

ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals

Purpose

The following minimum standard guidelines are intended to serve as a basic guide for the provision of pharmacy services in hospitals. These guidelines outline a minimum level of services that most hospital pharmacy departments should consistently provide. The reader is strongly encouraged to review the American Society of Health-System Pharmacy (ASHP) guidance documents referenced throughout these guidelines for more detailed descriptions. Certain elements of these guidelines may be applicable to other health care settings or may be useful in evaluating the scope and quality of pharmacy services.

Elements of Care

The mission of pharmacists is to help people make the best use of medications.¹ Therefore, pharmacists shall be concerned with not only the provision but the outcomes of pharmacy services. The elements of pharmacy services that are critical to safe, effective, and cost-conscious medication use in a hospital include (1) practice management, (2) medication-use policy development, (3) optimizing medication therapy, (4) drug product procurement and inventory management, (5) preparing, packaging, and labeling medications, (6) medication delivery, (7) monitoring medication use, (8) evaluating the effectiveness of the medication-use system, and (9) research. Although the scope of pharmacy services will vary from site to site, depending upon the needs of patients and the hospital as well as the resources available, these core elements are inextricably linked to successful outcomes. Failure to provide any of these services may compromise the quality of patient care.

Terminology

In these guidelines, the term “shall” is used to indicate a minimum standard of practice set forth in this document, in other ASHP policies, or in requirements established by laws, regulations, accrediting bodies, or other binding authorities. The term “should” is used to indicate a best practice that is strongly encouraged by ASHP but which may not be applicable to all institutions or in all circumstances.

Standard I. Practice Management

Effective leadership and practice management skills are necessary for the delivery of pharmacy services in a manner consistent with the hospital’s and patients’ needs. Such leadership should foster continuous improvement in patient care outcomes. The management of pharmacy services should focus on the pharmacist’s responsibilities as a patient care provider and leader of the pharmacy enterprise through the development of organizational structures that support that mission. Development of such structures will require communication and collaboration with other departments and

services throughout the hospital, which every member of the pharmacy team should cultivate at every opportunity.

A. Pharmacy and Pharmacist Services

Pharmacy Mission, Goals, and Scope of Services. The pharmacy shall have a written mission statement that reflects both patient care and operational responsibilities. Other aspects of the pharmacy’s mission may require definition as well (e.g., educational and research responsibilities). The mission statement shall be consistent with the mission of the hospital and, if applicable, aligned with the health system of which the hospital is a component. The development, prioritization, and implementation of the pharmacy’s goals should be consistent with the mission statement. Determination of short- and long-term goals and the undertaking of implementation activities should be performed in collaboration with institutional leadership and other hospital staff (e.g., pharmacy, nursing, and medical staff), and these should be integrated with the goals of the hospital. The mission statement may also incorporate consensus-based national goals, such as those expressed in the recommendations from the ASHP Pharmacy Practice Model Initiative.²

The pharmacy shall also maintain a written document describing the scope of pharmacy services. These services should be consistent with the hospital’s scope of services and should be applied throughout the hospital in all practice sites.

The mission, goals, and scope of services shall be clearly communicated to everyone involved in the provision of pharmacy services, including pharmacists, residents, students, technicians, and support staff.

24-Hour Pharmacy Services. Adequate hours of operation for the provision of needed pharmacy services shall be maintained; 24-hour pharmacy services should be provided when possible. Twenty-four hour pharmacy services should be employed in all hospitals with clinical programs that require intensive medication therapy (e.g., transplant programs, open-heart surgery programs, neonatal intensive care units, and trauma centers). When 24-hour pharmacy services are not feasible, a pharmacist shall be available on an on-call basis. Remote medication order processing may be employed (to the extent permitted by law and regulation) to help provide pharmacy services but is not a substitute for an on-call pharmacist.³ Automated drug dispensing equipment and computer databases are also not a substitute for the skills and knowledge of a pharmacist and should not be considered alternatives to 24-hour pharmacy services.⁴

After-Hours Pharmacy Access. In the absence of 24-hour pharmacy services, access to a limited supply of medications shall only be available to authorized, licensed health care professionals for use in carrying out urgent medication orders. Access to such medications shall be carefully monitored and documented, and after-hours access shall be reviewed regularly to ensure appropriate use. The list of medications to be accessible and the policies and procedures to be used (including subsequent review of all activity by a

pharmacist) shall be developed by a multidisciplinary committee of physicians, pharmacists, and nurses (e.g., by the pharmacy and therapeutics [P&T] committee or its equivalent).⁵ Access to medications should be limited to cases in which the P&T committee (or its equivalent) determines that the urgent clinical need for the medication outweighs the potential risks of making the medication accessible. The potential safety risks of medications should be considered in the decision to make them accessible, and medications, quantities, dosage forms, and container sizes that might endanger patients should be limited whenever possible.

Routine after-hours access to the pharmacy by non-pharmacists for access to medications shall not be permitted. The use of well-designed night cabinets, after-hours medication carts, automated dispensing devices,⁶ and other methods precludes the need for nonpharmacists to enter the pharmacy.⁴

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 ASHP, appropriate accrediting bodies (e.g., Joint Commission, American Osteopathic Association Healthcare Facilities Accreditation Program, Det Norske Veritas), and the Centers for Medicare and Medicaid Services shall be viewed as applicable, and the hospital should strive to meet all applicable standards.

B. Laws and Regulations

Applicable local, state, and federal laws and regulations shall be met, and relevant documentation of compliance shall be maintained.

C. Policies and Procedures

Policy and Procedures Manual. There shall be a policy and procedures manual governing pharmacy functions (e.g., administrative, operational, and clinical), and all pharmacy personnel shall follow those policies and procedures. The manual may include a statement of the pharmacy's mission, philosophy, or values (e.g., the pharmacy's mission or vision statement), but it should concentrate on operational policies and procedures to guide and direct all pharmacy services. The pharmacy's policies and procedures should be consistent with the hospital's policies and procedures, and the manual should be reviewed by a designated medical staff committee for potential conflicts and other medical issues. The manual shall be reviewed by pharmacy staff on a regular basis and revised as necessary to reflect changes in procedures, organization, objectives, or practices. The manual shall be accessible to pharmacy department personnel as well as other hospital employees (e.g., through the hospital's intranet), and all pharmacy personnel should be familiar with its contents. Appropriate mechanisms to ensure compliance with the policies and procedures should be established.

Personnel Safety. Pharmacy employees should be involved in the development of the hospital's plans for emergency response, infection prevention and control, management of hazardous substances and waste, and incident reporting, and all pharmacy staff shall receive education about those plans.

Emergency Preparedness. Facility emergency preparedness plans shall describe the role of pharmacy staff in emergency

response (including evacuation), and the facility's business continuity plan shall include procedures for providing safe and efficient pharmacy services in case of emergencies. Appropriately trained pharmacists should be members of emergency preparedness teams and participate in applicable preparations and drills.⁷ The pharmacy shall establish, in conjunction with the hospitalwide emergency plan, policies and procedures for the safe and orderly evacuation of pharmacy personnel in the event of an emergency in the hospital.

Medical Emergencies. The pharmacy shall participate in hospital decisions about the contents of code carts, emergency medication kits and trays, and the role of pharmacists in medical emergencies. Pharmacists should serve on cardiopulmonary resuscitation teams, and such pharmacists should receive appropriate training and maintain appropriate certifications (e.g., Basic Life Support, Advanced Cardiopulmonary Life Support, Pediatric Acute Life Support).

Immunization Programs. The pharmacy shall participate in the development of hospital policies and procedures concerning preventive and postexposure immunization programs for patients and hospital employees.⁸ When practical, pharmacists should participate as active immunizers for hospital and health-system-based preventive immunization programs (e.g., influenza).

Substance Abuse Programs. The pharmacy shall assist in the development of and participate in hospital substance abuse education, prevention, identification, treatment, and employee assistance programs.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 professional and supportive personnel shall be clearly defined in written position descriptions. These position descriptions shall be reviewed and revised as required by the hospital's policies. Position descriptions should reflect more general aspects of performance (e.g., communication, motivation, teamwork) in addition to specific responsibilities and competencies.

Director of Pharmacy. The pharmacy shall be managed by a professionally competent, legally qualified pharmacist. The director of pharmacy should be thoroughly knowledgeable about and have experience in hospital pharmacy practice and management. An advanced management degree (e.g., M.B.A., M.H.A., or M.S.) or an administrative specialty residency¹⁰ is desirable.

The director of pharmacy shall be responsible for

- Establishing the mission, vision, goals, and scope of services of the pharmacy based on the needs of the patients served, the needs of the hospital (and any health system of which the hospital may be a component), and developments and trends in health care and hospital pharmacy practice,
- Developing, implementing, evaluating, and updating plans and activities to fulfill the mission, vision, goals, and scope of services of the pharmacy,

- Actively working with or as a part of hospital or health-system leadership to develop and implement policies and procedures that provide safe and effective medication use for the patients served by the institution,
- 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 adherence to applicable state and federal laws and regulations, hospital privileging requirements, and national practice standards.

A part-time director of pharmacy shall have the same obligations and responsibilities as a full-time director.

Pharmacists. The pharmacy shall employ an adequate number of competent, legally qualified pharmacists to meet the specific medication-use needs of the hospital's patients. Pharmacists hired on a temporary or contract basis shall meet the same requirements as those employed by the hospital.

Support Personnel. Sufficient support personnel (e.g., pharmacy technicians and clerical or secretarial personnel) shall be employed to facilitate pharmacy services. Support positions shall have a written job description that includes a statement of the competencies required for that position. Support staff shall be properly trained and supervised, and professional development programs for them are desirable. Pharmacy technicians should have completed an ASHP-accredited pharmacy technician training program, should be certified by the Pharmacy Technician Certification Board, and shall meet the requirements of applicable laws and regulations. Pharmacy technicians working in advanced roles should have additional training and demonstrate competencies specific to the tasks to be performed.

Education and Training. All personnel shall possess the education and training required to fulfill their responsibilities and shall participate in relevant continuing-education programs and activities as necessary to maintain or enhance their competence.¹¹

Recruitment, Selection, and Retention of Personnel. Personnel should be recruited and selected by the pharmacy director on the basis of job-related qualifications and prior performance. An employee retention plan is desirable.¹²

Orientation of Personnel. There shall be an established, structured procedure for orienting new personnel to the pharmacy, the hospital, and their respective positions.⁹ Evaluation of the effectiveness of orientation programs should be done in conjunction with the competency assessment required before a new hire can assume full responsibility for the new position.

Work Schedules and Assignments. The director of pharmacy shall ensure that work schedules, procedures, and assignments optimize the use of personnel and resources. There shall be a written departmental staffing plan that addresses how patients' needs will be met during periods of staff

shortages and fluctuation in workload and/or patient acuity. Remote medication order processing may be employed to help address staff shortages or workload fluctuations.³

Performance Evaluation. There shall be procedures for regularly scheduled evaluation of the performance of pharmacy personnel. The evaluation format should be consistent with that used by the hospital. The competencies of the position shall be well defined in the position description, short- and long-term goals should be established for each employee, and the employee's competency shall be assessed regularly. The pharmacy director shall ensure that an ongoing competency assessment program is in place for all staff, and each staff member should have a continuous professional development plan.

Effective Communication. There should be established methods for communicating important information to staff in a timely manner (e.g., electronic communications, staff meetings, newsletters, bulletin boards). The pharmacy should establish appropriate mechanisms to regularly assess the effectiveness of such communications.

Ethical Conduct. Standards of ethical conduct shall be established, and there shall be procedures for educating all pharmacy staff regarding these standards. The institution's conflict-of-interest and ethical conduct policies shall be clearly communicated to all staff, with appropriate staff acknowledgement of conformance with these policies.¹³

E. Facilities

Pharmacy. Adequate space, equipment, and supplies shall be available for all professional and administrative functions relating to pharmacy services. These resources shall meet all applicable laws and regulations; shall be located in areas that facilitate the provision of services to patients, nurses, prescribers, and other health care providers; and shall be integrated with the hospital's communication and delivery or transportation systems.

Medication Storage and Preparation Areas. There shall be suitable facilities to enable the receipt, storage, and preparation of medications under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security to ensure medication integrity and personnel safety throughout the hospital.⁴

Compounding Areas. There shall be suitable facilities to enable the compounding, preparation, and labeling of sterile and nonsterile 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.^{14–20}

Patient Assessment and Consultation Area. In outpatient settings, a private area for pharmacist–patient consultations shall be available to confidentially enhance patients' knowledge of and adherence to prescribed medication regimens.²¹

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

Automated Systems. There shall be policies and procedures for the evaluation, selection, use, calibration, monitoring, and maintenance of all automated pharmacy systems. Automated mechanical systems and software can promote safe, accurate, and efficient medication ordering and preparation, drug distribution, and clinical monitoring. Use of such systems and software shall be structured so as to not hinder the pharmacist's review of (and opportunity to intervene in) medication orders before the administration of first doses. The maintenance, calibration, and certification of all automated systems shall be performed and documented as required by all applicable laws, regulations, and standards.^{6,22,23} 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.

Information Technology. A comprehensive pharmacy computer system shall be employed and should be integrated to the fullest extent possible with other hospital information systems and software, including computerized provider-order-entry, medication administration, electronic health record, and patient billing systems. 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 of care to and from other care settings. Pharmacists should be involved in the development and maintenance of order sets, templates, and dose ranges used in computerized provider-order-entry and clinical decision-support systems. Pharmacy computer systems should be integrated with the hospital's clinical, financial, and administrative information systems. All computer systems shall include adequate safeguards to maintain the confidentiality and security of patient records, and a backup system should be available to continue essential computerized functions (e.g., those that support patient care) during equipment failure.

Drug Information. Adequate space, current resources, and information-handling and communication technology shall be available to facilitate the provision of drug information. The department of pharmacy shall select its drug information resources, and pharmacists shall play a leadership role in the selection of drug information resources used by other health care providers in the hospital. Up-to-date, objective drug information shall be available, including current print or electronic periodicals, newsletters, best-practices guidelines, and recent editions of reference books in appropriate pharmaceutical and biomedical subject areas. Electronic drug information databases are preferred because they are frequently updated and can be made available to all health care professionals, but sufficient access to print information shall be available in case of equipment failure or downtime. Electronic and print drug information may be supplemented with medical libraries and other available resources. Appropriate drug information resources shall be readily accessible to pharmacists located in patient care areas.

Electronic databases and convenient methods of data dissemination (e.g., e-mail and handheld devices) are desirable. If such tools are employed, they should be made available to all health care practitioners who require access to the data.

Record Maintenance. All records shall be maintained in accordance with applicable laws, regulations, and institutional policies. Adequate space shall exist for maintaining and storing records (e.g., equipment maintenance, controlled substances inventory, and material safety data sheets) to ensure compliance with laws, regulations, accreditation requirements, and sound management practices. Appropriate licenses and permits shall be on display or on file as required by law or regulation. Equipment shall be adequately maintained and certified in accordance with applicable practice standards, laws, and regulations. There shall be documentation of equipment maintenance and certification.

F. Committee Involvement

A pharmacist shall be a member of and actively participate in hospital and health-system committees responsible for establishing and implementing medication-related policies and procedures as well as those committees responsible for the provision of patient care, including the P&T, infection-prevention and control, patient care, medication-use evaluation, medication safety, nutrition, and pain management committees (or their equivalents), as well as the institutional review board, quality-improvement, and information technology committees (or their equivalents).^{5,24-26}

Standard II. Medication-Use Policy Development

A. Policy Development

All committees that make decisions concerning medication management and use shall have at least one pharmacist as a member. This includes the P&T, infection-control, patient care, medication-use evaluation, medication safety, nutrition, pain management, and information technology committees, as well as the institutional review board (or their equivalents).^{5,24-26} Pharmacists shall be involved in the development, implementation, and assessment of care plans (protocols, critical pathways, disease state management programs, or clinical practice guidelines), standing orders, and order sets that involve medication therapy.²⁷

B. Formulary Management

Formulary. A well-controlled formulary of approved medications shall be maintained and regularly updated by the P&T committee (or its equivalent). The impact of and compliance with the formulary should be periodically reviewed (e.g., through drug-utilization reviews), and the P&T committee should regularly review the formulary for safety information. The P&T committee shall be responsible for developing and maintaining written criteria for drug product selection, which shall address formulary requests for medications intended for use in special populations (e.g., pediatric or geriatric populations). The P&T committee shall be responsible for developing and maintaining adequate product specifications to aid in the purchase of medications

and related supplies. The pharmacy shall disseminate the formulary by electronic (preferred) or other means to meet the needs of all health care professionals.

There shall be policies and procedures that address the use of dietary supplements and other alternative therapies.

There shall be policies and procedures for the procurement, control, and use of nonformulary medications required for patient care.⁵

Medication Therapy Monographs. Medication therapy monographs for medications under consideration for formulary addition or deletion shall be made available to the P&T committee for use in the decision-making process. These monographs should be based on evidence gathered through review and evaluation of the pertinent literature. Each monograph shall include a comparative therapeutic, economic, and risk assessment (inclusive of black-box warnings) of each medication. The risk assessment should address the likelihood of an error occurring and the risk of injury should that error occur.⁵

Nondrug Substances. There shall be policies and procedures that describe how the pharmacy shall seek and obtain documented authorization from appropriate medical staff and hospital committees prior to the medical use of any chemical substance that has not received Food and Drug Administration (FDA) approval for use as a drug or medical nutrition therapy. All chemical or biological substances whose administration is intended for pharmacological or medical effect or as a substitute for or complement to approved drugs shall be under the control of the pharmacy. Documentation shall exist to ensure that appropriate risk management measures (e.g., obtaining informed consent) have been taken.

C. Drug Information

Drug Information Requests. The pharmacist shall provide patient-specific drug information and accurate and comprehensive information about drugs and drug therapy to health professionals, patients, and patients' caregivers as appropriate. Responses to general and patient-specific drug information requests shall be provided in an accurate and timely manner by a pharmacist, and there should be a process for assessing and ensuring the quality of responses.²⁸

Dissemination of Drug Information. Pharmacists shall keep the hospital's staff and health care providers informed about the use of medications on an ongoing basis through appropriate publications, presentations, and programs. Pharmacists shall ensure timely dissemination of drug product information (e.g., recall notices, labeling changes, and changes in product availability). Electronic communications (e.g., websites, email newsletters, intranet postings) are preferred because of their timeliness and accessibility.²⁸

Standard III. Optimizing Medication Therapy

An important responsibility of the pharmacist is optimizing medication use. Pharmacists, in collaboration with medical and nursing staff, shall develop policies and procedures based on demonstrated best practices for ensuring the qual-

ity of medication therapy. Clinical imperatives should be the primary determinants of medication-use decisions.

A. Creating a Relationship with the Patient

Pharmacist Role in Direct Patient Care. Hospital and pharmacy department policies should encourage pharmacists to provide direct patient care to the greatest extent possible in both inpatient and outpatient settings. Hospital and pharmacy department policies should encourage pharmacists to engage in medication therapy management,²⁹ collaborative drug therapy management, immunization, medication ordering and administration, and other patient care activities to the extent permitted by law, regulation, and hospital requirements.

Continuity of Care. Pharmacists should assume responsibility for continuity of care for patients' medication therapy. Pharmacists and pharmacy departments should take a leadership role in developing and implementing policies and procedures for admissions, discharges, and transfers so that patients' medication therapy is well managed regardless of patient transitions across care settings (e.g., among different components of a health system or between inpatient and community pharmacies or home care services).

Patient Confidentiality. Systems shall be in place to ensure that patient confidentiality is maintained in accordance with applicable laws and regulations. All pharmacy personnel shall respect and protect patient confidentiality by safeguarding access to all patient information. Patient information shall be shared only with authorized health professionals and others authorized within the hospital or health system as needed for the care of patients.³⁰ Pharmacy personnel should periodically receive training in how to comply with patient confidentiality laws and regulations.

B. Acquiring Essential Patient Data

Pharmacists should obtain, prepare, or have immediate access to comprehensive medication histories for each patient, from the patient's medical record or other databases (e.g., a medication profile), or both. A pharmacist-conducted medication history for each patient is desirable. Electronic medical records should be constructed so that medication histories and other data required for medication management, including medication reconciliation, are available to all health professionals caring for a patient.

C. Consulting With Other Health Professionals About Medication Therapy

Pharmacist's Consultations. Pharmacists should provide oral and written consultations to other health professionals regarding medication therapy selection and management.³⁰

Medical Record Documentation. There shall be policies and procedures for pharmacist review of and documentation in patients' medical records. Recommendations made by the pharmacist and actions taken in response to those recommendations should be documented in the patient's medical record so that other health care providers have access to that information.³⁰

Medication Therapy Decisions. The pharmacist's prerogatives to initiate, monitor, and modify medication therapy for

individual patients, and to order laboratory tests to exercise those responsibilities, consistent with laws, regulations, and hospital policy, shall be clearly delineated and approved by the appropriate committee (e.g., P&T, patient care, or medical executive committee).

Standard IV. Drug Product Procurement and Inventory Management

The pharmacy shall be responsible for the procurement, distribution, and control of all drug products used in the hospital for inpatient and ambulatory patients. Policies and procedures governing these functions shall be developed by the pharmacy with input from other appropriate hospital staff and committees.⁴

A. Selecting Sources of Pharmaceutical Products

Medication Acquisition. There shall be policies and procedures for managing medication acquisition. These policies and procedures should address such issues as formulary development (including initial evaluation for formulary consideration, medication-utilization review programs, and therapeutic interchange), competitive bidding, group purchasing, best practices, medication shortages, outsourcing, and cost-effective patient services. Benchmarking of medication costs should be performed to determine whether medication expenses and the change in medication expenses over time are consistent with industry standards.^{4,31,32}

Pharmaceutical Manufacturers And Suppliers. Criteria for selecting drug product manufacturers and suppliers shall be established by the pharmacy to ensure the highest quality of and the best price for drug products. Although these duties may be delegated in part to a group purchasing organization, the pharmacy maintains the sole responsibility for ensuring the quality of drug products used in the hospital.^{31,32}

Pharmaceutical Manufacturers' Representatives. There shall be written policies governing the activities of manufacturers' representatives or vendors of drug products (including related supplies and devices) within the hospital. Representatives should not be permitted access to patient care areas and should be provided with written guidance on permissible activities within the hospital. All promotional materials and activities shall be reviewed and approved by the pharmacy.³³

B. Managing Inventory

Medication Storage. Medications shall be received, stored, and prepared under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security to ensure medication integrity and personnel safety.⁴

Drug Shortages. There shall be policies and procedures for managing drug product shortages. The pharmacy's inventory management system should be designed to detect subminimum inventory levels and alert the pharmacy to potential shortages, and pharmacy staff should monitor reliable sources of information regarding drug product shortages (e.g., the ASHP³⁴ and FDA³⁵ drug shortages web resource centers). The pharmacy should develop strategies for identifying alternative therapies, working with suppliers, collabora-

rating with physicians and other health care providers, and conducting an awareness campaign in the event of a drug product shortage.³⁶

Samples. The use of medication samples shall be eliminated to the extent possible. Medication samples shall never be used for inpatient treatment. If use of samples is otherwise permitted, there shall be policies and procedures to ensure their safe use. The pharmacy shall oversee the procurement, storage, and distribution of these products to ensure proper storage, maintenance of records, product integrity, and compliance with all applicable packaging and labeling laws, regulations, standards, and patient education requirements. Pharmacists should be involved in hospital efforts to secure safe and effective low-cost medications for low-income patients (e.g., through manufacturer patient assistance programs).^{4,5,33}

Patient Care Area Stock. The proper use of automated dispensing devices reduces the need for medications to be stored in nonpharmacy areas.⁶ Storage of medications in nonpharmacy areas (e.g., patient care and procedural areas) shall to the extent possible be limited to medications for emergency use and routinely used personal care items (e.g., mouthwash and antiseptic solutions). The list of medications to be accessible and the policies and procedures regarding their use shall be developed by a multidisciplinary committee of physicians, pharmacists, and nurses (e.g., the P&T committee).⁵ Access to medications should be limited to cases in which the committee determines that the 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. There shall be policies and procedures to ensure control of the distribution and use of controlled substances and other medications with a potential for abuse. These policies and procedures shall be consistent with applicable laws and regulations and shall include methods for preventing and detecting diversion.⁴

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

C. Inspecting Storage Areas and Inventory Items

All stocks of medications shall be inspected routinely to ensure the absence of outdated, unusable, recalled, or mislabeled products. Storage conditions that would foster medication deterioration, storage arrangements that might contribute to medication errors, and other safety issues shall be assessed, documented, and corrected.⁴

D. Returning Recalled, Expired, and Other Unusable Items

There shall be a written procedure for the timely handling and documentation of a drug product recall. These proce-

dures should include an established process for removing from use any drugs or devices subjected to a recall, notifying appropriate health care professionals, identifying 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 the nursing or medical staffs. All drug product defects should be reported to the FDA's MedWatch reporting program.⁴

Standard V. Preparing, Packaging, and Labeling Medications

A. Preparing Medications

Compounding. Drug formulations, dosage forms, strengths, and packaging that are not available commercially but are needed for patient care shall be prepared by appropriately trained personnel in accordance with applicable practice standards and regulations. The pharmacy shall provide adequate quality-assurance procedures 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.^{14–20}

Sterile Preparations. When possible, manufactured sterile preparations should be preferred to compounding in the pharmacy. All sterile medications shall be prepared and labeled in a suitable environment by appropriately trained personnel in accordance with established quality-assurance and expiration dating procedures.^{14,19} The use of sterile medications compounded outside the pharmacy should be avoided to the extent possible; when they are used, there shall be procedures for aseptic preparation, quality assurance, expiration dating, and ongoing competency evaluations for compounding personnel.^{14,19,37} Sterile compounding outside the pharmacy or satellite pharmacies (e.g., on nursing units) should be minimized and occur only in emergency situations.^{14,19}

Hazardous Drug Products. There shall be policies and procedures that describe special precautions, equipment, and training for preparation, handling, storage, and disposal of hazardous drug products and products used in their preparation. These policies and procedures shall be consistent with applicable laws and regulations and should be adequate to ensure the safety of staff, patients, visitors, the community, and the environment.¹⁷

B. Packaging Medications

Unit Dose Packaging. Whenever possible, medications shall be available for inpatient use in single-unit packages and in a ready-to-administer form. Manipulation of medications before administration (e.g., withdrawal of doses from containers, reconstitution of powdered drug products, labeling of containers, and splitting of tablets) by final users should be minimized.¹⁵

Bar-Coding of Unit Dose Packaging and Point of Care Administration. Unit dose packages should contain a bar

code and that code should be used in inventory management, dose preparation and packaging, dispensing, and administration. It is the responsibility of the pharmacy department to ensure the quality of all aspects of bar-code medication administration, including scanability of bar codes and database management.^{38,39}

Standard VI. Medication Dispensing and Delivery

A. Medication Dispensing

Prescribing. Medications shall be prescribed by individuals who have been granted appropriate clinical privileges in the hospital and are legally permitted to order medications. The pharmacy shall advocate and foster practitioners' conformance with standardized, approved, and safe terminology and abbreviations to be used throughout the hospital when prescribing medications and discourage use of nonstandard and unapproved terminology and abbreviations.⁴

Diagnostic or Therapeutic Purpose. Pharmacists should have immediate access to the patient's diagnosis or the intended therapeutic or medical purpose of medications.

Medication Orders. All patient medication orders shall be contained in the patient's medical record. A direct copy of the prescriber's order, either hard copy (including facsimile) or prescriber-entered electronic transmission (preferred method), shall be received by the pharmacist. Oral orders should be avoided to the extent possible. When oral orders are necessary, they shall follow the organization's established procedures for their use and documentation. Order transmittal safeguards should be used to ensure the security of the prescriber's order. Appropriate records of each medication order and its processing in the pharmacy shall be maintained in accordance with applicable laws and regulations.

A system shall exist to ensure that medication orders are not inappropriately continued.⁴

Review of Medication Orders. All medication orders shall be prospectively reviewed by a pharmacist and assessed in relation to pertinent patient and clinical information before the first dose is administered or made available in an automated dispensing device, except in emergent situations in which the treatment of the patient would be significantly compromised by the delay that would result from pharmacist review of the order. There shall be a procedure for retrospective review of these orders.

Any questions regarding an order shall be resolved with the prescriber prior to administration, and any action taken as a result of this intervention should be documented in the patient's medical record. Information concerning changes shall be communicated to the appropriate health professionals caring for the patient.⁴

B. Medication Delivery and Administration

Drug Delivery Systems, Administration Devices, and Automated Distribution Devices. The pharmacy shall have responsibility for developing policies, procedures, and quality-assurance programs regarding drug delivery systems,

administration devices, and automated distribution devices that ensure safety, accuracy, security, and patient confidentiality. The potential for medication errors associated with such systems and devices should be thoroughly evaluated.^{4,6} Pharmacy personnel shall supervise the stocking and documentation of medications in automated dispensing devices.⁶ Whenever possible, automated dispensing cabinets should employ profile-based technology integrated with remote medication order-entry capabilities.

Medication Administration. Only personnel who are authorized by the hospital in accordance with applicable laws and regulations and appropriately trained shall be permitted to administer medications to a patient. All administered, refused, or omitted medication doses should be recorded in the patient's medical record according to an established procedure, and all medications that have not been administered should be returned to the pharmacy. No medication should be administered to a patient unless medical and nursing personnel have been provided with adequate information about, and are familiar with, its therapeutic use, method of administration, potential adverse effects, and dosage.

Standard VII. Monitoring Medication Use

A. Reviewing Patient Responses to Medication Therapy

Medication therapy monitoring shall be conducted by pharmacists. Medication therapy monitoring includes a proactive assessment of patient problems and an assessment of

- a. The therapeutic appropriateness of the patient's medication regimen.
- b. Therapeutic duplication or omissions in the patient's medication regimen.
- c. The appropriateness of the dose of the medication, as well as the route, method, and frequency of administration of the medication.
- d. Patient adherence to the prescribed medication regimen.
- e. Medication–medication, medication–food, medication–dietary supplement, medication–laboratory test, and medication–disease interactions.
- f. Adverse drug reactions and other undesired effects.⁴⁰
- g. Patient medication allergies and sensitivities.
- h. Clinical and pharmacokinetic laboratory data to evaluate the efficacy and safety of medication therapy and to anticipate toxicity and adverse effects.
- i. Physical signs and clinical symptoms relevant to the patient's medication therapy.
- j. Assessment of the effectiveness of the patient's medication therapy.

B. Educating and Counseling Patients and Family

Pharmacists shall be available to participate in patient education. Pharmacists should help to ensure that all patients are given adequate information about the medications they receive in order to help patients participate in their own health care decisions and encourage adherence to medication regimens. Patient education activities shall be coordinated with the nursing, medical, and other clinical staff as needed. Medication-related material developed by other ser-

vices and departments as well as commercial sources should be reviewed by the pharmacy staff for accuracy, currency, literacy appropriateness, and completeness. If necessary, interpretative language services (written or oral) should be made available to patients.²¹

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

There shall be an ongoing, systematic program for quality assessment and improvement of pharmacy services and the medication-use system. The program should include routinely evaluating the literature for new technologies or successful practices that have been demonstrated to enhance safety in other organizations to determine if such technologies or practices can improve the hospital's medication-use system. This program should be integrated with the hospital's or health system's quality assessment and quality improvement activities. Quality-improvement activities related to the selection, prescription, procurement, storage, preparation, dispensing, distribution, administration, documentation, monitoring, and use of medications shall be routinely performed in cooperation with other health care providers. Feedback to appropriate individuals or entities about the quality achieved shall be provided.

A. Assessing Pharmacy Services and Practices

Documentation of Pharmacist-Provided Patient Care Services and Medication Therapy Outcomes. The pharmacy shall have an ongoing process for consistent documentation of the patient care services provided by pharmacists and patient outcomes from medication therapy.³⁰

Workload and Financial Performance. A process shall exist to routinely monitor and document workload and financial performance. Metrics should encompass the full scope of patient care services provided by pharmacists and the pharmacy enterprise. This process should provide for the determination and analysis of hospital and systemwide costs of medication therapy. A pharmacist should be an integral part of the hospital's leadership teams (e.g., administrative, financial).

B. Improving the Medication-Use Process

Medication-Use Evaluation. There shall be an ongoing program for monitoring drug utilization and costs to ensure that medications are used appropriately, safely, and effectively and to increase the probability of desired patient outcomes. The P&T committee (or its equivalent) should define specific parameters for evaluation (e.g., disease state, pharmacological category, or 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.^{32,41}

Medication Safety. Pharmacists should provide leadership to and participate in collaborative, multidisciplinary efforts to prevent, detect, and resolve drug-related problems that can result in patient harm. Pharmacists and other appropriate hospital personnel shall establish and regularly revise policies

and procedures regarding medication error and adverse event prevention and reporting. Monitoring, detecting, review, and analysis of the hospital and health system's medication errors and near-misses should be an ongoing process in a just culture environment,⁴² and corresponding corrective actions should be documented. An ongoing program for preventing, monitoring, resolving, and reporting adverse drug events shall be developed.⁴⁰ A pharmacist shall participate in appropriate organizational committees and work with physicians, nurses, administrators, and others to examine and improve systems to ensure that medication-use processes are safe.⁴¹

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 relevant multidisciplinary 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.²⁴

Standard IX. Research

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

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 assure that informed consent is obtained from the patient before the first dose of the study drug is administered.^{5,44,45}

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.^{5,44,45}

Institutional Review Board. A pharmacist shall be a member of the hospital's institutional review board (or equivalent body), if one exists.⁴⁴

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 investiga-

tional drugs, including possible adverse effects and adverse drug reactions, to nurses, pharmacists, physicians, and other health care professionals called upon to prescribe, dispense, and administer these medications.^{44,45}

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