

ASHP–PPAG Guidelines for Providing Pediatric Pharmacy Services in Hospitals and Health Systems

Lea S. Eiland, PharmD; Kim Benner, PharmD; Karl F. Gumpfer, MSMI; Melissa K. Heigham, PharmD; Rachel Meyers, PharmD; Katherine Pham, PharmD; and Amy L. Potts, PharmD

ABBREVIATIONS ADE, adverse drug event; ADR, adverse drug reaction; ASHP, American Society of Health-System Pharmacists; CDS, clinical decision support; CMS, Centers for Medicare and Medicaid Services; CPOE, computerized provider order entry; eMAR, electronic medication administration record; FDA, Food and Drug Administration; HIT, health information technology; ICU, intensive care unit; ISMP, Institute for Safe Medication Practices; IV, intravenous; P&T, pharmacy and therapeutics; RFID, radio frequency identification

KEYWORDS adolescents; neonate/neonatal; pediatric dosing; pediatric patients; pediatric pharmacokinetics; pediatric pharmacy services

J Pediatr Pharmacol Ther 2018;23(3):177–191

DOI: 10.5863/1551-6776-23.3.177

Purpose

The purpose of these guidelines is to assist pharmacists and pharmacy departments in meeting the special needs of pediatric patients in hospitals and health systems. Pharmacists encounter numerous challenges when providing care to pediatric patients, including the limited data available on the safety and efficacy of medications; the lack of appropriate commercially available medication dosage forms and concentrations; weight-based dosing; complex calculations, especially when dilutions are required; and patients' limited capacity to communicate regarding symptoms, responses to therapy, and possible adverse drug events (ADEs).¹ In addition, pediatric pharmacy practice is associated with different operational demands and requirements than a practice focused exclusively on adults. Pediatric patients are defined as all children from neonate until adulthood. These guidelines supplement the American Society of Health-System Pharmacists (ASHP) Minimum Standard for Pharmacies in Hospitals and provide additional recommendations specific to providing pediatric pharmacy services.²

Organizational Models

There are various models under which hospital or health-system pharmacy departments typically provide care to pediatric patients, ranging from children's hospitals to general hospitals or health systems providing services to pediatric patients. Depending on which model is adopted, pharmacy departments will provide a different scope of services for pediatric patients. Some institutions provide acute care for pediatric patients with general needs, while others will treat critically ill or specialty patients, such as oncology or transplant patients, in addition to general pediatric patients. Although the

pharmacy services provided may be distinctly different based on the type of institution and other factors, there are best practices listed within these guidelines to which all hospitals and health systems should aspire when caring for pediatric patients.

Elements of Care

The elements of pharmacy services that are critical to safe, effective, innovative, and cost-conscious medication use in hospitals and health-systems include the following:

- Practice management,
- Medication-use policy development,
- Medication therapy optimization,
- Drug product procurement and inventory management,
- Preparing, packaging, and labeling medications,
- Medication delivery,
- Medication-use monitoring,
- Evaluating the effectiveness of the medication-use system,
- Research, and
- Implementation and customization of healthcare technology.

Although the scope of pharmacy services will vary among sites depending on the needs of patients, the hospital or health system, and the resources available, these core elements are inextricably linked to successful outcomes. Failure to provide any of these services may compromise the quality of pediatric patient care.

Standard I. Practice Management

The pharmacy department should be organized under the direction of a qualified pharmacist competent to meet the needs of the institution's pediatric patients

and be provided with sufficient physical facilities, financial resources, personnel, and equipment to meet the pharmacy care needs of the pediatric population.

A. Pharmacy and Pharmacist Services. *Pharmacy Mission, Goals, and Scope of Services.* The pharmacy's mission statement shall address the specific patient care needs of pediatric patients. Measured outcomes that focus on value added by pediatric pharmacy practice should focus on safety, productivity, efficiency, quality, education, research, and innovation. Pharmacists' responsibilities for the timely, safe, and accurate order processing and medication reconciliation; medication delivery; prevention of readmissions; patient education at the time of discharge; and other specialized clinical interventions and cost avoidance associated with the prevention of ADEs are vital. Implementation of lean systems management in inpatient and outpatient operations and the innovative use of healthcare technology, revenue-generating services, and specialized pediatric care should be incorporated into the pharmacy practice model.

Hours of Pharmacy Services. Adequate hours of operation for the provision of needed pharmacy services shall be maintained; when possible, 24-hour pharmacy services should be provided to the pediatric population. Essential services include clinical pharmacy services in specialized, high-risk units (e.g., pediatric intensive care unit [ICU], neonatal ICU, hematology–oncology unit, operating rooms, emergency department). Satellite pharmacies in these locations are beneficial, especially if there is evidence of significant service failures caused by central pharmacy delays or if there are location-specific barriers that could affect efficiency or safety. When 24-hour pharmacy services are not feasible, a safe and consistent alternative process shall be established, and a pharmacist with pediatric training should be available on an on-call basis. Remote medication order processing may be employed (to the extent permitted by law and regulation) to help provide pharmacy services but is not a substitute for an on-call pharmacist.³ Pharmacists who participate in remote order processing should be trained in pediatric care or demonstrate competency in caring for pediatric patients. Automated drug dispensing equipment and computer databases are also not substitutes for the skills and knowledge of a pharmacist with pediatric training and should not be considered alternatives to 24-hour pharmacy services.⁴

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

a pharmacist) shall be developed by a multidisciplinary committee of physicians, pharmacists, and nurses (the pharmacy and therapeutics [P&T] committee or its equivalent).⁵ Access to medications should be limited to cases in which the P&T committee (or an equivalent multidisciplinary committee) determines that the urgent clinical need for the medication outweighs the potential safety risks of making the medication accessible. Medications, quantities, dosage forms, and container sizes that might increase the risk for ADEs shall also be evaluated. Routine after-hours access to the pharmacy by nonpharmacists for dispensing of medications shall not be permitted. The use of well-designed and secured cabinets, medication carts, automated dispensing devices, and other methods precludes the need for nonpharmacists to enter the pharmacy.^{4,6}

Practice Standards and Guidelines. The standards and regulations of all relevant government bodies (e.g., state boards of pharmacy, departments of health, Food and Drug Administration [FDA], United States Pharmacopeia, Drug Enforcement Administration) shall be met. The practice standards and guidelines of ASHP and appropriate accrediting bodies (i.e., the Joint Commission, Institute for Safe Medication Practices [ISMP], American Osteopathic Association Healthcare Facilities Accreditation Program, Det Norske Veritas, and Centers for Medicare and Medicaid Services [CMS]) shall be viewed as applicable, and the hospital should strive to meet all applicable standards. The pharmacy department is encouraged to seek further information on pediatric healthcare services from other organizations, such as the Children's Hospital Association, Pediatric Pharmacy Advocacy Group, Children's Oncology Group, American Society for Parenteral and Enteral Nutrition, and American Academy of Pediatrics.

B. Laws and Regulations. Applicable local, state, and federal laws and regulations shall be met, and relevant documentation of compliance shall be maintained. The pharmacy should actively participate and collaborate with local and national organizations, especially those specific to pediatric patient care.²

C. Policies and Procedures. *Policies and Procedures Manual.* The institution's policies and procedures manual shall address the care of pediatric patients, and all pharmacy personnel shall follow those policies and procedures, regardless of whether a pharmacist with pediatric training is on duty.

Emergency Preparedness. The facility's business continuity plan shall include procedures for providing safe and efficient pediatric pharmacy services to patients and their adult family members in case of emergencies or disaster situations.^{7,8} Adequate supplies shall be maintained for these situations, and the unique needs of the pediatric patient population must be considered when selecting these supplies. The institution's emergency preparedness team should have pediatric pharmacy representation and expertise.

Medical Emergencies. The pharmacy shall participate in hospital decisions about the contents of code carts, pediatric dosing references for emergency medication kits and trays, and the role of pharmacists in medical emergencies. Pharmacists should serve on trauma and cardiopulmonary resuscitation committees and teams, and such pharmacists should receive appropriate training and maintain appropriate certifications. Pharmacists with pediatric training should participate in neonatal and pediatric codes and be certified in basic life support, advanced cardiovascular life support, neonatal resuscitation program, or pediatric advanced life support. Health systems with rapid response teams should consider the inclusion of a pharmacist with pediatric training on such a team.

Immunization Programs. The pharmacy shall participate in the development of hospital and health-system policies and procedures concerning preventive and postexposure immunization programs for pediatric patients and hospital employees.⁹ When feasible and when permitted by state law or regulations, pharmacists should participate as active immunizers for hospital and health-system–based preventive immunization programs (e.g., influenza).

D. Human Resources. Position Descriptions. Areas of responsibility within the scope of pharmacy services shall be clearly defined. Position descriptions should reflect the position's responsibilities to the specific pediatric population being served (e.g., pediatric ICU, neonatal ICU, emergency department).

Director of Pharmacy. The director of pharmacy should understand the unique needs of pediatric patients and be knowledgeable about and have experience in pediatric hospital pharmacy practice. An advanced management degree (e.g., master of business administration, master of health administration) or an administrative specialty residency is desirable.¹⁰

Pharmacists. Pharmacy management shall employ an adequate number of competent, licensed pharmacists in good standing with their state board to meet the specific medication-use needs of the hospital's and health system's pediatric patients.

Support Personnel. Sufficient support personnel (e.g., pharmacy technicians, inventory coordinators, business managers, other administrative personnel) shall be employed to facilitate pharmacy services. Human resources collaboration and support are necessary, and additional education for practitioners in this area may need to be considered for practice leadership. A support position shall have a written job description that includes a statement of the competencies required for that position. Support staff shall be properly trained and supervised, and professional development programs for these staff are desirable. Pharmacy technicians should have completed an ASHP-accredited pharmacy technician training program, should be certified by the Pharmacy Technician Certification Board,

and shall meet the requirements of applicable laws and regulations. Pharmacy technicians working in advanced roles should have additional training and demonstrate competencies specific to the tasks to be performed for pediatric patients.

Education and Training. All personnel shall possess the education and training required to fulfill their responsibilities and shall participate in relevant continuous professional development (e.g., continuing-education programs) and activities as necessary to maintain or enhance their competence.¹¹ Pharmacists providing care to pediatric patients should possess the knowledge and skills necessary to make that care safe and effective for the patient population. The pharmacy department should provide adequate training for all staff members who may be called on to provide care to pediatric patients. Core competencies should be age based and include mastery of pharmacokinetic and pharmacodynamic differences, weight-based dosing and calculations, fluid and nutrition requirements, common pediatric diseases and drugs, pharmacogenomics, drug information resources, and specialized drug preparation and administration techniques for pediatric patients. Pharmacists' core competence in these areas should be established initially and then periodically reassessed based on the level of care provided.

The pharmacy director or designee should be responsible for all staff development, taking into account the specific needs of the department and the various pediatric populations served. Staff development programs should be current, frequently scheduled, and easily accessible. Online tools for continuing education and staff development can also be a convenient source for education and development.

Pharmacists seeking positions in pediatric pharmacy practice should complete postgraduate residency training to enhance their clinical skills and knowledge base in pediatric pharmacy practice. The knowledge, skills, and abilities obtained through completion of a postgraduate year (PGY) 1 residency are essential for new graduates seeking roles as pediatric pharmacists. Specialty training through a PGY2 pediatric residency program offers a unique opportunity to focus on practice in a specific pediatric population (e.g., critical care, neonatology, hematology–oncology) and is strongly recommended for pediatric pharmacists. Pharmacists, through experience, may also demonstrate mastery of the knowledge, skills, attitudes, and abilities to care for pediatric patients (e.g., PGY1 residency in a pediatric hospital, multiple pediatric rotations during a PGY1 program).

Pharmacy directors should encourage staff to seek competency-related certifications through the Board of Pharmacy Specialties certification (e.g., board-certified pediatric pharmacy specialist) or through other pediatric pertinent certifications (e.g., asthma education, immunization). Pharmacy directors should consider

incentives or recognition for pharmacists who seek additional training and certifications.

Orientation of Personnel. There shall be an established, structured procedure for orienting new personnel to the pharmacy, the hospital or health system, and their respective positions to provide care for the pediatric patient.¹² Evaluation of the effectiveness of orientation programs should be done in conjunction with the competency assessment required before a new hire can assume full responsibility for the position.

Work Schedules and Assignments. The director of pharmacy or designee shall ensure that work schedules, procedures, and assignments optimize the use of personnel and resources. Internal benchmarking may be useful to determine the best use of resources and personnel specific to pediatrics. National benchmarks may lack the understanding that workflow and workload for pediatric pharmacy are very different than for adult pharmacy practice and are not as standardized. The specialized and customized needs of pediatric patients require significantly more resources when compared with adult patients. There shall be a written departmental staffing plan that addresses how pediatric patients' needs will be met during periods of staff shortages, fluctuation in workload, inclement weather, or patient acuity. Remote medication order processing may be employed to help address staff shortages or workload fluctuations.³

Performance Evaluation. There shall be procedures for regularly scheduled evaluation of the performance of pharmacy personnel. The evaluation format should be consistent with that used by the hospital or health system. The competencies of the position should be well defined in the position description, short- and long-term goals should be established for each employee, and the employee's competency shall be assessed on a scheduled basis. Pediatric competencies should be routinely assessed for all pharmacists caring for pediatric patients. Pharmacists not meeting minimum standards for competency should be reassigned to other areas and not be allowed to practice until such competency is met. The pharmacy director shall ensure that an ongoing competency assessment program is in place for all staff, and each staff member should have a continuous professional development plan.

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

Outpatient Pharmacy Services. Outpatient pharmacy services should be attentive to the unique

medication needs of the pediatric patient. Outpatient pharmacy services should stock pediatric dosage forms (e.g., liquids, chewable tablets) and appropriate measuring devices (e.g., oral syringes) suitable for pediatric patients. All oral liquid medications for children should be dispensed with the appropriate measuring device. The pharmacy may provide flavoring services to improve the palatability of medications. In unique circumstances where medication preparation will need to be performed by the patient or caregiver (e.g., short-stability medications, reconstitution), education should be provided by the appropriate pharmacy staff member. Consideration must be given to the need for an extra medication supply with a labeled container to be taken to school, daycare, or other places where medication may be administered. For outpatient medication services (e.g., ambulatory care infusion centers, home infusion services, compounding services), issues, such as preparation and batching of medications, need to be considered. If a hospital or health system outsources for these services, selected facilities shall be able to support the care and needs of pediatric patients.

Medication Storage and Preparation Areas. There shall be suitable facilities to enable and document the receipt, storage, and preparation of medications under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security to ensure medication integrity and personnel safety throughout the hospital and health system.^{4,13}

Compounding Areas. There shall be suitable facilities to enable the compounding, preparation, and labeling of sterile and nonsterile products, including hazardous drug products, in accordance with national and local established quality assurance procedures. The work environment shall promote orderliness and efficiency and minimize the potential for medication errors and contamination of products.¹⁴⁻²⁰ Resources necessary for compounding and testing alternative doses and dosage forms of commercially available products are essential. Preparation of pediatric doses often requires more time and actions (e.g., calculation of proper dose, dilution, preparation of patient-specific dose in the most ready-to-administer form) than preparation of standard adult doses, many of which are available in ready-to-use form from manufacturers. Resources shall be allocated to maintain the efficiency and safety of the medication-use process while meeting the additional requirements of providing pediatric doses.

Information Technology. A comprehensive pharmacy computer system shall be employed and should be integrated to the fullest extent possible with other hospital information systems and software, including computerized provider order entry (CPOE), barcode-assisted medication administration, electronic health record, and patient billing systems. To obtain patient-specific clinical information for medication therapy monitoring and other clinical functions and to facilitate

the continuity of care to and from other care settings, computer resources should be used to support the following:

- Access the patient medical record,
- Document patient care activities,
- Interface with other computerized systems,
- Maintain patient medication profile records,
- Manage clerical functions,
- Manage drug product inventories,
- Manage electronic prescribing,
- Perform necessary patient billing procedures,
- Provide clinical decision support (CDS), and
- Provide drug information.

Pediatric specific needs within the computer resources shall be carefully evaluated and allow for customization if warranted. Additional informatics resources may need to be considered for implementation and development of sophisticated CDS. A pharmacist with pediatric training should be involved in the development and maintenance of order sets, templates, and dose ranges used in CPOE and CDS systems. Pharmacy computer systems should be integrated with the hospital's clinical, financial, and administrative information systems. All computer systems shall include adequate safeguards to maintain the confidentiality and security of patient records, and a backup system should be available to continue essential computerized functions (e.g., those that support patient care) during equipment failure.

Drug Information. Adequate space, current resources, and information-handling and communication technology shall be available to facilitate the provision of drug information. The pharmacy department shall select and standardize its drug information resources, and a pharmacist with pediatric training shall play a leadership role in the selection of pediatric drug information resources used by other healthcare providers in the hospital. Current objective pediatric and adult drug information shall be available, including print or electronic periodicals, newsletters, best practices guidelines, and recent editions of reference books in appropriate pediatric pharmaceutical and biomedical subject areas. Specifically, information on pediatric dosages, extemporaneous formulations, drug compatibilities and stability, toxicology, drug effects, and safety during pregnancy and lactation should be readily obtainable. Literature supporting the use of drugs for unlabeled uses in pediatric patients should also be accessible.²¹ Available information sources should support research on patient care issues and facilitate the provision of pharmacy care and safety in the medication-use process. Appropriate drug information resources shall be readily accessible to pharmacists located in specialized pediatric patient care areas (e.g., neonatal intensive care). This information may be accessed in conjunction with medical libraries and other available resources. Resources should have the capability to provide hard copies of drug information or counseling

points focused on the pediatric population that the pharmacist can provide to the patient and caregiver.

Electronic drug information databases are preferred because they are frequently updated and can be made available to all healthcare professionals, but sufficient access to print information shall be available in case of equipment failure or downtime. Electronic databases and convenient methods of data dissemination (e.g., e-mail, handheld devices) are desirable. Electronic drug information resources shall be accessible at the point of care for all healthcare personnel.

F. Health Information Technology. Standards.

The pharmacy director or designee shall maintain an understanding of current regulatory standards and best practices related to the use of health information technology (HIT), including but not limited to the Health Insurance Portability and Accountability Act, American Recovery and Reinvestment Act/Health Information Technology for Economic and Clinical Health, and CMS e-reporting requirements pertaining to medication use and pharmacy practice. Staff will comply with these regulations.

HIT Components of the Medication-Use Cycle.

Pharmacy HIT should be an integrated part of the health system's clinical and financial information systems. The pharmacy executive or designee shall be an active participant in the evaluation and decision to purchase any new clinical information system by the health system.

CPOE and CDS Systems. CPOE and CDS systems should be evaluated and customized as necessary to support age-specific requirements for safe and effective medication use. Computer systems shall report patient weight and height in metric units. At a minimum, these systems shall include age-specific, weight-specific, and body surface area-specific drug dose checking; dose capping; and drug-allergy, drug-drug interaction, and drug-disease state checking. CPOE order sets and order sentences intended for use in pediatric patients should be reviewed by the pharmacy department or by the pediatric pharmacy specialist in the case of a children's hospital or pediatric services within an adult hospital or health system.

Automation. Automation, including but not limited to dispensing cabinets, carousels, and robotics, should be used and able to accommodate pediatric dosage forms, dosage amounts, and delivery rates (e.g., neonatal intravenous [IV] syringes, oral liquid dose forms). Hospitals should evaluate the use of other barcode-enabled technologies to ensure patient safety, such as medication tracking and IV workflow software. Use of this automation should also include a continuous quality-improvement plan to optimize the effectiveness of these technologies for pediatric patients.

Electronic Medication Administration Record. Integration. An electronic medication administration record (eMAR) should be integrated or directly interfaced with the pharmacy information system. Information systems

should populate the eMAR with medication dose and volume for pediatric patients. The eMAR should include nursing notification for late doses as well as the ability to document a reason for any doses not administered. Ideally, the eMAR should be integrated with assistive technology (i.e., either barcode or radio frequency identification [RFID] technology) to provide electronic tracking and decision support around the 5 rights of medication administration.²² Documentation of medication-specific patient parameters (e.g., corresponding pain score with administration of a pain medication) should be encouraged.

Barcode or RFID Medication Administration. A point-of-care barcode or RFID medication administration system shall be employed and integrated with the eMAR and pharmacy information system.²³ Point-of-care technology shall be carefully evaluated for use in a pediatric setting, specifically success rates for scanning labels on smaller syringe dosages and on patient armbands sized for young children and infants. Careful consideration and monitoring of nursing workarounds should be evaluated periodically and specific barriers addressed by the medication safety team or committee. In those circumstances where barcode or RFID tags are applied onsite to compounded or repackaged medications, workflows and quality assurance procedures must be in place to ensure accurate labeling.

E-prescribing. E-prescribing systems shall include age- and weight-specific drug dose checking and drug–allergy, drug–drug interaction, and drug–disease state checking. When possible, e-prescribing systems should be integrated into the organization’s primary electronic medical record/CPOE system or, at a minimum, should be interfaced with the CPOE system in order to share allergy, drug interaction, and medication reconciliation history data.

Smart Infusion Pumps. The hospital shall purchase and maintain pumps that are built with a medication library (i.e., smart infusion pumps). These include large-volume bag pumps, small-volume syringe pumps, and patient-controlled analgesia pumps. Pharmacy departments should be involved in the purchasing, implementation, and maintenance of all infusion devices capable of administering medications to patients (e.g., magnetic resonance imaging compatible devices, epidural pumps). The medication library shall include standard concentrations of IV medications, dose limits, and warnings as appropriate. The medication library shall be maintained by a pharmacist with training in pediatrics. The library shall be maintained and checked on a regular basis, at least annually, and adjustments made as needed. Dosing alerts shall be installed as appropriate to add safeguards for high-risk medications. These alerts should use hard limits wherever possible, as they have been shown to decrease errors to a greater extent than soft limits, which can be overridden.²⁴ Pump usage should be closely monitored to

ensure that providers of care are appropriately using the library and not overriding safeguards.

CDS Technology. The pharmacy department shall actively participate in the acquisition, development, and maintenance of CDS systems that impact pharmacy services, including membership on any committee tasked with CDS governance. Policies and procedures shall be developed to describe the CDS request lifecycle and CDS governance process. Content and execution of CDS rules shall follow industry best practice. Opportunities for CDS should be continually evaluated based on hospital event reports and published sources. The effectiveness of any CDS intervention should be evaluated postimplementation and modified as needed. The pharmacy department shall be involved in the regular review of medication-related alerts and reminders within the electronic health record to ensure that CDS content remains current and accurate to minimize the generation of nuisance alerts and to identify and correct any CDS content that may lead to confusion or risk of medication errors.^{25,26}

CDS Governance. CDS rules may be locally developed or provided by the system vendor. A pediatric-specific workgroup that includes a pharmacist with pediatric training should be established for consideration of pediatric-specific workflow and needs assessment. In either case, rules should be as sensitive and specific as possible in order to minimize alert fatigue.²⁶ Vendor-supplied CDS rules should be evaluated and customized before implementation, and all CDS rules shall be evaluated on an ongoing basis to ensure continued relevance. At a minimum, the CDS system should provide mechanisms for drug–drug, drug–allergy, and drug–disease state interactions, as well as dose range checking and other dosing guidance. CDS should be utilized to collect quality measures data for reporting to CMS under the Meaningful Use of the Electronic Health Record Incentive Program.

CDS Development and Customization. Customization of vendor-supplied CDS or local development of CDS solutions shall follow a defined life cycle, which shall include the following stages²⁶:

- Requirements gathering: review of current workflow and identification of opportunities for CDS solutions,
- Detailed specifications for the proposed CDS solution to be developed in conjunction with a pharmacy informatics or information technology expert and approved by the affected clinical end users (e.g., nursing, medical, and pharmacy staff representatives) as well as quality-control and regulatory department representatives,
- Development and testing of the proposed CDS solution,
- Education of the affected end users regarding the proposed solution and any impact it may have on current workflow,

- Implementation of the CDS solution, and
- Ongoing monitoring as described above under CDS governance to identify and correct any unintended consequences of the new CDS rule.

G. Committee Involvement. A pharmacist with pediatric training shall be a member of and actively participate in hospital and health-system committees responsible for establishing and implementing medication-related policies and procedures for pediatric patients as well as those committees responsible for the provision of pediatric patient care, including the P&T, infection prevention and control, patient care, medication-use evaluation and process, medication safety, transitions-of-care, nutrition, and pain management committees (or their equivalents), as well as the institutional review board, quality-improvement committee, and information technology committee (or their equivalents).^{5,27–29}

A pharmacist with pediatric training should participate in or be appointed to the hospital's P&T committee and should provide input regarding all P&T decisions and their impact on pediatric patient populations. A pediatrics subcommittee or other appropriate pediatric representation should be established if the P&T committee is focused primarily on adult patients. If such a subcommittee is not established, all P&T committee decisions should denote whether they apply to pediatric patients or only adult patients.

A pharmacist with pediatric training should be similarly involved in the development, implementation, and assessment of care plans (medication-use processes, protocols, critical pathways, disease state management programs, transitions-of-care, and clinical practice guidelines), standing orders, and order sets that involve medication therapy for pediatric patients.

Standard II. Medication-Use Policy Development

A. Policy Development. All committees that make decisions concerning pediatric medication management and use shall have at least 1 pharmacist with pediatric training as a member. These include but are not limited to the P&T, infection control, patient care, medication-use evaluation, medication safety, transitions-of-care, nutrition, pain management, and information technology committees (or their equivalents), as well as the institutional review board.^{5,27–29} A pharmacist with pediatric training shall be involved in the development, implementation, and assessment of pediatric care plans (protocols, critical pathways, disease state management programs, and clinical practice guidelines), standing orders, and order sets that involve medication therapy.³⁰

B. Formulary. Formulary. A well-controlled formulary of approved medications shall be maintained and regularly updated by the P&T committee (or its equivalent). The impact of and compliance with the formulary should be periodically reviewed (e.g., through

drug utilization reviews), and the P&T committee should regularly review the formulary for pediatric efficacy and safety information. The P&T committee shall be responsible for developing and maintaining written criteria for drug product selection, which shall address formulary requests for medications intended for use in pediatric populations. The P&T committee shall be responsible for approving and maintaining adequate product specifications to aid in the purchase of medications and related supplies for pediatric patients. The pharmacy shall disseminate the formulary by electronic (preferred) or other means to meet the needs of all healthcare professionals.

There shall be policies and procedures for the following:

- Use of dietary supplements,
- Other alternative therapies, and
- Procurement, control, and use of nonformulary medications required for pediatric patient care.⁵

Nondrug Substances. Some institutions may have nondrug substances that may be handled or distributed by the pharmacy (donor breast milk and other nutrition products). There should be policies and procedures that describe how the pharmacy shall seek and obtain documented authorization from appropriate medical staff and hospital committees before the medical use of any nondrug substance, as well as appropriate documentation for tracking and quality-control purposes (e.g., lot numbers). These policies and procedures should clearly define the pharmacy procedure for storage, preparation, and distribution of these nondrug substances. A pharmacist with pediatric training should be involved in the development and approval of these policies and procedures.

C. Drug Information. Drug Information Services. Pediatric drug information services should be provided by the pharmacist practicing in the pediatric setting by supplying information unique to the pediatric population. These services may be developed as a focused service with pharmacists solely working in this area in the health system, or drug information responsibilities may be incorporated throughout the department with several pharmacists contributing to different services. A pharmacy department may have a drug information telephone line, e-mail address, or other mode of communication (e.g., text message, discussion board) to answer questions from practitioners. A pharmacist with pediatric training should provide the pharmacy department and other healthcare professionals with information on new and investigational drugs, adverse effects of and contraindications to drug therapy, compatibility and stability information, drug shortages and alternatives, dosage computations, pharmacokinetics, pharmacogenomics, and drug interactions related to the pediatric population. The drug information service should also conduct medication-use evaluations to assist the P&T committee or its equivalent and may

provide medication-use policies specific for pediatric patients (e.g., off-label use of medications, use of patient's home medications).

Drug Information Requests. The pharmacist shall provide pediatric patient-specific drug information and accurate, comprehensive information about drugs and drug therapy to health professionals, patients, and patients' caregivers as appropriate. Responses to general and patient-specific drug information requests shall be provided in an accurate and timely manner by a pharmacist, and there should be a process for documenting and ensuring the quality of responses.³¹ Documentation of drug information requests and other services shall be gathered and evaluated by the pharmacy department.

Dissemination of Drug Information. Pharmacists shall keep the hospital's staff and healthcare providers informed about the use of medications in the pediatric population on an ongoing basis through appropriate publications, presentations, and programs. Pharmacists shall ensure timely dissemination of drug product information (e.g., recall notices, labeling changes, changes in product availability). Electronic communications (e.g., websites, e-mail newsletters, intranet postings) are effective due to their timeliness and accessibility.³¹

Standard III. Optimizing Medication Therapy

An important responsibility of the pharmacist is optimizing medication use. A pharmacist with pediatric training, in collaboration with medical and nursing staff, shall develop policies and procedures based on demonstrated best practices for ensuring the quality of medication therapy in pediatric patients. Clinical imperatives should be the primary determinant of medication-use decisions.

Clinical Services. Clinical services provided by the pharmacy department will vary, depending on the needs of patients, the resources available, the structure of the department, and other factors. However, the goal should be to provide all children with the same level of clinical expertise on a consistent basis. Decentralized clinical pharmacy services are warranted for standalone children's hospitals and other hospitals that support a large number of pediatric patients. Clinical pediatric pharmacy services shall be prioritized to provide the highest level of care to populations that are at highest risk, such as patients in the critical care, neonatology, hematology–oncology, and emergency departments. If perioperative or procedural services are provided in the health system, a pharmacist should also be directly assigned to those units.³² The clinical pharmacy services provided should include but are not limited to patient care rounds, drug therapy monitoring, drug information, medication profile review, medication reconciliation, ADEs surveillance, patient education, and discharge counseling. Additional services provided by the pharmacy should include routine nursing and prescriber

education, order set development, policy development, drug evaluation reviews, and other medication safety and quality initiatives for pediatric patients. Hospitals should deploy additional clinical pediatric pharmacy specialists to high-risk care areas (e.g., critical care, neonatology, hematology–oncology, transplant, and emergency departments). Documentation of pharmacy services is warranted for quality assurance. Communication of patient care recommendations is also critical for continuity of care. Documentation in the electronic medical record is preferred when feasible.

A. Creating a Relationship With the Patient. Pharmacist's Role in Direct Patient Care. Hospital and pharmacy department policies should encourage pharmacists with pediatric training to provide direct patient care in both inpatient and outpatient settings. Hospital and pharmacy department policies should encourage pharmacists with pediatric training to engage in medication therapy management, collaborative drug therapy management, immunization, medication ordering and administration, and other patient care activities to the extent permitted by law, regulations, and hospital requirements.³³

Continuity of Care. Pharmacists should assume responsibility for continuity of care for patients' medication therapy. Pharmacists and pharmacy departments should take a leadership role in developing and implementing policies and procedures for medication therapy management for admissions, discharges, transfers, and transitions across care settings and shifts (e.g., hospital unit changes, outpatient clinics, home care).

B. Acquiring Essential Patient Data. Medication Histories. Pharmacists or their designee should obtain, prepare, or have immediate access to comprehensive medication histories for each patient, from the patient's medical record or other databases (e.g., a medication profile) or both. It is preferred that a pharmacist with pediatric training conduct a medication and vaccination history for each pediatric patient when feasible. The patient or caregiver may be interviewed, depending on the patient's level of communication. Electronic medical records should be constructed so that medication histories and other data required for medication management, including medication reconciliation, are available and easily accessible to all health professionals caring for a patient. For many pediatric patients, medication and vaccination histories may be obtained from caregivers who may or may not provide routine care for the child (e.g., grandparents, divorced parent). If available, efforts should be made to contact caregivers who provide routine care for the child and to pharmacies to gather accurate medication histories.

Standard IV. Managing Inventory

A. Medication Storage. Medications shall be received, stored, and prepared under proper conditions

of sanitation, temperature, light, moisture, ventilation, segregation, and security to ensure medication integrity and personnel safety in accordance with all federal and state laws.⁴

B. Drug Shortages. There shall be policies and procedures for managing drug product shortages. The pharmacy's inventory management system should be designed to detect and mitigate subminimum inventory levels and alert the pharmacy to potential shortages. Pharmacy staff should monitor reliable sources of information regarding drug product shortages (e.g., ASHP and FDA drug shortages web resource centers).^{34,35} The pharmacy should develop strategies for identifying alternative therapies, working with suppliers, collaborating with physicians and other healthcare providers, and conducting an awareness campaign in the event of a drug product shortage.³⁶ Pharmacy should provide leadership in communicating specific operational changes and work with appropriate medical personnel and the P&T committee or its equivalent for specific clinical changes affecting pediatric patient care due to drug shortages.

Standard V. Preparing, Packaging, and Labeling Medications

A. Preparing Medications. Compounding. Drug formulations, dosage forms, strengths, and packaging that are not available commercially but are needed for pediatric patient care shall be prepared by appropriately trained personnel in accordance with applicable practice standards and regulations. Medications shall be ordered by the institution in standardized concentrations of commercially available and validated master formulas—ideally evidence-based and referenced—as part of an effort to reduce medication errors. The pharmacy shall follow federal and state regulations and shall provide adequate quality assurance procedures for these operations.^{19,20,37} Pharmacy departments shall ensure patient safety as well as true patient need versus anticipated cost savings. Written master formulations and batch records (including product test results, as appropriate) shall be maintained, and a lot number or other method to identify each finished product with its production and control history shall be assigned to each batch.^{14–20} Sterile and nonsterile compounding shall meet all applicable federal and state laws, regulations, standards, and accreditation requirements.^{14,19,20}

Sterile Preparations. When possible, manufactured sterile preparations should be preferred to compounding in the pharmacy. All sterile medications shall be prepared and labeled in a suitable environment by appropriately trained personnel in accordance with established quality assurance and beyond use dating procedures.^{14,19} The use of sterile medications compounded outside the pharmacy (e.g., nursing units) should be avoided to the extent possible; when they are used in urgent or emergent circumstances, there

shall be procedures for aseptic preparation, quality assurance, expiration dating, and ongoing competency evaluations for compounding personnel.^{14,19,38} Sterile compounding outside the pharmacy or satellite pharmacies (e.g., on nursing units) should be minimized and occur only in emergency situations.^{14,19} If outsourcing of sterile compounding services is necessary, the pharmacy department shall ensure that the process provides appropriate guarantees of safety and quality assurance.³⁸

B. Packaging Medications. Unit Dose Packaging. A lack of availability of commercially prepared dosage forms, combined with the documented risk of calculation errors, requires the use of comprehensive unit dose drug distribution systems and IV admixture services for pediatric patients. The use of standardized doses for both oral and parenteral medications where appropriate may facilitate the provision of these services. Every attempt shall be made to provide patient-specific dosing, realizing that patient-specific doses are more often required in pediatric patients. All scheduled pediatric medications should be dispensed in patient-specific unit doses.

Manipulation of medications before administration (e.g., withdrawal of doses from containers, reconstitution of powdered drug products, labeling of containers, splitting of tablets) by final users or providers should be minimized.¹⁵ Repackaging of oral or sterile products shall meet all applicable laws, regulations, standards, and accreditation requirements.^{14,18,19}

Barcoding of Unit Dose Packaging and Point-of-Care Administration. Unit dose packages should contain a barcode, and that code should be used in inventory management, dose preparation and packaging, dispensing, and administration. It is the responsibility of the pharmacy department to ensure the quality of all aspects of barcode medication administration, including scannability of barcodes and database management.^{23,39}

Standard VI. Medication Delivery

A. Medication Prescribing. Prescribing. Medications shall be prescribed by individuals who have been granted appropriate clinical privileges in the hospital and are legally permitted to order medications. The pharmacy shall advocate and foster practitioners' conformance with standardized, approved, and safe terminology and abbreviations to be used throughout the hospital when prescribing medications and discourage use of nonstandard and unapproved terminology and abbreviations.⁴ The metric system shall be utilized for ordering oral liquid medications for the pediatric population.^{40,41}

Diagnostic or Therapeutic Purpose. Pharmacists shall have access to the patient's diagnosis or the intended therapeutic or medical purpose of medications in a timely manner. For many medications, pediatric

labeling does not exist, and off-label use is common. Resources shall be available to the pharmacist to assist with identifying medication indications or uses.

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

A system shall exist to ensure that medication orders are not inappropriately continued.⁴ The pharmacy department should establish, regularly review and revise, and enforce policies and procedures that ensure a prospective review of every medication order for a pediatric patient by a pharmacist trained in pediatrics. A standard definition should be established for who constitutes a pediatric patient in the institution; this definition may be based on weight, age, congenital defects, developmental delays, or a combination of these factors. All medication orders for pediatric patients shall include the patient's allergies, the patient's weight in kilograms, a weight-based dose designation (e.g., mg/kg), and a total dose, where applicable. Height, in centimeters, shall also be obtained to calculate body mass index, body surface area, and renal function. Standardization for doses to be provided in milligrams or milliliters should be evaluated closely, and the correct process for entering orders should be standardized and communicated to providers to mitigate order errors. All elements of the medication order are required. The use of abbreviations shall be limited based on specific recommendations provided by the Joint Commission on "do not use" abbreviations.⁴¹

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

Any questions regarding an order shall be resolved with the prescriber before dispensing or administration. Pharmacist consultations should be documented in the patient's medical record. Information concerning changes shall be communicated to the appropriate health professionals caring for the patient.⁴

B. Medication Delivery and Administration. Drug Delivery Systems, Administration Devices, and Automated Distribution Devices. The pharmacy shall be responsible for developing policies, procedures, and quality assurance programs regarding drug delivery systems, administration devices, and automated distribution devices to ensure safety, accuracy, security, and patient confidentiality in the pediatric population. Administration technology consideration shall include standard concentrations, patient size, and administration rate. The potential for medication errors associated with such systems and devices in the pediatric population shall be thoroughly evaluated.^{4,6} Pharmacy personnel shall supervise the stocking and documentation of medications in automated dispensing devices.⁶ Whenever possible, automated dispensing cabinets should employ profile-based technology integrated with remote medication order-entry capabilities.

Medication Administration. Only personnel who are authorized by the hospital in accordance with applicable laws and regulations and who are appropriately trained shall be permitted to administer medications to a patient. All administered, refused, or omitted medication doses shall be recorded in the patient's medical record according to an established procedure, and all medications that have not been administered shall be returned to the pharmacy or discarded appropriately. No medication should be administered to a patient unless medical and nursing personnel have been provided with adequate information about and are familiar with its therapeutic use, method of administration, potential adverse effects, and dosage. Caregivers and patients shall be informed of these policies on admission so they do not administer home medications without the healthcare provider's knowledge and approval.

Patients who are admitted to the hospital with functional insulin pumps shall work with the physician, nurse, and pharmacist to ensure that the pump is set up appropriately. The patient and/or parent must demonstrate competence in pump use and programming and agree to communicate all insulin doses with the nurse to ensure appropriate administration and documentation. Hospitals shall have a policy to address insulin pumps and their use in the hospital setting.

Standard VII. Monitoring Medication Use —

A. Reviewing Patient Responses to Medication Therapy. Medication Therapy Monitoring. Medication therapy monitoring shall be conducted by pharmacists. Medication therapy monitoring includes a proactive assessment of patient problems and an assessment of the following:

- The therapeutic appropriateness of the patient's medication regimen,
- Therapeutic duplication or omissions in the patient's medication regimen,
- The appropriateness of the dose of the medica-

tion, as well as the route, method, and frequency of administration of the medication,

- Patient adherence to the prescribed medication regimen,
- Drug–drug, drug–food, drug–dietary supplement, drug–laboratory test, and drug–disease interactions,
- Adverse drug reactions (ADRs) and other undesired effects,⁴²
- Patient medication allergies and sensitivities,
- Clinical and pharmacokinetic laboratory data to evaluate the efficacy and safety of medication therapy and to anticipate toxicity and adverse effects,
- Physical signs and clinical symptoms relevant to the patient’s medication therapy, and
- Assessment of the effectiveness of the patient’s medication therapy.

Therapeutic Drug Monitoring. Therapeutic drug monitoring services shall be provided by the pharmacy for all pediatric patients for medications that include, but are not limited to, drugs with a narrow therapeutic window (e.g., vancomycin, aminoglycosides, anticonvulsants, antirejection medications, digoxin), anticoagulation medications, and other medications associated with high rates of adverse events. Any pharmacists caring for pediatric patients must be knowledgeable of the unique pharmacokinetic differences in a pediatric patient, including alterations in absorption, distribution, metabolism, and excretion. The most important of these is the larger volume of distribution for water-soluble drugs (e.g., aminoglycosides), which can significantly affect dosing in younger patients. The pharmacist should ensure that the drug being monitored has been administered appropriately before samples are taken for the measurement of serum drug concentrations. The frequency and timing of sampling should also be coordinated to avoid excessive and traumatic sampling in pediatric patients. Documentation of pharmacokinetic services in a readily accessible format should be completed by the clinical pharmacist with pediatric training.

B. Educating and Counseling Patients and Family.

Patient Education. Counseling of pediatric patients and their caregivers is an important role for the pharmacist. For younger patients or patients who lack developmental cognition, the pharmacist may have to focus education toward the caregiver; older children and adolescents will require counseling and education provided at an age-appropriate level. When language barriers exist, interpreters may help communicate with non-English-speaking patients and caregivers. The education level and general health literacy of the patient and caregiver may also present barriers for verbal or written communication. Medication-related material developed by other services and departments as well as commercial sources should be reviewed by the pharmacy staff for accuracy, currency, literacy

appropriateness, and completeness. If necessary, interpretive language services (written or oral) should be made available to patients.⁴³ Commercially available, pediatric-friendly patient education handouts in multiple languages are warranted in a pediatric health system.

Patients and caregivers should be counseled on medication use both in the inpatient and outpatient settings and should be provided with the following information at a minimum:

- Medication’s brand and generic names,
- Dosing instructions,
- Methods of administration (e.g., crush, chew, apply),
- Information about potential adverse effects and drug interactions,
- Proper medication storage, and
- Strategies to prevent accidental ingestion.

Specifically, caregivers shall be instructed in the differences between milliliters and teaspoons for administration amounts. The recommended measurement to be used for liquid formulations is milliliter.^{40,44} Adherence shall be emphasized for all patients and caregivers. It is helpful to provide pediatric-specific patient care handouts with dosing instructions for discharge medications and education on the proper use of a pediatric-friendly measuring device (e.g., not the household teaspoon) and the possible options for flavoring medications. During a counseling session, the pharmacist is well positioned to play a role in preventive healthcare, including immunization and poison prevention.⁹

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

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

A. Assessing Pharmacy Services and Practices. Documentation of Pharmacist-Provided Patient Care Services and Medication Therapy Outcomes. The pharmacy shall have an ongoing process for consistent

documentation of all pharmacy interventions and the pediatric patient care services provided by pharmacists and patient outcomes from medication therapy.⁴⁵ This documentation can serve as objective data supporting the need to hire a full-time pharmacist with pediatric training in a particular area where focused services may not currently exist or optimization of pharmacy resources for the pediatric population is needed.

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

B. Improving the Medication-Use Process. Medication-Use Evaluation. There shall be an ongoing program for monitoring pediatric drug utilization and costs to ensure that medications are used appropriately, safely, and effectively and to increase the probability of desired patient outcomes. The P&T committee (or its equivalent) should define specific parameters for evaluation (e.g., disease state, pharmacologic category, high-use/high-cost drug products) as appropriate for the organization. Through the ongoing evaluation of pediatric medication use, areas in need of improvement in pediatric medication prescribing and management can be identified and targeted for intervention.^{46,47}

Medication Safety. Medication errors are common and costly.⁴⁸ Pediatric patients are most vulnerable and are 3 times more likely to be involved in a medication error than adults.⁴⁹ Pediatric patients have unique differences in pharmacokinetic and pharmacodynamic responses to medication therapy that put them at higher risk of experiencing ADEs.⁴⁹ In addition, there is a lack of ready-to-use medication forms available from manufacturers, and commercially available products often require extensive manipulation, which may include complex calculations, to make them suitable for pediatric patients. Medication dosing is more complex, because most doses are not standardized and are dependent on weight. Infants and children also lack the developmental ability to recognize or describe unintended adverse effects or ADRs should they occur.

Pharmacists shall provide leadership to and participate in collaborative, multidisciplinary efforts to prevent, detect, and resolve drug-related problems that can result in patient harm such as root cause analysis or failure mode and effects analysis. A pharmacist with pediatric training and other appropriate hospital personnel shall establish and regularly revise policies and procedures regarding pediatric medication error and adverse-event prevention and reporting. Monitoring,

detecting, review, and analysis of the hospital's and health system's medication errors and near misses should be an ongoing process in a just culture environment, and corresponding corrective actions should be documented.⁵⁰ An ongoing program for preventing, monitoring, resolving, and reporting ADEs shall be developed.⁴² A pharmacist shall participate in appropriate organizational committees and work with physicians, nurses, administrators, and others to examine and improve systems to ensure that medication-use processes are safe.⁴⁷ To ensure the safety of pediatric patients, the pharmacy department shall establish, regularly review and revise, and enforce pediatric-specific requirements for medication management, including considerations for look-alike/sound-alike drugs, high-alert medications, ready-to-administer doses, turnaround times, overrides, and medication storage and labeling.

Systems shall be in place to routinely evaluate medication errors that occur, and interventions should be made to processes to prevent error recurrence. Due to the complex nature of the pediatric medication-use system, including confusing packaging and dosage forms, proactive evaluation of errors reported from other sources (e.g., ISMP, the Joint Commission, the manufacturer) shall be routinely evaluated, and necessary process changes for error prevention should be made. Self-reporting systems for ADEs used in isolation are insufficient. An additional surveillance or trigger-based system shall also be in place to more adequately monitor for and capture events.^{51,52}

Adverse Drug Reactions. ADRs are defined as unintended responses to a drug that poses harm or other negative patient outcomes.⁴² Pharmacies should have a formal and comprehensive program to identify and report ADRs. Effective monitoring and evaluation of ADRs shall be focuses of such programs. ADRs should be reported through FDA's MedWatch program as a part of postmarketing data analysis in addition to internal hospital voluntary reporting mechanisms to ensure appropriate follow-up and evaluation.

Antimicrobial Stewardship and Infection Prevention and Control. There shall be policies and procedures to promote the optimal use of antimicrobial agents, reduce the transmission of infections, and educate health professionals, patients, and the public about these topics. Pharmacists should lead antimicrobial stewardship and infection prevention and control efforts through clinical endeavors focused on proper antimicrobial utilization and membership on relevant multidisciplinary work groups and committees within the health system. Efforts should be made to have a specific pharmacist with pediatric training devoted to antimicrobial stewardship and other infectious diseases programs that focus on the pediatric population.

Pharmacists should monitor patients' laboratory reports of microbial sensitivities or applicable diagnostic markers and advise prescribers if microbial resistance

is suspected, evaluate trends in microbial prescribing relative to changes in microbial resistance patterns, and assist in developing prescribing patterns to help minimize the development of drug resistance.²⁷

Standard IX. Research

The pharmacist should initiate, participate in, and support clinical and practice-related research appropriate to the goals, objectives, and resources of the specific hospital or health system. Pediatric patients have long been recognized as “therapeutic orphans” because of the relative absence of therapeutic trials in this patient population. The pharmacist must take into consideration that pediatric patients may not be able to provide informed consent and must have a procedure in place to address this vulnerable population. The reasons for this are numerous and include ethical issues, potential adverse publicity, possible litigation, methodological hurdles, and an inability to justify such studies for economic reasons. The advent of the Best Pharmaceuticals for Children Act of 2007^{53,54} and additional pediatric formulation initiatives has greatly improved the number of resources available and the amount of research performed in children. The pharmacist with pediatric training can be directly involved in collaboration with other healthcare providers in conducting pediatric research. Examples of pediatric research topics include, but are not limited to, the following:

- Safety and efficacy of drug products in pediatric patients,
- Pharmacokinetics and pharmacodynamics of new medications,
- Pharmacogenomic considerations and prediction of ADEs,
- Stability, safety, and efficacy of extemporaneously compounded sterile and nonsterile drug products,
- Safety and efficacy of administration techniques,
- Off-label use of medications,
- Comparative evaluations of medications addressing treatment regimens, outcomes of therapy, and their relative costs,
- Behavioral and socioeconomic adherence issues in pediatric pharmacy care, and
- New and existing pharmacy drug distribution systems and services for pediatric patients.

Examples of direct involvement include, but are not limited to, the following:

- Serving as a member of an institutional review board,
- Maintenance, oversight, and dissemination of all information on investigational drug studies, expanded access programs, and comparative trials involving medications in the pediatric population,
- Maintenance, coordination, and oversight of policies and procedures involving investigational drug studies, expanded access programs, and comparative trials involving medications in the

pediatric population, and

- Primary or coinvestigator of studies or trials described above.

Conclusion

The unique challenges of the pediatric population require careful consideration for pharmacists and pharmacy departments in hospitals and health systems. Pharmacists caring for pediatric patients must be knowledgeable and competent in pediatric pharmacy. Pharmacy departments must ensure that the elements of pharmacy services meet the pediatric patient needs that are critical to safe, effective, innovative, and cost-conscious medication use in a hospital or health system.

ARTICLE INFORMATION

Affiliations Auburn University Harrison School of Pharmacy (LSE), Auburn, Alabama; Samford University McWhorter School of Pharmacy (KB), Birmingham, Alabama; Boston Children’s Hospital (KFG), Boston, Massachusetts; St. Louis Children’s Hospital (MKH), St. Louis, Missouri; Ernest Mario School of Pharmacy (RM), Rutgers, The State University of New Jersey, Saint Barnabas Medical Center, Piscataway, New Jersey; Children’s National Medical Center (KP), Washington, District of Columbia; Vanderbilt Children’s Hospital Pharmacy (ALP), Nashville, Tennessee. At the time of writing, KP was affiliated with the Pew Charitable Trust, Washington, District of Columbia

Correspondence Lea Eiland, PharmD; eilanls@auburn.edu

Disclosures The authors declare no conflicts or financial interest in any product or service mentioned in the manuscript, including grants, equipment, medications, employment, gifts, and honoraria.

Acknowledgments The contributions of Eric Rose, PharmD, PMP, are acknowledged. PPAG gratefully acknowledges the following organizations and individuals for reviewing these guidelines (review does not imply endorsement): American Pharmacists Association; Ascension; ISMP; Kentucky Society of Health System Pharmacists; National Healthcareer Association; Valley Children’s Hospital; James L. Besier, PhD, MS, BScPharm; Carly Brown, PharmD; Derek R. Burns, PharmD; Christopher T. Campbell, PharmD; Mary Petrea Cober, PharmD; Justin W. Cole, PharmD; Michele Corriveau, BScPharm; Jeffrey Goff, MS; Charlene Hope, PharmD, MS; Peter Johnson, PharmD; Julie Kasap, PharmD; Susannah E. Koontz, PharmD; Ken Kurek, PharmD; Carlton K. K. Lee, PharmD, MPH; Nancy C. MacDonald, PharmD; Shannon Manzi, PharmD; Patrick McDonnell, PharmD; Julie Neuman, PharmD; Penny Ngo, PharmD; Barbara Petroff, MS; James Ponto, MS, BCNP; Robert Poole, PharmD; James R. Rinehart, MS; LCDR Teisha A. Robertson, PharmD, MBA; Colleen Smith, PharmD; Christine Steffensen, PharmD, MA; James Stevenson, PharmD; Sharon Ternullo, PharmD; Courtney Terry, PharmD; Carol G. Vetterly, PharmD; Jody Jacobson Wedret, BScPharm; Wyn Wheeler, PharmD; and Ed Wong, PharmD

Accepted May 19, 2018

Additional information These guidelines will also appear in the American Journal of Health-System Pharmacy. 2018;75:e136–150. DOI 10.2146/ajhp170827. Developed through the ASHP Section of Clinical Scientists and Specialists and PPAG and approved by the ASHP Board of Directors on October 23, 2017. This document supersedes a previous version approved by the ASHP Board of Directors on April 27, 1994.

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