

The coming infusion site-of-care shock: strategies, outcomes and opportunities

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Summary

Plans have long been frustrated by the growth of infusion care in expensive hospital outpatient departments. Given the continued growth in specialty drug costs and recent M&A driven consolidation of medical and pharmacy benefits management, national plans are starting to put multiple redirection strategies in place.

We estimate that up to 26% of infusion care currently delivered in the hospital outpatient department could be shifted to ambulatory settings, an estimated total of \$17B in 2022 infusion spend in what is, for hospitals, a highly profitable service. Where will this infusion demand go? About 30% to 50% of this redirection is likely to happen in geographies where integrated delivery systems have largely locked in physicians, giving them an edge in holding onto the infusions even as the site-of-care is shifted. We expect these systems to largely pivot towards integrating their own ambulatory settings. We also expect more independent physicians to expand in-office infusion care, absorbing about 20% of the redirected care. Underlying patient risk likely disqualifies patients getting infusions at hospital outpatient departments for redirection to home therapy.

Therefore, the remaining 30% to 50% of infusions redirected out of the HOPD (an estimated total of \$3.4 to \$5.5B in 2022 infusion spend) will lack a clear site-of-care. Meeting this demand is an opportunity for new entrants—whether private equity backed pure-plays or incumbents with existing distributed clinical networks that can add a new line of business.

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1. The coming infusion site-of-care shock

A quiet front heats up

Infusion therapy site-of-care has long been a topic of tension between plans and providers.¹

Patients on infusion are often very sick and the therapies hard to tolerate. Many patients need clinical support nearby when they undergo treatment. Prescribers use their clinical judgment to determine if the risks during treatment warrant ready access to hospital-level care, physician-level care (at a clinic or an ambulatory infusion site) or nurse-level care (e.g. at home).

Each of these sites of care—the hospital outpatient department (HOPD), the physician office (OIC), ambulatory infusion sites (either centers/AICs or suites/AISs²), and the home (HIT)—have different fee structures and markups on the drug, with HOPD being the most expensive for payers (on average 70% more than OIC infusions—See Figure 1) and correspondingly profitable for delivery systems.

If patients are evaluated by a clinician affiliated with a hospital, infusing at an HOPD can often seem like “just common sense.” Plans have long noted that, as hospital systems acquire physician practices, the practices’ patients tend to shift from OIC to the affiliated HOPD with a consequent sharp increase in infusion costs.

While observing this migration with chagrin, plans have been reluctant to step in. Employers have not pushed because the patients are so sick and other, less risky, opportunities to trim medical costs lay untapped.

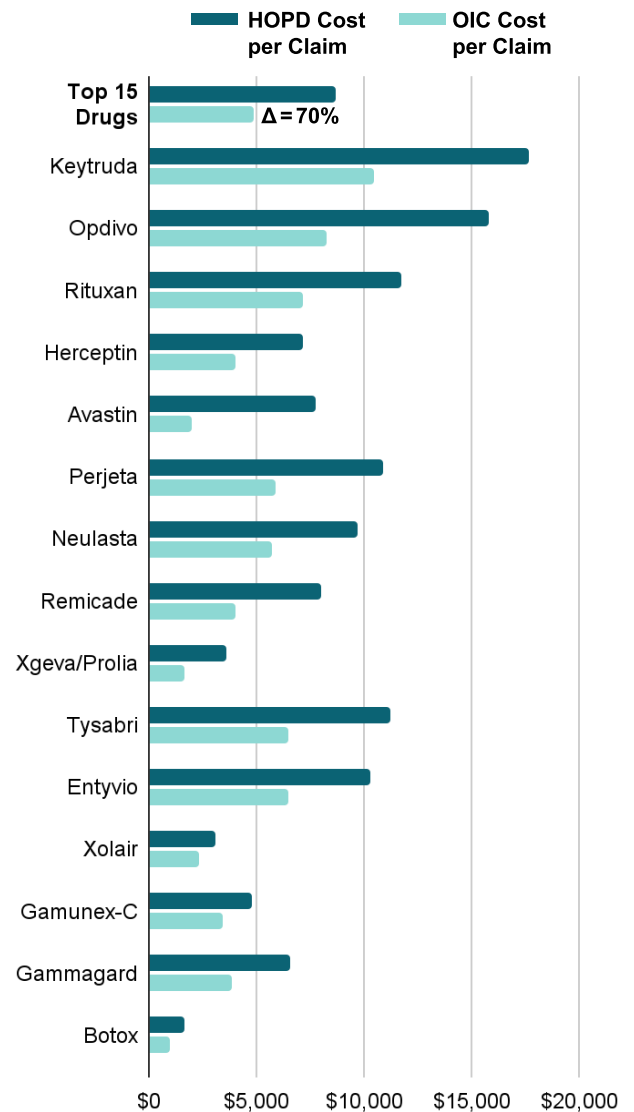


Figure 1. Cost per claim by site-of-care for a sample of the top 15 infusible drugs in 2019 by total revenue. Recon analysis of DHC data.

Also, infusion—as a pharmaceutical therapy typically covered under the medical benefit—has tended to fall through the cracks of expertise between the health plan and the pharmacy benefit manager (PBM), frustrating management efforts. Accordingly, the share of infusions being done at an HOPD has steadily grown in parallel with the hospital acquisition of specialty physician practices.³

Over the last several years, however, the context for infusions management has changed. Specialty medications have become a more visible cost trend driver.⁴ The market has become increasingly educated on the HOPD site-of-care mark-up. Employers—having exhausted the possibilities of employee cost sharing—are embracing stronger care interventions. And, perhaps most important of all, the big PBMs—already equipped with wide-ranging, relevant capabilities such as their own specialty pharmacy providers (SPPs) and HIT—have all now integrated with health plans, consolidating medical and pharmacy expertise, intervention levers and accountability into one set of hands.

Plans (especially big national ones with significant exposure to big employers)⁵ are now taking on infusion site-of-care.

One approach is to embed medical necessity requirements for an HOPD site-of-care in the infusion drug prior authorization (“site-of-care medical policies”).⁶ Cigna, for example, has rapidly expanded the list of infusion drugs covered under these policies. At this point, Cigna has about 120 drugs on their lists.⁷ These are not niche medications either: the specific drugs now covered under Cigna’s policies collectively represent 83% of the value of all HOPD infusions in 2020. See Figure 2.

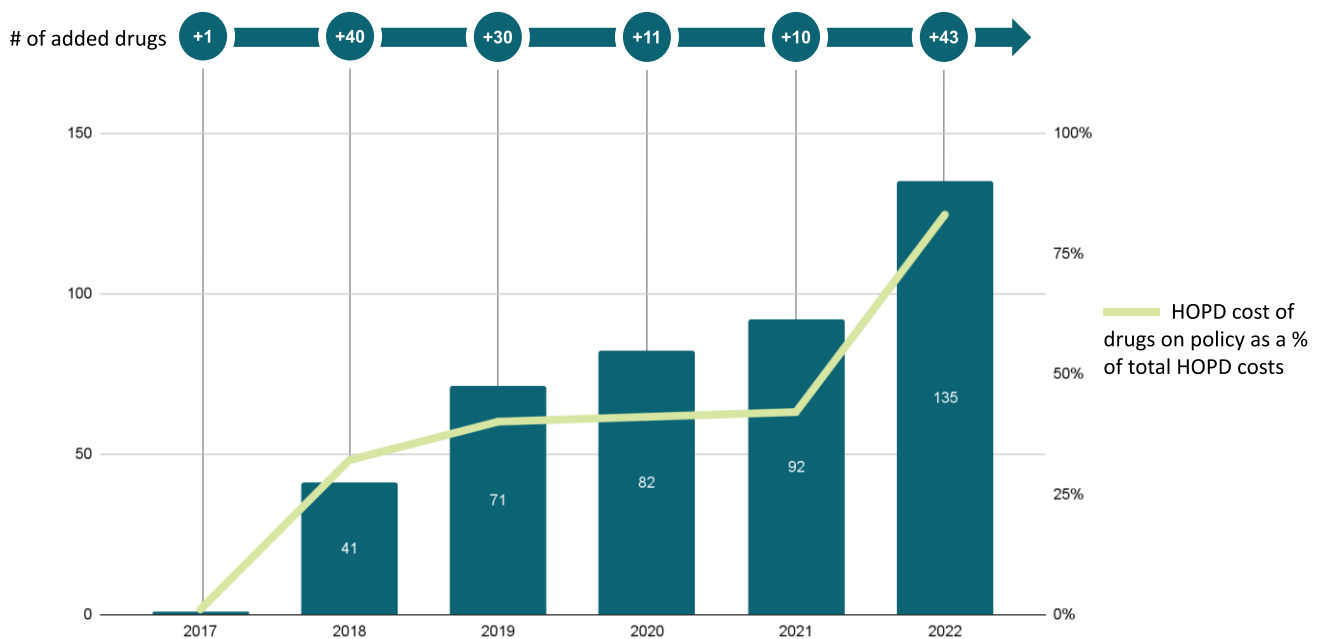


Figure 2. By year, the number of drugs added to Cigna’s site-of-care medical policy and the cost of all drugs on the Cigna policy as a share of total HOPD costs. Recon analysis of DHC data. Cigna Drug and Biologic Coverage Policy.

Another approach is to disrupt the traditional reimbursement model⁸ that has made HOPD infusions so profitable. Under “white bagging” mandates, plans arrange for an SPP to ship the patient’s infusion therapy to the infusing provider. The plan then pays the SPP for the drug⁹ and pays the infusing provider only for the infusion service. This removes the provider’s drug mark-up (which is typically a lot larger for drugs in the HOPD setting), making HOPD infusions much less profitable. Hospitals are thereby encouraged to shift their use of costly hospital outpatient space to other, more profitable uses.

Drugs can be subject to either site-of-care medical necessity or white bagging requirements or can be subject to both. Cigna has tended to use prior authorization for in-scope drugs, while Anthem and United, for example, have tended to overlay both requirements on the same drug. See Figure 3.

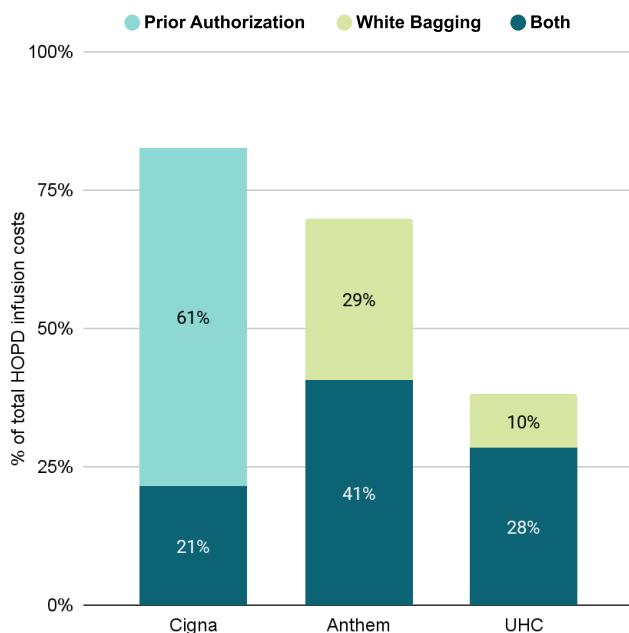


Figure 3. Scope of site-of-care interventions by policy type for a sample of three large national plans (HOPD cost of the drugs under each plan’s policy as a share of total HOPD infusion costs). Recon analysis of DHC data. See Figure Notes for medical policies referenced.

You may not see it in the stats, but implementation is well underway...

Policies on pdfs are one thing. Actual enforcement is something else.

The growing scope and energetic implementation of these policies are still too new to size the impact using publicly reported data.¹⁰ Further, the covid pandemic has slowed enforcement of a lot of care management interventions as plans and providers scrambled to find any way to maintain care continuity that was open, safe and acceptable to patients.

However, our recent discussions with both plans and providers confirmed that these policies are starting to bite hard. An illustrative example: a major specialty practice—affiliated with an integrated delivery network in the Mid-Atlantic nationally recognized as one of the most pugnacious in defending its site-of-care prerogatives—has seen all its infusion patients covered by national plans and the local Blue shift out of the flagship HOPDs and into affiliated OICs over the past 18 months. The only patients still getting infused in HOPDs are those covered by the system’s affiliated health plan.

Various regulatory and clinical guideline rearguard actions by hospital systems are playing out.¹¹ Yet, universally across our market checks, the view was that the economic heyday of HOPD infusions is over and that the market needed to prepare a decisive shift.

2. The site-of-care “state of play” and an initial sizing of the disruption

To size the impact of plan site-of-care interventions, we need to take a closer look at where HOPD infusions are happening currently. It turns out, there is wide variation in how HOPD infusion plays out across geographies.

For some markets, HOPDs deliver a sizable majority of the infusion care, while in others, the OIC remains the leading site-of-care. Figure 4 shows our high-level estimates for a selection of markets (see appendix for methodology and caveats).¹²

Why such large differences? Variations in demographics, clinical risk or diagnoses get pretty small at the market level so cannot materially explain such large differences. Instead, we should look to differences in clinical practice hardwired by differences in care delivery structure.

Markets where hospital systems have both strong incentives and the tools to influence site-of-care might be expected to have more HOPD infusion than others. A profitable pharmacy service line, enhanced by a historically powerful 340B incentives,¹³ might make a strong incentive. Deep physician affiliation or employment might offer hospitals the tools to influence site-of-care recommendations.

Markets where physicians are independent and entrepreneurial may be more willing to provide OIC services both for their own patients and perhaps for others referred from other practices. If these physicians are part of some value-based reimbursement (e.g., part of physician-owned ACO), they will have incentives to avoid costly HOPD infusions and a mechanism to cross-refer for OIC services. Thus, we might expect HOPD infusions to have a lower share.

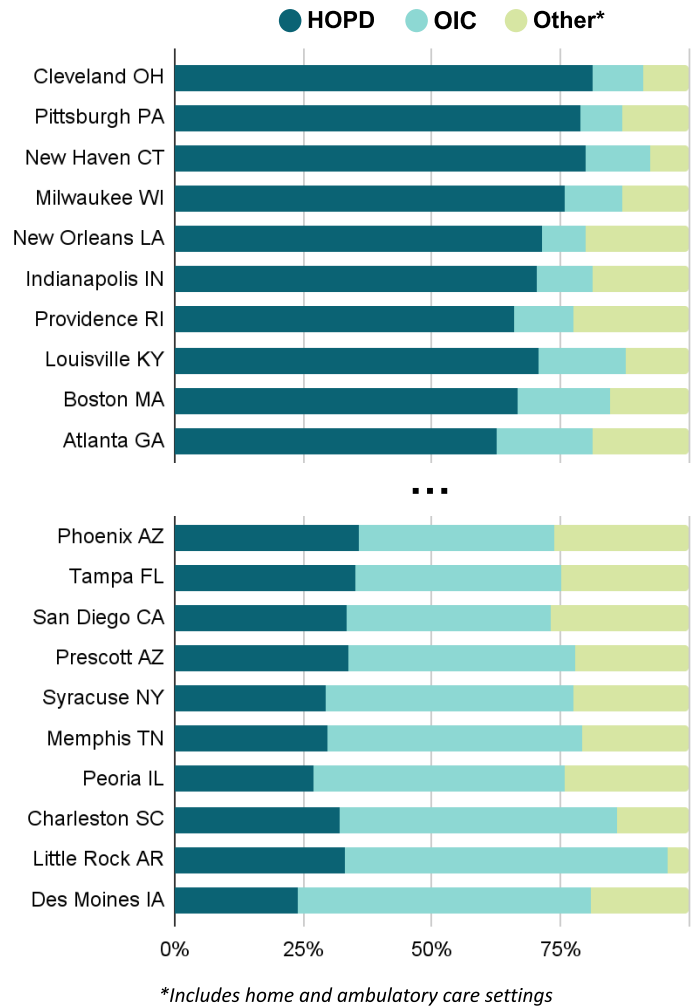


Figure 4. Estimated infusion market share by site-of-care for 20 sample markets. Recon analysis of DHC data.

The role of the HOPD in providing infusions varies widely across markets.

Sorting markets along these two axes—hospital integrative strength and independent physician entrepreneurial strength—confirms these presumptions: where hospitals are strong but physician independence is limited, HOPD share of infusions as a site-of-care in the market is higher (63%); conversely, in markets where hospitals are weaker and physicians more independent, the HOPD share of infusions is smaller (33%). See Figure 5.

There appear to be three broad market archetypes:

Hospital Leading. In these markets, most care is organized into Integrated Delivery Networks (IDNs) with large, well-coordinated networks of employed and aligned specialists and higher participation in 340B programs. Independent physicians are relatively few, tend to be less well organized or have their own value-based networks.

Physician Leading. These markets feature well organized and independent physician groups which operate their own value-based networks.

In Physician Leading regions, hospital systems tend to have a smaller share of physicians in the market employed or exclusively aligned. The hospitals in these markets also tend to participate less frequently in 340B.

Middle Ground. The remaining markets are less lopsided in their structure. IDNs may be integrated and incentivized to capture pharmacy but the independent physician groups are large and well organized as well. We might think of these as “battle ground” markets (in the lower right quadrant). In other cases, neither the hospitals nor the independent physicians are strongly incentivized or organized and therefore the site-of-care distribution is mostly an outcome of strategic neglect. We might think of these as “open ground” markets (in the upper left quadrant). In both cases, whether as a result of counter-balancing tension (“battle ground”) or lack of proactive effort (“open ground”) the HOPD share of infusions sites roughly midway between what we see in Hospital Leading and Physician Leading markets.

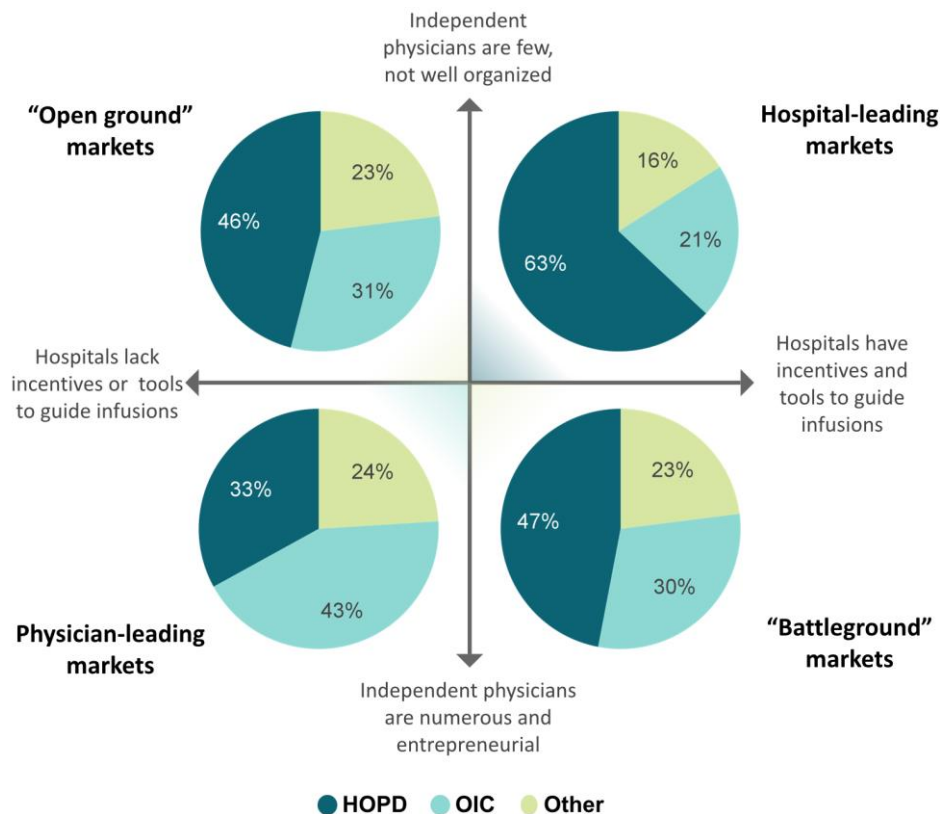


Figure 5. Estimated HOPD share of total infusions by market archetype. Recon analysis of DHC data.

Market archetype	# of markets	HOPD share within these markets	% of all infusions	% of HOPD infusions	Examples
Hospital Leading	114	63%	25%	33%	Cleveland OH; Minneapolis MN
Physician Leading	114	33%	25%	17%	Orlando FL; Nashville TN
Middle Ground					
Open Ground	86	46%	25%	25%	Salt Lake City UT; Charleston SC
Battleground	86	47%	25%	25%	Austin TX; Colorado Springs CO
Subtotal	172	47%	50%	50%	
All Markets	400	48%	100%	100%	

Figure 6. Summary statistics describing the concentration of HOPD infusions by market archetype. Recon analysis of DHC data.

While infusion patients are roughly evenly distributed across market archetypes (25% each in Hospital Leading and Physician Leading markets and 50% in Middle Ground markets), HOPD infusions are happening disproportionately more in Hospital Leading markets (33% of all HOPD infusions) and disproportionately less in Physician Leading markets (17%). See Figure 6.

A first order sizing of the HOPD infusion redirection opportunity

As plan site-of-care strategies take hold, what can we expect will happen?

The ultimate “floor” for HOPD share of infusion in any market will not be a simple function of plan policies. Practical factors will degrade the yield—for example: sensitivities around particularly severe conditions (e.g., oncology); variations, however minor, in population-level demographics, diagnoses, and, likely most important, social determinants of health barriers; profitability of infusing specific drugs in an alternative setting.

Given that all of these factors are currently at work in Physician Leading markets, however, we can conservatively use the current average share of HOPD infusions in these markets as a practical benchmark for the HOPD share floor elsewhere.¹⁴

Calculating the difference between the current share of HOPD infusions across all markets vs. this benchmark provides us with an initial estimate of the volume of shiftable HOPD infusions. Note that, by using the average HOPD share benchmark in Physician Leading markets as a target floor, we are effectively and conservatively assuming no change in the HOPD share in these markets. All the potential redirection will happen in either Hospital Leading or Middle Ground markets.

Our estimate is that this represents about 26% of all infusions done in the HOPD or about \$14B in 2019 prices and volume (so not including the impact of growth in the infusion medication pipeline). See Figure 7.

This should be taken as a first-order estimate. Notably, about half of the shiftable volume is in Hospital Leading markets, a logical outcome of IDNs in these markets systematically building up HOPD share. Having carefully constructed their HOPD profit engines, these same IDNs are unlikely to quietly accept their dismantling. Further, it is not immediately clear where all this volume will go unless there is significant dormant capacity in the ambulatory setting.

How will incumbent infusion providers react?

	Market Segment			
	(\$B)	Hospital Leading	Middle Ground	Physician Leading
HOPD cost by market segment (2019)	\$18	\$28	\$9	\$55
Current HOPD share of infusions	63%	47%	33%	47%
Difference from Physician Leading baseline	30%	14%	0%	14%
Share of HOPD cost potentially shiftable	48%	30%	0%	30%
Drugs bound to HOPD	\$9	\$20	\$9	\$38
Potentially shiftable cost	\$9	\$8	\$0	\$17
Unmanaged care (FFS Medicare + Medicaid)	28%	28%	28%	28%
Independent practices	40%	60%	75%	58%
Site-of-service shiftable HOPD value	\$7	\$7	\$0	\$14

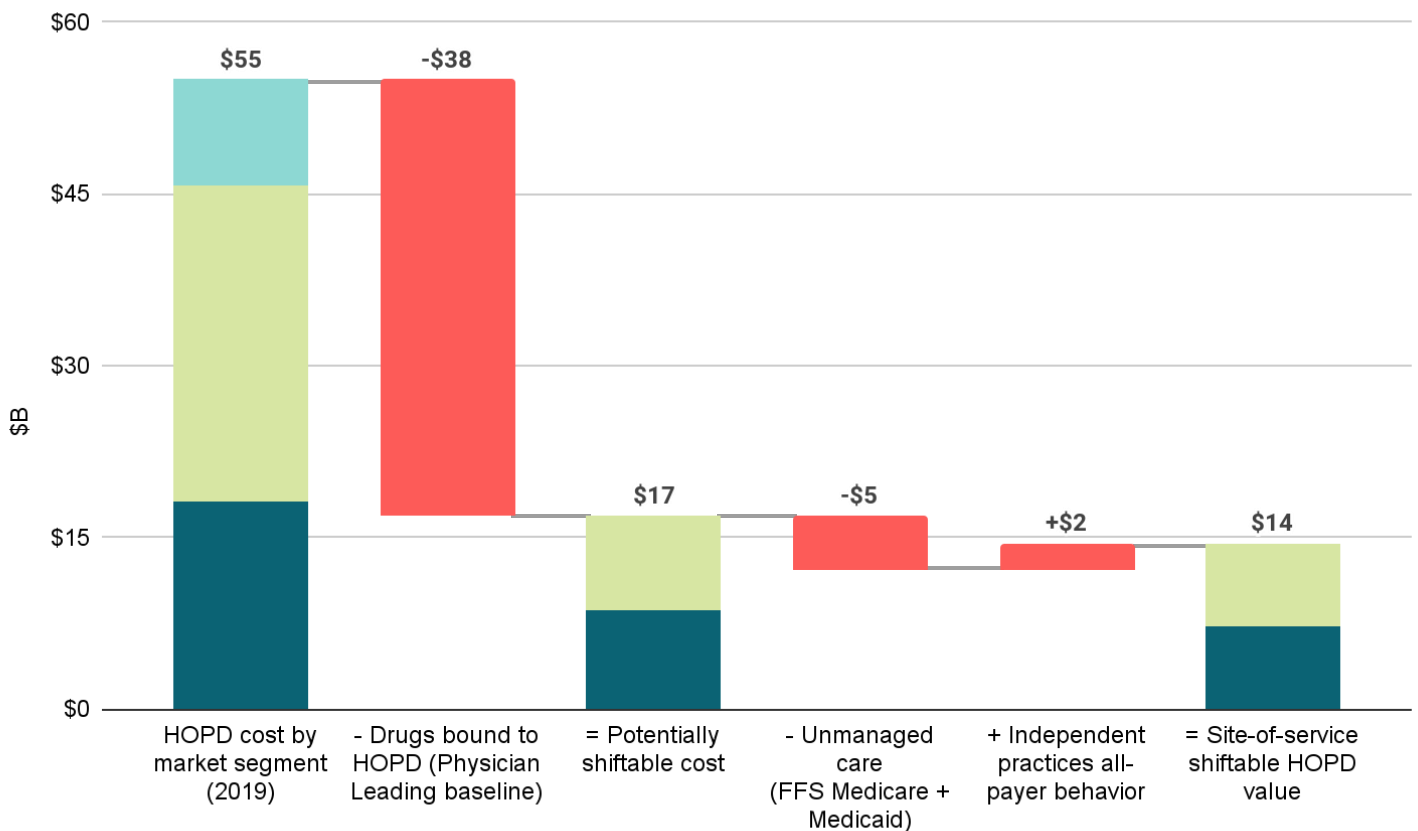


Figure 7. Estimate of infusion spend potentially shiftable out of the HOPD by market archetype. See Figure Notes for more on methodology. Recon analysis of DHC data.

3. Emerging incumbent countermoves

For some IDNs, pharmacy services have become strategic. Combining low drug procurement costs from 340B with capture of dispensing opportunities for prescriptions written by affiliated physicians and arranging for a high share of HOPD in infusion care can make pharmacy the biggest service line in terms of profits. Even as rearguard actions on site-of-care play out, forward-thinking IDNs are formulating their individual responses.

Here are a few that our market checks with plans and providers have revealed:

Resist. Provider systems with “must have” brands (you can guess the names) or deep strategic relationships with plans may get themselves exempted from payer interventions on site-of-care. There may also be encompassing risk deals leading to effective patient delegation or a patient mix so complex that plans are loath to second guess (these are the sorts of systems which attract patients who have exhausted their local care options). While the list of these systems is short, they are usually very influential within their markets.

Forward-thinking IDNs are already formulating responses to site-of-care pressure, aimed at holding onto infusion services one way or another.

Recontract. Some provider systems may “buy” their way out of the operational disruptions of site-of-care interventions or white-bagging by offering a price reduction on HOPD (or offering equivalent discounts elsewhere). The plan is primarily looking for savings, after all, and managing a site-of-care program is costly (a lot of pharmacy and clinical talent need to staff up the implementation).

Delivery systems can also recontract on a plan-by-plan basis, thereby limiting the economic “damage” to where they are most vulnerable, preserving the volume from other plans at higher rates for the time being.

Pivot. Some provider systems have decided to embrace the emerging site-of-care shift and build capabilities to retain the pharmacy business through the shift towards ambulatory. These may have a centralized pharmacy team that tracks prescriptions written and markets the system’s dispensing capabilities to their physicians. They may have established their own specialty pharmacy, allowing them to counter a plan’s “white bagging” mandate with a “clear-bagging” alternative.¹⁵ And, as site-of-care policies grow teeth, they are shifting patients to affiliated OICs (where there is capacity) and embedding ambulatory infusion sites in new locations billing at non-hospital rates.¹⁶

These “pivot” approaches enable a kind of site-of-care arbitrage depending on the plan’s policies (i.e. if plan medical policies do not allow a patient to get infused at an HOPD, the provider can send the patient to the affiliated AIC; however, if a plan’s medical policies are more lenient, then the patient can get sent to the HOPD; if the net revenue to the provider is greater if the drug is reimbursed under the pharmacy benefit, then appeal to the plan to change the model for that one patient, etc.).

Pivoting does not preserve all the pharmacy margin the system was making before the site-of-care shock. It also requires net new investment in capabilities. Why do this? Our market interviews suggested three rationales:

- Hold on to the pharmacy service line revenues while shifting towards a lower cost delivery model more resilient against plan interventions and, possibly, continued changes to the 340B program reducing its profitability (about which there continue to be regulatory rumblings, biopharma contract pharmacy restrictions as well as various lawsuits).
- Minimize infusion leakage for patients for whom the delivery system is at risk (i.e., avoid paying someone else to do the infusion at an ambulatory site-of-care potentially at a higher price than the system itself would charge).
- Widen the platform for rebate arrangements with biopharma. By having more end-to-end control of pharmacy, the delivery system can manage their own formularies and, on that basis, negotiate compelling rebate arrangements with biopharma.

Given their demonstrated abilities to manage HOPD strategically, we expect most IDNs in Hospital Leading markets to be able to hold on to the infusion services one way or another. However, even in these markets, not every IDN will have the option to resist, the bandwidth and resources to pursue a pivot in time or the willingness to recontract. Hospitals have a lot of irons in the fire right now. Further, in Middle Ground markets, only a portion of IDNs and hospitals will have the tools or the incentives to act strategically towards their HOPD infusions.

As plans start to push these infusions out of the HOPD, where will they go?

4. Shape of the ambulatory infusion opportunity

We make several key assumptions to translate the first order sizing of potential infusion redirection to a net new business opportunity to serve these patients:

Many IDNs will try to retain infusion share within their systems one way or another.

Key to responding to plan site-of-care strategies will be the IDN's influence over the prescriber who has enormous influence over the patient. We assume that an IDN will be able to hold on to infusion share in rough proportion to the share of prescribers aligned with that system.

It may be that these patients remain in the HOPD under a revised contract or are shifted to some new ambulatory infusion capacity that the system builds. Not all IDNs will be able to put "resist", "recontract" or "pivot" strategies in place, so we used a range.¹⁷

OIC capacity among independent physicians will capture some redirected HOPD patients.

Our analysis (see Appendix B) suggests that independent physicians who do in-office infusions tend to be more willing in Physician Leading markets than other markets to accept outside referrals. Why might this be?

Practices may introduce or expand infusion services in response to site-of-care redirection where access to patient volume has previously been a barrier.

Many factors determine whether a clinic will offer OIC, but access to patient volume is certainly one of them. OIC suppliers in Middle Ground and Hospital Leading markets simply have fewer patients seeking OIC care. If plans start redirecting patients out of the HOPD, however, then the number of patients seeking infusions at ambulatory sites will increase, potentially awakening dormant OIC capacity. PE-backed physician practice consolidators can also provide capital and expertise to expand infusion services.¹⁸

We therefore assume OIC capacity in the Hospital Leading and Middle Ground markets will increase to match what we see in Physician Leading markets.

HIT will have only a limited role in treating patients redirected out of the HOPD.

The pandemic has certainly opened the eyes of many regarding what care can effectively be delivered remotely and in the home. Still, our interviews suggest HIT will not play a major role in addressing the displaced HOPD infusions for three key reasons:

- Patients getting infused in the HOPD today are generally riskier. Prescribers (and plans) will be reluctant to have them jump from highest acuity to lowest acuity setting.¹⁹
- Many patients do not prefer HIT, given prior problems with scheduling, perceptions on clinical quality or preferences regarding privacy.²⁰
- HIT for particular therapies and in particular regions may not be available. HIT providers provide the medications which have attractive margins and serve in markets which are operationally easy to serve (e.g. urban areas where drive times between patients can be kept short).

Where will redirected infusions end up? A forecast

Infusions redirected out of the HOPD will be repriced to ambulatory rates. This redirected and repriced infusion volume will then flow into one of three types of capacity:

- Facilities affiliated with the strongest IDNs in line with the share of prescribing physicians they have aligned with their system (which, in the long run, will mostly be in converted or new ambulatory sites built by pivoting hospitals but will also include recontracted HOPD sites and—for the strongest brands—volume exempted from redirection)
- Expanded OIC capacity offered by entrepreneurial, independent physicians
- New ambulatory capacity built on a greenfield basis to serve the residual volume.

We expect, therefore, a need for new ambulatory infusion capacity sufficient to deliver \$2.8 to \$4.5B of redirected infusion care (priced 2019 at ambulatory rates). Assuming an average 7% CAGR on infusion spending growth²¹ and assuming the impact of the pandemic has stabilized, this demand would be \$3.4 to \$5.5B in 2022.

To meet the needs of the ~30-50% of redirected patients not captured by IDNs or served by expanded OICs, there will need to be a lot of new ambulatory infusion centers built. Who will build them?

Big HIT players could grow AIC capabilities.²² Such efforts will be constrained, however, by conflicting business priorities. HIT providers will tend to favor HIT solutions and be loath to take on the big, fixed costs of a broad network of conveniently accessible facilities or potential perceptions of conflicts with prescribers who refer out for HIT but operate their own OICs.

	(\$B)	Market Segment		Total
		Hospital Leading	Middle Ground	
Shiftable HOPD value (See Figure 7)	\$7.2	\$7.3	\$14.5	
Discount for rate differences	41%	41%	41%	
Shiftable ambulatory value	\$4.2	\$4.3	\$8.5	
<i>Base case: Broad IDN pivot</i>				
Share of prescribers aligned with IDNs	60%	40%		
Care retained by hospital pivots	\$2.5	\$1.7	\$4.2	
Care absorbed by flexed OIC capacity	\$0.4	\$1.1	\$1.5	
Demand not addressed by incumbents	\$1.3	\$1.5	\$2.8	
<i>Alternative scenario: Fragmentary IDN pivot</i>				
Share of prescribers aligned with IDNs	60%			
Care retained by hospital pivots	\$2.5		\$2.5	
Care absorbed by flexed OIC capacity	\$0.4	\$1.1	\$1.5	
Demand not addressed by incumbents	\$1.3	\$3.2	\$4.5	

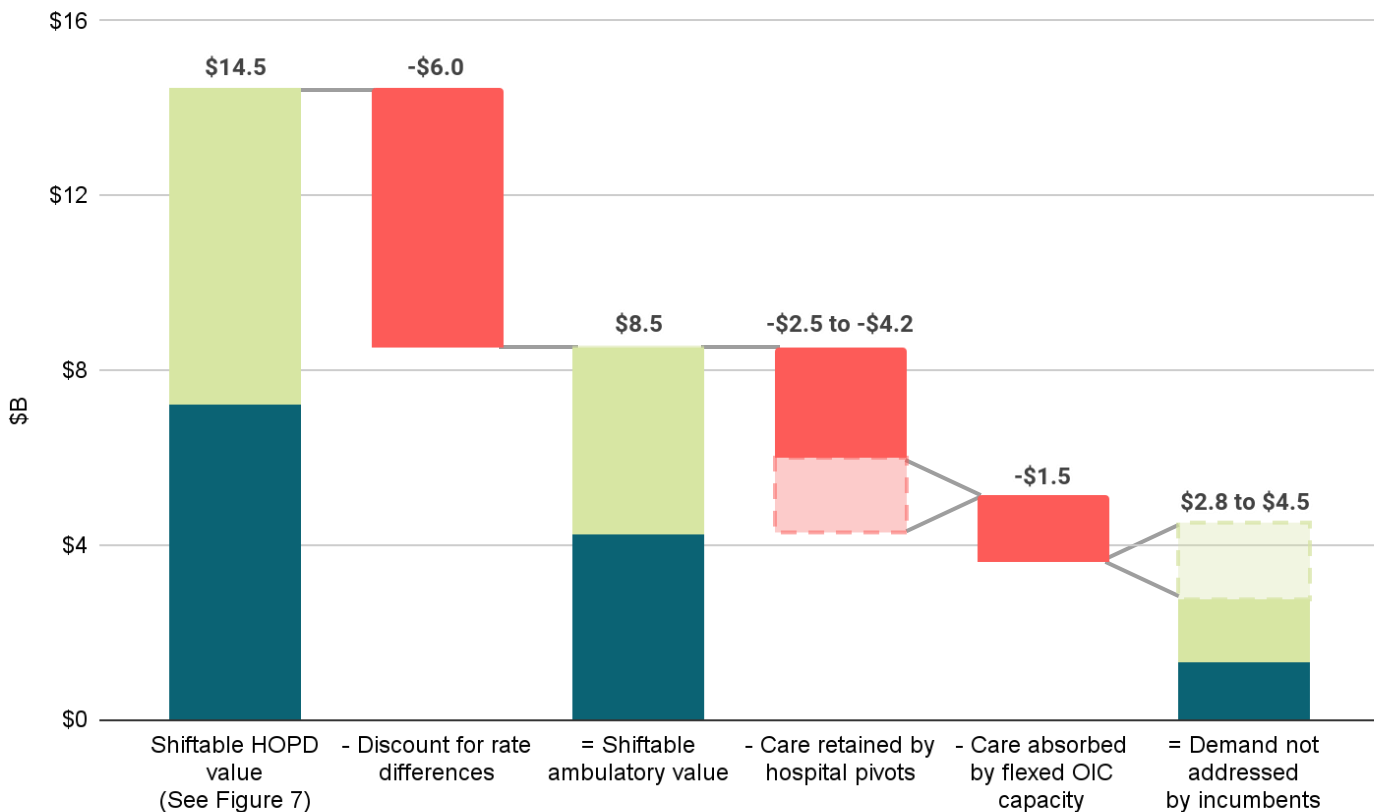


Figure 8. Estimate of demand for ambulatory infusion capacity after incumbent provider responses. Recon analysis of DHC data.

Private equity senses the opportunity... but are they the only ones?

New entrants seem like the most likely alternative for the bulk of this capacity. Not surprisingly, private equity has been growing its investments in stand-alone AIC ventures such as IVX and Palmetto (\$100M in Series F growth funding for IVX in September 2021). The networks of these players are growing but still regional patchworks at best. See Figure 9.

Timing will be tricky for these new entrants. Once established, AICs are pretty secure: referral relationships are hard to dislodge, the most convenient locations can only be leased to one player at a time and the fixed costs for each site effectively cap the number of sites in any one market. Accordingly, once site-of-care redirection becomes ubiquitous, ambulatory infusion will become a land grab.

In the meantime, however, these players must grow their networks surviving on the available volume of redirected patients from plans which are ratcheting up their site-of-care programs. Private equity backed players might therefore do well to look at finding opportunities in the other locations where redirected patients will get ambulatory infusions—for example, helping IDNs set up ambulatory infusion sites as joint ventures comparable to what has been done with ambulatory surgery and free-standing imaging (IDNs can be slow moving and capital constrained so may welcome partnerships), physicians with their own ambulatory facilities such as ASCs to expand into infusion, or working with entrepreneurial but inexperienced or under-resourced physicians to build out OIC services.

The ambulatory infusion opportunity may also beckon some other healthcare incumbents with operating distributed networks of clinical locations. What these players may lack in pharmacy expertise, they could balance by taking advantage of their existing infrastructure.

An orthogonal move anyone?

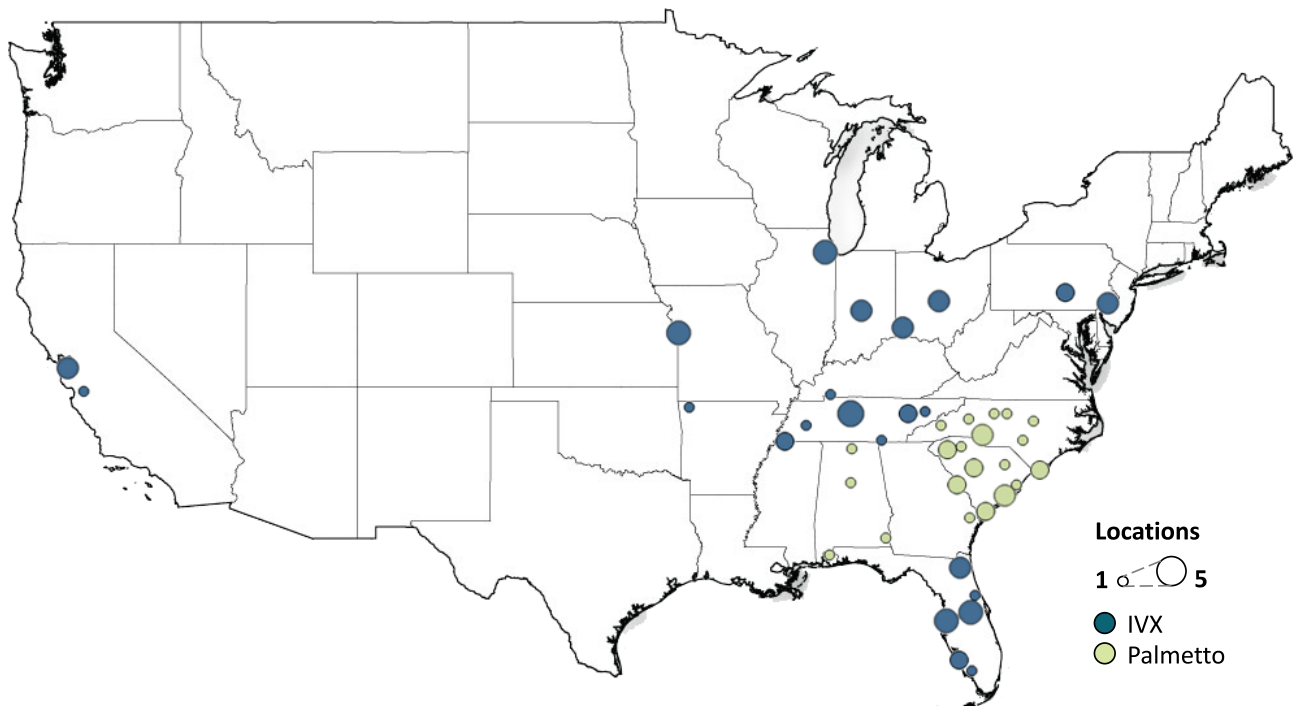


Figure 9. Map of 2022 IVX and Palmetto infusion center locations.

5. Concluding thoughts

Several factors have somewhat serendipitously come together to create the coming infusion site-of-care shock:

Market permission. Specialty drug costs have become regular headline news and big line items on medical cost trend reports, prompting employers to demand solutions from plans.

Burning platform. The strong infusion pipeline suggests that specialty medications will continue to make outsized contributions to the medical cost trend in the long run but also promises therapies that will be easier for patients to tolerate (a lot of monoclonal antibodies) and therefore be infused outside of the highest acuity settings.

Integrated management capabilities. The consolidation of pharmacy capabilities (PBM, SPP, HIT) with health plans (Optum and United, CVS and Aetna, and Express Scripts and Cigna) is allowing for an integrated approach to complex medications that require careful integration of the medical and pharmacy components.

Sensing opportunity, the big national plans have been aggressively deploying infusion site-of-care strategies. Other plans are sure to follow. While rearguard efforts to deflect and mitigate these strategies play out, incumbent delivery systems are starting to adapt to a new reality of a far greater share of infusions happening in ambulatory settings.

The pace of disruption will most likely be gated by the speed with which ambulatory capacity can be built to meet the redirected patient volume. Forward thinking integrated delivery systems will pivot, and, in some markets, office-based infusion capacity can grow. However, there will still be a lot of greenfield opportunity in markets where IDNs lack the tools or strategic foresight and where the entrepreneurial energy of physicians is already fully tapped.

Who will win in the greenfield space? It remains to be seen if new entrants can grow their networks fast enough to support the transition or if some other players outside the infusion space can bring pre-existing geographically dispersed, clinically capable networks to the opportunity.

Appendix A. Data sources and analytics methods

Data on infusion volumes and charges by J-code level, site of care and provider were essential for building the market level views and were supplied by Definitive Healthcare (DHC). We use 2019 as a benchmark year for two reasons.

First, there is a limited amount of recent and available infusion data that can be delineated down to a therapy-level. 2019 is also the most recent year reported on by most annual specialty pharmacy digests (e.g. Magellan Specialty Pharmacy Report) at the time of this analysis' publication. As such, grounding our analysis in 2019 allowed us to ensure the consistency of aggregate statistics across various sources to ensure a consistent baseline upon which we can more confidently suggest reasoned speculation about future years (through a mix of both topline time-series data and anecdotal evidence from our market checks).

Second, as has become expected in any provider strategy analyses of the last couple of years, temporal distortions in volume and site-of-care during the pandemic have served to obfuscate exogenous trends. For example, in our discussions with hospitals we heard that postponing of elective infusion care as well as patient apprehension for receiving care in the same hospital as covid patients led to quick step changes in both volume and site-of-care decisions. This means that both trends leading into the pandemic and trends coming out of the pandemic can be misleading. Data subsequent to this era of volatility (e.g. when 2022 data is made available) will be necessary to "bridge the gap" between the pre- and post-pandemic states of the market.

In some cases, we use time-series data extending into 2022 when available (see Figure 2), which aids in guiding our thinking of how the current state of the market may differ from 2019.

Site-of-care medical policies

We derive the number of drugs included in site-of-care medical policies from public-facing resources on plan websites (e.g. pharmacy newsletters, clinical guideline repositories) intended to be accessed by prescribing physicians. Policies differ in enforcement strategy and incidence of application (i.e. the medical necessity criteria). As such, the inclusion of each drug on these policies may not be uniformly additive as presented in Figures 2 and 3 nor strictly comparable across plans as presented in Figure 3. These estimates reflect an approximate and directional view of coverage and policy scope.

Infusion market share by site-of-care

To estimate the share of infusion costs by site-of-care and by market, we developed total infusion demand estimates derived from each market's population. For the purposes of this paper's snapshots of infusion activity, markets are defined as core-based statistical areas (CBSAs) with at least 90,000 residents. For each market, we summed the aggregate infusion costs reported by HOPDs and OICs and assessed the difference between total demand and HOPD and OIC supply as a residual likely made up of HIT and some AIC and AIS services (labeled as "Other" in Figures 4 and 5). Some manipulations were required to rebase the HOPD and OIC claims data available into actual reimbursements.

Additionally, some markets “export” care via patients traveling across CBSAs to seek a higher level of care, which can effectively overstate the ratio of infusions a hospital provides to its patient population. We correct for these cases by up-weighting our estimate for total infusion demand in markets identified as exporting care (and accordingly down-weight total infusion demand in the neighboring markets that are “importing” this care).

Market archetypes segmentation

Of the 400 largest markets in the US, we estimate the bed-weighted share of hospitals in each that possess 340B status or participate in an ACO. Those with the highest share are represented in the right half of Figure 5 and those with the lowest share on the left, such that both halves are equivalent in total population. Within each half, we estimate the share of physicians which are aligned with a local hospital system. Those with the highest share are represented in the top half of Figure 5 and those with the lowest share on the bottom, such that both halves are equivalent in total population. This methodology standardizes total infusion demand across each quadrant as implied by population. We do this so that our definitions of Hospital Leading and Physician Leading markets are comparable in terms of total population and demand.

Appendix B. OIC infusion supply response to the demand shock

OIC is an established model for a wide range of medications as well as providing that extra layer of clinical support during treatment likely appropriate for patients redirected out of the HOPD. Physicians might introduce or expand infusion services in their practices and either treat their own patients or take outside patients referred in for infusion.

To size this, we first looked at all practices in a selection of subspecialties where office-based infusions are common (oncology/hematology, family medicine/general practice, internal medicine, gastroenterology, immunology, infectious disease, neurology, ophthalmology, and rheumatology) and evaluated the share of these practices which provide OIC services.

Figure 10 provides a visualization of how the supply of OIC services varies across specialist practices in all markets. The practices have been bucketed based on the number of specialists in each practice. Infusion providing practices are segmented in quintiles of the amount of infusion charges per specialist in the practice (a kind of “intensity” of infusion care).

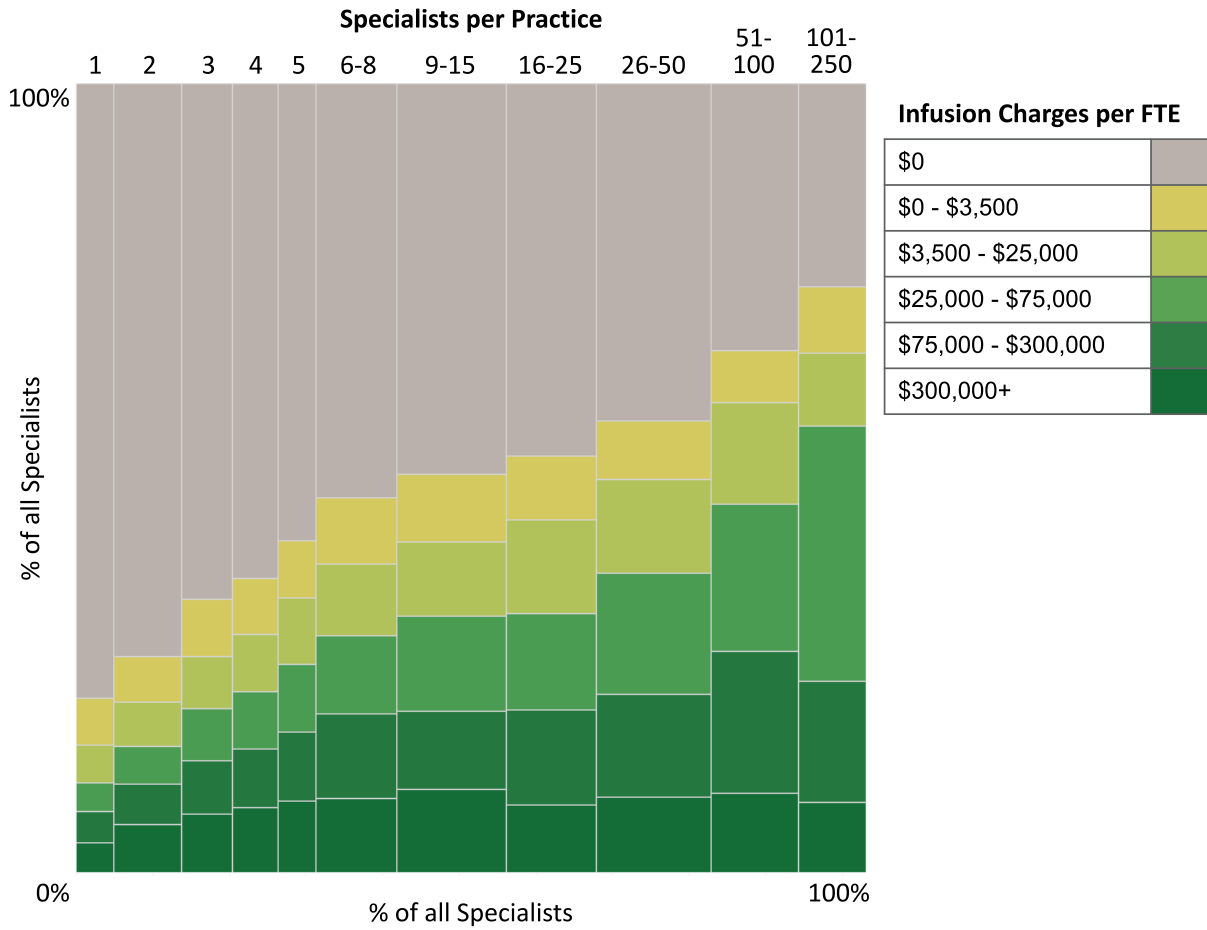


Figure 10. Share of specialists performing infusions by practice size and relative volume of infusions. See Figure Notes for more on methodology. Recon analysis of DHC data.

In aggregate, larger practices are more likely to provide office infusions (>\$0 infusion charges per physician FTE) than are small practices. However, practice size becomes less predictive of the highest intensity of infusion care at around 6 specialists or more.

Our approach is to use this framework to identify which practices primarily treat their own patients and which accept outside referrals for OIC care. We compared the average amount of infusion charges per specialist in the practice vs. the average amount of infusion prescriptions written by specialists across all practices and then evaluated this relative intensity of infusion care by practice as follows:

Where a practice has no infusion claims or a low intensity of office infusions, we assume that the practice largely refers patients out for infusion;

Where the office infusion intensity matched the average number of prescriptions for infusible drugs written by specialists generally, the practice is assumed to largely serve its own patients and not refer out;

Where the intensity exceeded the average amount of prescriptions written by specialists generally, we assume the practice is accepting a lot of outside patients for care.

Interestingly, the share of physician practices which perform office infusions for outside patients varies much more by whether the physicians are aligned with a hospital system than it varies by market.

Figure 11 provides a rough estimate of the share of specialty practices which perform infusions on their own patients broken out by practice size (scale is an important factor in the ability of a practice to support the investments, incremental staffing and working capital needs for an infusion service).

Some physician practices may also perform infusions on outside patients that have been deferred over by another physician together with a care plan and medication recommendation. Figure 12 provides an estimate of the share of practices which perform this service.

Figure 12 suggests that there is some potential for growth in OIC capacity open to external referrals (sized as the gap between the dotted blue line and the solid and dashed blue lines).

Thus, when there is more infusion to be done outside of a hospital setting, some small share of physicians will find the business attractive enough to scale up, build referral pipelines and create a real business.

Still, the potential lift is relatively small. A lot of independent physicians even in Hospital Leading markets are providing infusion services on referral already. The major difference again is between physician practices which are aligned with a hospital system (green) or not (blue). In other words, the major difference in relative OIC capacity across markets has more to do with the relative share of aligned vs. independent physicians than with the differences in propensity of physician practices to provide infusion services in the office. The amount of dormant OIC capacity that could be opened by plan site-of-care redirection is considerably less than the demand for ambulatory care suggested in Figure 8.

There is, therefore, the prospect of significant unmet demand in sites of care for infusion with robust clinical support capabilities but outside the HOPD.

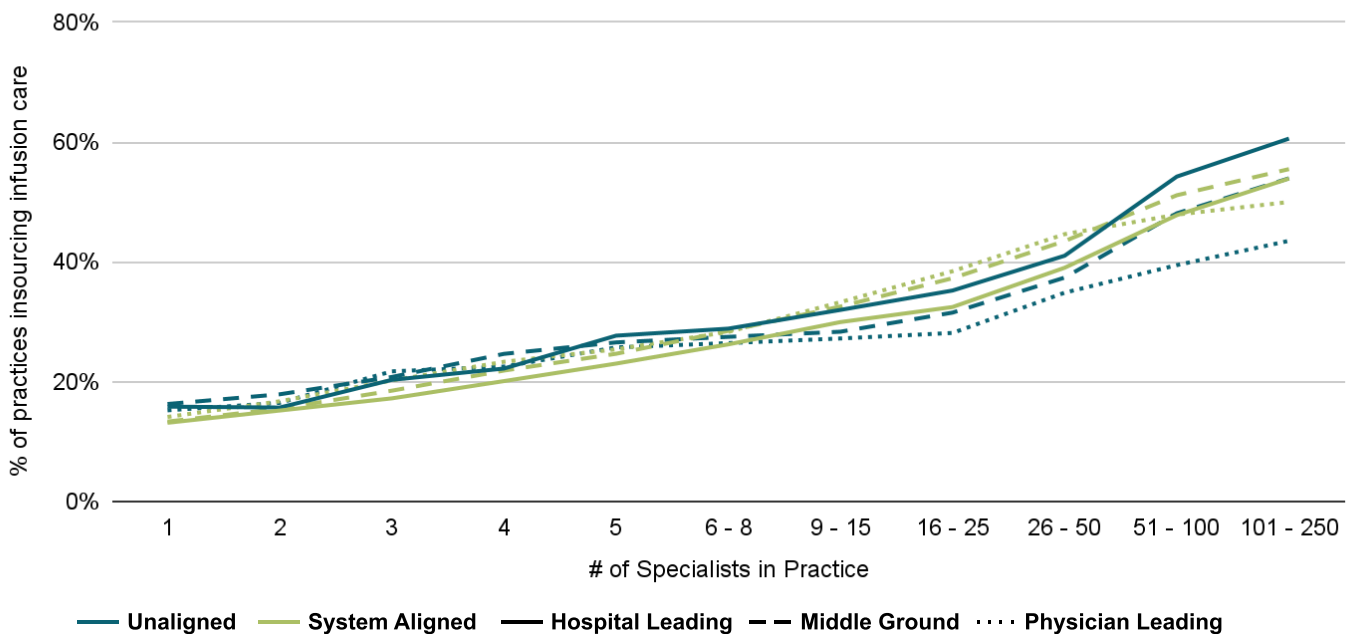


Figure 11. Share of practices that insource infusion care by number of specialists per practice and system-alignment. Recon analysis of DHC data.

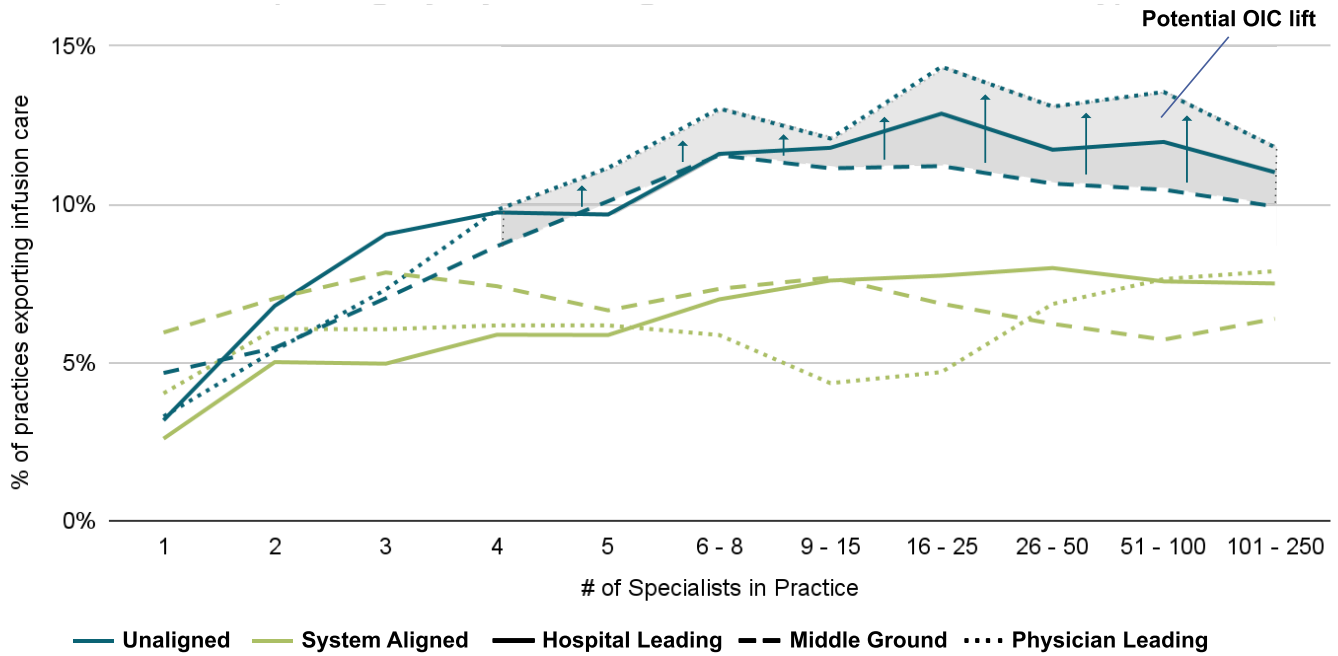


Figure 12. Share of practices that export infusion care by number of specialties per practice and system-alignment. Recon analysis of DHC data.

Figure Notes

Figure 3. For the 3 plans referenced with site-of-care interventions at EOY 2021, we estimate the HOPD cost of drugs under each plan’s medical policies (prior authorization and/or white bagging) as the share of total HOPD infusion costs. Note that the estimate is likely low: the weighting above is by all-payer HOPD spend; most site-of-care redirection is focused on commercial plans. The share of costs covered by site-of-care policies is likely higher for drugs commonly prescribed to the commercial population.

Sources: Medication Administration Site of Care. (2021 March). Cigna Drug and Biologic Coverage Policy. pg.2; Site of Care: Specialty Pharmaceuticals–CG-MED-83. (2021 August). Anthem BlueCross Clinical UM Guideline; Medication sourcing requirement. (2021 June). Specialty pharmacy requirements for UnitedHealthcare commercial plan members.

Figure 5. Markets where hospitals have the tools to guide where infusions happen (340B status, ACO participation, system-aligned physicians) have, on average, more infusions taking place in HOPDs than do markets where hospitals are not influencing where infusions happen (independent physicians, entrepreneurialism). See Appendix A for methodology on market segmentation and estimation of share by site-of-care.

Figure 7. To estimate the share of potentially shiftable HOPD cost (i.e. all drugs not bound to the HOPD) which could be shifted by plan site-of-care interventions, we exclude most “unmanaged care” (i.e. fee-for-service Medicare and Medicaid). However, there is an opportunity for some unmanaged care to be indirectly shifted out of the HOPD—specifically via small, independent practices which operate on an all-payer basis.

Whereas system-aligned practices may be incentivized to continue to refer unmanaged care patients to an HOPD, independent practices are more likely to consolidate all patient referrals under an all-payer strategy influenced by managed care interventions. Thus, we include unmanaged care referred by independent physicians in our estimate for site-of-care shiftable HOPD value.

Figure 10. Area corresponds to the share of all specialists who practice in groups of a given size (x axis) and whose practice reported a given amount of infusion charges per physician full-time equivalent (FTE) in 2019 (y axis). The median infusing practice recorded ~\$42,000 in charges per physician FTE. FTEs are estimated to reflect the relative activity of specialists and therefore avoid overrepresentation of part-time or semi-retired specialists. We define one specialist FTE as the median value of Evaluation and Management (E&M) visits a physician reports in a year. If a practice has no infusion charges, they appear in the gray area of the figure. A greater value of this ratio (displayed in darker green in the figure) implies that the practice recorded an above-average value of infusion charges given their physician FTE, derived from E&M activity.

Figure 11. Care insourcing is defined by the 2nd through 4th population quintiles of infusion charges per physician FTE. Values are charted as a 3-cluster moving average.

Figure 12. Care exporting is defined by the 5th population quintile of infusion charges per physician FTE. Values are charted as a 3-cluster moving average.

Endnotes

¹ This study focuses on interventions by health plans and does not evaluate the impact of changes in CMS strategy for FFS Medicare or Medicaid.

² The distinction between an ambulatory infusion center or suite is cloudy but is generally related to the location's size and level of clinical support available. A center may have 8-12 infusion chairs and have physician level care available while a suite may have 3-6 chairs and only have an infusion nurse staffed in the center. Generally both will have technical capabilities to administer immediate help if a patient experiences an adverse reaction (e.g. a crash cart).

³ Infusion therapy cost growth from 2015 to 2019 was greater in the HOPD (13% annually) than in either the physician's office (12%) or the home (8%). Source: Magellan Rx Management Medical Pharmacy Trend Report™, 11th Edition, © 2021. Used with permission. For Medicare, the share of HOPD infusions among all provider administered drugs covered by Part B went from 25% to 38% between 2010 and 2019. Source: Drug Channels Institute.

⁴ Indeed, the high prices of specialty drugs coupled with their proliferation has likely led to a material concentration of drug costs across the US population over the most recent decade. See Holle M, Wolff T, Herant M. Trends in the Concentration and Distribution of Health Care Expenditures in the US, 2001-2018. JAMA Network Open. 2021;4(9):e2125179. doi:10.1001/jamanetworkopen.2021.25179.

⁵ Smaller plans generally appear less aggressive to date than their nationally scoped competitors in managing site-of-care infusion. Collaborative relationships with local delivery systems are often critical for the niche positioning of smaller plans, making them less inclined to launch provider abrading initiatives. Nevertheless, over time, these plans will feel competitive pressures to match what the nationals are doing. We see this kind of "drafting" among the nationals already. For example, Aetna's addition of oncology support therapies to their site-of-care interventions in June 2020 was followed by Cigna in March 2021, United in June 2021, and Anthem in August 2021. Sources: Select oncology medications are being added to the Site of Care management program. (2020 June). Aetna OfficeLink Updates Newsletters. Pg.5; Medication Administration Site of Care. (2021 March). Cigna Drug and Biologic Coverage Policy. pg.2; Medication sourcing requirement. (2021 June). Specialty pharmacy requirements for UnitedHealthcare commercial plan members; Site of Care: Specialty Pharmaceuticals—CG-MED-83. (2021 August). Anthem BlueCross Clinical UM Guideline.

⁶ Typically, these policies are focused on HOPD only. As long as the drug is infused outside the hospital, the policy is not triggered so the infusion can happen at an OIC, HIT or at a stand-alone ambulatory infusion setting.

⁷ Policies differ in enforcement strategy and incidence of application (i.e. the medical necessity criteria). See Appendix A.

⁸ That model is called "buy-and-bill" under which the provider procures the drug for infusion themselves ("buys") and then asks the plan for reimbursement at a markup—often substantial if the drug is infused at an HOPD ("bills").

⁹ The SPPs can sometimes be subsidiaries of the national plans themselves.

¹⁰ Although there may be some early signals—preliminary data from the first half of 2021 suggests a two-year trailing CAGR of 6% growth in OIC revenues while the HOPD was roughly stagnant at 1%. Of those drugs added to Cigna’s site-of-care medical policy by 2019, annual HOPD cost growth since 2019 has been roughly 2 percentage points less than it was in the preceding period of 2017-2019 (while drugs not on Cigna’s site-of-care medical policy increased in annual cost growth by 3 percentage points). Collinearity by drug between coverage by a medical policy and therapeutic class, or the existence of competitor brands/biosimilars, obscures the causal effect of coverage on cost growth—more data is needed.

¹¹ For example, specialty societies are reportedly rewriting the guidelines regarding appropriate site-of-care for certain medications in ways that counter plans’ medical necessity criteria and providing fodder for appealing plan policies; some state legislatures have passed and others are considering prohibitions on “white bagging”.

¹² For each geography or market (defined using the Census’s core-based statistical areas), we developed estimates for the demand for infusion services of the resident population using national per capita averages and then summed the supply of HOPD and OIC infusions using claims for 2019 (made available to us from Definitive Health). The difference between total demand and HOPD and OIC supply is a residual likely made up of HIT and some AIC and AIS services. (Of course, the results are approximate, of course: the demographics of regions will vary; some patients may travel across core-based statistical areas for care, some manipulations were required to rebase the claims data available into actual reimbursements.) See Appendix A.

¹³ 340B status entitles “disproportionate share hospitals” (e.g., children’s, critical access, rural referral, community health) to a substantial discount on the procurement of outpatient infusion drugs. The additional margin provided by the 340B discount is intended to fund other less profitable, mission-oriented services, making outpatient infusions an integral service line for many of these hospitals. Source: The 340B Drug Pricing Program. (2021 March). American Hospital Association.

¹⁴ For a variety of reasons, this floor estimate may be conservative. For example, this assumes plans and providers maintain today’s patterns on oncology treatment site-of-care. Given cancer patient risk and the toxicity of chemotherapies, a large share of cancer care is done in the HOPD. However, there are major monoclonal antibody medications in the pipeline for oncology which are expected to be much easier to tolerate than today’s chemotherapies. Our market interviews with plans suggest that they expect substantial opportunity to shift more cancer infusions out of the HOPD with these medications.

¹⁵ Clear bagging replaces the plan’s preferred specialty pharmacy under white bagging with the provider’s own. The medication payment is still extracted from the buy-and-bill reimbursement framework and the plan still pays for the drug at specialty pharmacy rates (much lower than under buy-and bill). However, instead of paying its preferred specialty pharmacy (often a subsidiary), the plan pays the provider’s specialty pharmacy. The provider is thus still able to capture some margin on the medication.

¹⁶ 2022 has already seen a number of hospitals announce new, standalone ambulatory infusion centers to be built in the coming months. AtlantiCare plans to open an ambulatory rheumatology infusion center on its Health Park campus early in the year. Geisinger released its annual pharmacy review highlighting construction projects as a priority, including an ambulatory infusion center to open in Muncy in the winter. Hackensack Meridian’s recent oncology partnership with St. Joseph’s joined the host of hospital systems including OLOL and St. Luke’s that have opened oncology infusion centers over the past year.

¹⁷ To define the range boundaries, we assume as a floor that all IDNs in Hospital Leading markets are able to keep HOPD infusions within their system in proportion to their aligned prescriber share but none in Middle Ground markets are. For the ceiling, we assume that all IDNs in both Hospital Leading and Middle Ground markets hold on to HOPD infusions in proportion with their aligned prescriber share. The floor assumes that only IDNs with demonstrated success at strategically building their HOPD business will succeed in “resisting”, “recontracting” or “pivoting”. The ceiling assumes that, irrespective of past success, if IDNs have the tools, they will succeed in holding onto the infusion business. The actual outcome should lie somewhere between these two scenarios.

¹⁸ Efficient expansion into adjacent services is one of the core ways private equity adds value to acquired specialty practices. For example, PE-backed Gastro Health and Gastroenterology Associates have helped acquired practices move to new office space with room for an infusion suite, build a new endoscopy center with an infusion wing and open stand-alone infusion centers. Multiple consolidators and specialty MSOs advertise their ability to grow revenues for acquired or partnered practices by growing infusion services.

¹⁹ Plans can also be sensitive that these patients need clinical support, aware of some of the risks of HIT (for example, see Laday, J. (2021, June 22). Home biologic infusions linked to 25% increased odds of hospital admission. Rheumatology Practice Management).

²⁰ For example, one major GI practice indicated to us that while 50% of patient visits are done virtually, 80% of infusion patients came into the office for therapy even during the peak of the pandemic.

²¹ An average growth rate derived from IQVIA "Global Medicine Spending and Usage Trends" March 2020 and Credit Suisse "Global Pharmaceuticals PharmaValues 2021 strategic conclusions" 20 January 2021. This estimate is a net view incorporating the impact of biosimilars.

²² OptionCare for example have ambulatory infusion sites in a handful of markets but these are often out of the way sites collocated with the HIT's local pharmacy node. HIT providers embedded within big healthcare conglomerates have partnered among sibling companies for “pop up” AICs. In some markets, Optum's HIT has arrangements to infuse patients in OptumCare's urgent care subsidiary MedExpress. These kinds of solutions will, however, feel a bit jerry-rigged for the prescribing physician and patient and the big conglomerates may be disinclined to, in effect, compete with the significant share of prescribers that offer OIC services.

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