

ASHP Guidelines on Evaluating and Using Home or Alternate-Site Infusion Service Providers

These guidelines describe the roles of home or alternate-site infusion service providers and pharmacies (hereinafter “home infusion service providers” and “home infusion pharmacies”) and provide guidance on how to successfully work with a home infusion service provider in continuing care that has been initiated in a health system or other facility. For the purposes of these guidelines, a *home infusion service provider* is defined as an organization that continues or completes a patient’s parenteral medication in the home or alternate site after the patient is released from a hospital or other facility. A home infusion service provider may offer nursing or other services in addition to pharmacist care. A *home infusion pharmacy* is defined as a licensed pharmacy that prepares and dispenses parenteral sterile medications directly to a patient, pursuant to a valid individual prescription and in individualized doses.

Roles of Home Infusion Service Providers

The typical role of a home infusion service provider is to continue or complete a patient’s parenteral medication course of therapy in the home or in an alternate site (e.g., infusion suite) after the patient is released from the hospital or other facility. Regardless of the business model of the home infusion service provider (e.g., owned by a health system or a private company), the referring entity and the home infusion service provider maintain a relationship as direct healthcare providers with responsibility for patient care. After accepting a referral, the home infusion service provider is in direct contact with the patient for whom the medication is dispensed and shares responsibility with the prescriber for the clinical outcome of that patient’s care.^{1,2}

Where recommended due to patient safety concerns or insurance requirements, the parenteral medication may be infused in an infusion suite that is associated with the home infusion service provider, rather than at the patient’s residence. Home infusion service providers may employ their own infusion nurses or they may contract with a home health agency (HHA) to provide home nursing care to a patient. Office-based prescribers may also coordinate home infusion services with a home infusion service provider when parenteral medications are prescribed but hospitalization is not needed, which often results in lower healthcare costs.³

Roles of the Home Infusion Pharmacy

A home infusion pharmacy prepares and dispenses parenteral sterile medications directly to a patient, pursuant to a valid individual prescription and in individualized doses. These medications include many of the same sterile medications that are prepared in a hospital’s inpatient pharmacy, including i.v. antibiotics, antifungals, hydration fluids, parenteral nutrition, chemotherapy, and pain medications. Some home infusion pharmacies also supply i.v. and subcutaneous immune globulins, antihemophilic factor products, and other parenteral medications for chronic conditions. Unlike

a hospital pharmacy that dispenses i.v. medications to inpatients on a daily basis, home infusion pharmacies typically dispense on a weekly basis (subject to the stability and sterility parameters of the preparations dispensed).

Home infusion pharmacies differ in many respects from 503B-registered outsourcing facilities.^{4,5} A 503B-registered outsourcing facility manufactures multiple containers of a specific medication in batches and predetermined concentrations and sells these compounded sterile products under contract to end users (hospitals, health systems, or physicians’ offices). This manufacturing does not occur pursuant to an individual patient prescription, and the 503B-registered outsourcing facility has no direct relationship with the patient to whom the medication is administered. (More information on this topic can be found in ASHP Guidelines on Outsourcing Sterile Compounding Services.⁵) While some home infusion pharmacies may provide both home infusion and compounding pharmacy services, it is important to evaluate these distinct lines of service individually within the correct parameters.

Working with Home Infusion Service Providers

Parenteral medication administration is more complicated than other routes of medication delivery because aseptic technique must be used to prepare and administer each dose. In addition, many parenteral medications require the use of a pump or a rate-controlled delivery system for safe administration. Arranging postdischarge home infusion therapy requires planning to achieve a successful transition of care. Patients who are discharged with orders for parenteral medications to be administered at the home setting or alternate site of service usually require both home health nursing and home infusion pharmacy services. The pharmacy and nursing services may be provided by a single company or by separate providers. Hospitals and health systems should identify high-quality providers of home infusion services before patient discharge and engage in other advanced planning, including communication with the provider, so that the process of discharging a patient with parenteral medications is seamless and supports the patient’s clinical goals.

Identifying High-Quality Home Infusion Service Providers.

Most hospital discharge planning departments provide patients with a list of home infusion service providers to allow patients freedom in choosing a provider, which is a requirement of any government payer. A checklist that can be used when researching providers of home infusion services is provided in the appendix. Factors that will affect the selection of preferred providers of home infusion services include the following:

1. Whether the home infusion service provider’s nursing services are provided by its own employees or through a separate HHA.

- a. If HHAs are used, does the home infusion service provider offer seamless integration of home infusion therapy so that one call coordinates both pharmacy and nursing services? If the patient needs home nursing and has Medicare or Medicaid as the primary insurance payer, an HHA with the appropriate Medicare or Medicaid nursing licenses must be used.⁶ Does the home infusion service provider have relationships with Medicare-certified HHAs?
 - b. If the home infusion service provider coordinates with an HHA, does the provider maintain a preferred provider list of HHAs? How is that list determined? Accreditation or Medicare certification should be required for all providers of home infusion nursing.
 - c. Is the home infusion service provider willing to work with HHAs that the referral source prefers to use?
2. Whether the home infusion service provider is accredited and licensed. Accreditation should be required for a preferred home infusion service provider. Accreditation standards for home infusion (e.g., those of the Accreditation Commission for Health Care,⁷ Community Health Accreditation Program,⁸ Center for Pharmacy Practice Accreditation,⁹ Healthcare Quality Association on Accreditation,¹⁰ National Association of Boards of Pharmacy,¹¹ The Compliance Team,¹² or the Joint Commission¹³) are very similar to those applied to hospitals and ensure that the organization has undergone peer review and operates with best practices to safeguard patients. To ensure licensing and accreditation, the healthcare organization should
 - a. Request a copy of the home infusion service provider's pharmacy and Drug Enforcement Administration licenses.
 - b. Request a copy of the accreditation certificate and note the expiration date.
 3. Whether the home infusion service provider complies with appropriate compounding standards and regulations. To ensure compliance, the healthcare organization should
 - a. Request an attestation from the home infusion pharmacy stating that it complies with applicable state regulations and follows *United States Pharmacopeia (USP)* chapter 797 standards for compounding sterile preparations,¹ and request a recent copy of the pharmacy's *USP* chapter 797 gap analysis, if available.
 4. The provider's service area and normal hours of operation for pharmacy and nursing services.
 - a. For home infusion pharmacy services, the following questions may be pertinent to the selection of a provider:
 - i. Does the pharmacy hold any out-of-state pharmacy licenses (if there is a need to serve patient populations from multiple states)?
 - ii. Does the pharmacy have the capability to ship medications?
 - iii. Does the pharmacy have the capability to make local deliveries?
 - b. For home infusion nursing services, the following questions may be pertinent to the selection of a provider:
 - i. Is the area of service restricted to certain areas (e.g., counties)?
 - ii. Where applicable, is nursing service provided across state boundaries?
 - iii. What are the specific geographic boundaries of the nursing service area?
 - iv. What are the state requirements concerning licensed or nonlicensed agencies?
 5. Whether the home infusion service provider offers 24-7 patient services. If not, how does a patient reach a clinician after regular business hours?
 6. Whether the infusion provider offers specialized pharmacy or nursing services (e.g., nutrition support, particular expertise such as pediatric or neonatal, hemophilia, heart failure, or oncology) or advanced infusion skills certification (e.g., certified registered nurse infusion or oncology certification).
 7. Referral and transition-of-care process support by the home infusion service provider.
 - a. How is patient training performed, and who conducts the training?
 - b. Can the home infusion service provider provide a nurse to start the patient's medication in the hospital at the time of discharge for therapies that cannot be interrupted (e.g., pain management, inotropes)?
 - c. What is the expected turnaround time from the point of referral to delivery of patient medications and the first home nursing visit?
 8. Whether the home infusion service provider can demonstrate success (e.g., patient data showing positive clinical outcomes or positive patient satisfaction survey results).

Transitioning the Infusion Patient from Hospital to Home.

The hospital or health system should implement processes that support a successful transition of care for all discharged patients, but preplanning for patients to be discharged with home infusion services is critically important for ensuring a smooth transition of care.^{2,14-16} Advanced home infusion discharge planning includes the following:

- Gathering all of the information needed by the home infusion service provider.
- Checking that the home infusion services are covered by the payer and that the home infusion service provider has a contract with the payer. Therapies covered by Medicare must often meet Medicare criteria, which can include specific laboratory tests or invasive monitoring (e.g., inotropes, parenteral nutrition). It must be determined in advance of discharge that the patient's ordered home infusion therapy will be covered by Medicare or other insurance, and any co-payment or out-of-pocket expenses must be communicated to the patient in advance.
- Arranging prior authorization, if required by the payer; prior authorization may require several business days.
- Avoiding a weekend or holiday discharge, unless planned sufficiently in advance that the insurance has been verified and home nursing has been arranged. A

weekend or holiday discharge can be accommodated but is not recommended. Most insurance companies are closed on the weekend, and a patient's benefits cannot be determined until the next business day. Such a discharge could result in significant out-of-pocket costs for the patient. In addition, the home health nursing schedule may not permit opening a new case on a weekend.

- Allowing time for placement of a peripherally inserted central catheter (PICC) and PICC catheter tip evaluation before discharge, if necessary.
- Ensuring that a home infusion nurse is available for the first home visit. This visit may last more than two hours and includes a full nursing assessment; it may also include teaching the patient or caregiver how to prepare the medication, administer the medication (including the use of a pump or other medication delivery system), properly store the medication, and care for a vascular access device.
- Allowing time for the home infusion pharmacy to dispense the patient's medication, which includes pharmacist review of the patient's medication list, a check for drug interactions, clarification of any prescription information that is unclear or missing, time for compounding the medication, and time to arrange for the delivery of medications and supplies to the patient. Obtaining a complete and valid prescription from the prescriber who will be treating the patient can require extra time. A valid prescription includes orders for the medication, the number of doses or length of therapy, flushes for catheter care, nursing orders (if applicable), and laboratory test orders.
- Planning extra time to discharge patients who will require a continuous infusion of controlled substances or an inotrope. Typically, these patients need to have their home medication infusion initiated in the hospital at the time of discharge.

Transitional Care Program. A transitional care program for home infusion patients may be offered by the home infusion service provider. This type of program can help identify risk factors that could jeopardize the success of a planned discharge on home infusion therapy, so that any anticipated extra challenges (e.g., lack of a caregiver in the home, orders for more than one parenteral medication) can be mitigated before discharge.

Some home infusion service providers offer clinical liaison nurses who will meet with patients before hospital discharge to explain the patient's home infusion therapy and how those services will be provided. This service may also include initiation of the home infusion teaching process so that the patient or caregiver can become familiar with the home infusion therapy in advance. A clinical liaison nurse employed by a home infusion service provider must have the hospital or health-system's permission to meet with hospitalized patients. Where permitted by the hospital and required by the therapy (e.g., continuous parenteral pain management or inotropic therapy), a clinical nurse liaison may also be available at the time of discharge to initiate the home infusion service, including starting the first dose, which would avoid an interruption in the therapy as the patient transitions from the hospital to the home.

Communication with the Home Infusion Service Provider.

Communication between the hospital or health system and the home infusion service provider is essential for maintaining a positive working relationship that will ultimately benefit both patients and providers. It is important for hospital or health-system discharge planners, social workers, and prescribers to understand the information needed by an accredited home infusion service provider. The home infusion pharmacist should be provided with the patient's history and physical summary, a copy of the most recent laboratory test results, an accurate medication list, a document validating appropriate placement of a central venous access device, and complete orders for the infusion medications. The provider who receives the referral information, whether it is the home infusion pharmacy or an HHA, is responsible for communicating the patient's information to any other partners in the patient's home care.

A major challenge to home infusion service providers can arise when home infusion therapy is ordered without a clear plan for prescriber oversight after discharge (e.g., when there is a communication gap between the hospitalist physician who managed the patient's care during hospitalization and the patient's primary care or specialist physician at the point of discharge). If there is no firm arrangement for a prescriber to be responsible for the patient's infusion therapy after discharge and complications arise, the infusion pharmacist or nurse has no option but to refer the patient to the emergency department for a potential readmission. Hospitals and health systems can avoid such an outcome by implementing good advance discharge planning.

Conclusion

Home infusion therapy plays a crucial role in the provision of healthcare, including the provision of cost-effective care outside of an institutional setting. Choosing a home infusion service provider with high-quality standards can make a difference in whether a patient has a positive or negative response to treatment. In addition, a smooth transition of care based on advanced planning will improve outcomes and control costs.

References

1. Pharmaceutical compounding—sterile preparations (general information chapter 797). In: The United States pharmacopeia, 27th rev., and The national formulary, 22nd ed. Rockville, MD: United States Pharmacopeial Convention; 2004:2350–70.
2. Nigro SC, Garwood CL, Berlie H, et al. Clinical pharmacists are key members of the patient-centered medical home: an opinion statement of the Ambulatory Care Practice and Research Network of the American College of Clinical Pharmacy. *Pharmacotherapy*. 2014; 34:96–108.
3. Kennedy S. Home infusion therapy: safety, efficacy and cost-savings. <http://psqh.com/home-infusion-therapy-safety-efficacy-and-cost-savings> (accessed 2014 Nov 18).
4. American Society of Health-System Pharmacists. ASHP guidelines on home infusion pharmacy services. *Am J Health-Syst Pharm*. 2014; 71:325–41.

5. American Society of Health-System Pharmacists. ASHP guidelines on outsourcing sterile compounding services. *Am J Health-Syst Pharm.* 2015; 72:1664–75.
6. Centers for Medicare and Medicaid Services. Survey & certification—certification and compliance. www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/index.html (accessed 2014 Nov 5).
7. Accreditation Commission for Health Care. Home health accreditation. www.achc.org/programs/home-health (accessed 2016 Mar 9).
8. Community Health Accreditation Program. Pharmacy. www.chapinc.org/services-we-accredit/pharmacy.aspx (accessed 2016 Mar 9).
9. Center for Pharmacy Practice Accreditation. Community pharmacy practice accreditations. www.pharmacypracticeaccredit.org/practices (accessed 2016 Mar 9).
10. Healthcare Quality Association on Accreditation. Infusion pharmacy accreditation. www.hqaa.org (accessed 2016 Mar 9).
11. National Association of Boards of Pharmacy. DMEPOS accreditation program. www.nabp.net/programs/accreditation/dmepos (accessed 2016 Mar 9).
12. The Compliance Team. Exemplary provider accreditation program. www.thecomplianceteam.org (accessed 2016 Mar 9).
13. Joint Commission. Home care accreditation program. www.jointcommission.org/accreditation/home_care_accreditation.aspx (accessed 2016 Mar 9).
14. Hume AL, Kirwin J, Bieber HL, et al. Improving care transitions: current practice and future opportunities for pharmacists. *Pharmacotherapy.* 2012; 32:e326–37.
15. Tucker A, Ybarra J, Bingham A, et al. American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) standards of practice for nutrition support pharmacists. *Nutr Clin Pract.* 2015; 30:139–46.
16. Labson MC, Prosser BS, Tharp J. Establishing a culture of safety in the prevention of medication errors. Paper presented at the National Home Infusion Association, 2015 Annual Conference and Exposition. Phoenix, AZ; 2015 Mar.

Appendix—Checklist for Evaluating a Home Infusion Service Provider

Criterion	Yes	No
Does the provider service the area where the patient lives?		
Is the provider licensed by the State Board of Pharmacy?		
Is the provider accredited?		
Is the provider <i>United States Pharmacopeia</i> chapter 797 compliant?		
Does the provider have its own nursing staff?		
Is the provider willing to work with preferred nursing agencies?		
Are the provider's normal hours of operation sufficient to fulfill all requirements and needs?		
Does the provider provide 24-7 coverage for nursing?		
Does the provider provide 24-7 coverage for pharmacy?		
Does the provider have a nutrition support team? (if applicable)		
Does the provider have pediatric expertise? (if applicable)		
Does the provider have any other areas of expertise needed?		
Does the provider have clinical liaisons? (if applicable)		
Will the provider come to the hospital to initiate therapy if needed?		
Can the provider meet the expected turnaround time needed?		
Can the provider accept the patient's insurance?		
Does the provider have evidence of positive outcomes?		
Does the provider provide timely feedback?		
Will the provider accept after-hours referrals?		
Can the provider accept patients who do not speak English? (if applicable)		
Can the provider accept electronic prescriptions?		
Has the patient been a patient with this provider in the past?		

Approved by the ASHP Board of Directors on November 30, 2015, and developed through the ASHP Section of Ambulatory Care Practitioners Advisory Group on Home Infusion.

The authors have declared no potential conflicts of interest.

Barbara Petroff, M.S., FASHP, Soleo Health, Novi, MI.

Cathy Johnson, B.S.Pharm., Bioscrip, Cincinnati, OH.

ASHP gratefully acknowledges the following organizations and individuals for reviewing these guidelines (review does not imply endorsement): American Pharmacists Association; Idaho Society of Health-System Pharmacists; Infusion Nurses Society; New Hampshire Society of Health-System Pharmacists; Tolulope Akinbo, Pharm.D., M.P.H.; Megan Brafford, Pharm.D., BCOP;

Clyde Buchanan, M.S., FASHP; John S. Clark, Pharm.D., M.S., BCPS; Debra Cowan, Pharm.D., FASHP; Travis B. Dick, Pharm.D., M.B.A., BCPS; Kaci Elmore, RN; Michael Fadeyi, B.S., M.S.; Steven Gray, Pharm.D., J.D.; Kathleen M. Gura, Pharm.D., BCSP, FASHP, FPPAG, FASPEN; Lois F. Parker, B.S.Pharm.; James Ponto, B.S.Pharm., M.S., BCNP, FASHP; James R. Rinehart, M.S., FASHP; Brandon Shank, Pharm.D., BCOP; Marc Stranz, Pharm.D.; Paul Wittmer, M.B.A.; and Jody Jacobson Wedret, FASHP, FCSHP.

Copyright © 2016, American Society of Health-System Pharmacists, Inc. All rights reserved.

The bibliographic citation for this document is as follows: American Society of Health-System Pharmacists. ASHP guidelines on evaluating and using home or alternate-site infusion service providers. *Am J Health-Syst Pharm.* 2016; 73:922–6.