

ASHP Guidelines: Minimum Standard for Ambulatory Care Pharmacy Practice

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.¹ Ambulatory care pharmacy services are therefore an essential component of any comprehensive healthcare delivery system.

Pharmacists have become integral members of health-care 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.^{2,3} 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.⁴ 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 ad-

dress 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,⁵ 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.⁶

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.⁷

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.⁸

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.⁹

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.),

a residency, or both is desirable. Completion of an ASHP-accredited postgraduate year 1 (PGY1) residency should be considered a minimum competency, while completion of an ASHP-accredited postgraduate year 2 (PGY2) residency would be optimal.

The director of ambulatory care pharmacy services shall be responsible for

- Establishing the mission, vision, goals, and scope of services of the ambulatory care pharmacy practice setting on the basis of the needs of the patients served, the needs of the health system, and developments and trends in healthcare and pharmacy practice,
- Developing, implementing, evaluating, and updating plans and activities to fulfill the mission, vision, goals, and scope of services,
- Actively working with health-system leadership to develop and implement policies and procedures that provide safe and effective medication use for all patients served by the organization,
- Ensuring the development and implementation of policies and procedures that provide safe and effective medication use for the patients served by the organization,
- Mobilizing and managing the resources, both human and financial, necessary for the optimal provision of pharmacy services, and
- Ensuring that patient care services provided by pharmacists and other pharmacy personnel are delivered in compliance with applicable state and federal laws and regulations as well as national practice standards.

A part-time director shall have the same obligations and responsibilities as a full-time director.^{10,11}

The ambulatory care pharmacy team should be a cross-functional group whose skills set includes operations management, clinical care, financial management, process improvement, and informatics. Depending on the size and scope of the setting, these functional responsibilities may be assigned to a single person or a team. It is the responsibility of the director to monitor the status of the goals set forth in the vision, provide feedback to the pharmacy team as necessary, and support the team's implementation of the core functions of the pharmacy practice.

Pharmacist Licensure and Certification. All pharmacists must possess a current state license to practice pharmacy. Functional responsibilities may mandate additional degrees (M.S., M.B.A., M.H.A., M.P.H.), certificates, or credentials (e.g., Board of Pharmacy Specialties certification). Pharmacists who provide direct patient care and drug therapy management should be certified through the most appropriate Board of Pharmacy Specialties certification process. As appropriate, these pharmacists should also be privileged and credentialed by the health system.

Technician Requirements. The ambulatory care setting shall adhere to all state guidelines regarding pharmacy technician registration, certification, and licensure, as applicable. All pharmacy technicians should successfully complete a training course approved by the ambulatory care site that includes education on at least the following topics: the prescription-dispensing process, patient service skills, pa-

tient and employee safety, and pharmacy technician duties and responsibilities as defined by the board of pharmacy for that state. Pharmacy technicians should have completed an ASHP-accredited pharmacy technician training program and be certified by the Pharmacy Technician Certification Board (PTCB). The pharmacy should hire pharmacy technician trainees without those qualifications only if those individuals (1) are required to both successfully complete an ASHP-accredited pharmacy technician training program and successfully complete PTCB certification within 24 months of employment and (2) are limited to positions with lesser responsibilities until they successfully complete such training and certification. The pharmacy should require ongoing PTCB certification as a condition of continued employment.

Education and Training. All personnel should possess the education and training needed to fulfill their job responsibilities. All personnel should participate in relevant continuing-education programs, staff development programs, and other activities as necessary to maintain or enhance their competence. Both the ambulatory care pharmacy department and the health system should make available to personnel, as appropriate, training and education on new processes, procedures, and methods of patient care.¹² For pharmacists, ASHP-accredited PGY1 residency should be considered a minimum competency, while completion of an ASHP-accredited PGY2 residency would be optimal.

Recruitment, Selection, and Retention of Personnel. Qualities to consider in recruitment include completion of one or two years of postgraduate residency training, board certification, previous participation in a collaborative practice environment, and other credentials and privileges as appropriate. An ASHP-accredited PGY1 residency should be considered a minimum competency, while completion of an ASHP-accredited PGY2 residency would be optimal. Personnel should be recruited and selected on the basis of requirements in established position descriptions. Criteria used in the selection process should include the candidate's performance of similar job-specific duties, education history relevant to job-specific duties, and willingness to contribute to achieving the mission of the department and the health system. The director should assist in identifying the professional and technical requirements that a candidate must meet to qualify for the position. Clinical specialist positions are a necessary part of any health system in order to advance practice, education, and research activities. An employee retention plan is desirable.¹³

Orientation of Personnel. Personnel who are new to either a specific position or the organization should be oriented to their position through an established and structured procedure. During the orientation process, personnel should be trained in their new job functions by an employee knowledgeable in the work assigned. During the orientation period, the trainer's normal workload should be reduced in order to provide dedicated instruction time to the person being oriented, particularly in distributive settings. The orientation period of new personnel should be tailored to both the new employee's needs and the functions of the employee's position. Evaluation of the effectiveness of orientation programs should be done in conjunction with the competency assess-

ment required before a new hire can assume full responsibility for the new position.

Work Schedules and Assignments. Assignments of pharmacists and pharmacy technicians should be clearly defined to allow the optimal use of personnel and resources. Work schedules should take into account peak demand times for pharmacist-provided patient care. Sufficient personnel should be available to ensure the safe and timely delivery of pharmacy services. Hours of operation should be designed to meet the needs of the patient population given the available resources of the health system.

Performance Evaluation and Job-Specific Competencies. Scheduled periodic evaluations of performance should occur for all pharmacy personnel. Performance should be evaluated on the basis of position description requirements and expected competencies, and the evaluation format should be consistent with that used by the health system. Evaluations should include comments from professional and technical staff as well as other members of the healthcare team. Pharmacy staff should meet the expectations defined in their position descriptions for adequate performance of their duties. The director should ensure that an ongoing competency assessment program is in place for all staff, and each staff member should have a continuous professional development plan.

E. Facilities, Equipment, and Other Resources

Pharmacy. To ensure optimal performance and quality patient care, adequate space, equipment, and other resources should be available for all professional, administrative, distributive, and direct patient care functions. Patient care areas, which include the pharmacy counter, counseling rooms, and clinic offices or examination rooms where direct patient care is provided, should ensure proper patient confidentiality, promote safe and efficient patient care, and contain all tools and supplies necessary for the provision of such care. Pharmacy services operations shall be located in areas that facilitate the provision of services to patients and healthcare providers. Distributive areas should be constructed, arranged, and equipped to promote safe and efficient workflow for staff and patients and to ensure medication integrity. All facilities shall be designed to comply with applicable state and federal guidelines.

Medication Storage and Preparation Areas. Facilities should exist for the preparation and storage of drug products and medications under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security throughout the pharmacy and other patient care areas. Monitored, adequate refrigerator and freezer capacity should be available within the secure pharmacy area and, as necessary, in nonpharmacy areas.

Compounding and Packaging Areas. There shall be suitable facilities to enable the compounding, preparation, packaging, and labeling of sterile and nonsterile drug products, including hazardous drug products, in accordance with established quality-assurance procedures. The work environment should promote orderliness and efficiency and minimize the potential for medication errors and contamination of products.¹⁴⁻¹⁹

Patient Care and Counseling Areas. A designated area should be available for private patient care and counseling by pharmacists to enhance patients' knowledge and understanding of and adherence to prescribed medication therapy regimens and monitoring plans, to provide disease state management and patient care services, and to foster continuity of care. Space should accommodate the pharmacist and patient and, as appropriate, parents, caregivers, or chaperones. These areas should be stocked with relevant supplies and equipment, including computers, drug references, monitoring equipment, and other necessary tools.²⁰

Office and Meeting Areas. Adequate office and meeting areas should be available for administrative, educational, and training activities. These areas should be stocked with relevant supplies and equipment, including computers, drug references, and other necessary tools.

Automated Systems. Automated mechanical systems and software can promote safe, accurate, and efficient medication ordering and preparation, drug distribution, and clinical monitoring. Barcode technology that is associated with any of these systems provides an additional level of safety. The potential for medication errors with any of these systems should be thoroughly understood, evaluated, and eliminated to the greatest extent possible. Organizations should have policies and procedures for the evaluation, selection, use, calibration, monitoring, and maintenance of all automated pharmacy systems.^{21,22} The greatest benefits to safety and productivity are seen with robust functionality, proper system maintenance, and the prevention of workarounds.

Automated systems and devices should interface with pharmacy-based systems and support and augment the medication-use process. The replenishment of dispensing equipment should be overseen by pharmacists or by technicians who have been certified as part of a technician-checking program, depending on specific state board requirements. Calibration, maintenance, and certification as required by applicable standards, laws, and regulations should be continual and documented. All automated systems shall include adequate safeguards to maintain the confidentiality and security of patient records, and there shall be procedures to provide essential patient care services in case of equipment failure or downtime.

Health Information Technology. A comprehensive pharmacy computer system shall be employed and should be integrated to the fullest extent possible with other health-system information systems and software. Computer resources should be used to support clerical functions, maintain patient medication profile records, provide clinical decision support, perform necessary patient-billing procedures, manage drug product inventories, provide drug information, access the patient medical record, manage electronic prescribing, and interface with other computerized systems to obtain patient-specific clinical information for medication therapy monitoring and other clinical functions and to facilitate the continuity and transitions of care to and from other care settings.

Pharmacy-based systems experts who act as resources and consultants in maintaining current systems, planning for implementations and upgrades, and assisting in performance improvement and evaluation are critical to the success of informatics implementation and use.

Record and Equipment Maintenance. Adequate space should exist for maintaining and storing records (e.g., prescription records, equipment maintenance, controlled substances inventory) to ensure compliance with laws, regulations, accreditation requirements, and sound management practices. Appropriate licenses, permits, tax stamps, and other documents shall be on display or on file as required by law or regulation. All equipment shall be adequately maintained and certified in accordance with applicable standards, laws, and regulations. Equipment maintenance and certification shall be documented.

F. Managing Financial Resources

Budget Management. The pharmacy shall have a budget that is consistent with the health system's financial management process and supports the scope of and demand for pharmacy services. Oversight of workload and financial performance should be managed in accordance with the health system's requirements. Management should provide for the determination and analysis of pharmacy service costs, capital equipment costs, and new project growth.

The ambulatory care pharmacy budget processes should enable the analysis of pharmacy services by unit of service and other parameters appropriate to the organization (e.g., organizationwide costs by medication therapy, clinical service, specific disease management categories, and patient third-party enrollment). The director should have an integral part in the organization's financial management process.

Health-System Integration. Other functional units within the health system should factor the cost of pharmacy services being provided by the ambulatory care pharmacy into the departmental budget when appropriate.

Third-Party Contract Review. In conjunction with the organization's legal or contracting department, the pharmacy director's team should review third-party payer contracts to ensure that reimbursement is appropriate for services being rendered (including dispensing, patient care, and disease state management services) and the terms of the contract are in the best interest of the patient and the health system. The organization, pharmacy, or pharmacist should contract with third-party payers that are relevant to the ambulatory care pharmacy's patient population.

Revenue, Reimbursement, and Compensation. The director should be knowledgeable about revenues for pharmacy services, including reimbursement for medication dispensing, patient care, and disease state and drug therapy management services. Processes should exist for the routine verification of payment from third-party payers.

Drug Expenditures. Specific policies and procedures for managing drug expenditures should address such methods as utilization review programs, inventory management, and cost-effective care for patients with limited income and resources. The pharmacy department should use practices such as competitive bidding, group purchasing, and specialized pricing (e.g., 340B Drug Pricing Program) when applicable to develop a responsible drug purchasing model.

G. Committee Involvement

A pharmacist representative from the ambulatory care pharmacy team shall be a member of and actively participate on committees responsible for establishing and implementing medication-related policies and procedures, ambulatory care leadership, the provision of patient care, informatics, and performance improvement, as appropriate. Members of the pharmacy team should take part in staff recognition, patient service programs, and other programs as identified in the ambulatory care pharmacy service. Members of the pharmacy team should participate in the activities of similar committees of the health system, as applicable

Standard II. Managing the Medication-Use Process

A. Medication-Use Policy Development

Medication-use policy decisions should be founded on the evidence-based clinical, ethical, legal, social, philosophical, quality-of-life, safety, and economic factors that result in optimal patient care. Committees within the organization that make decisions concerning medication use (e.g., pharmacy and therapeutics, infection control) should include the active and direct involvement of physicians, pharmacists, other appropriate healthcare professionals, and patients, where appropriate. Pharmacists practicing in ambulatory care settings should actively participate on committees whose decisions could affect the quality, safety, effectiveness, or cost of pharmacy services or the medication-use process. Institutional and health-system pharmacists and pharmacy technicians shall be members of an interprofessional team accountable and responsible for medication reconciliation, patient counseling, and medication-related outcomes by establishing a medication-related continuity-of-care process for all patients. Pharmacists practicing in ambulatory care settings should be actively involved in the development, maintenance, and updating of medication-use policies, including tracking and trending of health-system antibiotic resistance patterns.

B. Formulary Management and Integration

Both the patients' diseases and the medications authorized for use by patients' third-party prescription drug programs should be taken into account when determining the ambulatory care pharmacy's inventory. The pharmacy should have access to specialty medications distributed through closed-network systems when needed to support consistent delivery of patient care and medication reconciliation.

Health systems should maintain a formulary that is efficacious and cost-effective. This formulary should be developed with feedback from professional healthcare providers (pharmacists, physicians, social workers, case managers). When possible, charity programs (patient assistance programs, copayment foundations) should be accessed to help patients with limited income and resources to procure their medications.

C. Clinical Care Plans and Disease State Management

Pharmacists in their scope of practice should be involved as part of an interprofessional team in the development and

implementation of clinical care plans with prescriptive authority in the healthcare setting (clinical practice guidelines, critical pathways) and disease state management programs involving collaborative drug therapy management (CDTM) agreements and treatment protocols. In addition, medication therapy management (MTM) services should be developed to assist with collaborative patient care. Emphasis should be placed on clinical care plans, primary care, and medication treatment protocols that cover dosage calculations and limits and medications frequently associated with adverse (potential and actual) events, including medication errors.^{23,24} Primary care protocols should consider whole-patient needs for health promotion and disease prevention measures as well as appropriate patient assessments, comprehensive management of chronic disease states, management of medication-related care problems, and referrals for acute medical care. The targeting of diseases should consider the prevalence of the disease in the population served by the organization and the potential impact on clinical and economic outcomes.²⁵

D. Drug Information

Policies and procedures should be in place for reviewing responses to requests for drug information for the purpose of performance improvement, safety, and education. Pharmacists should provide accurate, comprehensive, and patient-specific drug information to patients, caregivers, other pharmacists, physicians, nurses, and other healthcare providers as appropriate, both proactively and in response to requests associated with the delivery of pharmacist-provided patient care, educational programs, and publications. Expertise in evaluating literature on drugs should be considered essential to the provision of drug therapy management.

Drug information sources should include current professional and scientific periodicals, Web-based research tools (e.g., AHFS-DI, MicroMedex, Lexicomp Online), and the latest editions of reference books in appropriate pharmaceutical and biomedical subject areas that can be easily accessed. Available sources should support research on patient care issues, facilitate the provision of patient care, and promote safety in the medication-use process. When possible, a pharmacist should play a role in addressing complex drug information questions presented by professional staff within the health system (e.g., pharmacists, nurses, physicians).

E. Development of Patient Care Services

Pharmacists who practice in ambulatory care settings should be involved in the development, implementation, and evaluation of new or changing patient care services and drug therapy management services within the organization, such as the development of new clinic or office sites, medical homes, or accountable care organizations. In reviewing the potential for new services, both the value added to patient care by the new service and the financial and logistical implications of the new service should be considered. These efforts should promote the continuity of pharmacist-provided patient care across the continuum of care, practice settings, and geographically dispersed facilities, particularly for newly discharged patients. New services should be developed when opportunities arise for earlier involvement in medication therapy decisions (e.g., clinic rounds) and for continuity between patient encounters for the purpose of assessing therapy success, tolerance, toxicity, and adherence.

Standard III. Drug Product Procurement and Inventory Management

The pharmacy or contracted network pharmacies should be responsible for the procurement, distribution, and control of all drug products used in the treatment of the organization's patients. The pharmacy is responsible for the development of policies and procedures governing medication distribution and control. Policies and procedures should be developed in collaboration with other appropriate professionals, departments, and interprofessional committees of the organization.²⁶

A. Purchasing and Maintaining the Availability of Drug Products

Drug Product Acquisition and Availability. Drug products approved for routine use should be purchased, stored, and available in sufficient quantities to meet the needs of ambulatory care patients. Drug products not approved for routine use but necessary to meet the needs of specific patients or categories of patients should be obtained in response to orders, according to established policies and procedures.

Pharmaceutical Manufacturers and Suppliers. Criteria for selecting pharmaceutical manufacturers and suppliers shall be established to ensure that patients receive pharmaceuticals and related supplies of the highest quality and at the lowest cost.²⁷ Although these duties may be delegated in part to a group purchasing organization, the pharmacy maintains sole responsibility for ensuring the quality of drug products used in the hospital.^{27,28}

Pharmaceutical Manufacturers' Representatives. Policies and procedures should be developed governing the activities of manufacturers' representatives or vendors of drug products (including related supplies and devices) within the pharmacy, ambulatory care setting, and organization.²⁹ Representatives should not be permitted access to patient care areas and should be provided with written guidance on permissible activities. All promotional materials and activities shall be reviewed and approved by the pharmacy.²⁹⁻³¹

B. Managing Inventory

Medication Storage. Medication storage areas must have proper environmental controls (i.e., proper temperature, light, humidity, conditions of sanitation, ventilation, and segregation), be secure, and be constructed so that drugs are accessible only to authorized personnel.³² Adequate inventory controls must be maintained to allow proper inventory levels of medications based on utilization.

Drug Shortages. There should be policies and procedures for managing drug shortages, and pharmacy staff should monitor reliable sources of information regarding drug product shortages (e.g., drug shortages Web resource centers of ASHP³³ and FDA³⁴). The pharmacy should develop strategies for identifying alternative therapies, working with suppliers, collaborating with physicians and other healthcare providers, and conducting an awareness campaign in the event of a drug shortage.³⁵

Samples. The use of drug product samples should be prohibited to the extent possible.³² However, if samples are

permitted under certain circumstances, policies and procedures for their storage, control, and distribution should be in place. The pharmacy should oversee procurement, storage, and distribution of these products to ensure proper storage, record-keeping maintenance, product integrity, and compliance with all applicable packaging and labeling laws, regulations, standards, and patient education requirements. Pharmacists should be involved in the organization's efforts to secure safe and effective low-cost medications for low-income patients.^{32,36}

Patient Care Area Stock. Inventory of drug products held in nonpharmacy areas (e.g., nursing station, clinic, physicians' offices) for direct administration to ambulatory care patients should be minimal. To the extent possible, medications administered to patients in nonpharmacy areas should be prepared by the pharmacy. If this is not possible, automated medication dispensing machines should be used to dispense medications to patients. The list of medications to be accessible and the policies and procedures regarding their use shall be developed by an interprofessional committee of physicians, pharmacists, and nurses.³⁶ Access to medications should be limited to cases in which the committee determines that an urgent clinical need for the medication outweighs the potential patient safety risks of making the medication accessible. A separate assessment should occur for every location where a medication may be stocked.

Controlled Substances. Policies and procedures should ensure the distribution of controlled substances and other medications with the potential for abuse. Policies and procedures should be consistent with applicable laws and regulations and should include methods for preventing and detecting diversion.³³

Emergency Medications and Devices. The pharmacy should ensure the availability, access, and security of emergency medications, including antidotes. The telephone number of the local poison information center should be posted at or near all telephones for staff access. Pharmacists should have an authorized role in responding to medical emergencies.

All emergency medications should be stored in sealed containers that enable the staff to readily determine that the contents are complete and have not expired. All emergency medications should be available, controlled, and secured in the patient procedure areas.

Patient's Own Medications. Drug products and related devices brought into the organization by patients shall be identified by the pharmacy and documented on the patient's medical record if the medications are to be used. These medications shall be administered only pursuant to a prescriber's order and according to policies and procedures, which should ensure the pharmacist's identification and validation of the integrity as well as the secure and appropriate storage and management of such medications.

C. Drug Product Storage Area Inspections

All stocks of drug products, whether located within or outside the pharmacy area, should be inspected routinely and managed by pharmacy and location staff to ensure the absence of outdated, unusable, recalled, or mislabeled products. Storage conditions that would foster medication deterioration, stor-

age arrangements that might contribute to medication errors, and other safety issues shall be assessed, documented, and corrected.³³

D. Drug Recall and New Prescribing Information

Written procedures should exist for the timely intervention and dissemination of information regarding drug recalls. Procedures should include an established process for removing from use any drugs or devices subjected to a recall, notifying appropriate healthcare professionals, identifying any patients who may have been exposed to the recalled medication, and, if necessary, communicating available alternative therapies to prescribers. The pharmacy shall be notified of any defective drug products or related supplies and equipment encountered by nursing or medical staff. All drug product defects should be reported to FDA's MedWatch program.³³

Standard IV. Patient Care

Pharmacists play an integral role in the provision of pharmaceutical care, which is defined as the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life.³⁷ The concept of pharmaceutical care has evolved into a comprehensive, patient-focused model of pharmacist-provided care. The principal elements of pharmaceutical care are that it is medication related, is directly provided to the patient, and is provided to produce definite outcomes; these outcomes are intended to improve the patient's quality of life, and the provider must accept personal responsibility for the outcomes.³⁷ In 2008, a joint working group consisting of members and leadership from the American College of Clinical Pharmacy, the American Pharmacists Association, and the American Society of Health-System Pharmacists created a definition of ambulatory care practice as part of a petition to the Board of Pharmacy Specialties requesting recognition of ambulatory care pharmacy practice as a specialty. The definition described ambulatory care pharmacy practice as 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.³⁸⁻⁴⁰

The mission of the pharmacist is to help people make the best use of medications. At a minimum, pharmacists are responsible for assessing the legal and clinical appropriateness of medication orders (or prescriptions), educating and counseling patients on the use of their medications, monitoring the effects of medication therapy, and maintaining patient profiles and other records. In the ambulatory care setting, these responsibilities are best accomplished through the provision of pharmacist-provided patient care, whether in the context of collaborative agreements with physicians or

independent of such agreements. Pharmacists are responsible for establishing relationships with patients and providers who will facilitate the coordination and continuity of care, improve access to care, and improve patient outcomes.

Providing Comprehensive Patient Care. The addition of clinical pharmacy services to healthcare teams has produced significant cost savings to the healthcare system and improved patient satisfaction, medication safety, and therapy outcomes.⁴ Clinical pharmacy services are designed to improve patients' access to care, provide disease management, and focus on quality-related outcomes.

Recommendation B9 from the ASHP Pharmacy Practice Model Initiative specifically states that "for hospitals and health systems that provide ambulatory care services, drug-therapy management should be available from a pharmacist for each outpatient."⁶ Furthermore, many of the PPMI recommendations support the comprehensive care of patients by pharmacists practicing in ambulatory care settings through transitions of care; quality, safety, and financial outcomes; and facilitating continuity of care and medication reconciliation.

Interprofessional care models are accepted and promoted by the medical community. The American College of Physicians and the American Society of Internal Medicine have stated that "collaborative drug therapy is one of the best examples of how pharmacists work with physicians. It is designed to maximize the patient's health-related quality of life, reduce the frequency of avoidable drug-related problems, and improve the societal benefits of pharmaceuticals."⁴¹ In addition, governmental agencies support the work of pharmacists in the provision of direct patient care. The Medicare Modernization Act of 2003⁴² mandated that MTM services be offered by prescription drug plans to Medicare beneficiaries at high risk for ADEs.⁴³ While neither the legislation nor the final CMS regulation provided guidance on the design or reimbursement structure for MTM services, CMS stated that these programs should be "patient-focused services aimed at improving therapeutic outcomes that are developed in conjunction with practicing pharmacists."⁴² The Centers for Disease Control and Prevention endorsed pharmacists as integral members of the interprofessional healthcare team and supports the pharmacist's role in providing MTM services to improve patient outcomes.⁴⁴ The strongest statement about pharmacist-delivered direct patient care to date was presented in a report to the U.S. Surgeon General.⁴ This report described how innovative models of care that include pharmacists as members of the healthcare team can help to improve safety, access, quality, and cost while improving outcomes. Lastly, as the Patient Protection and Affordable Care Act is fully implemented, the involvement of pharmacists practicing in ambulatory care settings will be critical in the establishment of accountable care organizations. These integrated systems of care will heavily rely on the expertise of pharmacists to support safe and appropriate medication use.

Patient Care and Disease State Management Services. The purpose of a direct patient care or disease state management service is to optimize therapeutic outcomes for patients. Such services may include elements designed to promote enhanced patient understanding, increase patient adherence, and detect ADEs. Possible services may include perform-

ing a comprehensive medication review (comprehensive or targeted) to identify, resolve, and prevent medication-related problems (including ADEs); performing patient health status assessments; formulating medication treatment plans; selecting, initiating, modifying, discontinuing, or administering medication therapy; managing high-cost and specialty medications; administering antibiotic stewardship programs; evaluating and monitoring patient response to drug therapy; documenting the care delivered for and communicating essential information to the patient's other primary care providers; providing education and training designed to enhance patient understanding and appropriate use of his or her medications; providing information, support services, and resources designed to enhance patient adherence with his or her therapeutic regimens; coordinating and integrating MTM services within the broader healthcare management services being provided to the patient; and selecting, initiating, modifying, discontinuing, or administering medication therapy under state-approved CDTM agreements.

Relationships with Patients. Successful disease state and medication management begins with the relationship between the patient and the pharmacist. Pharmacists practicing in ambulatory care settings who provide direct patient care should develop and maintain a rapport with and the trust of the patient and the caregiver. The pharmacist should coordinate all aspects of the individual's pharmacist-provided patient care, serve as a patient advocate, and encourage patients to take responsibility for their health. The pharmacist should be flexible and adapt to patient-specific variables such as the patient's perception of how an illness or symptoms affect his or her life and the patient's readiness for change.

Relationships with Providers: CDTM Agreements. Almost every state has amended its pharmacy practice act to allow for the expansion of pharmacists' scope of practice. Pharmacists should actively participate in medication therapy decision-making and management through collaboration with patients, caregivers, physicians, and other healthcare providers. By participating in CDTM, the pharmacist takes an active role in the initiation, management, and monitoring of medication therapy based on pharmacokinetic parameters, genetic characteristics of the patient, serum concentrations of medications, laboratory values, and other patient-related health and social factors in order to take responsibility and have authority for achieving desired therapeutic outcomes. PPMI recommendation B14 states that, when possible through credentialing and privileging processes, pharmacists should include in their scope of practice prescribing as part of the collaborative practice team.⁶ A collaborative care agreement between the pharmacist and physician or other healthcare provider must comply with applicable laws and regulations and the organization's policies and procedures.

Patient History and Medication Reconciliation. Upon patient presentation for ambulatory care services, a pharmacist should obtain a patient and medication history and update and validate the patient's current medication list. Pharmacists should be integral in identifying, developing, reviewing, and approving new medications by conducting a patient-specific medication review before first-dose administration and evaluating patient response to therapy. The history should include pertinent demographic information;

known health problems and diseases; applicable measurements and laboratory values; known drug allergies and ADEs; behavioral, lifestyle, and socioeconomic influences on healthcare; and a comprehensive list of prescription and nonprescription medications and related medical devices currently being used. The current medication list should be maintained and updated during subsequent patient encounters in both the inpatient and ambulatory care settings. Pharmacists should routinely contribute to processes that ensure that each patient's care is maintained, regardless of transitions across the continuum of care and practice settings (e.g., between inpatient and community pharmacies or home care services). Moreover, pharmacists are uniquely positioned to aid in establishing a patient medication complexity index, which includes severity of illness, number of medications, and comorbidities.

Medication Therapy Assessment. Pharmacists practicing in ambulatory care settings must ensure safe and effective medication therapy. The assessment should include the appropriateness of the prescribed medication for the patient's diagnosis and history, identification of medication-related problems, and interventions for resolution. In addition, the assessment should produce a plan for monitoring patient adherence, therapeutic and adverse effects, and patient outcomes.

Medication Therapy Monitoring. The pharmacist should monitor patients' understanding of and adherence to the medication therapy plan as well as its effects and outcomes. During subsequent encounters, pharmacists should obtain appropriate information from patients, assess their progress, and identify and resolve problems. All interventions and assessments of the care plan should be documented and made available to all providers participating in the patient's care.

Documentation of Care Plan and Coordination of Care. Pharmacists should maintain a comprehensive care plan, preferably as a component of an interprofessional CDTM agreement. The care plan should be documented in the patient's medical record and be accessible to other healthcare professionals involved in patient care. The pharmacist is responsible for communicating the plan to the patient and other healthcare providers. The care plan should document the patient's medical and medication history, medication therapy assessment, and medication therapy regimen, including drug name, strength, and route of administration, indication for therapy, goal of therapy, monitoring parameters, and proposed length of therapy.

Pharmacist Skills and Competency. Pharmacists participating in direct patient care activities should demonstrate competency in the areas of care provided. Postdoctoral residency training, board certification, and continuing-education certification programs should be completed by all pharmacists and documented in a retrievable format. PPMI recommendation B10 states that pharmacists who provide drug therapy management should be certified through the most appropriate Board of Pharmacy Specialties certification process.⁶ Examples of minimum requirements include demonstration of proficient communication skills, basic physical assessment, laboratory interpretation, and disease- and age-specific competencies. Minimum requirements for level of education, experience, or postgraduate training

may be established for specific responsibilities or positions. Pharmacists in frontline practice should not be limited to competency in drug distribution and reactive order processing, and pharmacists engaged specifically in drug therapy management must have an understanding of and responsibility for the medication-use and delivery systems. Individual pharmacists must maintain competence in and accept responsibility for both the clinical and distributive activities of the pharmacy department. A model for ongoing evaluation, which may include peer review, should be developed to ensure that pharmacists remain competent.

Outcomes. Outcome measurements used to quantify the impact of the interventions of pharmacists practicing in ambulatory care settings can be divided into three categories: clinical, economic, and humanistic. Clinical outcomes may include rates of medication adherence, ADEs, and achievement and maintenance of evidence-based therapeutic goals. Examples of economic outcomes include hospitalization rates, emergency room visits, census growth, and revenue generation. Humanistic outcomes may include provider satisfaction, patient satisfaction, and measurements of impact on patient quality of life and personal productivity.

Patient Confidentiality. Policies and procedures for access to and dissemination of confidential patient information must meet all applicable legal and regulatory requirements, including those of the Health Insurance Portability and Accountability Act,⁴⁵ and be made readily available.

Standard V. Preparing, Packaging, and Labeling Medications

A. Preparing Medications

Preparation. The pharmacist should prepare or supervise the preparation of, in a timely and accurate manner, drug formulations, strengths, dosage forms, and packages prescribed.

Extemporaneous Compounding. Drug formulations, dosage forms, strengths, and packaging that are not available commercially but are deemed necessary for patient care should be prepared by appropriately trained personnel in accordance with applicable standards and regulations (e.g., FDA, United States Pharmacopeia [USP], state boards of pharmacy). Adequate quality-control and quality-assurance procedures should exist for these operations. Written master formulas and batch records (including product test results, as appropriate) shall be maintained, and a lot number or other method to identify each finished product with its production and control history shall be assigned to each batch. Commercially available products should be used to the maximum extent possible.^{14,15,17,18,46-48}

Compounded Sterile Preparations. Sterile compounding is regulated by various state and federal agencies and shall meet all applicable laws and regulations. When possible, manufactured sterile preparations should be preferred to compounding in the pharmacy. Whenever compounded sterile preparations are prepared, properly-trained staff shall use appropriate techniques to avoid contamination and assure quality; this includes but is not limited to the following:

(1) using aseptic technique; (2) maintaining clean, uncluttered, and functionally separate areas for product preparation to minimize the possibility of contamination; (3) using a primary engineering control that provides an International Organization for Standardization class 5 environment while preparing any intravenous admixture, any sterile preparation made from nonsterile ingredients, or any sterile preparation that will not be used within 1 hour; and (4) visually inspecting the integrity of the medications. *USP* Chapter 797¹⁸ and the ASHP Guidelines on Quality Assurance for Pharmacy-Prepared Sterile Products¹⁴ further define the compounding of sterile preparations and should be consulted by those responsible for this area of practice.

All sterile medications for use in the ambulatory care facility or for use by patients in the home should be prepared in a suitable environment by appropriately trained personnel and labeled appropriately for the user. Quality-control and quality-assurance procedures for the preparation of sterile products should exist, including annual competency assessment of the preparer's aseptic technique. For additional guidance regarding therapy in the patient home, refer to ASHP Guidelines on Home Infusion Pharmacy Services.⁴⁹

Hazardous Drug Products. All hazardous drug products for use in the ambulatory care facility or for use by patients in the home should be prepared in a suitable environment by appropriately trained personnel and labeled appropriately for the user.¹⁶ Special precautions, equipment, supplies (spill and eyewash kits), and training for storage, handling, and disposal of hazardous drug products should be in place to ensure the safety of personnel, patients, visitors, the community, and the environment. Quality-control and quality-assurance procedures for the preparation of hazardous products should be in place. Institutional policy should address the risk to personnel handling hazardous drug products, including periodic monitoring of personnel for adverse effects.¹⁶

B. Packaging and Labeling Medications

Packaging. Medications dispensed to ambulatory care patients should be packaged and labeled in compliance with applicable federal and state laws and regulations and with *USP* and other standards. When feasible, dispensing in unopened manufacturers' containers and in tamper-evident packaging is desirable. Packaging materials should be selected that preserve the integrity, cleanliness, and potency of compounded and commercially available drug products. Containers, including unit dose packages, for patients' home use shall comply with the Poison Prevention Packaging Act.⁵⁰

Labeling. At a minimum, labels for patient home use of medications shall comply with applicable federal and state laws and regulations. Generally, labels contain the name, address, and telephone number of the pharmacy; date of dispensing; serial number of the prescription; patient's full name; name, strength, and dosage form of the medication; directions to the patient for use of the medication; name of the prescriber; precautionary information; authorized refills; and initials (or name) of the responsible pharmacist. Other information may be required by individual state laws and regulations.

Standard VI. Medication Delivery

A. Dispensing Medications

Prescribing. Policies and procedures should be available to ensure that healthcare providers have applicable state and federal licensure and, if required, organizational authorization for prescribing medications. Medications should be administered and dispensed to ambulatory care patients only after receiving the spoken, written, faxed, or electronic prescription of an authorized prescriber. Spoken orders should be limited to nonroutine and emergency situations and should be strongly discouraged for drug products and regimens prone to medication errors and other ADEs. A pharmacist should, as soon as possible, reduce spoken orders to writing and verify them using the Joint Commission read-back procedure.

Pharmacists practicing in ambulatory care settings should advocate and foster healthcare provider conformance with the formulary, clinical care plans, disease state management programs, and standardized Joint Commission-approved terminology and abbreviations. Pharmacists practicing in ambulatory care settings should advocate the development and use of electronic prescribing systems (direct order entry by the prescriber).

Therapeutic Purpose. Before dispensing any medication, the pharmacist should substantiate the indication for which the medication was prescribed. Prescribers should be encouraged to routinely communicate the condition being treated or the therapeutic purpose with all medication orders.

Medication Orders. Medication orders (or prescriptions) shall contain at a minimum the following information: patient name and address; medication name, dose, frequency, route, and quantity or duration; prescriber name, address, and telephone number; and prescriber DEA number for controlled substances. All medication orders shall be reviewed for legality and clinical appropriateness by a pharmacist before being dispensed. Any questions should be resolved with the prescriber, and any approved changes to the prescription shall be documented in a written notation on the face of the prescription. Information concerning changes should be appropriately communicated to the patient, caregiver, and other involved healthcare providers.

Drug Delivery Systems and Administration Devices.

Pharmacists should provide leadership and advice in organizational and clinical decision-making regarding drug delivery systems and administration devices and should participate in the evaluation, use, and monitoring of these systems and devices. The potential for medication errors associated with such systems and devices should be thoroughly evaluated. Follow-up and education of staff should occur after systems errors are discovered to prevent future systems errors.

Mail Distribution. The pharmacy may mail medications to patients, preferably as part of a comprehensive pharmaceutical care program that gives patients access to a pharmacist. Mailed medications shall conform to all federal and state laws and regulations. Outer mailing packages and medica-

tion containers should protect the medication from heat, humidity, and other environmental conditions that can affect stability.⁵¹ A toll-free telephone service that is answered during normal business hours should be provided to enable communication between a patient or the patient's physician and a pharmacist with access to the patient's records. The pharmacy should have procedures for investigating, replacing, and reporting, as required, medications lost during delivery. Special requirements for mailing controlled substances vary according to state laws and regulations.

Standard VII. Evaluating the Effectiveness of the Medication-Use System

A. Assessing Pharmacy Services and Practices

Documentation and Measurement of Patient Care, Interventions, and Outcomes. An ongoing process should be in place for consistent documentation and measurement (and reporting to medical staff, administrators, and others) of pharmacist interventions, patient outcomes from MTM (including patient satisfaction with the care provided and quality of life), and pharmacists' contributions to patient care.⁵² Documenting pharmacy plans and recommendations in the patient's medical record is important for providing continuity of care between healthcare providers, communicating care plans, and underscoring the professional and legal responsibility a pharmacist assumes when making patient-specific recommendations and modifications in medication regimens. Participating in this program is an essential part of the role of every pharmacist practicing in ambulatory care settings. An electronic medical record should be used for documentation and measurement whenever possible, and the record should be designed to align pharmacists' documentation outlining care provided as well as a method to trace and ensure the quality of care provided with signed recommendations and follow-up notes in the patient's medical record.

Performance Improvement. The ambulatory care pharmacy service should have an ongoing, systematic program for assessing pharmacist-provided patient care.⁵³ Performance improvement activities based on assessments should be integrated with the health system's overall performance improvement activities, as applicable. The performance improvement team should work with frontline staff to implement systems that include proper checks and balances focused on protecting against human error. Performance improvement initiatives should be focused on error reporting trends and high-risk functions such as dispensing high-alert medications.

As part of the performance improvement program, operational and outcomes data should be benchmarked with those of other ambulatory care pharmacy services of similar size and scope. The results, including follow-up actions for improvement, should be documented and provided to the organization's managers, the frontline staff using the system, and others as appropriate.

B. Improving the Medication-Use Process

Medication-Use Evaluation. An ongoing program of both prospective and retrospective monitoring of drug utilization and costs should be in place to ensure that medications are

used appropriately, safely, and effectively and to increase the probability of desired outcomes within defined populations of patients. Proactive and continuous quality-improvement strategies aid in risk mitigation of medication-use systems. Pharmacists practicing in ambulatory care settings should play an integral role in this program. The medication-use policy committee should define specific variables for evaluation (disease state, pharmacologic category, high-use/high-cost drug products, high-alert medications, high-risk therapies, problem-prone regimens) as appropriate for the organization. Through this ongoing evaluation, areas in need of improvement in medication prescribing and management can be identified and targeted for intervention.

Medication Safety. Ambulatory care pharmacy services should be part of the health system's program for preventing medication errors and ADEs. The health system's medication safety team should be a cross-functional group of employees (e.g., pharmacists, physicians, nurses) and patients, when applicable. Pharmacists who practice in ambulatory care settings are an essential part of this medication safety team. The medication safety program should foster a just culture for error reporting. The medication safety team should

- Use a systems-based approach to review errors,
- Review near-miss medication errors (i.e., errors that did not cause patient harm but, if repeated, could cause patient harm),
- Analyze the root cause of medication errors, and
- Work with frontline staff to implement systems that include proper checks and balances focused on protecting against human error and mitigating risk.

The occurrence of medication errors should be reported to voluntary national reporting systems (e.g., USP Medication Errors Reporting Program, ISMP, and FDA MedWatch) to help prevent similar errors from occurring in other practice settings. Serious medication errors that result in temporary or permanent harm, disability, or death should be reported to the appropriate regulatory agency or accrediting body.

Patient Safety. Ambulatory care pharmacy services should be part of a health system's program to encourage patients' participation in and accountability for their care. Patient education should be sensitive to the individual patient's health literacy. To maximize the benefits of medication therapy and reduce the potential for errors, the program should encourage patients to ask questions about their medications and should emphasize adherence to their therapy plan. Pharmacist-patient dialogue, pamphlets, and videos should be used to teach patients how to ask questions about their medications. This process is particularly important for recently discharged patients.

Antimicrobial Stewardship and Infection Prevention and Control

There shall be policies and procedures to promote the optimal use of antimicrobial agents, reduce the transmission of infections, and educate health professionals, patients, and the public about these topics. Pharmacists should participate in antimicrobial stewardship and infection prevention and control efforts through clinical endeavors focused on proper antimicrobial utilization and membership on rel-

evant interprofessional work groups and committees within the health system.

Pharmacists should monitor patients' laboratory reports of microbial sensitivities or applicable diagnostic markers and advise prescribers if microbial resistance is suspected, evaluate trends in microbial prescribing relative to changes in microbial resistance patterns, and assist in developing prescribing patterns to help minimize the development of drug resistance.⁵⁴

Integration of Population-Based and Patient-Specific Activities. A mechanism should be in place for ensuring that the clinical and economic findings of population-based activities are appropriately incorporated into daily patient-specific practice. Population-based activities provide insight and guidance for the treatment of the average patient; however, all variables identified in the patient-specific encounter should be considered in therapeutic decision-making for individual patients.⁵⁵

Standard VIII. Research

The pharmacist should initiate, participate in, and support clinical and practice-related research appropriate to the goals, objectives, and resources of the specific health system.

Policies and Procedures. The pharmacist shall ensure that policies and procedures for the safe and proper use of investigational drugs and medication-related devices are established and followed and that these policies and procedures meet all applicable laws and regulations. There shall be a procedure to ensure that informed consent is obtained from the patient before the first dose of the study drug is administered.^{56,57}

Procurement, Distribution, and Control of Investigational Drugs. The pharmacy shall be responsible for overseeing the procurement, distribution, and control of all investigational drugs. Investigational drugs shall be approved for use by an institutional review board and shall be dispensed and administered to consenting patients according to an approved protocol.^{38,56,57}

Institutional Review Board. A pharmacist shall be a member of the hospital's institutional review board (or equivalent body), if one exists.⁵⁶

Drugs Not Approved by FDA. The pharmacy should seek and obtain documented authorization from appropriate committees (e.g., pharmacy and therapeutics committee) for the pharmacologic use of any chemical substance that has not received FDA approval for use as a drug. Documentation should exist to ensure that appropriate risk-management measures (e.g., obtaining informed consent) have been taken.

Information Regarding Investigational Drugs. The pharmacy shall have access to information on all investigational studies and similar research projects involving medications and medication-related devices used in the hospital. The pharmacy shall provide pertinent written information (to the extent known) about the safe and proper use of investigational drugs, including possible adverse effects and adverse drug reactions, to nurses, pharmacists, physicians, and other

healthcare professionals called on to prescribe, dispense, and administer these medications.^{56,57}

References

1. Johnson JA, Bootman JL. Drug-related morbidity and mortality, a cost-of-illness model. *Arch Intern Med.* 1995; 155:1949–56.
2. Lewis RK, Carter BL, Glover DG, et al. Comprehensive services in an ambulatory care pharmacy. *Am J Health-Syst Pharm.* 1995; 52:1793–7.
3. Segarra-Newnham M, Soisson KT. Provision of pharmaceutical care through comprehensive pharmacotherapy clinics. *Hosp Pharm.* 1997; 32:845–50.
4. Giberson S, Yoder S, Lee MP. Improving patient and health system outcomes through advanced pharmacy practice. A report to the U.S. Surgeon General (December 2011). www.usphs.gov/corpslinks/pharmacy/documents/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf (accessed 2013 Mar 18).
5. American Society of Health-System Pharmacists. ASHP/ASHP Foundation Ambulatory Conference and Summit: consensus recommendations (March 4, 2014). www.ashpmedia.org/amcare14/docs/preliminary_recommendations_2014-03-04.pdf (accessed 2014 Jul 8).
6. The consensus of the Pharmacy Practice Model Summit. *Am J Health-Syst Pharm.* 2011; 68:1148–52.
7. American Society of Health-System Pharmacists. ASHP statement on the role of health-system pharmacists in emergency preparedness. *Am J Health-Syst Pharm.* 2003; 60:1993–5.
8. American Society of Health-System Pharmacists. ASHP guidelines on the pharmacist's role in immunization. *Am J Health-Syst Pharm.* 2003; 60:1371–7.
9. American Society of Health-System Pharmacists. ASHP statement on the pharmacist's role in substance abuse prevention, education, and assistance (2013). www.ashp.org/DocLibrary/BestPractices/SpecificStSubstance.aspx (accessed 2013 Jul 29).
10. Crane VS, Hatwig CA, Hayman JN, et al. Developing a management planning and control system for ambulatory pharmacy resources. *Pharm Pract Manag Q.* 1998; 18:52–71.
11. Rosum RW. Planning for an ambulatory care service. *Am J Health-Syst Pharm.* 1997; 54:1584–7.
12. American Society of Hospital Pharmacists. ASHP statement on continuing education. *Am J Hosp Pharm.* 1990; 47:1855.
13. American Society of Health-System Pharmacists. ASHP guidelines on the recruitment, selection, and retention of pharmacy personnel. *Am J Health-Syst Pharm.* 2003; 60:587–93.
14. American Society of Health-System Pharmacists. ASHP guidelines on quality assurance for pharmacy-prepared sterile products. *Am J Health-Syst Pharm.* 2000; 57:1150–69.
15. American Society of Hospital Pharmacists. ASHP technical assistance bulletin on compounding nonsterile products in pharmacies. *Am J Hosp Pharm.* 1994; 51:1441–8.

16. American Society of Health-System Pharmacists. ASHP guidelines on handling hazardous drugs. *Am J Health-Syst Pharm.* 2006; 63:1172–93.
17. American Society of Hospital Pharmacists. ASHP guidelines for repackaging oral solids and liquids in single unit and unit dose packages. *Am J Hosp Pharm.* 1983; 40:451–2.
18. Pharmaceutical compounding—sterile preparations (general information chapter 797). In: The United States pharmacopeia, 34th rev., and The national formulary, 29th ed. Rockville, MD: United States Pharmacopeial Convention; 2011: 336–73.
19. Pharmaceutical compounding—nonsterile preparations (general information chapter 795). In: The United States pharmacopeia, 34th rev., and The national formulary, 29th ed. Rockville, MD: United States Pharmacopeial Convention; 2011:330–6.
20. American Society of Health-System Pharmacists. ASHP guidelines on pharmacist-conducted patient education and counseling. *Am J Health-Syst Pharm.* 1997; 54:431–4.
21. American Society of Health-System Pharmacists. ASHP guidelines on the safe use of automated dispensing devices. *Am J Health-Syst Pharm.* 2010; 67:483–90.
22. Glover DG. Automated medication dispensing devices. *J Am Pharm Assoc.* 1997; NS37:353–60.
23. Kernodle SJ. Improving health care with clinical practice guidelines and critical pathways: implications for pharmacists in ambulatory practice. *Pharm Pract Manag Q.* 1997; 17:76–89.
24. LaCalamita S. Role of the pharmacist in developing critical pathways with warfarin therapy. *J Pharm Pract.* 1997; 10:398–410.
25. Curtiss FR. Lessons learned from projects in disease management in ambulatory care. *Am J Health-Syst Pharm.* 1997; 54:2217–29.
26. American Society of Health-System Pharmacists. ASHP statement on the pharmacist's responsibility for distribution and control of drug products. In: Hawkins BH, ed. Best practices for hospital and health-system pharmacy, 2013–2014 edition. Bethesda, MD: American Society of Health-System Pharmacists; 2013:125.
27. American Society of Hospital Pharmacists. ASHP guidelines for selecting pharmaceutical manufacturers and suppliers. *Am J Hosp Pharm.* 1991; 48:523–4.
28. American Society of Health-System Pharmacists. ASHP guidelines on medication cost management strategies for hospitals and health systems. *Am J Health-Syst Pharm.* 2008; 65:1368–84.
29. American Society of Hospital Pharmacists. ASHP guidelines for pharmacists on the activities of vendors' representatives in organized health care systems. *Am J Hosp Pharm.* 1994; 51:520–1.
30. American Society of Hospital Pharmacists. ASHP guidelines on pharmacists' relationships with industry. *Am J Hosp Pharm.* 1992; 49:154.
31. PhRMA code on interactions with healthcare professionals. Washington, DC: Pharmaceutical Research and Manufacturers of America; 2004 Jan.
32. American Society of Hospital Pharmacists. ASHP guidelines on hospital drug and distribution control. *Am J Hosp Pharm.* 1980; 37:1097–103.
33. American Society of Health-System Pharmacists. ASHP Drug Shortages Resource Center. www.ashp.org/shortages (accessed 2013 Jul 17).
34. Food and Drug Administration. Drug shortages. www.fda.gov/cder/drug/shortages (accessed 2013 Apr 3).
35. American Society of Health-System Pharmacists. ASHP guidelines on managing drug product shortages in hospitals and health systems. *Am J Health-Syst Pharm.* 2009; 66:1399–406.
36. American Society of Health-System Pharmacists. ASHP guidelines on the pharmacy and therapeutics committee and the formulary system. *Am J Health-Syst Pharm.* 2008; 65:1272–83.
37. American Society of Hospital Pharmacists. ASHP statement on pharmaceutical care. *Am J Hosp Pharm.* 1993; 50:1720–3.
38. Lewis RK, Lasack NL, Lambert BL, et al. Patient counseling—a focus on maintenance therapy. *Am J Health-Syst Pharm.* 1997; 54:2084–98.
39. Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. *Am J Hosp Pharm.* 1990; 47:533–43.
40. Brennan C, Goode JV, Haines ST, et al. A petition to the Board of Pharmaceutical Specialties requesting recognition of ambulatory care pharmacy practice as a specialty (November 2008). www.accp.com/docs/positions/petitions/BPS_Ambulatory_Care_Petition.pdf (accessed 2015 Mar 19).
41. Keely JL, for the American College of Physicians—American Society of Internal Medicine. Pharmacist scope of practice. *Ann Intern Med.* 2002; 136:79–85.
42. Medicare Prescription Drug, Modernization, and Improvement Act of 2003, Pub. L. No. 108–173 (2003).
43. Academy of Managed Care Pharmacy. Sound medication therapy management programs: 2006 consensus document. www.pharmacist.com/sites/default/files/files/mtm_sound_programs_2006.pdf (accessed 2013 Jul 17).
44. Centers for Disease Control and Prevention. A program guide for public health: partnering with pharmacists in the prevention and control of chronic diseases. www.cdc.gov/dhdspp/programs/spha/docs/pharmacist_guide.pdf (accessed 2015 Mar 19).
45. Health Insurance Portability and Accountability Act of 1996. Pub. L. No. 104-191. www.cms.hhs.gov/HIPAAGenInfo/Downloads/HIPAAALaw.pdf (accessed 2013 Jul 17).
46. American Society of Health-System Pharmacists. ASHP guidelines: minimum standard for pharmacies in hospitals (2012). www.ashp.org/DocLibrary/BestPractices/SettingsGdlMinHosp.aspx (accessed 2013 Jul 17).
47. American Society of Hospital Pharmacists. ASHP technical assistance bulletin on single unit and unit dose packages of drugs. *Am J Hosp Pharm.* 1985; 42:378–9.
48. Pharmaceutical compounding—nonsterile preparations (general information chapter 795). In: The United States pharmacopeia, 35th rev., and The na-

- tional formulary, 30th ed. Rockville, MD: United States Pharmacopeial Convention; 2011:344–50.
49. American Society of Health-System Pharmacists. ASHP guidelines on home infusion pharmacy services. *Am J Health-Syst Pharm.* 2014; 71:325–41.
 50. Poison Prevention Packaging Act, 15 U.S.C. 1471–6.
 51. General notices and requirements—preservation, packaging, storage, and labeling. In: The United States pharmacopeia, 30th rev., and The national formulary, 25th ed. Rockville, MD: United States Pharmacopeial Convention; 2007:9–12.
 52. Borgsdorf LR, Mian JS, Knapp KK. Pharmacist-managed medication review in a managed care system. *Am J Hosp Pharm.* 1994; 51:772–7.
 53. MacKinnon N. Performance measures in ambulatory pharmacy. *Pharm Pract Manage Q.* 1997; 17:52–62.
 54. American Society of Health-System Pharmacists. ASHP statement on the pharmacist's role in antimicrobial stewardship and infection prevention and control. *Am J Health-Syst Pharm.* 2010; 67:575–7.
 55. Mutnick AH, Sterba KJ, Szymusiak-Mutnick BA. Integration of quality assessment and a patient-specific intervention/outcomes program. *Pharm Pract Manage Q.* 1998; 17:25–36.
 56. American Society of Health-System Pharmacists. ASHP guidelines on clinical drug research. *Am J Health-Syst Pharm.* 1998; 55:369–75.
 57. American Society of Hospital Pharmacists. ASHP guidelines for pharmaceutical research in organized health-care settings. *Am J Hosp Pharm.* 1989; 46:129–30.

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