

ASHP Guidelines on the Pharmacist's Role in Home Care

Purpose

The purpose of these guidelines is to define the role of the pharmacist in providing pharmaceutical care to patients in the home¹ or alternate-site setting. In broad terms, home care is the provision of specialized, complex pharmaceutical products and clinical assessment and monitoring to patients in their homes. This generally includes home infusion therapy and other injectable drug therapy and parenteral and enteral nutrition therapy. These therapies require resources and support beyond those of the traditional orally and topically administered therapies. Specific pharmacist education and training, drug product admixtures and administration techniques, equipment operation and maintenance, and patient monitoring 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 pharmaceutical 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 care 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.

Background

Home care services are provided by a variety of organizations, including hospitals, community pharmacies, home health agencies, hospices, and specialized infusion companies. Patients receive care in noninpatient settings, such as their homes and ambulatory infusion centers, or in alternate-site settings, such as skilled-nursing facilities. These guidelines apply to the provision of home care services by pharmacists practicing in all health care settings. It should be noted that different aspects of home care 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, and documented in advance by all providers.

Pharmacists' Responsibilities

Preadmission Assessment. The pharmacist should ensure that each patient referred for home care is assessed for appropriateness on the basis of admission criteria, including the following:

- The patient, family, and caregiver agree with provision of care services in the home.
- The patient or caregiver is willing to be educated about the correct administration of medications.
- The home environment is conducive to the provision of home care services (e.g., electricity and running water are present, and the home is clean).
- The home care 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 care services, and there is a prognosis with clearly defined outcome goals.
- The indication, dosage, and route and method of administration of medications are appropriate.
- 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.

Before the start of home care services, patients should be informed of their rights and responsibilities, including financial obligations. These should be explained in detail; given to the patient, family member, or other caregiver in writing; and documented in the patient's record.

In cases in which the first dose of a medication is to be given at home, the pharmacist should use clinical judgment in determining, in conjunction with the prescriber, home care nurse, and patient or caregiver, if home administration of the first dose is appropriate. Policies and procedures should define factors to be used in making this decision and precautions necessary when first doses are administered at home (e.g., emergency medications, monitoring and observation, and presence of a health care provider).²

Once a patient is accepted for home care, the pharmacist should assess the patient's current status and develop a patient database for ongoing drug therapy monitoring and as an evaluation tool for measuring patient outcomes. In most home care practice sites, the pharmacist is responsible for obtaining the medication order from the prescriber. In addition, the pharmacist should assess the legality and appropriateness of the medication order.

Initial Patient Database and Assessment. The complete patient database should be documented in the patient's home care 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,
- A care plan and a list of drug-related problems, if any,
- Treatment goals and the expected duration of therapy,
- Indicators of desired outcomes,
- Patient education previously provided,
- Any functional limitations of the patient, and
- Any pertinent social history (e.g., alcohol consumption and tobacco use).

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 care 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.

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 and 0.9% sodium chloride injection), and ancillary supplies (e.g., dressing kits, syringes, and administration sets).^{3,4} 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.

The home care pharmacist, in consultation with the prescriber, should determine when emergency medications and supplies (e.g., anaphylaxis "kits") should be dispensed

to home care 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.

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, the prescriber, the patient, and the caregiver. At a minimum, the pharmacist's contribution to the care plan should include the following⁵:

- 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.

The pharmacist is responsible for communicating care plan contributions to other health care providers involved in the patient's care, to the patient, and to the caregiver. Updates, as they occur, should be communicated to the appropriate persons. The care plan and updates should be a part of the patient's record.

Patient Education and Counseling. 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. A home care 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.

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,
- 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 their management,
- 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 care 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 care 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.

Effective communication with prescribers, nurses, and other health care providers. Effective communication among pharmacists, prescribers, nurses, 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). Both oral and written communication methods can be used for communicating patient information. All relevant clinical communication should be documented in the patient’s home care 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 (e.g., nurses, pharmacists, dietitians, delivery representatives, and reimbursement coordinators)

meet regularly to discuss the clinical status of the patient and any operational issues related to the patient’s care.

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.

Communication with the Patient and the Caregiver. The pharmacist providing home care services should establish free and open channels of communication with the patient or the caregiver. 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 care record.

Coordination of Drug Preparation, Delivery, Storage, and Administration. The pharmacist is responsible for ensuring the proper acquisition, compounding, dispensing, storage, delivery, and administration of all medications and related equipment and supplies. 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. Pharmacists may administer medications to patients in the home setting unless prohibited by applicable laws and regulations.

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).

Standard Precautions for Employee and Patient Safety. A home care organization is responsible for helping teach employees, patients, family members, and caregivers about standard safety precautions. The pharmacist should ensure

that the home care 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, handling of cytotoxic and hazardous medications,⁶ and material safety data sheets. The pharmacist should be a key resource in the development of such educational programs. The pharmacist should assume an active role in the home care organization's infection-control activities.

Documentation in the Home Care Record. A home care record should be developed and used for documenting the home care services provided to each patient. Written organizational policies and procedures should address the security of home care 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 care services (e.g., pharmacy, nursing, and respiratory therapy) to use a single home care 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.

Adverse Drug Event Reporting and Performance Improvement. The home care 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 inservice 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. Medication errors should be reported to the USP Practitioner Reporting Program. Sentinel events should be reported to the Joint Commission on Accreditation of Healthcare Organizations.

Participation in Clinical Drug Research in the Home. The pharmacist should play a key role in the development of policies and procedures for handling investigational drugs and their protocols in the home care setting. When patient participation in clinical drug research is initiated in the institutional setting or another setting before the patient's transfer to the home care setting, it is important that the home care pharmacist obtain and keep on file sufficient information about the investigational drug protocol and drugs. If an investigational drug is dispensed or administered by the home care organization, a copy of the completed and signed informed consent should be placed in the patient's home care record. The home care pharmacist should review the protocol before the patient is admitted to the home

care service to determine whether it would be appropriate to treat the patient at home. When investigational drug inventories are maintained in the home care pharmacy, the pharmacist is responsible for accurate record keeping. The pharmacist should be an active participant in coordinating and monitoring clinical drug research in home care.

Participation in Performance Improvement Activities. Pharmacists should be active participants in performance improvement activities in their organizations. A performance improvement program for home care should monitor patient satisfaction and outcomes. Aspects of care that may be monitored include, but are not limited to, the following:

- Unscheduled inpatient admissions,
- Unexpected discontinuation of infusion therapy,
- Interruption of infusion therapy,
- Development of infections or complications,
- Reported adverse drug reactions and adverse device-related reactions,
- Medication errors, and
- Medication-related problems.

The performance improvement program should include appropriate quality control measures for compounding sterile products and other activities.

Policies and Procedures. The home care pharmacist should be an active participant in the development of organizational policies and procedures. The organization should maintain current policies and procedures for all aspects of patient care and quality assurance. Activities that should be addressed in policies and procedures include criteria for accepting patients into home care services, patient education and counseling, drug preparation and dispensing, equipment maintenance, quality assurance in sterile product compounding, infection control, and documentation.

Licensure. Pharmacists who provide home care services must 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 know about all applicable federal and state laws and regulations.

Training, Continuing Education, and Competence. Pharmacists should receive training as necessary to ensure that they possess the knowledge and skills required for the provision of home care services. They should participate in ongoing continuing-education activities to update and enhance their knowledge and skills related to home care. Pharmacists should 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. 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 care providers. Pharmacists should

provide, to the extent possible in their organizations, student clerkship, externship, and internship training, as well as post-graduate residency training.

References

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