# Draft ASHP Guidelines on Home Infusion Pharmacy Services*

## Background and Purpose

**Background.** Home infusion services are provided by a variety of organizations, including hospitals, community pharmacies, home health agencies, hospices, and specialized infusion companies. Patients receive care in non-inpatient settings, such as their homes and ambulatory infusion centers, or in alternate-site settings, such as skilled-nursing facilities. Home infusion pharmacies may provide one or more of several service lines:

- infusion therapies (e.g., intravenous, subcutaneous, intrathecal, epidural);
- specialty pharmacy services;
- ambulatory infusion center services;
- home health nursing;
- private duty nursing;
- respiratory equipment and clinical respiratory services;
- home medical equipment and supplies (with or without oxygen service); or
- enteral products and supplies.

It should be noted that different aspects of home infusion can be provided by different organizations. When services are shared among providers, pharmacists have a professional responsibility to ensure that all patient care responsibilities are defined, understood, agreed

upon, coordinated, and documented in advance by all providers. These guidelines apply to the provision of home infusion services by pharmacists practicing in all health care settings.

**Purpose.** The purposes of these guidelines are to define the role of the pharmacist in providing home infusion care to patients and to outline minimum requirements (indicated by use of the word "shall") and best practices for the operation and management of services provided by pharmacies in the home or alternate-site setting. In broad terms, home infusion includes the provision of specialized, complex pharmaceutical products; development and execution of plans to manage the medication therapy of patients; and clinical assessment and monitoring of patients in their homes. These services generally include home infusion therapy, other injectable drug therapy, and parenteral and enteral nutrition therapy. As the number and types of therapies administered in the home and alternate sites expand, the resources and support required to provide these therapies will expand as well. Specific and unique pharmacist education and training, drug product admixtures and administration techniques, equipment operation and maintenance, patient monitoring, and patient and family education are required to ensure successful outcomes. These guidelines outline the pharmacist's role in providing these services and products. They are not intended to apply to home health services that do not involve the provision of home infusion pharmacy services.

Many of the activities included in these guidelines are the subjects of other ASHP policy and guidance documents, which should be referred to for additional information. Pharmacists practicing in home infusion should use professional judgment in assessing ASHP's policy and

guidance documents and in adapting them to meet their health care organizations' and patients' needs and circumstances.

To ensure the safe, appropriate, and effective use of medications in the home, home infusion pharmacies should develop comprehensive services to address factors unique to home infusion. Caregivers such as family members, who often have no health care experience, should be trained to properly administer, store, and dispose of medications; operate medication administration devices; and monitor patients as necessary. Many medications must be aseptically compounded, often in quantities sufficient for a weeks use, and delivered under conditions that will ensure that product potency and purity are maintained. Vascular access for infused therapies should be maintained for the intended duration of treatment, which may range from days to years. Medication administration devices should be selected and maintained to accurately and safely administer a variety of therapeutic regimens. Potential complications should be anticipated, and a proactive individualized plan of care should be established for monitoring, detecting, and managing complications, including those related to equipment, enteral and parenteral access, compliance, response to therapy, and patient and family education. Economic considerations should be taken into account so that care is provided in the most cost-effective manner. Finally, home infusion pharmacies should have an effective organizational structure with the flexibility to meet the changing needs of patients, as well as to keep pace with the rapid growth of the industry and changes in health systems. As health care providers in the home setting, pharmacists should be concerned with the outcomes of therapy and not just the provision of services. Effective management is necessary to ensure that quality outcomes of therapy are achieved. While the scope of pharmacy services is likely to

vary from site to site, depending upon the needs of the patients served, these criteria are strongly linked to patient outcomes, and neglect of any one area may compromise quality.

**Practice Management**

**Mission and goals of the home infusion organization.** The pharmacy or its affiliated organization should have a written mission statement that reflects patient safety, quality of care, and operational responsibilities. The statement should be consistent with the mission of the parent home infusion organization and/or health system, if applicable. The development and prioritization of goals, objectives, and work plans shall be consistent with the pharmacy's mission statement. The mission should be understood by employees, contract staff, and other participants (e.g., students and residents) in the pharmacy's activities.

**Laws and regulations.** The home infusion pharmacy shall comply with all applicable local, state, and federal laws and regulations. Laws and regulations change frequently, so it is imperative to remain up to date on these changes so that the pharmacy remains in compliance. The pharmacy shall maintain written or computerized documentation of compliance regarding procurement, storage, and distribution of drug products, patient information, and related safety regulations from applicable state boards of pharmacy, the federal Food and Drug Administration (FDA), United States Pharmacopeia (USP), Drug Enforcement Administration (DEA), Centers for Medicare & Medicaid Services (CMS), the Occupational Safety and Health Administration (OSHA), the National Institute for Occupational Safety and Health (NIOSH), and

the Environmental Protection Agency (EPA), among others. Pharmacy management of patient information shall conform to the Health Insurance Portability and Accountability Act of 1996[1] (HIPAA) and to the parent organization's policies and procedures. Pharmacies that participate in Medicare Part D plans shall comply with government regulations for Medicare Part D, which may include annual compliance training regarding Medicare fraud and abuse. Appropriate business licenses, permits, and tax stamps should also be available.

**Licensure.** Professional staff shall maintain pharmacist licensure in the state where their practice is located. Policies and procedures should be available to ensure that health care providers meet applicable state licensure and home infusion organization authorization, if required, for prescribing medications.

Many states require pharmacies with out-of-state pharmacy licenses to also have a pharmacist licensed in the state of the prescription recipient. Pharmacies dispensing drugs across state lines shall comply with out-of-state licensure requirements, as well as other state and federal interstate laws and regulations. The pharmacy director shall have a process in place for validating current licensure of all professional staff, and the source(s) of this validation shall also be verified. In locations in which pharmacy technicians are required to be registered and/or certified, such registration and/or certification shall be validated annually or as required by law or regulation.

**Accreditation.** Accreditation gives patients, referral sources, and payers the assurance that the pharmacy meets a basic level of quality in patient care. Accreditation may be required by some

payers and is recommended for the home infusion pharmacy. Accrediting bodies may include The Joint Commission, the Community Health Accreditation Program (CHAP), Pharmacy Compounding Accreditation Board (PCAB), Healthcare Quality Association on Accreditation (HQAA), Accreditation Commission for Healthcare (ACHC), and Medicare.

**Practice standards and guidelines.** Appropriate practice standards and guidelines of professional pharmacy organizations such as the American Society of Health-System Pharmacists (ASHP) should be assessed and utilized as appropriate to the scope of pharmacy services provided. The standards of other professional clinical organizations, such as the American Society for Parenteral and Enteral Nutrition (ASPEN), the Infusion Nurses Society (INS), Infectious Diseases Society of America (IDSA), and the Oncology Nursing Society (ONS), should also be assessed and used when applicable to the home infusion organization, its scope of services, and the population served. Such practice standards and guidelines should be adapted into the organization's policies and procedures when appropriate.

**Policies and procedures manual.** A policies and procedures manual governing the scope of the home infusion pharmacy services (e.g., administrative, operational, clinical, quality performance or improvement, infection control, drug preparation and dispensing, equipment maintenance) shall be properly maintained and available. The manual should be reviewed and revised annually or whenever necessary to reflect changes in procedures specific to the sites where the pharmacy's products and services are provided. All personnel should be familiar with

the contents of the manual. Appropriate mechanisms should be established to ensure compliance with the policies and procedures.

**Human Resources**

The responsibilities and related competencies for home infusion pharmacy employees should be clearly defined in written position descriptions for all job categories.

**Director of Home Infusion Pharmacy Services.** Effective leadership and practice management skills are necessary for pharmacists' delivery of care that meets the needs of patients and the health system and results in continuous improvement in patient outcomes. These guidelines use the term *director of home infusion pharmacy services* (or, more simply, *director*) to indicate the person responsible for managing those services. Depending on the health system's organizational structure and other factors, designations such as manager or pharmacist-in-charge may also be used.

The director of the home infusion pharmacy services must work in conjunction with appropriate health-system leaders to create a long-term vision for the home infusion pharmacy department that is consistent with that of the health system. The director of home infusion pharmacy services should be responsible for (1) setting short- and long-term goals for the pharmacy based on the needs of the patients served, the specific needs of the pharmacy (and any organizational arrangement of which the pharmacy patient care services may be a component), and developments and trends in health care and home infusion pharmacy practice; (2) developing plans and schedules for achieving these goals; (3) directing the

implementation of the plans and the day-to-day activities associated with them; (4) determining whether the goals and schedule are being met; and (5) instituting corrective actions where necessary. These core functions are implemented by the pharmacy team.

The home infusion pharmacy team should be a cross-functional group whose skill sets include operations management, clinical care, financial management, performance improvement, and information technology. Depending on the size and scope of the setting, these functional responsibilities may be assigned to a single person or a team. It is the responsibility of the director to monitor the status of the goals set forth in the department's vision, provide feedback to the pharmacy team as necessary, and support the team's implementation of the core functions of the pharmacy practice.

Home infusion pharmacy services should be managed by a professionally competent, legally qualified pharmacist. In addition to the requirements for a staff pharmacist, the director shall be thoroughly knowledgeable about home infusion pharmacy practice and management. Completion of a pharmacy residency program and/or home infusion experience are desirable.

The director shall be responsible for

- Establishing the mission, vision, goals, and scope of services of the pharmacy on the basis of the needs of the patients served, the needs of the health system, and developments and trends in health care;
- Developing, implementing, evaluating, and updating plans and activities to fulfill the mission, vision, goals, and scope of services of the pharmacy;
- Ensuring the development and implementation of policies and procedures that provide safe and effective medication use for the patients served by the institution;

- Mobilizing and managing the resources, both human and financial, necessary for the optimal provision of pharmacy services;
- Overseeing contracts; and
- Ensuring that pharmacy services are delivered in compliance with applicable state and federal laws and regulations, as well as national practice standards.

A part-time or contract director shall have the same obligations and responsibilities as a full-time director. The director, in carrying out these responsibilities, should supervise an adequate number of competent, qualified personnel.

**Home Infusion Pharmacists.** Pharmacists who provide home infusion services shall have an active license to practice pharmacy issued by the applicable state board of pharmacy and other credentials as required by local, state, or federal laws and regulations. Some states require special licensure or training for preparing sterile products. Pharmacists dispensing medications to patients who reside in other states may also be subject to laws and regulations in those states; additional licensure may be required. The pharmacist should be knowledgeable about all applicable federal and state laws and regulations. The pharmacist is responsible for:

- day-to-day supervision of dispensing and delivery activities;
- drug information provided to nurses, physicians, and patients;
- clinical monitoring, care planning, and assessment of home infusion patients;
- maintaining a professional image;
- maximizing work efficiently through the use of technology;
- maintaining confidentiality of patient and proprietary information; and

- utilizing support personnel effectively.

**Technicians and other support or clinical staff.** Sufficient support personnel (pharmacy technicians, clinical staff [e.g., nurses, dietitians, respiratory therapists], and customer service, procurement, delivery, clerical, and administrative personnel) should be available to facilitate the delivery of home infusion pharmacist care and services. Pharmacy technicians should have completed an ASHP-accredited pharmacy technician training program and be certified by the Pharmacy Technician Certification Board (PTCB). The pharmacy should hire pharmacy technician trainees without those qualifications only if those individuals (1) are required to both successfully complete an ASHP-accredited pharmacy technician training program and successfully complete PTCB certification within 24 months of employment, and (2) are limited to positions with lesser responsibilities until they successfully complete such training and certification. The pharmacy should require ongoing PTCB certification as a condition of continued employment. Appropriate supervisory controls should be maintained and documented, consistent with federal and state laws and regulations. In states in which registration of pharmacy technicians and/or special licensure or training is required for specific responsibilities (e.g., preparing sterile products), the pharmacy shall ensure that such requirements are met.

Pharmacy technicians are responsible for compounding sterile and nonsterile preparations, managing drug inventory, contacting patients about scheduled deliveries, and other duties as assigned. Customer service staff may be tasked with contacting patients about scheduled deliveries. Drivers and/or warehouse managers may be responsible for delivery of

medication to the patient, initial paperwork to be signed, storage of medication in the home, observation of quantities of medications and supplies left in the home, and/or communication with the pharmacist if anything appears wrong. Intake personnel, insurance verification staff, and/or billers take referrals, determine insurance coverage, obtain authorizations or precertifications and renew them as needed, bill payers for services provided, and follow up on rejected claims.

**Staffing, work schedules, and assignments.** The director should ensure that work schedules, procedures, and assignments make the best use of pharmacy personnel and other resources. Resources should be sufficient to ensure patient safety. Flex time, weekend options, exempt and nonexempt status, shift differentials, and on-call pay and responsibilities should all be considered when creating a staffing plan.

**Recruitment and selection of personnel.** Personnel should be recruited and selected on the basis of the requirements stated in the established job description, the candidates' job-related qualifications, and their prior performance. The pharmacy director should assist in identifying the relevant professional and technical qualifications for each job description and should participate in candidate interviews and final selection. The organization should have a human resources manual stating the requirements for reference checks, criminal history, and primary source verification of professional licenses. In addition, it should be organization policy that the Office of the Inspector General (OIG) List of Excluded Individuals/Entitites[2] is checked to ensure that potential candidates for employment have not been excluded from federally funded health

care programs. Employees' professional licenses and the OIG List of Excluded Individuals/Entities should be verified at least annually.

Recruitment for home infusion pharmacy positions can be a challenge, especially when the pharmacist labor market is tight. Home infusion pharmacy practice is a niche practice setting with which many pharmacists are not familiar, especially new graduates. Infusion pharmacy practice training in college of pharmacy curricula varies, so recruiting staff with home infusion experience may not be possible. Creative recruitment techniques, such as hiring multiple part-time pharmacists to cover open positions and offering on-site training, may help recruitment.

**Orientation and training.** All employees shall be oriented to the type(s) of care and services provided by the organization. There should be an established procedure for orienting new personnel to the pharmacy, the parent organization, the health system(s) that the home infusion pharmacy serves, and respective staff positions. All employees should understand the roles and responsibilities of others in the organization and should be oriented and demonstrate proficiency on equipment they are expected to operate or support as part of their duties. Employees should be knowledgeable about the supplies that are delivered to the patient. All personnel should possess the education and training needed to fulfill their responsibilities, including specific knowledge related to home infusion. All personnel should participate in continuing education programs and activities relevant to home infusion practice as necessary to maintain or enhance their competence.

A home infusion organization is responsible for helping teach employees, patients, family members, and caregivers about standard safety precautions. The pharmacist should ensure that the home infusion organization provides appropriate education for its employees and patients, including education about appropriate disposal and handling of medical waste, procedures for preventing and managing needle and sharps stick injuries,[3] handling of cytotoxic and hazardous medications,[4] and material safety data sheets (MSDSes).[5] The pharmacist should be a key resource in the development of such educational programs. The pharmacist should assume an active role in the home infusion organization's infection-control activities.

Pharmacists should receive training as necessary to ensure that they possess the knowledge and skills required for the provision of home infusion services. They should participate in ongoing continuing education activities to update and enhance their knowledge and skills related to home infusion. Pharmacists should also participate in an ongoing competence assessment program as part of an overall staff development program. A valid assessment of competence should consider the pharmacist's responsibilities and the types and ages of patients served. The assessment should be conducted and documented on an ongoing basis for all pharmacists. When appropriate, pharmacists should assist in training and in continuing education programs for other home infusion providers.

**Performance evaluation, contribution management, and competency assessment.** Policies and procedures should define the ongoing performance evaluations, contribution management, and competency assessments of home infusion pharmacy personnel. All home infusion pharmacy personnel should receive regular and timely evaluations. Performance

should be evaluated on the basis of position description requirements and expected competencies. ASHP guidelines[6] and USP Chapter 797[7] describe requirements for initial and ongoing assessment of compounding knowledge and skills. Competency assessments should include practical skills (e.g., aseptic technique challenge), clinical competencies (e.g. assessing patients, developing a plan to manage pharmacist care, and executing the plan), equipment competencies, and patient teaching competencies, if appropriate (i.e., if the employee will be instructing patients).

**Financial Management**

**Budget management.** The home infusion pharmacy should have a budget that is consistent with the health system's financial management process and supports the scope of and demand for pharmacy services. Oversight of workload and financial performance should be managed in accordance with the health system's requirements. Management should provide for the determination and analysis of pharmacy service costs, the determination and analysis of capital equipment costs, and the determination and analysis of new project growth.

The pharmacy budget processes should enable the analysis of pharmacy services by unit of service and other parameters appropriate to the organization (e.g., organizationwide costs by medication therapy, clinical service, specific disease management categories, and patient third-party enrollment). The director should have an integral part in the organization's financial management process.

**Health-system integration.** Other functional units within the health system should factor the cost of pharmacy services being provided by the home infusion pharmacy into their departmental budget when appropriate.

**Third-party contract review.** In conjunction with the organization's legal department, the pharmacy director's team should review third-party payer contracts to ensure that reimbursement is appropriate for services being rendered and that terms of the contracts are in the best interests of the patient and the health system. The pharmacy should contract with third-party payers that are relevant to the pharmacy's patient population.

**Drug and supply expenditures.** Specific policies and procedures for managing drug expenditures should address such methods as competitive bidding, group purchasing, utilization review programs, inventory management, and cost-effective patient services.

**Manufacturers and suppliers.** Criteria for selecting drug product manufacturers and suppliers should be established by the pharmacy to ensure the quality of drug products and the best prices, and that vendors are able to supply products in the volume required.

**Reimbursement.** The director of the pharmacy or home infusion organization should be knowledgeable about reimbursements for home infusion pharmaceutical services, medications, supplies, durable medical equipment, and, if applicable, nursing services. Processes should exist for routine verification of patient reimbursement benefits and for counseling patients about

their anticipated financial responsibility for planned therapies. A process should also exist for responding to service requests from medically indigent patients.

The director or home infusion organization should also be responsible for policies regarding drug procurement, drug expenditures, inventory turns, determination and analysis of pharmacy service costs, capital equipment acquisition, budgeting (including analysis of budgetary variances, patient revenue projections, and justification of personnel commensurate with workload productivity), and payer audits.

**Medication Use and Drug Information Services**

**Medication-use policy development.** Medication-use policy decisions should be founded on the evidence-based clinical, ethical, legal, social, philosophical, quality-of life, safety, and economic factors that result in optimal patient care. Committees within the organization (e.g., pharmacy and therapeutics, infection control) that make decisions concerning medication use should include the active and direct involvement of physicians, pharmacists, and other appropriate health care professionals. The pharmacy should actively participate on committees whose decisions could affect the quality, safety, effectiveness, or cost of pharmacy services or the medication-use process.

**Medication therapy decisions.** The pharmacist's prerogatives to initiate, monitor, and modify medication therapy for individual patients, consistent with laws, regulations, home infusion organization policy, and clinical protocols, should be clearly delineated and approved by the home infusion organization's authorized leadership.

**Formulary.** An independent home infusion provider does not have to abide by a formulary; drugs are dispensed according to the orders of the physicians in their service area. A hospital- or health-system-based infusion pharmacy may have to abide by the same formulary restrictions as the rest of the hospital or health system. The home infusion pharmacist should have a mechanism for providing input to the formulary committee. The pharmacy should have access to specialty medications distributed through closed network systems when needed to support consistent delivery of patient care and medication reconciliation.

**Selection of medications.** Policies and procedures addressing the selection of medications should be available. These policies should be based on clinical appropriateness and USP standards. For bulk powders, USP or chemical standards for purity should be applied. Selection criteria should also include safety (including clinical and labeling safety such as “tall man” lettering), efficacy, and ability to detect counterfeit medications.

**Drug information.** The home infusion pharmacist should provide accurate, comprehensive, and patient-specific drug information to patients, caregivers, other pharmacists, physicians, nurses, and other health care providers as appropriate, both proactively and in response to requests associated with the delivery of pharmacy patient care, educational programs, and publications. Pharmacists should provide concise, applicable, and timely responses to requests for drug information from health care providers and home infusion patients. Responses to general and patient-specific drug information requests should be accurate and prompt. Drug information

requests and responses should be documented and monitored for accuracy and timeliness as part of performance improvement activities. Physicians and nurses should receive adequate information about a medication's therapeutic use, dosage, potential adverse effects, and safe administration in the home, including storage and stability requirements, before the medication is administered.

Information about the stability of drugs for home infusion should address administration via a variety of alternative delivery devices, such as portable infusion pumps, syringe pumps, implantable infusion devices, and common peripheral and central-line administration.

Policies and procedures should be in place for reviewing responses to requests for drug information for the purpose of performance improvement and education.

Adequate space, resources, and information handling and communication technology shall be available to facilitate the provision of drug and related information to patients, caregivers, health care providers, multidisciplinary team members, and referring physicians. The director shall identify a core library (hard copy or electronic) appropriate for a home infusion pharmacy practice setting and ensure that those resources are readily available to users. Drug information sources should include current professional and scientific periodicals, Web-based research tools (e.g., AHFS-DI, MicroMedex, Lexi-Comp Online), the latest editions of drug compendia and textbooks in appropriate pharmaceutical and biomedical subject areas, and any references required by state boards of pharmacy. Availability of drug information on electronic media is desirable. Information may be accessed and provided in conjunction with medical libraries and other resources.

Available information sources should support research on patient care issues, facilitate provision of patient care, and promote safety in the medication-use process. When possible, a pharmacist should have a role within the health system for addressing complex drug information questions presented by professional staff (e.g., pharmacists, nurses, physicians).

If applicable, pharmacists should have access to information on all investigational studies and similar research projects involving medications and medication-related devices used by the organization. Pharmacists should, following the organization's procedures, provide pertinent written information (to the extent known) about the safe and proper use of investigational drugs, including possible adverse effects, to family members, nurses, pharmacists, physicians, and other health care providers involved in the care of patients admitted to the investigational drug protocols. Pharmacist representation on the health system's institutional review board is preferred.

**Education and mentoring of staff, students, and providers.** The home infusion pharmacy staff should provide in-service education to physicians, nurses, pharmacy technicians, and other practitioners on home infusion pharmacy-related issues. They should also provide, to the extent possible in their organizations, student clerkship, externship, and internship training, as well as postgraduate residency training. Home infusion pharmacy staff also has a responsibility to keep the home infusion organization's staff informed about the use of medications on an ongoing basis through appropriate consultations, publications, and presentations. Pharmacists should ensure the timely dissemination of drug product recall notices, safety alerts, market withdrawals, and labeling changes.

**Administration devices, delivery systems, and automated dispensing devices**. Home infusion pharmacists should provide leadership and advice in organizational and clinical decisions about the selection of drug delivery systems, administration devices, and automated compounding and dispensing devices, and should participate in the evaluation, use, and monitoring of these systems and devices. The potential for medication errors associated with such systems and devices should be thoroughly evaluated. Policies and procedures should be available for the certification (calibration) and maintenance of equipment and devices. Equipment should be adequately maintained and certified in compliance with applicable standards, laws, and regulations. Equipment maintenance and certification should be documented.

**Preventive and postexposure immunization programs.** The pharmacy should participate in the development of policies and procedures concerning preventive and postexposure programs for infectious diseases (including, but not limited to, human immunodeficiency virus infection, tuberculosis, and hepatitis) for patients and employees.

**Substance abuse programs.** The pharmacy should assist in the development of, and participate in, substance abuse prevention, education, and employee and patient assistance programs.

**Development of patient care services**. The home infusion pharmacy services team should be involved in the development, implementation, and evaluation of new or changing patient care services within the organization, such as the development of new clinic sites or new service

areas or lines. In reviewing the potential for new services, both the value added to patient care by the new service and the financial and logistical implications of the new service should be considered. These efforts should promote the continuity of pharmacist patient care across the continuum of care, practice settings, and geographically dispersed facilities.

**Committee involvement.** The director and other pharmacy staff should contribute to the organization's goals through effectively participating in or leading committees and informal work groups. The pharmacist should be involved in the home infusion organization's initiatives to develop model clinical protocols and assessments that develop pharmacist care plans, pathways, or disease management guidelines to ensure that pharmacist care elements are included. Clinical protocols should be used whenever appropriate to maximize the safety of medication use in the home.

A pharmacist should be a member of and actively participate on committees responsible for establishing policies and procedures for medication use, patient care, and performance improvement, among other things. Pharmacists should also participate in the activities of similar committees of a parent home infusion organization or health system, as applicable.

The director or a designee should be a member of the home infusion organization's or health system's institutional review board, if applicable.

**Drug Procurement and Management**

The home infusion pharmacy should be responsible for the proper acquisition, compounding, dispensing, storage, delivery, and administration of all drug products used in the treatment of

the organization's patients, as well as the proper use of related equipment and supplies. Policies and procedures governing medication procurement and management should be developed by the pharmacy in collaboration with other appropriate organization staff and committees.

Double checks are good practice in many steps of the pharmacy dispensing process. All high-risk calculations need to be checked by a second clinician. Pediatric doses, parenteral nutrition, chemotherapy, pain management, and inotropes are examples of high-risk therapies. It is also good practice that the pharmacist that processed a new order should not be the same person who checks the order for accuracy and completeness.

**Selection of medications and management of supplies and inventory.** Policies and procedures governing selection of medications and management of supplies and inventory should be developed by the pharmacy director in collaboration with other appropriate home infusion organization staff members.

**Procurement through wholesalers, manufacturers, or group purchasing organizations.** Each pharmacy should have a primary drug wholesaler for routine stock orders and a local source (e.g., a local hospital) for obtaining medications they do not have in stock. Group purchasing organizations (GPOs) may be used to control purchasing costs for drugs and supplies. Policies and procedures should address procurement and management of medications that must be obtained directly from the manufacturer a limited set of distributors.

**Storage and stock levels.** Each pharmacy should determine the appropriate level of stock required to serve the local patient population, and manage its physical inventory for maximum cost control and operational efficiency.

**Returns, recalls, and backorders.** Procedures should be in place for responding to drug and device product returns, recalls, and backorders; for identifying patients who received or used a recalled product; and for removing the drug or device product from the pharmacy or home when the recall is at the user level. All stocks of medications stored in the home infusion pharmacy or in the organization's facilities should be inspected routinely to ensure the absence of recalled, outdated, unusable, or mislabeled products. Inspections should include storage conditions that would compromise medication integrity, storage arrangements that might contribute to medication errors, and storage locations that might be vulnerable to drug diversion efforts.

**Compounding.** The home infusion pharmacist is responsible for preparing and dispensing medications using appropriate techniques, following the home infusion pharmacy's policies and procedures.

**Compounding sterile preparations.** Compounding of sterile products should comply with applicable practice standards, accreditation standards, and pertinent state and federal laws and regulations. If these services are being provided by another pharmacy, the pharmacist should

have reasonable assurance that these standards are being met by the pharmacy providing the service.

Home infusion pharmacists are responsible for ensuring the quality of sterile preparations intended for use in the home. Guidance is available from various sources for developing an adequately designed and equipped facility, training and validating employees, validating and documenting compounding procedures, practicing aseptic technique, monitoring the work environment, maintaining the facility and equipment, ensuring the quality of prepared products, and developing policies and procedures.[6,7]

**Stability and compatibility issues.** Home infusion pharmacies are often required to assign extended beyond-use dates to sterile products so that a multiple-day supply of medications can be dispensed and delivered. However, pharmacists should take into account circumstances that may affect the medication's potency and stability, including:

- delivery of sterile products to the home, either by the pharmacy's own vehicles or by a common carrier;
- storage of sterile products in the home before use;
- manipulation of sterile products in the home environment to add ingredients (such as vitamins) and to set up tubing and filters for administration; and
- administration of products at temperatures that is warmer than controlled room temperature because of administration in outdoor or non-air-conditioned environments or the use of ambulatory infusion pumps worn close to the body.

The home infusion pharmacist should consult USP 797[7] and other appropriate resources to establish an appropriate beyond-use date. Applying published stability data can introduce inaccuracies if the intended conditions of use differ greatly from the reported conditions. Pharmacists should maintain a record of the resources used for establishing beyond-use dates. A table or chart of accepted beyond-use dates, formulations, and conditions of use for commonly prepared products may be helpful in ensuring that assigned dates are consistent and appropriate. Patients should be trained to check products for current beyond-use dates prior to their use.

**Labeling.** Medications for home use should be labeled so that patients and caregivers can easily understand instructions for drug storage, preparation, and administration. Auxiliary labels should be used as necessary. When manipulation of medications is required before administration, labeling should clearly state current contents and the steps for measuring, reconstituting, or adding other ingredients. Labels for compounded medications should state the total content of the medication or nutrient per container so that it can be clearly known in case the patient is transferred to another treatment setting. If medications are to be administered with an infusion device, pump settings should be included on the label. All labels shall conform to the requirements of the law.

**Packaging and delivery.** Policies and procedures should be available to ensure product integrity and temperature control during home delivery or patient pickup of supplies and drugs. The pharmacist should ensure that the delivery of medications and supplies to the patient occurs in

a timely manner to avoid interruptions in drug therapy. Furthermore, the pharmacist should ensure that storage conditions during delivery and while in the patient's home are consistent with the recommendations for storing the product and beyond-use dating. The temperature of home refrigerators or freezers in which medications are stored should be within acceptable limits and should be monitored by the patient or caregiver. The pharmacist should ensure that an adequate inventory of medications and ancillary supplies is available in the patient's home. It may be appropriate to provide additional inventory for unforeseen circumstances in which extra doses or supplies may be required (e.g., waste, breakage, and emergencies). The pharmacist is responsible for providing sufficient quantities of medications and supplies to the patient, so that the ordered dosing regimen is maintained in the home setting without missed doses due to lack of drugs or supplies. Delivery to the patient should also include inventory management to avoid excessive accumulation of supplies and drugs. Excesses may indicate poor compliance, inadequate patient training, failure to assess patient needs, or ineffective inventory management by the patient. When common carriers are used, the pharmacy is responsible for ensuring that the carrier can provide timely delivery, proper handling, and external temperature control. Delivery personnel should know the shipping requirements for each package. If refrigerated products are packaged so that product labels containing storage instructions are concealed, an exterior "Refrigerate" label should be used. To protect patient confidentiality, prescription labels with medication names and directions should not be used to label boxes. Box labels should include only the patient's name and address, the storage requirements, and delivery instructions. Additional precautions (i.e. double bagging, using at least one leak proof container, and cushioning) should be used to safeguard hazardous

products from breaking and leaking. The delivery person, patient, and caregiver shall be trained to recognize and manage accidental spills. Packages containing hazardous products should have appropriate precautionary labels.

Products should be delivered in appropriate packaging to ensure that labeled storage requirements are met during transit under the expected environmental conditions. The pharmacy should develop and follow written procedures for packaging; these procedures should include privacy-protection considerations. Product confirmation after delivery should be used to ensure that the packaging procedures and materials used were effective in maintaining product integrity and temperature control during transit. The stability of refrigerated products at room temperature should be taken into account when in the development of packaging procedures. A few refrigerated products have extended stability at room temperature and may be safely delivered without refrigerated packaging. Products that are stable for 24 hours or less at room temperature should always be delivered in temperature-controlled packaging (coolers, ice packs, etc.).

**Hazardous drugs.** Policies and procedures for the definition of, storing, handling, and disposing of hazardous drug products should be available to ensure patient and employee safety in compliance with applicable local, state, and federal laws and regulations. Receipt, storage, and disposal of hazardous substances shall comply with all applicable federal, state, and local laws and regulations, including the Resource Conservation and Recovery Act, as well as applicable guidance (e.g., ASHP guidelines,[8] USP 797[7]). Hazardous drug products should be stored in a negative pressure compounding room whenever possible. Additional storage precautions may

include placement on a lower shelf or containment in a resealable plastic bag. Employees should be specially trained, and their handling and disposal of these products should be monitored. Spill kits should be available in locations where hazardous drugs are handled, and all personnel that handle these agents should be trained on using the kits.[3,8]

**Controlled substances.** Policies and procedures for the storage, distribution, use, and accountability of controlled substances should be available to ensure appropriate use and to prevent diversion in compliance with applicable local, state, and federal laws and regulations. Controlled substances shall be kept in a secure and locked storage area that meets the requirements of state law. Pharmacists should be aware of the ways drugs can be diverted. Employees should be carefully screened before hire. Processes need to be in place to detect diversion. Policies or procedures that prevent only one person having access should include activities such as ordering, receiving product, and conducting inventories.

**Drug samples.** The use of drug samples should be eliminated to the fullest extent possible. If samples are permitted, the pharmacy should control these products to ensure proper storage, records, labeling, and product integrity.

**Patient Care**

*Pharmaceutical care*, defined as the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life, has been adopted by much of the pharmacy profession. The concept of pharmaceutical care is evolving into a more

608 comprehensive, patient-focused model of pharmacist-provided care, sometimes termed
609 *pharmacist patient care*. The principal elements of such care are the same: it is *medication*
610 *related*; it is *care* that is *directly provided* to the patient; it is provided to produce *definite*
611 *outcomes*; these outcomes are intended to improve the patient's *quality of life*; and the
612 provider accepts personal *responsibility* for the outcomes.[9]

613 The mission of the pharmacist is to help people make the best use of medications. At a
614 minimum, pharmacists are responsible for assessing the legal and clinical appropriateness of
615 medication orders (or prescriptions), educating and counseling patients on the use of their
616 medications, monitoring the effects of medication therapy, and maintaining patient profiles
617 and other records. In the home infusion care setting, these responsibilities are best
618 accomplished through the provision of pharmacist-provided patient care in which pharmacists
619 are responsible for establishing relationships with patients and providers that will facilitate
620 coordination and continuity of care, improve access to care, and improve patient outcomes.
621
622 **Preadmission assessment by pharmacist.** The pharmacist should ensure that each patient
623 referred for home infusion is assessed for appropriateness on the basis of admission criteria,
624 including the following:

625 • the patient, family, and caregiver agree with provision of infusion services in the home;
626 • the patient or caregiver is willing to be educated about the correct administration of
627 medications;
628 • the pharmacy can provide this education in a manner that the patient, family and
629 caregiver can understand;

- the home environment is conducive to the provision of home infusion services (e.g., electricity and running water are present, and the home is clean);
- the home infusion provider has reasonable geographic access to the patient;
- there is psychosocial and family support (e.g., caregiver requirements and financial concerns are manageable, and the family environment is suitable);
- there is ongoing prescriber involvement in the assessment and treatment of the patient;
- the medical condition and prescribed medication therapy are suitable for home infusion services, and there is a prognosis with clearly defined outcome goals;
- the indication, dosage, and route and method of administration of medications are appropriate; and
- appropriate laboratory tests are ordered for monitoring the patient's response to medications.

Using the information collected during the preadmission assessment, the pharmacist, in conjunction with the other health care providers involved in the patient's care and the patient or caregiver, will determine the patient's appropriateness for home infusion services. The conclusions of the assessment should be communicated to all parties and appropriately documented.

**Initial patient database and assessment.** The complete patient database should be documented in the patient's home infusion record. This database should include, at a minimum, the following:

- the patient's name, address, telephone number, and date of birth;

- the person to contact in the event of an emergency, including the legal guardian or representative, if applicable;
- information on the existence, content, and intent of an advance directive, if applicable;
- the patient's height, weight, and sex;
- all diagnoses;
- the location and type of intravenous access and when it was placed, if applicable;
- pertinent laboratory test results;
- pertinent medical history and physical findings;
- nutrition screening test results;
- an accurate history of allergies;
- initial and ongoing pharmaceutical assessments;
- a detailed medication profile, including all medications (prescription and nonprescription), immunizations, home remedies, and investigational and nontraditional therapies;
- the prescriber's name, address, and telephone number and any other pertinent information (e.g., Drug Enforcement Administration number);
- other agencies and individuals involved in the patient's care and directions for contacting them;
- a history of medication use; and
- a care plan and a list of drug-related problems, if any.

To obtain this information, the pharmacist could use the medical record; laboratory test results; direct communication with the patient, caregiver, nurse, and prescriber; and direct observation.

When the pharmacist cannot directly observe the patient, the patient's home infusion nurse or other appropriate health care provider could provide the results of direct observation and physical assessment. If a shared-service agreement exists among multiple providers, the pharmacist should ensure that this agreement specifies the responsibilities of each provider for obtaining and sharing pertinent patient information.

**Medication reconciliation.** Pharmacists should prepare or have access to comprehensive medication histories for each patient, including prescription drugs, nonprescription drugs, and alternative therapies. A pharmacist-conducted medication history for each patient is desirable; however, another appropriate health care provider (e.g., home infusion nurse, pharmacy technician) may obtain and maintain current medication histories, provided this information is accessible to the pharmacist and other health care providers.

**Development of care plans.** The pharmacist, in collaboration with the patient or caregiver and other health care providers, is responsible for developing an appropriate and individualized care plan for each patient. The pharmacist's contribution to the care plan should be based on information obtained from the initial pharmacy assessment and other relevant information obtained from the nurse, prescriber, patient, and caregivers. At a minimum, the pharmacist's contribution to the care plan should include the following:

- a description of actual or potential drug therapy problems and their proposed solutions,
- a description of desired outcomes of drug therapy provided,
- a proposal for patient education and counseling, and

- a plan specifying proactive objective and subjective monitoring (e.g., vital signs, laboratory tests, physical findings, patient response, toxicity, adverse reactions, and noncompliance) and the frequency with which monitoring is to occur.

The care plan should be developed at the start of therapy and regularly reviewed and updated; the degree of detail of the plan should be based on the complexity of drug therapy and the patient's condition. Updates or changes to the plan, as they occur, should be communicated to other health care providers involved in the patient's care, to the patient, and to caregivers. The care plan and updates should be a part of the patient's record.

**Clinical monitoring.** The pharmacist is responsible for ongoing clinical monitoring of the patient's drug therapy according to the care plan and for appropriately documenting and communicating the results of all pertinent monitoring activities to other health care providers involved in the patient's care. The pharmacist is also responsible for ensuring that relevant information is obtained from the patient, the caregiver, and other health care providers and for documenting this information in the patient's home infusion record.

Pharmacists may, in collaboration with prescribers and others, wish to develop clinical monitoring protocols for various therapies that could be individualized in specific care plans. Pharmacists may receive laboratory test results before other health care providers. In such cases, the pharmacist is responsible for communicating the test results to the prescriber and other health care providers. The pharmacist should provide an interpretive analysis of the information and recommendations for dosage adjustments and for continuation or discontinuation of drug therapy. The pharmacist should ensure that sufficient laboratory test

results are readily available for monitoring the patient's therapy. In shared-service arrangements, clinical monitoring responsibilities should be delineated.

The patient, the family, the caregiver, and all health care providers involved in the patient's care should have access to a pharmacist 24 hours a day. The pharmacist is responsible for providing a summary of all relevant clinical information to another pharmacist providing coverage for that patient (e.g., an on-call pharmacist) before transferring patient care responsibilities.

**Patient consultation and education.** Home infusion pharmacists will primarily consult patients or caregivers over the telephone. Home visits should be considered for enhancing compliance or simplifying complex drug-related patient issues.

The home infusion pharmacist, or the home infusion nurse as the agent, should ensure that the patient, the caregiver, and other health care providers understand the proper use and administration of medications provided, including the intravenous access device and infusion device, as required. The home infusion pharmacist, or the nurse as the agent, should explain to the patient or the patient's agent the directions for use and any additional information.

The pharmacist is responsible for ensuring that the patient or caregiver receives appropriate education and counseling about the patient's medication therapy. The pharmacist should verify that the patient or caregiver understands the therapy. Other health care providers may be involved in the education and counseling. A home infusion pharmacist should be readily accessible if questions or problems arise. Supplementary written information should be provided to reinforce oral communications. Contingencies should be available to provide

education, counseling, and written materials to patients who do not speak English. Depending on the need, this might require access to interpreters or bilingual pharmacists. Patients who have hearing and sight impairments will potentially need other resources.

Professional judgment is required to determine what information should be included in patient education and counseling. The following should be considered:

- a description of medication therapy, including drug, dose, route of administration, dosage interval, and duration of therapy;
- the goals of medication therapy and indicators of progress toward those goals;
- self-assessment techniques for monitoring the effectiveness of therapy;
- the importance of following the therapeutic plan;
- proper aseptic technique;
- hand hygiene;
- proper care of the vascular-access device and site, if applicable;
- precautions and directions for administering medications;
- inspection of medications, containers, and supplies prior to use;
- equipment use, maintenance, and troubleshooting;
- home inventory management and procedures for securing additional supplies and medications when needed;
- potential adverse effects, drug–drug interactions, drug–nutrient interactions, contraindications, and adverse reactions, and the management of those events;
- special precautions and directions for the preparation, storage, handling, and disposal of drugs, supplies, and biomedical waste;

- information on contacting health care providers involved in the patient's care;
- examples of situations that should be brought to the attention of the pharmacist or other health care providers involved in the patient's care (e.g., missed doses, doses not given at the proper time, and low supplies); and
- emergency procedures.

Patient counseling and education should be performed in accordance with applicable state regulations and documented in the patient's home infusion record.

**Communication with patients and caregivers.** Effective communication among pharmacists, patients, and caregivers is also essential to ensuring high-quality care. The pharmacist providing home infusion services should establish free and open channels of communication with patients and caregivers. The pharmacist should contact the patient or the caregiver, as appropriate, to

- obtain information needed for the initial pharmacy assessment;
- provide supplemental patient education and counseling as needed;
- assess compliance with drug therapy;
- assess progress toward the goal of therapy;
- inform the patient how to contact the pharmacist when needed; and
- assess drug therapy problems (e.g., failure to respond to therapy and adverse drug events).

All contacts with the patient should be documented in the patient's home infusion record.

**Communication with physicians, prescribers, nurses, and other health care providers.** Effective communication among pharmacists and other health care providers is essential to ensuring continuous, coordinated care. The pharmacist should ensure that effective channels of communication about care are in place, including shared-service arrangements (e.g., regarding pain assessments and laboratory test data). Oral and written communication methods can be used for communicating patient information. All relevant clinical communication should be documented in the patient's home infusion record. The pharmacist is responsible for protecting the patient's privacy and confidentiality while communicating this information to other health care providers. It is recommended that personnel involved in the care of the patient meet regularly to discuss the clinical status of the patient and any operational issues related to the patient's care.

**Medication administration.** Policies and procedures on the administration of medications should be available. Only personnel who are authorized by the home infusion organization and are appropriately trained and licensed should be permitted to administer medications to a patient. Pharmacists, where legally permitted, may be authorized to administer medications after receiving appropriate training.

**Emergency medical care.** The home infusion pharmacist should participate in decisions about the emergency care of patients at home, including the development of protocols for using emergency drugs in the home. Policies and procedures should exist within the organization for providing appropriate levels of patient care during emergency situations 24 hours a day,

including access to the pharmacist responsible for their care, when appropriate. Appropriately trained pharmacists should have an authorized role in responding to medical emergencies. The pharmacy should participate in the development of policies and procedures to ensure availability of, access to, and security of emergency medications.

**Discharge from home infusion.** When patients have completed therapy as ordered, they should be discharged from service. Items that should be documented in the medical record upon discharge include the patient's response to therapy and status at discharge.

**Transfer to another care setting.** The pharmacists should ensure continuity of pharmacist care to and from the home and other patient-care settings. The pharmacist should routinely contribute to processes ensuring that each patient receives pharmacist care regardless of transitions that occur across different health care settings (for example, among different components of a health system and different types of home infusion services). When home infusion patients are admitted to a hospital, the home infusion pharmacy should inform the hospital about (1) the medications the patient is currently receiving from the home infusion pharmacy and (2) known allergies. The home infusion pharmacy should recognize hospital policy when considering whether properly stored medications and medical equipment from the home can be used during the home infusion patient's hospitalization.

**Documentation in the home infusion medical record.** Clinical actions and recommendations by pharmacists that are intended to ensure safe and effective use of medications and that have a

potential effect on patient outcomes should be documented in patients' home infusion medical records. Pharmacists should provide oral or written consultations to other health professionals regarding medication therapy selection and management. Consultations should be documented in the patient's home infusion medical record. The pharmacy should have an ongoing process for consistent documentation (and reporting to physicians, administrators, and others) of pharmacist care and patient outcomes resulting from medication therapy and other pharmacy actions. Patient privacy and confidentiality should be protected at all times.

A home infusion record should be developed and used for documenting the home infusion services provided to each patient. Written organizational policies and procedures should address the security of home infusion records and specify personnel authorized to review patient records and to make entries. The need to maintain confidentiality of patient information should be stressed to all personnel. The pharmacist is responsible for documenting all pharmacy clinical activities in the patient's record in a timely manner. General clinician-oriented forms are preferred over specific nursing, pharmacy, and other health care professional forms to minimize duplication of information. It may be advisable for organizations that provide multiple home infusion services (e.g., pharmacy, nursing, and respiratory therapy) to use a single home infusion record for documenting all clinical information regarding each patient. The patient's record should be accessible at all times to authorized personnel involved in the care of the patient, but confidentiality should be maintained.

**Selection of products, devices, and ancillary supplies.** The pharmacist, in collaboration with other health care providers and the patient, is responsible for selecting infusion devices,

ancillary drugs (e.g., heparin lock flush solution, 0.9% sodium chloride flush), and ancillary supplies (e.g., dressing kits, syringes, and administration sets). Pharmacists should be thoroughly trained and knowledgeable in the selection, proper use, and maintenance of these devices, drugs, and supplies. Factors involved in the selection of devices and ancillary supplies may include the following:

- the stability and compatibility of prescribed medications in infusion device reservoirs,
- the ability of an infusion device to accommodate the appropriate volume of medication and diluent, and to deliver the prescribed dose at the appropriate rate,
- the ability of the patient or caregiver to learn to operate an infusion device,
- the potential for patient complications and noncompliance,
- patient convenience,
- nursing or caregiver experience with therapies and selected devices,
- prescriber preferences,
- cost considerations, and
- the safety features of infusion devices.

**Patient's own medications.** Drug products and related devices not dispensed by the home infusion pharmacy that are to be used during the patient's course of therapy should be documented in the patient's home infusion medical record. When home infusion patients are known to be admitted to a hospital or other extended care facility, the home infusion pharmacy should inform the hospital about the medications the patient is currently receiving from the home infusion pharmacy and about any known allergies. The home infusion pharmacy should

recognize hospital policy when considering whether properly stored medications and medical equipment from the home can be used during the home infusion patient's hospitalization.

**Emergency medications.** The home infusion pharmacist, in consultation with the prescriber, should determine when emergency medications and supplies (e.g., anaphylaxis "kits") should be dispensed to home infusion patients. When standing orders for ancillary drugs or supplies or standardized treatment protocols are used, the pharmacist should review each protocol to determine its appropriateness for the patient.

**Performance Improvement Activities**

The home infusion pharmacy should have an ongoing, systematic program for assessing pharmacist patient care, and pharmacists should be active participants in performance improvement activities. A performance improvement program for home infusion should monitor patient satisfaction and outcomes, and the program should also include appropriate quality control measures for compounding sterile products and other activities. Performance improvement activities based on assessments should be integrated with the health system's overall performance improvement activities, as applicable. The performance improvement team should work with frontline staff to implement systems that include proper checks and balances focused on protecting against human error. Performance improvement initiatives should be focused on error reporting trends and high-risk functions such as dispensing high-alert medications.

**Benchmarking.** As part of the performance improvement program, operational and outcomes data should be benchmarked with those of other home infusion pharmacy services of similar size and scope. The results, including follow-up actions for improvement, should be documented and provided to the organization's managers, the frontline staff using the system, and others as appropriate.

**Clinical outcomes.** Most accrediting bodies and some regulatory agencies require the home infusion pharmacy to monitor clinical patient outcomes. Common measures that are tracked routinely by home infusion companies include the rate of i.v. catheter infections, adverse drug reactions, medication errors, warehouse/delivery errors, equipment malfunctions, and unplanned hospitalizations. In addition, the company should have an infection control program in which both staff and patient infection (communicable diseases) rates are monitored. The company may also select outcomes that are monitored over a short time as a specific process is improved.

**Medication error reporting.** Medication error monitoring and prevention should be part of every pharmacy's performance improvement program. Information about strategies to prevent medication errors is available from several sources, including the Institute for Safe Medication Practices (ISMP), which produces regular newsletters on this topic.

All pharmacies should have processes in place that are designed to prevent and detect medication errors before they leave the pharmacy. If an error does occur, the pharmacy director and staff should determine how and why the error happened, and what can be done to

prevent similar errors from occurring. Medication errors should be reported to voluntary national reporting systems and, as required, to accrediting organizations or regulatory agencies.

**Patient satisfaction.** Most accrediting bodies require the home infusion pharmacy to measure patient satisfaction with treatment and services. This function can be performed in-house by mailing questionnaires to the patient, or it can be outsourced to a contractor. Patient satisfaction surveys that are returned should be reviewed for both positive and negative comments so that corrective action can be targeted to service issues.

**Medication-use evaluation.** An ongoing program of monitoring drug utilization and costs should be in place to ensure that medications are used appropriately, safely, and effectively, and to increase the probability of desired outcomes within defined populations of patients. The medication-use policy committee should define specific parameters for evaluation (e.g., disease state, pharmacologic category, high-use/high-cost drug products, high-alert medications) as appropriate for the organization. Through this ongoing evaluation, areas in need of improvement in medication prescribing and management can be identified and targeted for intervention.

**Adverse drug event reporting.** The home infusion pharmacist should take a leadership role in the development of a program for reporting and monitoring all adverse drug events and device-related events, including adverse drug reactions and medication errors. The pharmacist should ensure that the prescriber is notified promptly of any suspected adverse drug events. Adverse

drug events should serve as outcome indicators of quality, and the monitoring of adverse drug events should be a part of the organization's ongoing performance improvement program. Relevant trends should be integrated into staff development and in-service education programs for pharmacists and nurses to improve the quality of care and patient outcomes. Serious adverse drug reactions and device-related problems should be reported promptly to the manufacturer and to the Food and Drug Administration's MedWatch program.

**Operations**

**Hours of operation.** Home infusion pharmacy services shall be available 24 hours a day, seven days a week. A pharmacist should be available for consultation or dispensing after hours. Home infusion pharmacy staff may be supplemented by knowledgeable and experienced part-time or on-call personnel to extend pharmacy services coverage.

**Pharmacy security and after-hours access.** Only authorized pharmacy personnel should have access to the pharmacy area. Other home infusion organization personnel may be in the pharmacy area only when an authorized pharmacist is present, in accordance with the home infusion organization's policies or as required by laws and regulations. In an emergency situation in which a pharmacist is not present, such as a fire or security alarm, policies and procedures should guide safe access to the pharmacy area and provide for notification of the pharmacist in charge or a designee.

**Emergency preparedness and business continuity planning.** Policies and procedures should be available that include a plan for providing pharmacy services in case of an area-wide disaster affecting the home infusion pharmacy or patients' home infusion settings. Appropriately trained pharmacists and representatives from the pharmacy team should be members of emergency preparedness teams and participate in drills. Patients should be informed about what to do to safely continue needed home therapies in the event of a disaster. The health system's business continuity plan should address the provision of pharmacy services in non-emergency situations, such as information system failures or disruptions of the drug procurement process.[10]

**Communications.** Staff meetings should be conducted on a regular basis for various purposes, which may include:

- brief daily meeting to review on-call issues, upcoming referrals, and current daily plan;
- hand-off communications to and from evening staff or on-call personnel;
- in-services regarding updates to policies or procedures, law, regulation, or services;
- review of new medications;
- analysis of sales and marketing efforts;
- performance improvement functions;
- team building among the staff; or
- interdisciplinary meetings or case conferences to communicate the pharmacist's care plan for a patient (with patients, caregivers, physicians, prescribers, or other health professionals).

**Equipment management.** Equipment may be owned, leased, or rented by the infusion pharmacy. It is usually most cost-effective to lease-purchase infusion pumps that are used in high volume. Pumps with specialized uses (e.g., micro-infusers) may be used less frequently and may be rented as needed. Equipment may be purchased or rented from a properly qualified vendor. Routine maintenance (i.e., basic safety checks, alarm testing, and accuracy validation) is performed between patient use, and preventive maintenance for medical equipment is defined by the manufacturer for each specific device. The manufacturer's preventive maintenance recommendations should be followed, and all equipment should be maintained so that the preventive maintenance is not overdue during patient use. Technical repair of medical equipment should be done by a properly qualified service technician. Home infusion pharmacies typically do not have the capacity to employ staff on site with the technical certification required for equipment preventive maintenance or repair. Outsourcing these functions is usually the most efficient and cost-effective way to maintain equipment in good working order.

**Records storage and maintenance.** Adequate space should be available for maintaining and storing records, including medication profiles and other patient information, management information, equipment maintenance sheets, controlled-substances inventory sheets, and material safety data sheets, among others, to ensure compliance with laws, regulations, accreditation requirements, and sound management practices. Patient records shall be secure. Records shall be retained according to applicable laws and regulations, which may vary by state

and by Centers for Medicare & Medicaid Services (CMS) participation guidelines. There may be additional record retention requirements for pediatric and gestational medical records in some states and according to accreditation standards.

**Information technology.** Computer resources should be used to maintain patient medication profiles, perform necessary patient billing procedures, manage drug product inventories, and interface with other available computerized systems to obtain patient-specific clinical information for drug therapy monitoring and other clinical functions and to facilitate the continuity of care after patients transfer to and from other care settings.

**Home infusion medical record systems.** A patient medication profile should be maintained by all home infusion pharmacies regardless of where the dispensing of medications takes place. The home infusion medical record should include assessment and care planning documents, progress notes, laboratory test results, and other patient information related to determining the appropriateness of medications and monitoring their effects. The system should provide safeguards against the improper manipulation or alteration of records and provide an audit trail.

An automated information system is preferred, but the system may be either manual, automated, or a combination of the two. If an automated information system is used, an auxiliary record-keeping procedure should be available for documenting medication information in case the automated system is inoperative, and a daily data backup system should be in place.

**Hazardous waste management.** Receipt, storage, and disposal of hazardous substances shall comply with all applicable federal, state, and local laws and regulations, including the Resource Conservation and Recovery Act, as well as applicable guidance (e.g., ASHP guidelines,[8] USP 797[7]). There are many ways to dispose of hazardous waste generated by the pharmacy. In addition to the established waste management companies, there are also mail-back services. For the traditional services, it is important to follow the company's requirements. Since much of the waste eventually is sent to dump sites, waste that needs to be incinerated should be discarded separately. The companies that provide mail-back service also incinerate all the waste they receive, so it is not necessary to separate the waste. It is also important that the pharmacist understand the OSHA and RCRA requirements regarding management and disposal of hazardous substances. There should be a designated area for hazardous waste, including sharps. Spill kits should be readily available in location where hazardous substances are handled, and all personnel that handle these agents should be trained on using these kits.[3,8]

**Facilities**

To ensure optimal operational performance and quality patient care, adequate space, equipment, and supplies should be available for all professional and administrative functions related to medication use. These resources should be located in areas that facilitate the provision of services to patients, nurses, prescribers, and other health care providers and should be integrated with the home infusion organization's communications, delivery, or

transportation systems. Facilities should be constructed, arranged, and equipped to promote safe and efficient work and to avoid damage to or deterioration of drug products.

**Ambulatory infusion center or infusion suite.** Pharmacies that have an on-site (ambulatory) infusion suite must include appropriate access to the facility (e.g., handicapped parking, sidewalk ramp, etc.) and other internal design features (e.g., restroom grab bar) according to the Americans with Disabilities Act. Local building code regulations may also apply. Accreditation standards for home care organizations typically include a section on infusion suites and cover such items as patient access, facility safety checks, nursing procedures, and room sanitation. State and local authorities may have additional regulations for ambulatory treatment centers; these should be researched before planning to offer ambulatory treatment services.

**Home infusion pharmacies.** Designated space and equipment for compounding and packaging sterile and nonsterile drug products should be available.[6,11] The compounding environment should be monitored and maintained on an ongoing basis. Appropriate facility space, equipment, and supplies for compounding hazardous drug products should be available.[6-8] Adequate facilities and equipment should be established for decontaminating, cleaning, and maintaining infusion devices, including durable medical equipment.

**General work area.** The pharmacy work area should allow pharmacists to observe work being done by support staff (telephone calls to patients, computer data entry, compounding, etc.).

Pharmacies should consider having an area dedicated to the function of checking compounded preparations and other prescriptions that is out of the main traffic pattern and where the checking pharmacist is not distracted by noise, telephones, or conversation.

**Stockroom and storage areas.** Facilities should be available for storing and preparing medications in the home infusion pharmacy under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security to ensure medication integrity and personnel safety and to prevent drug diversion. Adequate refrigeration and freezer capacity should be provided within the secure pharmacy area.

**Office and meeting space.** Office and meeting areas should be available for administrative, clinical, technical, and reimbursement staff. Ideally, interdisciplinary team members from pharmacy, nursing, and reimbursement are located within a proximate space.

**Cleanroom and anteroom (compounding area).** The home infusion pharmacy should follow all applicable federal, state, and local requirements, including USP Chapter 797,[7] for building and maintaining the pharmacy's compounding facilities. Options for building out a cleanroom include purchase of a modular prefabricated unit or building out an existing space with only those materials needed to bring the facility into compliance with laws, regulation, and guidance. Design and organization of the clean room should allow for pharmacist view of compounding activities through a large window or clear wall and efficient flow of materials and

compounding documents into the clean room for processing and out of the clean room for the checking/verification step.

Sterile medications shall be compounded within a primary engineering control such as a laminar flow hood or a compounding aseptic containment isolator. Compounding facilities shall be cleaned and maintained following federal, state, and local laws or regulations as well as applicable guidance (e.g., ASHP guidelines, USP Chapter 797). Environmental monitoring of the compounding facilities shall be ongoing and should include all elements required by federal, state, and local laws or regulations as well as applicable guidance (e.g., ASHP guidelines, USP Chapter 797).

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