

Sites of Infusion Care report

Helping providers make strategic decisions





Background

With the continued post-COVID-19 shift from treating patients in the inpatient setting to ambulatory settings, outpatient volumes are expected to grow 16% over the next decade, outpacing estimated population growth by 3%.¹ Continued shifts in sites of care to locations outside of the hospitals due to payer mandates could bring an additional 25% growth in ambulatory surgery centers, as well as 18% growth for physician offices and hospital outpatient departments by 2032.¹

Ambulatory infusion services provided by hospital-based infusion centers, physician offices and home infusion companies is a growing segment of the healthcare market. Three major factors have contributed to the expansion of ambulatory services:²

- A consolidating market to meet increasing demand of patient consumerism and convenience while lowering cost and focusing on population health
- New technology and techniques such as medical advancements in surgery, telehealth and data systems
- Payment reform and reimbursement particularly focused on the Center for Medicare and Medicaid Services (CMS)

Like the advancements in medical technology, pharmaceuticals have exponentially advanced with new infusion drugs available to treat numerous disease states, many of which can be administered in ambulatory environments.

Overall, outpatient ambulatory services create capacity and easier access for patients while keeping them in a single health system or hospital and can translate to an overall lower cost of care. Important elements to consider in determining the best site of care for infusions include patient safety, medication safety, payer restrictions, medication cost and reimbursement.

Infusion service locations

Historically, health systems have provided ambulatory infusion services in an integrated delivery network (IDN) or hospital-affiliated clinic and accessed the system's pharmacy, nursing and revenue cycle resources to prepare, administer and charge for medication infusions. However, charges for these infusions tend to be higher than other sites of care due to the high overhead costs associated with the around-the-clock nature of hospital care and high regulatory compliance requirements (e.g. USP standards). As payer rules continue to direct the infusion of outpatient drugs to alternate settings, health systems need to have a strategy to meet the requirements. These approaches include having the ability to provide service in various nonhospital-based practice settings including provider offices, free-standing infusion centers, the patient's home and pharmacy infusion suites. Table 1 provides a summary of the characteristics of each of these areas.

Table 1. Infusion site characteristics

Site of care	Workflow	Billing method	Pros³	Cons ³
Hospital-based infusion center or hospital outpatient	Medications are purchased by the hospital, prepared onsite in USP-compliant clean rooms and administered by skilled nursing staff	Through hospital billing system with place of service 19 and 22 Subject to PO, PN, TB, JG modifiers	 Best option for complex patients Better equipped to handle emergency situations Established clinic workflows Equipped to handle hazardous medications, sterile compounding and coordination of care Electronic medical record can handle multi-drug orders and labs Abides by CMS and Joint Commission standards 340B eligibility associated with hospital NPI 	 Charges reflect hospital mark-ups due to greater overhead needed in higher acuity settings that provide continuous care Patient co-pay often higher than for physician's office
Physician's office or provider-based infusion center	Medications are purchased by provider, prepared onsite by office staff and administered by skilled nursing staff	Billing as an independent entity with place of service 11 – office	 Patient familiar with office staff and knows their insurance is accepted Generally, least expensive for patients and payers Provider (physician, PA, NP) onsite 	Variability in workflows and clean rooms for preparation of sterile and/or hazardous medications
Freestanding infusion center or ambulatory infusion site	Medications are prepared onsite or off-site at an infusion pharmacy and delivered to the infusion center for administration by skilled nursing staff	Billing with place of service 11 – office or 49 – independent clinic	 More flexible hours to accommodate patient schedules Lower operating costs, resulting in lower costs to the patient and payer 	 Lack of well-designed workflows or clean rooms to prepare sterile and/or hazardous medications Less equipped to treat infusion or adverse reactions May not include direct physician oversight No access to 340B drug pricing program
Home infusion	Medications are prepared by a home infusion pharmacy and delivered to the patient's home for administration and/ or self-administration training by skilled nursing staff	Billing with place of service 12 – home	 Patients often prefer home care Increased access to diverse medications in the home setting Payer mandates preferring home infusion 	 Not all medications are appropriate to be given in the home Less equipped to treat infusion or adverse reactions Very limited Medicare coverage
Pharmacy infusion suite	Medications are prepared in an adjacent or nearby infusion pharmacy, delivered to infusion suite and administered by skilled nursing staff	Billing with place of service 11, 12 or 49 based on payer contract	Potentially greater adherence to compounding and accreditation standards	 Generally limited number of infusion chairs Very limited Medicare coverage

Abbreviations: USP = United States Pharmacopoeia; CMS = Centers for Medicare and Medicaid Services; NPI = National Provider Identifier; PA = Physician's Assistant; NP = Nurse Practitioner

Clinical considerations

To determine site of care eligibility, clinical considerations at the individual patient level must also be considered. Individual patient factors such as proximity to the infusion center, need for social support or survivorship resources and nursing availability at the various sites should be taken into consideration. Additionally, certain medications have a high risk of infusion reactions, and hospital or provider-based infusion centers are better equipped to respond to potential medical emergencies.

It is important to consider both the financial and safety implications of infusion location as well as the impact on patient experience when selecting an infusion site. When dealing with complex patients, peer-to-peer conversations with payer clinical personnel is often required in order to gain approval to obtain exceptions to site of care restrictions and administer the medication in a hospital outpatient setting. These exceptions to site of care restrictions may include physical or cognitive impairment of the patient, vascular access issues or potential lifethreatening adverse events.

Financial and operational considerations

Overall, the goal for both health systems and payers in determining the most appropriate site of care is to lower the cost of healthcare services while providing safe, effective and efficient care. Factors such as medication cost, estimated reimbursement, payer requirements, individual patient factors and clinical outcomes must be considered.

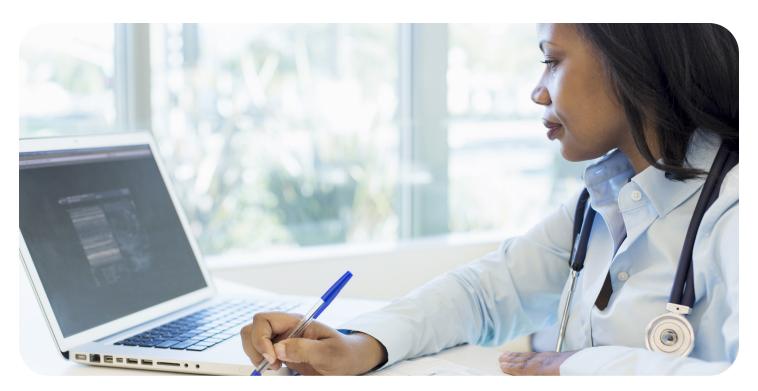
Cost and reimbursement

Medication acquisition cost will be different in each location of service based on the class of trade, contract availability and 340B participation. In general, 340B offers the lowest cost of goods followed by hospital 'own use'.

Reimbursement also differs by infusion site and is based on Medicare, Medicaid and commercial payer mix.

- Medicare Part B covers most infusion services in the hospital and provider-based setting; however, coverage is often limited for standalone and home infusion sites.
- Commercial payer reimbursement varies based on the individual contracts. Health systems may opt to negotiate a lower reimbursement rate with payers to continue providing the service in their hospital-based outpatient clinics rather than referring the patient to an alternate site.

Prior to scheduling an infusion, a benefits investigation should occur to determine any payer site of care mandates, prior authorization requirements and patient financial assistance needs. The leading practice for a health system is to have a centralized infusion referral team that handles all outpatient infusion requests. This team of experts would have advanced knowledge of payer requirements and the ability to navigate the patients to the most economical site of care for the patients and health system. For payers that do not have site of care requirements, this team can optimize which process would meet patient preferences and optimize patient out-of-pocket expenses and health system reimbursement.



Payer mandates

Over the past few years, there has been an increased focus on the cost of infusion medications by payers who are attempting to contain the rising spend on high-cost drugs administered in outpatient settings. Historically, hospital-based infusion centers and physician offices have operated under a "buy and bill" model in which the provider purchases the medication and bills the payer for the product and related administration fees. Payers would reimburse based on a standard markup of drug purchase price (Medicare) or a percentage of charges (commercial payers), both through the patient's medical benefit.

Several factors have prompted insurance plans to further scrutinize infusion management. First, the increasing number of specialty medication approvals coupled with the high cost of these medications has become a large target for reducing healthcare costs. Second, there is more awareness of the varying pricing programs (e.g., 340B) and markup practices in health systems. Finally, the integration of health plans with pharmacy benefits managers and employer-sponsored health plans allows more transparency into the variation in charges across different infusion sites.

As a result, payers have implemented various siteof-care policies, including requirements for formulary medications, requirements for prior authorizations and specialty pharmacy utilization and embedding medical necessity requirements for patients using hospital-based infusion centers.

In some cases, payer-mandated white bagging policies require that infusion medications be dispensed from third-party pharmacies. ^{4,5} To avoid the relatively higher medication charges from the provider, insurance plans pay the third-party dispensing pharmacy, often one owned by or affiliated with the plan, for the medication and pay the infusion provider for the administration services. These payer-mandated white bagging policies introduce potential issues with medication chain of custody, create access barriers for patients and complicate the established workflow at the infusion sites.

One strategy to bypass white bagging policies is to utilize the health system's specialty pharmacy to provide the medication through the pharmacy benefit. Previously referred to as clear bagging, the emerging concept of gold bagging represents the scenario where the health systemowned specialty pharmacy fills a prescription and delivers it to the final place of administration, often on the same campus as the hospital, provider office or infusion clinic. Gold bagging enables the health system to control the chain of custody of the medication throughout the process, share electronic medical record documentation with all parties and facilitate delivery to the specific appointment location.

Site-of-care considerations provide an opportunity for health systems and prescribers to optimize the patient experience while being good stewards of healthcare utilization and expenditures. With the predicted growth over the next 10 years, health systems need to have site-of-care service options for their patients and ways to evaluate and direct patients to the most appropriate site of care.

Develop a winning strategy

- Identify a multidisciplinary team to evaluate current health system infusion landscape (Appendix 1)
- Evaluate current infusion locations affiliated with your health system
- Create a workflow / centralized referral process to optimize the infusion location
- Educate providers and the care team on the health system ambulatory infusion referral process
- Determine if additional sites of care (e.g., freestanding infusion centers, home infusion program) are needed and align with the health system's strategic plan
- Review current available pharmacy contracts for individual sites of care
- Engage with finance and managed care to optimize payer contracts and reimbursement
- Leverage existing pharmacy services for clear bagging options

How Vizient can help

Vizient has proven expertise in helping hospitals and health systems evaluate and grow their pharmacy offering, ensuring its strategic place at the table. Additional resources are available including:

- · White Bagging 101
- · White and brown bagging impact report
- Home Infusion Market Report
- Site of care database

Vizient experts help evaluate and implement your winning site of care strategy, key to improving access and ensuring continuity of care across the health system. We offer comprehensive consulting services for personalized assessments and strategic planning. Reach out to our advisory team at pharmacyquestions@vizientinc.com for further information.

Appendix 1. Infusion gap analysis / Self-assessment

Evaluating the opportunity: Complete this self-assessment to determine current operations and develop an outpatient infusion strategy.

Questions

Infusion volume

How many outpatient infusion orders are currently being placed at your health system each year?

What infusion center models are currently in place?

Where are the locations in your health system that are ordering outpatient infusions? What is their primary service line?

What is the current mix of infusion orders being sent to your hospital-based infusion center, physician-owned infusion center or outside facilities?

How many infusions are ordered from 340B eligible locations?

What revenue is currently generated from hospital-based infusions?

How many of your hospital-based infusions would be appropriate for home infusion therapy?

Referral program

Do you have a referral program for infusions?

Which team members are currently involved in the infusion referral process?

Who currently completes benefits investigations for patients receiving infusions?

Do you currently have a medication assistance program?

Who is your organization's champion for creating a centralized referral process?

Which service line leaders need to be engaged for successful implementation?

Have you included the health system's finance and payer contracting teams in your discussions?

Payer

What are the top five payers for patients in your health system?

What are the payer policies for site-of-care requirements and white bagging?

Does your health system have a white bagging policy and procedure to ensure compliant reporting of billable vs. non-billable administered medications?

Operations

Where is the clinical and operational expertise in your organization that should be involved in your strategy?

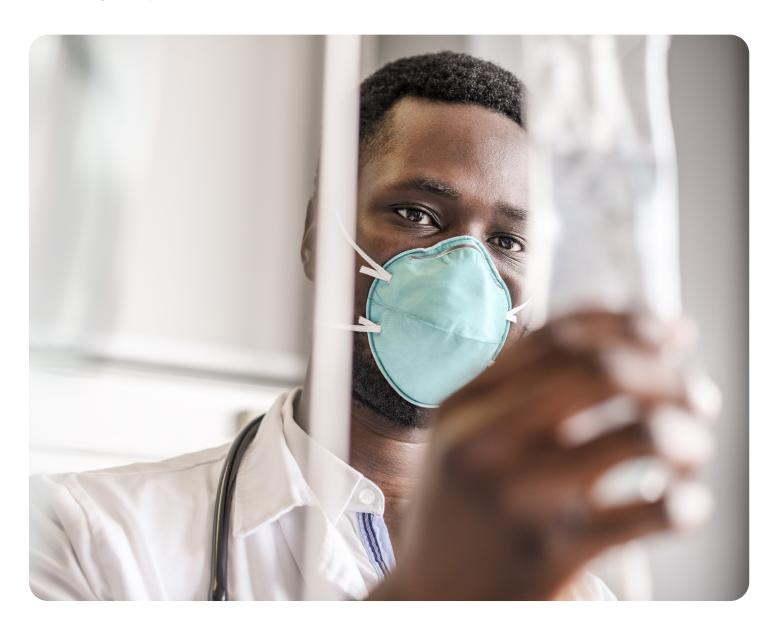
Does your health system have its own specialty pharmacy?

Which payer contracts include your health system retail and/or specialty pharmacy to allow for clear bagging opportunities?

Have you created a workflow to standardize your clear bagging process?

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