Launching a new therapy with a direct-to-patient cash model.

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The landscape of retail pharmacy is under extraordinary pressure, particularly in managing branded medications.

One significant concern is the sharp increase in National Drug Code (NDC) blocks, which have surged from 30 in 2018 to approximately 650 by 2023. This marks a remarkable growth of over 2000% in just five years. Initially intended to categorize new drugs offering comparable clinical benefits to existing treatments with negligible added value, NDC blocks have increasingly morphed into cost-control mechanisms for payers. This shift, along with stringent Generic Compliance Ratios (GCRs) and Generic Utilization Rates (GURs) imposed by distributors and Pharmacy Benefit Managers (PBMs) respectively, compels pharmacies to prioritize generic drugs over branded medications. These measures, designed to cap brand purchases at ~15% of total drug purchases, reduce reimbursement on ALL prescriptions if brands outpace generics beyond the limit, and reduce reimbursement rates, often leading to the suppression of branded prescriptions.

Adding insult to injury, the PBMs can create what they call “aberrant drug lists” which impose stringent restrictions on pharmacies regarding these drugs. Pharmacies are compelled to follow these restrictions meticulously; otherwise, they risk losing reimbursement or facing contract termination. This is all in addition to the persistent decline in reimbursement rates which all providers are facing.

In essence, wholesalers are pushing up brand costs, while PBMs are reducing reimbursements. As a result, retailers are rejecting branded prescriptions more than ever before. In response, direct-to-patient cash pharmacy solutions are gaining traction. These alternatives offer enhanced affordability, availability, and access to high-quality therapies outside the constraints of traditional distribution models.

> *“...launching a new therapy with a direct-to-patient cash model offers several strategic benefits.”*

For pharmaceutical manufacturers, launching a new therapy with a direct-to-patient cash model offers several strategic benefits:

- **Immediate Revenue Generation:** Cash sales generate revenue upfront. It ensures immediate revenue generation by bypassing the delays associated with payor negotiations and payments.
- **Simplicity and Speed:** This model simplifies and expedites transactions, sidestepping the complexities of payor negotiations and insurance contracts.
- **Price Control:** Manufacturers maintain price control, allowing them to set competitive cash prices and potentially optimize revenue based on market demand and competitive pricing strategies.
- **Access to Uninsured or Underinsured Patients:** Offering therapies at a cash price also broadens access, particularly for uninsured or underinsured patients who might be deterred by high deductibles or copays. As a result, it also expands the potential customer base.
- **Market Testing and Adoption:** This approach serves as an effective market testing ground, enabling manufacturers to assess demand and adoption rates before entering into long-term payor agreements, providing valuable insights for future pricing and strategy adjustments.
- **Flexibility:** The flexibility inherent in cash pricing allows rapid adaptation to market shifts or regulatory changes, without being restricted by extended payor agreements.
- **Brand Perception:** Depending on the therapeutic area and market dynamics, offering a cash price may enhance the brand's image, positioning the therapy as accessible and beneficial directly to consumers.

When manufacturers consider the advantages of direct-to-patient cash pharmacy solutions, they must be carefully weighed against potential limitations including restricted access for insured patients, lower utilization rates and navigating regulatory frameworks that may favor insurance-covered treatments. To succeed, manufacturers must develop strategies to address these challenges, ensuring their products are both accessible and appealing to consumers while complying with all regulatory requirements.

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