In recent years, there has been an increasing emphasis in health systems on the provision of ambulatory care services. Payers have created incentives to decrease hospitalization rates and length of stay, making way for a new shift toward pay-for-performance, outcomes-based reimbursement, and accountable care. There is also an increasing focus in medicine on preventive health, patient education, and care transitions. Yet, the number of patients with multiple chronic medical conditions that require longitudinal and integrated care management across a continuum of care settings is growing. Appropriate medication therapy in the ambulatory care setting is often the most common and most cost-effective form of treatment, yet the consequences of adverse drug events (ADEs) and the inappropriate use of medications in this setting can be catastrophic. Ambulatory care pharmacy services are therefore an essential component of any comprehensive healthcare delivery system.

Pharmacists have become integral members of healthcare teams in a variety of settings, such as patient-centered medical homes, community health centers, long-term care facilities, hospital outpatient departments, and freestanding pharmacies, among others; the care they provide has enabled patients, other providers, and payers to achieve their clinical, humanistic, and economic goals. There is growing recognition and understanding that ambulatory care pharmacy services extend far beyond the dispensing of medications and include direct patient care and the design and management of complex medication regimens and care delivery systems. Current evidence demonstrates that the inclusion of pharmacists practicing in ambulatory care settings on the healthcare team improves quality of care, enhances patient outcomes, and contributes to cost avoidance. Most states now allow pharmacists to provide direct patient care services under a physician–pharmacist collaborative agreement, further supporting the expansion of ambulatory care pharmacy services.

The primary purpose of these guidelines is to outline the minimum requirements for the operation and management of services for patients in this rapidly evolving ambulatory care setting. The elements of service that are critical to optimal, safe, and effective medication use in the ambulatory setting include (1) leadership and practice management, (2) patient care, (3) drug distribution and control, and (4) facilities, equipment, and other resources. Although the scope of pharmacy services will vary from site to site, depending on the needs of the patients served and the resources available, these elements are directly linked to improved patient, population, and health-system outcomes. Specific attention to each element is essential to delivering patient care of the highest quality. As providers of care to patients in ambulatory care settings, pharmacists should be concerned with and take responsibility for the outcomes of their services in addition to the provision of these services. Care should also extend into and be coordinated with care providers in other settings; therefore, these guidelines should be used, as applicable, in conjunction with minimum standards for other practice settings. Rather than including detailed advice in this document, readers should refer to other referenced documents that address many of the outlined topics for additional information and guidance. Aspects of these guidelines may not be applicable in some settings due to differences in settings and organizational arrangements and complexity. Pharmacists practicing in ambulatory care settings should use their professional judgment in assessing and adapting these guidelines to meet the needs of their own practice settings.

These guidelines are intended to be a comprehensive overview of current minimum requirements for the operation and management of services for patients in the ambulatory care setting. These guidelines are complemented by the ASHP/ASHP Foundation Ambulatory Conference and Summit consensus recommendations, which provide a long-term vision for aspirational and forward-thinking pharmacy practice models that will ensure that pharmacists participate as members of the ambulatory healthcare team who are responsible and accountable for patient and population outcomes.

**Standard I. Practice Management**

Effective leadership and practice management skills are necessary for the delivery of pharmacy services in a manner consistent with the health system’s and the patient’s needs. Such leadership should foster continuous improvement in patient care outcomes. The management of ambulatory care pharmacy services should focus on the pharmacist’s value and responsibilities as a patient care provider and leader of the pharmacy enterprise through the development of organizational structures that support this mission. Development of such structures will require communication and collaboration with other departments and services throughout the health system that support ambulatory care, which every member of the pharmacy team should cultivate at every opportunity.

**A. Pharmacy and Pharmacist Services**

*Pharmacy Mission, Goals, and Scope of Services.* Ambulatory care pharmacy services should have a written mission statement that, at a minimum, reflects both pharmacy patient care and service responsibilities. The mission should be consistent with the mission of the health system. The development and prioritization of goals, objectives, and work should be consistent with the mission statement. The mission statement may also incorporate consensus-based national goals, such as those expressed in the recommendations from the ASHP Pharmacy Practice Model Initiative.

Ambulatory care pharmacy services should also maintain a written document describing the scope of pharmacy services. These services should be consistent with the health system’s scope of services and should be applied in all practice sites. The mission, goals, and scope of services should be clearly communicated to everyone involved in the provision of pharmacy services.

*Practice Standards and Guidelines.* The standards and regulations of all relevant government bodies (e.g., state boards of pharmacy, departments of health) shall be met. The
practice standards and guidelines of the American Society of Health-System Pharmacists, the Joint Commission, the National Committee for Quality Assurance, and other appropriate accrediting bodies should be assessed and adapted, as applicable. Guidelines set forth by other independent organizations such as the Institute for Safe Medication Practices (ISMP) should be assessed and adapted as applicable. The health system and the pharmacy should strive to meet these standards, regardless of the particular financial and organizational arrangements by which pharmacy services are provided to the health system and its patients. Pharmacists practicing in ambulatory care settings should play a critical role in ensuring that the health system adheres to medication-related national quality indicators and evidence-based practice guidelines.

B. Laws and Regulations
Compliance with local, state, and federal laws and regulations applicable to the ambulatory care pharmacy shall be required. The pharmacy shall maintain relevant documentation of compliance with requirements concerning procurement, distribution, and disposal of drug products; security of patient information; and workplace safety from the state board of pharmacy, Food and Drug Administration (FDA), Drug Enforcement Administration (DEA), Centers for Medicare and Medicaid Services (CMS), Occupational Safety and Health Administration, and others. Ambulatory care pharmacies dispensing medications across state boundaries shall comply with out-of-state licensure requirements as well as other state and federal interstate laws and regulations. Pharmacists practicing in ambulatory care settings may enter into prescriptive authority and collaborative practice agreements that are state specific in scope. Finally, pharmacists practicing in ambulatory care settings should be knowledgeable about reimbursement rules and compliance and billing requirements.

C. Policies and Procedures
Policies and Procedures Manual. A policy and procedures manual governing the scope of the ambulatory care pharmacy services being provided (e.g., administrative, operational, and clinical) should be available and consistent with current department processes. The manual should be reviewed and revised on a regular basis to reflect changes in policies and procedures, the scope of services, organizational arrangements, objectives, or practices. All personnel should be familiar with and adhere to the contents of the manual. Appropriate mechanisms should be established to ensure compliance with all policies and procedures.

Personnel Safety. Ambulatory care pharmacy personnel should be involved in the health system’s plans for emergency response, infection prevention and control, management of hazardous substances and waste, and incident reporting. All pharmacy staff shall be familiar with these plans.

Emergency Preparedness. Policies and procedures should exist for providing pharmacy services during facility, local, or areawide disasters affecting the organization’s patients. Appropriately trained pharmacists and representatives from the pharmacy team should be members of emergency preparedness teams and participate in drills. Patients should be informed about what to do to safely continue medication therapy in the event of a disaster.

The health system’s business continuity plan should consider the provision of pharmacist patient care services in emergency situations. Factors to consider should include system failures and breakdowns in the drug procurement process.

Medical Emergencies. Policies and procedures should exist within the organization for providing appropriate levels of patient care during emergency situations 24 hours a day, including access to the pharmacist responsible for patient care, when appropriate. Pharmacists in the ambulatory care setting are an essential part of both rapid-response teams and resuscitation teams. Appropriately trained pharmacists should have an authorized role in responding to medical emergencies. The pharmacy should participate in the development of policies and procedures to ensure the availability of, access to, and security of emergency medications, including antidotes.

Preventive and Postexposure Immunization Programs. If appropriate, the pharmacy team should participate in the development of policies and procedures concerning preventive and wellness programs and postexposure programs for infectious diseases (e.g., human immunodeficiency virus, tuberculosis, hepatitis) for patients and employees. As appropriate, pharmacists should promote the use of immunizations and, when legally allowed, participate as active immunizers.

Substance Abuse Programs. If appropriate, the pharmacy team should assist in the development of and participate in the health system’s substance abuse education, prevention, identification, and organization-sponsored programs for staff and patients.

D. Human Resources
Position Descriptions. Areas of responsibility within the scope of pharmacy services shall be clearly defined. The responsibilities and related competencies of pharmacy personnel shall be clearly defined in written position descriptions. Pharmacists should be responsible for the provision of patient care and for the supervision and management of support staff. Sufficient support staff (pharmacy technicians, clerical) should be employed to facilitate the provision of care. Technicians should be responsible for aspects of drug procurement, dialogue with third-party payers, support of pharmacists’ patient care activities, and preparation of prescription orders for a pharmacist’s clinical review.

Director of Ambulatory Care Pharmacy Services. These guidelines use the term director of ambulatory care pharmacy services (or, more simply, director) to indicate the person responsible for managing these services. Depending on the health system’s organizational structure and other factors, designations such as manager or pharmacist-in-charge may also be used. Ambulatory care pharmacy services shall be managed by a professionally competent, legally qualified pharmacist. The director should be knowledgeable about and have experience in all aspects of pharmacy care for ambulatory care patients. Completion of an advanced management degree (e.g., M.B.A., M.H.A., M.S., M.P.H.),