



ASHP STANDARD FOR CERTIFICATION AS A CENTER OF EXCELLENCE IN MEDICATION-USE SAFETY AND PHARMACY PRACTICE

Introduction

The ASHP Standard for Certification as a Center of Excellence in Medication-Use Safety and Pharmacy Practice reflects contemporary best practices for hospital and health-system pharmacy practice. The certification process used by healthcare and other organizations worldwide indicates that an institution has met predetermined criteria through verification. Assessment of an organization's level of performance in relation to established standards allows the opportunity for implementation of ways to improve continuously.

The need for recognition of innovative, high quality, and safe and effective health-system pharmacy services has led the American Society of Health-System Pharmacists (ASHP) to develop a new certification process to allow health systems to differentiate themselves from others through excellence in medication-use safety and pharmacy practice. In this regard, this Standard embodies the processes of continuous quality improvement. This voluntary certification process is offered to health-system pharmacy departments with an interest not only in improving patient care and pharmacy services but also in earning this formal recognition of the value provided to their patients and their health system. Pharmacy departments that have achieved excellence, apply for, and successfully complete a rigorous formal certification process will be designated an "ASHP Certified Center of Excellence in Medication-Use Safety and Pharmacy Practice."

The ASHP Standard for Certification as a Center of Excellence in Medication-Use Safety and Pharmacy Practice addresses the following primary areas:

Placement of Pharmacy Department within the Health System

1. Organizational Relationships
2. Team-Based Care

The Pharmacy Department and its Services

3. Leadership and Management
4. Patient Care Services
5. Operations

6. Quality and Performance Improvement
7. Financial Management
8. Education, Training, and Research
9. People

Health-System Processes Supporting Safe Medication Use and Pharmacy Practice

10. Medication Use and Safety
11. Information and Medication-Use Technology
12. Automation and Technology

Within each Standard are key areas of focus in which the health system and/or pharmacy department must demonstrate excellence. Evaluation of the practice is conducted through review of documents, data, and exhibits, and an onsite or virtual survey.

Purpose of the Standard

The purpose of the ASHP Standard for Certification as a Center of Excellence in Medication-Use Safety and Pharmacy Practice (hereinafter “the Standard”) is to establish criteria to guide, describe, and gain recognition for highly advanced, excellent-quality, safe, and effective hospital and health-system pharmacy services. The development of a standards-based certification process is critical for recognition of consistent excellence and continuous quality improvement. Achievement of certification provides evidence of excellence in leadership and management, medication-use policy and safety, systems effectiveness, and delivery of current, cutting-edge, best practice pharmacy services that are associated with high quality care and desired patient care outcomes.

The Standard describes the criteria used in evaluation of hospitals and health systems that apply for certification of their hospital or health-system pharmacy services. The certification program is conducted under the authority of the ASHP Board of Directors. The *ASHP Regulations on Certification as a Center of Excellence in Medication-Use Safety and Pharmacy Practice* describes the policies governing this program and procedures for seeking certification.¹

The term “health system” is used in this Standard and refers to both hospitals and health systems, defined as occurring in both acute and ambulatory settings.

ASHP values the principles of diversity, equity, and inclusion in its policies and practices, and uses the term “underrepresented groups” for a collective description. This term is further defined in the glossary of this Standard.

PLACEMENT OF PHARMACY DEPARTMENT WITHIN THE HEALTH SYSTEM

Standard 1: Organizational Relationships

1.1: Pharmacy Executive Position in the Organization and Organizational Responsibilities

Pharmacy departments of leading health systems are led by a pharmacy executive who is responsible for strategic planning, design, operation, and improvement of the health system's medication management systems. Contemporarily, this individual is referred to as the "chief pharmacy officer" in many health systems; in the Standard, this individual will be referred to as the "pharmacy executive."

The pharmacy executive is positioned within the organizational structure to report directly to, or in a matrix relationship that includes, the health system's executive (e.g., chief executive officer, chief operating officer, chief clinical officer, chief medical officer) to promote effective communication, collaboration, strategic alignment of goals, and teamwork with other disciplines and to ensure that the strategic and innovative vision of the pharmacy executive can be achieved. The pharmacy executive:

- Has a market-competitive title internally consistent with other executive leaders who report at the same organizational level;
- Holds membership on the medical executive committee (or equivalent, even if nonvoting) and other committees that have responsibility for medication-use policy, patient care, and practice/management;
- Maintains an active role in the health system's strategic planning committee(s) regarding all aspects of the medication management processes across the continuum of care to improve healthcare outcomes and ensure alignment of health-system goals and priorities;
- Ensures that pharmacy services align fully with the health system's centers of excellence;
- Ensures that medication use and benefit design focus on total health through the formulary, with procurement driven by clinical efficacy and safety;
- Collaborates with other healthcare executives within and external to the health system to foster and build cross-functional relationships and align interprofessional services that are measured using quality, financial performance, pharmacotherapeutic outcomes that involve all patient populations served, and other metrics on balanced scorecards;
- Ensures that medication-use systems function safely, effectively, and efficiently across all points of care in the health system; and
- Advances patient care services through use of data, process standardization, and pharmacy best practices and innovations in education, training, technologies, and automation.

The pharmacy executive ensures that policies, procedures, and systems promote safe, effective, and efficient medication use within the pharmacy department and the health system reflect interprofessional collaboration and practice and are consistently employed throughout the health system.²⁻⁵

1.1.1: Pharmacists and Pharmacy Technicians Working Outside of the Pharmacy

The pharmacy executive maintains responsibility for all pharmacy functions and employees who practice pharmacy throughout the health system and ensures that employees are optimally positioned and resourced to improve the quality, safety, and efficiency of medication management needs and medication-related patient outcomes across the continuum of care in the most cost-effective manners.

When pharmacists and pharmacy technicians are placed within other functional areas of health systems, such as patient or medication safety, quality, risk management, academic units, informatics departments, and physician offices or clinics, the pharmacy executive maintains sole responsibility for, or collaborates with other leaders to maintain shared responsibility for, management of such pharmacy practitioners.^{6,7}

1.1.2: Affiliations with Academic Institutions and Community Colleges

The pharmacy executive collaborates with state and federal regulatory agencies to advance the roles of pharmacists and pharmacy technicians. The pharmacy executive also develops and maintains affiliations with academic institutions and community colleges to promote the diversity of populations served and the value of cultural competency, and work to improve health outcomes of underrepresented minorities⁸ to offer opportunities for trainees of colleges of pharmacy and pharmacy technician training programs. Training opportunities also extend to employed intern programs and postgraduate residency training programs as described in Standard 8.

1.2: Committee Work

The pharmacy executive establishes and maintains key relationships across the health system with internal and external customers. Pharmacy leaders, managers, and pharmacists, as well as pharmacy technicians when appropriate, are members of health-system committees and task forces focused on medication management. Examples of these include at a minimum: pharmacy and therapeutics (P&T), patient care, interdisciplinary medical staff committees, medication safety, quality management, ethics, nutrition, pain management, medication stewardship, institutional review board(s) (IRBs), and information technology (IT) committees. Pharmacists and pharmacy technicians also have active roles on nursing unit and/or service line quality, performance improvement, and safety committees, among others, to ensure safe medication use and optimization of medication management systems.

A pharmacist representative is a member of and actively contributes to activities of 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 engagement, patient service programs, and other programs as identified by the pharmacy department leaders.

Standard 2: Team-Based Care

2.1: Pharmacy Department Integration into Healthcare Teams and the Care Delivery Model

Comprehensive medication management (CMM) services extend to all parts of the health system and to all patient care settings where medications are used. Services support a teams-based approach to patient care, including medical, nursing, and other clinical services and members of learning teams. Pharmacists are recognized as medication therapy experts on the healthcare teams. CMM services and overall pharmacy services are structured to ensure optimized medication-use outcomes. New service implementation is prioritized and developed based upon an assessment of need performed by pharmacy department leaders in cooperation with medical, nursing, and health-system leadership.

Pharmacists provide CMM as integral members of interprofessional care teams. As providers of care, they are responsible and accountable for ensuring that all patient care and population health needs involving the use of medications are addressed. Pharmacy technicians maintain advanced roles to provide comprehensive pharmacy services across the continuum of care.

2.2: Acute Care

Acute care pharmacists provide CMM to acute care patients during all hours, independent of time and day and during all phases of a patient's stay. As such, all acute care patients have access to a pharmacist throughout their admission. At admission, the pharmacy department is responsible for obtaining medication histories, developing and recording an accurate medication list, and resolving any discrepancies. Throughout the patient's admission, pharmacists are responsible for ensuring appropriate, evidence-based medication therapy plans through all transitions of care using ongoing assessments and reassessments of pertinent patient information. At discharge, the pharmacy department provides or collaborates with other disciplines to provide patient-centered processes that ensure the appropriateness of discharge medications, such as Meds-to-Beds programs, for dispensing medications and educating patients and their family members or caregivers on these medications and for communicating patient care medication needs to the next level or location of care. In some cases, pharmacists share education responsibilities with nurses, dietitians, and other healthcare professionals. Post-discharge follow-up of high-risk patients based upon populations served is conducted to prevent readmissions and adverse drug events.

2.3: Ambulatory Care

Ambulatory care pharmacists provide CMM services as members of the patient's healthcare team in a continual and ongoing manner to meet the patient's medication needs fully and improve medication-related outcomes. Pharmacists are integral members of team-based collaborative care provided through a mode that best meets a patient's needs (i.e., in-person visit or telehealth). Pharmacists provide CMM for patients in all ambulatory care settings, including transitions from acute care admissions to ambulatory care clinics for continued care. Ideally, pharmacists provide CMM to all patients at transitions of care, and, at a minimum, CMM is provided for high-risk patients and for other identified groups of patients.

2.4: Disease Prevention and Wellness Promotion

As part of the collaborative interprofessional patient care team, pharmacists and pharmacy technicians are involved in disease prevention and wellness promotion programs in all areas of the health system. Examples include immunization programs and clinics, smoking cessation, cardiac risk reduction, weight management, osteoporosis management, and other disease prevention and population health management programs.^{9,10}

2.5: Other Segments of the Health System

Collaborative, team-based CMM extends to all parts and all settings of the health system, including community and/or outpatient pharmacy, specialty pharmacy, home infusion, skilled nursing care, long-term care, and population health.

2.6: Emergency Preparedness

Pharmacy department leaders and pharmacists take leadership roles for medication-related aspects of, and are active members of, emergency preparedness team(s). Policies and procedures outline how pharmacy services are provided during facility, local, or area-wide disasters affecting the health system's patients and are readily available. Appropriately trained pharmacy department staff are active members of preparedness drills. A process is used to inform patients on how to continue using their medication(s) in the event of a disaster. The 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 medication procurement process.

Pharmacy department staff conduct a self-assessment of need compared with published lists of essential drugs for emergency management of infectious, radiological, chemical, and nuclear threats (e.g., Executive Order 13944: List of Essential Medicines, Medical Countermeasures, and Critical Inputs).¹¹ The United States Food and Drug Administration (FDA), federal government, and/or professional medical and pharmacy societies may publish such lists.

During all phases of a public health emergency or disaster event, pharmacy executive presence in the health system or the health system's emergency operations center is pivotal for proactive planning and maintaining secure, functional, and resilient health and public health critical infrastructure.

THE PHARMACY DEPARTMENT AND ITS SERVICES

Standard 3: Leadership and Management

3.1: 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 health system. The pharmacy organizational chart should be developed by the pharmacy executive and approved by the pharmacy leadership team and health-system administration.

Effective leadership and practice management skills are necessary for the delivery of pharmacy services in a manner consistent with health-system 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 department through organizational structures that illustrate this mission. Such structures require communication and collaboration with other departments and services throughout the health system that support pharmacist patient care. Every member of the pharmacy department cultivates communication and collaboration at every opportunity with other departments that support pharmacist patient care.

3.2: Pharmacy Strategic Planning, Mission, Vision, and Goals

With full department input, pharmacy department leaders develop the department's written mission statement that, at a minimum, reflects both pharmacist patient care and service responsibilities. The mission is consistent with the mission of the health system. The development and prioritization of goals, objectives, and work are consistent with the mission statement. The mission, vision, and goals are reviewed and updated based upon need.

3.2.1: Strategic Planning

Pharmacy department strategic planning and determination of measurable short- and long-term quality and safety goals and implementation activities are linked to operational and financial goals, performed in collaboration with institutional leadership and other health-system staff (e.g., nursing, clinical, and medical staff), and aligned to be consistent and relevant with the goals of the health system. Forward-thinking recommendations, such as the ASHP Practice Advancement Initiative (PAI) 2030,¹² the Report of the ASHP Taskforce on Racial Diversity, Equity, and Inclusion,⁸ and the ASHP Research and Education Pharmacy Forecast¹³ are used to increase attention to long-term strategic issues.

The pharmacy department develops and maintains its work or action plan using the SMART (specific, measurable, achievable, relevant, and time-based) goal-setting approach. The work plan is updated and reviewed by the pharmacy leadership team routinely (e.g., monthly).

3.2.2: Measuring and Managing Performance

Pharmacy department leaders use a dashboard (e.g., balanced scorecard) to measure and manage performance. Targets are set within each strategic priority area to improve performance. Dashboard results are shared with staff members, medication management committees, and health-system leadership to promote quality improvement and accountability. Pharmacy department leaders and

managers use system and professional benchmarking activities to achieve transparency and foster healthy competition among departments in the health system.¹⁴

3.3: Pharmacy Department Culture

Pharmacy department leaders create and work with staff members to maintain a culture of professionalism in their pharmacy department and practice. This culture extends to involve employee recruiting, orientation, performance evaluation, and professional development processes, a stimulating clinical and operational practice, and maintaining a clean and sufficiently spacious environment to promote harmony and safe medication-use practices. All members of the pharmacy department are involved with developing and sustaining a culture of responsibility and accountability, and all individuals are treated with respect and dignity.¹⁵

The pharmacy department culture reflects zero tolerance of all forms of discrimination, harassment, and intimidating and/or malicious behaviors.^{16,17} The pharmacy department culture also reflects a diverse and inclusive workforce that reflects the diverse patients for whom they provide pharmacist patient care.

The pharmacy department and/or health system provides continuous professional development and training programs for pharmacy department and other healthcare personnel on diversity, equity, and inclusion principles to enable employees to recognize desirable and undesirable aspects of a professional pharmacy culture and practice.⁸

3.4: Scope of Services

The pharmacy department maintains a written document describing the scope of pharmacy services provided in all areas of the health system. Services are consistent with the health system's scope of services, compliant with state practice acts and regulations, and applied in all practice sites.

The pharmacy department's mission, goals, and scope of services are clearly communicated to everyone involved in the provision of pharmacy services. The mission statement is reviewed by health-system leadership, pharmacy department leadership, and staff regularly for necessary modifications based on scope of practice.

3.5: Practice Standards and Guidelines

3.5.1: Standards, Regulations, and Best Practices

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 (TJC), or other appropriate accrediting bodies. Guidelines set forth by other independent organizations, such as the Institute for Safe Medication Practices, are assessed and adopted as applicable.

3.5.2: Strategies to Meet Standards

The health system and the pharmacy department employ strategies to meet these standards, regardless of the financial and organizational arrangements by which pharmacy services are provided to the health system and its patients. Pharmacists practicing in health systems play a critical role in ensuring that the health system adheres to medication-related national quality indicators and evidence-based practice guidelines and to measures selected by the health system and/or pharmacy department.¹⁸

3.6: Legal and Regulatory

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 statutes and regulations. The pharmacy department maintains relevant documentation of compliance with requirements concerning procurement, distribution, and disposal of medications and related products; security of patient information; workplace safety; controlled substances; and other applicable regulations.

3.7: Safety

Pharmacy department personnel are involved in the health system'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 are familiar with these plans.

3.8: Policies and Procedures

3.8.1: Availability and Accuracy

A policy and procedures manual governing the scope of the pharmacy services provided (e.g., administrative, operational, and clinical) is available and consistent with current department processes. The manual is reviewed and revised by leaders and staff members on a regular basis to reflect changes in policies and procedures, scope of services, organizational arrangements, objectives, practices, and/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.

3.8.2: Documentation of Policies and Procedures

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

3.8.3: Education and Training

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

3.9: 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; revoke (deprovision) access when appropriate; and periodically evaluate employee lists for continuing access at existing level. Staff training and competency measurements are conducted regularly.

3.10: Communication

An internal and external plan of communication that describes the specific audiences (e.g., pharmacy staff, medical staff, administration, professional colleagues, and/or public), communication methods to be used, and the frequency of communication is used by the pharmacy executive, other pharmacy leaders, and staff members. Pharmacy department leaders use effective methods to communicate with

employees within the pharmacy department and health system. Such communications may involve changes in medication-use policies and procedures, changes in operations, and other appropriate information that employees need to perform their jobs effectively and efficiently. Such communication processes may involve, among other things, regular and timely meetings, team huddles, shift debriefs, leadership rounds, learning boards, email communication, and personal communication with managers to achieve established objectives. Pharmacy staff members are empowered to use communication processes with colleagues and pharmacy department leaders through established mechanisms. Pharmacy department leaders and staff members use appropriate mechanisms regularly to assess the effectiveness of such communications.

Progress on the annual work plan, performance indicators (dashboard), and other project updates are communicated at regular intervals. An annual report of the pharmacy department describing accomplishments, awards, recognition and publications is published and shared with pharmacy and health-system staff, administration, and professional colleagues.

3.11: Staffing and Competencies

3.11.1: Position Descriptions

Areas of responsibility within the scope of pharmacy services are clearly defined, and 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 (e.g., pharmacy technicians, clerical persons, interns) is employed to facilitate the provision of care. Pharmacy technicians are responsible for aspects of medication procurement, inventory management, distribution, and dispensing; assist with pharmacists' patient care activities; and prepare prescription orders for a pharmacist's clinical review.

3.11.2: Pharmacy Executive

Depending on the health system's organizational structure and other factors, designations such as chief pharmacy officer, pharmacy director, or pharmacist-in-charge may also be used. Notwithstanding the title, a professionally competent, legally qualified pharmacist clinician manages the pharmacy department. The pharmacy executive is knowledgeable about and has experience in all aspects of pharmacy care. Completion of advanced management training or a management degree is highly desirable.

In addition to the responsibilities of the pharmacy executive outlined in Standard 1 and previously in Standard 3, the pharmacy executive is responsible for:

- Energizing, empowering, assisting, and communicating with other pharmacy department leaders and staff members;
- Establishing the mission, vision, goals, and scope of services of the pharmacy practice setting on the basis of the needs of the patients served, developments and trends in healthcare and pharmacy practice, and in alignment with the health system;
- Developing, implementing, evaluating, and updating plans and activities to fulfill the mission, vision, goals, and scope of services;
- Designing the organizational leadership structure of the department;
- Ensuring the development and implementation of policies and procedures that provide safe and effective medication use for all patients served by the health system;

- 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 well-being, career development, performance review, and retention of pharmacy staff members; 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.

The pharmacy department is a cross-functional group whose skills set includes operations management, clinical care, financial management, informatics and analytics, and process improvement. Depending on the size and scope of the setting, these functional responsibilities may be assigned to a single person or a team. The pharmacy executive is responsible for monitoring the status of the goals set forth in the vision, providing feedback to the pharmacy team as necessary, and advancing the department's implementation of the core functions of the pharmacy practice.¹⁹

3.11.3: 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. The department maintains a process to ensure that all licensed staff have an active license and that certifications and other documentation of competency are in good standing.

3.11.4: Pharmacy Technician Requirements

The health system adheres to all national and state regulations and guidelines regarding pharmacy technician registration, certification, and licensure, as applicable. All newly hired pharmacy technicians have successfully completed a pharmacy technician training program accredited by ASHP and the Accreditation Council for Pharmacy Education (ACPE)²⁰ that includes education on at least the following topics:

- Medication distribution,
- Medication preparation and compounding,
- Prescription-dispensing process,
- Patient service skill,
- Patient and employee safety, and
- Pharmacy technician duties and responsibilities as defined by regulations.²¹

In addition, all pharmacy technicians obtain and maintain Pharmacy Technician Certification Board (PTCB) certification.²⁰

3.11.4.1: Career Advancement

The pharmacy department provides career advancement opportunities for pharmacy technicians and has defined entry-level, advanced, and specialized roles, such as obtaining patient medication histories, assisting with meds-to-beds programs, order fulfillment, tech-check-tech, supervisory roles, regulatory compliance and inspection roles, supply chain management, informatics, automation management, diversion prevention, medication safety, revenue cycle management, and patient assistance programs.^{21,22}

3.11.5: Pharmacists' Practice

3.11.5.1: Roles of Pharmacists

The department clearly defines the roles of pharmacists in clinical and in operations and distribution systems practice. The Standard uses the term “clinical pharmacist” to indicate a pharmacist who practices clinically, providing CMM and related care for patients in a healthcare setting. Depending on the health system’s organizational structure and other factors, designations such as clinical pharmacist, clinical specialist, and clinical pharmacy specialist, among others, may be used.

3.11.5.2: Requirements and Qualifications

Clinical pharmacists are licensed pharmacists with specialized advanced education and training who possess the clinical competencies necessary to practice in team-based, direct patient care environments.²³ These requirements 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. Pharmacists practicing in specialty areas are board certified through the Board of Pharmacy Specialties or other appropriate bodies. Pharmacists practicing in operations areas of the pharmacy department (e.g., pharmacy satellites, inpatient pharmacy, sterile products preparations areas, outpatient dispensing pharmacies) are licensed pharmacists with training and competencies necessary to practice in their respective areas.

3.11.5.3: Credentialing and Privileging

The department uses an ongoing credentialing process to obtain, verify, and assess the qualifications of pharmacists. A privileging process is used to define the pharmacist’s scope of practice within the health system based on evaluation of credentials and performance. In some health systems (e.g., Veterans Administration health systems), this process is also described as pharmacists having a scope of practice. Pharmacists, where allowed, leverage and use an expanded scope of practice, including prescribing, to optimize patient care. An ongoing competency program assesses activities of these pharmacists. Peer review may also be used to assess competency and consistency of pharmacists who prescribe medications and laboratory tests and to drive educational needs for staff members.

3.11.5.4: Collaborative Practice

Collaborative practice agreements (CPAs) are used by the health system to create a formal practice relationship between pharmacists and physicians. CPAs are aligned with a pharmacist’s education and training and allow a pharmacist to assume responsibility for specific patient care functions that are otherwise beyond their typical scope of practice. The extent of services authorized under a CPA depends on the state’s statutory and regulatory provisions, as well as the terms of the specific agreement between the pharmacist and physician(s). CPA records are maintained in the pharmacy department and perhaps in the human resources department as well). CPAs may not be applicable if pharmacists are privileged by the medical staff, or, as in the case of the Veterans Administration facilities, there are “pharmacists with a scope of practice” who undergo peer review and annual (or more frequent) evaluations.

3.12: Education and Training

3.12.1: Continuing Professional Development Plans

All personnel possess the education and training needed to fulfill their job responsibilities and have individualized continuing professional development plans.

3.12.2: Continuing Education Programs

All personnel contribute to relevant continuing education programs, staff development programs, and other activities as necessary to maintain or enhance their competency. Pharmacy education, residency training, and continuing education programs include healthcare reimbursement, payment, and business management as topics in all areas of practice, among other things.

3.12.3: Health-System Resources

The health system makes available to personnel, as appropriate, training and education on new processes, procedures, and methods of patient care. The health system also makes available to personnel time off to attend professional conferences and funds for meeting expenses, when possible.

3.13: Recruitment and Selection of Personnel

Personnel are recruited and selected based on requirements outlined by established position descriptions. Criteria used in the selection process include the candidate's performance of similar job-specific duties, education and training history relevant to job-specific duties, and willingness to contribute to achieving the mission of the department and the health system. Pharmacy department processes include initiatives to achieve equity, diversity, and inclusion in all technical, clinical, and leadership roles.

3.13.1: Orientation of Personnel

Personnel who are new to either a specific position or the health system are oriented to their position through an established and structured process. During the orientation process, an employee knowledgeable in the work assigned trains personnel in their new job functions. During the orientation period, the trainer's normal workload is reduced 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.

3.14: Ethical Conduct

Standards of ethical conduct are established, and all pharmacy department staff are educated regarding these standards. The institution's conflict-of-interest and ethical conduct policies are clearly communicated to all staff, with appropriate staff acknowledgment of conformance with these policies. Ethical principles drive all clinical and business decisions related to medication use.

3.15: Performance Evaluation and Staff Development

Scheduled periodic evaluations of performance occur for all pharmacy department personnel. Performance is evaluated based on position description requirements and expected competencies, and the evaluation format is consistent with that used by the health system. 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.

3.16: Competency Assessment

An ongoing competency assessment program is used for all pharmacy staff members. Pharmacy department leaders routinely evaluate pharmacy department staff for areas of aptitude and provides or

facilitates 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, competency management for all levels of all pharmacists and pharmacy technicians, and professional development programs ensure compliance with appropriate licensures and other credentials.

3.17: Work Schedules and Assignments

The pharmacy department staffing plan is based on workload statistics and patient care needs. Pharmacist and pharmacy technician assignments 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.

3.18: Optimal Pharmacy Staffing

Pharmacy leaders collaborate with physicians, nurses, health-system administrators, and others to outline key pharmacy services that are essential to safe and effective patient care and employee engagement as outlined in the scope of services document. Pharmacy leaders use innovative approaches to consider potential benefits and risks of flexible staffing models, telehealth practices, legal requirements, accreditation standards, professional standards of practice, and the resources and technology available in individual settings. Pharmacy leaders develop contingency plans for changes in staffing models to accommodate changes in the healthcare environment while meeting the needs of patients and staff. Pharmacy leaders develop and use key performance indicators to substantiate safe staffing models.²⁴

3.19: Innovations

3.19.1: Monitoring the Healthcare Industry

The pharmacy executive maintains vigilance and a watchful eye on the healthcare industry and all related landscapes that affect healthcare and pharmacy practice. This individual demonstrates passion for innovation and an impatience for the status quo, and seeks opportunities to trial and integrate new technologies, practice models, care models, and use of personnel and assets. The pharmacy executive collaborates with leaders in other healthcare disciplines to promote interprofessional innovation centers designed to pursue breakthroughs in areas such as patient experience, medication use, clinical outcomes, operational efficiency, technology, and revenue generation.

3.19.2: New Programs and Services

The pharmacy executive and leaders use pharmacy analytics to optimize clinical practices and medication-related outcomes. They create new pharmacy service offerings (e.g., granular, interactive data-driven dashboards of actual clinical care outcomes) that provide evidence-based medication-use guidance to healthcare providers in all service areas, remove barriers, and improve patient outcomes and medication use.

3.19.3: Involvement in Professional Organizations

The pharmacy executive maintains a profile in professional organizations and seeks and uses opportunities to share thoughts and observations and their effects on the profession with other thought leaders. The pharmacy executive collaborates with other leaders within and external to the health

system to shape a vision for innovations in patient care, pharmacy practice, and training, as well as with colleagues to investigate opportunities to ask critical questions and clear new professional pathways.

Standard 4: Patient Care Services

4.1: Clinical Pharmacy Services

4.1.1: Team Membership and Services^{25,26}

CMM is an essential service within the health system. Pharmacists are core members of all interprofessional teams throughout the health system in all acute and ambulatory settings. Pharmacists providing CMM services use current medical evidence and standards of practice in care of patients, are responsible and accountable for addressing all medication-related needs of the patients and the populations they serve, and share accountability with their teams for achieving optimal medication-related patient and population outcomes. CMM services are provided based on patient need and, therefore, are independent of the time of day or day of the week. CMM services meet the medication needs of the health system's patient population and the community served. The pharmacy workforce leads medication reconciliation processes during care transitions (e.g., emergency department, upon admission and discharge, ambulatory care setting, community pharmacy, long-term care). CMM services include but are not limited to pharmacokinetic-, pharmacodynamic-, and pharmacogenomic-related care; drug information; and disease prevention and wellness programs, among others.

Pharmacists and their interprofessional teams utilize the CMM systematic approach to assess and address medication management needs of patients using the following steps^{27,28}:

1. Identify patients that have not achieved clinical goals of therapy;
2. Understand the patient's personal medication experience, history, preferences, and beliefs;
3. Identify actual use patterns of all medications;
4. Assess each medication for appropriateness, effectiveness, safety, and adherence;
5. Identify all drug-related problems;
6. Develop a care plan, including changes needed to achieve optimal outcomes;
7. Ensure the patient agrees with and understands the plan of care, which is communicated to the prescriber for content and support;
8. Document all steps and current clinical status vs. goals of therapy;
9. Conduct follow-up evaluations to determine the effects of changes, reassess outcomes, and recommend therapeutic changes to achieve desired clinical outcomes and goals; and,
10. Coordinate care with other team members and communicate personalized goals of therapy.

4.1.2: Qualifications and Competencies

CMM is provided by licensed pharmacists with the education, training, and clinical competencies necessary to practice team-based, direct patient care as a generalist or in their respective specialty area of practice as noted in Standard 3.11: Staffing and Competencies. Accordingly, they are credentialed as primary care providers in the health system.

4.1.3: Scope of CMM Services

The scope of CMM services is well defined and documented, and it is consistent with the health system's scope of services and provides accessible, efficient, and effective care at the patient and population levels. Scope of practice is defined through policies, CPAs, and treatment protocols in collaboration with medical staff, nursing staff, health-system leaders, and other members of the healthcare team and is guided by state and federal laws and regulations.

4.1.4: Documentation of Services

Pharmacists document patient encounters and the service provided in the patient's medical record in accordance with standards and regulations of practice as required by compliance rules and regulations set forth by state and federal governments and payer contracts, as well as to meet the needs of communication and continuity of care with other team members. Documentation is accessible to the patient and the patient's healthcare team as appropriate, and it is easily retrievable for assessing outcomes of CMM. The pharmacist promotes continuity of care for the patient by communicating effectively and collaboratively in a timely manner with the patient's healthcare team, as well as with the patient and the patient's family members and caregivers.

4.1.5: Quality and Economic Outcomes

Quality and economic measures are used to monitor the effectiveness of CMM services and identify opportunities for change or improvement. Identified changes and improvements are implemented and monitored using continuous quality improvement methods.

4.2: Emergency Services

4.2.1: Membership on Response Teams

Appropriately trained pharmacists have an authorized role in responding to medical emergencies and are members of the cardiac arrest/cardiopulmonary resuscitation or code blue and other code response teams. Pharmacists with authorized roles receive appropriate training and maintain appropriate certifications (e.g., Basic Life Support, Advanced Cardiopulmonary Life Support, Pediatric Acute Life Support).

4.2.2: Patient Care during Emergent Situations

Policies and procedures exist within the health system 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 assists with the development of policies and procedures to ensure the availability of, access to, and security of emergency medications, including antidotes. All emergency medications are stored in sealed or tamper-evident containers that enable the staff to determine readily that the contents are complete and have not expired. All emergency medications are available, controlled, and secured in patient care and procedure areas.

4.3: Surgical Services and Procedures Areas²⁹

4.3.1: Medication Preparation and Dispensing

Pharmacy services are provided to surgical services, anesthesia, and all other procedures areas. These services include the preparation, distribution, and control (including reconciliation and disposal) of medications and controlled substances used in the surgical areas, as well as patient-specific clinical pharmacy services. Medication preparation and distribution are assisted by automation. Hours of service to these areas are based upon an assessment of need for the pharmacy services and are documented in the pharmacy scope of services document.

4.3.2: Clinical Pharmacy Services

Clinical pharmacy services for perioperative and procedures areas may include medication therapy management, medication information, formulary management, adverse reaction monitoring and reporting, pain management, emergency response participation, and education.

4.4: Investigational Drug Service^{30,31}

The pharmacy department, generally through the investigational drug service (IDS), maintains control of all medications used for research purposes in the health system and ambulatory clinics. As such, the pharmacy department (or IDS) provides receiving, storage, accountability, and dispensing functions for medications used for research in the health system and its ambulatory clinics, provides clinical pharmacy review of protocols and patient care services, and contributes to monitoring activities for patients and research sponsors.

The pharmacy department maintains access to information on all investigational medications used in the health system. Such information is available in the pharmacy department and in patient care and/or treatment areas and includes known pharmacologic information, safe and proper use, adverse effects, and adverse medication reactions. Medication events involving investigational medications are reported to investigators and are reported in the health system's medication reporting system.

Standard 5: Operations¹⁰

5.1: Facilities and Equipment

Adequate space, design, equipment, and supplies are available for all professional and administrative functions of the pharmacy department. The space and design allow pharmacy staff to conduct its operations, maintain workflow, and deliver patient care services, including private consultations and education, efficiently, safely, and effectively. The workspace is structured to minimize interruptions and allow staff to concentrate on their assigned duties.

5.1.1: Space and Equipment

The space and equipment resources meet all applicable laws and regulations and are located in areas that facilitate the provision of pharmacy services to patients and other healthcare professionals. These include the central pharmacy and pharmacy satellites, sterile product preparation areas, outpatient and specialty pharmacies, infusion centers, medication storage areas in patient care units and diagnostic and treatment areas of the health system, and office and meeting space for pharmacy department leaders and staff members.

All areas in the health system where medications are prepared and stored are under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.

The pharmacy department ensures accurate, efficient, and timely distribution of medications using applicable IT and automation at each step in the medication-use process as outlined in Standards 11 and 12 to document receipt, storage, preparation, distribution, and administration of medications.

5.1.2: Medication Storage

Products with look-alike medication names and packaging that are potentially problematic are stored separately and segregated according to accepted best practices (e.g., not alphabetical). Regular reviews of medication storage areas are conducted and audited for error-prone situations. This includes the nearby storage of look-alike or sound-alike medications or of medications in similar manufacturer packages. Audits are conducted with particular care in areas where pharmacists are not often present (e.g., procedure areas, diagnostic areas).

5.2: Medication Order Review and Verification

5.2.1: Access to Patient Diagnosis

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

5.2.2: Medication Order Review

All medication orders are prospectively reviewed by a pharmacist and assessed in relation to available pertinent patient and clinical information before medication preparation, dispensing (including dispensing by automated devices), and administration in inpatient care areas, treatment areas, and ambulatory care clinics. Exceptions are emergent situations in which treatment of the patient would be significantly compromised by the delay resulting from pharmacist review of the order.

5.2.3: Medication Order Review Process

The medication order review process may be centralized or decentralized and involve staff pharmacists or clinical pharmacists practicing at all levels (e.g., residents to clinical pharmacy specialists). A system for retrospective medication order review is used for medications that are removed from floor stock supply, during emergent conditions when time does not safely permit prospective review, and in cases of medication administration controlled by physicians (e.g., procedures areas, operating rooms). Questions that arise from medication order review are resolved with prescribers before continued processing of the medication orders, and actions taken are documented in the electronic health record (EHR).

A strategy for order review and verification considers times and days of the week and patient care needs and is considered when developing the pharmacy staffing plan. Such plan is reflected in the pharmacy scope of services document. Quality improvement processes are used for monitoring time required for review and verification, accuracy, and error occurrences. Pharmacy personnel involved in order review and verification have completed required EHR training, and their competency is measured routinely. Some medications may be approved for autoverification according to medication-use policy under the authority of the P&T committee. The pharmacy department maintains quality assurance metrics for this process and/or medication safety committee processes of the health system.

5.2.4: Remote Order Review

Medication orders are reviewed and verified from centralized and/or decentralized locations within the health system 24 hours daily. In the event that the pharmacy is not open 24 hours daily, the pharmacy department uses remote medication order review and verification before the preparation and dispensing of medications occurs in all parts of the health system. In such cases, agreements outlining all parameters of services are maintained with the pharmacy department providing remote services, and P&T committee-approved policies and procedures for pharmacy and medication access, selection, preparation, and dispensing are available to all caregivers. Additionally, the pharmacy department providing remote services has access to the formulary and all medication-use policies, guidelines, and restrictions. When the pharmacy reopens, reconciliation is done for all medications prepared and/or dispensed while the pharmacy was closed.³²

5.3: Medication Preparation, Dispensing, and Handling^{33,34}

5.3.1: All medications are prepared and dispensed for patient use in single-unit packages (unit dose packaging) and in a ready-to-administer form with machine-readable coding in all areas of the health system, including unit-of-use packages dispensed for outpatient use.

5.3.2: Medications remain in unit dose packaging until the point of administration.

5.3.3: Manipulation of medications before administration (e.g., reconstitution of powdered medication products, labeling of containers, and splitting of tablets) is permitted only in emergency situations.

5.4: Hazardous Medication Products

Policies and procedures outline special precautions, equipment, and training for preparation, handling, storage, and disposal of hazardous medication 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.³⁵

5.5: Medication Delivery

The pharmacy department is responsible for control of and has written procedures for medication transport to all areas of the health system. Pharmacy technicians, couriers, and other delivery personnel deliver medications to patient care areas according to established schedules and ensure secure storage at destination. Pneumatic tubes are also used to transport medications to patient care and procedures areas according to policies and procedures established for safe medication transport using such devices. A list of medications that cannot be delivered via pneumatic tube is developed and used.

Pharmacy department personnel supervise the stocking, restocking, and documentation of medications in automated dispensing devices, if present.

5.6: Management of Medications at High Risk of Diversion and Diversion Prevention

5.6.1: Roles and Responsibilities

Pharmacy department leaders and staff members collaborate with nursing department leaders and staff members, anesthesia department leaders and staff members, the medication safety officer, risk managers, and others to maintain a real-time, efficient and effective medication diversion prevention program that includes controlled substances,³⁶ high-cost medications, and other diversion-prone medications. This group oversees compliance with organizational policies and laws, and pertaining to controlled substance medication-use integrity systems. The program includes a rigorous surveillance program to detect medication diversion evaluation of health-system performance against best practices, and implementation of action plans. Electronic diversion prevention software is deployed to capture all access points and provide use trends, and ensure real-time surveillance and auditing. Video cameras are used throughout the pharmacy department and health system for medication diversion monitoring. The compliance program is interprofessional and exists to focus on diversion prevention, detection, and response.

5.6.2: Dedicated Personnel

The health system has at least one position dedicated to auditing controlled substance diversion. This position is generally within the pharmacy department and/or nursing departments.

5.6.3: Security

Controlled substances, high-cost medications, and other medications at high risk of diversion are secured at all points in the chain of custody, including procurement, preparation and dispensing, prescribing, administration, waste, and disposal. This system interfaces with the EHR and automated dispensing cabinets (ADCs) and captures medication dispenses, administrations, and waste or return verification. Policies and procedures are consistent with applicable laws and regulations.

5.6.4: Audits

The pharmacy department integrates data and establishes teams to conduct audits of inventory and billing systems between the medications purchased, received, and dispensed, and the amounts charged and/or payments received for controlled substances and high-cost medications.

5.7: Hours of Service and Staffing Pattern

The pharmacy department maintains 24 hours of operation daily for the provision of needed pharmacy

services, and 24-hour pharmacy services are required for all health systems 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 is available on an on-call basis to come onsite to prepare and dispense medications needed that are not contained within ADCs. Alternatively, the medications needed may be sent ready-to-administer from another hospital by courier. Remote clinical services and medication order processing are employed (to the extent permitted by law and regulation) to provide pharmacy services using profiled ADCs.

5.8: Optimal Pharmacy Staffing

5.8.1: Staffing Levels

Pharmacy leaders collaborate with physicians, nurses, health-system administrators, and others to outline key pharmacy services that are essential to safe and effective patient care and employee engagement as outlined in the scope of services document. Pharmacy leaders use innovative approaches to consider potential benefits and risks of flexible staffing models, telehealth practices, legal requirements, accreditation standards, professional standards of practice, and the resources and technology available in individual settings.

5.8.2: Contingency Plans

Pharmacy leaders develop contingency plans for changes in staffing models to accommodate changes in the healthcare environment while meeting the needs of patients and staff. Pharmacy leaders develop and use key performance indicators to substantiate safe staffing models.²⁴

5.9: Outpatient and Specialty Pharmacy

5.9.1: Practice Model

Pharmacy department leaders and staff members collaborate with health-system leaders, medical staff members, nursing leaders, and others to assess patient needs for services such as specialty pharmacy services, infusion pharmacy services, and/or outpatient pharmacy services. When offered, outpatient and specialty pharmacy services ensure patient access to medications, improve medication adherence, provide continuity of care, and improve patient outcomes. Patient care services are offered in a setting that maintains privacy and confidentiality and provides the pharmacy staff access to relevant patient information.

The practice model includes clinic-based pharmacists who practice in the health system's specialty clinics. Pharmacy technicians (e.g., specialty pharmacy liaisons) work under the purview of a pharmacist to provide medication prior authorization (PA), refill authorizations, benefits investigation (BI), and medication assistance program support services for all health-system patients who are prescribed new specialty medications.

5.9.2: Pharmacy Encounter Process

The pharmacy department has a defined encounter process in which the pharmacist, in providing care to their patients, uses a standard process of care. The pharmacy department provides CMM for patients receiving high-cost specialty and clinic-administered medications throughout the health system and affiliate locations. Outcomes metrics are analyzed regularly and are used to improve pharmacy services.

5.9.3: Accreditations

The quality of care from the outpatient and specialty pharmacies is assessed by specific accreditation, such as ASHP, Accreditation Commission for Health Care (ACHC), and URAC.

5.9.4: Hours of Service

Outpatient and specialty pharmacy hours are sufficient for patients to receive their medications in a timely manner. Prescription dispensing is available through the inpatient or outpatient pharmacy 24 hours daily for inpatient (bedside) and clinic discharges and for patients receiving care in urgent care or the emergency department. If 24-hour discharge prescription dispensing services are not offered by the health system, open hours for the outpatient pharmacy are determined by the pharmacy executive based upon an assessment of needs and as illustrated in the pharmacy scope of services document. Patients requiring prescriptions during closed hours are referred by the health system to local pharmacies offering 24-hour dispensing services. The specialty pharmacy provides patients with in-person or remote access to clinical pharmacy resources 24 hours daily.

5.9.5: Scope of Services

The scope of services for the outpatient and specialty pharmacies is aligned with the scope of pharmacy services of the health system. It includes the population(s) served, medications dispensed and related protocols, clinical management of specialty medications, patient care services provided (including methods and evidence-based guidelines), patient support services (e.g., financial assistance information, patient education), desired therapeutic goals (e.g., disease cure, quality of life, symptom reduction), and other information as appropriate. The methods and guidelines used for patient services, communications with patients and healthcare providers, patient records, and other documentation are factored into the description of the scope of services.

5.9.6: Policies and Procedures

The outpatient and specialty pharmacies have current policies and procedures specific to unique elements of their services and aligned with the health system. These are readily available and followed by appropriate pharmacy staff in everyday practice.

5.9.7: Mail Delivery

Since a high percentage of specialty medications must be delivered via mail or courier service, the specialty pharmacy practice delivers medications by the most appropriate method to ensure patient privacy, safety of the medications, and maintenance of required storage conditions of the therapeutic agent being shipped. While disposable temperature sensors and non-pharmacy-based packaging suppliers exist, the pharmacy ensures that appropriate internal procedures are developed and used for medication delivery, including routine and seasonal temperature monitoring. The specialty pharmacy has internal policies and procedures to ensure that internal packaging protocols are appropriate for temperature integrity of packaged medications. Medications are packaged and shipped by an appropriate courier to ensure that the manufacturer's or United States Pharmacopeia (USP) storage requirements for the medication are maintained while in transit through receipt of the package by the patient or caregiver.

5.9.8: Specialty Pharmacy Medication Access Support

The specialty pharmacy provides services that enable patient access to medications.

The specialty pharmacy completely and accurately provides BI, PA, and benefits coordination services to patients in a consistent manner. These services enable access to specialty pharmaceuticals, proper patient education, patient acceptance of medication therapy, and formulary and benefits coverage compliance. BI services may include complete insurance review (i.e., medical and/or pharmacy benefit), formulary status assessment, hub coordination between drug manufacturers and patients, financial assistance enrollment, payment clearance, selection of appropriate specialty pharmacy, selection of appropriate route of delivery of the specialty medications, and patient advisement related to all of these services. The specialty pharmacy assists prescribers in the management of PA for specialty medications.

The consistent services provided by the specialty pharmacy may include complete insurance coverage review, clinical information assessment, and prospective reauthorization management.

The specialty pharmacy conducts benefits coordination when providing BI and PA assistance services by coordinating information and involvement of the prescriber, other healthcare providers, and other sources of assistance. In particular, as part of benefits coordination, the specialty pharmacy identifies various sources of financial assistance (e.g., manufacturer-sponsored copay cards, manufacturer product assistance, foundation assistance) and enrolls patients on their behalf after they authorize the service.

The outcome of BI and PA services and benefits coordination, especially patient financial assistance, and the dispensing of specialty pharmacy medications is communicated to the prescriber.

5.9.9: Home Infusion Pharmacy Services

Home infusion pharmacy services are provided by the health-system pharmacy department or are contracted to external pharmacies to provide such services. Dedicated roles for each of the pharmacy department/health system and the external vendor are clearly defined, contractually documented, and of an appropriate scope (including clinical as well as dispensing services and access to all required patient information). Contracts include training and competency requirements of contracted staff providing services, and the contracted pharmacy vendor is responsible for all aspects of the delegated services. Contracts are reviewed at negotiated regular intervals to ensure that services are appropriately provided and to ensure that contracts are current and accurate.

5.9.10: Contract Development and Management

Pharmacy leadership, including outpatient leaders, engage with the organization's contract management services to gain access to payer and pharmacy benefit manager (PBM) outpatient and specialty pharmacy networks. Together, they identify and create reportable data elements that provide evidence of quality of care, cost avoidance, and overall reduced cost of care of the health system's population and the populations specific to individual payers and PBMs. Pharmacy leaders identify and establish reportable data elements that provide evidence of quality of care necessary for limited distribution drug networks established by manufacturers and risk-sharing contracts with manufacturers.

5.10: Sterile Products Compounding, Facilities, and Equipment

5.10.1: Standards, Regulations, and Best Practices

Sterile preparation occurs in facilities and equipment that comply with appropriate standards, regulations, and best practices, including appropriate 503A and 503B compounding guidance from the FDA,³⁷ USP General Chapters <797>³⁸ and <800>,³⁹ CMS Conditions of Participation,^{40,41} and state board

of pharmacy (or equivalent) regulations. Facilities also meet requirements for CMS accreditation and incorporate best practices from safety and professional organizations (e.g., ISMP, ASHP⁴²).

5.10.2: Sterile Preparation Workspace

Sterile products are prepared in appropriate primary and secondary engineering controls. Engineering controls are inspected and certified according to standards and regulatory requirements. Secondary engineering controls, whether buffer rooms or segregated compounding areas, are within positive- or negative-pressure specifications as required for nonhazardous or hazardous medication handling and meet required air changes per hour. Containment secondary engineering controls are exhausted externally. Temperature and humidity are measured and recorded. The space is conducive to workflow, including positive- or negative-pressure workflows and movement, and has adequate lighting. Shelves, floors, walls, and ceilings are cleanable and kept clean. Unnecessary supplies, medications, and equipment are not stored in the sterile preparation room.

5.10.3: Equipment

Primary engineering controls are appropriate for the workspace, type of compounding, and volume of compounding. Primary engineering controls are placed according to USP standards and meet Controlled Environment Testing Association (CETA) certification specifications. Primary engineering controls used for preparation of sterile hazardous medications are externally exhausted. Other equipment, such as scales or balances, are also calibrated and certified according to standards or manufacturer's instructions for use. Smoke studies are performed to ensure first air is not obstructed by items kept in primary engineering control, such as technology-assisted compounding devices or other equipment. Equipment or materials kept inside the secondary engineering control are durable and can be cleaned during regular cleaning of the compounding room. Equipment or materials are disinfected as they enter secondary engineering controls and again when entering primary engineering controls.

5.10.4: Cleaning

Primary and secondary engineering controls are cleaned and disinfected according to USP standards. Cleaning activities are documented and records maintained according to state requirements or health system policies. Cleaning and disinfecting agents are appropriate for the activity and surface being cleaned. Deactivation and decontamination agents are used in containment primary and secondary engineering controls.

5.10.5: Quality Control and Policies and Procedures

Comprehensive policies and procedures describe cleaning schedules and agents used, air and environmental sampling schedules, and locations. Air and environmental sampling are performed according to USP standards. When USP limits for air particles, viable air particles, or environmental samples are exceeded, appropriate action is taken. Surface sampling for hazardous drug contamination is performed at regular intervals at specified locations according to policies and procedures. Quality data are shared with the health-system medication safety or quality committee, and health-system epidemiologists are consulted when appropriate.

Assigned beyond-use dates for compounded sterile products are appropriate for the compounding environment and risk level of the preparation.

5.10.6: Personnel Training and Competencies

Personnel preparing sterile products complete a training program consisting of both didactic and hands-on skills education. The training program can be developed in-house or offered by a provider accredited by ACPE. Knowledge and skills are assessed, and training and assessment are documented and kept in personnel files. Before compounding, personnel complete media-fill and glove-tip testing according to USP standards and state regulations. Remediation plans are included in policies and procedures to address failed knowledge or competency assessments.

5.10.7: Policies and Procedures

Comprehensive policies and procedures describe hand hygiene, donning and doffing garb and personal protective equipment (PPE), movement and cleaning of materials and supplies, and routine cleaning materials, schedules, and techniques.

5.10.8: Technology and Automation

Technology and automation are used in compounding processes as described in Standard 12. Pull-back syringe techniques for checking compounded preparations are not used.

5.10.9: Sterile Products and Preparations

Premixed products are used whenever commercially available. If proprietary bag-and-vial products are used, manufacturer instructions for use are followed and the products are assigned appropriate beyond-use dates. Vendors used for procurement of outsourced preparations are thoroughly vetted for quality assurance and regulatory compliance. Outsourced products are reviewed to ensure assigned beyond-use dates are appropriate.⁴³ Compounding from bulk active pharmaceutical ingredients (APIs) is only performed when necessary and is completed according to specific nonsterile-to-sterile policies, procedures, training, and competencies.^{37,38,42}

5.11: Purchasing, Procurement, and Supply Chain

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

5.11.1: Medication Product Acquisition and Availability

Medication products approved for routine use are purchased, stored, and available in sufficient quantities to meet the needs of patients. Medication 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.

5.11.2: Pharmaceutical Manufacturers and Suppliers

The pharmacy department minimizes risk of counterfeiting, diversion, cargo theft, and importation of unapproved or otherwise substandard medications, devices, and supplies. Criteria for selecting pharmaceutical manufacturers and suppliers are established and used to ensure that patients receive medications and related supplies of the highest quality at the lowest cost. Although these duties may be delegated in part to a group purchasing organization (GPO), the pharmacy department maintains sole responsibility for ensuring the quality of medication products used in the health system. Pharmacy department or health-system staff members ensure compliance with contractual agreements.

5.12: Managing Inventory

5.12.1: Stock Inspections

All stocks of medication 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. Adequate inventory controls are maintained to allow proper inventory levels of medications based on use.

5.12.2: Environmental Conditions for Medication Storage Areas

Medication storage areas have proper environmental controls (i.e., temperature, light, humidity, conditions of sanitation, ventilation, segregation) and are secure and constructed so that medications are accessible only to authorized personnel. Wireless temperature monitoring is used for temperature monitoring of refrigerated or frozen medications in collaboration with facilities management.

5.13: Medication Shortages

5.13.1: Management Systems

A system to prevent, minimize, manage and mitigate medication shortages to minimize patient risk is used within the health system and coordinated by the pharmacy department. Policies, procedures, and strategies for addressing medication shortages are used by task forces or committees and are approved or reviewed by the P&T committee. The medication shortage management program includes interprofessional, key stakeholder involvement. As appropriate, ethical discernment is included in decisions related to shortage management. Processes for tracking and trending medication shortage events, their management solutions, and any related sequelae are used and reported to the P&T committee and to physicians, nurses and other healthcare providers across the health system.

5.13.2: Pharmacy Department Roles

Pharmacy staff monitors reliable sources of information regarding medication product supply and shortages and develops strategies for identifying alternative therapies. Adequate pharmacy department personnel and resources are devoted to these efforts. Pharmacy staff works with suppliers, collaborates with physicians and other healthcare providers, coordinates processes for making associated changes in all pharmacy IT systems and the EHR, conducts an awareness campaign in the event of a medication shortage, and assembles the health system's ethics committee, when appropriate.⁴⁴

5.14: Samples

The use of medication 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 the 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, the pharmacy department accesses charity programs (e.g., patient assistance programs, foundations) to help patients with limited income and resources to procure their medications and related supplies. Pharmacists are involved in the health system's efforts to secure safe and effective low-cost medications for low-income patients.

5.15: Medication Stock in Patient Care Areas

Inventory of medication products stored outside pharmacy areas (e.g., patient care units, clinics, physician offices) for direct administration to patients is minimized. Medications accessed from stock in patient areas are removed from secured storage areas and/or ADCs and are 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 review medications removed from the stock in patient care areas periodically to determine whether the removal was according to policies and procedures.

5.16: Emergency Medications and Devices

The pharmacy department ensures the availability, access, and security of emergency medications, including antidotes. All emergency medications are stored in sealed or tamper-evident containers (trays or kits) that enable the staff to determine readily that the contents are complete and have not expired. Kits may include rapid-sequence intubation kits, travel kits for safe patient transport, and others kits used in all areas of the health system. Decisions about the contents of emergency medication trays, kits, and trolleys are outlined in policy and procedures. All emergency medications are available, controlled, and secured in the patient procedure areas. RFID tagging is used for emergency kit tracking and to track inventory amounts and locations, as well as medication distribution, when possible. The pharmacy department secures medication trays and maintains a log of locks used and the locations of all trays and kits. Policies and procedures are used to outline these processes.

5.17: Patient's Own Medications

Policies and procedures guide the use of patient's own medications within the health system. Their use is minimized to the extent possible. Medication products and related devices brought into the health system by patients are identified by the pharmacy department and documented on the patient's medical record if the medications are to be used. When patient's own medications are used, they are not stored at bedside, and they are administered only pursuant to a prescriber's order and according to policies and procedures that ensure the pharmacist's identification and validation of the integrity of the medication, as well as its secure storage.

5.18: Pharmaceutical Waste Stream Management

A hazardous waste pharmaceutical management and disposal system is used in pharmacy and patient care areas that is compliant with the U.S. Environmental Protection Agency (EPA), U.S. Drug Enforcement Agency (DEA), and U.S. Department of Labor Occupational Safety and Health Administration (OSHA).

5.19: Returning Recalled, Expired, and Other Unusable Medications and Devices

Written policies and procedures guide the timely handling and documentation of medication product or device recalls and expired medications. This procedure includes an established process for removing from use any medications or devices subjected to a recall, notifying appropriate healthcare professionals, identifying patients who may have been exposed to the recalled medication or device,

and, if necessary, communicating available alternative therapies to prescribers. The pharmacy department is notified of any defective medication products or related supplies and equipment encountered by the nursing or medical staffs, and assumes responsibility for disposal of such products. Expired medications are returned to the pharmacy from patient care areas according to policies and procedures, and are returned to wholesalers or manufacturers according to policies and procedures.

Standard 6: Quality and Performance Improvement⁴⁵⁻⁴⁷

6.1: Continuous Quality Improvement

The pharmacy department implements and maintains a continuous quality improvement (CQI) program. The CQI program is structured to assess the effectiveness and safety of patient care services, adherence to standards, and overall quality and integrity of the practice. It is aligned with the health system's overall plan and system for quality improvement and with payer contractual obligations for quality reporting. The pharmacy department maintains internal procedures for ongoing surveillance and reporting to assess overall appropriateness of services and implement quality improvements as needed to integrate quality metrics to drive quality improvement and refocus efforts on areas of need. The pharmacy department maintains procedures for monitoring and reporting on quality indicators required externally by payers, accrediting organizations, and other stakeholders.

6.2: Operation of a CQI Program

6.2.1: Quality Culture

The success of a CQI program is dependent on a quality culture championed and embraced by leadership, management, and staff. A CQI program is a structured plan for performance and process improvement. The approach is in compliance with federal, state, and local regulations related to the pharmacy department and health system, and it includes a framework for quality monitoring, evaluation, and reporting. The plan for the CQI program is reviewed and updated on a regular and ongoing basis.

6.2.2: Quality Assessments

The pharmacy department uses an ongoing, systematic program to assess the quality of all pharmacy services. The program includes routine evaluation of all aspects of the medication-use process, application of evidence-based practice for the implementation of new services, performance of automation and technology, and comparison with peer organizations for evaluation and innovation. External tools are also used for benchmarking and planning, such as those published by professional organizations (e.g., ASHP Practice Advancement Initiative 2030,¹² ISMP self-assessments).

The pharmacy department aligns the CQI program with measures and/or indicators of the following:

- Health system,
- Department or service line,
- Measures of clinical programs (e.g., inpatient, outpatient, specialty, clinical programs),
- Pharmacist interventions (recorded in EHR or pharmacy information system),
- National indicators¹⁸ (e.g., TJC National Patient Safety Goals⁴⁸),
- Peer benchmarking, and
- Internal benchmarking.

6.3: Quality Indicators and Outcomes

6.3.1: Quality Metrics

Data reporting on quality metrics and quality outcomes represents a critical component of the pharmacy department's comprehensive CQI program. The ability to integrate data directly into practice to influence patient care decisions, improve patient outcomes, and transform service delivery is a core responsibility of the pharmacy department. The pharmacy department's quality program indicators, measures, and metrics (hereafter "metrics") are developed in collaboration with the pharmacy

department and other healthcare personnel and reflect the health system's quality performance priorities (e.g., financial, customer, internal business processes, learning, growth) and payer expectations.

6.3.2: Reporting

The pharmacy department uses a balanced scorecard, dashboard, or similar approach that monitors patient outcomes, medication safety, productivity, and financial impact. Metrics evaluating the pharmacy department's services are also balanced by type and impact: structure (resources and infrastructure available for care delivery), process (activity of care), outcome (result of care), and humanistic (patient-centered). In addition, metrics are specific, measurable, achievable, relevant, and time bound.

6.4: Implementation of CQI Projects

6.4.1: Pharmacy Department Metrics and Results

The direct use of data to influence and improve the overall pharmacy department is critical to improving patient care. The pharmacy department's quality performance metrics and measures and corresponding results are reported routinely to interprofessional stakeholders, including medical staff, nursing staff, health system leaders, and others, as appropriate. The pharmacy department's quality performance metrics and measures and corresponding results, including those related to telehealth pharmacy practice, are reported routinely to interprofessional stakeholders, including medical staff, nursing staff, health system leaders, and others, as appropriate.

6.4.2: Quality Process and Feedback Loop

The pharmacy department is actively engaged in quality improvement projects and initiatives derived from quality reports and other data and assists with identifying opportunities for performance improvement. The pharmacy department has a CQI process and feedback loop in place that translates analysis to initiatives and initiatives to measured and improved outcomes using appropriate tools derived from implementation science.

6.5: Training and Education of Pharmacy Staff on Quality Improvement Initiatives

Educating pharmacy department personnel is critical to the success of the CQI program. A culture of continuous learning for all levels of employees, with methods of education tailored to each, will achieve the greatest impact. Components of a training program include determination of education and training needs, development of a performance and quality improvement curriculum based on knowledge and skills needed at the level of personnel (leader, manager, staff), and evaluation and documentation of training and education. Because CQI is a fluid and evolving process, staff receive initial and ongoing education on the need for improvements so that a culture is established to integrate recommendations into practice. The pharmacy department makes staff training and educational materials available and removes barriers for such training, allowing open participation. The pharmacy department documents staff training received as part of the CQI program.

Standard 7: Financial Management

7.1: Leadership and Health-System Structure

The pharmacy department has a designated pharmacy executive as its leader and sufficient personnel to oversee the department's financial affairs and interface with the health-system finance department. The pharmacy executive has an integral role in the health system's financial management process and demonstrates a deep understanding of the financial performance and position of the health system. The pharmacy executive fosters strong relationships with health-system finance leaders to allow pharmacy leaders to establish plans that are in tune with the health system and increases the likelihood of success.¹³

7.2: Budget Development

The pharmacy department budget is consistent with the health system's financial management process, is based on patient care needs, and supports the scope of and demand for pharmacy services. Oversight of workload and financial performance is managed in accordance with the health system's requirements. Pharmacy department management provides for the determination and analysis of pharmacy service costs, capital equipment costs, and new project growth.

The pharmacy executive sets financial goals for the upcoming fiscal year early in the budget process. National data and medication expenditures specific for the health system are used to project medication expenditures for the upcoming fiscal year. Medication budget forecasts include input from medical staff on changes impacting medication use, as well as an evaluation of predicted use of medications projected to enter the market. Budgeting on a line-item basis is done for the top medication expenditures (e.g., top 80% of the budget, less than 20% of products). Predictions of the use of such medications need to be focused on discussions with prescribers and other administrators, and controls on major fluctuations should be established.¹³

The budget plan guides the collection of information required to develop the capital, operating, and revenue budgets. The capital budget comprises items that cost more than a fixed-threshold amount (e.g., an expense greater than \$5,000) and have a useful life greater than a specified number of years (e.g., five years). Typical examples include new IV admixture hoods, pharmacy renovations, or ADCs. The operating budget is a forecast of the daily expenses to operate the pharmacy, including labor, medications, supplies, and other support below the capital expenses threshold. The revenue budget includes inpatient, outpatient, and retail patient charges and revenue generated by professional services, including consultations, management of research studies, education, and other support services.

The pharmacy department budget processes enable the analysis of pharmacy services by unit of service and other parameters appropriate to the health system (e.g., system-wide costs by medication therapy, clinical service, specific disease management categories, and patient third-party enrollment).

7.3: Revenue and Expense Management, Analysis, and Reporting

The pharmacy department uses a monthly and quarterly pharmacy department and medication budget monitoring and reporting system to evaluate performance, take corrective action, and assist in future budget predictions. Explanations of major variances to the budget are completed to justify fluctuations. The pharmacy financial management staff and the health-system finance department liaison prepare a

report of significant (e.g., greater than 5%) favorable and unfavorable variances in volumes, expenses, and revenues distributed to pharmacy leadership and the finance department liaison. An action plan is developed and operationalized to mitigate substantive unfavorable trends and/or take advantage of favorable trends.

7.4: Revenue Cycle Management

The pharmacy department is accountable for ensuring optimal medication revenue integrity, limiting medication-related financial liability, and ensuring appropriate site of care selection for high-cost medications.

The pharmacy department employs a reimbursement specialist with extensive knowledge of disease-specific medication therapies and managed care plans to oversee all reimbursement issues and collaborate with the health system's finance department to do the following:

- Ensure figures, such as cost, average wholesale price (AWP), and average sales price (ASP), are updated routinely in pharmacy and/or health-system billing software;
- Ensure accuracy of the medication compendium;
- Maintain accuracy of J codes and other necessary billing codes;
- Monitor medication reimbursement changes from private and government payers and ensure health-system billing and coding procedures stay current;
- Develop systems for account receivable reconciliation to monitor pharmacy net margins; and
- Leverage healthcare models that acknowledge pharmacist value and align payment with quality of outcomes.

If the reimbursement specialist is not a pharmacy employee, the specialist is accountable to the pharmacy department through at least a matrix relationship with the other department.

Pharmacy department staff, in collaboration with finance, payer contracting, and applicable patient care areas, coordinates a system-wide medication revenue integrity team. Revenue cycle monitoring tools are employed to ensure timely and accurate receipt of payments, track denials, and audit for billing accuracy. A process for review and escalation of denials and uncollected claims is established, including pursuing options for recovery through payer clinical justification, patient assistance programs, and safety net insurance coverage. Trends in denials and billing errors are reviewed, and action plans for prevention or improvement are implemented. Payer policy and contract changes related to medications are routinely reviewed and assessed for potential impact on the health system.¹³

Barcode-assisted medication administration (BCMA) is used to ensure accurate inpatient and outpatient charge capture, documentation of medication charges at the time of administration, and accurate billing. Medications administered in a clinic setting should be dispensed from, billed through pharmacy services, and charted via BCMA. Documentation and billing policies and procedures for pharmacist cognitive services should be put in place where applicable. Price updates for medications should be completed frequently (at least once per quarter), as should actual charge captures of reimbursement. Regular review of CMS coding of medications for reimbursement should occur quickly to capture when changes are made in reimbursement or billing codes are implemented for new medications.

Together, pharmacy and fiscal administrators analyze and minimize the extent and time frame for

reimbursement by major payers to determine the effect on net revenues. Such a process ensures that

- Claims are completed, filed in a timely manner, and contain all supporting documentation;
- Documentation forms and a billing procedure are in place to charge for cognitive services; and
- Documentation of clinical pharmacy interventions demonstrate the benefits and prospective cost savings of clinical pharmacy services to current and potential payers.

7.5: Contracting

Medication contracting, procurement, and distribution is managed by the pharmacy department for all sites of care. Contract enhancement opportunities available through GPO portfolios and direct manufacturer offers are reviewed and evaluated on an ongoing basis. Major contracts for medication, equipment, and services (e.g., wholesaler, automation, software) are periodically evaluated through an RFP process. Medication purchases are monitored for alignment with anticipated contract and tiered pricing, with systems in place to recover savings when appropriate. Purchasing coalitions are leveraged to enhance contracting opportunities. Contracts are negotiated in accordance with appropriate class of trade.⁴⁹

7.6: 340B Program Management

For qualifying 340B-covered entities, the 340B program is managed effectively to ensure compliance, with savings optimized across the health system. The pharmacy department implements best practices to provide oversight for the 340B program (e.g., system-wide steering committee, continuous internal compliance assessments, annual external auditing). Purchases by account (e.g., 340B, GPO, wholesale acquisition cost [WAC]) are monitored for compliance and optimization opportunities. Contract pharmacy arrangements are optimized for savings in a compliant manner.⁴⁹

7.7: Business Growth

Pharmacy leadership identifies, assesses, designs, implements, and monitors entrepreneurial opportunities for the pharmacy department. Business planning processes for the health system integrate pharmacy as a core element to ensure decision-making reflects current and future therapy, facility, technology, and staffing requirements.

The pharmacy strategic planning process includes environmental scanning, opportunity assessment, and goal alignment related to new business ventures within the pharmacy enterprise. Resources and expertise exist within the pharmacy department to provide new business ventures (e.g., finance, project management, data analysts, and scientists). Business planning includes pro formas, analysis of return on investment, buy/lease vs. build assessment, estimation of resources (e.g., labor, operational budget, capital), project management, and follow-up monitoring to determine if business plan goals are achieved.

Contemporary and progressive business ventures are implemented (e.g., pharmacy benefits management for health-system insurance product[s], specialty pharmacy, home infusion pharmacy, 503 A/503B compounding, central fill). Pharmacy-related ambulatory business growth opportunities are routinely evaluated and maximized.

Pharmacy department leaders and financial management personnel leverage healthcare payment models that adequately reimburse the health system for pharmacist-provided CMM services and acknowledge pharmacist value to align payment with quality of outcomes.¹²

Standard 8: Education, Training, and Research

8.1: Education and Training

Pharmacy department leaders demonstrate a commitment to education and training and, together with pharmacy department staff members, actively contribute to interprofessional educational programs offered by the health system, including those offered by professions other than pharmacy. Such programs may include grand rounds, in-service education programs, experiential learning opportunities for students, internships, fellowships, and residency programs. If colleges of medicine, nursing, pharmacy, allied health, and other professions are present on the same campus, the pharmacy department actively supports those programs, including, among other things, providing didactic and experiential learning experiences for their students. Continuing education programs provided by the pharmacy department are accredited by ACPE and other accrediting bodies, as appropriate. Postgraduate year one and postgraduate year two (PGY1 and PGY2) residency programs provided by the pharmacy department are accredited by ASHP.

8.2: Pharmacist Models

Pharmacy department education and training programs are a reflection of the pharmacy department's practice model, and all trainees contribute to the active delivery of pharmacy services. The pharmacy department affiliates with colleges of pharmacy to provide didactic, introductory pharmacy practice experience (IPPE), and advanced pharmacy practice experience (APPE) for students. When the pharmacy department provides or collaborates to provide educational programs involving multiple levels of learners (e.g., APPE students, paid pharmacy department interns, PGY1 residents, PGY2 residents, fellows), layered-learning models are used to optimize opportunities for education and pharmacy services, and all learners provide services at the highest level of their educational preparation and legal capacity. All education and training programs demonstrate positive impacts on pharmacy practice, services to patients, and include emphases on health disparities and social determinants of health, including race and socioeconomic status.⁸ Preceptors who are employees of the health system have appointments in colleges for which they provide instruction and preceptor services, and colleges provide appropriate resources for preceptors to assume their roles and responsibilities. College of pharmacy faculty members that provide patient care services and precept experiential learning experiences in health-system facilities have agreements with the health system that outline roles and responsibilities, as well as reporting relationships. Colleges of pharmacy may also sponsor residency programs using health-system practice sites; appropriate agreements outlining roles and responsibilities and reporting relationships of all personnel involved are maintained.

8.3: Pharmacy Technician Models

The pharmacy department provides an ASHP/ACPE-accredited pharmacy technician training program or collaborates with community colleges and other healthcare entities to provide ASHP/ACPE-accredited pharmacy technician training programs through didactic and experiential learning experiences. Affiliation agreements between entities outline roles and responsibilities of all participating institutions and their personnel. Pharmacy leaders, pharmacists, and pharmacy technicians are appointed as instructors and/or preceptors for students, and their roles are supported by the pharmacy department and affiliated organizations. Like those provided for pharmacists, all pharmacy technician education and training programs demonstrate positive impacts on pharmacy practice, services to patients, and include emphases on health disparities and social determinants of health, including race and socioeconomic status.⁸

8.4: Research^{8,30,31}

8.4.1: Research Types

The pharmacy department conducts medication-related and/or pharmacy-related research within the health system and/or collaborates with other professions (e.g., medicine, nursing) and/or with colleges of pharmacy, medicine, nursing, or others in research efforts within the health system. Such research projects may include, but are not limited to, the following:

- All patient populations served by the health system, including minorities and underrepresented populations;
- Pharmaceutical research, including the development and testing of new medication dosage forms, as well as methods and systems of medication preparation and administration;
- Clinical research, such as therapeutic characterization, evaluation, comparison, and outcomes of medication therapy and medication 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 may also participate in research sponsored by the pharmaceutical industry conducted within the health system.

8.4.2: Investigational Review Boards

Clinical pharmacist(s) are members of the institutional review board(s) (IRBs). Alternatively, if the health system does not have an IRB, clinical pharmacists communicate with external IRBs engaged by the health system. The pharmacy department complies with applicable peer-review requirements of the health system's IRB or external IRB engaged by the health system, as well as with requirements of the research sponsor, if any.

8.4.3: Policies and Procedures

Policies and procedures for the safe and proper use of investigational medications and medication-related devices are used to ensure applicable laws and regulations are followed and medications are used safely. Policies and procedures include obtaining informed consent from a patient before administration of the first dose of study medication.

Standard 9: People

9.1: Employee Engagement

The pharmacy department conducts independent programs or maintains active roles in health-system programs to measure and sustain or improve employee engagement within the pharmacy department and health system. Such programs are conducted with sufficient regularity to ensure opportunities to make meaningful change. When employee engagement programs are used, pharmacy department leaders do the following:

- Select tools used to measure employee engagement (independently or by participating in selection process, if appropriate);
- Establish tool lifecycles;
- Conduct measurements of employee engagement and receive the results;
- Review results and communicate results to staff members;
- Develop and implement timelines to write action plans with accountabilities and priorities to address opportunities for improvement;
- Determine how successes will be celebrated;
- Establish goals or desired measures of action plan results and implement action plans; and
- Conduct repeat measurements of employee engagement according to the predetermined schedule.

Known common opportunities for improvement in many employee engagement plans include such factors as communication, reward and recognition, employee trust in leaders, employee relationships with managers or supervisors, employee pride for the organization, and involvement of staff members in decisions that affect work. Aside from these and other factors identified, action plans address opportunities for improvement, including measures for initiatives affecting department and/or health-system financial success and profitability.⁵⁰

9.2: Improving Employee Performance and Efficiency

In addition to aforementioned employee engagement programs, pharmacy department leaders employ programs focused on improving employee performance and efficiency, understanding staff commitment, and sustaining or improving employee retention and loyalty, such as reward and recognition programs, coaching and mentoring programs, employee rounding programs, staff development, professional development and advancement programs, social events, and career ladders. These programs can be done independently or in collaboration with other health-system departments, as appropriate. Such programs may, when appropriate, differentiate pharmacy technician from pharmacist efforts and are offered on a regular basis according to plans developed by pharmacy department leaders or as established by the health system.²¹

9.3: Well-being and Resilience

Pharmacy department leaders provide resources for the professional, emotional, physical, and social well-being and resilience of the pharmacy staff by modeling life-work balanced behaviors; developing and implementing programs to measure and affect positive change in employee well-being and resilience; and developing programs aimed at the prevention, recognition, and treatment of burnout. Such programs may be independent of or a part of programs offered by the health system. 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.

The pharmacy department reviews hiring and promotion practices and strives to achieve equity, diversity, and inclusion in all technical, clinical, and leadership roles.

HEALTH-SYSTEM PROCESSES SUPPORTING SAFE MEDICATION USE AND PHARMACY PRACTICE

Standard 10: Medication Use and Safety

10.1: Medication-Use Policy

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-centered care. The pharmacy department is actively engaged in all aspects of medication-use policy development and approval across all parts of the health system. Committees within the health system that make decisions concerning medication use (e.g., P&T, infection control, IRBs) include the active and direct involvement of physicians, nurses, pharmacists, other appropriate healthcare professionals, and patients.

10.1.1: Pharmacy and Therapeutics Committee

The pharmacy and therapeutics (P&T) committee or its equivalent is the interprofessional committee responsible for developing and recommending approval of medication-use policies, including written criteria for medication product selection, formulary management, medication guidelines, medication restrictions, and therapeutic interchange. In addition, the P&T committee actively contributes to pharmacy department and/or health system coordinated performance improvement activities related to procurement, prescribing, dispensing, administering, monitoring, and overall use of medications. The P&T committee serves in an evaluative, educational, and advisory capacity to the medical staff and health-system administration in all matters that pertain to the use of medications. The committee is a policy-recommending body to the medical staff and the administration of the health system on matters related to the safe and therapeutic use of medications.⁵¹ The committee is a forward-thinking body that uses processes of examining (and revising, if necessary) existing policies related to the use of therapies not approved by the FDA.

The P&T committee is composed of actively practicing physicians and other prescribers, pharmacists, nurses, administrators, quality-improvement managers, medical informaticists, and other healthcare professionals and staff who have roles in the medication-use process.

P&T committee members are generally appointed by the medical executive committee (or equivalent) within the health system, to which the P&T committee is accountable either directly or indirectly. In the case of large health systems, there may be a singular health-system P&T committee, or there may be P&T committees at each of the member hospitals. In each case, evidence demonstrates consistency of policy and process across the health system and member hospitals. The P&T committee meets on a regular schedule, at least quarterly. Minutes of the P&T committee are advanced to the medical executive committee for review and approval. There is an established process for notifying the medical, pharmacy, nursing, and ancillary staff of P&T committee decisions.

10.1.2: Coordination of Medication-Use Policy

The pharmacy department has a proactive, strategic, structured process and sufficient resources to provide a center for medication-use policy or a similarly named division or process within the pharmacy department or process that is responsible for medication-use policy development, formulary management, and P&T committee processes. At minimum, the center for medication-use policy assists in developing P&T committee agendas and associated documents and recording minutes of the

meetings. The center and pharmacy department are accountable for educating others within the health system on medication-use policy decisions, medication-use outcomes monitoring, and research. The center for medication-use policy also collaborates closely with pharmacy and/or health-system IT staff members to ensure appropriate implementation of medication-use policy decisions in the EHR.

10.1.3: Formulary Management⁵¹

The P&T committee develops an evidence-based formulary of medications and medication-associated products and devices accepted for use in the health system. The formulary is based on the best evidence available and reflects the current clinical judgment of the medical staff, pharmacists, nurses, and other healthcare experts. The formulary is reviewed on an ongoing basis for necessary additions and deletions. Formulary decisions reflect evidence-based analyses of comparative efficacy and safety and analyses of economic and humanistic outcomes, at minimum. Formulary decisions also reflect the impact of medication use across the continuum of care (e.g., inpatient to outpatient care environments). The committee minimizes unnecessary duplication of formulary products.

Formulary decisions are communicated to prescribers and all other healthcare workers, and the current formulary list is available electronically throughout the health system and is integrated into the computerized medication ordering process.

10.1.4: Medication Monographs

New medication monographs are prepared by the center for medication-use policy for the P&T committee formulary management process. Monographs are evidenced-based and include information on clinical trial analysis, comparative efficacy, adverse effects, medication safety considerations, dosing and pharmacokinetic considerations, ethical considerations, use in special populations, and cost and pharmacoeconomic impact. The monographs are made available via electronic or other means to prescribers, pharmacists, nurses, and other healthcare professionals.

10.1.5: Medication-Use Guidelines

The P&T committee (or equivalent) has responsibility for development, evaluation, and approval of all medication-use guidelines. Guidelines may be focused on individual medications or medication classes or may involve management of complex disease states. The center for medication-use policy develops medication-use guidelines in collaboration with physician stakeholders and other healthcare professionals. Guidelines are developed using evidence-based analyses of the literature and include a process for eliciting feedback and input from local stakeholders. Approved guidelines are readily available and integrated into the EHR to guide medication use at the time of medication prescribing. Through medication-use evaluation, a process exists for evaluating the effectiveness and outcomes of approved medication-use guidelines.

10.1.6: Medication Restrictions

Medication restriction formulary management strategies are used to ensure the safe and appropriate use of high-risk or high-cost medications. Restrictions may include limitations of use in certain populations, by certain prescribers, or by dosing or monitoring requirements. Medication restrictions are readily available (preferably electronically) to all healthcare professionals and are included in the electronic medication prescribing system (prescriber order entry). Pharmacists and other pharmacy department staff partner with prescribers for accountability of implementation of approved restrictions.

Compliance to medication restrictions is routinely evaluated by the center for medication-use policy as part of the medication-use evaluation process and reported to the P&T committee.

10.1.7: Medication-Use Evaluation

The center for medication-use policy and P&T committee establish an organized, ongoing, criteria-based process to evaluate the effectiveness of the pharmacy department's medication-use system. Evaluations include clinical and fiscal responsibility and the safety of, and compliance with, established therapeutic and medication guidelines. Criteria for evaluation are developed at the time of formulary approval, or are developed at later times, based upon observation of medication-use and other data in collaboration with the P&T committee or its subcommittee(s). Medication-use evaluation is conducted as a collaborative effort of prescribers, pharmacists, nurses, administrators, and other healthcare professionals on behalf of their patients. Results and recommendations from medication-use evaluations are reported to the P&T and medical executive committees, at minimum, as well as stakeholders.⁵²

10.1.8: Nonformulary Use Management

The nonformulary process enables individual patient needs to be met with nonformulary medication products when demonstrated to be clinically justified by the physician or other prescriber. Defined health-system policies are used to direct ordering and the use of and evaluation of nonformulary medications. The use of nonformulary medications is reviewed, tracked, and trended by the center for medication-use policy and reported regularly to the P&T committee.

10.1.9: Specialized Dosing Processes¹⁰

To the extent possible, dosing and dosage forms specific to special populations or medications (e.g., pediatrics, geriatrics, high-cost or high-risk medications) are standardized across the health system, embedded in the electronic ordering system, and approved through the P&T committee process. All medications are prescribed using the metric system. Standardized medication administration times approved by the P&T committee are used for all medication prescribing and administration, including certain high-risk medications, with few exceptions. If the P&T committee approves dose-rounding processes, the approved rounding processes are included in electronic provider ordering. Dosing program guidelines in collaborative practice agreements that allow for pharmacist adjustment of medication dosages for select medications (e.g., high-risk medications, antimicrobials, anticoagulants) are approved by appropriate committees, and their outcomes are tracked and reported to the P&T committee. These guidelines are readily available (preferably electronically) to all healthcare professionals.

10.1.10: Therapeutic Interchange

Therapeutic interchange, defined as the authorized exchange of therapeutic alternatives in accordance with previously established and approved written guidelines, policies, or protocols within a formulary system, is incorporated into the formulary management strategy.¹⁰ Therapeutic interchange policies are developed by the center for medication-use policy and presented for approval by the P&T committee. When patients' medications are affected by therapeutic interchange, continuity of care and/or medication reconciliation processes ensure that original treatments are renewed at discharge, if appropriate.

10.1.11: Other Formulary Management Processes

Systematic processes are used, backed by policies and procedures, to manage FDA's Risk Evaluation and Mitigation Strategy (REMS) program, black-box warnings, recalled medications, and medications used for nonapproved indications. Pharmacists ensure that patients are educated according to program requirements and notified when recalls occur. Electronic clinical decision support (CDS) is used to assist with managing the strategies. The P&T committee approves and the center for medication-use policy tracks compliance with the REMS and black-box warning programs. The center for medication-use policy ensures that nonapproved uses are substantiated by evidence-based literature. Pharmacists collaborate with prescribers for accountability of medications used for nonapproved uses and their outcomes.

10.1.12: Ethical Decision Making

Pharmacy department leaders and staff members collaborate with medical staff and nursing staff, as well as patient safety, risk management, legal, and medical ethics representatives, to manage delicate and potentially emotionally charged situations, such as decisions about which patients will receive available medications affected by medication shortages, high-cost therapies with unknown benefits to offset costs, and complex therapies at end of life. P&T committees may have an ethics committee as a part of their subcommittee structure.

10.1.13: Communications with Interprofessional Teams

The pharmacy department regularly communicates medication information to clinical care providers across the health system and to members of the informatics teams to make needed changes in the EHR. Such communications generally include information regarding changes in the formulary, guidelines and restrictions, warnings or notices about prescribing or monitoring changes, medication-use evaluation results, medication safety data and/or trends, and more. The content and frequency of publication of the communications is based on analysis of needs.

10.2: Management of Medication Information Resources

The pharmacy department manages appropriate print and electronic medication information resources to all pharmacy department locations according to patient care and department needs. Pharmacy department representatives (e.g., center for medication-use policy staff, clinical pharmacists representing patient populations, and pharmacy leaders) collaborate with nursing department leaders and medical staff members to determine medication information resource needs for patient care units and other identified clinical areas of the health system and then provide needed print and electronic resources accordingly.

Medication information print resources include textbooks, reference materials, and journal subscriptions (electronic resources may include the same); wall charts and compatibility tables as identified by needs analyses; and other internet and intranet materials. Any print materials are of the current edition and/or are assessed for relevance on a regular basis. Electronic intranet resources include medication-related policies and procedures; medication guidelines, pathways, protocols and/or restrictions, among other things; telephone numbers for pharmacy department locations and staff members; pharmacy newsletters and other medication information communications; poison control center contact information; and the medication formulary. These systems also house information needed to report medication events (e.g., links to the online medication reporting system, links to forms needed to report medication events). The intranet may also house a form requesting medication

information or contact information for staff members to recommend process improvement. The health system may also provide access to medication resources for staff members to use on personal electronic devices.

Pharmacy department leaders and staff members collaborate with other health-system leaders and staff members (e.g., medical, nursing, biomedical engineering, human factors, risk management, quality) using a process to evaluate new IT needs of the health system and its employees. Such process may be a technology assessment committee or a similar body, or it may be another committee charged with this responsibility.

10.3: Medication Safety⁵³⁻⁵⁵

Medication safety and safe medication practices are health-system priorities, as demonstrated in their prominence within strategic plans and/or annual plans within the health system and the pharmacy department. Medication safety systems encompass all steps of the medication-use process, whether they are within the health system or the pharmacy department. Pharmacy department employees assess and mitigate medication-use systems across all settings.

10.3.1: Just Culture

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

10.3.2: Medication-Use Safety Planning

Pharmacy department leaders assume responsibility and accountability roles for medication safety within interprofessional committees of the health system, as well as within the pharmacy department. Such committees evaluate and monitor all aspects of the medication-use process to identify risk points, improve systems, and ensure such systems are safe.

Evidence exists of medication-use safety planning as demonstrated by the organizational culture, use of an event reporting and trending system and communication plan for results at all levels of the health system, influence on medication-use policy development and medication use, and systems for education of staff members regarding medication-use safety.

10.3.3: Medication Safety Committee

Medication safety committees may be freestanding committees within the hospital or health system or may be subcommittees of the P&T committee, a quality committee, or another medical staff committee or interprofessional committee that includes physicians, nurses, pharmacists, and other healthcare professionals but which reports to a medical staff committee such as the medical executive committee. Without regard to such structure, the medication safety committee has a qualified medication safety leader (commonly named the “Medication Safety Officer”), who ideally is a pharmacist but may also be a physician or nurse with sufficient dedicated time to lead and manage the committee. This leader and the committee are responsible for the health system’s (and perhaps the pharmacy department’s) medication safety planning and operations efforts. If the leader of the medication safety committee is not a pharmacist, the pharmacy department organizational structure includes a position for a pharmacy

medication safety leader or a position that includes responsibilities of a pharmacy medication safety leader (e.g., assistant director with such job responsibilities).

Subcommittees may exist to evaluate high-risk medication use for such populations as pediatrics, oncology, or other patient populations. The pharmacy department may also maintain a medication safety committee in addition to the health-system medication safety committee.

10.3.3.1: Standardization

The medication safety committee maintains roles for oversight of standardization of processes (e.g., determination and use of definitions of medication events, standardized concentrations, use of medication administration devices, use of automation, development and maintenance of high-alert medication lists). The medication safety committee also monitors professionally developed guidelines and self-assessment tools to evaluate safety practices in the pharmacy department and the health system (e.g., those developed and published by ISMP and external reports of errors).

10.3.3.2: Medication Event Reporting Processes

The medication safety committee establishes, reviews, and revises policies and procedures regarding medication event reporting, analysis, aggregation, and trending; completes medication safety risk assessments to help identify risks within the health system; communicates to healthcare professionals regarding events and any related practice or medication-use policy changes; and follows up on 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. The health system reports sentinel events related to serious medication errors to relevant authorities.

10.3.4: Medication Event Reporting System

An easily accessible event reporting system is used by health-system personnel to report medication events that may occur prospectively, concurrently, and retrospectively. In this Standard, medication events include medication errors, adverse drug events, and near misses. Pharmacy department leaders lead health-system efforts or collaborate with the medication safety or other appropriate committee(s) to, among other things, do the following: identify potential and actual medication events; determine and evaluate data that will be collected by the reporting system; use trigger tools to identify potential or real events by healthcare professionals and medical records staff members; and are active members of event review, analysis efforts, and chart review teams. Efforts exist to prevent, detect, and resolve medication-related problems that may result in patient harm from medications or the prescribing, preparation, and/or administration of medications. The pharmacy department reports medication events to external sources (e.g., FDA MedWatch reporting program, Vaccine Adverse Event Reporting System [VAERS], ISMP medication error reporting programs) when appropriate.

10.3.5: Medication Safety Strategies

The pharmacy department assumes leadership roles or leads strategies to enhance the safety of medication-use systems within the health system, including but not limited to the following:

- Using processes for medication selection for the formulary (e.g., conducting a medication safety assessment in the review process);

- Collaborating on the development, implementation, review, and evaluation of medication guidelines, protocols, pathways, and restrictions;
- Implementing standardized concentrations and limits for concentrations used for all routes of all medications (e.g., those administered orally, intravenously, and epidurally, among others);
- Ensuring that medications are stored safely and securely outside of the pharmacy, in collaboration with clinical department leaders and medical staff members;
- Monitoring the literature for new safety warnings and mechanisms to assess risk;
- Maintaining an proactive process to assess the medication-use system continually for safety;
- Participating in national event reporting systems and encouraging event reporting;
- Assisting with evaluations of vendors and manufacturers for inclusion in the supply chain procurement process;
- Participating in medication shortage management processes;
- Collaborating with IT leaders and staff members to ensure safe use of informatics systems and the EHR, including medication prescribing and administration documentation using the electronic medication administration record (eMAR); monitor processes in the EHR; develop, monitor, and evaluate medication-related rules and alert firings; and use systems to minimize alert fatigue for all healthcare disciplines;
- Using automation and informatics systems to store and dispense medications safely on patient care units, in procedures areas, and in areas where medications may be dispensed and administered, including inpatient areas, diagnostic and treatment areas, and ambulatory care clinics;
- Educating or collaborating with other healthcare professionals to assess patient and employee medication safety educational needs, and then developing and delivering educational programs focused on safe medication use;
- Conducting research, or collaborating with other healthcare professionals to conduct research, related to systems and processes surrounding and affecting safe medication use; and
- Ensuring evidence-based medication use continually by analyzing and reporting use patterns and outcomes.

10.3.6: Medication Safety within the Pharmacy Department

The pharmacy department employs systems to ensure safe medication handling, including the following:

- Using electronic systems, such as barcode or radiofrequency identification (RFID) scanning, to manage receiving, storage, and dispensing processes;
- Ensuring safe and secure storage conditions for all types of medications by using segregation, labeling, and other techniques;
- Ensuring that employees are trained to use, maintain, and have ongoing competency for informatics and automation systems and all other medication-use processes associated with safe medication use; and
- Educating employees about safe medication-use systems used within the department and the health system.

10.4: Performance Improvement

10.4.1: Pharmacy Department Roles within the Health System

Quality management is a “strategic, integrated management system, which involves all managers and employees and uses quantitative methods to continuously improve an organization’s processes to meet and exceed customer needs, wants, and expectations.”⁴⁵ Excellence in medication-use safety and pharmacy practice exemplifies quality management as a strategic value and a core component of its operations. The pharmacy department strives for medication safety and quality by identifying and prioritizing quality improvement efforts that align with national and health-system goals. The pharmacy executive and pharmacy department leaders actively engage with the health system’s executive leadership and quality and safety experts to ascertain goals, aims, and interventions for the system and to influence medication-related goals, aims, and interventions in the pursuit of high-value care and improved patient outcomes.

10.4.2: Reviews of Reports from Regulatory and Other Bodies

Reports from regulatory bodies and accreditation organizations provide an opportunity to perform self-assessment. Pharmacy department leaders review reports related to health-system and departmental compliance on an ongoing basis (versus just-in-time preparation) in order to make sustained improvements and develop a perpetual-readiness infrastructure. Subsequently, they conduct ongoing self-assessments and embed the findings into annual quality plans or budget presentations to executive leadership, quality and safety committees, and the governing body. Examples of regulatory bodies, accreditation organizations, and standard-setting organizations are as follows:

- National regulatory bodies, such as U.S. Centers for Medicare & Medicaid Services (CMS), FDA; U.S. Drug Enforcement Administration;
- State regulatory bodies, such as state boards of pharmacy and departments of health;
- Accreditation organizations, such as TJC, Det Norske Veritas (DNV) Healthcare, URAC, ACHC, and ASHP;
- Standard-setting organizations, such as ISMP;
- Baldrige Performance Excellence Program, Leapfrog healthcare ratings and reports.

10.4.3: Performance and Process Improvement Approaches

Health systems, as complex adaptive systems, require leadership commitment to cultivate a culture of safety and quality. A complex adaptive system recognizes three characteristics: heterogeneity within the people and parts of the system, interaction between people and parts of the system, and the culmination of each that creates the whole of the people and parts. Systemness is a term that embodies a desired state of a complex adaptive system in which its people and parts are working cohesively to ensure person-centered, high-value care across the continuum. To find order in the complexity, pharmacy department leaders apply proven approaches to redesign and improve the system using one or more of the following proven approaches to redesign and improve the system:

- Rapid-Cycle Improvement
- Six Sigma
- Lean Enterprise
- Learning Healthcare System

10.5: Medication Stewardship⁵⁶⁻⁶¹

10.5.1: Stewardship Programs

The pharmacy department collaborates with other disciplines to provide medication stewardship programs, which are designed to improve patient outcomes, minimize unintended consequences of medication use, and control medication costs. Medication stewardship programs may include, but are not limited to, antimicrobial, anticoagulant, and other hematologic, opioid, and high-risk or high-cost therapy programs, and they may include prophylactic, empiric, and therapeutic medication uses.

10.5.2: Program Structure and Process

The pharmacy department uses medication-use data, medication contracting and/or purchase data, medication safety data, benchmarking data, and observational processes to identify opportunities in stewardship programs, including individual medications or medication classes. While employing medication-use evaluation techniques, stewardship programs are much more complex than medication-use evaluations. Pharmacy department leaders and clinicians collaborate with key physician and service line/management stakeholders to establish common goals, gain support for initiatives, and strategize processes to ensure successful program development, implementation, and use. Clear lines of responsibility and accountability are evident for individual patient management of medications involved in stewardship programs.

The pharmacy department collaborates with the P&T committee (or equivalent) to evaluate medication-use patterns and formulary needs using available data; such processes may result in the development or revision of medication-use policy/policies, medication guidelines, pathways, and/or restrictions to guide medication use.

10.5.3: Information Technology

To ensure safe medication-use system processes, the information technology (IT) department is engaged to develop and implement order-entry and processing systems (including rules-based flags and alerts, as appropriate) to ensure appropriate selection, optimal dosing, escalation and de-escalation parameters, optimal duration of therapy, and appropriate monitoring parameters, at minimum.

10.5.4: Educational Programs

Educational programs regarding stewardship programs are developed by the pharmacy department (and other disciplines, when needed) and used to ensure optimal program use and outcomes. Patient education programs are also developed and used, as appropriate, to promote medication adherence to prescribed instructions and evaluate the stewardship program's other appropriate medication-related parameters.

10.5.5: Outcomes

Following stewardship program implementation, data are collected according to parameters set by the program or medication-use policy and are evaluated to determine successes in clinical and economic outcomes, opportunities for program improvement, opportunities for program expansion, and opportunities for education to ensure or improve compliance with the stewardship program parameters. When appropriate, adjustments to programs are made while continuing to provide care, and program adjustments are re-evaluated to determine the success of program changes.

10.5.6: Reporting

Results of medication stewardship programs are reported to prescribers, medication-use policy, medication safety, medication quality/performance improvement, financial, and leadership committees/bodies of the health system.

Standard 11: Information and Medication-Use Technology

11.1: Electronic Health Record (EHR)

The health system uses an electronic information management system to maintain patient records, such as an integrated or closed-loop information system or EHR for all inpatients and outpatients. Such systems are interoperable and transparent with respect to usability, security, and functionality across the continuum of care. Alternatively, a comprehensive pharmacy information system is used that is interfaced with other health-system information systems and software systems, such as a prescribing system, laboratory system, nursing charting and documentation system, radiology and other diagnostic department systems, ambulatory care or physician office practice systems, and other appropriate systems to promote safe and effective medication use. If a comprehensive pharmacy information system is used, pharmacy leaders and staff employ high-reliability principles when designing and selecting IT systems.

11.1.1: Coding and External Access

Pharmacy department leaders, financial managers, and clinicians collaborate with health-system financial leaders to establish and use IT tools that improve care and interoperability. Options include SNOMED CT (Systematized Nomenclature of Medicine – Clinical Terms) and other coding systems, value sets, Pharmacist eCare Plan and other Consolidated Clinical Document Architecture (C-CDA), Fast Healthcare Interoperability Resources (FHIR), and CDS tools. Patient portals, connections, and audio/visual systems facilitate communications with patients and pharmacy department care team members using telehealth services. Financial systems interface with outside organizations like Surescripts Network Alliance to assist clinicians in identifying medications and quantities dispensed for their patients in the past 180 days, as needed.

11.1.2: EHR Functions

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

11.1.3: Security of Patient Information

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

11.2: Availability of Information

All healthcare professionals in the health system and in the pharmacy department are provided access to needed information. Terminals to access the EHR or pharmacy information system and all other information systems and software systems are located in the pharmacy department and all of its

facilities; in patient care areas, including medication storage and preparation rooms; and in diagnostic areas.

11.2.1: Electronic and Print Materials

The health-system intranet provides access to medication-use policies and procedures, the medication formulary, approved guidelines and restrictions, and medication information resources from local, national, regional, and international publishers that are needed by healthcare professionals.

11.2.2: Information Technology Tools Access

Pharmacy staff use an array of IT assets, whether provided by the health system or personally owned devices, as tools needed to complete their responsibilities and accountabilities. When personal devices are used, appropriate security mechanisms are integrated into systems used to prevent security breaches and ensure data integrity. Devices provided by the health system (e.g., laptop computers, tablets, smart telephones, secure text devices or communication tools) are used to provide in-person and virtual patient care services and to communicate with patients and healthcare team and pharmacy department staff members and contain all necessary software and applications required to provide services to which the pharmacy department is committed. The pharmacy staff is competent in health IT and receives ongoing education and training needed for complete and competent use.

11.3: Telehealth

Clinical pharmacy services are provided to patients that are geographically restricted from the health system or during times of irregular operations using technology to meet patients' medication-related needs, such as during pandemics when clinical pharmacists may provide clinical services and patient education using electronic media. Telehealth pharmacy services may also include operational pharmacy services (e.g., medication selection, order review and dispensing, IV admixture verification, medication and disease management programs, compliance management services). Telehealth pharmacy services are maintained by appropriate infrastructure and technology.

11.4: Prescribing Medications

11.4.1: Prescribing

Medications are prescribed by individuals who have been granted appropriate clinical privileges in the health system 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 health system when prescribing medications and discourages use of nonstandard and unapproved terminology and abbreviations.

11.4.2: Verbal Orders

Oral or verbal orders are avoided except in emergency situations, and established procedures are developed for their use and documentation.

11.4.3: Access to External Systems

The health system uses a fully deployed electronic prescribing system for ordering medications. If separate EHR systems are used for ambulatory care or in physician offices, the pharmacy department staff has access to patient records in those systems.

11.4.4: Guidelines, Standing Orders, and Order Sets

The electronic prescribing system contains the medication formulary or formularies (e.g., in cases when differences exist for ambulatory care), medication guidelines and restrictions, and decision support tools to provide safe and effective medication use.

Pharmacists collaborate with physicians to write medication order sets and/or standing orders or protocols, all of which are reviewed by and approved by appropriate medical staff committees of the health system. Standardization of doses and medication administration times are used, when appropriate.

11.5: Clinical Decision Support^{10,62}

11.5.1: Types of Alerts and Other Tools

Clinical decision support (CDS) tools are incorporated as alerts into clinical information systems by EHR vendors to make patient care decisions more efficient and effective and are used for all patient care settings (e.g., inpatient care and ambulatory care clinics). Such tools may be expressed as medication rules, rounding, alerts, and more. Pharmacists collaborate with other healthcare professionals to define medications and associated parameters involved in CDS tool development and implementation; developed tools reflect use of current evidence-based guidelines and artificial intelligence (AI) to guide providers to develop care plans that are individualized to the patient. Tool warnings fire in real time and are tailored to incorporate patient-specific parameters with information from medication database vendors.

11.5.2: Alert Firings

Alert firings are monitored and adjusted to minimize alert fatigue for all caregiver disciplines (e.g., medicine, nursing, pharmacy). Alert inclusion and exclusion criteria may include verification of diagnosis or review of laboratory test results before initiation of medication therapy and medication-order-specific factors, such as dosage forms, routes of administration, frequencies, dose, order status, and ordering provider, among other things. Alerts are configured to guide prescriber actions, such as to discontinue a conflicting order, cancel an order, modify the order (e.g., change the dose, dosage form, route, frequency, start date, end date), modify pre-existing medication orders, add monitoring orders, continue with the order, and/or suspend the order. The CDS system logs all alert warnings and resultant user actions taken in response to the alert for quality improvement analyses.

11.5.3: Use of Advanced Analytics

Pharmacy department leaders collaborate with IT leaders and staff members, when appropriate, to foster the development and application of advanced analytics (e.g., machine learning and AI) in activities such as risk assessment, monitoring performance metrics, identifying patients in need of pharmacist care, optimizing medication use, and business management. Further, pharmacy department leaders establish standards for the application of AI in the various steps of the medication-use process, including prescribing, reviewing medication orders, and assessing medication-use patterns in populations.

11.6: Medication Administration and the Medication Administration Record

11.6.1: Medication Administration

Only personnel who are authorized by the health system in accordance with applicable laws and regulations and who are appropriately trained are permitted to administer medications to patients. All administered, refused, or omitted medication doses are recorded in the patient's EHR 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.

11.6.2: Medication Administration Record

A medication administration record (MAR) generated by the EHR or pharmacy information system is used throughout the health system. The electronic MAR (eMAR) contains all patient and medication information needed for safe administration of all medications used (e.g., medication name, dose, dose units, route, and duration of administration, frequency) in addition to all required patient information.

Nurses and other healthcare professionals use the eMAR to guide medication administration and to document medication administration (success, failure, omission, or hold). Medication holds, reasons for the holds, and any reactions to medications noted are documented in the patient chart and preferably in the eMAR.

11.6.3: Downtime Operations

Manual systems exist for downtime operations. When eMARs cannot be accessed due to downtime or other systems failures, manual systems are used throughout the health system, and such systems contain the same patient and medication information as contained within eMARs. 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 for eMARs, and downtime procedures are readily available for all staff members.

11.7: Barcode Medication Administration

11.7.1: Use of Barcode Medication Administration

Barcode medication administration (BCMA) technology is used by nurses to document medication administration, unless emergent circumstances preclude use. The pharmacy department dispenses all medications with unique barcodes and uses systems to generate barcodes if they are not provided by manufacturers. Systems exist to log barcodes generated by the pharmacy department, and policies and procedures are used to guide these processes. Pharmacy department representatives collaborate with nursing department representatives to develop, implement, use, review, and revise policies and procedures regarding use of patient barcodes (usually wrist bands or ankle bands) and requirements for scanning medications before administration and for identifying and resolving barcode reader and barcode incompatibilities. Data provided by BCMA vendors are used by pharmacy and nursing department leaders and representatives, as well as by representatives of other appropriate disciplines (e.g., medication safety, quality, risk management), for quality improvement initiatives to optimize use of scanners and determine reasons and resolutions for lack of use or errors. Surveillance data are reported back to nursing department unit leaders for quality improvement and medication safety initiatives.

11.7.2: Equipment Failures Management

All medications are scanned before administration, and scan failures are reported to the pharmacy department for immediate resolution. Policies and procedures address requirements for scan or equipment failures and information system downtimes.

11.7.3: Scan Compliance and Continuous Quality Improvement

The pharmacy department collaborates with nursing department leaders and staff members and other healthcare professionals to understand, evaluate, and establish a goal for barcode scan compliance of both patients and medications. The pharmacy department leads efforts to develop and ensure appropriate oversight over barcode scanning compliance. Additionally, the pharmacy department partners with nursing department leaders and staff members to use a reporting structure for continuous improvement around barcode scanning and collaborates with the IT department to ensure success regarding improving the barcode scanning rate at the health system.

11.8: Smart Infusion Pumps

11.8.1: Smart Infusion Pump Use

Intravenous medication administration pumps with infusion libraries are used for controlled administration of all sterile product medications throughout the health system. These “smart pumps” are wirelessly integrated through a bidirectional interface with the health system’s EHR.

11.8.2: Infusion Libraries

Infusion libraries and dosing parameters, frequently referred to as guardrails, use standardized medication concentrations, and are developed and maintained by an interprofessional committee of health-system leaders and employees, including perspectives from medicine, nursing, pharmacy, risk management, safety, engineering, IT, and others determined by the health system.

11.8.3: Quality Assurance

An interprofessional committee manages policies and procedures, reviews device quality data, and determines changes needed for libraries, infusion parameters, and other data. Appropriate resultant actions are taken and reported to appropriate medication and/or patient safety, medication-use policy, and quality improvement committees, at minimum.

Standard 12: Automation and Technology¹⁰

12.1: Plan for Technology Integration

The pharmacy department, in collaboration with appropriate departments, uses a plan for the use of integrated automation throughout the health system. Such plan includes a needs assessment, parameters for specifications and selection of devices to be used (in the pharmacy department and throughout the health system), guidelines for developing new automation implementation plans, guidelines for developing initial and ongoing training, policies and procedures for all areas requiring them, and a process for monitoring 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 use 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.

12.2: Barcoding of Unit Dose Packaging

Two-dimensional (2D) and/or three-dimensional (3D) barcodes are used to manage the use of medications and any related medication administration devices in automated systems.

12.2.1: Barcode Use

All unit dose medication packages contain such barcodes, and these barcodes are used in inventory management, dose preparation and packaging, dispensing, and administration. The pharmacy department ensures the quality of all aspects of barcode medication administration, including ability to scan barcodes and manage the associated database.

12.2.2: Quality Assurance

The pharmacy department manages quality assurance concerns for all medication packaging, repackaging, and compounded dosage forms whether these processes occur within the department or are done by a contracting service. The pharmacy department works collaboratively with nursing department leaders and staff members and IT departments to identify and resolve barcode scanning challenges and manage the associated database.

12.3: Barcode Dispensing

12.3.1: Dispensing Practices

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

12.3.2: Scanning

Barcode scanning is used in medication compounding processes for both nonsterile and sterile products, including for all compounding devices used in sterile products clean rooms (e.g., parenteral nutrition pumps, repeater pumps).

12.3.3: Policies and Procedures

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

12.4: Automated Dispensing Cabinets

12.4.1: Use and Placement

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

12.4.2: Profiling

ADCs are profiled with the clinical information system of the health system or pharmacy department. In such circumstances where ADCs cannot be profiled, the pharmacy department collaborates with other departments to understand which cabinets cannot be profiled and the reasons why. The desired practice is to minimize the number of ADCs that are not profiled.

12.4.3: Interfaces

ADCs and their databases contain patients' medication profiles, current inventory information, current formulary information and any applicable restrictions, and cost information. They are interfaced with barcode medication administration scanners and related databases when used.

12.4.4: Policies and Procedures

Policies and procedures related to ADCs include the following:

- User information, access, restrictions, and privileges
- ADC requirements for medication control and dispensing
- Initial medication storage requirements, including an inventory for antidotes, rescue agents, and reversal agents⁶³
- Process for requesting a new medication or removing a medication from the ADC
- Procedures for loading, removing, and returning medications; checking for expiring medications; and resolving discrepancies for controlled substances, at minimum
- Process for placing medications on override
- Procedure for override review and auditing
- Procedure for organizing and optimizing the inventory within a cabinet
- Policy and procedure for operations when cabinets experience downtimes
- Process for leaders, within and external to the pharmacy department, to request ADCs

12.4.5: Overrides

The pharmacy department establishes target rates for acceptable limits of overrides; gains approval from the P&T committee and/or medication safety committee; and monitors, measures, and reports override metrics and trends to the P&T committee, the medication safety committee, appropriate patient care units and/or service lines and their leaders, and quality committee(s).

12.4.6: Safety Processes

Pharmacy department leaders and staff members use available self-assessment tools and recommendations, such as ISMP guidelines,⁶³ for the safe use of ADCs. This includes the following core safety processes:

- Providing a safe and ideal environmental condition for the safe use of ADCs,
- Establishing ADC system security,
- Providing profiled ADCs and monitoring system overrides,
- Selecting and maintaining appropriate ADC configuration and functionality,
- Selecting and maintaining optimal ADC inventory,
- Implementing safe ADC stocking and return processes,
- Displaying important patient and medication information,
- Developing procedures for accurate ADC withdrawal and transfer to the bedside for administration, and
- Providing staff education and competency validation.

ADCs may be used for inventory control and dispensing of large- and small-volume intravenous solutions, safe and reliable storing of emergency kits, devices, and other unique materials. ADC databases are used for monitoring and surveillance of medications, kits, and devices that are removed.

12.5: Inventory Management

12.5.1: Systematic Approach for Inventory Management

The pharmacy department uses 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, partially automated, or fully automated, and they may be conducted by third-party vendors. Monitoring systems and alarms, response procedures, and policies and procedures ensure product integrity.

Pharmacy department leaders and staff members evaluate the feasibility, risks, and benefits of using high-density storage devices in the inpatient pharmacy department, storeroom or warehouse, pharmacy satellites, or elsewhere in the health system. This includes robotics that may be carousel or conveyer based, static shelving on automated tracks that collapse, or other technology. The department evaluates and uses automation that best ensures secure, temperature-controlled storage of medications. At minimum, the department uses an electronic tracking system to assess inventory levels on hand.

12.5.2: Barcode Scanning

Barcode scanning systems are used 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 health system and pharmacy department using barcode scanning systems, and barcode scanning systems are used when transferring medications within the pharmacy department and its satellites to all locations within the organization.

12.5.3: Inventory Management Systems

Medication inventory management systems are documented and implemented. Centralized oversight of

medication inventory management is established. Perpetual inventory software is used to monitor high-cost medication inventory in real time. Medication par levels in all storage areas are routinely reviewed and optimized based on current use data. Inventory turnover rates are calculated and reported for all storage locations.

Strategic sourcing is used to bring the highest value to the pharmacy supply chain (e.g., long buy, use of secondary wholesalers). Inventory at risk of expiring is redistributed to the highest area of use to minimize waste. High-cost medications are purchased, stored centrally, monitored, and distributed as needed in low units of measure throughout the organization.

The pharmacy department uses an electronic tracking system for inventory management that supports electronic data interchange (EDI) based inventory-purchasing interfaces. As a part of the selection process, the pharmacy department conducts strengths/weaknesses/threats/opportunities (SWOT) and/or gap analyses to measure the advantages and disadvantages of a given system and uses a criteria- and/or literature-based process to ensure the most advantageous system is selected for the department. The pharmacy department maintains this system on a server or other cloud-based system within the pharmacy department or health system (in collaboration with the IT department). While not required, it is preferred to have the inventory system live on more than a single computer to ensure that it can be updated in real time through multiple locations.

12.5.4: Radiofrequency Identification Tracking

Radiofrequency identification (RFID) tracking solutions are used as a component of the inventory management and replenishment system. Pharmacy department leaders collaborate with appropriate department representatives within the health system (e.g., medical materials supply, IT) 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 CQI principles are used in the use of RFID in the pharmacy department and the health system.

12.5.5: Policies and Procedures

In addition to selecting an inventory management system, the department uses well-developed policies and procedures for managing medications. At minimum, the pharmacy department has policies and procedures for inventory tracking, management of expired medications, management of recalled medications, procedures for annual or biannual inventory valuation, and procedures for the receipt, storage, security, and handling of controlled substances throughout the medication-use process. The ideal state for inventory management is a closed system tied to revenue cycle management.

12.5.6: Safety Concerns

When carousels and robotics are incorporated into the inventory management process, all safety-related functions of the carousel (e.g., barcoding, medication selection) are used to ensure safe medication storage and distribution, including receiving into and dispensing from the carousel. When used, ADCs and carousels are fully interfaced and integrated to ensure patient safety.

12.6: Sterile Compounding

12.6.1: Compounding Device Use and Placement

Compounding devices are used in the pharmacy department for sterile and nonsterile 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 is documented. Appropriate policies and procedures, staff training, and ongoing competency assessments are maintained. Barcoding is integrated into the compounding device software to assist in ensuring safe medication-use practices. When placed in sterile environments (e.g., in hoods or isolators, on benches in open-architecture clean rooms), such placement does not negatively impact the quality of the sterile environment, and appropriate best practices, guidelines, or regulations (e.g., USP General Chapters <797> and <800>) are maintained.

12.6.2: Use of Repeater Pumps and Total Parenteral Nutrition Compounders

The pharmacy department uses automated compounding devices (ACDs) for workflows, such as repeater pumps if engaged in batching sterile medications, and compounders for preparation of total parenteral nutrition (TPN). If ACDs are used for TPNs, hard and soft limits should be set for electrolytes to ensure patient safety is not compromised.

12.6.3: Quality Assurance

The pharmacy department uses quality assurance policy/policies for oversight of compounding devices. Additionally, the pharmacy department collaborates with the IT department when upgrades, changes, and new implementations are needed. The pharmacy department assumes full ownership of these devices but allows the IT and biomedical engineering departments to maintain security and other areas inside the expertise of those departments.

12.6.4: Sterile Compounding Workflow

The pharmacy department, to the extent possible, uses intravenous technology-assisted workflow (IV TAWF) in sterile compounding processes. This may include volumetric, gravimetric, workflow queues, or barcode scanning. The pharmacy department uses a thoughtful criteria- and/or literature-based strategy for evaluating and implementing these technologies. If these technologies have not been implemented, the pharmacy department should have a rationale for not using them.

12.7: Nonsterile Compounding Devices

Powder hoods and biologic safety cabinets used for nonsterile medication compounding, including medications involved for investigational studies, are selected, maintained, and integrated into systems in the same manner as described for sterile products compounding. Nonsterile compounding devices are routinely calibrated as recommended by the vendor. The pharmacy department uses a thoughtful process for the selection of vendors for these devices and an evaluation process to ensure they continuously improve workflow. Additionally, the pharmacy department uses a monitoring plan to ensure these devices are working correctly.

12.8: Outpatient Pharmacy Automation

12.8.1: Integration with EHR and Pharmacy Systems

The pharmacy department uses automation in the outpatient pharmacy(ies) to assist in safe and efficient medication control, storage, dispensing, and inventory management. Devices, such as carousels and other inventory management systems, electronic counters, and automated prescription filling devices, use barcode technologies and are interfaced with the pharmacy and/or health system's EHR

and patient queueing systems. 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, and it is cleaned and maintained as recommended by the manufacturer.

Appropriate policies and procedures, staff training, and ongoing competency assessments are maintained. Barcoding and interfacing with the health system's EHR and other appropriate safeguards assist in ensuring safe medication-use practices.

The ambulatory care IT assets are integrated with those of the pharmacy department and/or health system. Ambulatory care pharmacists and technicians have access to the EHR in all order review, order processing, and dispensing areas. With the ever-growing automation that is available to the outpatient pharmacy environment, the pharmacy department uses an ongoing strategy to evaluate suitable automation to ensure safe and efficient dispensing.

12.9: Repackagers

12.9.1: Use of Repackagers

The pharmacy department employs a strategy to determine which medications should be outsourced and insourced for repackaging needs. Repackagers are used to repackage solid and liquid dosage forms into unit-of-use or unit dose packages when such doses are not available commercially from manufacturers. If this function is outsourced to an external vendor, selection processes include, among other things, an onsite evaluation to ensure quality and safety of the processes. Vendors undergo a criteria-based selection process, quality and safety reviews, and parameters of the contracted services are documented.

12.9.1.1: Policies and Procedures

Policies and procedures are used to outline medications that may be repackaged and corresponding dosage forms; labeling requirements, including lot numbers and expiration dates; record-keeping requirements; staff competencies and training requirements; and quality assurance requirements.

12.9.1.2: Barcode Use

Barcodes are used for identification of medications to be repackaged. Unique barcodes are developed when needed for all medications that are repackaged and do not have a manufacturer barcode, and these unique barcodes are integrated into all informatics, inventory management, and automated systems.

12.10: Staff Resources

The pharmacy department has sufficient resources to develop, implement, and maintain technology-related medication-use safety standards.

12.11: Video Cameras

12.11.1: Use and Placement

Video cameras are used throughout the pharmacy department and health system, where needed, to monitor staff access to medications and ensure medication security and the safety of staff members. Video cameras are used in sterile product cleanrooms and are integrated into sterile production processes. Cameras are routinely placed at entry points to the pharmacy facilities, at dispensing

windows, and in locations where medications are stored. Cameras are used in pharmacy warehouses, satellites, and investigational drug service pharmacies to ensure medication security. They are installed in sterile products compounding facilities and equipment and in workflow management systems to facilitate remote checking of products and processes and to ensure quality systems. Policies and procedures guide video camera use, and all staff members are educated about and aware of their use.

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Glossary

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

Barcoded Medication Administration (BCMA): An inventory control system that uses barcodes to prevent human errors in the distribution of prescription medications at 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 at improving clinical processes and outcomes.

Clinical Pharmacist: Pharmacists who work directly with physicians, other healthcare professionals, and patients to provide comprehensive medication management to ensure optimal medication use for patients and the best possible health outcomes. Clinical pharmacists practice in healthcare settings as core members of the healthcare team.

Comprehensive Medication Management (CMM): A patient-centered approach to optimizing medication use and improving patient health outcomes that is delivered by a clinical pharmacist working in collaboration with the patient and other healthcare providers.

Collaborative Pharmacy Practice Agreement (CPPA): A formal practice between one or more prescribers and one or more pharmacists that specifies what functions (in addition to the pharmacist's typical scope of practice) can be delegated to the pharmacist by the collaborating prescriber, including selecting, initiating, monitoring, continuing, and adjusting medication regimens and affiliated services.^{1,2}

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 medications.

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 continually updated list of available medications and related information, representing the clinical judgment, resulting from a review of the clinical evidence, of physicians, pharmacists, and other clinicians in the diagnosis, prophylaxis, or treatment of disease and promotion of health. 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.³

Formulary System: The ongoing process through which a healthcare organization establishes policies regarding the use of drugs, therapies, and drug-related products, including medication delivery devices, and identifies those that are most medically appropriate, safe, and cost-effective to best serve the health interests of a given patient population.³

High-Density Storage: Storage that provides larger 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 that support the applicable scope of services, including but not limited to the following:

- Documentation of all clinically relevant patient information necessary for the scope and size of the practice;
- Effective prospective and retrospective medication-use review;
- 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 to optimize care for a patient or group of patients.

Just Culture: 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: Any prescription medications, sample medications, herbal remedies, vitamins, nutraceuticals, vaccines, or over-the-counter drugs; diagnostic and contrast agents used on or administered to persons to diagnose, treat, or prevent disease or other abnormal conditions; radioactive medications, respiratory therapy treatments, parenteral nutrition, blood derivatives, and intravenous solutions (plain, with electrolytes and/or drugs); and any product designated by the Food and Drug Administration (FDA) as a drug. This definition of medication does not include enteral nutrition solutions (which are considered food products), oxygen, and other medical gases.⁴

Metrics: Standardized, quantitative measures 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 where sterile medications and infusions are compounded 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 medication 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 medication.

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

Underrepresented Groups: In medicine this term “means those racial and ethnic populations that are underrepresented in the medical profession relative to their numbers in the general population”⁵ and may include differences in race, gender, religion, sexual orientation, gender identity, ethnicity, nationality, socioeconomic state, language, (dis)ability, age, and/or political perspective.⁶

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Approved by the ASHP Board of Directors on May 25, 2021.

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