MARWOOD GROUP

Hub Service Expansion In The Era Of Specialty Drugs

Executive Summary And Outline

The rise of complex and relatively expensive biologic therapies in the early 2000s brought the earliest patient support services, predominately focused on financial assistance. Initially developed internally, growing complexity has driven manufacturers to outsource these "hub" services. Today, they tackle not only affordability but onboarding, adherence, supply chain and market data. Herein, we address the defining features of hub services, transactions in the space as pure play solutions and platforms evolve, and both strategic as well as regulatory considerations in the patient assistance ecosystem.

I. The Need For Hub Services In An Era of Specialty Pharmacy
II. Specialty Pharmacy Hub Service Design
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IV. Manufacturer Copay Assistance Strategy & Payor/PBM Counterstrategy Challenges
V. Regulatory Considerations Of Copay Assistance And Other Forms Of Patient Support
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I. The Need For Hub Services In An Era of Specialty Pharmacy

Although only 2% of the US population utilizes specialty medications, they now account for over half of drug spend, with the market expected to grow at a ~10% CAGR over the next 5 years.[1] Premium priced with potentially complex dosing and administration requirements, adverse event profiles requiring physician attention, and cold-chain requirements, they demand additional resources to optimize access, efficacy and safety. Initially developed by health plans and PBMs internally, the vendor landscape has exploded from specialist (i.e., benefit verification) to *a la carte* platforms.

II. Specialty Pharmacy Hub Service Design

Specialty pharmacy hub services are structured to optimize capture of eligible patients and ensure a smooth onboarding and retention process to maximize adherence. Providing a singular point of contact with patients, they are an immense source of rich data for course correction and future launches:

Onboarding: Provider comfort with payor prior authorization processes can frustrate onboarding and negatively impact prescriber enthusiasm, particularly for less established therapies. Hubs provide digital tools to steer providers through the prior authorization process in a manner conducive to the physician workflow. This increasingly includes the management of diagnostic requirements associated with targeted therapies to confirm eligibility.

Affordability: Patient comfort with affordability can frustrate the onboarding process and negatively impact prescriber enthusiasm, particularly for less established therapies. Hubs function to help

[1] Optum. (2022). Specialty drug prices giving you sticker shock? www.optum.com/business/resources/library/specialty-compass-2022.html (Accessed June 2022)

patients gain access by mitigating financial barriers. This includes reducing out-of-pocket expenses through manufacturer-sponsored copay-assistance programs or free medications via patient assistance program (PAP) or charitable foundations. As discussed subsequently, the scope and structure of assistance is rapidly evolving to meet regulatory challenges.

Supply Chain: Hubs engage sophisticated processes and tracking systems to ensure reliable temperature-controlled delivery and precise chain-of-custody of specialty pharmacy drugs, with high-visibility tracking along the way. For physician-administered drugs, this increasingly includes white-bagging wherein the drug is billed to patient pharmacy and delivered to the physician. As the cost of specialty therapies increase, the ability of providers to otherwise procure and hold these therapies on their books via a traditional buy-and-bill, is challenged, making this a more viable option, especially for smaller practices.

Adherence: Poor adherence is a leading cause of reduced clinical outcomes and diminished brand reputation. Multimedia training tutorials ranging from self-injection to side effects can be provided via smartphone app. Social determinants of health are playing an increasing part of hub services. Vendors and manufacturers are working in tandem to design HIPAA-compliant interventions that can help patients to address transportation and housing issues, health literacy, food insecurity and more. These are not without regulatory challenges as discussed below.

Data: Hubs share data with the manufacturer. Typical metrics that are tracked through a product hub include (but are not limited to) the number of calls handled, average speed to therapy, time to refill, duration on therapy, turnaround time for benefits verification and PA reconciliation, prescription-abandonment rates, patient health-literacy scores, use of manufacturer copay-assistance programs, number of preventable hospitalizations and emergency room visits. Key performance indicator data can also help stakeholders identify bottlenecks, inform continuous improvement and drive process efficiency. Meanwhile, advanced data-analytics capabilities—based on the use of NLP, artificial intelligence and machine learning techniques—are enabling patient hubs to uncover hidden trends from massive amounts of structured and unstructured data. Manufacturers utilize this data to course-correct brand resource allocation in real time as well as plan future launches and resource allocations.

III. Hub Service Need Driving Vendor Design And Transactional Considerations

Hub services vary depending on the needs of the client. For example, if a drug is in a limited or exclusive distribution network, only specifically mandated distributors and specialty pharmacies are included in the fulfillment process. Manufacturers can use internal hubs to maintain tight control over the process. Where manufacturers continue to internalize other processes, vendors may provide more limited offerings, such as benefits investigation and prior authorization.

With the growth of hub service vendors and differential outsourcing amongst manufacturers has come a range of offerings, from one-stop-shop platforms on one end to best-in-class individual services on the other. The efforts to build and bolt-on capability to full-service platforms or simply refine best-in-class services, will continue to drive transactional activity in this growing, yet highly competitive, space. The year has already seen several transactions including TrialCard's acquisition of the strategy consultancy, Triangle Insights Group; United BioSource's acquisition of the drug benefit company MSM; and the CareMetx hub's acquisition of the patient support program provider, HCS **(Table 1)**.

Provider	Description	Recent Activity	Transaction
TrialCard	Processor of complex insurance coverage submissions on behalf of patients for specialty drugs; provides patient reminders	Apr-22	Acquisition of Triangle Insights Group, a strategy consulting firm
United BioSource	Provider of pharmaceutical support services	Mar-22	Acquisition of MarketShare Movers (MSM), a data-driven prescription drug benefit and affordability company
CareMetx	Technology-enabled hub services platform facilitating patient access to specialty medications	Jan-22	Acquisition of Human Care Systems, Inc. (HCS), a provider of patient support programs that deliver improved access, use, experience, and outcomes from medicines by helping patients better manage complex diseases and therapies.
ConnectiveRx	Connects patients with prescribed medications through hub services, affordability, awareness, and adherence solutions	Dec-21	Acquisition by Rx Savings Assistant® from Medicom Digital. RxSavings software automatically finds prescription savings offers and embeds them into qualifying patient records where healthcare providers see the offers inside their EHR (electronic health record) workflow and deliver them to patients directly.
Shield Health Solutions	Integrated, health system specialty pharmacy approach	Sep-21	Investment by Walgreen Co. of approximately $970 million investment; builds on a minority equity investment that it announced in July 2019.
Lash Group/ Amerisource Bergen	Operates over 100 patient support programs serving more than 15 million patients	Aug-21	AmerisourceBergen acquired FirstView Financial (FirstView), a fintech solutions provider that delivers innovative digital payment processing services to support patient affordability and access programs, pharmacy and provider networks, and payors and plan administrators.
Perigon Health 360	Precision digital pharmacy platform utilizing advanced data gathering to close the information loop by monitoring patient's real-time medication compliance	Jul-21	Lifeboost, Inc. and Valeda Rx merged, to form Perigon Health 360.
Diligent Health Solutions	A multifaceted healthcare call center	Sep-20	Acquired by Uniphar, a diversified international healthcare services provider
Conduent Inc	Conduent provides business services such as medical billing, patient support services, Medicaid screening, and prepaid card processing for government benefits	Jan-19	Acquisition of Health Solutions Plus (HSP), a software provider of healthcare payer administration solutions.
RxCrossroads by McKesson	RxCrossroads provides hub service programs encompassing reimbursement support, integration with network pharmacies, patient adherence programs, specialty logistics services, sales operations support and mail-order pharmacy services to pharmaceutical, and medical device manufacturers	Jan-18	McKesson purchased RxCrossroads, a Kentucky-based specialty solution provider, from CVS Health Corporation in a deal valued at $735M, funded by cash on hand
AssistRx	Technology-enabled therapy initiation and patient support solution that improves patient uptake, visibility and outcomes	Jan-17	Acquisition of Caret, providing users with cutting edge technology to boost patient care management, adherence, and compliance
McKesson Specialty Health	Offers solutions designed to improve purchasing efficiency, enhance productivity, and support patient care	Jan-17	Acquired CoverMyMeds, a healthcare software company that creates software to automate the prior authorization process used by some health insurance companies

Table 1: Recent Hub Services Transactions

IV. Manufacturer Copay Assistance Strategy & Payor/PBM Counterstrategy Challenges

Pharmaceutical manufacturers offer copayment offset programs (also called copay cards or coupons), which cover a portion of a beneficiary's out-of-pocket costs for a brand-name drug. These programs support beneficiaries with commercial insurance. Patient assistance programs, supported by manufacturer sponsored foundations and brand-agnostic foundations, provide additional patient assistance. As such, total patient assistance has been calculated in the range of $18B/year with manufacturer offered copay support consisting of roughly a half to a third of this amount.

As copay assistance reduces patient sensitivity to out-of-pocket cost, commercial payors have grown concerned that these programs create perverse economic incentives that distort utilization by blunting intended patient willingness-to-pay. They have consequently implemented adjustments known as "copay accumulators" or "copay maximizers" which lessen the value of a manufacturer sponsored copay assistance program to the patient and allow the PBM/payor to capture manufacturer spend **(Figure 1)**. This has not come without manufacturer pushback in the form of legislation efforts.

Manufacturer Intention – Copay Assistance Program

A manufacturer's copay program counts toward a patient's deductible and annual out-of-pocket maximum. With these annual limits reached, the plan pays all subsequent costs. In this example, if the drug is $2000/mo and total copay assistance is $6000, then the manufacturer will cover the deductible ($2000) and 20% co-insurance ($400) to the out-of-pocket maximum ($4000). Burden is relieved from the patient and the manufacturer only pays $4000.

Payor/PBM Counterstrategy - Accumulator Adjustment

The manufacturer's support is frontloaded. The patient will pay nothing for 3 months. In month 5, the patient will need to pay the full deductible and subsequent co-insurance until their out-of-pocket maximum is reached ($4000). Burden is now $6000 on the manufacturer, $4000 on the patient, but reduced to $14,000 for the payor.

Payor/PBM Counterstrategy – Maximizer Adjustment

The support is applied evenly throughout the benefit year to the payor portion($500/mo). This will reduce the cost of the drug to $1500/mo wherein the patient still needs to reach their deductible (ex., $2000) before paying coinsurance (ex. $300 at 20% coinsurance) up to their out-of-pocket maximum ($4000. Burden is also $6000 on the manufacturer, $4000 on the patient, but reduced to $14,000 for the payor.

Case Study Scenario Details

Manufacturer		Payor	
Cost of Drug	$2000/mo	Deductible	$2000
Copay Max	$6000	Co-insurance	20%
		Patient Out of pocket Maximum	$4000

Manufacturer Intended Copayment Offset/Assistance

Month	1	2	3	4	5	6	7	8	9	10	11	12	Total
Manufacturer	$2000	$400	$400	$400	$400	$400	$0	$0	$0	$0	$0	$0	$4000
Patient	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	0
Payor	0	$1600	$1600	$1600	$1600	$1600	$1600	$1600	$1600	$1600	$1600	$1600	$17,600

Payor/PBM Counterstrategy - Accumulator Adjustment

Month	1	2	3	4	5	6	7	8		9	10	11	12	Total
Manufacturer	$2000	$2000	$2000	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$6000
Patient	$0	$0	$0	$2000	$400	$400	$400	$400	$400	$0	$0	$0	$0	$4000
Payor	$0	$0	$0	$0	$1600	$1600	$1600	$1600	$1600	$2000	$2000	$2000	$2000	$14,000

Payor/PBM Counterstrategy – Maximizer Adjustment

Month	1	2	3	4	5	6	7	8	9	10	11	12	Total
Manufacturer	$500	$500	$500	$500	$500	$500	$500	$500	$500	$500	$500	$500	$6000
Patient	$1500	$700	$300	$300	$300	$300	$300	$300	$0	$0	$0	$0	$4000
Payor	0	$800	$1200	$1200	$1200	$1200	$1200	$1200	$1500	$1500	$1500	$1500	$14,000

Figure 1: Manufacturer Copay Strategies And Payor/PBM Adjustment Counterstrategies

V. Regulatory Considerations Of Copay Assistance And Other Forms Of Patient Support

CMS published a final rule on December 21, 2020, requiring pharmaceutical manufacturers to ensure the benefit of co-pay assistance programs goes only to patients in order to maintain the exclusion from Medicaid best price reporting. This rule directly impacts the co-pay accumulator scenario and had the potential to disrupt manufacturer support for these programs, or at least require a redesign to avoid running afoul of noncompliance with the Medicaid Drug Rebate Program or impacting Medicaid Best Price. The rule, set to go into effect in January 2023, will no longer move forward after PhRMA won its legal challenge of the rule.

The Notice of Benefit and Payment Parameters for 2021 ("2021 NBPP Final Rule"), which went into effect on July 13, 2020, expressly allows certain health plans to determine, to the extent permitted by state law, whether to count pharmaceutical manufacturer assistance with enrollee cost-sharing toward the plan's annual limit on cost-sharing. This policy applies to health plans sold on the Affordable Care Act (ACA) exchanges, as well as non-grandfathered individual and group health plans (including self-insured plans). This policy makes it easier for group plans and issuers to adopt copay accumulator and maximizer programs. To implement a maximizer, plans will deem many specialty drugs "non-essential health benefits." Non-essential drugs are still covered by the plan, but they are not subject to the ACA's Essential Health Benefit requirements and can be removed from the out-of-pocket maximums required by the ACA.

In addition, several states have enacted legislation that outright prohibits copay-accumulator programs or limits their use in commercial plans. However, many large employer-based health plans are exempt from such state plans. Through May 2022, 14 states have enacted laws banning payor and PBM use of copay accumulator programs. These state laws apply to state-regulated health plans, including the individual, fully insured large-group and small-group markets. Today, 10% of the total US commercial market—14.8 million individuals—are enrolled in plans that must count any form of copay assistance toward patient cost-sharing limits.

Within the broader patient assistance program landscape, strategies to address specific social determinants of health are under intense regulatory scrutiny. To a great degree, there are limits on services that can be provided without being considered inducements. For example, in December of 2020, the US Office of Inspector General (OIG) wrote an opinion that indicated a specific company's program can indeed provide travel and hotel/meal expense to patient. However, the OIG also noted that generally assisting patients in these logistics would have otherwise been out of the question.

VI. Future Considerations

Hub services will continue to be a fixture of the growing specialty pharmacy space. Target analysis in this environment requires an understanding of emerging federal and state regulatory and legislative policies impacting copay assistance and the broader patient assistance program space, as well as health plan/PBM counterstrategies. Investment in the space also requires strategic evaluation vendors, narrow specialists and platforms, and the manufacturer landscape where product, pipeline and considerations of insourcing versus outsourcing dominate hub considerations. Marwood's services span federal and state regulatory and legislative considerations, payor/PBM dynamics from a Medicare, Medicaid and commercial perspective, strategic considerations of landscape, market sizing, and the evolution of brands and drug pipelines and compliance diligence.

About the Author

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