ASHP ACCREDITATION STANDARD
FOR INTERNATIONAL HOSPITAL AND HEALTH-SYSTEM PHARMACY SERVICES

Preamble

Accreditation is a process used by health care organizations worldwide to accurately assess their level of performance in relation to established standards and to implement ways to continuously improve.

Accreditation specific to pharmacy can foster further development of pharmacy delivered patient care services and advance practice. The need for recognition of innovative, high quality, safe and effective hospital and health-system pharmacy services throughout the world has led ASHP to develop a new international accreditation standard and survey process. In this regard, this accreditation standard embodies the processes of continuous quality improvement. This voluntary accreditation process is offered to those international hospital and health-system pharmacies and their associated ambulatory care services with an interest in improving patient care and earning this formal recognition of the value provided to their patients and organization.

The ASHP Accreditation Standards for International Hospital and Health-System Pharmacy Services address these primary areas for high quality pharmacy practice:
1. Leadership and Management
2. Quality
3. Medication Policy and Drug Information
4. Medication Safety
5. Information Management
6. Supply Chain
7. Medication Use Process
8. Clinical Pharmacy Services
9. Facilities
10. Education and Training
11. (With Commendation) Automation
12. (With Commendation) Collaborative Medication Management
13. (With Commendation) Research
14. (With Commendation) Residency Education and Training

Within each standard are key areas of focus in which the pharmacy must demonstrate competency. Evaluation of the practice is conducted through review of documents and an on-site survey.

Introduction

Purpose of this Standard: the *ASHP Accreditation Standard for International Hospital and Health-System Pharmacy Services* (hereinafter the Standard) establishes criteria to guide, describe, and gain recognition for innovative, high quality, safe and effective hospital and health-system pharmacy services. The development of a standards-based accreditation process is critical for continuous quality improvement and consistency. Achievement of accreditation provides evidence of medication safety, effectiveness, and delivery of high quality of care, which leads to desired health outcomes.

Application of the Standard: the requirements serve as the basis for evaluating international pharmacy services in hospitals and health-systems for accreditation.

The Standard describes the criteria used in evaluation of hospital and health-systems that apply for accreditation of their hospital or health-system pharmacy services. The accreditation program is conducted under the authority of the ASHP Board of Directors. The *ASHP Regulations on Accreditation of Pharmacy Services* describes the policies governing the accreditation program and   procedures for seeking accreditation.

The term hospital will be used in the standard and refers to both hospitals and health-systems, defined as both acute and ambulatory settings.

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Standard 1: Leadership and Management

1.1 Leadership and Organizational Structure

The pharmacy department has a clearly defined organizational leadership structure. The organizational structure includes the direct and indirect reporting relationships within the pharmacy department and the organization.   The pharmacy organizational chart should be signed by the pharmacy director and approved by the hospital administration.

Effective leadership and practice management skills are necessary for the delivery of pharmacy services in a manner consistent with hospital and patient needs. Such leadership fosters continuous improvement in patient care outcomes and operations. Pharmacy department management focuses on the pharmacist's value and responsibilities as a patient care provider and as a leader of the pharmacy enterprise through organizational structures that support this mission. Such structures require communication and collaboration with other departments and services throughout the hospital that support pharmacy patient care. Every member of the pharmacy department cultivates communication and collaboration at every opportunity with other departments that support pharmacy patient care.

1.2 Pharmacy Strategic Planning, Mission, Vision, Goals, and Scope of Services

The pharmacy department has a written mission statement that, at a minimum, reflects both pharmacy patient care and service responsibilities. The mission is consistent with the mission of the hospital. The development and prioritization of goals, objectives, and work is consistent with the mission statement. Strategic planning, 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, vision, and goals are reviewed and updated based upon need.

The pharmacy department maintains a written document describing the scope of pharmacy services. These services are consistent with the hospital's scope of services and are applied in all practice sites. The mission, goals, and scope of services are clearly communicated to everyone involved in the provision of pharmacy services. The mission statement is reviewed by organizational leadership, pharmacy department leadership, and staff regularly for necessary modifications based on scope of practice.

1.3 Practice Standards and Guidelines

The pharmacy department meets the standards and regulations of all relevant government bodies. The pharmacy department has assessed and adopted all applicable practice standards and guidelines of ASHP, the Joint Commission International, or other appropriate accrediting bodies. Guidelines set forth by other independent organizations such as the Institute for Safe Medication Practices (ISMP) are assessed and adopted as applicable. The hospital and the pharmacy department strive to meet these standards, regardless of the particular financial and organizational arrangements by which pharmacy services are provided to the hospital and its patients. Pharmacists practicing in hospitals and health-systems play a critical role in ensuring that the hospital adheres to medication-related national quality indicators and evidence-based practice guidelines.

1.4 Laws and Regulations

Patient care, dispensing services, and support services provided by the pharmacy department are provided as described in a Scope of Services document, and such services demonstrate compliance with all relevant government regulations. The pharmacy department maintains relevant documentation of compliance with requirements concerning procurement, distribution, and disposal of drug products; security of patient information; and workplace safety; narcotics and controlled substances; and other applicable government regulations.

1.5 Pharmacy Services

1.5.1 Twenty-Four-Hour Pharmacy Services. The pharmacy department maintains adequate hours of operation for the provision of needed pharmacy services; 24-hour pharmacy services are provided when possible. Twenty-four hour pharmacy services are employed in all hospitals with clinical programs that require intensive medication therapy (e.g., transplant programs, open-heart surgery programs, intensive care units, and trauma centers). When 24-hour pharmacy services are not feasible, a pharmacist should 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.

1.5.2 After-Hours Pharmacy Access. In the absence of 24-hour pharmacy services, access to a limited supply of medications is only available to authorized, licensed health care professionals for use in carrying out urgent medication orders. When possible, the number of individuals who have access to these medications is limited (e.g. charge nurse or shift supervisor). Access to such medications is carefully monitored and documented, and after-hours access is 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) are developed by a multidisciplinary committee of physicians, pharmacists, and nurses (e.g., by the pharmacy and therapeutics [P&T] committee or its equivalent). Access to medications is 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 are considered in the decision to make them accessible, and medications, quantities, dosage forms, and container sizes that might endanger patients are limited whenever possible. Routine after-hours access to the pharmacy by non-pharmacists for access to medications is not permitted. The use of well-designed night cabinets, after-hours medication carts, automated dispensing devices, and other methods precludes the need for non-pharmacists to enter the pharmacy.

1.6 Financial Performance

1.6.1 Budget Management. The pharmacy department has a budget that is consistent with the hospital's financial management process and supports the scope of and demand for pharmacy services. Oversight of workload and financial performance is managed in accordance with the hospital's requirements. Pharmacy department management provides for the determination and analysis of pharmacy service costs, capital equipment costs, and new project growth. The pharmacy department budget processes enable the analysis of pharmacy 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 third-party enrollment). The pharmacy director has an integral part in the organization's financial management process.

1.6.2 Health-System Integration. Other functional units within the hospital factor the cost of pharmacy services being provided by the pharmacy department into the departmental budget when appropriate.

1.6.3 Revenue, Reimbursement, and Compensation. The pharmacy director is knowledgeable about revenues for pharmacy services, including reimbursement for medication dispensing, patient care, and disease state and drug therapy management services where applicable.

1.6.4 Drug Expenditures. Specific policies and procedures for managing drug expenditures address such methods as utilization review programs, inventory management, formulary systems, and cost-effective care for patients with limited income and resources.

1.7 Emergency Preparedness/Contingency Plans

1.7.1 Emergency Preparedness. Policies and procedures exist for providing pharmacy services during facility, local, or area-wide disasters affecting the organization's patients. Appropriately trained pharmacists and representatives from the pharmacy department are members of emergency preparedness teams and participate in drills. Patients are informed about how to safely continue medication therapy in the event of a disaster. The hospital health-system's business continuity plan considers the provision of pharmacist patient care services in emergency situations. Factors to consider include system failures, technology disruptions, and breakdowns in the drug procurement process.

1.7.2 Medical Emergencies. The pharmacy department participates in decisions about the contents of emergency carts/trolleys, emergency medication kits and trays, and the role of pharmacists in medical emergencies. It is desirable for appropriately trained pharmacists to have an authorized role in responding to medical emergencies. Pharmacists with authorized roles receive appropriate training and maintain appropriate certifications (e.g., Basic Life Support, Advanced Cardiopulmonary Life Support, Pediatric Acute Life Support). Pharmacists serve on cardiopulmonary resuscitation teams.

Policies and procedures exist within the organization for providing appropriate levels of patient care during emergency situations 24 hours a day, including access to the pharmacist responsible for patient care, when appropriate. The pharmacy department participates in the development of policies and procedures to ensure the availability of, access to, and security of emergency medications, including antidotes.

1.8 Safety

Pharmacy department personnel are involved in the hospital's plans for emergency response, infection prevention and control, compounding of medications, management of hazardous substances and waste, and medication safety and incident reporting. All pharmacy department staff is familiar with these plans.

1.9 Policies and Procedures

A policy and procedures manual governing the scope of the pharmacy services being provided (e.g., administrative, operational, and clinical) is available and consistent with current department processes. The manual is reviewed and revised on a regular basis to reflect changes in policies and procedures, the scope of services, organizational arrangements, objectives, practices, or enactment of a new regulation. All personnel are familiar with and adhere to the

contents of the manual. Appropriate mechanisms are established to ensure compliance with all policies and procedures.

Policies and procedures are documented in a consistent format and include dates of creation, reviews, revisions and approvals.

New and revised policies and procedures are provided and available to the pharmacy department staff on an ongoing basis in a readily retrievable format, such as online or an easily accessed binder in each facility and, when necessary, staff is provided training and education related to policies and procedures.

1.10 Patient Confidentiality

The pharmacy department ensures compliance with regulations protecting patient confidentiality and ensures pharmacy data are secure and protected from unauthorized access. The pharmacy department protects and secures the integrity and confidentiality of patient and transactional data. The pharmacy department has protocols to establish (provision) access to sensitive information including patient and human resource information, to revoke (deprovision) access when appropriate, and to periodically evaluate employee lists for properly continuing access at existing level.

1.11 Committee Work

A pharmacist representative is a member of and actively participates on committees responsible for establishing and implementing medication-related policies and procedures, leadership actions, the provision of patient care, and performance improvement. Members of the pharmacy department take part in staff recognition, patient service programs, and other programs as identified by the pharmacy department.

1.12 Staffing and Competencies

1.12.1 Position Descriptions. Areas of responsibility within the scope of pharmacy services are clearly defined. The responsibilities and related competencies of pharmacy department personnel are clearly defined in written position descriptions. Pharmacists are responsible for the provision of patient care and for the supervision and management of support staff. Sufficient support staff (pharmacy technicians, clerical) is employed to facilitate the provision of care. Technicians are responsible for aspects of drug procurement and inventory management, drug distribution and dispensing, support of pharmacists' patient care activities, and preparation of prescription orders for a pharmacist's clinical review.

1.12.2 Director of Pharmacy. These standards use the term *director* to indicate the person responsible for managing the pharmacy department. Depending on the hospital or health system's organizational structure and other factors, designations such as manager or pharmacist-in-charge may also be used. The pharmacy department is managed by a professionally competent, legally qualified pharmacist. The director is knowledgeable about and has experience in all aspects of pharmacy care. Completion of advanced management training or a degree is highly desirable.

The director of the pharmacy department is responsible for

- Establishing the mission, vision, goals, and scope of services of the pharmacy practice setting on the basis of the needs of the patients served, the needs of the

hospital, and developments and trends in healthcare and pharmacy practice,
- Developing, implementing, evaluating, and updating plans and activities to fulfill the mission, vision, goals, and scope of services,
- Actively working with health-system leadership to develop and implement policies and procedures that provide safe and effective medication use for all patients served by the organization,
- Ensuring the development and implementation of policies and procedures that provide safe and effective medication use for all patients served by the organization,
- Mobilizing and managing the resources, both human and financial, necessary for the optimal provision of pharmacy services,
- Ensuring effective and timely recruitment, orientation, training, education, mentoring, employee wellbeing, career development, performance review and retention, and
- Ensuring that patient care services provided by pharmacists and other pharmacy department personnel are delivered in compliance with applicable laws and regulations as well as national practice standards.

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

The pharmacy department is a cross-functional group whose skills set includes operations management, clinical care, financial management, and process improvement. Skills in informatics and analytics are desirable. Depending on the size and scope of the setting, these functional responsibilities may be assigned to a single person or a team. The director is responsible for monitoring the status of the goals set forth in the vision, providing feedback to the pharmacy team as necessary, and supporting the department's implementation of the core functions of the pharmacy practice.

1.12.3 Pharmacist Licensure and Certification. All pharmacists possess a current applicable license to practice pharmacy as required by local regulations. Functional responsibilities may mandate additional degrees, certificates, or credentials.

1.12.4 Pharmacy Technician (or Pharmacist Assistants or Other Pharmacist Supportive Personnel) Requirements. The hospital adheres to all regulations and guidelines regarding pharmacy technician registration, certification, and licensure, as applicable. All pharmacy technicians successfully complete an approved training course that includes education on at least the following topics:

- drug distribution,
- medication preparation and compounding,
- the prescription-dispensing process,
- patient service skill,
- patient and employee safety, and
- pharmacy technician duties and responsibilities as defined by regulations.

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

enhance their competence. The hospital makes available to personnel, as appropriate, training and education on new processes, procedures, and methods of patient care.

1.12.6 Recruitment, Selection, and Retention of Pharmacist Personnel. Clinical specialist positions are a necessary part of any hospital in order to advance practice, education, and research activities. The director assists in identifying the professional and technical requirements that a candidate must meet to qualify for the position. These requirements may include completion of one or two years of postgraduate residency training, board certification, previous participation in a collaborative practice environment, and other credentials and privileges as appropriate. Personnel are recruited and selected on the basis of requirements in established position descriptions. Criteria used in the selection process include the candidate's performance of similar job-specific duties, education history relevant to job-specific duties, and willingness to contribute to achieving the mission of the department and the hospital. An employee retention plan is desirable.

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

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

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

1.13 Performance Evaluation and Staff Development

Scheduled periodic evaluations of performance occur for all pharmacy department personnel. Performance is evaluated on the basis of position description requirements and expected competencies, and the evaluation format is consistent with that used by the hospital. Evaluations include comments from professional and technical staff and, where possible, other members of the healthcare team. Pharmacy department staff meets the expectations defined in their position descriptions for adequate performance of their duties.

The pharmacy director ensures that an ongoing competency assessment program is in place for all staff, and it is desirable for each staff member to have a continuing professional development plan consistent with responsibilities and like positions in the organization.

The pharmacy department has a process to evaluate pharmacy department staff for areas of aptitude and will provide or facilitate opportunities for continuing professional development of

skills and competencies required to provide safe, high quality patient care. The pharmacy department also facilitates staff development by providing access to appropriate evidence-based training materials and primary literature. The specific competencies are based on factors such as patient population needs and the patient care services provided. Continuing education and professional development ensures compliance with appropriate licensures and other credentials.

1.14 Work Schedules and Assignments

The pharmacy department staffing plan is based on workload statistics and patient care needs. Pharmacist and pharmacy technician assignment are clearly defined to allow the optimal use of personnel and resources. Sufficient personnel are available to ensure the safe and timely delivery of pharmacy services while complying with applicable labor laws.

1.15 Interprofessional Education

The pharmacy department actively participates in interprofessional educational programs offered at the hospital, including those offered by disciplines other than pharmacy. Such programs may include grand rounds and similar offerings, experiential learning experiences for students, internships, fellowships, and residency programs. When possible, all pharmacy department-provided continuing education programs are accredited by the appropriate accrediting body or bodies.

1.16 Well-Being and Resilience

Workforce well-being and resilience supports improved patient safety, patient-clinician relationships, high-functioning care teams, and engaged and effective staff.   Pharmacy staff burnout can cause significant human suffering and can negatively impact patient safety and overall healthcare quality throughout entire organizations and systems. The pharmacy department supports the professional, emotional, physical, and social well-being and resilience for of their staff. Dedicated resources are available to help staff maintain their compassion for others and self; maintain their sense of purpose, meaning, and professional fulfillment; develop resiliency skills; and maintain or develop habits of healthy living and self-care.

Standard 2: Quality

2.1 Quality Plan

A plan for pharmacy quality improvement initiatives is developed and updated on a regular and on-going basis and reflects pharmacy department and hospital components. The pharmacy department uses an ongoing, systematic program to assess the quality of all pharmacy services provided in the organization. The program includes all aspects of the medication-use process, routine evaluation of literature for the implementation of new practices, the use of automation and technology where applicable, comparison with peer organizations for evaluation and innovation, and is aligned with the hospital's overall plan and system for quality improvement. Quality programs utilize current evidence to support safe medication use or for comparison of pharmacy department programs and services with identified contemporaries. External tools are also used for benchmarking and planning, such as those published by professional organizations (e.g., ASHP Practice Advancement Initiative, ISMP self-assessments, etc.).

Prescribing data is used by pharmacists in collaboration with the medication policy, safety, quality, and other medication-use related committees to monitor medication use in the organization.

2.2 Metrics

Pharmacy department quality program indicators, measures, and metrics are developed in collaboration with other health care professionals and reflect hospital quality indicators, measures, and metrics. Metrics encompass all aspects of clinical and operational pharmacy services, patient care need-associated metrics, hospital metrics, financial metrics, and other metrics designated by professional standards, accrediting bodies or regulatory bodies.

The pharmacy department quality programs specifically include:
- internal evaluations of
  - clinical services,
  - pharmacy operations,
  - use of automation and technology,
  - financial and workload performance,
  - alignment with best practices,
  - employee engagement, and
  - appropriate programs and/or services indicators.
- external components of
  - customer satisfaction and patient satisfaction indicators,
  - patient needs indicators, and
  - instruments developed and used by professional organizations.

2.3 Quality Outcomes

Quality program measures and results of initiatives lead to appropriate actions such as practice changes, modification of workflows, education of staff members, or policies and procedures of the pharmacy department and its programs and services.

Pharmacy quality program performance measures and indicators and corresponding results are reported routinely to pharmacy department, medical staff, nursing staff, hospital leaders, and other appropriate staff members. Dashboards, balanced scorecards, and/or other organizational or professionally developed reporting methods are utilized for reporting quality program measures or indicators and corresponding results to pharmacy department employees and other health care professionals. Such information may also be reported to hospital Boards of Directors or other oversight bodies.

Standard 3: Medication Policy and Drug Information

Medication-use policy decisions are founded on evidence-based clinical, ethical, legal, social, philosophical, quality-of-life, safety, and economic factors that result in optimal patient care. Committees within the organization that make decisions concerning medication use (e.g., pharmacy and therapeutics, infection control) include the active and direct involvement of physicians, pharmacists, other appropriate healthcare professionals, and patients, where appropriate. Pharmacists actively participate on committees whose decisions could affect the quality, safety, effectiveness, or cost of pharmacy services or the medication-use process. Pharmacists and pharmacy technicians are members of interprofessional teams. They are accountable and responsible for safe and timely medication preparation and delivery, medication reconciliation, patient counseling, and medication-related outcomes through the medication-related continuity-of-care process for all patients. Pharmacists are actively involved in the development, maintenance, and updating of

medication-use policies. Medication use policy and drug information processes are adequately supported by current references i.e. online, books, and periodicals.

3.1 Pharmacy & Therapeutics (P&T) Committee

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

The hospital maintains a formulary that is efficacious and cost-effective. This formulary is developed with feedback from professional healthcare providers (pharmacists, physicians, nurses, social workers, case managers). The pharmacy department disseminates the formulary by electronic (preferred) or other means to meet the needs of all health care professionals.

There are policies and procedures that describe how the pharmacy department seeks and obtains documented authorization from appropriate medical staff and hospital committees prior to the medical use of any chemical substance, i.e. dietary supplements, that has not received regulatory 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 are under the control of the pharmacy department.

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

3.2 Drug Information

Expertise in evaluating literature on drugs should be considered essential to the provision of drug therapy management. Policies and procedures are in place for reviewing responses to requests for drug information for the purpose of performance improvement, safety, and education. Pharmacists provide accurate, comprehensive, and patient-specific drug information to patients, caregivers, other pharmacists, physicians, nurses, and other healthcare providers as appropriate, both proactively and in response to requests associated with the delivery of pharmacist-provided patient care, educational programs, and publications. When possible, a pharmacist should play a role in addressing complex drug information questions presented by professional staff within the health system (e.g., pharmacists, nurses, physicians).

Standard 4: Medication Safety

4.1 Medication Event Reporting System

An easily accessible event reporting system is utilized by the hospital to report medication events. Efforts exist to prevent, detect, and resolve medication-related problems that may result in patient harm from medications or the administration of medications.

4.2 Medication Safety Committee

4.2.1 Structure. The pharmacy department leads or collaborates with other health care professionals on an interprofessional medication safety committee, which reports to a medical staff committee such as the pharmacy and therapeutics committee, patient safety committee, quality committee, or medical executive committee. Subcommittees may exist to support high-risk medication use for such populations as pediatrics or oncology or other patient populations. The pharmacy department may also maintain a medication safety committee that supports the work of the hospital medication safety committee.

4.2.2 Medication Safety Officer. A qualified individual is designated to lead the medication safety program within the hospital and is named the "Medication Safety Officer." Pharmacists are uniquely qualified to perform this function, but in some cases nurses or physicians may serve in this role.

4.2.3 Role. The committee maintains roles for oversight of standardization of processes (use of medication administration devices, use of automation, maintenance of high-alert lists, etc.). The safety committee also monitors professionally developed guidelines and self-assessment tools to evaluate safety practices in the pharmacy department and the hospital (e.g., those developed and published by ISMP, etc.).

The safety committee establishes, reviews, and revises policies and procedures regarding medication event reporting, analysis, aggregation, and trending; communication efforts to health care professionals regarding events and any related practice changes; and follow-up actions resulting from events reported. Such events include actual errors or near misses. Systems such as root-cause analysis, failure mode effect analysis and other appropriate tools are used by the pharmacy department and the medication safety committee when appropriate. The hospital reports sentinel events related to serious medication errors to the relevant authorities as needed.

4.3 Just Culture

Pharmacy department managers and staff members exert leadership in establishing, maintaining, and refining a just culture in the hospital and in the pharmacy department. Evidence exists of a non-punitive approach to reporting medication events, near misses, and errors in the pharmacy department and in the hospital. Analysis of medication event reports and near misses begin with a systems-based approach rather than starting with individual failures.

Standard 5: Information Management

The hospital utilizes an electronic information management system to maintain patient records, such as an integrated or closed-loop information system or electronic health record (EHR) for all inpatients and outpatients. Alternatively, a comprehensive pharmacy information system is used that is interfaced with other hospital information systems and software systems such as a prescribing system, laboratory system, nursing charting and documentation system, radiology and other diagnostic departments systems, ambulatory care or physician office practice systems, and other appropriate systems to promote safe and effective medication use.

The hospital EHR or pharmacy information system houses patient information (age, height, weight, allergies/sensitivities, at minimum), patient medication profiles, the hospital medication formulary and all relevant guidelines and restrictions, clinical decision support tools, and all diagnostic information needed to perform all pharmacy clinical and operational functions for safe medication ordering, preparation, dispensing, administration and monitoring. The hospital EHR or pharmacy information system also houses billing information and may contain information regarding product inventories. If used, automated dispensing cabinets placed in patient care areas and other areas of the hospital are fully interfaced with the EHR or pharmacy information system.

All electronic records and computer systems containing patient information have adequate safeguards to maintain the confidentiality and security of patient information and are supported by redundant back-up systems to ensure continuous use. Downtime procedures are developed and are readily available to all staff members in cases of equipment failure or other interruptions in electronic system use.

5.1 Availability of Information
The EHR and/or pharmacy information system and all other information systems and software systems are available in the pharmacy department and all of its facilities, in patient care areas and diagnostic areas, to provide adequate access to information for all health care professionals in the organization and in the pharmacy department. If present, the hospital intranet provides access to medication policies and procedures, the medication formulary and any guidelines or restrictions, and drug information resources from local, national, regional and international publishers that are needed by health care professionals. Reference books that provide needed medication information are provided for health care professionals to supplement electronic resources, or exist in place of electronic resources, and are placed throughout the organization for convenient and immediate use by health care practitioners.

5.2 Computerized Prescriber Order Entry (CPOE)
The hospital uses a safe and reliable mechanism for ordering medications, and a computerized prescriber order entry system (CPOE) is preferred. If separate systems are utilized for ambulatory care or in physician offices, the pharmacy department staff has access to patient records in those systems. The CPOE system contains the medication formulary or formularies (in cases when differences exist for ambulatory care, etc.), medication guidelines and restrictions, and decision support tools to support safe and effective medication use.

Pharmacists collaborate with physicians to write medication order sets and/or standing orders or protocols; all of these order sets, standing orders or protocols are reviewed by and approved

by appropriate medical staff committees of the organization. Standardization of doses is used when appropriate.

5.3 Medication Administration Record (MAR) Computerized Generation

A computer generated MAR is utilized throughout the organization. The MAR contains all patient and medication information needed for safe administration of all medications used in the organization (e.g., medication name, dose, dose units, route and duration of administration, frequency, etc., in addition to all required patient information. An electronic medication administration record (eMAR) is preferred.

Nurses and other health care professionals use the MAR to guide medication administration and to document medication administration (success and failure, omission). Any medication holding and reasons for holding and any reactions to medications noted are documented in the patient chart and preferably in the MAR.

Manual systems exist for down time or when computers do not exist. When eMARs do not exist, manual systems are used throughout the organization and such systems contain the same patient and medication information. Appropriate double checks are used to minimize transcribing errors, and quality systems exist for monitoring manual system effectiveness and safe use.
Policies and procedures are readily available to support eMARs and manual systems, and downtime procedures are also readily available for all staff members, if needed.

Standard 6: Supply Chain

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

6.1 Purchasing and Maintaining the Availability of Drug Products

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

6.1.2 Pharmaceutical Manufacturers and Suppliers. The pharmacy department acts to minimize risk of counterfeiting, diversion, cargo theft, and importation of unapproved or otherwise substandard drugs, devices, and supplies. Criteria for selecting pharmaceutical manufacturers and suppliers are established to ensure that patients receive pharmaceuticals and related supplies of the highest quality and at the lowest cost. Although these duties may be delegated in part to a group purchasing organization, the pharmacy department maintains sole responsibility for ensuring the quality of drug products used in the hospital.

6.2 Managing Inventory

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

6.2.2 Drug Shortages. There are policies and procedures for managing drug shortages, and pharmacy department staff monitors reliable sources of information regarding drug product supply and shortages. The pharmacy department has developed strategies for identifying alternative therapies, working with suppliers, collaborating with physicians and other healthcare providers, and conducting an awareness campaign in the event of a drug shortage.

6.2.3 Samples. The use of drug product samples is limited to the extent possible. However, if samples are permitted under certain circumstances, policies and procedures for their storage, control, and distribution are in place. The pharmacy department oversees procurement, storage, and distribution of these products to ensure proper storage, record-keeping maintenance, product integrity, and compliance with all applicable packaging and labeling laws, regulations, standards, and patient education requirements. When possible, charity programs (patient assistance programs, foundations) are accessed to help patients with limited income and resources to procure their medications and related supplies. Pharmacists are involved in the organization's efforts to secure safe and effective low-cost medications for low income patients.

6.2.4 Patient Care Area Stock. Inventory of drug products stored outside pharmacy areas (e.g., nursing station, clinic, physicians' offices) for direct administration to patients is minimized. Medications accessed from patient area stock are removed from secured storage areas and administered only pursuant to a prescription or order by a qualified prescriber. The list of medications to be accessible and the policies and procedures regarding their use is developed by an interprofessional committee of physicians, pharmacists, and nurses. Access to medications is limited to cases in which the committee determines that an urgent clinical need for the medication outweighs the potential patient safety risks of making the medication accessible. A separate assessment occurs for every location where a medication may be stocked. A quality assurance program is in place to periodically review medications removed from the patient care area stock and determine whether the removal was according to policies and procedures.

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

6.2.6 Emergency Medications and Devices. The pharmacy department ensures the availability, access, and security of emergency medications, including antidotes. It is preferable that pharmacists have an authorized role in responding to medical emergencies. All emergency medications are stored in sealed or tamper-evident containers that enable the staff to readily determine that the contents are complete and have not expired. All emergency medications are available, controlled, and secured in the patient procedure areas.

6.2.7 Patient's Own Medications. Drug products and related devices brought into the organization by patients are identified by the pharmacy department and documented on the patient's medical record if the medications are to be used. These medications are not stored at bedside and are administered only pursuant to a prescriber's order and according to policies and procedures, which ensure the pharmacist's identification and validation of the integrity as well as the secure and appropriate storage and management of such medications.

6.3 Drug Product Storage Area Inspections

All stocks of drug products, whether located within or outside the pharmacy area, are inspected routinely and managed by pharmacy department and location staff 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 are assessed, documented, and corrected.

6.4 Returning Recalled, Expired, and Other Unusable Items

There is a written procedure for the timely handling and documentation of drug product recalls. This procedure includes 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 department is notified of any defective drug products or related supplies and equipment encountered by the nursing or medical staffs.

Standard 7: Medication Use Process

7.1 Preparing, Packaging, and Labeling

7.1.1 Preparing Medications

7.1.1.1 Compounding. Drug formulations, dosage forms, strengths, and packaging that are not available commercially but are needed for patient care are prepared by appropriately trained personnel in accordance with applicable practice standards and regulations. The pharmacy department provides adequate quality-assurance procedures for these operations. Written master formulas and batch records (including product test results, as appropriate) are maintained, and a lot number or other method to identify each finished product with its production and control history is assigned to each batch.

7.1.1.2 Sterile Preparations. Use of manufactured sterile preparations is preferred over those compounded in the pharmacy. All compounded sterile medications are prepared and labeled in a suitable environment by appropriately trained personnel in accordance with established quality-assurance and expiration dating procedures. The use of sterile medications compounded outside the pharmacy is avoided to the extent possible; when they are used, there are procedures for aseptic preparation, quality assurance, expiration dating, and ongoing competency evaluations for compounding personnel. Sterile compounding outside the pharmacy or satellite pharmacies (e.g., on nursing units) is minimized.

7.1.1.3 Hazardous Drug Products. There are 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 are consistent with applicable laws and regulations and are adequate to ensure the safety of staff, patients, visitors, the community, and the environment.

7.1.2 *Packaging Medications*. Whenever possible, medications are available for inpatient use in single-unit packages (unit dose packaging) 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 is minimized.

7.2 Medication Dispensing

7.2.1 Prescribing. Medications are prescribed by individuals who have been granted appropriate clinical privileges in the hospital and are legally permitted to order medications. The pharmacy department advocates and fosters practitioners' conformance with standardized, approved, and safe terminology and abbreviations used throughout the hospital when prescribing medications, and discourages use of nonstandard and unapproved terminology and abbreviations.

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

7.2.3 Medication Orders. All patient medication orders are 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), is received by the pharmacist. Oral orders are avoided to the extent possible and established procedures are developed for their use and documentation. Order transmittal safeguards are used to ensure the security of the prescriber's order. Appropriate records of each medication order and its processing in the pharmacy department are maintained in accordance with applicable laws and regulations. A system exists to ensure that medication orders are not inappropriately continued.

7.2.4 Review of Medication Orders. All medication orders are 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 is a procedure for retrospective review of these orders. Any questions regarding an order are resolved with the prescriber prior to administration, and any action taken as a result of this intervention is documented in the patient's medical record. Information concerning changes is communicated to the appropriate health professionals caring for the patient.

7.3 Medication Delivery and Administration

7.3.1 Drug Delivery Systems, Administration Devices, and Automated Distribution Devices. The pharmacy department has 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 is thoroughly evaluated.

Pharmacy department personnel supervise the stocking and documentation of medications in automated dispensing devices if present. Whenever possible, automated dispensing cabinets employ profile-based technology integrated with remote medication order-entry capabilities.

If automated dispensing cabinets are not used to control and dispense ward stock medications or patient-specific medications, medication cabinets and patient medication carts are located in patient care areas in secure locations with appropriate security (locks). Keys for locks are secure and policies and procedure outline required actions for lost keys or keys taken home accidentally. Recordkeeping is maintained for controlled substances, narcotics, and other medications as required by regulatory bodies.

7.3.2 Medication Administration. Only personnel who are authorized by the hospital in accordance with applicable laws and regulations and appropriately trained are permitted to administer medications to a patient. All administered, refused, or omitted medication doses are recorded in the patient's medical record according to an established procedure, and all medications that have not been administered are returned to the pharmacy. No medication is 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 8: Clinical Pharmacy Services

Clinical pharmacy services of an appropriate scope, depth, and consistency are provided to patients in the organization based upon an assessment of need conducted by the pharmacy department staff in collaboration with medical staff, nursing staff leaders and members, and hospital leaders. Such assessment of need reflects not only patient and family needs, but also supports a team-based approach to care and therefore include the needs of other disciplines such as medicine, nursing, respiratory therapy, and other healthcare team members and their learners. Clinical pharmacy services and programs focus not only on disease treatment, but also disease prevention and wellness promotion in acute care and ambulatory care settings. If appropriate, the pharmacy department staff members participate in the development of policies and procedures concerning preventive and wellness programs, population health, and post-exposure programs for infectious diseases (e.g., human immunodeficiency virus, tuberculosis, hepatitis) for patients and employees. As appropriate, pharmacists promote the use of immunizations and, when legally allowed, participate as active immunizers.

If appropriate, the pharmacy department staff assists in the development of and participates in the health system's substance abuse education, prevention, identification, and organization-sponsored programs for staff and patients.

Clinical pharmacy services are provided in the emergency department, in the operating rooms and peri-operative areas, and for diagnostic areas of the hospital, as indicated by the needs assessment.

Clinical pharmacy services and related programs are developed, implemented, and routinely monitored using medication event reporting data and continuous quality improvement techniques. Quality measures (outcomes) and economic measures are utilized to monitor the effectiveness of services and programs and to identify opportunities for change or improvement. Identified changes and improvements are implemented and monitored using the continuous quality improvement

process cycle. Measures and metrics utilized to monitor clinical pharmacy services are reported independently or as a part of a dashboard or similar process within the pharmacy department and the hospital.

If policy allows, pharmacists prescribe medications and order laboratory tests under collaborative drug therapy protocols; appropriate credentialing programs are utilized by the pharmacy department and organization to appoint such pharmacists, and their activities and outcomes are monitored according to policies of the pharmacy department and organization. A competency program using Ongoing and Focused Professional Practice Evaluation will assess ongoing activities of these pharmacists.

Pharmacists are appointed as members of medication safety committees, quality improvement committees, and other committees at patient care unit, pharmacy department and organizational levels.

Clinical pharmacy services are described within the overall practice model of the pharmacy department as well as in the scope of service document.

Pharmacy department leaders and managers ensure that pharmacist-to-patient ratios for inpatient clinical pharmacy services and for outpatient clinics are appropriate to meet patient care, department, and organizational needs; that pharmacists have space needed to provide services, and that appropriate information technology tools are available and utilized as designed.

8.1 Inpatient

Clinical pharmacy services are provided by qualified and credentialed (if applicable) pharmacists, pharmacy technicians, clerks, learners, and others as appropriately identified by pharmacy department leaders and pharmacy department policies. Pharmacists provide direct patient care services in roles such as clinical pharmacy specialist, clinical pharmacist, decentralized pharmacist, or unit-based pharmacist as defined by the department of pharmacy. As full-time members of interprofessional teams, pharmacists are responsible and accountable for pursuing optimal medication-related patient care outcomes. Pharmacists use required information sources to identify patient-specific medication-related problems and collaborate with interprofessional teams to prospectively develop patient-specific medication therapy and treatment plans, monitor responses to therapies, and make appropriate adjustments to the treatment plans when needed. Pharmacists document their clinically relevant patient care activities which significantly impact individual patient care in the patient's permanent medical record, preferably in the progress notes section. Pharmacists also document other activities according to pharmacy department policies and procedures (e.g., interventions) in the pharmacy information system or the integrated electronic health record.

Pharmacists', and pharmacy technicians' where appropriate, involvement in transitions of care activities are driven by hospital and pharmacy department policies and procedures, and may involve acquisition of the medication history at any entry point of the healthcare system, review of medication lists and profiles at all changes in levels of care in the healthcare system, and at the point of discharge from the hospital to home or another healthcare facility. Pharmacists and their learners (when appropriate) educate all patients, their family members, and caregivers regarding their medications during the hospital stay and before discharge from the facility, determine the effectiveness of such education, and document the provision of education in the patient's permanent medical record. All pharmacists report medication events using the pharmacy department and/or hospital event reporting system.

Clinical pharmacy programs are provided to patients in accordance with medication policy and formulary parameters, including but not limited to renal dosing programs, therapeutic substitution programs, pharmacokinetic dosing, responses to medical emergencies, antimicrobial and other stewardship programs, medication restrictions, and others, and are standardized across the organization, with outcome measures incorporated into quality improvement programs in the pharmacy department and the organization.

8.2 Outpatient/Ambulatory

Ambulatory care clinical pharmacy services are provided by qualified and credentialed pharmacists, with assistance from pharmacy technicians, clerks, learners, and others as appropriately identified by pharmacy department leaders. Clinical pharmacists, clinical specialists and other practitioners provide patient care services according to their scope of practice, and are members of interprofessional teams in the development and implementation of clinical care plans. These pharmacists may have prescriptive authority in the healthcare setting (clinical practice guidelines, critical pathways) and disease state management programs involving collaborative practice agreements and treatment protocols. In addition, medication therapy management (MTM) services are provided to assist with collaborative patient care. Emphasis is placed on clinical care plans, primary care, and medication treatment protocols that cover dosage calculations and limits and medications frequently associated with adverse (potential and actual) events, including medication errors. Primary care protocols consider whole patient needs for health promotion and disease prevention measures as well as appropriate patient assessments, comprehensive management of chronic disease states, management of medication-related care problems, vaccinations, and referrals for acute medical care. Disease state target measures consider the prevalence of the disease in the population served by the organization and the potential impact on clinical and economic outcomes.

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

Standard 9: Facilities

9.1 Adequate Space

Adequate space, equipment, and supplies are available for all professional and administrative functions of the pharmacy department. These resources meet all applicable laws and regulations and are located in areas that facilitate the provision of pharmacy services to patients and other health care professionals; these include the central pharmacy and pharmacy satellites; sterile products preparation areas; outpatient/ambulatory care pharmacies; medication storage areas in patient care units, diagnostic and treatment areas of the hospital; and office and meeting space for pharmacy department leaders and staff members. All areas in the organization where medications are stored are appropriately secured and are clean, adequately lit, ventilated, and have appropriate temperature and humidity controls.

9.2 Patient Counseling Space

The organization provides adequate space and tools (e.g., computers, models for teaching, printed educational materials, etc.,) needed to provide confidential patient, family, and caregiver education. Such areas are located in outpatient or ambulatory pharmacy areas, inpatient pharmacy areas (where needed), and in patient care areas of the hospital.

9.3 Cleanroom

The sterile products preparation area(s) or cleanrooms are used for compounding sterile products for patient use throughout the organization. Wherever located, cleanrooms meet applicable laws and regulations and are equipped to meet the intent of best practices and applicable laws and regulations. Any staff who work in clean rooms is adequately trained initially, maintains continuous competence, and adheres to professionally developed standards and best practices.

Standard 10: Education and Training

The pharmacy department actively participates in interprofessional educational programs offered at the organization, including those offered by disciplines other than pharmacy. Such programs may include grand rounds and similar offerings, experiential learning opportunities for students, internships, fellowships, and residency programs. When possible, all pharmacy department-provided continuing education programs are accredited by the appropriate accrediting body or bodies.

The pharmacy department is involved with the education and training of future pharmacy practitioners and may include technicians, pre-pharmacy and pharmacy students, and pharmacy residents.

Standard 11 (With Commendation): Automation

The pharmacy department, in collaboration with appropriate departments of the hospital or health care organization, utilizes a plan for the use of integrated automation throughout the organization. Such plan includes a needs analysis, parameters for specifications and selection of devices to be used (in the pharmacy department and throughout the organization), a plan for implementation, a plan for initial and ongoing training, policies and procedures for all areas requiring them, and a process for monitoring the use of the device(s). The maintenance, calibration, and certification of all automated systems and their related databases are performed and documented as recommended by the manufacturer and as required by all applicable laws, regulations, and standards. All automated systems utilize safeguards to maintain patient confidentiality securely. Policies and procedures outline processes to provide essential patient care services in the case of equipment failure or downtime.

Whenever possible, bar codes (2D, 3D) are utilized to manage the use of medications and any related medication administration devices in automated systems.

11.1 Bar-Coding of Unit Dose Packaging and Point of Care Administration

Unit dose packages contain a bar code and that code is used in inventory management, dose preparation and packaging, dispensing, and administration. The pharmacy department ensures the quality of all aspects of bar-code medication administration, including ability to scan bar codes and manage the associated database.

11.2 Bar Coded Dispensing

The pharmacy department dispenses all medications to all areas within the department and to all areas outside of the department using bar code scanning devices (e.g., its satellites, patient care units for ward stock or for entry into automated dispensing cabinets, to diagnostic areas, ambulatory care clinics, physician offices, etc.,) to minimize opportunities for errors in medication selection, expired medications or recalled medications to be released for patient use.

Bar code scanning is utilized in medication compounding processes, for both non-sterile and sterile products, including for all compounding devices utilized in sterile products clean rooms (e.g., Total Parenteral Nutrition pumps, repeater pumps, etc.).

Policies and procedures are utilized to outline all steps, required staff training and competencies, and quality assurance requirements.

11.3 Bar Coded Medication Administration

Bar code medication administration (BCMA) technology is utilized by the organization in all patient care areas of the hospital, diagnostic and treatment areas, ambulatory care clinics and physician office practices to enhance the safety of the medication-use process. Pharmacy department leaders collaborate with nursing leaders and staff members to develop, implement, use, and review and revise policies and procedures regarding use of patient bar codes (usually wrist bands or ankle bands) and requirements for scanning medications prior to administration. All medications are scanned prior to administration and scan failures are reported to the pharmacy department for immediate resolution. Policies and procedures address requirements for scan failures or equipment failures, and information system downtimes.

11.4 Automated Dispensing Cabinets

Automated dispensing cabinets (ADCs) are used for medication control and security throughout the organization and are interfaced with the hospital and/or pharmacy clinical information system as a closed-loop system. ADCs are utilized to contain all ward stock in all patient care areas and diagnostic areas of the hospital, to contain all controlled substances and narcotics, to contain first doses of select medications, to contain all scheduled medications, or any combination of these approaches. Decisions regarding how ADCs are utilized are made by pharmacy department leaders in collaboration with nurse leaders and managers, and other appropriate health care professionals or organizational leaders. All ADCs are profiled with the organization's or pharmacy department's clinical information system.

ADCs and their databases contain patients' medication profiles, current inventory information, current formulary information and any applicable restrictions, and cost information. They are interfaced as well with bar code medication administration scanners and related databases when used. Policies and procedures include

- user information and restrictions or "privileges,"
- ADC requirements for medication control and dispensing (procedures for loading, removal and return of medications, at minimum), and
- override conditions and process.

ADCs ensure safe medication storage, distribution, access, and use and are placed in locations that support health care professionals' workflow patterns at appropriate par levels established

utilizing medication use pattern data. An appropriate number of ADCs are assigned to patient care units, usually proximal to a computer terminal used to access the electronic health record. Medications are assigned to locations in ADCs to optimize patient safety and medication security (e.g., pockets with lids restricting access to only one medication versus open "matrix" drawers or doors). Medications are loaded into ADCs using bar code technology to ensure placement in the correct location. Quality assurance processes are employed to identify opportunities for improvement and patient safety.

ADCs may be used for inventory control and dispensing of large volume IV solutions, for emergency kits, for devices, and for other unique situations. ADC databases are used for monitoring and surveillance of medications that are removed from the devices, especially controlled substances and narcotics. Policies and procedures that are unique to this use are developed and utilized by pharmacy department, nursing department and other appropriate personnel.

11.5 High-Density Storage/Inventory Management

The pharmacy department utilizes a systematic approach for inventory management of medications and medication-related devices. Such approach outlines all steps from purchasing and procurement through dispensing to patient care areas, pharmacy areas, ambulatory clinics and off-site physician offices (if applicable). Inventory management systems may be manual, may be partially automated, or may be fully automated.

Bar-code scanning systems are utilized at all points of the inventory management process to ensure that all products are correct as intended, have not expired, and have not been recalled. Medications are received into the hospital and pharmacy department utilizing bar-code scanning systems and transferred within the pharmacy department and its satellites to all locations within the organization.

When carousels are incorporated into the inventory management process, all safety-related functions of the carousel (e.g., bar-coding, medication selection, etc.,) are utilized to ensure safe mediation storage and distribution, including receiving into and dispensing from the carousel. When used, automated dispensing cabinets and carousels are fully interfaced and integrated to ensure patient safety.

11.6 Compounding Devices

Compounding devices are used in the pharmacy department for sterile and non-sterile medication compounding when appropriate. Equipment is selected from appropriate vendors and is validated initially, and as recommended by the manufacturer and regulatory bodies. The equipment is calibrated daily, or at appropriate intervals based upon designed use. Maintenance of the equipment should be documented. Appropriate policies and procedures, staff training and ongoing competency assessments are maintained. Bar-coding is integrated into the compounding device software to assist in ensuring safe medication use practices. When placed in sterile environments (e.g., hoods, isolators, on benches in open-architecture clean rooms, etc.), such placement does not negatively impact the quality of the sterile environment and appropriate best practices, guidelines, or regulations (e.g., USP 797, 800) are maintained.

11.7 Smart Pumps

Intravenous infusion devices with drug libraries and dose error reduction systems (smart pumps) may be used in some or all parts of many health care organizations. When used,

wireless pumps that are integrated through a bidirectional interface with the organization's electronic health record are most desirable. Whenever such devices are utilized, the pharmacy department collaborates with nursing department leaders, managers and staff; information technology staff; risk management staff; quality and safety leaders and staff members; and other appropriate staff members to design drug libraries and parameters used to guide safe medication administration. Optimally, these individuals comprise an interprofessional committee. Pharmacy department leaders or appropriate staff members assume leadership roles on the committee and ensure that regular meetings are held to manage policies and procedures, review device quality data, and determine changes needed for libraries, infusion parameters, and other data.

11.8 Outpatient Pharmacy Automation

The pharmacy department uses automation in the outpatient pharmacy to assist in safe and efficient medication control, storage and dispensing. Devices such as carousels and other inventory management systems, electronic counters, automated prescription filling devices (i.e. ScriptPro and others) that are interfaced with the pharmacy and/or organization's electronic health record, and patient queueing systems are commonly used. Equipment is selected from appropriate vendors and is validated initially, and as recommended by the manufacturer and regulatory bodies. The equipment is calibrated daily, or at appropriate intervals based upon designed use. Appropriate policies and procedures, staff training and ongoing competency assessments are maintained. Bar-coding and interfacing with the organization's electronic health record and other appropriate safeguards assist in ensuring safe medication use practices.

11.9 Radiofrequency Identification Tracking

Radiofrequency identification (RFID) tracking solutions are utilized as a component of the inventory management system. Pharmacy department leaders collaborate with appropriate organizational department representatives (e.g., Medical Materials Supply, Information Technology, etc.,) to use a process for selection of medications and/or devices for RFID use, and develop and implement policies and procedures for management of RFID medications and devices. Appropriate staff training and ongoing competencies, routine validation of devices required for use, and continuous quality improvement principles are utilized in the use of RFID in the pharmacy department and the organization.

11.10 Repackagers

Repackagers are utilized to repackage solid and liquid dosage forms into unit-of-use or unit dose packages when such doses are not available commercially from manufacturers. Policies and procedures are utilized to outline medications that may be repackaged and corresponding dosage forms; labelling requirements, including lot numbers and expiration dates; record keeping requirements, staff competencies and training required; and quality assurance requirements. Bar codes are used for identification of medications to be repackaged. Unique bar codes are developed when needed for all medications that are repackaged and that do not have a manufacturer bar code, and are integrated into all informatics, inventory management, and automated systems.

Standard 12 (With Commendation): Collaborative Medication Management Services

Pharmacists in their scope of practice are involved as part of an interprofessional team in the development and implementation of clinical care plans with prescriptive authority (initiating, modifying, discontinuing, monitoring) in the healthcare setting (clinical practice guidelines, critical pathways) and disease state management programs involving collaborative pharmacy agreements and treatment protocols.

12.1 Medication Therapy Decisions
The pharmacist's prerogative 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, are clearly delineated and approved by the appropriate committee (e.g., P&T, patient care, or medical executive committee).

Standard 13 (With Commendation): Research

The pharmacy department conducts medication-related or pharmacy-related research within the hospital, and/or collaborates with other disciplines (e.g., medicine, nursing,) and/or with colleges of pharmacy, medicine, or nursing in research efforts within the organization. The pharmacy department may also participate in pharmaceutical industry-sponsored research conducted within the hospital. Such research projects may include, but are not limited to, the following:

- pharmaceutical research, including the development and testing of new drug dosage forms and drug preparation and administration methods and systems,
- clinical research, such as therapeutic characterization, evaluation, comparison, and outcomes of drug therapy and drug treatment regimens,
- health services research and development, including behavioral and socioeconomic research such as cost-benefit issues in pharmaceutical care, and
- operations research, such as time and motion studies and evaluation of new and existing pharmacy programs and services.

The pharmacy department complies with applicable peer-review requirements of the organization or sponsoring entity, such as the Institutional Review Board or similar entity. The pharmacy department maintains control of all medications used for research purposes in the hospital and in the ambulatory clinics, if applicable. The pharmacy department provides the receiving, storage, and dispensing functions for medications used for research in the hospital and its ambulatory clinics and participates in monitoring efforts for patients and for research sponsors.

Standard 14 (With Commendation): Residency Education and Training

The pharmacy department offers professionally developed residency programs for pharmacists that are accredited by appropriate local, national, regional or international accrediting bodies, including ASHP.

Glossary

Automated Dispensing Cabinet (ADC): A cabinet or drug storage device that electronically dispenses medications in a controlled fashion and tracks their use, replacing or supporting the traditional unit-dose drug delivery system.

Barcoded Medication Administration (BCMA): An inventory control system that uses barcodes to prevent human errors in the distribution of prescription medications at hospital or health-systems. The information encoded in barcodes allows for the comparison of the medication being administered with what was ordered for the patient.

Clinical Decision Support (CDS): A process for enhancing health-related decisions and actions with pertinent, organized clinical knowledge and patient information to improve health and healthcare delivery. CDS should be intelligently-filtered and presented at the appropriate times to the appropriate people. With the growing use of technology in healthcare, CDS tools are often included within the electronic health record. These tools include alerts, reminders and documentation templates aimed to improve clinical processes and outcomes

Clinical Pharmacist: Clinical pharmacists work directly with physicians, other health professionals, and patients to ensure that the medications prescribed for patients contribute to the best possible health outcomes. Clinical pharmacists practice in health care settings where they have frequent and regular interactions with physicians and other health professionals, contributing to better coordination of care.

Collaborative Medication Management Services: see Medication Management Services

Collaborative Pharmacy Practice Agreement: A formal agreement in which a licensed provider makes a diagnosis, supervises patient care, and refers patients to a pharmacist under a protocol that allows the pharmacist to perform specific patient care functions.

Compounding: The process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Compounding includes the combining of two or more drugs.

Continuing Professional Development: A self-directed ongoing, systematic and outcomes-focused approach to lifelong learning that is applied to practice. It involves the process of active participation in formal and informal learning activities that assists individuals in developing and maintaining continuing competence, enhancing their professional practice, and supporting achievement of their career goals.

Dashboard: A succinct, easily readable, usually graphical display of the key performance indicators a management team wants to monitor regularly. It provides a single view of information from across an organization and presents it in a readily accessible way.

Formulary: A formulary includes, but is not limited to, a list of medications and medication-associated products or devices, medication-use policies, important ancillary drug information, decision-support tools, and organizational guidelines. The formulary system is the ongoing process through which a health care organization establishes policies on the use of drugs, therapies, and drug-related products and identifies those that are most medically appropriate and cost-effective to best serve the health interests of a given patient population.

High-Density Storage: High density storage provides a larger storage capacity in less space than traditional shelving for storing healthcare supplies such as medications, dialysis equipment, catheters, surgical kits, and other patient supplies.

Information System: The electronic and/or paper driven systems and resources available to the pharmacist at the point of care which support the applicable scope of services, including, but not limited to:
- the documentation of all clinically relevant patient information necessary for the scope and size of the practice
- effective prospective and retrospective Drug Utilization Review (DUR);
- relevant clinical decision support;
- safety and efficiency in the care process;
- sharing of relevant patient information among the patient care providers;
- ensuring the integrity, security, and privacy of patient information and other data;
- timely and accurate data reporting requirements; and
- accurate, timely, and complete billing, reimbursement, and fiscal management.

Interprofessional Team: A team composed of members from different professions and occupations with varied and specialized knowledge, skills, and methods. The team members integrate their observations, bodies of expertise, and spheres of decision making to coordinate, collaborate, and communicate with one another in order to optimize care for a patient or group of patients.

Just Culture: Just culture refers to a values-supportive model of shared accountability. It is a culture that holds organizations accountable for the systems they design and for how they respond to staff behaviors fairly and justly. In turn, staff members are accountable for the quality of their choices and for reporting both their errors and system vulnerabilities.

Medication Management Services: variety of terms, such as Medication Therapy Management (MTM), Comprehensive Medication Management (CMM), Collaborative Medication Management. A Medication Management Service includes the following elements:
- Patient-centered approach to care – the service is individualized for a specific patient, focuses on the patient's needs and concerns, and involves the patient in the care process.
- Assessment of medication appropriateness, effectiveness, safety, and adherence. Consideration should be given to accessibility and cost of medications.
- Collaborative approach to care that involves the patient, caregiver(s), pharmacists, and other healthcare providers
- Focus on health outcomes

Medication Therapy Management: Medication therapy management (MTM) services are patient-centered, based on individual patient need, and use a standard patient care process. MTM services are delivered by a pharmacist and focused on improving a patient's therapeutic outcomes. Delivery of MTM services includes a comprehensive approach to identifying and resolving medication therapy problems in collaboration with other health care providers during the time period the patient is under the pharmacist's care. The service design empowers patients to take an active role in managing their medications.

Metrics: Metrics are standardized measures (quantitative) or performance thresholds used to monitor quality, efficiency, outcomes, and other key parameters of a pharmacy practice and its operation.

Pharmaceutical Clean Room: A controlled, typically aseptic environment within a pharmacy in which the concentration of airborne particles is reduced by particle filtration and by air locks or positive pressure ventilation and in which surfaces are easily cleaned or decontaminated. It is used to compound sterile drugs and infusions for dispensing. Operators within the clean room wear gowns, hoods, and masks to avoid shedding cellular debris.

Point of Care Administration: Any location where patient care is provided, e.g., the bedside, radiology suite, emergency room, clinic, or ambulance.

Repackaging: The act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug.

Transition of Care: The point in the patient care process that involves hand-off of responsibility for the continuation of patient services to another provider.