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Unlocking Access: **Direct-To-Patient Cash Solutions for Pharma Manufacturers**

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1-85-KnippeRx
(1-855-647-7379)

www.KnippeRx.com

Access@KnippeRx.com

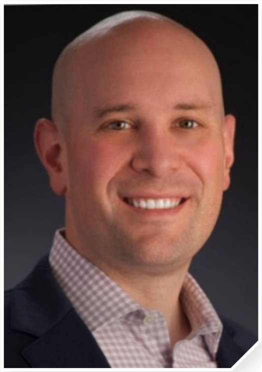
Introduction

In recent years, the utilization of cash models in retail pharmacies has increased, driven by a myriad of market factors. This paper, from a March 26, 2024, Fierce Pharma webinar, features acknowledged subject matter experts (SMEs), **Steve Gransden**, Executive Vice President, Strategy and Solutions, Knipper Health Trade Services, and **Michael Zangrilli**, Senior Director, Commercial Development KnippeRx, Inc. In *Unlocking Access: Direct-To-Patient Cash Solutions for Pharma Manufacturers*, they share their knowledge, expertise, and insights as they examine and analyze the key drivers of this trend, the impact on retail pharmacy services, consumer behavior shifts, benefits of cash models, implementation considerations, and future trends in the evolving landscape of healthcare.

STEVE GRANSDEN

Executive Vice President, Strategy and Solutions, Knipper Health Trade Services

Steve Gransden, Executive Vice President of Strategy and Solutions for Knipper Health has devoted twenty-five years to the pharmaceutical/biotech industry. His very diverse leadership background spans IT, Operations, Sales and Marketing, Strategic Planning, and Solutions Development. Working with countless brands over multiple decades, Steve has developed state-of-the-art platforms, and re-engineering processes to create more streamlined and efficient solutions. Steve's subject matter expertise encompasses both the commercial and non-commercial Pharmacy Services business, expertise, and insights as they examine and analyze the key drivers of this trend, the impact on retail pharmacy services, consumer behavior shifts, benefits of cash models, implementation considerations, and future trends in the evolving landscape of healthcare.



MICHAEL ZANGRILLI

Senior Director, Commercial Development KnippeRx, Inc.

Michael Zangrilli, Senior Director of Commercial Development for KnippeRx has spent a decade in the pharmaceutical/biotech industry, principally on the manufacturer side. As an Associate Director of Sales Solutions and Strategy, he has assisted multiple brands in successfully commercializing and launching products into the market utilizing a strategy built on alternative commercial and non-commercial distribution channels that help patients achieve brand access.

MODERATOR (FIERCE PHARMA):

We are seeing notable increases in the utilization of cash models. What are some of the market factors contributing to this trend?

STEVE GRANSDEN:

The reality is that retail pharmacies are facing significant challenges regarding branded medications. One critical issue is the substantial increase in NDC blocks. From 2018 to 2023, these blocks increased dramatically from 30 to approximately 650, marking a staggering surge of more than **2000%** in just five years. Originally intended for situations where new drugs offered similar clinical benefits as existing ones without additional value to patients, NDC blocks now seem to primarily serve as a cost-control tool for payers.

Another pressing concern is the pressure exerted by distributors, who compel pharmacies to prioritize generics over brands through Generic Compliance Ratios (GCRs). Typically set at **85%** generics to **15%** brands, these GCRs penalize pharmacies financially if they exceed the specified threshold for brand purchases. Distributors have even resorted to allocating brands, further limiting their availability.

> *"The reality is that retail pharmacies are facing significant challenges regarding branded medications."*
>
> \- Steve Gransden

Similarly, Pharmacy Benefits Managers (PBMs) mandate retailers to emphasize generics through Generic Utilization Rates of **85%** to **15%**, with reimbursement reductions for all prescriptions if brands exceed the designated ratio. They also implement *"aberrant drug lists,"* which restrict the dispensing of specific brands to a minimal percentage of total reimbursement.

These challenges compound the ongoing reductions in contracted reimbursement from PBMs each year. Consequently, wholesalers are pushing brand costs up, while PBMs are driving reimbursement down.
As a result, retailers are increasingly declining branded prescriptions, reaching unprecedented levels.

MODERATOR:

How is this impacting the retail environment in general, particularly regarding pharmacy services?

STEVE GRANSDEN:

I recently came across an article by one of the EVPs at a major retail pharmacy. In it the author remarks that the retail pharmacy industry has reached an inflection point due to the current environment of decreasing reimbursement and increasing drug costs which is unsustainable for pharmacies. The article also makes the point that by maximizing generic drug dispensing, brand drug dispensing has been minimized.

The author then elaborates on the belief in a *"new approach."* In reality, this is nothing more than a rebranded version of Cuban's *"Cost Plus"* model tailored for the major chain pharmacies that will dictate the drug cost and corresponding reimbursement with contracted PBMs based on their acquisition; so it's really their cost, plus a predetermined margin.

Furthermore, they plan to extend this new *"standard of compensation"* to select third-party discount card administrators beginning in 2025, with the updated prices initially available to consumers paying *"cash"* for their prescriptions. Regardless of the fancy terminology, it's clear that even major retail pharmacies are acknowledging the growing shift towards cash-pay pharmacy.

> *"Another significant impact worth noting is the decline in independent pharmacies."*
>
> \- Steve Gransden

Another significant impact worth noting is the decline in independent pharmacies. According to a recent McKinsey report, the number of independent pharmacies has decreased by nearly **50%** since 1980. I recently came upon a comment from the SVP of an independent group of pharmacies in the Northeast, who remarked that the point has been reached where everyone cannot continue to keep taking losses. He further noted that every brand name medicine has become a loser, and conditions have only gotten worse this year.

Ultimately, all of this is by design. The aim is to reduce the utilization rates of branded drugs, and this transformation shows no signs of abating anytime soon.

MODERATOR:

Are there any other significant factors contributing to the increase in cash-pay adoption?

STEVE GRANSDEN:

One notable driver is the proliferation of High Deductible Health Plans (HDHPs) in the insurance market. These plans, intentionally structured to elevate out-of-pocket costs for patients, have seen a rapid uptick. Recent studies indicate that over half of private sector workers in the U.S. are now enrolled in such plans.

Consider that the maximum out-of-pocket expense for individuals in these plans can exceed $8,000 and surpass $16,000 for families, marking a **7%** increase from 2023.

Consequently, patients are directly absorbing high copays at the point of sale or relying on copay assistance for subsidy. Even under Medicare Part-D's standard drug benefit for 2024, once an individual and their plan spend $5,030 combined on drugs, they may still be responsible for up to **25%** of prescription costs until their out-of-pocket spending.

High-deductible health plan (HDHP) requirements	2023	2024	Increase
Minimum deductible for an individual	$1,500	$1,600	7%
Minimum deductible for a family	$3,000	$3,200	7%
Out-of-pocket expenses maximum for an individual	$7,500	$8,050	7%
Out-of-pocket expenses maximum for a family	$15,000	$16,100	7%

Source: Healthcare.gov

MODERATOR:

Can you point to any shifts you're observing in consumer or patient behavior that contribute to the rise in cash transactions?

MICHAEL ZANGRILLI:

Consumers are becoming more proactive in managing their healthcare, including their treatment choices, and how they access them. There's a growing demand for convenience, with patients seeking streamlined, online ordering processes that offer delivery straight to their doorstep, ideally at minimal additional cost.

> *"Consumers are becoming more proactive in managing their healthcare, including their treatment choices, and how they access them."*
>
> - Michael Zangrilli

Moreover, there's a clear call for greater transparency and affordability in healthcare, particularly concerning drug prices. Cash pharmacy transactions have emerged as the fastest-growing segment, accounting for **10%** of total prescriptions.

MICHAEL ZANGRILLI *(continued)*:

According to a 2022 report by Prescryptive Health, **61%** of surveyed consumers had opted for cash prices for prescriptions, even when covered by insurance. Additionally, **50%** of urban residents noted that paying out of pocket was more cost-effective than using insurance.

MODERATOR:

What are some of the benefits of employing cash models?

MICHAEL ZANGRILLI:

There are advantages for both manufacturers and patients. From the manufacturer's perspective, it creates a new channel for their brand to operate in without the risk of switching or abandonment.

Switching or abandonment occurs when a patient goes to their local pharmacy to collect their prescription and the product is replaced by a generic or any other alternative. In this circumstance, manufacturers strategically bypass retail pharmacies and collaborate with pharmacies committed to filling prescriptions as written by healthcare providers, at a cost-effective rate.

Another benefit for manufacturers is the ability to eliminate payors from the equation, along with any prior authorization or limitations, enhancing patient access and affordability.

Additionally, simplifying marketing and messaging streamlines the process and boosts sales representative confidence. This streamlined approach allows sales teams to focus more on highlighting product features and benefits, as administrative hurdles are minimized. Transparent data further reinforces sales reps' confidence, as they can see the tangible impact of their efforts in prescription volumes. This transparency builds trust in healthcare providers' referrals and the pharmacy's ability to promptly initiate therapy for patients.

On the patient side, utilizing this direct-to-patient model offers significant advantages. Patients receive their medication at an affordable price and enjoy a positive, customized experience. The patient's journey becomes seamless and tailored to their individual needs.

MODERATOR:

When it comes to cash-based programs, is there a standard framework that suits most requirements, or are there specific considerations that guide the selection of a model?

STEVE GRANSDEN:

There's no one-size-fits-all approach for cash pharmacy programs. It depends on the specific circumstances and the ultimate objectives of the stakeholders involved.

When making recommendations, we typically begin by pinpointing key factors crucial to the design. For instance: Is the solution aimed at supporting a single brand, or does it entail a broader strategy encompassing multiple brands within the manufacturer's portfolio?

STEVE GRANSDEN *(continued)*:

Essentially, are we looking at a straightforward brand-focused solution or a more comprehensive *"manufacturer"* solution?

> *"There's no one-size-fits-all approach for cash pharmacy programs."*
>
> \- Steve Gransden

This distinction matters in that it significantly influences the platform development process. With a single-brand focus, the brand enjoys substantial autonomy over the portal's appearance, the patient journey, workflow, and so forth.

Single-brand implementations tend to be simpler, with lower total ownership costs and quicker deployment times. Conversely, when multiple brands are in play, a more templated approach is often preferred. The goal is to maintain consistency in user experience while allowing each brand some degree of flexibility to showcase its unique attributes.

As a result, multi-brand implementations necessitate more careful planning and, to some extent, greater complexity in that they may need to have a higher degree of configuration capability or input from a broader set of stakeholders. In addition, they may require additional integration points with third-party service providers like digital health platforms, PSPs, Hubs, or even data aggregators.

MODERATOR:

Are there any other significant factors to consider?

STEVE GRANSDEN:

There are. Distribution strategy plays a crucial role. Will a single nationwide pharmacy suffice, or is it necessary to establish a network? While a single pharmacy approach is often the simplest and most cost-effective, practicality may vary depending on therapeutic considerations and strategic variables.

Telehealth is another key consideration. While it may offer significant benefits depending on the therapeutic category and drug class, it also entails additional integration points and workflow processes. A telehealth strategy may also influence decisions regarding the implementation of a "white-labeled" pharmacy approach.

Essentially, *"white-labeled"* means that pharmacy services are provided under the branding of a specific customer. Patients and prescribers interact with this white-labeled pharmacy instead of potentially unfamiliar pharmacies.

> *"Distribution strategy plays a crucial role."*
>
> \- Steve Gransden

STEVE GRANSDEN *(continued)*:

All marketing materials for patients and prescribers are tailored in a white-labeled program, simplifying messaging, and fostering a closer relationship between the brand, prescriber, and patient.

Moreover, as a fully licensed pharmacy, the white-labeled pharmacy is integrated into all electronic medical records (EMRs), facilitating prescription routing for healthcare providers. One significant advantage of this approach is that these pharmacies typically only need to be licensed in one state, as prescriptions can be transferred to dispensing pharmacies with licenses in multiple or all states.

It's important to note that a white-labeled *"service"* doesn't necessarily equate to a white-labeled *"pharmacy."* While a branded patient access service or a direct-to-patient *"cash"* service may benefit from a branded physical pharmacy, the level of benefit may vary.

MODERATOR:

Can you provide an example where this scenario might apply?

STEVE GRANSDEN:

A good example would be a situation where a customer's strategy hinges on leveraging telehealth to streamline patient prescribing. In such instances, where telehealth services serve as the primary conduit for patient communication, healthcare providers (HCPs) are already familiar with the prescription routing process. Given that patients are predominantly serviced by the telehealth provider, the advantages of white labeling the pharmacy may not be as compelling, except for any physical pharmacy locations involved.

MODERATOR:

What type of things are involved in implementing a direct-to-patient (DTP) cash solution?

MICHAEL ZANGRILLI:

When embarking on the implementation of a DTP cash solution, the focus lies on optimizing the patient journey and user experience. Whether it entails forging partnerships with virtual healthcare platforms like Medlify or integrating telehealth solutions to enhance the patient funnel, the strategy should prioritize patient-centric approaches.

> *"When embarking on the implementation of a DTP cash solution, the focus lies on optimizing the patient journey and user experience."*
>
> \- Michael Zangrilli

Launching direct-to-consumer (DTC) marketing campaigns can lay a solid foundation for brand building before the channel goes live. The program design should aim to maximize outreach. Utilizing contemporary technology enables cost-effective scalability by reaching more individuals.

MODERATOR:

What technology tools are commonly employed today to develop the most cost-efficient model?

STEVE GRANSDEN:

Two key categories of technology are pivotal: customer experience technology and pharmacy experience technology.

Regarding customer experience, the enrollment process should be streamlined, offering a user-friendly interface with minimal clicks. Once enrolled, patients should navigate through mandatory questions swiftly to facilitate prescription fulfillment. A branded enrollment and virtual platform serve to reinforce product awareness.

On the pharmacy front, employing robotics for picking, packing, and shipping reduces labor costs significantly. Incorporating such technology not only optimizes the patient's journey but also streamlines the prescription process, allowing manufacturers to delve deeper into their DTC marketing initiatives while realizing substantial operational cost savings.

MODERATOR:

What future trends do you foresee in DTP cash solutions, and how can pharmaceutical manufacturers adapt their strategies to stay ahead in the market?

STEVE GRANSDEN:

Cash transactions represent the fastest-growing segment within the pharmacy sector, currently constituting over **10%** of total prescriptions. Various factors contribute to this trend, such as substantial increases in National Drug Code (NDC) blocks and lists of aberrant drugs, as well as the utilization of generic compliance ratios by distributors and generic utilization rates by Pharmacy Benefit Managers (PBMs). Additionally, there's a persistent decline in drug reimbursement rates. These market dynamics show no indication of reversal.

> *"Patients increasingly demand price transparency and enhanced affordability..."*
> - Steve Gransden

Patients increasingly demand price transparency and enhanced affordability while assuming greater control over their healthcare decisions.

They seek streamlined and convenient pathways to accessing therapies.

MICHAEL ZANGRILLLI:

Here's an example of how increased distribution costs are impacting decisions around cash. This breakdown is for a typical product with a $600.00 Wholesale Acquisition Cost (WAC).

10-12% Wholesaler Costs - Discounts/Shipping	**$60 - $72**
0.5% Shipping to Wholesaler	**$3**
2% Cash Discount	**$12**
50% Payer Discount & Rebates to get a reasonable formulary position (not preferred mind you)	**$300**
5% Wholesaler/Retail Returns	**$30**
2% Copay Adminstration	**$12**
15% Sales/Marketing	**$90**
5% Corporate Costs - legal, regulatory, market acess, finance, etc.	**$30**
Total distribution cost:	**$537**

In the end you are lucky to be left with **10%** of WAC - all the while fighting an uphill battle to get your brand's prescriptions filled and at increasingly low rates. All of this leads me to believe that the DTP cash market will continue to grow at an increasing rate, for the foreseeable future.

MODERATOR:

Considering the challenges posed by generic competition, where else can a DTP cash solution be leveraged as a strategic tool to mitigate the impact of generics on market share and help ensure a level of sustained profitability for the brand?

MICHAEL ZANGRILLLI:

Brands within the Loss of Exclusivity (LOE) products or in crowded therapeutic categories, present promising opportunities for cash programs.

> *"With a competitively priced cash-based alternative, brands can retain substantial market share."*
>
> - Michael Zangrilli

Many branded therapies maintain significant brand loyalty despite potential absence from formularies. Additionally, even if a generic alternative exists, it may not necessarily offer therapeutic equivalence. Patients adhering to these therapies often exhibit reluctance to switch to generics, especially if they are experiencing positive outcomes with the brand. Moreover, prescribers are typically inclined to maintain patients on effective treatments. With a competitively priced cash-based alternative, brands can retain substantial market share. This hinges on effective promotion of the channel, ensuring a straightforward process, and delivering superior service.

In Conclusion

The trend in cash model utilization in retail pharmacies reflects a broader shift towards consumer-centric healthcare delivery. By understanding and adapting to market dynamics, manufacturers can leverage cash models as strategic tools to mitigate the impact of generics, maintain market share, and ensure sustained profitability.

As the healthcare landscape continues to evolve, embracing innovative approaches that prioritize patient needs and streamline access to therapies will be paramount for success.