

ASHP Guidelines: Minimum Standard for Pharmaceutical Services in Ambulatory Care

In recent years there has been an increasing emphasis in health care on the provision of ambulatory care services. This shift away from acute hospital care is due to several factors. Managed care has created incentives to decrease hospitalization rates and length of stay. The number of elderly patients with multiple chronic medical conditions that require longitudinal management is growing. There is more focus in medicine on preventive health and patient education. Appropriate medication therapy in the ambulatory care setting is often the most common and most cost effective form of treatment, yet the clinical, humanistic, and economic consequences of adverse drug events and the inappropriate use of medications in this setting could be catastrophic.¹ As providers of pharmaceutical care to patients in the ambulatory care setting, pharmacists should be concerned with and take responsibility for the outcomes of their services in addition to the provision of these services.

The provision of pharmaceutical services for ambulatory patients occurs in a variety of settings including free-standing pharmacies, ambulatory clinics, hospital outpatient departments, assisted living centers, and others. Pharmacists in ambulatory care settings could also provide some aspects of pharmaceutical services to patients through a mail-order prescription service, patients receiving home care, and patients residing in long-term care and other extended-care settings. Organizational arrangements may vary with the pharmaceutical services operating independently, or as components in local health care organizations that may be independent or affiliated with larger local and regional health systems.^{2,3} Furthermore, in some settings the delivery of pharmaceutical care may be independent and separated from distributive services. For brevity, these guidelines will use the terms pharmaceutical services and organizations to imply any arrangement.

The primary purpose of these guidelines is to outline the minimum requirements for the operation and management of pharmaceutical services for patients in the ambulatory care setting. Pharmaceutical services, especially the provision of pharmaceutical care, in the ambulatory care setting should be coordinated among 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 ASHP documents that address many of the topics outlined for additional information and guidance. Because of differences in settings and organizational arrangements and complexity, aspects of these guidelines may not be applicable in some settings. Ambulatory care pharmacists should use their professional judgement in assessing and adapting these guidelines to meet the needs of their own practice settings.

In circumstances where a pharmacy or network of pharmacies are contracted to provide pharmaceutical services to the organization's patients, the following minimal standards should be incorporated into contract language.

The criteria for pharmaceutical services in the ambulatory care setting that are covered in these guidelines are distributed among the following categories: (1) leadership and

practice management, (2) medication therapy and pharmaceutical care, (3) drug distribution and control, and (4) facilities, equipment, and other resources. Collectively, the criteria represent a minimum level of quality that pharmaceutical services for ambulatory patients should strive to provide on a consistent basis. While the scope of pharmaceutical services will likely vary from site to site, depending upon the needs of the patients served, the criteria are strongly linked to patient outcomes and neglect in any one may compromise quality.

Standard I: Leadership and Practice Management

Effective leadership and practice management skills are necessary for the delivery of pharmaceutical services in a manner consistent with the organization's and patients' needs and for the continuous improvement in patient care outcomes. Pharmaceutical service management should focus on the pharmacist's responsibility to provide pharmaceutical care and the development of the personnel, facilities, and other resources to support that responsibility. The guidelines use the term, director of ambulatory care pharmaceutical services or, director, to indicate the person responsible for managing services. Depending on the health care organization's structure and other factors, designations such as manager, pharmacist-in-charge, or responsible pharmacists are used.

The director of ambulatory care pharmaceutical services should be responsible for (1) setting the short- and long-term goals of the pharmacy based on the needs of the patients served, the specific needs of the pharmacy (and any organizational arrangement of which the pharmaceutical services may be a component), and developments and trends in health care and ambulatory care pharmacy practice, (2) developing plans and schedules for achieving these goals, (3) directing the implementation of the plans and the day-to-day activities associated with them, (4) determining whether the goals and schedule are being met, and (5) instituting corrective actions where necessary.^{4,5} The director, in carrying out the aforementioned responsibilities, should employ an adequate number of competent, qualified personnel.

Managing Pharmaceutical Services

Education and Training, Director. Pharmaceutical services should be managed by a professionally competent, legally qualified pharmacist. The director of the ambulatory care pharmaceutical service should be thoroughly knowledgeable about and have experience in ambulatory care pharmacy practice and management. The director should have completed an applicable accredited pharmacy residency program or have equivalent training and experience. Completion of an advanced management degree (e.g., M.B.A., M.H.A., M.S.) and/or practice management residency is desirable.

Mission. The pharmaceutical service should have a written mission statement that, at a minimum, reflects patient care

and customer service responsibilities and, if applicable, is consistent with the mission of the organization of which the pharmacy may be a component. The mission should be understood by every employee and other participants (e.g., students and residents) involved with the pharmacy's activities. The development and prioritization of goals, objectives, and work tasks should be consistent with the mission statement.

Laws and Regulations. Compliance with local, state, and federal laws and regulations applicable to pharmaceutical services in the ambulatory care setting is required. The pharmacy shall maintain written or computerized documentation of compliance with requirements concerning procurement and distribution of drug products, patient information, and related safety from the board of pharmacy, Food and Drug Administration, Drug Enforcement Administration, Health Care Financing Administration, Occupational Health and Safety Administration, among 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.

Policies and Procedures Manual. A policies and procedures manual governing the scope of ambulatory care pharmaceutical services (e.g., administrative, operational, and clinical) should be available and properly maintained. The manual should be reviewed and revised annually or whenever necessary to reflect changes in policies and procedures, scope of services, organizational arrangements, and other factors. All personnel should be familiar with the contents of the manual. Appropriate mechanisms should be established to ensure compliance with the policies and procedures.

Practice Standards and Guidelines. The practice standards and guidelines of the American Society of Health-System Pharmacists, the National Committee on Quality Assurance (NCQA), the Health Plan Employer Data and Information Set (HEDIS), and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or other appropriate accrediting body should be assessed and adapted, as applicable. The pharmacy should strive to meet these standards regardless of the particular financial and organizational arrangements by which pharmaceutical services are provided to the organization and its patients.

Managing the Medication-Use Process

Medication-Use Policy Development. Medication-use policy decisions should be based on clinical, quality-of-life, and pharmacoeconomic factors that result in optimal patient care. Committees within the organization (e.g., pharmacy and therapeutics, infection control) that make decisions concerning medication use should include the active and direct involvement of physicians, pharmacists, and other appropriate health care professionals. The pharmacy should prepare and present to these committees drug product evaluation reports that consider all aspects of safety, effectiveness, and cost.

Clinical Care Plans and Disease State Management. Pharmacists should be involved as part of an interdisciplinary team in the development and implementation of clinical care plans (clinical practice guidelines, critical pathways)

and disease state management programs involving medication therapy, collaborative care agreements, and treatment protocols. Emphasis should be placed on clinical care plans, primary care, and medication treatment protocols that cover dosage calculations and limits, and use of medications frequently associated with adverse events, including medication errors.^{6,7} Primary care protocols should consider whole patient needs for health promotion and disease prevention measures as well as appropriate patient assessments, 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 for impact on clinical and economic outcomes.⁸

Drug Information. Pharmacists should provide accurate, comprehensive, general and patient-specific drug information to patients, caregivers, other pharmacists, physicians, nurses, and other health care providers, as appropriate, in response to requests, in the delivery of pharmaceutical care, or through educational programs and publications.

Drug information sources should include current professional and scientific periodicals and the latest editions of textbooks in appropriate pharmaceutical and biomedical subject areas. Available information sources should support research on patient care issues and facilitate provision of pharmaceutical care and safety in the medication-use process. This information may be accessed in conjunction with medical libraries and other available resources. Appropriate drug information sources should be readily accessible to professional staff.

If applicable, pharmacists should have access to information on all investigational studies and similar research projects involving medications and medication-related devices used by the organization. Pharmacists should provide pertinent written information (to the extent known) about the safe and proper use of investigational drugs, including possible adverse effects, to nurses, pharmacists, physicians, and other health care providers involved in the care of patients admitted to the investigational drug protocols.

Development of Patient Care Services. Pharmacists should be involved in the development, implementation, and evaluation of new or changing patient care services within the organization, such as the development of new clinic or office sites. These efforts should promote the continuity of pharmaceutical care across the continuum of care, practice settings, and geographically dispersed facilities.

Preventive and Postexposure Immunization Programs. The pharmacy should participate in the development of policies and procedures concerning preventive and postexposure programs for infectious diseases (including, but not limited to, HIV, tuberculosis, and hepatitis) for patients and employees. As appropriate, pharmacists should promote the use of and may administer immunizations, when legally allowed.

Substance-Abuse Programs. The pharmacy should assist in the development of and participate in the organization's substance-abuse prevention, education, and employee and patient assistance programs.

Medical Emergencies. The pharmacy should participate in the development of policies and procedures to ensure the availability,

access, and security of emergency medications, including antidotes. Appropriately trained pharmacists should have an authorized role in responding to medical emergencies.

Institutional Review Board. Pharmacist's membership on the organization's institutional review board is preferred depending on the prevalence of clinical drug research.

Committee Involvement. A pharmacist should be a member of and actively participate in those committees responsible for establishing policies and procedures for medication-use, other aspects of patient care, and performance improvement and others, as appropriate. Also, pharmacists should participate in the activities of similar committees of a parent health system, as applicable.

Formulary Management and Integration. The pharmacy should maintain an up-to-date formulary of drug products approved by the medical staff. Drug products should be selected for the formulary through a medication-use policy development process (pharmacy and therapeutics committee or equivalent) that ensures the availability of the most appropriate drug products for the population served. The formulary should limit choices based on clinical evidence of efficacy and safety as well as cost to essential drug products with few duplicates. Drug products of marginal benefit should be eliminated or restricted, to the extent possible.

When applicable, the pharmacy should integrate the formularies (or approved drug lists) of third party payers into a patient care process that ensures optimal and cost-effective patient outcomes. Organizations with multiple practice settings such as acute inpatient and ambulatory care should coordinate formularies to promote continuity of care. A process should exist to obtain non-formulary drug products when medically necessary for the care of specific patients.

Disaster Services. Policies and procedures should exist for providing pharmaceutical services during facility, local, or area-wide disasters affecting the organization's patients. Appropriately trained pharmacists should be members of emergency preparedness teams and participate in drills. Patients should be informed about what to do in the event of a disaster to safely continue medication therapy.

Managing Performance Improvement

Performance Improvement. There should be an ongoing, systematic program for assessing the delivery of pharmaceutical care and services and of the utilization of medications in patient care.⁹ Performance improvement activities based on assessments should be integrated with the organization's or health system's overall performance improvement activities, as applicable. Corrective actions should be planned and implemented for identified deficiencies and reassessed at appropriate time intervals. Operational and outcomes data should be bench-marked with those of other ambulatory care pharmaceutical services of similar size and scope. The results, including follow-up actions, of improvement efforts should be documented and provided to the organization's managers and others, as appropriate.

Medication-Use Evaluation. An ongoing program of monitoring 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 patient outcomes within defined populations of patients. The medication-use policy committee should define specific parameters for evaluation (disease state, pharmacological category, high-use/high cost drug products) as appropriate for the organization. Through the ongoing evaluation of medication-use, areas in need of improvement in medication prescribing and management can be identified and targeted for intervention.

Documentation and Measurement of Pharmaceutical Care, Interventions, and Outcomes. Pharmaceutical services should have an ongoing process for consistent documentation and measurement (and reporting to medical staff, administrators, and others) of pharmaceutical care, interventions, and patient outcomes from medication therapy (including patient satisfaction and quality of life) and pharmacists' contributions to patient care.¹⁰

Adverse Drug Reactions. An ongoing program should be in place for preventing, monitoring, and reporting adverse drug reactions. The program should include timely communications about the occurrences of adverse drug reactions to affected patients, their caregivers, and other providers. The pharmacy should submit adverse drug reaction reports to the FDA MedWatch program and drug products' manufacturers, as appropriate.

Medication Errors. The ambulatory care organization should have an ongoing program to prevent medication errors, including nonpunitive reporting and analysis. Pharmacists, physicians, nurses, and other health care personnel involved in the medication-use process should monitor for, document, and report medication errors. The organization, with the participation of pharmacists, should analyze the causes of medication errors and implement corrective actions. The occurrence of medication errors should be reported to voluntary national reporting systems (e.g., USP Medication Error Reporting Program and FDA MedWatch) and, as required, to accrediting organizations.

Integration of Population-Based and Patient-Specific Activities. A mechanism to ensure that the clinical and economic findings of population-based activities are appropriately incorporated into daily patient-specific practice should exist. Population-based activities provide insight and guidance in the treatment of the average patient, however, all variables identified in the patient-specific encounter should be considered in the therapeutic decision making for an individual patient.¹¹

Managing Human Resources

Work Schedules and Assignments. The director should ensure that work schedules, procedures, and assignments optimize the use of personnel and other resources. Sufficient personnel should be available to ensure the safe and timely delivery of pharmaceutical services and patient care.

Position Descriptions. The responsibilities and related competencies of professional and supportive personnel should be clearly defined in written position descriptions. Pharmacists should be responsible for the provision of pharmaceutical care and for the supervision and management of support staff. Sufficient support staff (pharmacy technicians, clerical, secretarial) should be employed to facilitate the provision of pharmaceutical care. Technicians should be

responsible for most aspects of drug distribution, including the processing of medication orders. This should be supervised and checked by a pharmacist. Roles of technicians and pharmacists should be clearly delineated to maximize the use of technicians in activities they can legally and safely perform.

Recruitment and Selection of Personnel. Personnel should be recruited and selected on the bases of requirements in established position descriptions. The personnel selection process should include an assessment of prior performance in job-related functions and the candidate's ability and willingness to contribute to achieving the pharmacy's mission. The director should assist in identifying the relevant professional and technical qualifications and should participate in candidate interviews and selections.

Performance Evaluation. Scheduled, periodic evaluations of performance should occur for all pharmacy personnel. Performance should be evaluated on the bases of position description requirements and expected competencies. Evaluations should include comments from professional and technical staff as well as other members of the health care team. Customer service should also be included in the evaluation process.

Education and Training. All personnel should possess the education and training needed to fulfill their responsibilities. All personnel should participate in relevant continuing education programs, staff development programs, and other activities as necessary to maintain or enhance their competence.

Pharmacist Licensure and Certification. All pharmacists shall possess a current state license to practice pharmacy. Board of Pharmaceutical Specialties' certification of pharmacists to provide specialty services to patients and selected patient care is encouraged, as applicable.

Technician Certification. Certification of pharmacy technicians by the Pharmacy Technician Certification Board should be strongly encouraged or required, as feasible. In addition, completion of an accredited training program is preferred.

Orientation of Personnel. All new personnel should be oriented to their positions' responsibilities and continued competencies, and applicable pharmacy and organization policies and procedures.

Managing Financial Resources

Budget Management. The pharmacy should have a budget consistent with the organization's financial management process that supports the scope of and demand for pharmaceutical services. Oversight of workload and financial performance should be managed in accordance with the organization's requirements. Management should provide for (1) determination and analysis of pharmaceutical service costs, (2) analysis of budgetary variances, (3) capital equipment acquisition, (4) patient revenue projections, and (5) justification of personnel commensurate with workload productivity.

Processes should enable the analysis of pharmaceutical services by unit-of-service and other parameters appropriate

to the organization (e.g., organization-wide costs by medication therapy, clinical service, specific disease management categories, and patient health plan enrollment). The director should have an integral part in the organization's financial management process.

Drug Expenditures. Specific policies and procedures for managing drug expenditures should address such methods as competitive bidding, group purchasing, utilization review programs, inventory management, and cost-effective patient services.

Revenue, Reimbursement, and Compensation. The director should be knowledgeable about revenues for pharmaceutical services including reimbursement for the provision of drug products and related supplies and compensation for pharmacists' cognitive services. Processes should exist for routine verification of patient benefits and for counseling patients about their anticipated financial responsibility for planned medication therapies. A process should also exist for responding to services requests from medically indigent patients. (For additional information, see: Coding and Reimbursement Guide for Pharmacists, St. Anthony Publishing; Directory of Prescription Drug Patient Assistance Programs, Pharmaceutical Research and Manufacturers Association.)

Standard II: Medication Therapy and Pharmaceutical Care

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 pharmaceutical care whether in the context of collaborative agreements with physicians or independent of such agreements. The pharmaceutical care activities may vary, however, depending on whether agreements are in place, pharmacists have delegated authorities in patient care, and these are supported by provisions in the organization's policies and procedures. Individual state laws and regulations may establish specific requirements and limits.

Providing Pharmaceutical Care

Pharmaceutical care involves establishing a relationship with the patient; obtaining patient and medication history information; assessing the appropriateness of medication orders; preventing, identifying and resolving medication or other problems; educating and counseling patients; and monitoring the patient and medication effects.¹² When authorized for collaborative medication therapy or primary care, pharmacists may also participate in medication therapy decision-making and administering medications.

Pharmaceutical Care Plan. Pharmacists should maintain a comprehensive, on-going pharmaceutical care plan, either separately or as a component of a multidisciplinary care plan, for each patient based on level of responsibilities. The pharmaceutical care plan, if separate, should be accessible to prescribers, pharmacists, and other health care providers

involved in patient care. The pharmacist should be responsible for communicating the contents to the patient and other health care providers. The pharmaceutical care plan should, at a minimum, document the patient's medical and medication history, medication therapy assessment, and the medication therapy regimen, including drug name, strength, route of administration, indication of therapy, goal of therapy, monitoring parameters, and proposed length of therapy.

Depending on applicable laws and regulations and the organization's policies and procedures, the pharmaceutical care plan, or elements, may be a part of the patient's medical record or maintained in a separate pharmacy record or patient profile, preferably electronic.

Relationships with Patients. Patient-based medication therapy and pharmaceutical care begins with the relationship between the patient and the pharmacist. The ambulatory care pharmacist in the role of providing direct patient care should develop and maintain a level of rapport and trust with the patient and caregiver to effectively provide pharmaceutical care. The pharmacist should coordinate all aspects of the individual patient's pharmaceutical care and serve as a patient advocate. The pharmacist should be flexible and adapt to patient-specific variables such as the patient's perception of how their illness and/or symptoms impact his or her life and the patient's readiness for change.

Medication-Therapy Decisions. Pharmacists should actively participate in medication therapy decision-making and management through collaboration with the physician, patient, and other health care providers. By participating in collaborative drug therapy management, the pharmacist takes an active role in the initiation, management, and monitoring of medication therapy and takes responsibility for achieving desired therapeutic outcomes. The development of a collaborative care agreement between the pharmacist, prescriber, and the patient should occur in compliance with applicable laws and regulations and the organization's policies and procedures, as applicable.

Pharmacist Prescribing. When permitted by applicable state laws and regulations, pharmacist may be delegated prescriptive authority in accordance with established collaborative drug therapy management agreements.

Therapeutic Goals. The pharmacist and patient should work together and with other health care providers to set goals, time-tables, and therapeutic milestones for all pharmacotherapy.

Patient and Medication History. Upon patient admission for ambulatory care services, a pharmacist should obtain, or conduct as necessary, a patient and medication history (or profile). The history should include, but not be limited to, known health problems and diseases, applicable measurements and laboratory values, known drug allergies and adverse drug experiences, and a comprehensive list of prescription and nonprescription medications and related medical devices currently being used. The history should be maintained and updated during subsequent patient encounters.

Medication Therapy Assessment. The pharmacist should assess medication orders, new and refill, prior to dispensing, to ensure safe and effective medication therapy. The assessment should include the appropriateness of the prescribed

medication(s) for the patient's diagnosis and history, the identification of medication-related problems, and interventions for resolving the problems, if any. Problems should be resolved with the prescriber before further processing of the medication order. In addition, the assessment should produce a plan for monitoring patient adherence, therapeutic and adverse effects, and patient outcomes.

Patient Education and Counseling

Patient education and counseling are essential components of pharmaceutical care in the ambulatory care setting and pharmacists' provision should exceed the minimal legal requirements.¹³ A simple offer to counsel is inconsistent with pharmacists' responsibilities. The pharmacist should ensure that the patient understands all information required for the safe and proper use of the medication and devices, as applicable. Directions for use should be clearly expressed. Supplementary written information should be provided as necessary to reinforce oral communications. Contingencies should be available to provide education, counseling, and written materials to non-English speaking patients, where applicable. Depending on need, this might require access to interpreters or bilingual pharmacists.

At a minimum, the pharmacist should verify that patients and caregivers, understand what medications (prescription, nonprescription, and alternative substances) they are using, why they are using them, how to use them, what therapeutic effects to expect, what potential adverse effects to watch for, and what actions to take if adverse effects occur. Counseling should also include the patients responsibility for adherence to and reporting on their experience with the medication therapy plan.

Medication Therapy Monitoring. The pharmacist should monitor patient understanding and adherence to their medication therapy plan and its effects and outcomes. During subsequent encounters with patients for medication order refills or follow up visits, pharmacists should obtain information, as appropriate, from patients, assess patient progress, identify any problems, and resolve problems either with the prescriber or in accord with a collaborative agreement.

Medication Administration. Only personnel who are permitted by law and regulation, authorized by the organization, and appropriately trained should administer medications to patients. Pharmacists should participate in establishing policies and procedures for medication administration in the ambulatory care setting. When legally permitted, medication administration by appropriately trained pharmacists may be within their scope of practice, depending on the ambulatory care setting's workload distribution among members of the health care team. As appropriate, pharmacists may witness now or one-time doses of medications self-administered by patients.

Supporting Pharmaceutical Care

Continuity of Care. Pharmacists should routinely contribute to processes that ensure each patient's pharmaceutical 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).

Emergency Access to Pharmaceutical Care. Policies and procedures should exist within the organization to provide patients access to appropriate levels of pharmaceutical care during emergent situations 24 hours a day, including access to the pharmacist responsible for their care, if appropriate.

Medical Record Documentation. Clinical actions and recommendations by pharmacists that are designed to ensure safe and cost effective use of medications and that have a potential effect on patient outcomes should be documented in patients' medical records. Pharmacists' documentation in the patients' medical records may require organization-specific training and authorization.

Patient Confidentiality. Policies and procedures for access to and dissemination of confidential patient information should be available. Patient privacy and confidentiality should be protected by safeguarding access to all sources of patient information, including financial (billing), medication profiles, medical records, and organization reports, whether in computer databases or hard copy. Patient information should be shared only with authorized health care providers and others within the pharmacy or the organization as needed for the care of patients. Patient information should only be shared with family members and caregiver(s) upon the request of the patient. Privacy shall be maintained during all communication with a patient.

Standard III: Drug Distribution and Control

The pharmacy and/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. Policies and procedures governing medication distribution and control should be developed by the pharmacy in collaboration with other appropriate organization staff and committees.

Purchasing and Maintaining the Availability of Drug Products

Drug Product 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 or contracting with group purchasing organizations should be established by the pharmacy to ensure the quality and best price of drug products. Preference should be considered for manufacturers and suppliers that provide packaging and labeling designed to reduce vulnerability to medication errors (e.g., bar-coding).

Pharmaceutical Manufacturers' Representatives. Policies and procedures governing the activities of representatives (including related supplies and devices) within the pharmacy, ambulatory care setting, and organization should exist. Representatives should be provided written guidance on their activities. All promotional materials and activities should be

reviewed and approved by the pharmacy. Representatives should not have access to patient care areas.

Samples. The use of drug product samples should be prohibited to the extent possible. However, if samples are permitted under certain circumstances, policies and procedures for their use should exist. The pharmacy should control samples to ensure proper storage, record keeping, and product integrity, if allowed by state law and regulation. Samples dispensed to patients should meet all applicable packaging and labeling laws and regulations and standards.

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 should be monitored to ensure compliance with environmental requirements and to assess, document, and correct any conditions that might foster medication deterioration and storage arrangements that might contribute to medication errors. Appropriate security must prevent the access of unauthorized staff and others (technical, health care provider, housekeeping, patients and caregivers) to stock medications and medication order forms (prescription blanks).

Patient Care Area Stock. Stocks of drug products held in nonpharmacy areas (e.g., nursing station, clinic, or physicians' offices) for direct administration to ambulatory patients should be minimal. To the extent possible, stocks should be limited to medications for emergency, diagnostic, and routine treatments, including certain injectables (e.g., local anesthetics and vaccines). The potential for medication errors and adverse effects should be considered for any drug product stocked outside of the pharmacy. Drug products shall be under control at all times to prevent unauthorized access and diversion.

Emergency Medications. The pharmacy should ensure the availability, access, and security of emergency medications, including antidotes. Pharmacists should have an authorized role in responding to medical emergencies.

Drug Recall and New Prescribing Information. An ongoing program should exist for timely intervention and dissemination of information regarding drug recalls and release of new prescribing or adverse drug reaction information on specific drug products. For situations in which the potential for an adverse event is possible, the pharmacy should have procedures in place to identify all patients of the organization using the product, to identify the prescribers of the product, and to intervene with specific alternatives to reduce the risk of adverse events.

Policies and procedures should exist for removing recalled drug products from all storage and patient care areas, and when the recall is to the user level, for notifying patients who have received recalled products and for replacing patients' supplies.

Processing the Medication Order

Prescribing. Policies and procedures should be available to ensure that health care providers meet applicable state licensure and, if required, organizational authorization for prescribing medications. Medications should be administered

and dispensed to ambulatory patients only upon the oral or written order of authorized prescribers. Oral new orders should be limited to non-routine and emergent situations and strongly discouraged for drug products and regimens prone to adverse events, including medication errors. A pharmacist should verify and reduce oral orders to writing as soon as possible.

The pharmacy should advocate and foster prescriber's conformance with the formulary, clinical care plans, and disease state management programs, and with standardized, approved terminology and abbreviations when prescribing medications. The pharmacy should advocate for the development and use of electronic prescribing systems (prescriber direct order entry).

Therapeutic Purpose. Prior to 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 of medications 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, quantity (duration), prescriber identification (and prescriber DEA number for controlled substances) and signature, and date. 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 a written notation made in the patient's pharmacy record or profile. Information concerning changes should be appropriately communicated to the patient, caregiver, and other involved health care providers.

Preparing, Packaging, and Labeling Medications

Preparation. The pharmacist should prepare or supervise the preparation, in a timely and accurate manner, those drug formulations, strengths, dosage forms, and packages prescribed, including those that are not commercially available but are needed in the care of patients.

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, U.S.P., state board of pharmacy). Adequate quality control and quality assurance procedures should exist for these operations. Commercially available products should be used to the maximum extent possible.

Sterile Products. 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 periodic assessment of personnel on aseptic technique.

Cytotoxic and Hazardous Drug Products. All cytotoxic and 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. Special precautions, equipment, supplies (spill kits), and training for storage, handling, and disposal of cytotoxic and hazardous drug products should exist to ensure the safety of personnel, patients, and visitors. Quality control and quality assurance procedures for the preparation of cytotoxic and hazardous products should exist. Personnel handling cytotoxic and hazardous drug products should be monitored periodically for adverse effects.

Controlled Substances. Pharmacists are responsible for a lead role in the control of drug products that are subject to diversion and misuse. Pharmacists have primary responsibility for receipt, storage, security, distribution within the facility and to patients for home use, and disposal of controlled substances and for related records. Policies and procedures shall exist to ensure compliance with the Comprehensive Drug Abuse Prevention and Control Act of 1970 and with state laws and regulations that may be more stringent. Storage within the pharmacy and nonpharmacy (e.g., emergency room) areas are secure and have controlled access to only authorized personnel. Procedures are in place to detect and investigate inventory shrinkage.

Investigational Drugs. The pharmacy should be responsible for overseeing the 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.

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

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' and in tamper-evident packages 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 patient home use shall comply with the Poison Prevention Packaging Act.

Labeling. At a minimum, labels for patient home use of medications shall comply with applicable federal and state laws and regulations. Generally, labels contain: 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 law and regulation.

Drug Delivery Systems and Administration Devices. Pharmacists should provide leadership and advice in organizational and clinical decisions 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.

Mail Distribution. The pharmacy may mail medications to patients, preferably when part of a comprehensive pharmaceutical care program, which provides patients access to a pharmacist. Mailed medications shall conform to all federal and state laws and regulations. Outer mailing packages and medication containers should protect the medication from heat, humidity, and other environmental conditions that would affect stability.¹⁴ A toll-free telephone service should be provided that is answered during normal business hours to enable communication between a patient or a physician of a patient 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 by state law and regulation.

Standard IV: Facilities, Equipment, and Other Resources

To ensure optimal performance and quality patient care, adequate space, equipment, and other resources should be available for all professional and administrative functions relating to medication use. Pharmaceutical services operations should be located in areas that facilitate provision of services to patients, nurses, prescribers, and other health care providers. Facilities should be constructed, arranged, and equipped to promote safe and efficient work flow for staff and patients and to avoid damage to or deterioration of drug products.

Information Technology. Computer-based (electronic) information systems are preferred to maintain patient pharmaceutical care plans and medication profiles; perform necessary patient billing procedures; manage drug product inventories; and interface with other available computerized systems to obtain patient specific clinical information. Information is essential for medication therapy monitoring and other clinical functions, to facilitate the continuity of care to and from other care settings, and to produce drug utilization, cost, and related reports.

Medication Storage and Preparation Areas. Facilities should exist to store and prepare 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 refrigeration and freezer capacity should be available within the secure pharmacy area and, as necessary, in nonpharmacy areas.

Compounding and Packaging. Designated space and equipment for compounding and packaging of sterile and nonsterile drug products, including hazardous drug products, should exist. The compounding and packaging areas should be clean and orderly and routinely monitored and maintained to minimize the risk of errors and contamination of drug products.

Patient Assessment and Counseling Area. A designated area for private patient assessment and counseling by pharmacists should be available to enhance patients' knowledge, understanding, and adherence to prescribed medication therapy regimens and monitoring plans. Space should accommodate the pharmacist and patient and, as appropriate, parents, caregivers, or chaperones.

Automation. There should be policies and procedures on the evaluation, selection, use, calibration and monitoring, and maintenance of all automated pharmacy systems.¹⁵ Automated dispensing systems and software may be useful in promoting accurate and efficient medication ordering and preparation, dispensing, and distribution. The potential for medication errors associated with automated systems should be thoroughly evaluated and eliminated to the extent possible. Automated dispensing systems should support the pharmacist's assessment of medication orders (and opportunity to intervene) and checking of filled orders before dispensing.

Automated dispensing systems and automated storage and distribution devices should be controlled by the pharmacy's computer-based information system. An interface with the organization's information system is strongly encouraged. A pharmacist should supervise the stocking of medications in automated dispensing systems and in automated storage and distribution devices. The maintenance, calibration, and certification, as required by applicable standards, laws, and regulations, should be ongoing and documented.

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

Office and Meeting Area. Adequate office and meeting areas should be available for administrative, educational, and training activities.

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