

ASHP Guidelines: Minimum Standard for Home Care Pharmacies

Purpose

Home care pharmacies provide pharmaceutical products and clinical monitoring services to patients of all ages in their homes, including home infusion therapy, oral medications, home hospice pharmaceutical services, and parenteral and enteral nutrition. Pharmacists practicing in home care pharmacies provide a specialized form of pharmaceutical care to the patients they serve. Home care pharmacies, whether they are hospital-based, long-term-care pharmacies, community pharmacies, independent organizations, or multisite organizations, should be viewed as an integral component of the overall health care system.

Home care patients require systemwide continuity of care. Mechanisms should exist for appropriate and confidential sharing of patient information among responsible providers and caregivers across the continuum of care and in various components of health systems. Systemwide communication, through interfacing patient information systems, oral and written communication, and consistent product labeling, is important to optimize care and minimize the risk of health care misadventures.

The purpose of these guidelines is to outline the minimum requirements for the operation and management of pharmaceutical services to be provided by home care pharmacies. However, as noted, the provision of pharmaceutical care in the home care setting should be coordinated among other settings. Therefore, as applicable, these guidelines should be used in conjunction with minimum standards for other practice settings. Many of the topics outlined are the subject of other ASHP practice standards, which should be referred to for additional information and guidance. Because of differences in settings and in organizational arrangements and complexities, aspects of these guidelines may be more applicable to some settings than others. Managers of home care pharmacies should use their professional judgment in assessing and adapting these guidelines to meet their own needs and circumstances.

To ensure the safe, appropriate, and effective use of medications in the home, home care pharmacies should develop comprehensive services to address factors unique to home care. Caregivers such as family members, who often have no health care experience, should be trained to properly administer medications, operate medication administration devices, and monitor patients as necessary. Medications must be aseptically compounded, often in quantities sufficient for several days' use, and delivered under conditions that will ensure that product potency and purity are maintained. Vascular access should be maintained for the intended duration of therapy, 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 plan of care should be established for monitoring, detecting, and managing complications. Economic considerations should be taken into account so that care is provided in the most cost-effective manner. Finally, home care 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 providers of pharmaceutical care in the home setting, pharmacists should be concerned with the outcomes of their services and not just the provision of these services. Effective management is necessary to ensure that quality outcomes of therapy are achieved.

The criteria for home care pharmacy that are covered in these guidelines are distributed among the following categories: (1) leadership and practice management, (2) drug information, education, and counseling, (3) care planning, monitoring, and continuity, (4) drug distribution and control, and (5) facilities, equipment, and information systems. Collectively, these criteria represent a minimum level of quality that all home care pharmacies should strive to provide consistently. While the scope of pharmaceutical 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.

Standard 1: Leadership and Practice Management

Effective leadership and practice management are necessary for the delivery of pharmaceutical services in a manner consistent with the needs of the home care patient, the needs of the home care organization and pharmacy, and the requirements for continuous improvement in patient care outcomes. The pharmacy manager should focus on the pharmacist's responsibility for providing pharmaceutical care and on the development of an infrastructure for supporting pharmaceutical care.

Managerial responsibilities include (1) setting the short-term and long-term goals of the pharmacy according to the needs of the patients served, (2) developing plans and schedules for achieving these goals, (3) directing implementation of the plans and the day-to-day activities associated with them, (4) determining whether the goals and schedules are being met, and (5) instituting corrective actions when necessary. The pharmacy manager, in carrying out these responsibilities, should supervise an adequate number of competent, qualified personnel. A part-time or contract manager has the same basic obligations and responsibilities as a full-time manager.

Managing the Pharmacy

Education and Training of the Home Care Pharmacy Manager. The home care pharmacy should be managed by a professionally competent, legally qualified pharmacist. The manager should be thoroughly knowledgeable about home care pharmacy practice and management. Completion of a pharmacy residency program and home care experience are desirable.

Pharmacy Mission. The pharmacy or its affiliated organization should have a written mission statement that, at a minimum, reflects both patient care and operational responsibilities.

The statement should be consistent with the mission of the home care organization and parent health system, if applicable. The mission should be understood by employees, contract staff, and other participants (e.g., students and residents) in the pharmacy's activities. The development and prioritization of goals, objectives, and work plans should be consistent with the mission statement.

Laws and Regulations. Compliance with local, state, and federal laws and regulations applicable to the home care pharmacy is required. The pharmacy should maintain written or computerized documentation of compliance concerning requirements for procurement and distribution of drug products, patient information, and related safety from the state board of pharmacy, Food and Drug Administration, Drug Enforcement Administration, Health Care Financing Administration, and Occupational Safety and Health Administration, among others. Home care pharmacies dispensing drugs across state boundaries shall comply with out-of-state licensure requirements, as well as other state and federal interstate laws and regulations.

Policy and Procedure Manual. A policy and procedure manual governing the scope of the home care pharmaceutical services (e.g., administrative, operational, and clinical) should be available and properly maintained. 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.

Practice Standards and Guidelines. The practice standards and guidelines of accrediting and professional organizations, such as the American Society of Health-System Pharmacists (ASHP) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), should be assessed and adapted when applicable to the home care organization, the scope of pharmaceutical services, and the patient population served.

Managing Financial Resources

Financial Management. Oversight of workload and financial performance should be managed in accordance with the home care organization's requirements. Management should provide for (1) determination and analysis of pharmacy service costs, (2) analysis of budgetary variances, (3) capital equipment acquisition, (4) patient revenue projections, and (5) justification of personnel commensurate with workload productivity. The pharmacy manager should be an integral participant in the home care organization's financial management process.

Drug 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.

Reimbursement. The manager of the pharmaceutical services or home care organization should be knowledgeable about reimbursements for home care pharmaceutical services, medications, supplies, durable medical equipment, and, if applicable, nursing services support. 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.

Managing Pharmaceutical Care

Committee Involvement. 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. Also, pharmacists should participate in the activities of similar committees of a parent home care organization or health system, as applicable.

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

Selection of Medications. Policies and procedures addressing the selection of medications should be available. These policies should be based on clinical appropriateness.

Home Care Medical Record Systems. 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 care medical records. In addition, a patient medication profile should be maintained by all home care pharmacies regardless of where the dispensing of medications takes place. The home care medical record should include 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 or automated. 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.

Medication Histories. Pharmacists should prepare or have access to comprehensive medication histories for each patient's home care medical record and other databases (e.g., prescription and nonprescription medication profile), or both. A pharmacist-conducted medication history for each patient is desirable; however, a home care nurse may obtain and maintain current medication histories, provided this information is accessible to the pharmacist and other health care providers.

Patient Confidentiality. Patient confidentiality should be protected by safeguarding access to all sources of patient information, including financial (billing), medication profiles, and home care medical records. Patient information should

be shared only with health care providers within the home care pharmacy, home care organization, or health system authorized to care for the patient. Written policies and procedures for access to and dissemination of confidential patient information should be available. All employees should respect patient privacy and maintain confidentiality during home visits and deliveries.

Clinical Protocols. The pharmacist should be involved in the home care organization's initiatives to develop model clinical protocols, care plans, pathways, or disease management guidelines to ensure that pharmaceutical care elements are included. Clinical protocols should be used whenever appropriate to maximize the safety of medication use in the home.

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, HIV 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.

Twenty-Four-Hour Pharmaceutical Services. Home care pharmaceutical services should be available 24 hours a day, seven days a week. A pharmacist should be available for consultation or dispensing after hours. Home care pharmacy staff may be supplemented by knowledgeable and experienced part-time or on-call personnel to extend pharmaceutical services coverage.

Pharmacy Security and Access After Hours. Only authorized pharmacy personnel should have access to the pharmacy area. Other home care organization personnel may be in the pharmacy area only when an authorized pharmacist is present, in accordance with the home care 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.

Disaster Situations. Policies and procedures should be available for providing pharmaceutical services in case of an areawide disaster affecting the home care pharmacy or patients' home care settings. Patients should be informed about what to do to safely continue needed home therapies in the event of a disaster.

Institutional Review Board. The manager of the pharmacy, or a designee, should be a member of the home care organization's or health system's institutional review board.

Managing Human Resources

Work Schedules and Assignments. The pharmacy manager 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.

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

Performance Evaluation. Policies and procedures should define the ongoing performance evaluations of home care pharmacy personnel. All home care pharmacy personnel should receive regular and timely evaluations. Performance should be evaluated on the basis of position description requirements and expected competencies.

Support Personnel. Sufficient support personnel (pharmacy technicians and customer service, procurement, delivery, clerical, and administrative personnel) should be available to facilitate the delivery of pharmaceutical care and services. Pharmacy technician certification by the Pharmacy Technician Certification Board is desirable; alternatively, technicians should complete an equivalent state-approved pharmacy technician training program, if available. Appropriate supervisory controls should be maintained and documented consistent with federal and state laws and regulations.

Education and Training. All personnel should possess the education and training needed to fulfill their responsibilities, including specific knowledge related to home care. All personnel should participate in continuing-education programs and activities relevant to home care practice as necessary to maintain or enhance their competence.

Recruitment and Selection of Personnel. Personnel should be recruited and selected on the basis of the requirements in the established job descriptions and candidates' job-related qualifications and prior performance. The pharmacy manager should assist in identifying the relevant professional and technical qualifications and should participate in candidate interviews and selections.

Orientation of Personnel. There should be an established procedure for orienting new and current personnel to the pharmacy, the home care organization, the health systems that the home care pharmacy serves, respective positions, relevant home care services, community resources, and the parent organization.

Managing Performance Improvement

Performance Improvement. There should be an ongoing, systematic program for assessing the delivery of pharmaceutical care and services. Performance improvement activities based on assessments should be integrated with the home care organization's or health system's overall performance improvement activities. Operational and outcomes data should be benchmarked with those of other home care pharmacies of similar size and scope. Outcomes, including follow-up actions, of performance improvement efforts should be documented and provided to the home care organization's managers and others, as appropriate.

Medication-Use Evaluation. An ongoing medication-use-evaluation program should be in place to ensure that medications are used appropriately, safely, and effectively.

Adverse Drug Reactions. An ongoing program should be in place for monitoring, reporting, and preventing adverse drug

reactions. The pharmacist should submit reports of adverse drug reactions to FDA's MedWatch program and the drug's manufacturer, as appropriate.

Medication Errors. The home care organization should have an ongoing program to prevent medication errors. Pharmacists, physicians, nurses, and other appropriate home care personnel should monitor for and document medication errors. The home care organization should analyze the causes of medication errors and implement corrective actions. Medication errors should be reported to voluntary national reporting systems and, as required, to accrediting organizations.

Drug Product Recalls. Procedures should be in place for responding to drug and device product recalls, 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.

Standard 2: Drug Information, Education, and Counseling

The home care pharmacist should provide accurate, comprehensive general and patient-specific drug information to patients, caregivers, other pharmacists, physicians, nurses, and other health care providers, as appropriate, in response to requests, in the delivery of pharmaceutical care, or through educational programs. Physicians and nurses should receive adequate information about a medication's therapeutic use, dosage, potential adverse effects, and safe administration in the home—in particular, stability requirements—before the medication is administered.

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

Up-to-date drug information resources should be available in the home care pharmacy, including current periodicals, the latest editions of drug compendiums 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.

Drug Information Requests. 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.

Patient Education and Counseling. Home care pharmacists should be available for and actively participate in patient education and counseling. The pharmacist is responsible for ensuring that the patient and, as appropriate, the caregiver receive information, are counseled, and understand the patient's medication therapy. Patient education and counseling should be coordinated with the patient's other health care providers. The content and form of the education and counseling should be specific to the patient's assessed needs, abilities, and readiness, consistent with care plans and services provided. Patient and caregiver compliance, understanding,

knowledge, and skills should be periodically reassessed. A home care pharmacist should be readily accessible to patients and caregivers if questions arise. Patient education and counseling should be performed in accordance with applicable federal and state laws and regulations and documented in the patient's home care record.

Medication Teaching Materials. Educational material tailored to the patient and the medication therapy should be provided to the patient and the caregiver for use at home. Specifically, medication teaching materials for drugs most often used in home care practice should be available for dissemination to patients, caregivers, and other health care providers. These materials should be based on information most appropriate for safe medication use in the home. Educational materials should contain, but not be limited to, the following: name and description of the medication; usual dose; dosage interval; duration of therapy; goals of drug therapy; importance of compliance; proper aseptic technique in preparation for use (if applicable); proper administration of medication; inspection of medication, containers, and related supplies before use; common severe adverse effects, drug–drug interactions, drug–nutrient interactions, and their management; proper use of medication-related equipment and supplies; emergency-response instructions; instructions for storing, handling, and disposing of the drug; and procedures to follow if a dose is missed.

Dissemination of Drug Information. Pharmacists should keep the home care 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.

Pharmacist Consultations. 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 care medical record.

Investigational Drug Information. The home care pharmacist should have access to information on all investigational studies and similar research projects involving medications and medication-related devices used in the home care, hospital, or alternate-site setting. The pharmacist should provide pertinent written information (to the extent such information exists) about the safe and proper use of investigational drugs, including possible adverse effects and adverse drug reactions, to nurses, pharmacists, physicians, and other health care providers participating in clinical drug research.

Standard 3: Care Planning, Monitoring, and Continuity

An important aspect of pharmaceutical care is optimizing medication use for individual patients. This should include processes designed to ensure the safe and effective use of medications and to increase the probability of desired patient outcomes. The pharmacist, in collaboration with the patient, caregiver, physician, nurse, and other health care providers, should be responsible for developing an individualized care plan for each patient.

Care Plan. The care plan should be based on information obtained from the initial pharmacy assessment and other relevant information obtained from the patient, caregiver, physician, nurse, and other health care providers. At a minimum, the plan should include actual or potential medication therapy problems and proposed solutions, desired outcomes or goals of the medication therapy, and the objective and subjective parameters for monitoring outcomes or goals and medication therapy-related problems. The plan should be developed at the initiation of medication therapy, reviewed, and updated, if necessary, on a regular basis according to the home care organization's policies. The degree of detail of the plan should be based on the complexity of the patient's health problems and drug therapy. The pharmacist is responsible for ensuring that the medication therapy (pharmaceutical care) elements of the plan are communicated to appropriate parties involved in the patient's care. All the patient's health care providers should routinely share care plan information and actions. The plans and updates should be a part of the patient's home care medical record.

Initial Patient Assessment. The pharmacist should ensure that each patient referral for home care is assessed for appropriateness on the basis of formal, predetermined admission criteria, as outlined in the ASHP Guidelines on the Pharmacist's Role in Home Care.¹ Before the start of home care services, patients should be informed of their rights and responsibilities. These should be explained in detail and given in writing to the patient and a family member or other caregiver. Once a patient is accepted for home care services, but before the initiation of therapy, the organization should ensure that the patient's current clinical status, home environment, and support systems are assessed. A thorough patient database should be prepared to identify pharmaceutical care needs and to provide the basis for ongoing medication therapy monitoring and for measuring patient outcomes. The patient database should be documented in the patient's home care medical record. Information that minimally should be included in the database is outlined in the ASHP Guidelines on the Pharmacist's Role in Home Care.¹ Information for the database can be gathered from the past and current medical record; laboratory test results; direct communication with the patient, caregiver, physician, nurse, and other health care providers; and the home care pharmacist's direct observations.

Medication Orders. Medication orders should be assessed by a pharmacist before the first dose is dispensed. A pharmacist should receive the physician's order. If not received by a pharmacist, the order should be verified by a pharmacist. The pharmacist should assess the order for the following:

1. Therapeutic appropriateness of the patient's medication regimen,
2. Therapeutic duplication in the patient's medication regimen,
3. Appropriateness of the route and method of administration of the medication,
4. Drug–drug, drug–nutrient, drug–laboratory test, and drug–disease interactions, and
5. Clinical and pharmacokinetic laboratory data for evaluating the efficacy of medication therapy and anticipating toxicity and adverse effects.

Any questions about the order should be resolved with the prescriber, and a written notation should be made in the

patient's home care medical record or pharmacy copy of the prescriber's order. Information concerning changes should be communicated to the patient's other health care providers.

First-Dose Precautions. The pharmacist, in collaboration with other health care providers, should assess whether a first dose of a medication can be safely administered in the home or whether the patient should be referred to an alternative treatment site for the initiation of therapy. Policies and procedures should outline the situations and therapies for which medications for treating anaphylaxis should be dispensed so that the pharmacist can ensure that the appropriate medications are available when a first dose is to be administered.

Patient Education and Counseling. The home care pharmacist, or the nurse as the agent, should ensure that the patient, the caregiver, and other health care providers understand the proper use and administration of medications, including the intravenous access device and infusion device, as required. The home care 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. Also, prescriptions delivered outside the confines of the pharmacy should be discussed.

Medication Therapy Monitoring. After the initiation of medication therapy, the pharmacist collects and reviews data from physical and nutritional assessments, laboratory tests, and oral communication with the patient, caregiver, nurse, and physician (1) to evaluate the clinical status of the patient and the response to medication therapy, (2) to determine whether the patient's pharmaceutical care needs are being met, and (3) to ascertain whether the care plan designed for the patient is effective. The monitoring plan, which should be detailed in the care plan, guides medication therapy-monitoring activities and facilitates evaluation of the patient's progress by the pharmacist. Additionally, the pharmacist should, in collaboration with other professional staff members, monitor the following:

1. Functional status of the drug delivery system,
2. Patient utilization of medications, supplies, and equipment,
3. Patient compliance with the prescribed regimen,
4. Patient adaptation to delivery of care in the home, and
5. Patient satisfaction with the care and service delivered.

If the patient is responding and has no new identified pharmaceutical care needs or medication-related problems, but has not completed the course of therapy, pharmaceutical services should be continued as planned. If it is determined that the patient is not responding, or if new medication-related problems are identified, the plan should be revised and implemented.

Medical Emergencies. The home care 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.

Documentation of Pharmaceutical Care and Outcomes. The pharmacy should have an ongoing process for consistent documentation (and reporting to physicians, administrators, and others) of pharmaceutical care and patient outcomes resulting

from medication therapy and other pharmacy actions. Patient privacy and confidentiality must be protected at all times.

Continuity of Care. The pharmacist should routinely contribute to processes ensuring that each patient receives pharmaceutical 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 care services). When home care patients are admitted to a hospital, the home care pharmacy should inform the hospital about (1) the medications the patient is currently receiving from the home care pharmacy and (2) known allergies. The home care pharmacy should recognize hospital policy when considering whether properly stored medications and medical equipment from the home can be used during the home care patient's hospitalization.

Standard 4: Medication Distribution and Control

The home care pharmacy should be responsible for the procurement, storage, distribution, and control of all drug products it dispenses (including medication-related devices and pharmaceutical diagnostics). Policies and procedures governing these functions should be developed by the pharmacy manager in collaboration with other appropriate home care organization staff members.

Processing the Medication Order

Medication Orders. All patient medication orders should be documented in the patient's home care medical record. The home care pharmacist should obtain a signed original of the prescriber's order, a direct copy of the prescriber's order, an oral order from the prescriber or his authorized agent, or an electronically transmitted, prescriber-entered order consistent with applicable laws and regulations. Safeguards should be in place to ensure the security of electronically transmitted prescriber orders. All medication orders should be reviewed by a pharmacist and assessed in relation to the medication profile and, as appropriate, an established procedure for using an approved list of medications for specific treatment circumstances and emergencies. A system should exist to ensure that medication orders are not inappropriately continued.

Prescribing. Policies and procedures should be available to ensure that health care providers meet applicable state licensure and home care organization authorization, if required, for prescribing medications. The pharmacy should advocate and foster conformance with standardized, approved terminology and abbreviations when medications are being prescribed.

Therapeutic Purpose. Prescribers should be encouraged to routinely communicate the condition being treated or the therapeutic purpose of medications with all prescription and medication orders.

Preparing, Packaging, and Labeling Medications

Sterile Products. Home care pharmacists are responsible for ensuring the quality of sterile products intended for use in the home. Guidance is available 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.^{2,3}

Beyond-Use Dating. Home care 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 (1) delivery of sterile products to the home, either by the pharmacy's own vehicles or by a common carrier, (2) storage of sterile products in the home before use, (3) manipulation of sterile products in the home environment to add ingredients (such as vitamins) and to set up tubing and filters for administration, and (4) administration of products at temperatures that are 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.

Beyond-use dates should be based on the manufacturer's approved product labeling; however, information about the long-term stability of products for home use may not be included in the labeling. In addition, information may not accurately reflect the product's intended conditions of use in home care, including the concentration, diluent, container, and infusion conditions. The home care pharmacist should either consult the manufacturer for an appropriate beyond-use date or determine the date by reviewing the literature. 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.

Packaging for Home Delivery. 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.).

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.⁴ If medications are to be administered with an infusion device, pump settings should be included on the label.

Delivery and Handling of Medications in the Patient's Home

Delivery. Policies and procedures should be available to ensure product integrity and temperature control during home delivery or patient pickup of supplies and drugs. Delivery to the patient should 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 (such as double bagging [including at least one leakproof container] and cushioning) should be used to safeguard hazardous products from breaking and leaking. The delivery person, patient, and caregiver must be trained to recognize and manage accidental spills. Packages containing hazardous products should have appropriate precautionary labels.

Universal Precautions in Patients' Homes. Home care pharmacy personnel delivering medications or supplies to patients' homes should use universal precautions. Patients and caregivers should be instructed on the application of universal precautions in the home. The provision of instructions on universal precautions, as well as the provision of other information and counseling, should be documented. Personnel should always wash their hands before assisting patients with the handling of supplies in the home.

Storage in the Home. The pharmacy should take precautions to ensure that medications are properly stored with respect to temperature, light, and other labeled storage conditions. If sterile or other products require refrigeration, appropriate methods should be used to segregate them from food to avoid contaminating the outside of the container. Patients, caregivers, or delivery personnel should be trained to check the refrigerator on a regular basis to determine whether temperatures are within an acceptable range to ensure product integrity. If the patient does not have an appropriate environment for storage of medications, the pharmacy should make alternative arrangements so that medications are properly stored. Drugs and supplies that do not require refrigeration should be stored in a separate, restricted location not accessible to children and pets.

Waste Disposal. Patients receiving hazardous drugs in the home should be instructed in proper waste-disposal methods that comply with federal and state laws and regulations. Needles and other sharps should be placed in appropriate disposal containers, and a process should be established for the safe removal and disposal of the waste. Local codes may have specific disposal requirements.

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

The Patient's Own Medications. Drug products and related devices not dispensed by the home care pharmacy that are to be used during the patient's course of therapy should be documented in the patient's home care medical record. When home care patients are admitted to a hospital, the home care pharmacy should inform the hospital about the medications the patient is currently receiving from the home care pharmacy and about any known allergies. The home care pharmacy should recognize hospital policy when considering whether properly stored medications and medical equipment from the home can be used during the home care patient's hospitalization.

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

Controlling Certain Categories of Medications

Cytotoxic and Hazardous Drug Products. Policies and procedures for storing, handling, and disposing of cytotoxic and other hazardous drug products should be available to ensure patient and employee safety in compliance with applicable local, state, and federal laws and regulations. Employees should be specially trained, and their handling and disposal of these products should be monitored. Spill kits should be available.⁴

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.

Investigational Drugs. Policies and procedures for the safe and proper use of investigational drugs should be established and followed. The pharmacy should be responsible for overseeing the distribution and control of all investigational drugs. Investigational drugs should be dispensed and administered to consenting patients in accordance with an approved protocol. Home care pharmacists should initiate, participate in, and support medical and pharmaceutical research appropriate to the goals, objectives, and resources of the home care organization.

Standard 5: Facilities, Equipment, and Information Resources

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 care organization's communication and 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.

Medication Storage and Preparation. Facilities should be available for storing and preparing medications in the home care 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.

Medication Storage Area Inspections. All stocks of medications stored in the home care 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 and Packaging. Designated space and equipment for compounding and packaging sterile and non-sterile drug products should be available.^{2,5} The compounding environment should be monitored and maintained on an ongoing basis.

Cytotoxic and Hazardous Drug Products. Appropriate facility space, equipment, and supplies for compounding cytotoxic and hazardous drug products should be available (to include a biological safety cabinet, spill kits, eye-washing station, and protective garb).⁶

Drug Information. Adequate space, resources, and information handling and communication technology should be available to facilitate the provision of drug and related information to patients, caregivers, health care providers, multidisciplinary team members, and referring physicians.

Pharmacist–Patient Consultation. Home care 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.

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. Sufficient educational and training

activities should be established. Adequate facilities and equipment should be established for decontaminating, cleaning, and maintaining infusion devices, including durable medical equipment.

Drug Delivery Systems, Administration Devices, and Automated Dispensing Devices. Home care 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 must 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.

Record 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. Appropriate licenses, permits, and tax stamps should be available.

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.

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Suggested Reading

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Barbara McKinnon, Pharm.D., Karen E. Bertch, Pharm.D., Lawrence P. Carey, Pharm. D., Terry D. Leach, Larry D. Pelham, M.S., FASHP, Brian G. Swift, Pharm.D., and J. Scott Reid, Pharm.D., are gratefully acknowledged for drafting this document.

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