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Touchpoints in the Pharmaceutical Supply Chain

by Stephen Pickett, Ph.D.
Healthcare Economist

Key Points

- Drug spending in the United States has been increasing in recent years and is expected to continue to grow due to rising drug prices and increased drug utilization.
- It is important for policymakers to understand the role of everyone involved in the supply chain in order to craft effective legislation to help control rising drug costs.

Executive Summary

In the United States, healthcare expenditures and prescription drug costs have been increasing in recent years and policymakers have been interested in slowing down these rising costs. To adequately address rising costs, there needs to be a solid understanding of where the money is going, who is involved, and what role everyone plays. Most people understand that manufacturers produce drugs and pharmacies sell drugs, but they probably are not aware of the existence of many of the other entities involved in the process. These entities play an important role, such as packaging the drugs, negotiating drug formularies, and facilitating payments. This paper identifies the prominent entities involved in the pharmaceutical supply chain and briefly explains their role.

Introduction

In 2019, prescription drug expenditures totaled approximately $360 billion and with rising drug prices and increasing drug utilization, expenditures are expected to continue to grow over the next decade (Sisko et al., 495; Statista). There are many entities involved in the process of producing and delivering drugs to consumers. Drug manufacturers discover new drug compounds, study their safety and efficacy, and manufacture them to be sold to consumers. Pharmacies are the most common point of contact for consumers needing to purchase prescription drugs. In addition to manufacturers and pharmacies, there are many other entities involved in the process, including wholesalers, third-party payers, pharmacy benefit managers (PBMs), pharmacy services administration organizations, and PBM auditors. Many of the entities are relatively unknown to consumers compared to manufacturers and pharmacies. As lawmakers and regulators at federal and state levels continue considering legislation to address increasing healthcare prices, particularly prescription drug costs, it is important for policymakers to understand who is involved in the process as they attempt to address rising pharmaceutical costs.

The purpose of this paper is to review the different touchpoints in the prescription drug supply chain, identifying the primary entities in the business. This is not intended to be a comprehensive list of every entity involved, nor will this process be true for every drug or every consumer. However, this paper illustrates how a typical prescription drug purchased from a pharmacy by an individual with health coverage will flow from the manufacturer to the end consumer and identifies the primary entities involved and how they earn revenue from the payments made by consumers.

This paper is divided into two sections. The first section introduces the entities that supply the physical drug to the consumer. The second section introduces the service providers that do not physically handle the drugs but are an important part of the financial transactions.

continued

Product Supply Chain

Drug Manufacturers

For a drug to reach the market in the United States, it needs to undergo a lengthy process of research and development, clinical trials, and eventually approval by the Food and Drug Administration (FDA). The details of this process are outside the scope of this policy perspective (see the FDA website for details on this process).

The manufacturer conducts extensive research and development to find a new drug to bring to the market. On average, it costs $2.6 billion and takes 10 years for a drug to complete the process of basic discovery through clinical trials and to be approved by the FDA (PhRMA, 22). Once a drug is approved by the FDA, it is ready to be sold to consumers. The manufacturer does not sell directly to consumers but will first sell its product to a wholesaler, which sells the drug to pharmacies, which eventually sell it to consumers.

Wholesalers

Once a drug is produced by the manufacturer it is sold in large quantities to wholesalers. The wholesaler typically receives discounts for buying in larger quantities, paying promptly, and purchasing drugs that have a relatively short expiration date (KFF 2015, 9). Wholesalers can broadly be categorized into two groups: full-line wholesalers and specialty distributors. Full-line wholesalers will sell a variety of drugs to a variety of purchasers, such as independent pharmacists, chain and grocery store pharmacies, mail-order pharmacies, and specialty pharmacies. Specialty distributors will typically only handle certain types of drugs that require extra care and/or sell to a specific group of purchasers (e.g., nursing homes) (Fein).

Working with wholesalers are several smaller entities, frequently subsidiaries of the larger wholesaler, that help safely distribute drugs to the pharmacies. *Pharmaceutical repackagers* repackage the drugs into smaller quantities to be distributed to pharmacies. *Labelers* work with distributors to ensure that the drugs are appropriately labeled, both to help consumers understand what they are taking and how to properly take the drugs. After the drug is packaged and labeled, it is then sold to the pharmacy which eventually sells the drug to the consumer.

Pharmacies

Pharmacies are frequently the final entity in the supply chain that sells prescription drugs to the end consumer. Pharmacies purchase prescription drugs from wholesale distributors, store the drugs, and sell them to patients. There are many different types of pharmacies. Most familiar to consumers are *retail pharmacies*, such as independent pharmacies, chain pharmacies (e.g., Walgreens, CVS), and grocery store pharmacies.

In addition to traditional retail pharmacies, several other forms of pharmacies sell prescriptions to patients. *Mail-order pharmacies* will distribute prescription drugs but do not have a physical location for consumers to visit. Instead, once they receive a prescription from a provider, they send patients their prescriptions through the mail.

Service Providers

In addition to the entities that produce and deliver prescription drugs to consumers, other entities involved in the process provide services but do not directly handle drugs. Here we describe the more prominent entities and the role they play in order for consumers to purchase their prescription drugs.

Third-Party Payers

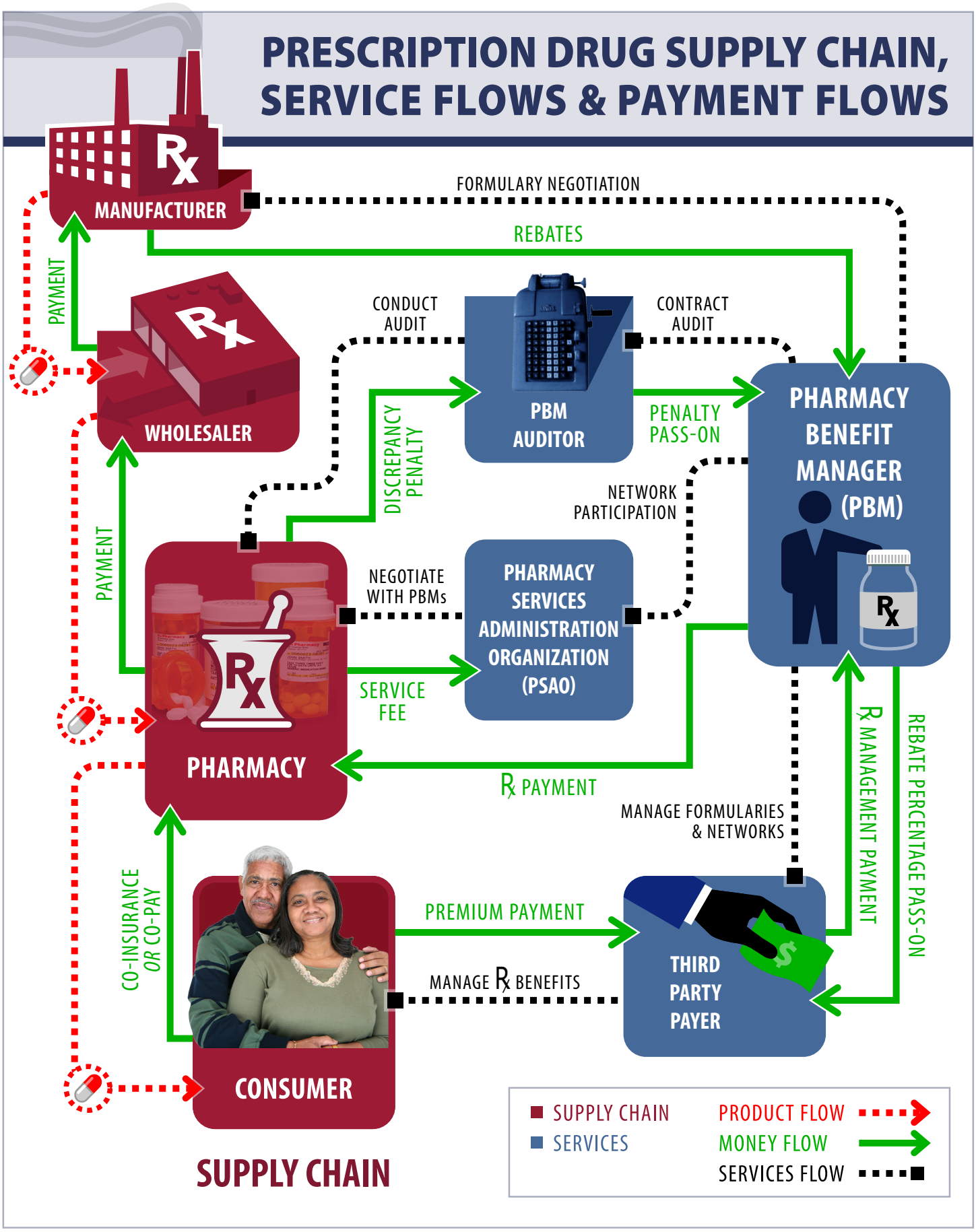
Third-party payers are the entities that offer pharmacy benefit plans to consumers in exchange for a premium. Third-party payers can be insurance companies, the federal government, state governments, or employers. Consumers with prescription drug coverage frequently have this combined with their health insurance; however, it can be a separate policy from their medical coverage (e.g., Medicare Part D beneficiaries). In the United States, roughly 98 percent of all retail pharmaceutical purchases are through third-party payers (KFF 2019).

The third-party payer is involved in several financial transactions when consumers receive prescription drugs. First, the consumer pays insurance premiums to third-party payers for prescription drug coverage. On behalf of the beneficiary, the third party determines the benefit levels of the plan, works with a PBM to create formularies indicating which prescriptions are covered in the plan, and negotiates prices, rebates, and care programs with the manufacturer. When a beneficiary purchases a prescription from the pharmacy, the third-party payer reimburses the PBM, who in turn reimburses the pharmacy.

Pharmacy Benefit Managers

Pharmacy benefit managers work on behalf of third-party payers to negotiate drug formularies and rebates with manufacturers, to create pharmacy networks, and to dispense the covered drugs. Originally PBMs were created to adjudicate pharmacy claims for third-party payers (Werble 2017b). However, in recent years, they have become more prominent in the industry now that they negotiate drug formularies, rebates, and pharmacy networks and offer care management.

PRESCRIPTION DRUG SUPPLY CHAIN, SERVICE FLOWS & PAYMENT FLOWS



Their primary role is to negotiate drug formularies and rebates (Werble 2017b). Drug formularies place drugs in tiers, which determine different levels for member cost-sharing. A typical formulary will have generic drugs in Tier 1; Tier 2 are preferred brand-name drugs; Tier 3 are nonpreferred brand-name drugs; and Tier 4 are specialty drugs(Werble 2017a). PBMs use pharmacy and therapeutics (P&T) committees, consisting of physicians, pharmacists, nurses, and other healthcare professionals, to recommend which drugs are included in the formulary and where the drugs are placed (ASHP, 1; Rumore and Vogenberg).

Lower formulary placement corresponds to lower out-of-pocket costs for consumers, so manufacturers are interested in receiving lower placement to increase their likelihood of being purchased by the consumer. Manufacturers often pay rebates to the PBMs to get a preferential placement on the formulary for their products. PBMs typically keep a percentage of the rebates as payment for their services and pass along the remainder to the third-party payer, which may retain the rebate for their administrative services or pass it along to the consumer in the form of lower premiums.

In addition to rebates, PBMs earn revenue through practices called *clawbacks* and *spread pricing*. For many prescription drugs, a patient will pay a copayment, and the insurer will pay the remainder of the price. However, sometimes the copayment is more than the total cost of the prescription. In these situations, the PBM will keep the difference between the copayment and the drug cost, which is known as a clawback. A 2018 study found that 23 percent of pharmacy fills involved a patient overpaying for the prescription by at least $2.00 (Van Nuys et al.). Spread pricing occurs when a PBM charges the insurer a higher price than what is paid to the pharmacy (Kouvelis et al.). The PBM will keep the difference as revenue.

Pharmacy Services Administration Organizations

Pharmacy Services Administration Organizations (PSAOs) are organizations that contract with pharmacies (typically smaller independent pharmacies) to perform various administrative functions. The primary services PSAOs offer are typically contract negotiations with PBMs and third-party payers. Additionally, PSAOs offer a variety of other administrative services, such as claims adjudication, audit assistance, compliance support, or communications (GAO, 2).

Third-party payers contract with PBMs to create networks of retail pharmacies for their beneficiaries and negotiate prices with the pharmacies. Smaller, independent pharmacies that lack bargaining power against PBMs frequently contract with PSAOs. PSAOs negotiate on their behalf with PBMs and other third-party payers regarding networking, reimbursement rates, payment terms, and audit provisions, among other things (GAO, 2).

PBM Auditors

PBMs contract with PBM auditors to occasionally audit pharmacies to ensure accurate payments and accurate fulfillment of prescriptions to consumers. Audits are intended to ensure proper payments and prevent fraud, waste, and abuse. If the audit turns up inappropriate practices by the pharmacy, the PBM penalizes the pharmacy (Baird).While the intent of audits is to monitor payments and fulfillment of prescription drugs, concerns have been raised as to whether auditors are always acting in good faithto detect fraud, waste, and abuse (NCPA).

Conclusion

In this paper, we discussed many of the entities involved in the pharmaceutical supply chain and the associated entities that provide services throughout the process in which consumers buy prescription drugs. The average consumer likely does not know these different entities are involved in the process. As pharmaceutical expenditures are expected to increase in the coming years (Sisko et al., 495), consumers, employers, taxpayers and policymakers will want to know where their money is going. As policymakers look to curb rising drug costs, it is important to understand who is involved, what services they are providing, and how they are being compensated.

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ABOUT THE AUTHOR

Stephen Pickett, Ph.D., is a healthcare economist for the Right on Healthcare Initiative at the Texas Public Policy Foundation. Prior to joining the Foundation, Pickett worked in the health insurance industry where he researched the relationship between different insurance products and healthcare utilization and outcomes, as well as alternative provider reimbursement strategies. His research during graduate school focused on the impacts of the Affordable Care Act's marketplaces on Texans and how providers change their behavior when alternative payment models are introduced.

Pickett received his Ph.D. and M.A. in economics from Rice University and his B.B.A. in business fellows and mathematics from Baylor University.

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