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Pharmacy practice in the home (non-hospital) setting in the USA

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1. Pharmacy practice outside the hospital setting

The practice of pharmacy in the United States of America (USA) is multi-faceted, and incorporates many practice settings. This article will provide an overview of the non-hospital care of patients in the USA who require extended infusion medications, parenteral nutrition (PN), and other complex injectable therapies—all of which are typically referred to as ‘home infusion’ or ‘alternate site’ pharmacy services. The non-hospital practice settings for these services vary due to business arrangements, insurance and government payment (or non-payment) for services, specialized care needs, geography, and demographics of any given service area.

Home infusion pharmacy

Home infusion (HI) pharmacy services have been in place since the late 1970’s in the USA. The first HI pharmacies provided primarily PN compounding and dispensing for patients with no clinical reason to stay hospitalized. The enhancements of intravenous access devices such as in-dwelling central and mid-

line catheters helped to spur the growth of other longer term intravenous therapies suitable for HI. Economic pressures to reduce hospital expenditures and lengths of stay factored into the growth of HI services in the 1980’s. The HI pharmacy market, business models, scope of services, and standards of practice have evolved significantly over the past thirty-plus years. HI pharmacy ownership today consists of any (or a mixture of) the following:

- Corporate multi-site (privately held or public companies)
- Hospitals or health-systems
- Health insurance/managed care companies
- Independent pharmacies

Many consolidations, acquisitions, mergers, expansions, and unique business arrangements have changed the face, but not the fundamental standards, of pharmacy care for HI pharmacy.

Ambulatory care and community pharmacy services

Ambulatory care and community pharmacies in the USA primarily offer the traditional pharmacy services that are common in most developed countries. This includes drug use review and dispensing of all types of medications. These pharmacies can provide specialty injectable medications and clinical support for patients whose therapies do not require sterile compounding.

Specialty pharmacy services

Specialty pharmacy includes the clinical care management and dispensing of high cost therapies for patients with complex and typically chronic disease states. The recent growth and new product pipeline for the many oral and injectable specialty drugs, including biologics, has increased the focus on the care models needed for this aspect of pharmacy practice.¹ Many of the service models for HI care also incorporate some aspect of, and the scope for, specialty pharmacy services, particularly for therapies that require intravenous admixture and administration by clinical professionals.

Ambulatory Infusion Services

Ambulatory infusion services (AIS) support patients who require periodic or regular infusions in a structured clinic-like setting but return home after the treatment. Nurses administer the medications and usually monitor the patients for the full infusion time. In some cases, the patient receives a first dose of an infused medication in this setting and then is sent home to self-administer

future doses of the prescribed regimen as is typical for an HI patient. The pharmacy services, including sterile compounding, for AIS programs may be from affiliated or separate infusion pharmacy operations.

Clinics with infusion pharmacies

The clinic model of care is typical for hospitals, health systems, large group (physician) practices, and vertically integrated models of care, and specialized chronic or extended therapies (e.g. oncology care, immunology, gastrointestinal diseases, and neurologic diseases.) In the hospital/health system affiliated clinics, the infusion pharmacy is provided by employee pharmacists and staff, and physicians may be on staff or private attending doctors. In a private practice clinic (typically physician/group owned) the pharmacists may be employed by the clinic, or the clinic may contract with an outside HI provider for pharmacy support, depending on the volume and scope of services needed.

Vertically integrated systems can provide all levels of care from ambulatory, to clinic, to hospital, to home; they are employers of all the care providers including the pharmacy team. These ambulatory care pharmacies are generally part of a hospital or managed care system, and typically can offer vertically integrated medication support for patients receiving all levels of care.

Long term care (subacute and extended care)

While not a primary focus of their care model, long term care facilities also serve

as care sites for infusion patients. These facilities, which may be the temporary or more permanent homes for some patients, are primarily supported by in-house or long-term care pharmacy providers of non-acute services. When infusion services are needed, the pharmacies may provide them directly or contract with more specialized HI pharmacies for sterile compounding support.

Other non-hospital care services

Home care pharmacy provider organizations may also be involved in other non-acute care

services that facilitate patient independence at home. These can include any of the following:

- Home oxygen/respiratory care
- Home enteral nutrition
- Home medical equipment
- Veterinary medicine (e.g. PN for horses, IV fluids and medications for house pets.)

2. Factors and considerations for the non-hospital practice of pharmacy

There are many factors that US pharmacy practitioners must take into consideration when determining what, for whom, and how the care is provided.

The current US methods of payment for home pharmacy services

A complete discussion of the methods for health care insurance and payment is beyond the scope of this article; the limitations, financial incentives and disincentives, and disparities in coverage for medications and services all affect where and by whom alternate site/HI pharmacy care is provided.

Medicare

US Medicare coverage is available to those 65 years and older, and to those with a qualified disability. There are different types of Medicare coverage for non-hospital care. HI medications are primarily covered as an optional benefit (Part D.) The service and

supply component of non-hospital (home) infusion care is not covered by Medicare. There is a financial disincentive for patients and home care providers to provide HI therapies outside a hospital; there is some coverage in nursing homes for Medicare recipients. Thus, a Medicare patient who needs several weeks of intravenous therapy (i.e. for a post-operative infection or an osteomyelitis) may wind up in a nursing home to avoid the personal expense of HI services. The hospitals are de-incentivized financially, as well as by length of stay measures, to keep patients hospitalized solely for infusion support. The HI industry continues to push for a change in this disparate coverage. Medicare provides some coverage for home PN as well a few other drugs administered via electronic infusion devices (i.e. inotropic drugs for heart failure.)

Private health insurance

Many under-65 individuals have private health insurance, either purchased via their employer plan or through the health

insurance marketplace. Many health insurance plans use a managed care process to pre-authorize HI services, then pay a contractual amount that may or may not fully pay for the drugs, sterile admixture services, administration supplies, and clinical pharmacy services. Drug formularies and restrictions to specific providers may limit the physician and the patient choice in what and by whom the HI care is provided.

State payors (Medicaid, Child services)

Each of the individual state-funded health payors differ in what they will cover in the home care setting. If a HI therapy is covered by the US Federal Medicare program, the state funded programs will usually cover it as well. The state payor programs cover lower income individuals who do not have the means to purchase private health insurance or the extra coverage sections of Medicare.

Veterans Administration Health Plans (VA)

US service veterans have access, with certain limitations, to health care provided by the VA. Since the VA does not have its own HI pharmacies, it typically subcontracts with non-VA providers when eligible veterans require this type of care.

Uninsured (self-pay) and underinsured

Those who have no coverage under private or publicly supported health insurance are considered “self-pay” patients. Some may have health insurance, but with very high copays and/or deductibles; in these cases, they may not be able to afford to pay their out of pocket costs for HI: hence the term “underinsured.”

Despite these challenges of financial coverage disparities and their impact on access to HI pharmacy services, this area of practice continues as a viable component of the US health care system.

Location

The geographic area in which a patient resides or requires care can play a major role in where and how HI pharmacy service is provided. The US population of over 325 million people is spread over 3.8 million square miles (9.8 million km².) The population density varies greatly, with much of this population found in or near metropolitan statistical areas (MSAs).² The access to specialized health care can be much more challenging for residents of the more rural areas with lower population density; there are fewer health care providers, and they are typically for general, not specialized health care such as HI care.

Care model availability

In addition to a sterile compounding pharmacy and an experienced pharmacy team, the care model for HI pharmacy services includes a full team of health care providers: nursing services with home care and intravenous therapy experience, physicians who follow the patient and provide the orders, and access to laboratory and other care monitoring services (i.e. blood work for therapeutic drug monitoring, routine labs, and other specialized support needs such as radiology.) While some of these services can be provided remotely (lab testing, compounding/dispensing, reviewing drug regimens,) the home nursing support and periodic physician office or clinic visits work best with a local presence in the patient’s geographic region.

Law, regulations and practice standards

HI pharmacy services are covered by a variety of regulations and practice standards.

USP Chapter <797> Compounding Sterile Preparations (USP <797>) is a national compendial level standard which pertains to all practitioners, including pharmacies, who compound, store, and transport sterile preparations.³

Pharmacy practice is regulated by the individual states, and the applicable regulatory requirements can vary. Some states have their own sterile preparation regulations, while other states have adopted USP <797>. These variable regulatory requirements present challenges for pharmacy organizations which have pharmacies, or support patients, in multiple states.

Professional associations also address home pharmacy practice in their practice standards. The National HI Association (NHIA) has standards related to intravenous devices and access.^{4,5} The American Society of Parenteral and Enteral Nutrition (ASPSN) standards focus on the care process and safe compounding and distribution of PN in applicable practice settings, including home care.⁶ American Society of Health-System Pharmacists (ASHP) has several relevant guideline documents, including ASHP Guidelines on Home Pharmacy Services⁷ and ASHP Guidelines on Compounding Sterile preparations.⁸

Accreditation options for HI pharmacy

In the US, many organizations pursue accreditations for validation of compliance

with certain quality and practice standards. Some payors may require one or more “voluntary” accreditations as a prerequisite for contracting to pay for HI services. There are multiple options for pharmacy accreditation in the US.⁹⁻¹² Some of the independent accrediting agencies’ standards cover multiple areas of service, such as hospitals, long term care, and ambulatory care, in addition to home health care, home medical equipment and home pharmacy services. Others are more scope-specific (e.g. community pharmacy, compounding pharmacies, home care pharmacy, or specialty pharmacy). The accreditation process includes a review of relevant policies, procedures, patient records, and quality improvement processes; typical on-site surveys include observation of applicable patient care processes, including dispensing, compounding/sterile preparations, and clinical pharmacy services.

Acuity and monitoring requirements for admission to HI pharmacy

The complexity of the medication therapy management processes varies by type of therapy, disease state, patient acuity, and co-morbidities. Patient safety, willingness, and ability to manage complex therapies at home is always of paramount concern. HI pharmacies have admit-to-service criteria to screen and determine if a patient can be safely and economically cared for at home vs. a hospital or a nursing home. The pharmacy conducts a *preadmission assessment*⁷ against these criteria before the patient is accepted on service for HI. The pharmacist, usually in conjunction with the other professionals involved in the patient’s care, evaluates the clinical appropriateness of the therapy for HI,

if the patient is clinically stable (acuity level) for a transition to the home, any complicating co-morbidities (i.e. visual impairment, mobility issues,) if there is a qualified and willing caregiver (e.g. a family member) who can be trained to safely perform and/or support the medication administration in the home, and if there is access to ongoing laboratory tests and other diagnostic or

monitoring resources (i.e. radiology, visiting home nurses, a local physician to follow the care if the patient lives some distance from the referring /following physician.) When all or most of the key admission criteria are not met, the patient remains in or enters a hospital, or is referred for care in another setting, such as a long-term care facility or sub-acute care center.

3. Focus on Home Infusion practice

The primary focus of HI pharmacies is, not surprisingly, care in the patient's home or place of residence.

US infusion market and typical diseases managed outside the hospital

The US market for HI services has grown tremendously since it emerged in the early 1980's, spurred by reimbursement changes that encouraged hospitals to decrease lengths of stay. Various estimates place the global HI market, including infusion, to grow from \$15 billion USD to nearly \$28 billion by 2022. The 2016 NHIA 2016 estimate was revenue between \$9-11 billion USD earned by 700 to 1000 HI companies.¹³ Disease states that previously required long hospitalizations to complete courses of infusions, or frequent rehospitalizations for intermittent dosing, continue to be the largest target for the HI pharmacy provider market.

Infectious Diseases

Home parenteral anti-infectives make up the largest component of the HI pharmacy census. Treatment for osteomyelitis, cellulitis, Lyme disease, pneumonia, secondary infections in immune suppressed patients, and post-operative infections make up the mainstay or 'bread and butter' business of full scope HI providers. Most of these patients have relatively short (i.e. less than 60 days) lengths of service on HI care. Cellulitis and osteomyelitis are often seen along with uncontrolled diabetes as a common comorbidity; diabetes management patient education is a core component of the care plans for these patients, and a key to resolving infection as well as preventing recurrence.

Gastrointestinal (GI) Disorders

Patients with cancer or other conditions that require surgical interventions (e.g. short bowel) or bowel rest are usually placed on PN if they are unable to obtain sufficient

nutrition via the GI tract. When extended courses of PN are required, they may obtain all or part of their nutrients via home PN.

Scientific advances in the management of underlying GI diseases include immunotherapies, which include chronic infusions or injections of targeted immunomodulators (e.g. tumor necrosis factors.) These can often be administered in the HI setting, or in ambulatory infusion suites. Due to the risks of infusion reactions, these are typically administered by nurses rather than self-infused. Their impact on the quality of life for individuals with Crohn's Disease and other inflammatory bowel disorders (IBD) is well documented.¹⁴

Heart diseases

Heart failure, (HF) often referred to as 'congestive heart failure – CHF' is singled out as an 'epidemic' by the National Institutes of Health (NIH.) US prevalence of HF is nearly 6 million cases, with more than half a million new cases diagnosed annually. Fortunately, the incidence of new cases has remained stable while survival has increased in the past 20+ years due to improvements in therapy and earlier management of causative conditions (i.e. hypertension). Thus, HF has become a chronic disease, associated with frequent hospitalizations, morbidity, and a significant mortality rate in the over-65 population.¹⁵ The role for HI in HF has traditionally been the parenteral administration of inotropic agents for patients with advanced HF. Parenteral inotropes, coupled with other medications, are used for two major segments of the HF population: those patients who need a 'bridge to transplant' while awaiting a new heart; and those patients who are not transplant candidates, who receive parenteral inotropes

to improve their symptoms and quality of life as part of a palliative care plan.

Pulmonary Arterial Hypertension (PAH) is considered a rare disease. The complete epidemiology of PAH in the US is unknown, but it usually strikes young and otherwise healthy individuals, and women twice as much as men. Both the primary (underlying) condition and the PAH require treatment. When oral medications used for HF and PAH are not fully effective, patients may require continuous intravenous or subcutaneous infusion of synthetic prostacyclin analogues which cause pulmonary and systemic vasodilation and inhibition of platelet aggregations.¹⁶ These medications typically require continuous (nonstop) infusions due to the pharmacokinetics (very short half-life). In some cases, PAH patients also need parenteral inotropes and parenteral diuretics. These complex cases require specialized expertise in the care management process in any practice setting.

Genetic diseases

Advances in the treatment of rare genetic diseases have opened new opportunities for HI pharmacies and ambulatory infusion centers. Specific enzyme replacement therapy (ERT) infusions are used in lysosomal storage diseases, Gaucher's disease, and Pompe's disease. Chronic augmentation of Alpha-1 Antitrypsin Deficiency with an enzyme inhibitor that blocks the breakdown of alpha 1 antitrypsin has been part of the HI arsenal of treatments since this plasma-derived biologic therapy entered the market. ERTs are usually administered by a nurse in an ambulatory infusion setting. The alpha-1 inhibitor (augmentation) therapies may also be administered in the home care setting;

stable patients with no infusion reaction history typically are taught to prepare and self-administer these regimens.

Autoimmune diseases

In addition to IBD, other autoimmune disorders are responsive to infusion therapy with immunomodulators such as TNFs. While a few immunomodulators used in chronic therapies are available as self-injectable medications, some of the specific monoclonal antibodies (mAbs) must be administered via intravenous infusion. The most common of the autoimmune diseases treated with home and ambulatory infusions are IBD, rheumatoid arthritis, psoriasis and multiple sclerosis. Ongoing research and development is expected to generate even more uses for the disease-targeting mAbs which are part of the over 300 agents reported in the pharma pipeline for autoimmune diseases.¹⁷

Oncology

Conventional chemotherapy agents are not usually administered in the home or ambulatory infusion suite, with a common exception-- patients who required continuous and multi-day infusions of chemotherapy drugs (e.g. 5-Fluorouracil). The continuous infusions are typically started in the clinic setting, then managed at home for the remaining course of therapy. When a HI pharmacy is part of this care process, the team is usually involved in the preparation and dispensing of the medication, infusion device, and related IV access care support.

Some mAbs are used in oncology (e.g. breast cancer, lymphomas, and chronic lymphocytic leukemia.) With some exceptions, most of the mAbs with a place in current cancer therapy are administered in controlled settings such as the oncology clinic, rather than in HI.

Immunodeficiencies

According to the World Health Organization, there are over 300 known types of primary immunodeficiency diseases (PID.) These are rare hereditary disorders which affect one or more components of a person's ability to maintain a normal immune response. Typically, a workup for PID results when a person experiences repeat, persistent, or unusual infections requiring hospitalizations or intravenous anti-infective therapy.¹⁸ Once a diagnosis of PID is established, the treatment consists of periodic intravenous (IV) or subcutaneous (SC) infusions of immunoglobulin (IG) products. The frequency of treatment depends on the severity of the deficiency and the patient's ability to tolerate large dosages (which would be less frequent.) IG preparations are blood-derived biologic agents; when given via the IV route, IG preparations are usually administered by a nurse in the home or ambulatory infusion suite over a few to many hours.

IG preparations that are formulated specifically for SC administration have been approved in the US for several years; specialized administration sets are available to allow the dosage to be administered into multiple SC sites over a relatively shorter period than the IV route would require. Advantages to the SC infusion route include patient/caregiver control over when the infusion is started, since they are taught to self-inject and infuse with these sets and an infusion device to control the rate.

The HI pharmacy typically does not have to pool or mix IG preparations, but may do so for when needed for ease of patient use. While many of the IGs do not require pharmacy compounding, they are still treated as infusion therapies, since the overall medication distribution and care management pro-

cess is within the scope of HI and ambulatory infusion pharmacy practice.

Other disease states requiring infusion therapies

Chelation therapy for iron overload (either transfusion related, or due to non-transfusion dependent thalassemia) has been part of HI therapy for many years. With the introduction of newer oral treatment options for iron overload, the use of continuous subcutaneous infusions of deferoxamine with an infusion pump is a less attractive but still viable therapy option.

HI providers may also provide pain management therapy with intravenous, subcutaneous, intraosseous and intra-spinal infusions. Oncology, post-surgical, palliative, and hospice care patients may require short term or long-term treatments with parenteral narcotic analgesics and other adjunctive pain management medications such as local anesthetics (e.g. bupivacaine.) Intra-spinal infusions require specialized experience with ordering, preparation, care management, and patient monitoring.

Ongoing drug research and new drug approvals address a wide variety of diseases that will be managed with infused or injectable medications; we can expect at least some of these to make their way into the HI practice setting.

Unique requirements for the most common home parenteral therapies

Foundational criteria for the most common HI therapies include:

- the method of administration (electronic infusion device, elastomeric pump, IV Push or gravity infusion)
- vascular access device (VAD) requirements (Centrally placed VAD, peripherally inserted central catheter-PICC, implanted port, midline VAD, or short peripheral VAD). The VAD requirement may also be duration dependent
- appropriate for patient/caregiver vs clinician (nurse) administration
- appropriate for initial dosing in the home, if applicable
- unique care planning issues common to the type of therapy

A complete discussion of all aspects of every HI therapy is beyond the scope of this overview article (see Table 1).

Vascular access requirements in HI

One of the key factors that affect a decision to provide HI therapy is the availability of a vascular access device (VAD) that is appropriate for the therapy/drugs to be infused. The pharmacist needs to know the VAD tip placement, size, volume, number of lumens, and catheter material to determine if the medication or therapy can be managed with that VAD. This is important for many reasons: if the VAD stops functioning, the patient may miss dosages with clinical consequences of therapy interruption; if the VAD is not placed properly (i.e. not central) then irritating medications with high or low pH and/or high or low osmolarity solutions can cause chemical phlebitis inside the vein, or even cause extravasation into surrounding tissues with a result of tissue or nerve damage. The size and number of lumens may be important depending on the number of different medications to be infused as well as the viscosity of the infusate.¹⁹

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Table 1.

Unique HI therapy-specific requirements and considerations.

HI Therapy	Vascular access device requirements	Administration considerations	Unique care planning considerations
Total Parenteral Nutrition (TPN 2 in 1) Total Nutrient Admix. (TNA 3 in 1)	Centrally placed VAD, PICC, or Port. Multiple lumen preferred.	Patient/Caregiver taught. Typically uses portable ambulatory infusion pump for 12 to 14- hour infusion daily.	Patients are taught to add vitamins and unstable meds to the PN solution prior to infusion. Management and monitoring is required to ensure ongoing nutritional and metabolic needs met. Complexities of stability increase when lipids are mixed as 3-in-1 / TNA.
Anti-infectives	Therapy > 3 days—midline or central. Drug chemistry and dilution dependent, will dictate VAD as well as device selection. Dual lumen VAD preferred for multiple anti-infectives or infusion of other therapies.	Patient/Caregiver taught. IV Push, IV gravity, or elastomeric for 1-3 intermittent doses/day. Frequent dosing or longer infusions typically require a portable electronic infusion device.	Special considerations if ‘first dose outside the hospital’ is required to minimize potential for anaphylaxis. Intermittent dosing requires specialized VAD flush procedures to ensure that heparinized lines do not cause drug precipitation. “SASH” technique refers to ‘Saline-Antibiotic-Saline-Heparin’ as the sequence of flush / administration / flush / heparinization steps for each dose and each lumen used.
Inotropic Therapy	Centrally placed VAD, PICC or Port. Dual lumen preferred in case other IV therapies are needed.	Patient/Caregiver taught. Uses portable electronic infusion device.	Continuous therapy, requires backup pump so that there are no breaks in care in the event of pump failure.
Pain Management	Duration dependent. Midlines may be ok. Central VAD is best for longer use if anticipated. Intraspinal devices are typically implanted by an anesthesiologist.	Patient/Caregiver (IV, SC). Nurse (Intraspinal care and for VAD starts).	Controlled substances present challenges for drug control in the home; pain titration may require changing drugs, with equianalgesic dosing titration challenges between routes and drugs.
Biologicals (mAbs, IG)	For long term patients, an implanted Port may be desired. Generally done as single IV start for each IV dose. For SC IG, specialized multi-site sets are used. Infusion with an electronic pump or other rate controlling device is required.	Nurse infused (usually) after peripheral or midline VAD start if patient does not have a centrally placed VAD.	Many of these agents have infusion reaction warnings. Nurse controls the rate and monitors the patient during the infusion.
Steroids	Peripheral or mid line.	Nurse for VAD start. Patient/Caregiver administers.	These are shorter courses of therapy, typically for exacerbation of symptoms of Multiple Sclerosis. Patients are usually started at home rather than as hospital discharge.

4. Roles of the pharmacist in home care

Pharmacists practicing in the home care setting typically have a multi-dimensional set of responsibilities. The pharmacy practice setting is very specialized, requires practice management skills, competency and experience in clinical consultation with multiple disciplines, knowledge and application of sterile preparation methods and quality requirements, and care management skills. In small HI pharmacies, one or two pharmacists may “wear many hats” on any given day.

Practice Management

Practice management involves the knowledge and ongoing application of methods to maintain the physical plant, personnel management, scheduling, administrative infrastructure, drug information support, policies and protocols, and direct patient care services while meeting established standards of practice.

Facility requirements

Infusion pharmacies require a clean room complex for sterile preparations, pharmacy

and non-pharmacy office space, warehouse for storage of bulk items, a supply management area for the devices and disposable items sent to patients, and access control limits for non-pharmacy personnel. The clean room complex size and layout will vary with the anticipated workload and variety of compounded sterile preparations (CSP). Increasingly strict regulations now mandate compliance with USP <797> and with all the quality requirements, including incubation of test media for the air and surface sampling.

Staff requirements

Due to the complexities of the US health care payment system in the US, most HI providers have a fiscal/reimbursement as well as a pharmacy/operations component within their structure. The pharmacy operations typically take an on-call pager for afterhours support, and make a pharmacist available for questions, therapy issues, or dispensing (if needed) 24-7. The operation generally has either a driver, or retains a delivery service for safe and secure dispensing directly to the patient’s residence. In some circumstances,

a shipping service is used (in the US, United Parcel Services, Federal Express are most common.)

The 'patient care team' approach

As with all health care, a team approach is essential to maintain continuity of care within and outside the HI pharmacy organization⁷. Typical members and roles of the patient care team include:

- *Pharmacists:* Overall responsibility for patient medication management, procurement, dispensing, sterile compounding supervision, and all drug information/medication consultation. A pharmacist-in-charge (PIC) is required for the pharmacy (facility) license.
- *Pharmacy technicians:* May handle purchasing, inventory management, sterile compounding, infusion device cleaning and maintenance, and supply support. Some states require technician certification; this is strongly recommended in professional practice guidelines.⁷
- *Patient/customer services representatives:* Can be pharmacy technicians; handle some intake; routine communications with patients/caregivers, nurses, and prescribers for medication and supply refills; may also handle certain reimbursement functions (drug claims adjudication.)
- *Nurses:* Participate in the start of care/intake, visit patients prior to hospital discharge (liaisons), and conduct home visits to teach, monitor patients, and administer medications where ordered.

A supervisory nurse is responsible for the home health agency licensure when required by the state.

- *Other support staff:* Large HI organizations may have separate staff to handle the functions of patient intake, nurse scheduling, medical records management, supply management, equipment management, purchasing, shipments and deliveries, information technology support, and administrative support for the PIC and other management.
- *Finance and reimbursement:* Some organizations outsource all or part of the financial management/reimbursement function, depending on the overall organizational structure. Regardless of where this is handled, the successful payment for services depends on complete and accurate clinical, dispensing, and shipment/delivery records which are generated by the patient care team and all pharmacy and clinical functions.

Policies/procedures, staff development and competency

All aspects of the pharmacy and HI operations should be supported with useful and accurate policies, procedures, training materials, and competent staff. The leadership of a HI pharmacy ensures that these are in place, and then evaluates their effectiveness.

Written policies and procedures address all aspects of the pharmacy operation, most especially the medication use and care management process, as well as for the compounding and quality control of sterile preparations. Clinical procedures are based on evidence-based criteria, and, where

appropriate, allow for flexibility when dealing with multiple referral sources or home health agencies. For example, a policy on selection of the infusion method for a specific antibiotic will focus on the preferred options for administration device, not unduly restrict options so that a referral source is not comfortable with the decision. A solid and referenced basis for why a route or method is acceptable (e.g. IV push for a cephalosporin) should be part of a written “preferred” standardized method for IV push. When supported in written policy based on evidence and clinical expertise, the referral source or nursing agency will be most likely to accept the pharmacy recommendation.

Staff development efforts for HI are usually designed to focus on gaps in staff experience and competency, as observed or perceived by the leadership. In the US, most clinicians (especially pharmacists) are required to complete 15 to 20 hours of professional continuing education each year to maintain a practice license. Staff are encouraged to complete continuing education that is most relevant to their area of responsibility. Additional staff development efforts are usually organization-specific, focusing on changes in process, policy, equipment, and application of technology. Staff development activities become part of the pharmacy operations or human resources records, and are usually reviewed for accreditation compliance.

Clinical competency assessment is not unique to HI practice. The pharmacy outlines those competencies that must be demonstrated initially (during an orientation process) as well as periodically. The most common competency assessment is observation of technique by another qualified practitioner.

HI pharmacy staff typically complete an “observed and documented” compounding activity for each type of sterile preparation offered by the organization. This includes the complete startup of the daily procedures in the sterile processing complex, preparation of materials, gowning/garbing/handwashing, record keeping and daily quality check documentation, and the actual sterile technique used for compounded sterile preparations (CSPs) and additives to various devices (e.g. using syringes, bags, elastomeric devices, PN compounders.) Several facets of this competency assessment are also part of quality assurance requirements for CSPs—the preparation of sterile media fills that are incubated to evaluate sterile technique, followed by the ‘gloved fingertip test’ on agar plates done before re-sanitizing the sterile gloves with alcohol.

Quality programs

Every HI pharmacy has a quality assurance program. In addition to any specific requirements for state licensure and accreditation, most pharmacies will focus on the quality measures of sterile compounding and the sterile processing complex, patient satisfaction, and timeliness of services, as well as key clinical outcomes (rehospitalization rate, successful completion of the treatment (care) plan, quality of life measures, and VAD infection rates.) Performance improvement efforts can be generated from any of the measures, or from other areas of the HI operation that may require focused attention. One of the most challenging areas for compliance with policies, and a frequent focus of accreditation surveyors, is the improvement of the accuracy and timeliness of the medication reconciliation process, especially during a patient’s transition to another care setting.

Clinical consultation

Home care pharmacists have been sought out as clinical experts for medication issues since the early days of HI. The close workings of interdisciplinary care teams, and the general comfort level with telephonic and electronic communication about patient issues lends itself to formal and informal clinical roles.

Drug information and education

Most home care pharmacies do not have immediate access to the resources of a major drug information center. Corporate entities may have a clinical support 'help line' to provide policy guidance and access to literature resources. The home care pharmacists provide the patient-focused clinical consultation and education that the physicians, nurses, patients, caregivers, and other pharmacists require. This support is both case by case, as well as via training programs and other methods of education.

Drug product and infusion device selection

Most HI providers do not maintain a closed drug formulary. The drug and treatment modality selection decisions often start in the hospital. When a patient is referred for HI therapy, the physician and care team have options prior to hospital discharge to modify therapy to be most suited to the home care setting. For example, a short stability antibiotic therapy that requires multiple doses a day might be replaced with a longer stability drug that has longer dosing intervals; when the new medication is available at the hospital, the hospital should make the switch while the patient is still there to determine if the patient will tolerate it and be clinically

stable on it at home. Admittedly this is not always possible, and so the HI provider team must determine the best way to initiate a new parenteral drug safely at home or in a controlled setting such as an infusion suite, consistent with policies and protocols.

Compounding and dispensing sterile preparations (CSPs)

A complete description of the compounding and dispensing of sterile preparations in alternate site practice is beyond the scope of this paper. The techniques and procedures used for CSPs are like those in hospital pharmacies. Key differences in non-hospital CSP processes include the determination of the stability of the medication, as well as any unique supplies and administration devices not commonly used in hospitals (e.g. elastomeric drug reservoirs, ambulatory device cassettes, and dual chamber bags to keep the lipids separate from the PN solutions until activated prior to administration.)

Beyond Use Dating (BUD) challenges outside the hospital

One of the most common challenges that home care pharmacists face is establishing a beyond-use or expiration date for a CSP. The typical dispensing and delivery (refill) interval for clinically-stable HI patients is about a 7 to 10-day supply of medications. When a HI pharmacy compounds the CSPs following all established standards of practice and quality assurance, the sterility-based beyond use date assigned to home care CSPs can be up to 14 or 9 days refrigerated based on the USP <797> risk level. These dates are for CSP's prepared from commercially available, FDA approved sterile pharmaceuticals and solutions.⁷ In

addition to the USP <797> sterility-based dating, the pharmacist must also consider the chemical stability of the medication under the noted conditions and container material (e.g. PVC, glass, polypropylene, EVA, and various elastomers.)¹⁹ The BUD assigned to the CSP is the shorter of the documented chemical stability or USP sterility-based dating. Manufacturer labeled chemical stability typically does not address all the various container types and concentrations used in clinical practice. Helpful drug stability studies have been conducted and reported in the literature and container-specific product information, and are summarized in various drug information compendia. HI providers must consult these sources when establishing the concentrations and selecting the container/device type for each CSP. When there is no documented stability data for a CSP, the patient or caregiver is taught to prepare the dosage for IV administration at home; it is considered an 'immediate use' CSP with no longer than 1-hour expiration date.

Meeting USP standards for CSPs

The USP <797> standards for CSPs evolved from the USP Chapter <1206> Sterile Drug Products for Home Use, which was issued in the late 1990's. Many HI pharmacies operated clean rooms with detailed quality assurance procedures some 15 years before hospitals faced compliance challenges with the initial (2004) USP <797> requirements. USP <797> is more stringent than the former <1206> in many areas, with very detailed standards for sterile processing, specific quality assurance measures, and air and surface sampling requirements. While not a simple task, the transition from <1206> to <797> was relatively seamless for most HI pharmacies.

Role of the pharmacy technician in CSPs

Certified and highly trained pharmacy technicians conduct most of the CSP in the US. The pharmacist(s) supervise and check the CSPs. The technicians follow detailed procedures to clean and maintain the facility and equipment, and assemble the supplies needed for CSP steps. The technicians document the components used on each CSP prescription compounding record; clean and test any automated compounding devices used in CSP preparation; maintain the quality assurance records for the CSP area, and file compounding records after the pharmacist checks the CSPs. In short, the certified technicians are essential to operational efficiency of the sterile processing work flow.

Care management

The most important component of a successful HI pharmacy is the clinical focus on the patient. The HI model for care management has incorporated a clinical pharmacy component since its inception. A fully interdisciplinary approach to patient care is essential to successful outcomes, since many of the patient care processes take place physically remote from the patient.

Care planning and coordination (initial/ongoing/interdisciplinary with key providers and patient/caregiver)

At the core of care management is a patient-focused, customized care plan that is established in conjunction with all the providers involved in the care, and with the involvement of the patient and caregivers.²⁰ The pharmacist, nurse, prescriber and patient should all know the goals and any

updates to the care plan. These care planning goals, while unique to the patient, are based on evidence-based care processes for the specific disease and or therapy. Patient-focused care planning has been used in HI for at least 20 years, in most cases replacing the 'drug related problems' focus with a patient focus. The care plan starts with a preadmission evaluation (as part of intake) where any exceptions to the pre-admission protocols are noted and dealt with before the start of care (for example, how the situation might be managed if the patient does not have air conditioning in a hot climate, and the medications are temperature sensitive at the warmer than room temperature.) Once care is initiated, the plan will document the initial assessment of the patient, the specific treatment, including type of infusion device, any additional exceptions noted to the treatment protocols, and how they will be handled.

The initial patient/caregiver education is noted, again with any unique exceptions to the protocol (e.g. if the patient does not have the manual dexterity to demonstrate the ability to activate or manipulate the infusion connections without breaking aseptic technique...then the type of device or approach to drug container might be changed.)

A well-designed care plan outlines key points where interventions should occur (such as laboratory or other clinical measures), and what the patient, caregiver, or clinician should do if these occur. A good example of an anticipated intervention is the potential effect of nocturnal diuresis during overnight infusions of high volume of PN. When the patient...and/or caregiver...is unable to get a good night's rest, then the care plan might be

modified to either extend the infusion over a longer period, start it earlier in the evening, or infuse during the day time. Another predictable intervention is instruction to report on the development of any signs of infection, such as fever or redness at the VAD insertion site. This care plan reinforces what the patient and caregiver are taught by the nurse on admission, and reinforced as needed throughout the course of therapy during home visits and telephonically. Patients who receive services in the ambulatory infusion suite setting may have a slightly modified care plan, since all the assessments and the administration of medication take place in the presence of a clinician.

Clinical monitoring

Ongoing clinical monitoring is conducted by the visiting nurse, and via phone calls with the pharmacy. The infusion pharmacist does not always speak to the patient on every 'refill planning' call, but is available to address questions or concerns that the patient or any of the interdisciplinary team may have regarding medication management. When laboratory monitoring, and especially therapeutic drug monitoring are part of the care plan, the pharmacist and nurse review the labs, determine if there is any need for a recommendation to modify the medication regimen and/or care plan, and confer with the physician as required. And the patient should always be kept in the loop for these discussions and any changes. For example, consider a patient receiving vancomycin therapy where a trough is too high. First the pharmacist and nurse will verify the timing of the labs vs when the patient completed the prior infusion. If what is referred to as a 'critical lab value' turns out to be accurate, then after consultation

with the physician, there may need to be an adjustment in the therapy, possibly including holding doses, then resuming the same dose at a specified time but with a longer interval between doses. This allows for use of the doses already dispensed and in the home. If a dosage change is required, a replacement prescription order is obtained and dispensed, with plans for another trough at the appropriate time based on pharmacokinetic parameters. This is documented in clinical notes which also specify the modification to the care plan and the next steps planned. While most of these steps are very similar to the management of vancomycin in an acute care setting, the logistics of HI come into focus when immediate changes in therapy are required.

Huddles and morning meetings

HI providers conduct 'morning meetings' which are like a "start of shift report". Key participants from all areas review what is scheduled for the day, any issues that arose with patients from the on call report the night before, and any known pending new patients or anticipated discharges of patients that have been hospitalized while receiving HI care. This touch-base meeting might be an 'all hands' listen in; for larger organizations, it may be divided up into care teams with assignment for a designated group of HI patients. HI pharmacists and teams can plan

at the start of the day what can reasonably be expected.

"Huddles" take their name from a 'mid-game' quick team 'regroup' to plan for the next play in American football. Whenever a new patient referral is received, when a readmission to home care occurs with a new therapy, or if a significant change is needed for an active patient (i.e. change the drug therapy to a different drug,) then key team members meet to review the preadmission or new information and conduct or confirm the evaluation that will become the start of the new care plan.

Huddles and morning meetings are usually conducted in person; however, with remote telecommunications technology, always mindful of patient privacy issues, these may be conducted virtually for efficiency of communications.

Transitioning off service

Although home care patients are already at home, the pharmacy 'discharges' them from service when the therapy ends or if they change their site of care, such as to a nursing home or to the care of another home care provider. The clinical team documents the outcome of the therapy in a clinical note, and when a transition is required to another provider, a brief history and medication reconciliation record is provided to accompany the patient.

5. The future for home care pharmacy in the USA

Despite some of the reimbursement and payment challenges that still exist in 2017, home care pharmacy has remained viable and grown over the past 40 years. With lobbied for and anticipated improvements in the payment models for HI, this market can remain viable. Demonstration projects related to continuity of care for ambulatory and home patients should help to convince legislators and payors of the safety and economic value of HI pharmacy services. The face of the HI industry continues to shift to more corporate and hospital-owned rather than independent home care pharmacies. Corporate entities which are also managed care organizations,

pharmacy benefit managers, and other payors have purchased or partnered with HI providers to more vertically integrate their care as well as to gain increased control over the expenditures and outcomes. Pharmacists who have worked in many practice settings over the years continue to flock to this care setting, despite the long hours and late night on-call pages. It is a very professionally rewarding area of practice, one that allows them to contribute to and see the end results of the care processes for these higher-acuity and the successful management of chronic care patients.

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