

*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 in medication use for preventive and chronic care. 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 varies, 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 supports 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.