DRIVERS OF CHANGE

Top drivers of change in the infusion market

Three key drivers reshaping the infusion services landscape

The infusion services landscape has consistently grown and evolved over the past several years. In this report, we outline three of the major trends shaping the infusion market today, with an eye towards the impact of policy, competition, and new treatment options.

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Read time – 10-min read

Audience

- All healthcare organizations

Advisory Board

Introduction

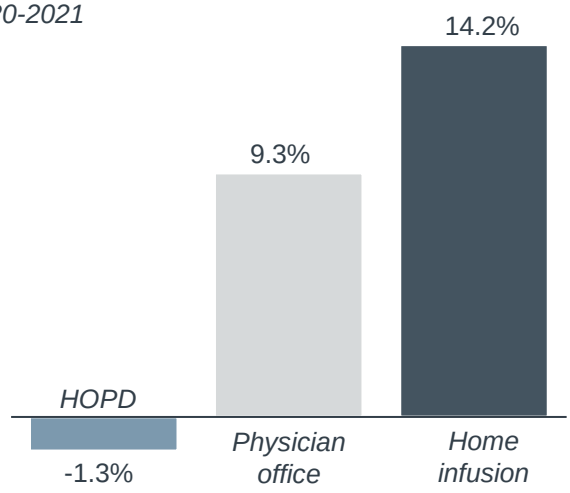
Outpatient oncology and non-oncology infusion volumes have steadily risen over the past several years. This growth is likely attributed to market forces such as an aging population, a rise in chronic disease prevalence, and new infusion treatment options. The U.S. Food and Drug Administration (FDA) has approved a steady stream of infused drugs over the past several years. As of September 2022, half of all novel drugs approved by the FDA were infused medications.

Outpatient infusions are shifting out of hospital outpatient departments (HOPD)

While the infusion market is growing, it's also shifting, moving out of HOPDs and into alternative sites of care such as physician offices and patient homes.

Growth in national claims volumes for specialty medications covered by the medical benefit, by site of care

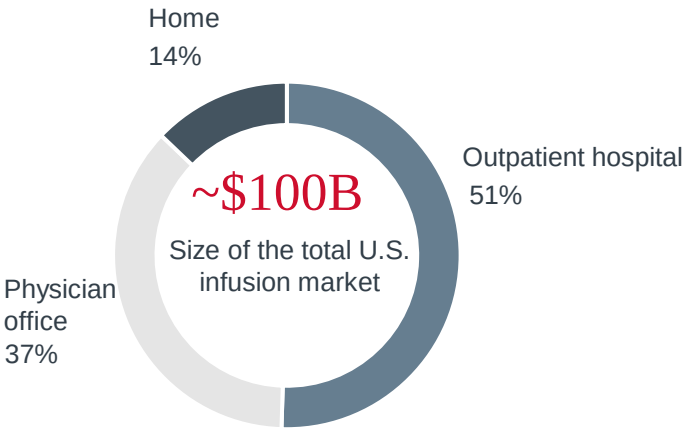
2020-2021



Still, HOPDs were the largest percentage of commercial spend for provider-administered infusion care in 2021.

Percentage of commercial spend on specialty medications covered by the medical benefit, by site of care

2021



Source: "New Indications and Dosage Forms for Existing Drugs," Drugs.com; "Novel Drug Approvals for 2022," U.S. Food and Drug Administration; "Novel Drug Approvals for 2017," U.S. Food and Drug Administration; Pharmaceutical Strategies Group, Armetrx State of Specialty Spend and Trend Report,, 2022; "Pharmacy and Infusion Services Market Update," Harris Williams, October 2021.

Drivers of change

SECTION	DRIVER	CHANGE
01	**A shifting policy environment**	New state and federal legislation and updates to existing policies are poised to impact the way that infused medications are developed, priced, and reimbursed, creating uncertainty across stakeholders.
02	**An increasingly competitive market**	Bolstered by new drugs and patient preferences, payer site-of-care policies are driving infusions outside of the hospital to sites where they are cheaper to administer and where there is lower perceived risk of exposure to COVID-19.
03	**New treatment options**	From biosimilars generating billions of dollars in savings, to cell and gene therapies with their high price tags, every new drug iteration and novel therapy further complicates infusion economics—offering many patients expanded treatment options but nebulous financial impacts.

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TOOLKIT
Resources to optimize infusion center business and operations

01 A shifting policy environment

What's happening?

New legislation and updates to existing policies are poised to impact the way that infused medications are priced and reimbursed. In 2022, Congress passed the Inflation Reduction Act, which includes an inflation rebate penalty and Medicare price negotiation. The 340B program also came under judicial scrutiny in 2022, and the Centers for Medicare and Medicaid Services raised their reimbursement rate for 340B drugs to average sales price +106% for the last three months of 2022 and into 2023. At a state level, legislation related to infusion care is moving more slowly. Despite 13 states introducing white bagging regulation in 2022, none of the bills were passed.

Policy	Implications for infusion care
340B Drug Pricing Program	• 340B institutions will see nearly $2 billion in additional revenues in 2023 • There is uncertainty regarding how long the increased rate will stay
Inflation Reduction Act	• Cost of infused drugs may rise at a slower rate than previous years • Negotiation for top drugs may mean lower reimbursement to providers • The cost of new-to-launch drugs may increase
State white bagging legislation	• State-specific white bagging regulation is unlikely to stop the practice Infusion providers will continue to see operational and financial challenges as white bagging replaces buy-and-bill

Why does this matter today?

Each of these policies sparks an array of questions. The Inflation Reduction Act may prompt manufacturers to change their drug development, launch, and competitive strategies. While the courts seem to have settled the most recent 340B reimbursement challenge, debate continues about the use of contract pharmacies. States appear to be losing momentum to advance white bagging legislation, which may mean white bagging is here to stay barring a federal spotlight. Ultimately, the shifting policy landscape will require infusion stakeholders to remain agile and responsive to any ripple effects.

Source: Sachs R, "Understanding The Democrats' Drug Pricing Package," Health Affairs, August 2022; "Calendar Year 2023 Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System proposed rule," CMS, July 2022; National Conference of State Legislators, Prescription Drug State Bill Tracking Database, 2015-Present.

Potential impacts of industry actions

Impact to stakeholder expected to be: + *Positive* − *Negative* ? *Too soon to tell*

+ **Governments** will potentially reduce health spending on high-cost drugs.
? **Health plans** may renegotiate drug prices following the government's lead but will likely also investigate other strategies, such as white bagging, to lower spend.
+ **Patients** will potentially save on out-of-pocket infusion drug costs.
− **Pharmaceutical companies** will face increasing regulation and reduced revenue from Medicare negotiation.
? **Providers** may see higher drug-related reimbursement in the near-term if they participate in the 340B program, but other providers will likely see decreased reimbursement and all infusion providers may see a revenue hit if the Inflation Reduction Act lowers drug prices.

Expected stakeholder actions

- **Health plans** will evaluate strategies to lower plan spending on infusions, such as following the government's lead in renegotiating lower drug prices with manufacturers, especially when white bagging is not an option.
- **Health systems and physicians** at 340B-eligible health systems will see a short-term increase in drug-related reimbursement. However, the broader reimbursement trend for infusion providers is negative, which will likely spur strategic changes related to resource allocation.
- **Life science companies** may look to shift their drug development and competitive strategy to guard against revenue losses due to increasing regulation, allocate the financial burden appropriately according to their business needs, and take on the right amount of risk.
- **Patients** enrolled in Medicare are anticipating lower out-of-pocket costs for drugs negotiated by Medicare under the Inflation Reduction Act, which may enable more patients to consistently access medications that previously were unaffordable.

Source: Advisory Board interviews and analysis.

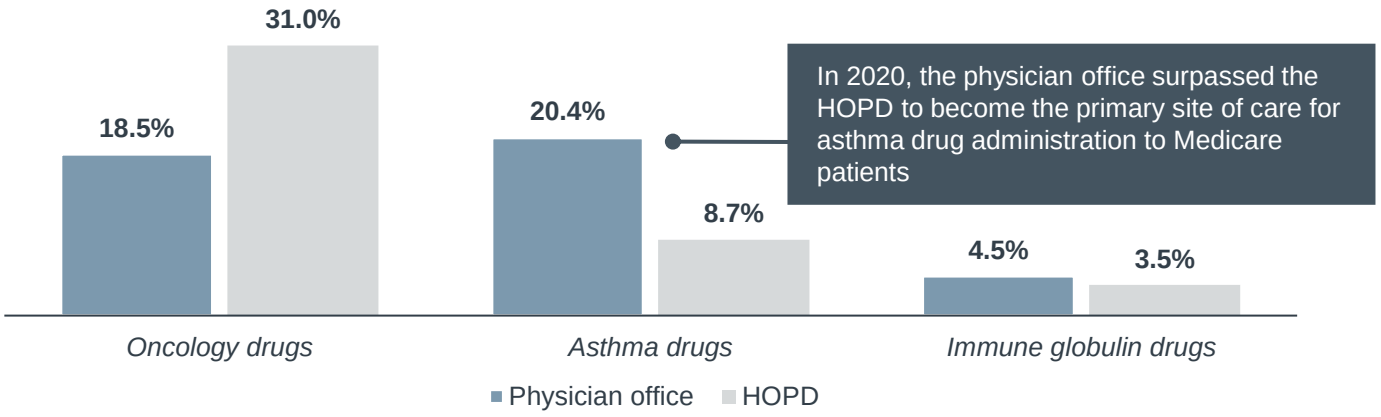
02 An increasingly competitive market

What's happening?

Over the last few years, payer site-of-care policies have driven infusions outside of the hospital to sites where they are cheaper to administer and where there is lower perceived risk of exposure to COVID-19. There is increasing evidence that providing many infusions outside of the hospital is safe, especially with newer drugs that have fewer side-effects. Patients are also more open to freestanding, clinic-based, or home infusion, especially when that care is less expensive and more convenient.

Growth in Medicare utilization[1] of select physician-administered drugs, by site of care

CAGR,[2] 2017-2020



Why does this matter today?

While health systems and physician practices have traditionally dominated the business of providing infusions, other players are now investing in this market. Private equity firms have recognized the potential for high revenues in the infusion business and are buying and expanding freestanding infusion providers. National payer organizations are building out their own infusion services and attempting to capture volumes from traditional providers. In response to growing competition in the market, health systems and physician practices are expanding their infusion footprints by building new sites of care that may appeal to patients and payers.

1. Utilization reflects units billed of certain drugs, selected because they are often subjected to payer white-bagging policies.
2. Compound annual growth rate

Source: "Calendar Year 2023 Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System proposed rule," CMS, July 2022.

Potential impacts of industry actions

Impact to stakeholder expected to be: + *Positive* – *Negative* ? *Too soon to tell*

? **Health plans** will potentially increase their ability to generate revenue and/or lower costs through offering integrated infusion care.

– **Health systems** will face increasing competition for infusion patients and may have to send patients to lower-revenue sites of care or out of the health system completely.

? **Patients** will have more options for care, either increasing convenience or stress.

+ **Pharmaceutical companies** may see an increase in patient access to their drugs as patients explore new, lower cost options for care.

? **Private equity** firms will see an unknown return from the millions of dollars invested in infusion providers.

– **Providers** may struggle to oversee care for patients receiving treatment at new locations.

Expected stakeholder actions

- **Health plans** with a national scope will continue to add infusion providers, which may put pressure on smaller plans to do the same. Health plans will assess whether investing or partnering to provide infusion services best balances patient choice and access with potential cost.
- **Health systems** will continue to face increasing competition from lower-cost infusion providers. To stay competitive, they may consider factors such as payer mix, case mix, and local market dynamics in determining whether to offer non-HOPD infusion sites of care.
- **Life science companies** that manufacture infusion treatments will see more patients access medications from non-HOPD infusion sites. These manufacturers should consider how to demonstrate the value and safety of their products across these different sites, such as by launching community-based clinical trials with home infusion options.
- **Patients** may feel overwhelmed by the proliferation of infusion care options, especially if patients can't receive care at their preferred location or their infusion provider doesn't proactively coordinate care with their referring provider.
- **Physicians** will further develop their role in coordinating infusion care. Physicians are likely to evaluate whether available infusion options are convenient and cost-effective for their patients, or whether there is value in offering these services directly.

Source: Advisory Board interviews and analysis.

03 New treatment options

What's happening?

New drugs are entering the infusion market.

- Biosimilar adoption has grown rapidly in recent years, with utilization growing by 81% from 2020-2021. This adoption has already led to billions of dollars of savings.
- Cell and gene therapies are entering the market with high price tags. As of September 2022, there are 25 cell and gene therapies on the market, with more expected to launch before the end of the year.
- Manufacturers are pursuing new formulations for drugs already on the market, moving towards faster infusions and injections.

81%

Increase in biosimilar utilization from 2020 to 2021

$3M

Cost of Skysona, a gene therapy treatment launched in September 2022, the highest price tag to date

Why does this matter today?

As new drugs enter the market, the infusion landscape grows more complex. The coming years will bring waves of new biosimilar launches and patent expirations for top infusion drugs. At the same time, spending on cell and gene therapies will balloon as an estimated 1 million patients are treated between 2020 and 2035. New drug formulations will reduce infusion times, expanding infusion center capacity and increasing the feasibility of care delivery outside of the HOPD. Coverage for these treatments may also shift from the medical to the pharmacy benefit, which may place more cost sharing burden on patients, depending on their benefit design.

Sources: "Drug Channels Update: Buy-and-Bill Market Trends," Drug Channels Institute, September 2021; "State of Specialty: Spend and Trend Report," PSG, August 2022; Liu, A., A $3M gene therapy: Bluebird bio breaks its own pricing record with FDA approval of Skysona," Fierce Pharma, September 2022.

Potential impacts of industry actions

Impact to stakeholder expected to be: + *Positive* – *Negative* ? *Too soon to tell*

? **Health plans** will face new complexities in managing new drugs along with greater flexibility in determining formularies for both medical and pharmacy benefits.

? **Patients** may benefit from new treatment options or see higher out of pocket costs.

\+ **Pharmacy benefit managers** may benefit from drugs moving from provider-administered to self-administered formulations.

\+ **Pharmaceutical companies** may reach new patient populations and ward against competition.

? **Providers** will see new therapies offer cheaper alternatives to current treatments, which could lower reimbursement under buy-and-bill but benefit providers under risk-based agreements.

Expected stakeholder actions

- **Health plans** may feel pressure to adapt their coverage criteria and reimbursement formulas in response to new treatment options. Health plans will likely invest in gathering better data about long-term costs and patient outcomes to inform increasingly complex coverage decisions.
- **Health systems and physicians** will endeavor to stay top of innovations in order to offer access and support to patients while ensuring their own reimbursement, especially as new high-cost drugs are approved, and other drugs change administration protocols.
- **Life science companies** will remain an important part of information dissemination and clinical consensus. However, health plans are increasingly able to influence product selection. Accordingly, building relationships will be pivotal in increasing uptake and subsequently patient access and outcomes.
- **Patients** will benefit from new treatment options, lower costs, and more convenient formulations. However, they may still face issues with medication access as expensive treatments enter the infusion care landscape.

Source: Advisory Board interviews and analysis.

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