

Impact of Pandemic-Related Drug and Supply Shortages on the Home and Alternate Site Infusion Industry

Background

National shortages of drugs and parenteral nutrition components have been a chronic problem in the home and alternate setting for many years, however shortages of critical disposable supplies such as personal protective equipment (PPE), single-use catheter flushing solutions, and administration sets were especially burdensome for infusion providers during the pandemic. Shortages of disposable supplies during the pandemic were a result of unprecedented demand, manufacturing delays, transportation logjams, and scarce raw materials.

Pre-pandemic, approximately 220 medications were listed on the American Society of Health-System Pharmacy's (ASHP) Drug Shortage list. Additionally, a large proportion of the medications in shortage are sterile injectables used to compound parenteral nutrition (PN). PN is routinely compounded into individualized formulations by home infusion pharmacies from approximately 24 ingredients, 17 of which have appeared on ASHP's shortage list at some point in the past year. During the pandemic, shortages not only represented a significant threat to patient care, but they added to the stress on clinicians who were dealing with the personal threat of COVID-19 and increased demand for home-based care. The added stress placed on the health care system as a whole has been well documented, however the direct cost increases from shortages have not been assessed and quantified.

Significant cost increases for PN components and disposable supplies are of particular concern for the home and alternate site infusion industry due to the reimbursement structure used by most payors of the service. Disposable supplies are bundled with professional services, equipment, and administrative costs and paid as a set amount to the provider each day the patient infuses the medication. In most cases, drugs are billed separately, so as the cost for a drug increases over time, the indexed allowable for the drug also tends to increase. The exception to this rule is drugs that are considered standard ingredients in PN. Unlike other therapies where drugs are billed separately, standard PN nutritional components are all bundled into the per diem payment. Standard ingredients for PN include items such as: non-

specialty amino acids, concentrated dextrose, sterile water, electrolytes, standard multi-trace element solutions, and standard multi-vitamin solutions.

While the per diem payment model is well-established and has proven highly successful in creating broad access to home infusion services, it leaves providers vulnerable to economic shocks created by shortages or policy changes that impact items and services included in the payment bundle. With reimbursement relatively fixed, patient care providers have almost no flexibility to offset the rapid increases in acquisition costs resulting from shortages and providers have little choice but to pay for the needed ingredients to ensure patient's nutrition needs are met.

This paper summarizes the impact of cost increases incurred by home and alternate site infusion providers during the pandemic years, however we acknowledge there are likely additional factors at play other than shortages. For example, the Food and Drug Administration's (FDA's) unapproved drug initiative reviewed products that preceded the modern approval process. The result was that several PN ingredients that had been previously available as generic products were removed from the market and replaced by branded products at much higher prices. Most notably in 2019, American Reagent reformulated intravenous selenium resulting in a 1200% price increase. While it is not possible to attribute every price increase to a specific cause, the data indicates that pandemic-related shortages likely had the most significant impact on provider's costs.

Data Collection

The National Home Infusion Association (NHIA) partnered with a distributor of disposable infusion supplies and an infusion pharmacy software vendor to collect data related to acquisition costs for disposable supplies and PN ingredients over a timeframe of several years, including 2020 and 2021, considered the peak pandemic years.

Data for 223 stock keeping units (SKUs) were analyzed and aggregated into 17 item groups to determine prices as well as back order and allocation status in 2021.

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TABLE 1
Infusion Disposable Items on Back Order/Allocation and Associated Cost Increases

Category	Item Groups	SKUs	Allocation / Back Order	Category Avg Annual Increase %
Catheter Care	Extension Sets	6	No	10%
	Needle-Free Connectors	3	No	
	Pre-Filled Syringes	7	Yes	
	Dressing Change/IV Start Kits	3	Yes	
	Disinfecting Caps	3	Yes	
	Securement Devices	4	Yes	
	IV Catheters	11	Yes	
Pump Disposables	Elastomerics	11	Yes	12%
	Infusion Pump Sets	31	Yes	
	Enteral Feeding Sets	13	No	
Admin Sets	Flow Regulator Sets	2	Yes	7.5%
	IV Admin Sets (Gravity)	2	Yes	
	SCIG Sets	44	No	
Compounding	EVA Bags	11	Yes	10%
	PPE	14	Yes	
	Admixture (Syringes, bags, spikes)	54	Yes	
	Disinfectants	4	Yes	
TOTAL		223		9.88%

The 17 groups were further organized into 4 primary categories of supplies: catheter care supplies, pump supplies, administration sets, and compounding supplies (see Table 1).

To assess the year-over-year costs associated with PN ingredients, 12 pharmacy locations provided cost data related to the preparation of PN bags over a 6-year period using a custom report built by the software vendor to accomplish this project. The report quantified the cost per bag of PN by calculating the annual aggregate weighted average of the acquisition cost of all drugs and supplies utilized to prepare each bag of PN. Only drugs added to the bag of PN by the pharmacy were counted for in this report. Drugs dispensed separately to the patient for addition to the bag just prior to administration were not included. This per bag cost

also does not include the equipment and supplies used to administer the PN or the catheter care supplies used to maintain the vascular access device (VAD).

Results

Infusion Disposable Supplies

Of the 17 item groups assessed, 12 groups contained SKUs that were on backorder or subjected to an allocation process in 2021. All groups in the compounding category contained SKUs that were on backorder or allocation at some point in 2021. The pump disposables experienced the highest average increase in cost at 12% annually. The mean overall cost increase for all 223 disposable supplies SKUs in 2021 was 9.88% (see Table 1). Prior to 2021, the typical cost increase was reported by the distributor to be on average 5% annually.

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PN

A total of 402,940 bags of PN were included in this analysis from 12 home infusion providers. During the pre-pandemic years analyzed (2016-2019), ingredient costs rose on average 4.34% per year. In 2020 and 2021, the peak pandemic years, PN ingredient costs increased by 16.44% and 13.52% respectively. The cumulative 5-year price increase per bag of PN is 50.12% over 2016 costs (see Table 2).

Discussion

Shortages of PN ingredients and infusion-related disposable supplies resulted in substantial cost increases to infusion providers. This was the case during the peak pandemic years, and despite some relief within the supply chain, persistent inflationary pressures have extended cost increases to the present day. In addition to higher direct product costs, home and alternate site infusion providers continue to dedicate significant staff time to procuring essential supplies and PN ingredients to support the growing demand for home-based services. When demand exceeds available supply, infusion pharmacists and dietitians coordinate with patients and referring practitioners to allocate PN ingredients to populations that need it most.

Temporary government funding in the form of pandemic-related provider relief funds may have helped some providers weather the high cost of goods in the short term, however payor reimbursement has not kept pace with infusion providers' actual cost of doing business since the pandemic began. Unless insurance plans adjust contracted rates to reflect higher costs, patients dependent on home infusions are at risk of losing access to these highly specialized services. Long-term solutions are needed to ensure home and alternative site infusion services remain viable and readily available to patients across the U.S.

TABLE 2

Cost of PN Ingredients 2016-2021 and Percentage Increase for Previous Year

	Bags of PN	Increase from previous year
2016	62,800	—
2017	64,502	3.18%
2018	66,976	6.43%
2019	65,259	3.42%
2020	71,651	16.44%
2021	71,752	13.52%

Solutions

NHIA recommends payors consider the increased cost of items and services included in per diem payment bundle as they negotiate rates with providers and ensure that payment reflects the complexity of the care being provided. Additionally, payors should review their PN payment policies to ensure they align with the HCPCS code description and allow providers a to bill separately (outside of the per diem) for lipids, specialty amino acid formulas, and other non-standard drugs. NHIA's National Coding Standard for Home Infusion Claims includes details on which PN drug ingredients are considered standard and which should be billable separately.

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1 Provider Relief Funds, <https://www.hrsa.gov/provider-relief>
2 NHIA National Coding Standard for Home Infusion Claims, https://nhia.org/wp-content/uploads/2023/01/NHIA_Code_Std.pdf