

Turning differentiation into value: How health-system specialty pharmacies can align to an outcomes-focused mission

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Despite the known differentiators of the health-system specialty pharmacy (HSSP) model such as proximity to provider, interdisciplinary team participation, and electronic medical record (EMR) access, the translation to value for external stakeholders continues to be underrealized. These challenges are partially drawn from the variable level of maturity of system-based operations but also, more importantly, from lack of defined outcomes measures for specialty therapies.

To change the narrative surrounding medication access and inclusion in third-party payer contracts, the HSSP model needs leadership. In this case, leadership must come from a panel of thought leaders from mature programs who can come together and chart the course for integrated dispensing peers. Through this approach, members can take critical steps to lean into differentiators associated with the model and develop standardized tools. This approach requires a nimble and thought-leadership approach from established programs to:

- Define critical therapeutic areas of focus and differentiation
- Define critical patient journey interventions and services to align with dispensing operations
- Define differentiated metrics for patient performance measurement and outcomes reporting
- Define internal and external stakeholders for outcomes messaging and performance

By establishing a hub-and-spoke information dissemination model (Figure 1), the standardized methodology and measurements originating with the thought-leadership group can be shared via communication amongst peers. This model further creates a unified front, which elevates clinical practice and patient experience, while taking a financial

stewardship approach to the development of well-defined and measurable therapeutic outcomes. Through this approach, health systems can deliver on the promise of proving their differentiation within the marketplace—something that has been messaged to the marketplace for over a decade.

Background. As the pharmacy product landscape has evolved throughout the years, so have the dispensing models and intermediaries within the industry. Historically, pharmacies were primarily brick-and-mortar and community focused. Increases in competition and margin pressures pushed the industry towards consolidation and mail-order dispensing. Specialty pharmacies began forming a new model in the 1980s, but it wasn't until the 1990s and 2000s that they became more common and better defined as they aimed to better support the unique needs of specialty medications. Offerings from specialty pharmacies evolved to assist patients and providers through the growingly burdensome process of accessing specialty medications and provide thorough, longitudinal clinical services to patients in the management of their complex disease states.¹⁻⁴ This development led to the maturation of specialty pharmacy as an industry with common elements and services viewed as cornerstone defining criteria for the model. Those services and offerings became the benchmark criteria for accrediting bodies, which have become increasingly prevalent over the past decade, and are now considered a standard of practice. Although key features of specialty pharmacies may vary based on site of care, clinical area(s) of focus, and level of sophistication, the National Association of Specialty Pharmacy defines them as state-licensed pharmacies that solely or largely provide only medications for people with serious health conditions requiring complex therapies.⁴

Meanwhile, health-system pharmacies were primarily focused on critical programs for managing inpatient medication delivery and safety. In the late 1980s and early 1990s,

systems began investing in outpatient pharmacy services to augment their growing ambulatory clinic presence and meet the patient access expectations of the retail pharmacy boom. These dispensing locations gradually adopted specialty pharmacy characteristics as providers and clinic staff became frustrated with the administrative burden of managing specialty medications, and clinic pharmacies became both a patient and provider support mechanism for access to therapy^{2,5}. However, it wasn't until the 2000s that health systems began to develop focused, centralized internal solutions for patients prescribed specialty medications, with most early operations evolving from the back end of a traditional retail dispensing location.⁶ These early adopters created roadmaps and educational opportunities to provide implementation support and business rationale for their peers, and the growth in hospital-owned specialty pharmacy has been significant^{2,6-8}. These models can function as a central point of integration with the larger healthcare system via some combination of EMR connectivity, physically embedded staff, and system-level strategic planning. Through this integration, HSSPs, in theory, are well positioned to improve upon the existing clinical care model to facilitate appropriate patient medication access and adherence while supporting operational investments through revenue growth associated with the dispensing of medications.

Challenges across the specialty pharmacy marketplace. While there are many opportunities for HSSPs to build successful programs, there are challenges associated with entering a highly fragmented and competitive environment. Many HSSPs are “own-use” operations, meaning they solely provide services for a defined population, such as patients treated by health system–affiliated providers or members of the health plan managed by the institution. For certain external stakeholders, such as drug manufacturers and health plans that are responsible for the development and management of national dispensing

provider networks, the own-use model can be frustrating. It introduces complications for limited drug distribution and payer networks whereby health systems are unable to service a national footprint, and externally referred patients raise challenges for network construction and maintenance. These complications have been further exacerbated by growth in the volume and cost of specialty medications; as a result, the ecosystem to support product distribution and access has become increasingly complex. Specialty manufacturers define the requirements for pharmacy providers to be able to purchase their products, creating a myriad of challenges for HSSPs to navigate these requirements for each drug they wish to carry. Similarly, payers and pharmacy benefit managers (PBMs) often have limited networks of contracted specialty pharmacy providers, which function as a control mechanism for managing pharmacy reimbursements, medication access, and the resulting cost of healthcare benefits. These limited drug and payer networks are often built around a small number of specialty pharmacy providers that can service a large portion of the patient population.^{3,9} As a result, marketplace expectations of the legacy specialty pharmacy models are misaligned to the HSSP model, wherein local “touch” and coordination are hallmarks of the service offering.

Access to specialty medications varies, but HSSPs can leverage their capabilities, classes of trade, clinical centers of excellence, and partnerships with manufacturers to meet inclusion criteria for purchasing most specialty medications. However, some health systems lack the informatics resources to support the data requirements that can be mandated by manufacturers with limited distribution products, particularly when the data may exist within disparate systems. While this is a challenge for some health systems, it is also an opportunity for those that have developed well-integrated data systems to provide actionable insights to front-line staff, the health system’s leadership, and industry partners.

Inclusion in payer networks is much more varied. Despite the holistic, patient-centric approach, HSSPs are heavily reliant on Medicare and Medicaid because their networks are more open than those of commercial plans, but many Medicaid plans may present reimbursement challenges to specialty pharmacy providers.¹⁰ Despite the reimbursement considerations, retaining Medicare and Medicaid patients in the integrated model aligns with the clinical mission of HSSP programs and supports risk-based contracting initiatives. These plans stand in contrast to commercial payer and PBM networks, which continue to present a significant challenge for a health system's participation and represent a significant portion of total business opportunity. Programs have described successful strategies to partner with the managed care teams for the health-system as they engage in medical plan negotiations with commercial payers, which can be jointly leveraged for pharmacy discussion.¹¹ Many HSSPs have also partnered with a health system–owned health plan or employee benefit plan, which can serve as an innovation incubator for clinical programs and performance-based intervention measurements.¹¹

Despite evidence to support the value proposition of the integrated model,¹²⁻²⁰ HSSPs continue to struggle against a lack of external market awareness and acceptance. While some programs have differentiated themselves by clinical or outcomes reporting capabilities, HSSPs to face challenges when being compared with mass-market specialty pharmacy providers. To capitalize on their unique set of capabilities and fill an emerging unmet need, HSSPs must create differentiation from the legacy specialty pharmacy model and thereby be defined by more representative criteria and quality measurements for the uniqueness of the offering.

Stepping up to the plate: developing meaningful marketplace metrics and outcomes measures. To understand where the future opportunities for differentiation exist,

we need to start with a consistent recognition of the weaknesses in the existing marketplace. The rapid maturation of the specialty pharmacy model and adoption of standardized reporting for specialty pharmacy accreditation resulted in a marketplace dependency on operational performance measures. While metrics such as call center performance, time to fill (TTF), medication possession ratio (MPR), proportion of days covered (PDC), and dispensing accuracy are routinely referred to as benchmark “outcomes” of the industry,²¹ these markers do little to contextualize the ability to reach clinically meaningful therapeutic endpoints. In many cases, true clinical endpoints for specialty therapies have not been fully established or measured, but such endpoints represent the key point of potential differentiation within an increasingly commoditized space. This approach requires alignment to physician and provider leaderships and access to the patient EMR profile in order to extract the nondispensing information necessary to provide visibility to a comprehensive patient treatment journey. Additionally, effective management of many of the current specialty disease states relies on subjective interim measures of disease response, thereby complicating the measurement and monitoring of disease progression and medication efficacy. However, the ability to provide end-to-end outcomes measurement and reporting is a pivotal cornerstone of the integrated dispensing model and one that has not been capitalized upon to date.

While the industry routinely talks about outcomes, we need to differentiate between “data” and “outcomes.” The 3 key elements of measuring outcomes are (1) utilizing appropriate measurement and reporting methods (data), (2) overlaying clinical measures and monitoring (clinical management), and (3) developing standardized methodology (a critical factor) for data management. Through this approach, performance measures and reporting can be aligned with the clinical needs of other members of the healthcare value

chain while allowing for collaborative identification of meaningful reporting for nonclinical internal and external stakeholders. In the absence of all 3 components, benchmarking across peer groups is impossible and the comparison of outcomes or impacts to stakeholder decision-making processes is invalidated.

Similar to standardization of marketplace metrics, development of an outcomes measurement strategy continues to face several rate limiters, including lack of bona fide outcomes measures, lack of marketplace benchmarking, and misalignment to a pharmaceutical manufacturer or third-party payer reporting focus. The pivotal element of any outcomes measurement program (local or national) is the development of a standardized methodology for outcomes measurement and data inclusion in order for the measures to be viewed as more than data reporting.

Translating differentiated HSSP capabilities into value. By leveraging the full capacity of their organizational infrastructure and resources, HSSPs have access to more data, healthcare expertise, and research resources and greater patient access than any other competitor in the market. The collective use of these resources enables these pharmacies to become the leaders in shaping specialty pharmacy industry standards rather than waiting for accreditors, manufacturers, payers, or other industry stakeholders to do this on behalf of the greater specialty marketplace (Table 1).

By reaching beyond the pharmacy, HSSPs have the internal tools to execute on the outcomes-focused strategy and serve a significant unmet need. Done correctly, outcomes measurement can serve key stakeholders across the healthcare industry in making informed decisions on therapeutic interventions and drive value creation for all links in the healthcare value chain.

Defining stakeholders and meaningful measures. The measurement of metrics and outcomes reporting is nothing more than an academic exercise unless the intended measures are aligned to key consumers of the information.

Once the clinical reporting and monitoring infrastructure is identified, organizations must develop customized marketplace messaging for third-party payers, pharmaceutical manufacturers, and patients in order to drive programmatic value messaging. The mere presence of outcomes measures does not translate to value to and alignment with external consumers of the information. Value messaging requires careful thought and must be tailored to the individual level to address the unique interests of the party receiving the value message (Table 2).

Call to action: What is next for the HSSP? Pharmaceutical manufacturers and third-party payers are inundated with messaging from health systems about the unique benefits of the integrated dispensing model, but we need to ask ourselves: Is it really differentiated in its current form? We need to understand how HSSPs are presenting the model to the marketplace and how that informs bias toward the model. We need to collectively acknowledge that we're dealing with a lack of consistency in integrated practice models and benchmarking for outcomes-focused performance. These influences negatively impact the value messaging of the model and raise concerns among payers and manufacturers responsible for network inclusion and participation decisions. The key drivers of those network decisions are consistency of the patient journey and ability to optimize patient experience, both of which should be core strengths of the integrated dispensing model but are being lost in collective translation.

Our reality is that HSSPs continue to be viewed through the lens of traditional specialty pharmacy operations and performance measurement. This challenge is even

reflected in our own vernacular, as evidenced by the way that dispensing operations are named, referred to with internal and external stakeholders, and measured against competing offerings in the marketplace. The time has come to change the narrative surrounding the integrated model, but it requires leadership to develop clear, actionable messaging to define the what, the how, and the why surrounding the capabilities of the model:

- **What** is different about the model, what is being measured, and what are the standards of practice within the dispensing location?
- **How** is care being delivered, how do patients interact with the model, and how is the care integrated with the clinical decision-making process of prescribers?
- **Why** should external stakeholders consider the integrated dispensing model, why do patients and providers utilize the model, and why will the organization continue to invest resources in the dispensing operation?

To be actionable and break the mold of the traditional specialty model, HSSPs must chart the course for practice and operational consistency. HSSPs must first define the targeted outcomes measures for a limited range of therapeutic areas in order to drive focus and patient management consistency across the HSSP peer cohort.

To be practical, HSSPs need to become curators of outcomes data and must measure, aggregate, and validate data reporting for publication and messaging to external entities. Only by starting with a standardized, focused set of measures within defined therapeutic areas can HSSPs achieve differentiation through consistency. By establishing best practices and outcomes measures, future HSSP program implementations will have a blueprint for practice focus and data measurement. In the absence of service

standardization and delivering on the differentiated reporting capabilities for tracking patient outcomes, the HSP model will continue to be plagued by misaligned messaging and practice model variability that is viewed as a risk for manufacturer and third-party stakeholders seeking consistency in the patient journey as a cornerstone of brand management.

Disclosures

The authors have declared no potential conflicts of interest.

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Figure 1: Hub-and-spoke information dissemination model. Through this model the standardized methodology and measurements originating with the thought-leadership group can be shared via communication amongst peers. This model further creates a unified front, which elevates clinical practice and the patient experience while promoting a financial stewardship approach to the development of well-defined and measurable therapeutic outcomes. TA indicates therapeutic area.

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Table 1. Health-System Organizational Capabilities Lending to a Competitive Advantage Within Specialty Pharmacy

Area	Capabilities
Patients	<ul style="list-style-type: none"> Patient cohorts and comorbidity interrelationships Direct access to patients across multiples sites of care (eg, inpatient, ambulatory, outpatient, home, and long-term care) Trusted relationships
IT and analytics	<ul style="list-style-type: none"> Ability to access, extract, and manipulate data from multiple sources
Data	<ul style="list-style-type: none"> Clinical patient data (demographics, conditions, therapy goals, interventions, therapies, laboratory/imaging results, outcomes) Pharmacy operations and dispensing data Medical benefit claims Pharmacy benefit claims Patient financial data Patient-reported outcomes Patient experience and perceptions
Providers and healthcare experts	<ul style="list-style-type: none"> Physician key opinion leaders Industry thought leaders, experts, and influencers in all clinical disciplines Specialty-trained pharmacists, nurses, and other healthcare providers Healthcare regulatory and policy experts
Research	<ul style="list-style-type: none"> Clinical trial research infrastructure, capabilities, and resources Key research leaders and influencers in all clinical disciplines Systems, processes, and tools to evaluate the impact of interventions on clinical patient outcomes Statisticians and data scientists

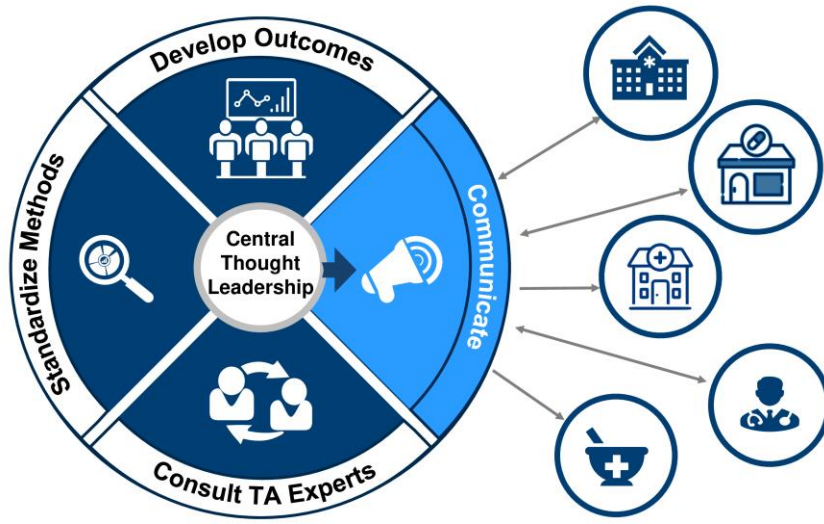
Abbreviation: IT, information technology.

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Table 2. Value of Standardized Outcomes Measurement Across Multiple Industry Stakeholders

Stakeholder	Value Proposition
Providers	<ul style="list-style-type: none">▪ Provides information to inform treatment selection or modification▪ Provides the ability to evaluate effectiveness of covered therapies to inform future coverage decisions and programs▪ Enables payers to appropriately monitor pharmacy performance against industry segment benchmarks to inform pharmacy network strategies▪ Informs the correlation of specialty medication management with total cost of care
Payers	
Pharmacies	
Drug manufacturers	
Healthcare and pharmacy accrediting bodies	<ul style="list-style-type: none">▪ Creates clearly defined and standardized measures that are consistent across the specialty pharmacy industry▪ Creates the opportunity for industry benchmarking for market segments (or peer groups) to monitor performance against outcome goals or standards▪ Supports the growing need for real world evidence generation, collection, and evaluation▪ Allows for the deployment of performance-based contracting initiatives with third party payers▪ Enables manufacturers to access and measure performance of industry partners who they partner with to provide patients access to therapies▪ Creates the ability to set clear and measurable standards for pharmacies across operational and clinical care areas▪ Builds the foundation for accrediting bodies to evaluate performance on basis of accurate industry benchmarking standards
Patients	
	<ul style="list-style-type: none">▪ Aligns service deployments and interventions at the time of need and maximal impact in order to reduce treatment fatigue and therapy attrition▪ Enables patients to make decisions about where their care is received that are aligned with their needs, wants, and care goals

[fig 1]



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