

# ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals

Pharmacists work closely with other health practitioners to meet the needs of the public. The various societal needs for pharmaceutical care require that pharmacies provide a wide array of organized services. The primary purpose of this document is to serve as a guide for the provision of pharmaceutical services in hospitals; however, certain elements may be applicable to other health care settings. These Guidelines should also be useful in evaluating the scope and quality of these services.

As providers of pharmaceutical care, pharmacists are concerned with the outcomes of their services and not just the provision of these services. The elements of a pharmacy program that are critical to overall successful performance in a hospital include (1) leadership and practice management, (2) drug information and education, (3) activities to ensure rational medication therapy, (4) drug distribution and control, (5) facilities, and (6) participation in drug therapy research. Collectively, these elements represent a minimum level of practice that all hospital pharmacy departments must 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, these elements are inextricably linked to outcomes. Hence, failure to provide any of these services may compromise the overall quality of pharmaceutical care.

These Guidelines outline the minimum requirements for pharmaceutical services in hospitals. The reader is encouraged to review the ASHP practice standards referenced throughout this document for a more detailed description of the components of these services.

## 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 hospital's and patients' needs as well as continuous improvement in patient care outcomes. Pharmaceutical service management must focus on the pharmacist's responsibility to provide pharmaceutical care and to develop an organizational structure to support that mission.

The director of the pharmacy shall 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 hospital (and any health system of which the hospital may be a component), and developments and trends in health care and hospital 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. The director of the pharmacy, in carrying out the aforementioned tasks, shall employ an adequate number of competent, qualified personnel. A part-time director of the pharmacy has the same basic obligations and responsibilities as a full-time director.

- **Education and training, director.** The pharmacy shall be managed by a professionally competent, legally

qualified pharmacist. The director of the pharmacy service must be thoroughly knowledgeable about hospital pharmacy practice and management. He or she should have completed a pharmacy residency program accredited by the American Society of Health-System Pharmacists.<sup>1</sup> An advanced management degree (e.g., M.B.A., M.H.A., M.S.) is desirable.

- **Pharmacy mission.** The pharmacy shall have a written mission statement that, at a minimum, reflects both patient care and operational responsibilities. Other aspects of the mission may be appropriate as well, for example, educational and research responsibilities in the case of teaching and research hospitals. The statement shall be consistent with the mission of the hospital (and health system of which the hospital may be a component). The mission should be understood by every employee and other participant (e.g., students and residents) in the pharmacy's activities.
- **Support personnel.** Sufficient support personnel (pharmacy technicians, clerical, secretarial) shall be employed to facilitate the implementation of pharmaceutical care. Pharmacy technicians should be certified by the Pharmacy Technician Certification Board and should have completed an accredited training program. Appropriate supervisory controls must be maintained and documented.
- **Work schedules and assignments.** The director of the pharmacy shall ensure that work schedules, procedures, and assignments optimize the use of personnel and resources.
- **Education and training.** All personnel must possess the education and training needed to fulfill their responsibilities. All personnel must participate in relevant continuing-education programs and activities as necessary to maintain or enhance their competence.<sup>2</sup>
- **Recruitment and selection of personnel.** Personnel must be recruited and selected on the basis of job-related qualifications and prior performance.
- **Orientation of personnel.** There must be an established procedure for orienting new personnel to the pharmacy, the hospital, and their respective positions.<sup>3</sup>
- **Performance evaluation.** Procedures for the routine evaluation of the performance of pharmacy personnel shall exist.
- **Position descriptions.** Areas of responsibility within the pharmacy shall be clearly defined. Written position descriptions for all categories of pharmacy personnel must exist and must be revised as necessary.
- **Operations manual.** An operations manual governing pharmacy functions (e.g., administrative, operational, and clinical) shall exist. It should include long-term goals for the pharmacy. The manual must be revised when necessary to reflect changes in procedures, organization, and objectives. All personnel should be familiar with the contents of the manual. Appropriate mechanisms to ensure compliance with the policies and procedures should be established.
- **Drug expenditures.** Policies and procedures for managing drug expenditures shall exist. They should address

such methods as competitive bidding, group purchasing, utilization-review programs, and cost-effective patient services.<sup>4</sup>

- **Workload and financial performance.** A process shall exist to routinely monitor workload and financial performance. 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 financial management team.
- **Committee involvement.** A pharmacist should be a member of and actively participate in those committees responsible for establishing medication-related policies and procedures as well as those committees responsible for the provision of patient care.
- **Quality assessment and improvement.** There shall be an ongoing, systematic program for quality assessment and improvement of the pharmacy and medication-use process. 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 distribution, administration, and use of medications shall be routinely performed. Feedback to appropriate individuals about the quality achieved shall be provided.
- **24-hour pharmaceutical services.** Adequate hours of operation for the provision of needed pharmaceutical services must be maintained; 24-hour pharmaceutical services should be provided if possible. Twenty-four-hour pharmaceutical services should exist in *all* hospitals with clinical programs that require intensive medication therapy (e.g., transplant programs, open-heart surgery programs, and neonatal intensive care units). When 24-hour pharmacy service is not feasible, a pharmacist must be available on an on-call basis.
- **After-hours pharmacy access.** In the absence of 24-hour pharmaceutical services, access to a limited supply of medications should be available to authorized nonpharmacists for use in carrying out urgent medication orders. 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 the pharmacy and therapeutics (P&T) committee (or its equivalent). Items for such access should be chosen with safety in mind, limiting wherever possible medications, quantities, dosage forms, and container sizes that might endanger patients. Routine after-hours access to the pharmacy by nonpharmacists (e.g., nurses) for access to medications is strongly discouraged; this practice should be minimized and eliminated to the fullest extent possible. The use of well-designed night cabinets, after-hours medication carts, and other methods precludes the need for nonpharmacists to enter the pharmacy.<sup>5</sup> For emergency situations in which nonpharmacist access is necessary, policies and procedures should exist for safe access to medications by persons who receive telephone authorization from an on-call pharmacist.
- **Practice standards and guidelines.** The practice standards and guidelines of the American Society of Health-System Pharmacists and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or other appropriate accrediting body should be viewed as

applicable, and the hospital should strive to meet these standards regardless of the particular financial and organizational arrangements by which pharmaceutical services are provided to the facility and its patients.

- **Laws and regulations.** Applicable laws and regulations must be met and relevant documentation of compliance must be maintained (e.g., records, material safety data sheets, copies of state board regulations).
- **Patient confidentiality.** The pharmacist shall respect and protect patient confidentiality by safeguarding access to computer databases and reports containing patient information. Patient information should be shared only with authorized health professionals and others authorized within the hospital or health system as needed for the care of patients.

## Standard II: Drug information and Education

The pharmacist shall provide patient-specific drug information and accurate and comprehensive information about drugs to other pharmacists, other health professionals, and patients as appropriate.

Up-to-date drug information shall be available, including current periodicals and recent editions of textbooks in appropriate pharmaceutical and biomedical subject areas. Electronic information is desirable. This information may be provided in conjunction with medical libraries and other available resources. Appropriate drug information resources shall be readily accessible to pharmacists located in patient care areas. No medication should be administered to a patient unless medical and nursing personnel have received adequate information about, and are familiar with, its therapeutic use, potential adverse effects, and dosage.

- **Drug information requests.** Responses to general and patient-specific drug information requests shall be provided in an accurate and timely manner. A process shall exist to assess and ensure the quality of responses to requests.
- **Medication-therapy monographs.** Medication-therapy monographs for medications under consideration for formulary addition or deletion shall be available. These monographs should be based on an analytical review of pertinent literature. Each monograph shall include a comparative therapeutic and economic assessment of each medication proposed for addition.
- **Patient education.** Pharmacists should be available for and actively participate in patient education. Pharmacists must help to ensure that all patients are given adequate information (including information on ethical issues, if any) about the medications they receive. Patient education activities shall be coordinated with the nursing, medical, and other clinical staff as needed.<sup>6</sup>
- **Dissemination of drug information.** Pharmacists should keep the hospital's staff informed about the use of medications on an ongoing basis through appropriate publications, presentations, and programs. Pharmacists should ensure timely dissemination of drug product information (e.g., recall notices, labeling changes).

### Standard III: Optimizing Medication Therapy

An important aspect of pharmaceutical care is optimizing medication use. This must include processes designed to ensure the safe and effective use of medications and increase the probability of desired patient outcomes. The pharmacist, in concert with the medical and nursing staff, must develop policies and procedures for ensuring the quality of medication therapy.

- **Medical record documentation.** Clinical actions and recommendations by pharmacists that are designed to ensure safe and effective use of medications and that have a potential effect on patient outcomes should be documented in patients' medical records.<sup>7</sup>
- **Medication histories.** Pharmacists should prepare or have immediate access to comprehensive medication histories for each patient's medical record or other databases (e.g., medication profile), or both. A pharmacist-conducted medication history for each patient is desirable.
- **Medication orders.** All prescribers' medication orders (except in emergency situations) must be reviewed for appropriateness by a pharmacist before the first dose is dispensed. Any questions regarding the order must be resolved with the prescriber at this time, and a written notation of these discussions must be made in the patient's medical record or pharmacy copy of the prescriber's order. Information concerning changes must be communicated to the appropriate health professional.
- **Medication-therapy monitoring.** Medication-therapy monitoring shall be conducted for appropriate patients and medication use. Medication-therapy monitoring includes an assessment of
  - a. The therapeutic appropriateness of the patient's medication regimen.
  - b. Therapeutic duplication in the patient's medication regimen.
  - c. The appropriateness of the route and method of administration of the medication.
  - d. The degree of patient compliance with the prescribed medication regimen.
  - e. Medication–medication, medication–food, medication–laboratory test, and medication–disease interactions.
  - f. Clinical and pharmacokinetic laboratory data to evaluate the efficacy of medication therapy and to anticipate toxicity and adverse effects.
  - g. Physical signs and clinical symptoms relevant to the patient's medication therapy.
- **Therapeutic purpose.** Prescribers should be encouraged to routinely communicate the condition being treated or the therapeutic purpose of medications with all prescription and medication orders.
- **Pharmacist consultations.** Pharmacists should provide oral and written consultations to other health professionals regarding medication-therapy selection and management.
- **Medication-use evaluation.** An ongoing medication-use evaluation program shall exist to ensure that medications are used appropriately, safely, and effectively.<sup>8</sup>
- **Medication-use policy development.** The pharmacist shall be a member of the P&T committee, the institutional review board, and the infection control, patient

care, medication-use evaluation, and other committees that make decisions concerning medication use.

- **Documentation of pharmaceutical care and outcomes.** The pharmacy shall have an ongoing process for consistent documentation (and reporting to medical staff, administrators, and others) of pharmaceutical care and patient outcomes from medication therapy and other pharmacy actions.
- **Continuity of care.** The pharmacist shall routinely contribute to processes ensuring that each patient's pharmaceutical care is maintained regardless of transitions that occur across different care settings (for example, among different components of a health system or between inpatient and community pharmacies or home care services).
- **Work redesign initiatives.** The pharmacist must be involved in work redesign initiatives such as patient-focused care, where they exist. These efforts should be such that pharmaceutical care is enhanced and supported.
- **Clinical care plans.** Pharmacists must be involved in the development of clinical care plans involving medication therapy.
- **Microbial resistance.** Policies and procedures addressing microbial resistance to anti-infectives shall exist. Pharmacists should review laboratory reports of microbial sensitivities and advise prescribers if microbial resistance is noted.
- **Medication-therapy decisions.** The pharmacist's prerogatives to initiate, monitor, and modify medication therapy for individual patients, consistent with laws, regulations, and hospital policy, shall be clearly delineated and approved by the P&T committee (or comparable body).
- **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.<sup>9</sup>
- **Substance-abuse programs.** The pharmacy shall assist in the development of and participate in hospital substance-abuse prevention and employee assistance programs, where they exist.

### Standard IV: Medication Distribution and Control

The pharmacy shall be responsible for the procurement, distribution, and control of *all* drug products used in the hospital (including medication-related devices and pharmaceutical diagnostics) for inpatient and ambulatory patients.<sup>10</sup> Policies and procedures governing these functions shall be developed by the pharmacy with input from other appropriate hospital staff and committees.

- **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 or prescriber-entered electronic transmission (preferred method), shall be received by the pharmacist. Order-transmittal safeguards should be used to ensure the security of the prescriber's order. All medication orders shall be reviewed by a pharmacist and assessed in relation to a medication profile before administration, unless an established procedure exists for the use of an

approved list of medications for specific treatment circumstances and emergencies. A system shall exist to ensure that medication orders are not inappropriately continued.

- **Formulary.** A formulary of approved medications shall be maintained by the pharmacy.<sup>11</sup>
- **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 terminology and abbreviations to be used throughout the hospital when prescribing medications.
- **Medication administration.** Only personnel who are authorized by the hospital and appropriately trained shall be permitted to administer medications to a patient. This may include pharmacists and other pharmacy personnel.
- **Extemporaneous 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 (e.g., FDA, state board of pharmacy). Adequate quality assurance procedures shall exist for these operations.<sup>12</sup>
- **Sterile products.** All sterile medications shall be prepared and labeled in a suitable environment by appropriately trained personnel. Quality assurance procedures for the preparation of sterile products shall exist.<sup>13</sup>
- **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 multidose containers, labeling containers) by final users should be minimized.<sup>14</sup>
- **Medication storage.** Medications shall be stored and prepared under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security to ensure medication integrity and personnel safety.
- **Adverse drug reactions.** An ongoing program for monitoring, reporting, and preventing adverse drug reactions shall be developed.<sup>15</sup>
- **Medication errors.** Pharmacists, with physicians and other appropriate hospital personnel, shall establish policies and procedures with respect to medication-error prevention and reporting.<sup>5</sup> Ongoing monitoring and review of medication errors with corresponding appropriate action should be maintained.
- **Drug product recalls.** A written procedure shall exist for the handling of a drug product recall. There should be an established process for removing from use any drugs or devices subjected to a recall.
- **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.
- **Vendors' representatives.** Written policies governing the activities of representatives of vendors of drug products (including related supplies and devices) within the hospital shall exist.<sup>16</sup>

- **Samples.** The use of medication samples shall be eliminated to the extent possible. However, if samples are permitted, the pharmacy must control these products to ensure proper storage, maintenance of records, and product integrity.
- **Manufacturers and suppliers.** Criteria for selecting drug product manufacturers and suppliers shall be established by the pharmacy to ensure high quality of drug products.<sup>17</sup>
- **Cytotoxic and hazardous drug products.** Policies and procedures for storage, handling, and disposal of cytotoxic and other hazardous drug products shall exist.<sup>18</sup>
- **Controlled substances.** Accountability procedures shall exist to ensure control of the distribution and use of controlled substances and other medications with a potential for abuse.<sup>19</sup>
- **Nondrug substances.** The pharmacy shall seek and obtain documented authorization from appropriate medical staff and hospital committees for the pharmacologic use of any chemical substance that has never received FDA approval for any drug use. Documentation must exist to ensure that appropriate risk management measures (e.g., obtaining informed consent) have been taken.
- **Medication storage area inspections.** All stocks of medications shall be inspected routinely to ensure the absence of outdated, unusable, or mislabeled products. Storage conditions that would foster medication deterioration and storage arrangements that might contribute to medication errors also must be assessed, documented, and corrected.
- **Floor stock.** Floor stocks of medications generally shall be limited to medications for emergency use and routinely used safe items (e.g., mouthwash, antiseptic solutions). The potential for medication errors and adverse effects must be considered for every medication allowed as floor stock.
- **Disaster services.** A procedure shall exist for providing pharmaceutical services in case of disaster.
- **Medical emergencies.** The pharmacy shall participate in hospital decisions about emergency medication kits and the role of pharmacists in medical emergencies.
- **Drug delivery systems, administration devices, and automated dispensing machines.** Pharmacists shall provide leadership and advice in organizational and clinical decisions regarding drug delivery systems, administration devices, and automated dispensing machines and should participate in the evaluation, use, and monitoring of these systems and devices.<sup>20</sup> The potential for medication errors associated with such systems and devices must be thoroughly evaluated.

## Standard V: Facilities, Equipment, and Information Resources

To ensure optimal operational performance and quality patient care, adequate space, equipment, and supplies shall be available for all professional and administrative functions relating to medication use. These resources must be located in areas that facilitate the provision of services to patients, nurses, prescribers, and other health care providers and must be integrated with the hospital's communication and delivery or transportation systems. Facilities shall be constructed, arranged, and equipped to promote safe and efficient work and to avoid damage to or deterioration of drug products.

- **Medication storage.** Facilities shall exist to enable the 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.
- **Packaging and compounding.** Designated space and equipment for packaging and compounding drug products and preparing sterile products shall exist. There shall be a suitable work environment that promotes orderliness and efficiency and minimizes potential for contamination of products.<sup>13,14</sup>
- **Cytotoxic and hazardous drug products.** Special precautions, equipment, and training for storage, handling, and disposal of cytotoxic and other hazardous drug products shall exist to ensure the safety of personnel, patients, and visitors.<sup>11</sup>
- **Drug information.** Adequate space, resources, and information-handling and communication technology shall be available to facilitate the provision of drug information.
- **Consultation space.** In outpatient dispensing areas, a private area for pharmacist–patient consultations shall be available to enhance patients’ knowledge and compliance with prescribed medication regimens.
- **Office and meeting space.** Office and meeting areas shall be available for administrative, educational, and training activities.
- **Automation.** Automated mechanical systems and software may be useful in promoting accurate and efficient medication ordering and preparation, drug distribution, and clinical monitoring, provided they are safely used and do not hinder the pharmacist’s review of (and opportunity to intervene in) medication orders before the administration of first doses. An interface with a comprehensive pharmacy computer system is encouraged. Pharmacy personnel must supervise the stocking of medications in dispensing machines.
- **Record maintenance.** Adequate space shall 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 techniques. Appropriate licenses, permits, and tax stamps shall be present. 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.
- **Computerized systems.** Computer resources should be used to support secretarial functions, maintain patient medication profile records, perform necessary patient billing procedures, manage drug product inventories, and interface with other available 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.
- **Policies and procedures.** The pharmacist shall ensure that policies and procedures for the safe and proper use of investigational drugs are established and followed.<sup>22</sup>
- **Distribution and control.** The pharmacy shall 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.<sup>22</sup>
- **Institutional review board.** A pharmacist shall be included on the hospital’s institutional review board.
- **Drug information.** The pharmacist shall have access to information on all investigational studies and similar research projects involving medications and medication-related devices used in the hospital. The pharmacist shall provide pertinent written information (to the extent known) about the safe and proper use of investigational drugs, including possible adverse effects and adverse drug reactions to nurses, pharmacists, physicians, and other health care professionals called upon to administer, dispense, and prescribe these medications.

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8. American Society of Hospital Pharmacists. ASHP guidelines on the pharmacist’s role in drug-use evaluation. *Am J Hosp Pharm.* 1988; 45:385–6.
9. American Society of Hospital Pharmacists. ASHP technical assistance bulletin on the pharmacist’s role in immunization. *Am J Hosp Pharm.* 1993; 50:501–5.
10. American Society of Hospital Pharmacists. ASHP statement on the pharmacist’s responsibility for distribution and control of drug products. *Am J Hosp Pharm.* 1995; 52:747.
11. American Society of Hospital Pharmacists. ASHP statement on the formulary system. *Am J Hosp Pharm.* 1983; 40:1384–5.

## Standard VI: Research

The pharmacist should initiate, participate in, and support medical and pharmaceutical research appropriate to the goals, objectives, and resources of the specific hospital.<sup>21</sup>

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