily on specialized knowledge to support important functions related to chronic and preventive medication management issues for complex ambulatory patients.

### **Guideline 3. Discuss in detail how this specialized knowledge differs from the knowledge base of a recent graduate with a Doctor of Pharmacy degree.**

An individual who has earned a doctor of pharmacy degree is educated to provide care in generalized practice in a variety of patient care settings. The scope of practice defined by licensure examination (though the North American Pharmacy Licensure Examination [NAPLEX] in most states) assures that a licensed pharmacist has met the baseline,

minimum standards to practice pharmacy. An earned degree from an accredited school or college of pharmacy and licensure by examination prepare an entry-level pharmacist to deliver generalized pharmaceutical care better than any other type of health professional in the U.S. healthcare system.

The licensure examination, by definition, sets a *minimum* competency standard. Specialty certification, by contrast, confirms the acquisition of specialized knowledge that prepares a pharmacist specialist to “contribute at ... evolving, advanced practice levels.”<sup>7</sup> As established under Criterion A, increasing numbers of ambulatory patients have multiple chronic conditions and are on complex medication regimens to treat disease, prevent complications, maintain wellness, and address lifestyle problems. The incidence of chronic diseases and medication use among younger and older segments of the U.S. population is rising, as are the daunting statistics and associated consequences of medication errors, drug misuse, ADEs, and nonadherence.<sup>5,8,9</sup> A growing number of patients who receive care in ambulatory settings require the skillful, specialized knowledge and medication therapy management provided by ambulatory care pharmacist specialists in order to reach their desired health outcomes.

The NAPLEX Blueprint<sup>10</sup> (see Appendix D-3) is a list of competency statements describing the knowledge, judgment, and skills expected of an entry-level pharmacist. The licensure examination establishes the acquisition, comprehension, and application of basic, general pharmacy practice knowledge, but not the analysis, synthesis, and evaluation of specialized knowledge in relation to complex medication therapy. The minimum competency standards set by licensure fall short of the validated knowledge and expertise required of an ambulatory care pharmacist specialist.

Ambulatory care pharmacist specialists apply specialized knowledge in the domains of direct patient care, practice management, public health, medical informatics and professional development, and patient advocacy. These domains include specialized knowledge in the pharmaceutical, biological, and behavioral sciences associated with managing and optimizing medication use, developing individualized care plans (including clinical pharmacokinetic dosing when necessary), and developing long-term relationships with patients and other health professionals. Required specialized knowledge also includes expertise associated with the conduct and evaluation of research; evidence-based medicine and clinical guidelines; and communication, motivation, and negotiation strategies. In addition, the knowledge underpinning immunizations and health promotion and disease prevention are required to support specialized practice. While many of these concepts are introduced in the doctor of pharmacy curriculum, they are neither mastered at a specialty level during entry-level education nor measured by the licensure examination.

**Guideline 4. Discuss in detail how this specialized knowledge differs from the knowledge base of those specialty areas already recognized by BPS.**

No currently recognized BPS specialty encompasses the domains and specialized areas of knowledge required of ambulatory care pharmacist specialists. Nuclear pharmacy lacks the fundamental pharmacotherapeutic, medication management, and direct patient care–related knowledge of ambulatory care and the related emphasis on chronic disease states. Specialties in nutritional support, psychiatry, and oncology focus on relatively narrow

segments of ambulatory care patients and therefore lack the required breadth. Further, these specialties do not emphasize preventive and chronic care. The sole BPS specialty that initially appears to require specialized knowledge in areas that overlap with those of the proposed ambulatory care specialty is pharmacotherapy. A close look at the domains and specialized areas of knowledge for both specialty areas, however, reveals significant differences.

The BPS-recognized specialty in pharmacotherapy is divided into three domains: patient-specific pharmacotherapy; retrieval, generation, interpretation and dissemination of knowledge in pharmacotherapy; and health system–related pharmacotherapy. Table D-2 compares these domains with the five domains of the proposed ambulatory care specialty.

**Table D-2: Comparison of Domains in Ambulatory Care Pharmacy and Pharmacotherapy**

<b>Ambulatory Care Pharmacist Specialist Domains (Proposed Examination Percentage)</b>	<b>Pharmacotherapy Specialist Domains (Examination Percentage)</b>
Direct patient care (50 percent)	Patient-specific pharmacotherapy (55 percent)
Practice management (18 percent)	Retrieval, generation, interpretation, and dissemination of knowledge in pharmacotherapy (30 percent)
Medical informatics and professional development (17 percent)	Health system–related pharmacotherapy (15 percent)
Patient advocacy (11 percent)	
Public health (4 percent)	

While some overlap in knowledge domains exists, the differences between the domains in the two specialty areas are significant. Ambulatory care pharmacist specialists require defined knowledge in patient advocacy and public health, as well as practice management outside of the health systems. While both specialties emphasize medical informatics, pharmacotherapy specialists require the knowledge necessary to serve as research investigators in institutional settings, whereas ambulatory care pharmacist specialists require knowledge to engage in ambulatory practice–based research activities. While the pharmacotherapy specialist must possess in-depth knowledge regarding acute care pharmacotherapeutics, the ambulatory care pharmacist does not. Indeed, as the role delineation survey reveals, the ambulatory care pharmacist specialist possesses a greater depth of knowledge areas that underlie a breadth of direct patient-care skills, including patient interviewing and assessment, physical examination techniques, point-of-care and self-testing devices, motivational interviewing, and documentation practices and systems. Significant differences in the knowledge areas within each of these domains differentiate these two specialties. Table D-3 lists the knowledge areas defined by the pharmacotherapy exam content outline and the specialized areas of knowledge listed in Table D-1 that are required with greater depth and emphasis by ambulatory care pharmacist specialists.

**Table D-3: Contrast in Knowledge Areas between Ambulatory Care Pharmacy and Pharmacotherapy**

<b>Ambulatory Care Pharmacist Specialist</b>	<b>Pharmacotherapy Specialist</b>
<p><b>Domain 1: Direct Patient Care</b></p> <ul style="list-style-type: none"> <li>• Knowledge of physical assessment techniques</li> <li>• Knowledge of common immunizations</li> <li>• Knowledge of recent advances related to pharmacotherapy in ambulatory practice</li> <li>• Knowledge of factors affecting medication and treatment adherence</li> <li>• Knowledge of effective interventions to address medication and treatment nonadherence</li> <li>• Knowledge of the techniques for use of point of care testing (for example, blood glucose, cholesterol, INR)</li> <li>• Knowledge of patient interviewing skills</li> <li>• Knowledge of motivational interviewing techniques</li> <li>• Knowledge of how to assess the patient's readiness and/or willingness to participate in their own care</li> <li>• Knowledge of how to prioritize patient needs and/or drug-related problems</li> <li>• Knowledge of how to implement an effective, individualized treatment plan</li> <li>• Knowledge of the format for documentation of patient-care activities, plans, and recommendations (for example, SOAP notes)</li> <li>• Knowledge of the types, indications, and uses of health-related screening tests (for example, home pregnancy tests, hemoccult tests)</li> <li>• Knowledge of the types, indications, and uses of self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors)</li> <li>• Knowledge of how to effectively communicate with the patient</li> <li>• Knowledge of the principles and practices of wellness and prevention</li> </ul> <p><b>Domain 2: Practice Management</b></p> <ul style="list-style-type: none"> <li>• Knowledge of the collaborative care relationships necessary in fulfillment of the pharmacist's role in a successful ambulatory care practice</li> <li>• Knowledge of the regulations surrounding collaborative drug therapy agreements</li> <li>• Knowledge of the strategies and resources necessary for establishing a collaborative care agreement and referral process</li> <li>• Knowledge of implementation strategies for ambulatory care pharmacy services</li> <li>• Knowledge of procedures for coding and</li> </ul>	<p><b>Domain 1: Patient-Specific Pharmacotherapy</b></p> <ul style="list-style-type: none"> <li>• Anatomy and physiology</li> <li>• Pathophysiology</li> <li>• Pharmacotherapy</li> <li>• Laboratory and disease/drug monitoring parameters, including point-of-care testing and regulations</li> <li>• Recent advances related to pharmacotherapy</li> <li>• Patient education principles and methods</li> <li>• Pharmacogenomics</li> <li>• Formats used to document pharmacotherapy recommendations and follow-up</li> <li>• Humanistic factors or outcomes</li> </ul> <p><b>Domain 2: Retrieval, Generation, Interpretation, and Dissemination of Knowledge in Pharmacotherapy</b></p> <ul style="list-style-type: none"> <li>• Primary (e.g., original research reports), secondary (e.g., indexing and abstracting services), and tertiary (e.g., textbook review articles) references</li> <li>• How to formulate a search strategy to retrieve information from the biomedical literature</li> <li>• Research methodology to interpret study validity in assessing the objective of research reports (e.g., study design, population selection, blinding, statistical analysis)</li> <li>• Strengths and limitations of various study methods</li> <li>• Clinical vs. statistical significance</li> <li>• How data from a study or multiple studies can be applied to pharmacotherapy practices</li> <li>• Principles and methods of educating healthcare students and professionals</li> <li>• How to define a research hypothesis</li> <li>• Appropriate research methodology to design studies to assess a research hypothesis</li> <li>• Granting agencies and their application procedures</li> <li>• Regulatory requirements for the coordination of research (e.g., HIPAA, IRB, OSHA)</li> <li>• Elements of informed consent</li> <li>• Survey procedures</li> <li>• Data management</li> <li>• Data analysis and statistical methods</li> <li>• Uniform requirements (developed by the International Committee of Medical Journal Editors) for manuscripts submitted to biomedical journals</li> <li>• Components of well-written research abstracts, reports, and monographs</li> <li>• Structure and interrelationships within the organization for a practice setting (e.g., interdepartmental and intradepartmental) in</li> </ul>

<p>billing as relevant to pharmacy practice</p> <ul style="list-style-type: none"> <li>• Knowledge of tasks involved in managing the implementation of a new service or program</li> <li>• Knowledge of effective marketing strategies for initiating or expanding ambulatory pharmacy services</li> <li>• Knowledge of systems for patient referral and follow up</li> <li>• Knowledge of regulations with regard to point-of-care testing (for example, OSHA, CLIA, state board of pharmacy, other state laws)</li> <li>• Knowledge of cost-effective alternative and therapeutic interchange options</li> <li>• Knowledge of service development process (for example, needs assessment, business plan, SWOT [strengths, weaknesses, opportunities, and threats] analysis)</li> <li>• Knowledge of process necessary for evaluation, analysis, and justification of services</li> </ul> <p><b>Domain 3: Public Health</b></p> <ul style="list-style-type: none"> <li>• Knowledge of resources available through relevant groups, organizations, and agencies (for example, ADA, AHA, NIH, CDC, AAAAI)</li> <li>• Knowledge of disease prevention strategies</li> <li>• Knowledge of disease screening guidelines</li> </ul> <p><b>Domain 4: Medical Informatics and Professional Development</b></p> <ul style="list-style-type: none"> <li>• Knowledge of common resources of biomedical literature applicable to ambulatory pharmacy practice</li> <li>• Knowledge of the ethical principles surrounding research on human subjects</li> <li>• Knowledge of elements of informed consent</li> </ul> <p><b>Domain 5: Patient Advocacy</b></p> <ul style="list-style-type: none"> <li>• Knowledge of patient-specific factors that may impact access to medications (for example, socioeconomic)</li> <li>• Knowledge of the structure, guidelines, and process of patient and/or medication assistance programs</li> <li>• Knowledge of the healthcare resources and services available to ambulatory care patients (for example, disease-specific websites, medication assistance programs, social services).</li> <li>• Knowledge of collaborative relationships necessary to enable case management of ambulatory care patients</li> </ul>	<p>adverse drug event reporting</p> <ul style="list-style-type: none"> <li>• Process/procedures for reporting to the FDA new, unusual, or severe adverse drug events and problems observed with drug products</li> <li>• Process/procedures for reporting to the USP problems observed with medical devices and laboratory products</li> <li>• Process/procedures for reporting in the biomedical literature adverse drug reactions, and problems observed with drug products, medical devices, and laboratory products</li> </ul> <p><b>Domain 3: Health System–Related Pharmacotherapy</b></p> <ul style="list-style-type: none"> <li>• Evidence-based clinical practice and patient-care standards</li> <li>• Health system–based standards (e.g., JCAHO, NCQA, OSHA, CMS, HEDIS, LEAPFROG)</li> <li>• Local, state, and federal regulations</li> <li>• Principles of medication-use evaluation, adverse drug event and medication errors surveillance</li> <li>• Elements of regulations pertaining to healthcare related data security and privacy (e.g., HIPAA)</li> <li>• Regulatory authority of the FDA (i.e., NDA process, oversight of marketing plans, generic drugs)</li> <li>• Compensation policies of federal and private agencies</li> <li>• Healthcare system models</li> <li>• Principles of formulary decision making/management</li> <li>• Structure and interrelationships within the organization for a practice setting (e.g., interdepartmental and intradepartmental)</li> </ul>
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- <sup>1</sup> Professional Examination Services. Report of the Role Delineation Study of Ambulatory Care Pharmacists. Washington, DC: Board of Pharmaceutical Specialties, 2007.
- <sup>2</sup> Accreditation Council for Pharmacy Education. *Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree*. 2007. Available at: <http://www.acpe-accredit.org/standards/default.asp>. Accessed August 10, 2008.
- <sup>3</sup> Bloom BS, ed. *Taxonomy of Educational Objectives: The Classification of Educational Goals*. Susan Fauer Company, Inc. 1956.
- <sup>4</sup> Anderson LW, Krathwohl DR, Airasian PW, et al. , eds. *A Taxonomy for Learning, Teaching, and Assessing — A Revision of Bloom's Taxonomy of Educational Objectives*. Addison Wesley Longman, Inc. 2001.
- <sup>5</sup> Gandhi TK, Weingart SN, and Borus J. Adverse drug events in ambulatory care. *N Engl J Med* 2003;348:1556–64.
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- <sup>7</sup> Board of Pharmaceutical Specialties. Why BPS? Available at: [http://www.bpsweb.org/01\\_About.html](http://www.bpsweb.org/01_About.html). Accessed September 7, 2008.
- <sup>8</sup> Institute for Safe Medication Practices. Protecting U.S. Citizens from Inappropriate Medication Use. A White Paper on Medication Safety in the U.S. and the Role of Community Pharmacists, 2007.
- <sup>9</sup> Institute of Medicine. Committee on Identifying and Preventing Medication Errors. *Preventing Medication Errors: Quality Chasm Series*. Aspden P, Wolcott J, Bootman JL, and Cronenwett LR, eds. Washington, DC: National Academies Press, 2007.
- <sup>10</sup> NAPLEX Blueprint: NAPLEX competency statements. Available at: [www.nabp.net/ftpfiles/NABP01/updatednaplexblueprint.pdf](http://www.nabp.net/ftpfiles/NABP01/updatednaplexblueprint.pdf). Accessed September 1, 2008.

## **Criterion E: Specialized Functions**

The area of specialization shall represent an identifiable field of pharmacy practice which requires specialized functioning by the practitioner and which is distinct from other BPS-recognized pharmacy specialties. ***This criterion refers to SPECIALIZED FUNCTIONS.***

**Guideline 1. Specify and describe in detail, specialized functions performed routinely by practitioners in the proposed specialty which are not performed by pharmacists in general.**

Ambulatory care pharmacy services provided by ambulatory care pharmacist specialists are qualitatively different from those provided by generalist pharmacist practitioners. While ambulatory care pharmacist specialists may routinely perform some of the same functions as a generalist pharmacist practitioner, certain functions performed by a specialist are distinctly different. Likewise, the generalist pharmacist practitioner may at times perform functions that could be identified as specialist ambulatory care functions. However, pharmacists in specialized ambulatory care practice routinely perform these and other unique functions and additional functions at greater depth, or with greater emphasis, than do their generalist pharmacist counterparts.

BPS analyzed these functions in its Role Delineation of Ambulatory Care Pharmacists, which describes and empirically validates the domains, tasks, and knowledge that comprise ambulatory care pharmacy practice.<sup>1</sup> According to the BPS task analysis, the following are the domains of ambulatory care pharmacy specialty practice that are performed, regardless of practice site:

- direct patient care
- practice management
- public health functions
- medical informatics and professional development
- patient advocacy

Within these domains the role delineation study presents 97 tasks that have been validated on the basis of the importance of the task statement and the frequency that the tasks are performed. The full list of Validated Tasks and Knowledge in Ambulatory Care Practice can be found in Exhibit 3 of Appendix D-1.

In 2007, the petitioning organizations convened joint task force of ambulatory care pharmacist specialists to review the results of the BPS role delineation study. Task force participants further segmented the 97 validated tasks to determine those that are unique to

specialized practice or that are required at greater depth or with greater emphasis within the five domains. These recommendations are reported in Table E-1.

**Table E-1: Functions that are unique or emphasized in specialized ambulatory care pharmacy practice**

Domain	Functions that are unique or are performed at a greater depth/emphasis in specialized ambulatory care pharmacy practice
<p><b>Domain 1: Direct Patient Care</b></p>	<p>1.1 Establish a caregiver relationship with the patient that fosters trust and open communication, and encourages patient self-management.</p> <p>1.6 Perform pertinent physical assessments as they relate to patient's current condition and/or therapies (for example, vital signs, weight, palpation, auscultation, visual inspection).</p> <p>1.7 Perform point-of-care testing (for example, blood glucose, cholesterol, INR, bone mineral density, peak flow).</p> <p>1.8 Determine patient's willingness to work with an ambulatory care pharmacy specialist on health- and medication-related issues.</p> <p>1.9 Assess patient's self-management knowledge, understanding, skills, and willingness and ability to actively participate in his/her own care.</p> <p>1.13 Identify and refer (i.e., triage) patients with needs beyond the scope of the ambulatory care pharmacy specialist.</p> <p>1.14 Recognize patient-specific barriers to successful drug therapy (for example, social situations, patient denial, literacy, mental capacity, culture, language) and implement a plan to overcome these (involving, for example, home visits, an interpreter, picture-based education).</p> <p>1.16 Evaluate the patient's technique for administering medications that are not administered orally (for example, nasal inhalers, oral inhalers, eyedrops, eardrops, subcutaneous injections).</p> <p>1.18 Provide wellness and prevention education/counseling (for example, lifestyle modifications, immunizations).</p> <p>1.20 Administer appropriate immunizations to specific patients.</p> <p>1.22 Perform collaborative drug therapy management via protocol or signed collaborative agreements with healthcare providers.</p> <p>1.23 Provide integrated disease-state management (for example,</p>



	<p>pharmacotherapy clinics or primary care clinics where more than one disease may be addressed in a visit).</p> <p>1.24 Provide focused disease-state management (for example, diabetes, hypertension, asthma, heart failure, anticoagulation, dyslipidemia, mental health, chronic pain).</p> <p>1.25 Provide wellness and preventive programs for individual patients (for example, weight management, tobacco cessation, immunization).</p> <p>1.28 Recommend appropriate self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors).</p> <p>1.29 Teach patients how to use self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors).</p> <p>1.30 Recommend appropriate health-related screening tests (for example, home pregnancy tests, hemoccult tests).</p> <p>1.31 Teach patients how to use appropriate health-related screening tests (for example, home pregnancy tests, hemoccult tests).</p> <p>1.32 Define treatment goals in collaboration with the patient and other healthcare providers.</p> <p>1.33 Determine patient's ability and willingness to pay for services (for example, insurance coverage, out-of-pocket expenses).</p> <p>1.40 Conduct follow-up visits to assess response to drug and non-drug therapy and to assure safety.</p> <p>1.43 Determine patient-specific reasons for lack of adherence to recommended treatment and, in collaboration with the patient, develop a plan for improving adherence.</p>
<p><b>Domain 2: Practice Management</b></p>	<p>2.1 Identify the need for ambulatory clinical pharmacy services in response to patient care needs and/or business potential (for example, medication therapy management, focused or integrated disease-state management programs/clinics).</p> <p>2.2 Establish new ambulatory clinical pharmacy services in response to patient care needs and/or business potential (for example, medication therapy management, focused or integrated disease-state management programs/clinics).</p> <p>2.4 Promote and market patient care services to patients and</p>

	<p>healthcare providers.</p> <p>2.5 Establish and maintain a system for patient referral.</p> <p>2.6 Establish and maintain a system for patient follow-up.</p> <p>2.11 Organize the practice in a manner that supports efficient work flow and integration of care, and assures timely patient visits and follow-up (for example, use of ancillary personnel, group visits, disciplined appointment system, technology, coordination of care between clinical and medication dispensing functions).</p> <p>2.12 Manage a financially viable practice (for example, cash-flow management, cash-payment systems, insurance contracting, accounting systems, pricing, expense analysis).</p> <p>2.13 Develop systems to obtain reimbursement for ambulatory clinical pharmacy services.</p> <p>2.16 Manage point-of-care testing in accordance with regulatory requirements (for example, Occupational Safety and Health Administration [OSHA], Clinical Laboratory Improvement Amendments [CLIA]).</p>
<p><b>Domain 3: Public Health Functions</b></p>	<p>3.1 Provide general information to the public regarding preventive health issues (for example, cardiovascular disease, tobacco cessation, immunizations).</p> <p>3.3 Advise and direct the public and consumers to appropriate resource groups, organizations, and agencies (for example, Alzheimer's Association, American Cancer Society).</p> <p>3.4 Participate in community health screening programs.</p> <p>3.6 Advocate to ensure appropriate healthcare policy for ambulatory care pharmacy practice.</p>

**Guideline 2. Describe the special skills required to perform functions specified above.**

All pharmacists are educated to obtain, interpret, and evaluate patient information to appropriately manage drug therapy, assess the need for treatment and/or referral, and identify patient-specific factors that affect health, pharmacotherapy, and/or disease management. Ambulatory care pharmacist specialists have refined and expanded these skills, often through additional training, experience, and credentials, and more frequently perform specialized functions in caring for patients suffering from chronic disease and those

who manage complex medical therapies. The specialized functions described in Guideline 1 are the foundation for the analytic and problem-solving skills required by ambulatory care pharmacist specialists.

Based on a review of the follow-up analysis of the Role Delineation of Ambulatory Care Pharmacist (see Appendix D-2) and the educational outcomes of residents who have completed a PGY2 ambulatory care pharmacy residency program, the following are skills required to perform the specialized functions outlined in the BPS role delineation report:

*Manage the drug regimen by monitoring and assessing the patient and/or patient information, developing individualized care plans, collaborating with other health care professionals, and providing patient education.*

Specialists treat and appropriately triage ambulatory patients with the most complex chronic and acute illnesses, including individuals those with multiple disease states and serious complications. Specialists identify, evaluate, and communicate to the patient or healthcare provider information on the appropriateness of the patient's pharmacotherapeutic agents, dosing regimens, dosage forms, routes of administration, and delivery systems. They reconcile issues with drug therapy. This skill requires specialists to gather and assess complete information related to drug problems and response to therapy.

1. *Communicate in ways that foster the development of effective, collaborative, long-term relationships with patients and their caregivers, peers, and other healthcare professionals.*

Specialists employ exceptional communications skills, negotiation skills, and conflict-resolution techniques that motivate patients to adhere to prescribed therapies and make choices that have a positive influence on their health status, and to detect ADEs or other medication problems. They possess interviewing skills that enable them to obtain information relevant to the care of the patient, discover pertinent elements of the patient's history, assess information to identify nonmedication factors that may affect patient outcomes, and determine potential issues with health literacy or cultural competency.

Ambulatory care pharmacist specialists rely on close collaboration with prescribers and other members of the healthcare team in managing ambulatory patients. These professional interactions require performance of specialized functions in communication and negotiation strategies both with peers and subordinates, as well as knowledge of legal and practical activities associated with collaborative practice development.

2. *Conduct physical assessments, administer medications, and perform point-of-care testing for patients at risk for disease and for the purpose of monitoring and adjusting drug therapy.*

Specialists have the knowledge and skills to employ specific physical assessments during the evaluation, assessment, and management of patients and of medication use problems. Specialists understand and use point-of-care technology associated

with screening, detecting, and managing patients. Specialists are able to integrate knowledge of laboratory analyses and their relation to health status and drug therapy into therapeutic care plans. Ambulatory care pharmacist specialists administer medications and train patients on the use of medication administration devices (for example, inhalers, nebulizers, syringes, pumps).

3. *Design and implement clinical services and take full responsibility for the ongoing management of and planning for those services.*

Ambulatory care pharmacy specialists employ evidence-based medicine and clinical guidelines to plan, develop, and implement patient care programs. They must demonstrate the ability to secure the agreements necessary for the establishment of a collaborative, interdisciplinary ambulatory practice and understand methods and systems for documenting patient care activities and plans (for example, through SOAP notes or electronic communication systems). Specialists also have the skills necessary to evaluate the success of patient-care programs and to plan for program expansion or improvement.

4. *Retrieve and assess relevant medical information.*

Specialists must have the skills to investigate, search for, and retrieve information from a variety of sources, including patient sources, medical records, the professional literature, clinical guidelines, screening guidelines, and information and resources for patients and health professionals that are available through national organizations such as the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, the National Heart, Lung and Blood Institute, and others. Specialists are able to analyze medical information and apply it to the management of individual patients.

5. *Model ambulatory practice leadership.*

This skill includes the ability to perceive the need for and to deliver a wide range of programs that contribute to the public health, active participation in professional organizations, mentoring skills, and an advanced capability to provide insightful education or training for student pharmacists, pharmacy residents, pharmacy colleagues, nurses, physicians, and medical residents. The leadership skills of ambulatory care pharmacist specialists reinforce their role as the medication management experts for ambulatory patients.

**Guideline 3. Discuss in detail how these specialized functions differ from the functioning of a recent graduate with a Doctor of Pharmacy degree.**

A recent graduate with a doctor of pharmacy (PharmD) degree is educated to provide care in generalized practice in a variety of settings. The scope of practice defined by the licensure examination assures that a licensed pharmacist has met the baseline, minimum standards to practice pharmacy. The licensure examination, by definition, sets a *minimum* competency standard. BPS certification confirms the acquisition of specialized knowledge

that prepares a pharmacist specialist to “contribute at ... evolving, advanced practice levels.”<sup>2</sup>

As established under Criterion A, increasing numbers of ambulatory patients take multiple chronic medications to treat and prevent chronic diseases and complications. The incidence of chronic diseases and medication use is rising among both younger and older segments of the U.S. population, as are the associated consequences of medication errors, drug misuse, ADEs, and nonadherence.<sup>3,4,5,6</sup> A growing number of patients who receive care in ambulatory settings require the specialized skills provided by ambulatory care pharmacist specialists in order to reach their desired health and medication-use outcomes.

The NAPLEX Blueprint<sup>7</sup> (see Appendix D-3) is a list of competency statements describing the knowledge, judgment, and skills expected of an entry-level pharmacist. Achieving a passing score on the licensure examination confirms the acquisition, comprehension, and application of basic, general pharmacy practice skills; it does not indicate the ability to engage in the specialized tasks or functions in relation to complex medication therapy that are outlined in the Role Delineation for Ambulatory Care Pharmacists. These minimum competency standards do not encompass the validated functions and skills required of the ambulatory care pharmacist specialist.

Ambulatory care pharmacist specialists engaged in specialized functions have obtained competencies in the domains of direct patient care, practice management, public health, medical informatics, professional development, and patient advocacy. The functions and skills associated with these domains include managing and optimizing medication use, developing individualized care plans, and developing effective long-term relationships with patients and other health professionals. Additional skills include conducting and/or evaluating research; employing evidence-based medicine and clinical guidelines; and communication, motivation, and negotiation strategies. While pharmacy students acquire and practice some of these skills and functions during their PharmD program, they are neither mastered at a specialty level during entry-level education nor measured by the licensure examination.

**Guideline 4. Discuss in detail how these specialized functions differ from the functions required in those pharmacy specialties already recognized by BPS.**

No currently recognized BPS specialty encompasses the specialized functions required of the ambulatory care pharmacist specialist. For example, specialists in nuclear pharmacy lack the fundamental pharmacotherapeutic, medication management, and direct patient-care skills of ambulatory care pharmacist specialists and the related emphasis on management of patients with chronic disease. Specialties in nutritional support, psychiatry, and oncology focus on the relatively narrow segments of ambulatory care and consequently lack the required breadth. Furthermore, these specialties do not emphasize preventive and chronic care.

The sole currently recognized specialty area that appears to require specialized knowledge in areas that overlap with those of the proposed ambulatory care specialty is pharmacotherapy. A closer look at the domains and specialized areas of knowledge for both specialty areas, however, reveals significant differences.

The BPS-recognized specialty in pharmacotherapy is divided into three domains:

1. patient-specific pharmacotherapy
2. retrieval, generation, interpretation, and dissemination of knowledge in pharmacotherapy
3. health system–related pharmacotherapy

Table E-2 compares the pharmacotherapy specialist domains with those outlined in the Role Delineation Study of Ambulatory Care Pharmacists.

**Table E-2: Comparison of Domains in Ambulatory Care Pharmacy and Pharmacotherapy**

<b>Ambulatory Care Pharmacist Specialist Domains (Proposed Exam Percentage)</b>	<b>Pharmacotherapy Specialist Domains (Exam Percentage)</b>
Direct patient care (50 percent)	Patient-specific pharmacotherapy (55 percent)
Medical informatics and professional development (17 percent)	Retrieval, generation, interpretation, and dissemination of knowledge in pharmacotherapy (30 percent)
Practice management (18 percent)	Health system–related pharmacotherapy (15 percent)
Patient advocacy (11 percent)	
Public health (4 percent)	

While some overlap in functional domains exist, the differences are significant. Ambulatory care pharmacist specialists require skills that allow them to engage in defined and important tasks and functions in patient advocacy and public health, as well as in practice management outside of health systems. Most important, ambulatory care pharmacist specialists perform a broad range of skills related to direct patient care. Although these skills are required to some degree in other specialties, they are not performed in the same frequency, or with the same depth, as they are in ambulatory care specialty pharmacy.

While pharmacotherapy specialists must perform functions related to acute care pharmacotherapeutics, the ambulatory care pharmacist does not. Indeed, as the role delineation survey reveals, the ambulatory care pharmacist specialist performs in depth a significant range of direct patient care functions, such as patient interviewing and assessment techniques, employing point-of-care and self-testing devices, and implementing

practices and systems. These specialists also possess exceptional communication skills that foster strong, long-term relationships with patients and caregivers, conduct motivational interviewing that is conducive to behavioral change, and assess patient self-management and skills. Significant differences in the functional areas within each of these domains differentiate the two specialties.

In addition, while both specialties emphasize medical informatics, pharmacotherapy specialists often function as primary investigators of studies primarily in institutional settings. Ambulatory care pharmacist specialists, by contrast, engage in ambulatory practice-based research activities. Very little of the pharmacotherapy specialist's domain of health system-related pharmacotherapy applies to the ambulatory care pharmacist specialist. Significant differences in the functional areas within each of these domains further differentiate the two specialty areas. Table E-3 lists the tasks defined by the pharmacotherapy examination content outline and the specialized functions listed in Table E-1 that are unique to, or that require greater depth and emphasis, by ambulatory care pharmacist specialists.

**Table E-3: Contrast in Functional Areas between Ambulatory Care and Pharmacotherapy**

<b>Functions of the Ambulatory Care Pharmacist Specialist</b>	<b>Functions of the Pharmacotherapy Specialist</b>
<p style="text-align: center;"><b><u>Domain 1: Direct Patient Care</u></b></p> <p>1.1 Establish a caregiver relationship with the patient that fosters trust and open communication, and encourages patient self-management.</p> <p>1.6 Perform pertinent physical assessments as they relate to patient's current condition and/or therapies (for example, vital signs, weight, palpation, auscultation, visual inspection).</p> <p>1.7 Perform point-of-care testing (for example, blood glucose, cholesterol, INR, bone mineral density, peak flow).</p> <p>1.8 Determine patient's willingness to work with an ambulatory care pharmacy specialist on health- and medication-related issues.</p> <p>1.9 Assess patient's self-management knowledge, understanding, skills, and willingness and ability to actively participate in his/her own care.</p>	<p style="text-align: center;"><b><u>Domain 1: Patient-Specific Pharmacotherapy</u></b></p> <p>1. Collect patient-specific data to identify problems and individualize care</p> <ul style="list-style-type: none"> <li>a. Review patient data generated by others regarding history (including social and review of systems), physical assessment, working diagnosis, laboratory and other diagnostic tests, and orders regarding drug therapy</li> <li>b. Perform relevant physical assessments</li> <li>c. Interview patient, family, and healthcare team members to augment patient's medical history, medication history, and review of systems</li> <li>d. Request additional pertinent data.</li> </ul> <p>2. Interpret data to identify problems and individualize care</p> <ul style="list-style-type: none"> <li>a. Identify the known or possible therapeutic outcomes by assessing known data with regard to the</li> </ul>

<p>1.13 Identify and refer (i.e., triage) patients with needs beyond the scope of the ambulatory care pharmacy specialist.</p> <p>1.14 Recognize patient-specific barriers to successful drug therapy (for example, social situations, patient denial, literacy, mental capacity, culture, language) and implement a plan to overcome these (involving, for example, home visits, use of an interpreter, picture-based education).</p> <p>1.16 Evaluate the patient's administration technique for medications that are not administered orally (for example, nasal inhalers, oral inhalers, eyedrops, eardrops, subcutaneous injections).</p> <p>1.18 Provide wellness and prevention education/counseling (for example, lifestyle modifications, immunizations).</p> <p>1.20 Administer appropriate immunizations to specific patients.</p> <p>1.22 Perform collaborative drug therapy management via protocol or signed collaborative agreements with healthcare providers.</p> <p>1.23 Provide integrated disease-state management (for example, pharmacotherapy clinics, primary care clinics where more than one disease may be addressed in a visit).</p> <p>1.24 Provide focused disease-state management (for example, diabetes, hypertension, asthma, heart failure, anticoagulation, dyslipidemia, mental health, chronic pain).</p> <p>1.25 Provide wellness and preventive programs for individual patients (for example, weight management, tobacco cessation, immunization).</p>	<p>biomedical literature, standards of health care, and prior experience</p> <p>b. Interpret laboratory data</p> <p>c. Identify drug-induced abnormalities and medication errors</p> <p>d. Develop a problem list.</p> <p>3. Design a therapeutic plan for patient-specific problem(s) through the integration of pathophysiologic, pharmacotherapeutic, pharmacokinetic, pharmacodynamic, pharmacogenomic, pharmoeconomic, quality of life, patient-safety, technological, and ethical/legal considerations</p> <p>a. Determine and prioritize treatment goals</p> <p>b. Determine ethical/legal, economic, quality of life, and safety priorities</p> <p>c. Select appropriate drug and/or non-drug interventions based on risk-benefit analysis</p> <p>d. Identify drugs with potential for drug-drug, drug-disease, drug-nutrient, and/or drug-laboratory interactions</p> <p>e. Select appropriate monitoring parameters and timing of follow-up.</p> <p>4. Communicate the therapeutic plan</p> <p>a. Communicate the recommended therapeutic plan to healthcare practitioners in a manner appropriate to their training, skills, and needs</p> <p>b. Document the recommended therapeutic plan in a manner appropriate for the medical record, health professionals, patients, lay people, and healthcare managers.</p> <p>5. Implement the therapeutic plan</p> <p>a. Evaluate and resolve potential and/or actual patient or healthcare-system problems in the implementation of the patient's therapeutic plan</p> <p>b. Prescribe drug therapy</p> <p>c. Order laboratory tests</p> <p>d. Administer drugs or biological</p>
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<p>1.28 Recommend appropriate self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors).</p> <p>1.29 Teach patients how to use self-care devices for monitoring chronic diseases (for example, blood glucose meters, peak flow meters, blood pressure monitors).</p> <p>1.30 Recommend appropriate health-related screening tests (for example, home pregnancy tests, hemocult tests).</p> <p>1.31 Teach patients how to use appropriate health-related screening tests (for example, home pregnancy tests, hemocult tests).</p> <p>1.32 Define treatment goals in collaboration with the patient and other healthcare providers.</p> <p>1.33 Determine patient's ability and willingness to pay for services (for example, insurance coverage, out-of-pocket expenses).</p> <p>1.40 Conduct follow-up visits in order to assess response to both drug and non-drug therapy and assure safety.</p> <p>1.43 Determine patient-specific reasons for lack of adherence to recommended treatment and, in collaboration with the patient, develop a plan for improving adherence to therapy.</p>	<p>(e.g., immunizations, parenteral contraceptives)</p> <p>e. Perform laboratory tests (e.g., venipuncture, pulmonary function testing, point-of-care testing)</p> <p>f. Supervise administration of medicine by technical personnel.</p> <p>6. Educate patients regarding initial or modified therapeutic plans</p> <p>a. Identify appropriate patient education needs</p> <p>b. Recognize patient education barriers</p> <p>c. Select and use appropriate educational method(s) to educate patients' regarding drug therapy</p> <p>d. Assess patients' knowledge/skill acquisition.</p> <p>7. Monitor/modify the therapeutic plan</p> <p>a. Monitor the therapeutic plan by collecting and interpreting data</p> <p>b. Modify the therapeutic plan as needed.</p> <p>8. Document patient-care outcomes</p> <p>a. Identify appropriate documentation methods</p> <p>b. Select the relevant information to document patient-care outcomes consistent with the therapeutic plan.</p>
<p style="text-align: center;"><b><u>Domain 2: Practice Management</u></b></p> <p>2.1 Identify the need for ambulatory clinical pharmacy services in response to patient care needs and/or business potential (for example, medication therapy management, focused or integrated disease-state management programs/clinics).</p>	<p style="text-align: center;"><b><u>Domain 2: Retrieval, Generation, Interpretation, and Dissemination of Knowledge in Pharmacotherapy</u></b></p> <p>1. Retrieve biomedical literature by use of appropriate manual and computerized techniques.</p> <p>2. Interpret biomedical literature with regard</p>

<p>2.2 Establish new ambulatory clinical pharmacy services in response to patient care needs and/or business potential (for example, medication therapy management, focused or integrated disease-state management programs/clinics).</p> <p>2.4 Promote and market patient care services to patients and healthcare providers.</p> <p>2.5 Establish and maintain a system for patient referral.</p> <p>2.6 Establish and maintain a system for patient follow-up.</p> <p>2.11 Organize the practice in a manner that supports efficient work flow and integration of care, and assures timely patient visits and follow-up (for example, use of ancillary personnel, group visits, disciplined appointment system, use of technology, coordination of care between clinical and medication-dispensing functions).</p> <p>2.12 Manage a financially viable practice (for example, cash-flow management, cash-payment systems, insurance contracting, accounting systems, pricing, expense analysis).</p> <p>2.13 Develop systems to obtain reimbursement for ambulatory clinical pharmacy services.</p> <p>2.16 Manage point of care testing in accordance with regulatory requirements (for example, OSHA, CLIA).</p>	<p>to study design and methodology, statistical analysis, and significance of reported data and conclusions.</p> <ol style="list-style-type: none"> <li>3. Educate pharmacists, physicians and other allied health care professionals and students in the principles and practice of pharmacotherapy.</li> <li>4. Conduct research as principal investigator or subinvestigator to generate clinical, economic, humanistic or translational knowledge applicable to patient care.</li> <li>5. Prepare and disseminate results of investigations (including case reports, abstracts, reviews, and monographs) through publications.</li> <li>6. Document and report new, unusual, or severe pharmacotherapeutic events (e.g., adverse reactions, drug interactions, medication errors, drug/device/assay defects).</li> </ol>
<p style="text-align: center;"><b><u>Domain 3: Public Health</u></b></p> <p>3.1 Provide general information to the public regarding preventive health issues (for example, cardiovascular disease, tobacco cessation, immunizations).</p> <p>3.3 Advise and direct the public and</p>	<p style="text-align: center;"><b><u>Domain 3: Health System–Related Pharmacotherapy</u></b></p> <ol style="list-style-type: none"> <li>1. Collect data to characterize/identify health system–related problems in providing optimal health care.</li> <li>2. Interpret data to characterize health system-related problems.</li> </ol>

<p>consumers to appropriate resource groups, organizations, and agencies (for example, Alzheimer's Association, American Cancer Society).</p> <p>3.5 Participate in community health-screening programs.</p> <p>3.6 Advocate to ensure appropriate healthcare policy for ambulatory care pharmacy practice.</p>	<p>3. Design a plan to improve the delivery and quality of pharmacotherapy.</p> <p>4. Develop justification for and garner support for the implementation of the plan.</p> <p>5. Design measures to monitor the success of the plan during and following implementation.</p> <p>6. Collaborate to implement the plan.</p> <p>7. Monitor the plan and implement appropriate modifications.</p> <p>8. Educate appropriate audiences on results of health system–related pharmacotherapy problems assessment and recommended solutions.</p>
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<sup>1</sup> Professional Examination Services. Report of the Role Delineation Study of Ambulatory Care Pharmacists. Washington, DC: Board of Pharmaceutical Specialties, 2007.

<sup>2</sup> Board of Pharmaceutical Specialties. Why BPS? Available at: [http://www.bpsweb.org/01\\_About.html](http://www.bpsweb.org/01_About.html). Accessed September 7, 2008.

<sup>3</sup> Institute for Safe Medication Practices. Protecting U.S. Citizens from Inappropriate Medication Use. A White Paper on Medication Safety in the U.S. and the Role of Community Pharmacists, 2007.

<sup>4</sup> Institute of Medicine Committee on Identifying and Preventing Medication Errors. *Preventing Medication Errors: Quality Chasm Series*. Aspden P, Wolcott J, Bootman JL, and Cronenwett LR, eds. Washington, DC: National Academies Press, 2007.

<sup>5</sup> Gandhi TK, Weingart SN, and Borus J. Adverse drug events in ambulatory care. *N Engl J Med* 2003;348:1556–64.

<sup>6</sup> National Council for Patient Information and Education. Enhancing Prescription Medicine Adherence: A National Action Plan. 2007. Available at:

[http://www.talkaboutrx.org/documents/enhancing\\_prescription\\_medicine\\_adherence.pdf](http://www.talkaboutrx.org/documents/enhancing_prescription_medicine_adherence.pdf). Accessed July 3, 2008.

<sup>7</sup> Available at: [www.nabp.net/ftpfiles/NABP01/updatednaplexblueprint.pdf](http://www.nabp.net/ftpfiles/NABP01/updatednaplexblueprint.pdf). Accessed September 1, 2008.

## **Criterion F: Education and/or Training**

The area of specialization shall be one in which schools and colleges of pharmacy and/or other organizations offer recognized education and training programs to those seeking advanced knowledge and skills in the area of specialty practice. ***This criterion addresses EDUCATION and/or TRAINING.***

**Guideline 1. Describe in detail the education training, and/or experience required to acquire such specialized knowledge and skills. Discuss how such education, training and/or experience differs from the education, training and/or experience of a recent graduate with a Doctor of Pharmacy degree.**

According to the Accreditation Council for Pharmacy Education (ACPE) *Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy (PharmD) Degree Program*, the pharmacy curriculum provides a thorough foundation in the biomedical, pharmaceutical, social/behavioral/administrative, and clinical sciences and prepares graduates with the competencies needed to enter pharmacy practice in any setting and to contribute to the profession of pharmacy throughout their careers.<sup>1</sup>

The curriculum ensures optimal medication therapy outcomes and patient safety, satisfies the educational requirements for licensure as a pharmacist, and meets the requirements of universities for the degree. The curriculum also develops in graduates the knowledge that meets the criteria of good sciences, professional skills, attitudes, and values, as well as the ability to integrate and apply learning both to the present practice of pharmacy and to the advancement of the profession.

The PharmD degree curriculum provides the basic education and training that graduates need to practice at a generalist level. It also provides the basic education and training for the ambulatory care pharmacist specialist. Current ACPE Standards require that advanced pharmacy practice experiences (APPEs) include primary, acute, chronic, and preventive care among patients of all ages and that these experiences develop pharmacist-delivered patient care competencies. APPEs are required in ambulatory care practice and emphasize the need for continuity of care throughout the health care delivery system, including the availability and sharing of information regarding a patient's condition, medications, and other therapies. In addition, ambulatory care pharmacist specialists are required to serve as preceptors to train pharmacy students in these practice experiences.

Following completion of the academic degree program, pharmacists must pass the NAPLEX, developed by the National Association of Boards of Pharmacy® (NABP®). Successful performance on the NAPLEX is an indication that the candidate demonstrates the knowledge, judgment, and skills required of an entry-level pharmacist.

The three areas of expected competency assessed on the NABPLEX are as follows:

Area 1: Assure Safe and Effective Pharmacotherapy and Optimize Therapeutic Outcomes

Area 2: Assure Safe and Accurate Preparation and Dispensing of Medications

Area 3: Provide Health Care Information and Promote Public Health

Following licensure, pharmacists can acquire the differentiated knowledge and skills required for specialized ambulatory care pharmacy practice by a variety of methods. These methods may include:

- PharmD degree education, clinical work experience, and self-study
- PharmD degree education, postgraduate year 1 (PGY1) residency training, clinical work, experience, and self-study
- PharmD degree education and PGY1 residency training, followed by postgraduate year 2 (PGY2) residency in ambulatory care, clinical work experience, and self-study

The most effective way to prepare for a career as an ambulatory care pharmacist is to complete a PGY1 residency in pharmacy practice or community practice, followed by completion of a PGY2 residency in ambulatory care. Residency programs provide the most effective structured experiential learning opportunities in ambulatory care.

The PharmD degree alone does not provide knowledge of sufficient depth and breadth for a career as an ambulatory care pharmacist specialist; additional training, clinical work experience, and study are necessary. Because ambulatory care is an evolving specialty, many ambulatory care pharmacist specialists have obtained the needed knowledge, skills, and abilities through mechanisms other than structured training programs.

**Guideline 2. Describe in detail the nature of training programs in the area of specialty practice including their length, content and objectives.**

As stated above, there are numerous ways in which ambulatory care pharmacist specialists can attain the knowledge and skills they need to practice their chosen specialty. Perhaps the most efficient way is through an accredited PGY2 residency in ambulatory care pharmacy practice. In 1994, ASHP published accreditation standards for specialized residency training. In 2005, ASHP approved accreditation standards for PGY2 pharmacy residencies and published educational outcomes, goals, and objectives for PGY2 ambulatory care pharmacy residency programs.

PGY2 residency training is an organized, directed, accredited program that builds upon the competencies established in PGY1 residency training. The PGY2 program increases the resident's depth of knowledge, skills, attitudes, and abilities in order to raise his or her level of expertise in medication therapy management and clinical leadership in the area of focus. PGY2 residency programs are also designed to develop accountability; practice patterns;

habits; and expert knowledge, skills, attitudes, and abilities in the respective area of pharmacy practice.

PGY2 residencies build upon the broad-based competencies achieved in a PGY1 residency, deepening the resident's ability to provide care in the most complex of cases or to support care through practice leadership. Therefore, PGY2 residencies provide residents with opportunities to function independently as practitioners by conceptualizing and integrating accumulated experience and knowledge and transforming both into improved medication therapy. A resident who successfully completes an accredited PGY2 residency should possess the competencies needed to earn Board certification in the practice area (provided that certification for that practice area exists).

An ambulatory care PGY2 pharmacy residency emphasizes communication and assessment skills, chronic disease management and preventive care, acute care, and emergency-care triage, and therapy modifications for special patient groups. Other skills developed include drug literature analysis and the ability to develop new clinical services in a variety of ambulatory care settings. Opportunities for further refinement in drug information, pharmacokinetic consults, and maintaining patient records and statistical data for continuity-of-care and research activities are available to pharmacists who participate in this training program.

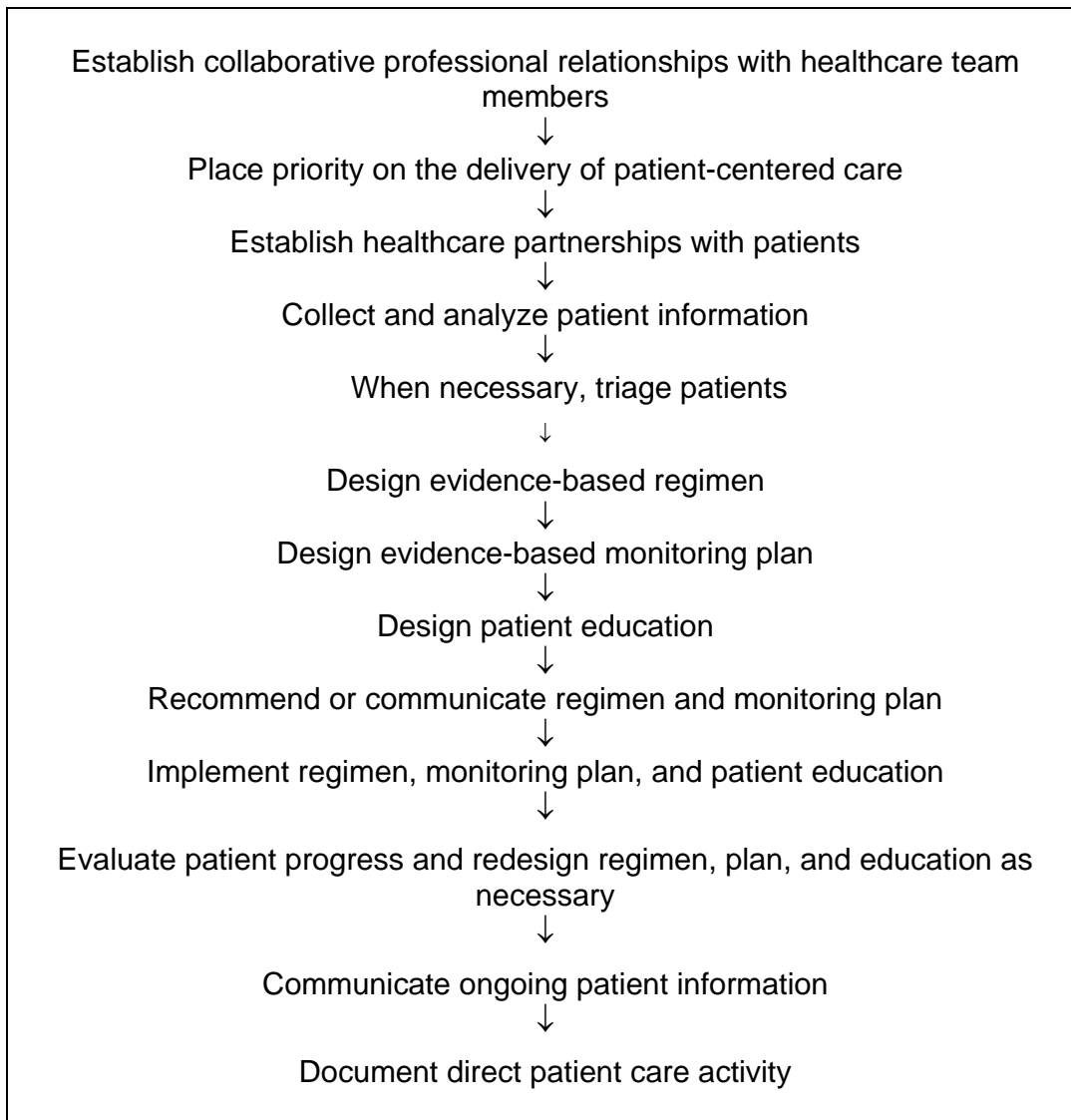
The PGY2 residency in ambulatory pharmacy is designed to transition PGY1 residency graduates from generalist practice that includes the ambulatory environment to specialized practice specific to the needs of ambulatory patients. PGY2 residency graduates have the ability to secure the agreements necessary for the establishment of a collaborative, interdisciplinary ambulatory practice. They have the capability to design and implement the services made possible by these approvals or agreements and to take full responsibility for managing and planning those services, including skills to assess their success via outcomes analyses. The residency's graduates are empowered to treat and triage the most complex chronic and acute illnesses presented by ambulatory patients, including those with multiple diseases and serious complications. This care is delivered within the context of a long-term partnership with the patient that emphasizes health improvement, wellness, and disease prevention.

PGY2 residency graduates are also primed for ambulatory practice leadership. This includes the ability to perceive the need for and deliver a wide range of programs that contribute to the public health, active participation in professional organizations, mentoring skills, and advanced capability to provide education or training for students, pharmacy residents, pharmacy colleagues, nurses, physicians, and medical residents. The leadership skills of these graduates equip them to serve the ambulatory practice as the expert on medication prescribing, including dealing with drug shortages and managing the prescribing and procurement of special-order medications.

Expected outcomes for PGY2 residencies in ambulatory care include the following:

Outcome R1: Establish a collaborative interdisciplinary practice.

Outcome R2: In a collaborative, interdisciplinary ambulatory practice, provide efficient, effective, evidence-based, patient-centered treatment for chronic and/or acute illnesses in all degrees of complexity.



Outcome R3: Demonstrate leadership and practice management skills.

Outcome R4: Promote health improvement, wellness, and disease prevention.

Outcome R5: Demonstrate excellence in the provision of training or educational activities for healthcare professionals and healthcare professionals in training.

Outcome R6: Serve as an authoritative resource on the optimal use of medications.

A copy of the *Educational Outcomes, Goals, and Objectives for Postgraduate Year Two (PGY2) Ambulatory Care Pharmacy Residency Program* is attached as Appendix F-1. Traditionally, completion of these goals and objectives would provide the education and training needed to sit for the BPS certification exam.

**Guideline 3. Provide a comprehensive listing of such programs, detailing sponsoring organizations or institutions, locations and individuals in charge.**

Table F-1 lists PGY2 ambulatory care residency programs as of July 1, 2008. Forty-five programs with 62 residency positions were available on that date.

**Table F-1: PGY2 Ambulatory Care Residency Programs as of July 1, 2008**

<b>Sponsoring Organization</b>	<b>Status</b>	<b>City</b>	<b>State</b>	<b>Program Director</b>	<b>Number of Residency Positions</b>
Auburn University Harrison School of Pharmacy	Candidate for accreditation	Auburn	AL	Amy R. Donaldson	1
Bay Pines Veterans Affairs Health Care System	Precandidate for accreditation	Bay Pines	FL	Valerie A. Stanard	1
Bernard J. Dunn School of Pharmacy, Shenandoah University/Amherst Family Practice	Candidate for accreditation	Winchester	VA	Dawn E. Havrda	1
Boston Medical Center	Accredited	Boston	MA	Lori Arena	1
Central Arkansas Veterans Healthcare System	Accredited	Little Rock	AR	Holly Rickman	1
Columbus Regional Healthcare System	Accredited	Columbus	GA	Jane Kimble Jenkins	2
Duke University Health System	Accredited	Durham	NC	Philip T. Rodgers	1
Harper University Hospital	Accredited	Detroit	MI	Candice Garwood	1
Health Alliance - The University Hospital	Accredited	Cincinnati	OH	Kelly T. Epplen	1
Huntington Veterans Affairs Medical Center	Accredited	Huntington	WV	James Allman II	1
James A. Haley Veterans Hospital	Accredited	Tampa	FL	Douglas F. Covey	2
Kaiser Permanente Colorado	Accredited	Denver	CO	Rachana J. Patel	6
Mayo Clinic Rochester	Candidate	Rochester	MN	Marcel D. Bizien	1
Medical College of Virginia/VCU Health Systems	Accredited	Richmond	VA	Adraine Lyles	1
MUSC Medical Center/College of Pharmacy	Accredited	Charleston	SC	Sarah Shrader	1
MUSC Medical Center/College of Pharmacy	Accredited	Charleston	SC	Pamela J. Mazyck	1
Parkland Health and Hospital Systems	Accredited	Dallas	TX	Elizabeth Moss	2



Providence Health System: Providence Medical Group	Accredited	Beaverton	OR	Ginger Pape	2
Providence Veterans Affairs Medical Center	Accredited	Providence	RI	Bradley E. Peterson	1
Roudebush VA Medical Center/ Purdue University	Accredited	Indianapolis	IN	Deanna S. Kania	1
SEAHEC	Accredited	Wilmington	NC	Kim Thrasher	1
Shands Jacksonville	Accredited	Jacksonville	FL	Karen Malcolm	1
South Texas Veterans Health Care System	Accredited	San Antonio	TX	Tera Moore	1
St. Vincent Indianapolis Hospitals	Precandidate for accreditation	Indianapolis	IN	Karie Morriscal- Kline	1
Texas Tech University Health Sciences Center - School of Pharmacy/North Texas Veterans Affairs Health Care System	Accredited	Dallas	TX	Krystal L. Edwards	1
The Johns Hopkins Hospital Department of Pharmacy	Accredited	Baltimore	MD	Jeffrey M. Brewer	1
The University of Iowa Hospitals and Clinics	Accredited	Iowa City	IA	Deanna L. McDanel	1
University of Colorado Denver School of Pharmacy	Accredited	Aurora	CO	Joseph J. Saseen	2
University of Georgia College of Pharmacy	Pre-candidate	Athens	GA	Beth Phillips	1
University of Illinois College of Pharmacy	Accredited	Chicago	IL	Nancy L. Shapiro	1
University of Kentucky Medical Center	Accredited	Lexington	KY	Aimee Gelhot Adams	2
University of Maryland School of Pharmacy	Accredited	Baltimore	MD	Charmaine D. Rochester	1
University of North Carolina Hospitals and Clinics/UNC School of Pharmacy	Accredited	Chapel Hill	NC	Betsy Bryant Shilliday	1
University of Oklahoma College of Pharmacy	Accredited	Oklahoma City	OK	Mark L. Britton	1
University of Pittsburgh Medical Center	Accredited	Pittsburgh	PA	Deanne L. Hall	1
University of Tennessee Medical Center	Accredited	Knoxville	TN	Holly M. Allum	2
University of Texas College of Pharmacy/Blackstock Family Practice	Accredited	Austin	TX	Debra Lopez	1
University of Virginia Health System	Precandidate for accreditation	Charlottesville	VA	Donna M. White	1
University of Washington Medical Center/Harborview Medical	Accredited	Seattle	WA	Alvin Goo	1
VA Maryland Health Care System	Accredited	Baltimore	MD	Karen Korch Black	2
VA San Diego Healthcare System	Accredited	San Diego	CA	Tung N. Le	3

Veterans Affairs Medical Center	Accredited	Cleveland	OH	Mary Ellen O'Day	2
Wilkes University	Accredited	Wilkes-Barre	PA	Eric A. Wright	1
William Beaumont Hospital	Accredited	Royal Oak	MI	Megan B. Bestul	1
William S. Middleton VA Medical Center	Accredited	Madison	WI	Arthur A. Schuna	2

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<sup>1</sup> Accreditation Council for Pharmacy Education. *Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree*. Adopted January 15, 2006.

## CRITERION G: Transmission of Knowledge

The area of specialization shall be one in which there is an adequate transmission of specialized knowledge through professional, scientific and technical literature immediately related to the specialty area. ***This criterion refers to the TRANSMISSION OF KNOWLEDGE.***

Transmission and dissemination of specialized knowledge in ambulatory care pharmacy practice occur through formal networking groups within professional practice associations, peer-reviewed publications and periodicals, live educational programming, certificate training programs (CTPs), and enduring educational resources in print- and web-based vehicles.

### ***Formal Networking Groups***

Major pharmacy practice associations have formal networking sections and groups dedicated to ambulatory care pharmacist specialists. These groups foster professional interaction and provide opportunities for practice advancement through educational programming, newsletters, research networks, and leadership. As an example, networking groups that currently exist in the three petitioning organizations are shown in Table G-1.

**Table G-1: Ambulatory Care Networking Groups within Pharmacy Practice Associations**

<b>Association</b>	<b>Networking Groups</b>	<b>Description</b>
American College of Clinical Pharmacy	Ambulatory Care Practice and Research Network (PRN)	Dedicated to improving patient care and clinical practice in ambulatory and family practice settings  Provides a means for ambulatory care pharmacist specialists to gather for professional interaction, networking, and continuing education with regard to practice and research interests  Conducts educational programs at the ACCP Annual Meeting and the Spring Practice and Research Forum  Approximately 1,000 members.

<p>American Society of Health-System Pharmacists</p>	<p>Section of Home, Ambulatory, and Chronic Care Practitioners</p>	<p>Supports and advances the practice of pharmacists who are medication-use specialists, care providers, and specialists in home, ambulatory, and chronic care settings</p> <p>Provides a formal mechanism for networking among section members.</p> <p>Plans and develops education programming, tracks, and workshops offered at ASHP meetings</p> <p>Approximately 2,500 members</p>
<p>American Pharmacists Association</p>	<p>APhA Academy of Pharmacy Practice and Management (APPM) Section on Community and Ambulatory Care</p> <p><i>Ambulatory care pharmacist specialists also participate in APhA's APPM Section on Clinical/Pharmacotherapy.</i></p>	<p>Identify and respond to issues that affect APhA members within a community or ambulatory care practice site</p> <p>Identify, develop, and provide programs, services, and projects in response to member needs</p> <p>Promote and support innovative pharmacy practice and research in the community/ambulatory care environment</p> <p>Provide mentoring, networking opportunities and recognition for our members.</p> <p>Approximately 2,500 members</p>

**Guideline 1. Identify journals and other periodicals dealing specifically with the proposed specialty.**

***Journals***

Issues related to practice in ambulatory care are of widespread interest within many areas of pharmacy practice. Many pharmacy and primary care practice journals consistently publish articles highlighting evidence, outcomes, and contributions to patient care through ambulatory care pharmacy practice. Examples of such journals include the *American Journal of Health-System Pharmacy*, the *Journal of the*

*American Pharmacists Association, Pharmacotherapy, the Annals of Pharmacotherapy, the Journal of Family Practice, and the American Journal of Pharmaceutical Education.*

The following examples illustrate the scope and substance of specialized ambulatory care practice information disseminated through such publications:

- Practice Report: Characteristics of ambulatory care clinics and pharmacists in Veterans Affairs medical centers: An update. *Am J Health-Syst Pharm* 2008;65: 631-5. Cone SM, Brown MC, and Stambaugh RL
- Practice Report: Survey of care provided by ambulatory care pharmacists to patients with chronic kidney disease. *Am J Health-Syst Pharm* 2006;63:2123-7. Bennett RE, DeHart RM, and Lauderdale SA
- Special issue of the *Journal of the American Pharmacists Association* (March/April 2008); issue focused on pharmacy practice-based research in community and ambulatory care
- Theme issue of the *American Journal of Pharmaceutical Education: Community Pharmacy* (2006)

Ambulatory care pharmacy columns and features are published in the *Annals of Pharmacotherapy* and the *Journal of Family Practice*. *The Annals of Pharmacotherapy* is an independent, peer-reviewed journal that publishes evidence-based articles on practice, research, and education. Four ambulatory care pharmacy specialists are members of its Ambulatory Care Editorial Board.

The *Journal of Family Practice (JFP)* is a peer-reviewed journal that publishes primary and secondary research reports of relevant, valid evidence-based research in a form useful to family medicine physicians and other clinicians in the provision of primary and ambulatory care. *JFP* publishes original research that reports outcomes immediately applicable to clinical practice. In the past three years, pharmacists have contributed 38 articles on medication use.

### **Newsletters and Online Periodicals**

Professional pharmacy practice associations publish a variety of print and online media that disseminate ambulatory care practice information. ACCP publishes the *ACCP Ambulatory Care PRN Newsletter*, representing members with a professional interest in ambulatory care practice. APhA publishes *Pharmacy Today*, a monthly magazine with a primary emphasis on ambulatory care and community pharmacy practice. *Focus* and *Focus Extra* e-news are weekly electronic newsletters featuring updates in pharmacy practice—many of which are relevant to ambulatory care. ASHP publishes the *Home, Ambulatory, and Chronic Care NewsLink*, an electronic resource reporting news of relevance to pharmacists who are medication-use specialists, care providers, and specialists in home, ambulatory, and chronic care settings.

The ACCP Ambulatory Care PRN listserv is a mechanism for sharing, obtaining, and reporting data among ambulatory care pharmacist specialist members. The ASHP Section of Home, Ambulatory, and Chronic Care Practitioners hosts a listserv to

facilitate communication and problem solving among members. Medscape, available at [www.medscape.com](http://www.medscape.com), is another online resource for dissemination of ambulatory care specialty practice information.

**Guideline 2. Provide a comprehensive bibliography of articles in the professional literature dealing with the proposed specialty published during the three most recent calendar years.**

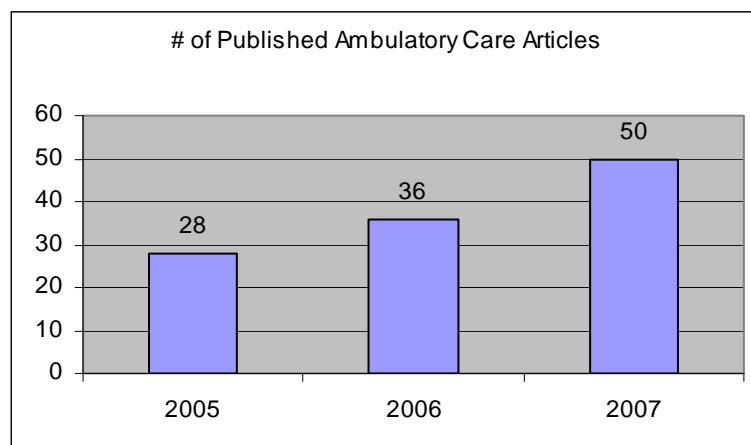
As of August 1, 2008, 127 articles related to ambulatory care practice had been published in the professional literature over the past three years. More than half a dozen Institute of Medicine committees and numerous reports have emphasized the importance of improving quality of health care in the United States and have named chronic disease management as a critical factor in mitigating the current health crisis in our nation.

The prevalence of articles in pharmacy and pharmacotherapy journals focusing on ambulatory care pharmacy practice and patient care of complex ambulatory patients by ambulatory care pharmacist specialists provides further evidence of this emerging specialty. A bibliography of articles and resources published on specialized ambulatory care pharmacy practice and related issues is attached as Appendix G-1.

**Guideline 3. Include copies of sample peer-reviewed articles dealing with the proposed specialty.**

Over the past five years, the number of peer-reviewed articles dealing with ambulatory, chronic, and preventive care published in pharmacy and medical journals by ambulatory care pharmacist specialists has sharply increased (see Figure G.1). Ambulatory care pharmacist specialists in a variety of settings are demonstrating and publishing positive clinical and economic outcomes resulting from effective management of ambulatory patients with chronic diseases. Their collective work documents the validity of this proposed specialty.

**Figure G-1: Number of Articles on Ambulatory Care Pharmacy Practice Published in the Peer-Reviewed Literature, 2005–2007**



Examples of peer-reviewed articles dealing with specialized ambulatory care pharmacy practice are attached as Appendix G-2.

**Guideline 4. Describe methods of knowledge transmission through symposia, seminars, workshops, etc., and enclose representative programs concerning these activities.**

The specialized knowledge required for ambulatory care specialty practice is transmitted through a variety of methods, including symposia, live and web seminars, interactive workshops, CTPs, and enduring resources. Each year, national pharmacy associations offer live programming to disseminate the latest evidence for managing patients with chronic diseases and sharing innovations in specialized ambulatory care pharmacy practice. Hundreds of hours of programs are available annually to ambulatory care pharmacist specialists through national clinical meetings and web-based programs.

CTPs are another important method for transmitting specialized knowledge and providing training opportunities in ambulatory care. Many CTPs are available through national professional pharmacy associations, schools and colleges of pharmacy, and other organizations (see Table G-2).

**Table G-2: Certificate Training Programs in Ambulatory Care**

<b>Ambulatory Care Certificate Training Programs</b>			
<b><u>Sponsoring Organization</u></b>	<b><u>Type of Program</u></b>	<b><u>Brief Description</u></b>	<b><u>Length</u></b>
American Pharmacists Association	Pharmacy-Based Immunization Delivery	Provides comprehensive immunization education and reviews basic immunology. Provides pharmacists with the skills, resources, and materials necessary to establish and promote a successful immunization service. Trains pharmacists to identify at-risk patient populations needing immunizations and to maintain necessary immunization records.	12-hour (1.2 CEU) self-study modules with case studies and assessment exam and an 8.0-hour (0.80 CEU) live seminar with final exam
American Pharmacists Association	Pharmaceutical Care for Patients with Diabetes	Provides a comprehensive overview of diabetes pathophysiology. Teaches current approaches to the management of diabetes and its complications. Introduces pharmacists to their role as a diabetes educator and their part in the collaborative team approach.	15-hour (1.5 CEU) self-study modules with case studies and assessment exam and an Eight-hour (0.8 CEU) live seminar with final exam

American Pharmacists Association	Pharmacy-Based Lipid Management	Enhances the pharmacist's knowledge of the pathophysiology and treatment of lipid disorders. Educates pharmacists about optimal treatment strategies for patients at varying degrees of cardiovascular risk with various comorbidities. Introduces pharmacists to point-of-care testing technology, which can be used in the management of patients with lipid disorders.	11-hour (1.1 CEU) self-study modules with case studies and assessment exam and 8 hour (0.8 CEU) live seminar with final exam
American Pharmacists Association	OTC Advisor Advancing Patient Self-Care	Enhances pharmacists' skills in communicating with self-treating patients and other healthcare providers. Provides pharmacists with cutting-edge information about nonprescription remedies for common ailments. Has many interactive learning modules.	11-hour (1.1 CEU) self-study modules with case studies and assessment exam and 8-hour (0.8 CEU) live seminar with final exam
American Pharmacists Association	Delivering Medication Therapy Management in the Community	Helps participants obtain the clinical knowledge, skills, and motivation needed to establish MTM services for patients with complex drug regimens. Helps pharmacists learn to conduct a patient medication history, complete a personal medication record, and develop a medication action plan.	Eight online self-study modules and assessment exams (total 18.5 hours)
From ACPE PLAN Database 046-003340 Winston Salem, NC	Anticoagulation Certificate Program	Provides pharmacists with disease state management skills to care for patients who require anticoagulation therapy.	
From ACPE PLAN Database 294-000121 Richmond, VA	Anticoagulation Management Certificate Program for Pharmacists	Helps participants describe the pathophysiology, including predisposing factors, and presenting signs and symptoms of thrombotic disorders; design, recommend, monitor, and evaluate patient-specific anticoagulant regimens that incorporate the principles of evidence-based medicine; identify appropriate goals and outcomes of pharmacologic treatments of selected thrombotic conditions, common adverse effects, common drug interactions, and impact of diet on patient outcomes; and use effective oral and written communication skills to	



		communicate with patients, caregivers, and other healthcare professionals regarding safe and optimal anticoagulation therapy.	
AHEC: From ACPE PLAN Database 046-003441 www.aheconnect.com	Cardiovascular Disease Certificate Program	Increases the pharmacist's knowledge of hyperlipidemia and hypertension management using current national guidelines; assists in developing hyperlipidemia and hypertension management skills that the pharmacist can incorporate into practice; exposes pharmacist to patient interviewing, physical assessment, pharmacotherapy, documentation of interventions and outcomes, and billing.	
From ACPE PLAN Database 154-000120 Las Vegas	Clinical Pharmacist Diabetes Management Program	Prepares the community pharmacist to implement a comprehensive diabetes management program managing diabetes using national standards in a cost-effective and clinically significant manner.	
From ACPE PLAN Database 154-000120 Los Angeles	Clinical Pharmacist Diabetes Management Program	Prepares the community pharmacist to implement a comprehensive diabetes management program managing diabetes using national standards in a cost-effective and clinically significant manner.	
From ACPE PLAN Database 047-000116 Bismarck	Diabetes Care Certificate Program	Seeks to assure competencies of diabetes disease state management for pharmacists. Successful completion of the program qualifies individual pharmacists to deliver diabetes management services to eligible North Dakota Public Employees Retirement System members.	

## Ambulatory Care Traineeship Programs

<u>Sponsoring Organization</u>	<u>Type of Program</u>	<u>Brief Description</u>	<u>Length</u>
American College of Clinical Pharmacy Research Institute in collaboration with the University of Texas and the Anticoagulation Clinics of North America	Anticoagulation Traineeship	Prepares pharmacy students, residents, and fellows to provide services that reduce bleeding and thromboembolic complications and to advance therapy through clinical research and the systematic analysis of patient data for quality control purposes. Includes a structured didactic component, extensive clinical experience, and participation in clinical research.	Minimum of a four weeks, with possible extension of one to two weeks if needed to meet academic requirements of the trainee's academic institution.
American College of Clinical Pharmacy Research Institute	Heart Failure Traineeship	Includes extensive clinical experience in the ambulatory care and/or inpatient setting(s), a structured didactic component, and exposure to ongoing clinical research. Seeks to provide pharmacy practitioners, fellows, and residents with knowledge and skills central to the management of patients with heart failure. Designed to provide sufficient knowledge and experience to enable participants to establish a heart failure clinic or disease management program within their own practices.	Two to four weeks (depending on site)
American Society of Consultant Pharmacists Foundation	Parkinson's Disease Pharmacotherapy Traineeship	An in-depth program requiring familiarity with pretraineeship reading materials and interaction with patients and the interdisciplinary team at the traineeship sites. Although the focus is Parkinson's disease, other movement disorders and conditions are encountered.	10-hour self-study (1.0 CEU) plus an 8-hour live training seminar (0.8 CEU). The postseminar exercise is approved for 3 hours (0.3 CEU) of continuing education credit.

American Society of Consultant Pharmacists Foundation	Pain Management Traineeship	An in-depth program requiring familiarity with pretraineeship reading materials, advance preparation of one case study that is used to illustrate important therapeutic problems and issues during the traineeship, and interaction with patients and the interdisciplinary team at the traineeship sites. Primary focus is pain management, although other diseases and conditions are encountered.	Ten-hour self-study (1.0 CEU) plus an 8-hour live training seminar (0.8 CEU). The postseminar exercise is approved for 3 hours (0.3 CEU) of continuing education credit.
American Society of Health-System Pharmacists Foundation	Antithrombotic Pharmacotherapy Traineeship	The traineeship is designed to prepare participants with little experience managing patients with thromboembolic conditions to design patient-specific pharmacotherapy; solve drug therapy problems; and develop protocols, policies, and procedures for the treatment of patients with thromboembolic disorders.	Ten hour self-study program (1.0 CEU) and a five-day, 35-hour (0.35 CEU) experiential program. Post completion, participants must meet follow-up requirements in program implementation and patient care.
American Society of Health-System Pharmacists Foundation	Cardiovascular Risk/Dyslipidemia Traineeship	Designed for participants with limited experience managing patients' cardiovascular risk. Traineeship prepares pharmacists to design patient-specific pharmacotherapy; solve drug therapy problems; and develop protocols, policies, and procedures for the treatment of patients with dyslipidemia or who otherwise would benefit from cardiovascular risk reduction.	Ten hour self-study program (1.0 CEU) and a five-day, 35-hour (0.35 CEU) experiential program. Post experiential program: participants must meet follow-up requirements in program implementation and patient care.

American Society of Health-System Pharmacists Foundation	Type 2 Diabetes Patient Care Traineeship	Designed to prepare pharmacists (including those with limited experience in diabetes care) to implement specialized services for improving outcomes for patients with type 2 diabetes. Participants will be able to design patient-specific pharmacotherapy; solve drug therapy problems; and develop protocols, policies, and procedures for the treatment of patients with type 2 diabetes.	11.5-hour self-study program (1.15 CEU) and a five-day, 35-hour (0.35 CEU) experiential program.
American Society of Health-System Pharmacists Foundation	Pain Management Traineeship	The traineeship prepares pharmacists practicing in pain management to design patient-specific pharmacotherapy; solve drug therapy problems; and develop protocols, policies and procedures for the treatment of such patients.	12-hour self-study program (1.2 CEU) and 7-hour (0.7CEU) experiential program.

Select sample program materials from traineeships, certificate training programs, educational programs and newsletters are attached as Appendix G-3.

**Guideline 5. Provide the number of such events, included in #4 above, which occur on an annual basis, and estimate average and total attendance at such programs.**

Over the past year, the petitioning organizations have collectively offered 332 hours of educational programming on ambulatory pharmacy care at national meetings, with a cumulative pharmacist attendance of 29,796. Table G-3 outlines these programs.

**Table G-3: Live and Web-Based Programming in Ambulatory Care Provided by ASHP, APhA, and ACCP during the Past Year**

<b>Pharmacy Association</b>	<b>Hours of Ambulatory Care Programming and Attendance</b>
ASHP	<ul style="list-style-type: none"> <li>• 174 hours through Summer Meeting and Midyear Clinical Meeting</li> <li>• 19,668 pharmacists in attendance at ambulatory care programming</li> <li>• Web-based programming not included</li> </ul>
APhA	<ul style="list-style-type: none"> <li>• 145 hours of live programming; 7,605 pharmacists attended</li> <li>• 20 hours of web-based (real-time) programming; 2,323 pharmacists participated</li> </ul>
ACCP	<ul style="list-style-type: none"> <li>• 13 hours of live programming; 2,070 pharmacists participated</li> <li>• 1-hour web-based program; 600 pharmacists participated</li> </ul>

Tens of thousands of pharmacists have acquired specialized knowledge and skills in ambulatory care through the CTPs noted in Guideline 4. Table G-4 delineates programs and participation over the past three years.

**Table G-4: Pharmacist Participation in Certificate Training Programs and Traineeships in Ambulatory Care**

<b>Name/Topic of Certificate Program</b>	<b># Certificants 2008</b>	<b># Certificants 2007</b>	<b># Certificants 2006</b>
APhA—Immunizations	15,000 (estimated)	10,699	6,328
APhA—Diabetes	200 (estimated)	855	408
APhA—Lipid Management	150 (estimated)	333	214
APhA—OTC Advisor	63	19	154
APhA—Medication Therapy Management	500 (estimated)	410	n/a
ASHP Research and Education Foundation (REF) Antithrombotic Traineeship	14	14	0
ASHP REF Cardiovascular Risk and Dyslipidemia Traineeship	8	8	0

ASHP REF Diabetes Patient Care Traineeship	0	0	13
ASHP REF Pain Management Traineeship	6	4	4
ASHP REF Oncology Patient Care Traineeship	6	8	8
ACCP Research Institute Heart Failure Traineeship	33	12	14
ACCP Research Institute Anticoagulation Traineeship	4	9	5

### **Added Mechanisms for Dissemination of Knowledge**

In addition to the methods discussed in each of the guidelines above, enduring publications and professional award programs serve an important function in the dissemination of knowledge in the proposed specialty.

### ***Nonperiodical Publications***

Many enduring publications and resources that have been published in recent years enhance the skills and knowledge of ambulatory care pharmacist specialists.

Examples of such publications include:

- *Essentials of Cultural Competence in Pharmacy Practice* (Halbur KV and Halbur DA, 2008)
- *Evidence-Based Pharmacotherapy* (Chiquette E and Posey LM, 2007)
- *A Practical Guide to Pharmaceutical Care, 2<sup>nd</sup> edition* (Rovers JP et al., 2007)
- *Conducting a Practice-Based Project: A Guide for Community Pharmacy Residents and Preceptors* (APhA, 2006)
- *Building a Successful Collaborative Pharmacy Practice*. (Bennett M and Jacobson-Wedret JE, 2004)
- *Diabetes Management Services: A Pharmacist's Resource Guide* (APhA Foundation, 2004)
- *A Practical Guide to Contemporary Pharmacy Practice*. (Thompson JE and Davidow JE, 2003.
- *Managing the Patient-Centered Pharmacy* (Hagel HP and Rovers JP, 2002)
- Medication Therapy Management
  - *100 MTM Tips for the Pharmacist* (Millonig M, 2008)
  - *Medication Therapy Management Manual and CD-ROM Complete Set* (APhA/NACDS Foundation, 2008)
  - *Medication Therapy Management Services: A Critical Review* (APhA, The Lewin Group, 2006)
  - *Medication Therapy Management: Training & Techniques* (APhA/NACDS Foundation, 2006)

- Medication Therapy Management Services in Community Pharmacy (APhA/NACDS Foundation, 2005)

**Professional Awards**

Award programs in pharmacy practice also serve to enhance and recognize accomplishments of pharmacists. Through the American Pharmacists Association, several awards recognize the distinguished practice of ambulatory care pharmacist specialists (see Table G-5).

**Table G-5: APhA Awards That Recognize Excellence in Community and Ambulatory Care**

<b>Award</b>	<b>Description/Comments</b>
Daniel B. Smith Practice Excellence Award	<p>Recognizes a pharmacist in any practice setting who has distinguished himself/herself and the profession by outstanding performance. APhA's premier practice award; named in honor of the association's first president.</p> <p><i>Ambulatory care pharmacist specialists are among recipients over the past 10 years.</i></p>
APhA Community Pharmacy Residency Excellence in Precepting Award	<p>Recognizes a community pharmacy residency director or preceptor who has demonstrated excellence in precepting, mentoring, leadership, and community pharmacy residency program administration.</p> <p><i>Residency preceptors play a critical role fostering the acquisition of specialized knowledge and skills to perform specialized functions of ambulatory care pharmacist specialists.</i></p>
<p>APhA Academy of Pharmacy Practice and Management (APhA-APPM) Distinguished Achievement Awards</p> <ul style="list-style-type: none"> <li>• The nominee for the APhA-APPM Distinguished Achievement Award in Community and Ambulatory Practice</li> <li>• APhA-APPM Distinguished Achievement Award in Clinical/ Pharmacotherapeutic Practice</li> </ul>	<p>Recognize the achievements of individuals who have made significant or sustained contributions to the provision of pharmaceutical care within the practice areas represented by the APhA-APPM Community and Ambulatory Practice and the Clinical/ Pharmacotherapeutic Practice sections.</p> <p><i>Many of the individuals recognized over the past five years have distinguished themselves as ambulatory care pharmacist specialists.</i></p>

<p>APhA-APPM Merit Award</p>	<p>Recognizes pharmacy practitioners who have accomplished a single, outstanding achievement that has promoted or elevated the standard of practice.</p> <p><i>Many of the recipients accomplished their outstanding achievement in specialized ambulatory care.</i></p>
<p>Pinnacle Awards</p>	<p>Inspired and created by the APhA Foundation in response to the increasing importance of the proper use of medications in today's healthcare environment. These awards recognize individuals, health systems, and government/volunteer organizations that demonstrate significant improvements in medication use in the U.S. healthcare system are possible. They recognize bold and innovative approaches to improving our nation's health.</p> <p><i>Each of the 2008 recipients was recognized for contributions to chronic and preventive care.</i></p>