

Prescription Drugs: Path to the Patient

Alex Rosenberg

legislative analyst



© 2019 Wisconsin Legislative Reference Bureau One East Main Street, Suite 200, Madison, Wisconsin 53703 http://legis.wisconsin.gov/lrb • 608-504-5801

This work is licensed under the Creative Commons Attribution 4.0 International License. To view a copy of this license, visit http://creativecommons.org/licenses/by/4.0/ or send a letter to Creative Commons, PO Box 1866, Mountain View, CA 94042, USA.

Overview

Prescription¹ drugs are a major component of modern health care and can be among the most visible and interactive pieces of patient care. They also represent a significant portion of U.S. health care spending, accounting for about 10 percent of total health care costs.² As well-publicized cost drivers for health care, prescription drugs are often targets of legislative action intended to help control health care costs. However, even experts in the field can have trouble tracking all aspects of prescription drug spending, let alone recommending policy levers that could best influence that spending. For example, the IQVia institute, a research organization that releases a widely cited yearly report on U.S. medication use and spending, discovered and reported some "divergent trends" in 2017:

- Pharmacy prices for branded prescription drugs increased by 58 percent over five years, but patients' out-of-pocket costs declined by 17 percent.
- Only 0.2 percent of prescriptions had out-of-pocket costs over \$250, but those prescriptions made up 9 percent of all out-of-pocket drug costs.
- Medication use by patients has continued to rise, but overall spending on retail drugs and mail-order pharmacy drugs declined by 2.1 percent.3

These apparent anomalies, IQVia states, "reflect the complex dynamics determining how much patients pay for their medicines and the influence those costs have on whether they fill their prescriptions." The complexity of those dynamics can also make it more difficult to know how best to bring down prescription drug costs.

This report examines the players, processes, policies, and payments underlying the prescription drug market with the goals of providing (1) an overview of how drugs get to patients and (2) how the costs for those drugs are determined. On that basis, the report then describes policy options that can be applied to the various areas of the market in order to reduce costs.

From factory to patient

Broadly speaking, the prescription drug pathway from factory to consumer is as follows:

- 1. The drug is manufactured from raw materials.
- 2. The drug is purchased by a wholesaler for redistribution, repackaging, or both.
- 3. The drug is stocked at pharmacies.
- 4. Reimbursement negotiations by insurers, pharmacy benefit managers, or some combination thereof establish reimbursement rates for prescriptions.

^{1.} Semibolded words are defined in the Glossary—Appendix 4 (pp. 15-18).

^{2.} Centers for Medicare and Medicaid Services, "National Health Expenditures 2017 Highlights," https://www.cms.gov/.

^{3.} IQVia Institute, "Medicine Use and Spending in the U.S.," April 19, 2018, https://www.iqvia.com.

- 5. The drug is prescribed to a patient by a physician or other medical **practitioner**.
- 6. The drug is **dispensed** at a pharmacy, where the patient's copay or coinsurance is collected.

The primary actors involved in the U.S. prescription drug market are the following:

• Manufacturers create the drugs. For name-brand drugs, the manufacturer has often done the research and development to invent the drug; otherwise, a factory might license the right to manufacture a drug from the developer. Generic drugs can be manufactured and sold after the original drug's patent expires.

A USC Schaeffer Center for Health Policy and Economics study estimates that 17 percent of gross U.S. prescription drug spending is consumed by research, development, and production costs before the drug ever hits the market.⁴ These costs of production can vary considerably between new branded drugs and generics; the research and development required to invent a drug can cost as much as 2.6 billion dollars.⁵

Drug manufacturers make up a large portion of the prescription drug market, but perhaps less than might be assumed. The Schaeffer Center study estimates that manu-

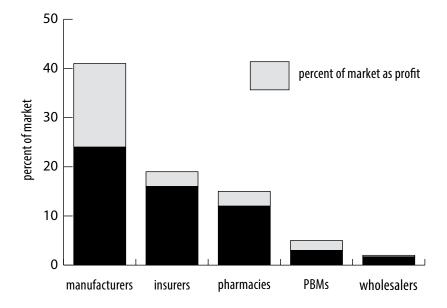


Figure 2. Shares of spending and profit in the U.S. prescription drug market

Note: Pre-market research and development consumes the remaining 17 percent of spending and is not included in this chart in order to maintaim the consistency of market share and profit comparisons between primary market actors.

^{4.} Neeraj Sood et al., "Flow of Money Through the Pharmaceutical Distribution System," (USC Schaeffer Center for Health Policy & Economics, June 2017), 5, https://healthpolicy.usc.edu.

^{5.} Joseph A. DiMasi, Henry G. Grabowski, and Ronald W. Hansen, "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs," Journal of Health Economics 47 (May 1, 2016): 20–33, https://www.sciencedirect.com.

facturers keep about 41% of all U.S. prescription drug spending. Just over a third of what they keep—about 15 percent of U.S. prescription drug spending—is manufacturer profit.6 Fifty-nine percent of U.S. prescription drug spending, therefore, goes to other actors.

• Wholesalers buy drugs from manufacturers; manage the financial, logistical, and staffing requirements of distribution; and resell the drugs in smaller quantities, sometimes repackaged into smaller bottles or cartons. Because wholesalers buy large amounts of drugs, they can negotiate significant volume discounts as compared to smaller purchasers.

Three major wholesalers (AmerisourceBergen, Cardinal Health, and McKesson) control 90 percent of the U.S. market.8 Wholesalers keep an estimated 2 percent of all U.S. spending on prescription drugs. About 0.3 percent of all U.S. spending on prescription drugs is wholesaler profit.9

- Employers offer insurance coverage to employees. As of 2016, 55.7 percent of the U.S. population has employer-based health insurance coverage. 10 While the insurer or its PBM (see below) establish the availability and coverage levels for prescription drugs under the plan, the employer can negotiate for the best plans to purchase and offer to employees.¹¹
- Insurers cover patients' prescription drugs and prescriber visits. Patients may be insured by one or a combination of employer-based insurance, individual insurance, or government-based insurance such as Medicare or Medicaid. Insurers allocate a portion of the premiums they collect to pay for patients' prescription drugs, either through direct payments to pharmacies or through contracts with intermediaries that manage patients' drug coverage, such as pharmacy benefit managers.¹²

Insurers keep about 19 percent of all U.S. spending on prescription drugs. About 3 percent of all total U.S. spending on prescription drugs is insurer profit.¹³

• Pharmacy benefit managers (PBMs) contract with insurers to manage prescription drug formularies and claims. They act as intermediaries between drug sellers and insurers, negotiating discounts on drug purchases in exchange for giving those drugs prefereable placement on a formulary—the tiered list of drugs covered by the patient's

^{6.} Sood et al., "Flow of Money through the Pharmaceutical Distribution System," 5. Similarly, another study found that brand manufacturers receive 39 percent of gross U.S. drug expenditures: Aaron Vandervelde and Eleanor Blalock, "The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized by Stakeholders," (Berkeley Research Group, 2017), 1, https://www. thinkbrg.com.

^{7.} Health Care Distribution Alliance, "Pharmaceutical Distributors: Understanding Our Role in the Supply Chain," accessed October 1, 2018, https://www.hda.org.

^{8.} Adam J. Fein, "MDM Market Leaders | Top Pharmaceutical Distributors," 2017, https://www.mdm.com.

^{9.} Sood et al., "Flow of Money through the Pharmaceutical Distribution System," 5.

^{10.} US Census Bureau, "Health Insurance Coverage in the United States: 2016," September 12, 2017, https://www.census.gov.

^{11.} Wisconsin Office of the Commissioner of Insurance, "Guide to Health Care Insurance," November 2017, https://oci.

^{12.} The portion of premiums allocated to drug costs is typically kept confidential, but a report compiled from disclosures required by the state showed that California's commercial insurers spent an average of 13.6 percent of premiums on prescrip-

^{13.} Sood et al., "Flow of Money through the Pharmaceutical Distribution System," 5.

insurance.¹⁴ Since most patients only purchase drugs covered by their insurance, manufacturers can sell more drugs by getting those drugs placed on formularies for as many patients as possible.

PBMs pay a pharmacy each time the pharmacy dispenses a drug to a patient covered by one or more of the PBM's contracted insurers. Contracts between PBMs and pharmacies set rates for these payments based on each drug's wholesale price.

Three major PBMs (CVS/Caremark, ExpressScripts, and Optum) control at least 80 percent of the U.S. market, but many others still do significant business.¹⁵ The State of Wisconsin, for example, uses Navitus as the PBM for its group health insurance programs.

There is some controversy over PBMs' role and profits within the drug market. PBMs have been called, for example, "the hidden villain of big pharma" for their perceived lack of transparency. ¹⁶ In their defense, PBMs argue that "a lack of transparency into their operations is what makes them successful in negotiating with drug companies." ¹⁷

PBMs keep about 5 percent of all U.S. spending on prescription drugs. About 2 percent of all U.S. spending on prescription drugs is PBM profit.¹⁸

• **Pharmacies** distribute drugs to patients. Types of pharmacies include brick-and-mortar retailers such as Walgreens and CVS, mail-order firms such as ExpressScripts, and inpatient pharmacies in facilities like hospitals and nursing homes.

Specialty pharmacies and specialty medications are a quickly growing subset of pharmacy activity in the United States.¹⁹ According to the Accreditation Commission for Health Care, an independent accrediting organization, "Specialty medications target a specific population with a chronic and sometimes life-threatening disease. Specialty Pharmacy services include disease-specific clinical monitoring, as well as patient compliance and adherence programs."²⁰ Specialty pharmacies are often involved in complex and sometimes even experimental treatments for diseases such as multiple sclerosis, cancers, and rare genetic conditions.

Pharmacies keep about 15 percent of all U.S. spending on prescription drugs. About 3 percent of all U.S. spending on prescription drugs is pharmacy profit.²¹

^{14.} Judy Buckalew, "Pharmacy Benefit Managers Play Significant Role in Drug Pricing," October 2017, https://www.aaos.org.

^{15.} Community Oncology Alliance, "PBM DIR Fees Costing Medicare and Beneficiaries," January 2017, https://www.communityoncology.org.

^{16.} Jessica Wapner, "<u>Understanding the Hidden Villain of Big Pharma: Pharmacy Benefit Managers</u>," *Newsweek*, March 17, 2017, https://www.newsweek.com. Critics of PBMs' transparency practices often took issue with "gag causes" in PBM contracts with pharmacies, which prevented pharmacists from informing customers that they could pay a lower price in cash rather than using insurance (and the PBM) to pay for a drug. About half of U.S. states banned gag clauses in state law, but in October 2018, President Trump signed two bills into law to do so at the federal level; <u>S. 2553</u> and <u>S. 2554</u> prohibit PBM gag clauses for both private insurance and Medicare plans.

^{17.} Buckalew, "Pharmacy Benefit Managers Play Significant Role in Drug Pricing."

^{18.} Sood et al., "Flow of Money through the Pharmaceutical Distribution System," 5.

^{19.} Adam J. Fein, "Exclusive Update: The State of Specialty Pharmacy Accreditation in 2017" (Drug Channels Institute, April 13, 2017), https://www.drugchannels.net.

^{20.} Accreditation Commission for Health Care (ACHC), "Pharmacy Accreditation," accessed October 1, 2018, https://www.achc.org.

^{21.} Sood et al., "Flow of Money through the Pharmaceutical Distribution System," 5.

• Patients receive prescriptions and take prescribed drugs. Patients interact directly with prescribers, pharmacies, employers, and insurers. Patients rarely deal directly with the drug manufacturer, wholesaler, or PBM.

In total, according to the USC Schaeffer Center study, 23 percent of all U.S. consumer spending on prescription drugs is profit. Of the profits, 65 percent (15 percent of total spending) goes to manufacturers. The remaining 35 percent (8 percent of total spending) is split among the intermediaries: wholesalers, insurers, PBMs, and pharmacies.²²

Appendix 1 contains a table describing the details and calculations underlying the flow of money through the stages of the supply chain.

Appendix 2 shows a breakdown of each actor's sales and purchases both in the prescription drug supply chain and for drug-related services.

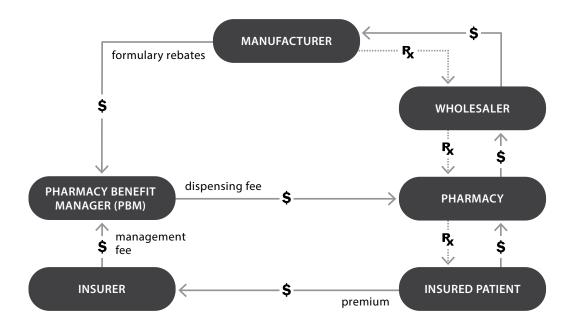


Figure 1. Pharmaceutical supply chain

Determining what a patient pays for a drug

The cost that an insured patient pays for a drug is mostly a function of formularies. At the most basic level, a formulary is a list of drugs covered by an insurer. It may be created in-house by the insurer or, as is increasingly common, delegated to a PBM to create and manage.23

^{22.} Ibid.

^{23.} Bruce Japsen, "Cigna To Buy Express Scripts For \$54 Billion, Ending The Era Of The Standalone Drug Middleman," Forbes, March 8, 2018, https://www.forbes.com.

A Health Affairs policy brief on formularies describes them as "both drug-selection and cost-control tools" for payers.²⁴ They fulfill this function through the use of "tiers." With a tier system, not all drugs on the formulary are covered identically; some preferred drugs may be reimbursed completely or almost completely, while others may have significant out-of-pocket costs for the patient. The difference in cost can be a powerful tool to steer a patient toward certain options and away from others.

According to Health Affairs, "a typical four-tier formulary might include generic, preferred brand, nonpreferred brand, and specialty tiers. Higher-price products appear on the higher tiers and carry the highest coinsurance rates." See Appendix 3 for a hypothetical example of a formulary tier list.

How tiers are assigned

According to a Kaiser Family Foundation report, insurers and PBMs use formularies for three primary purposes:²⁶

- Negotiating deeper price discounts. PBMs negotiate with manufacturers over whether a drug will be included on a formulary and in what tier. In exchange for payments from the manufacturer for each time a drug is dispensed, a PBM may agree to give a drug more favorable placement than competing products.
- **Influencing beneficiary utilization rates**. Tier placement can influence patients' consumption, especially when combined with other measures the insurer or PBM might implement, such as quantity limits and **prior authorization** requirements. For example, patients may ask their doctors to prescribe a drug on the least costly tier.
- Encouraging beneficiaries to use a mix of preferred or lower-cost covered products. Placing effective but cheaper generic options on lower tiers can deliver the same clinical outcomes as using costlier branded prescription drugs, but at significant savings for the insurer.

Statutory requirements at both the state and federal levels place limits on insurers' and PBMs' formulary and tier development. Medicare Part D is the most visible case. The Center for Medicare and Medicaid Services' *Medicare Prescription Drug Benefit Manual* requires that "Part D sponsor formularies must include all or substantially all drugs in the immunosuppressant (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes."²⁷ In addition,

^{24. &}quot;Formularies," Health Affairs, September 14, 2017, para. 1, https://www.healthaffairs.org.

^{25.} Ibid

^{26.} Kaiser Family Foundation, "Follow The Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain," March 2005, 14, https://www.kff.org.

^{27.} Centers for Medicare and Medicaid Services, "Prescription Drug Benefit Manual," January 15, 2016, sec. 30.2.5, https://www.cms.gov.

each category or class within a formulary is required to include at least two drugs, and these two cannot be only variations of brand-versus-generic, strengths, or forms.

Medicaid drug reimbursement

Medicaid programs use a different prescription drug reimbursement model that does not involve formulary tiers.²⁸ Instead, Medicaid prescription drug reimbursement is governed by both state and federal law:

In order for a drug to qualify for federal statutory Medicaid matching funds, manufacturers must sign an agreement with the Secretary of Health and Human Services stating that they will rebate a specified portion of the Medicaid payment for the drug to the states, which in turn share the rebates with the federal government. In return, Medicaid must cover almost all FDA-approved drugs that those manufacturers produce. The formula for the amount of the rebate is set in [state] statute and varies by type of drug . . . most states also negotiate supplemental rebates with manufacturers.²⁹

In short, federal law sets overarching requirements for Medicaid reimbursement and matching funds, while states lay out the specific reimbursement formula for their respective Medicaid programs.

For outpatient drugs—those not included as part of other services such as a hospital stay—Medicaid programs pay based on an ingredient cost and a dispensing fee.³⁰ State programs have some flexibility within federal regulations on how to calculate and apply these two factors.

For ingredient costs, for example, the February 2016 Centers for Medicare & Medicaid Services (CMS) Final Rule sets a basis for determining ingredient cost, but states can select from multiple methods to establish the calculated actual acquisition cost (AAC) for a drug.³¹ CMS maintains a <u>list of states' methods</u> on its website.³² Wisconsin calculates ingredient cost as the lowest of the National Average Drug Acquisition Cost formula (NADAC) or the usual and customary charge to the general public.³³ "Usual and customary," as defined by CMS, means "the amount charged by the provider for the

^{28.} Wisconsin and other states do still maintain "preferred drug lists," which are reimbursed the same as other drugs, but for which no prior authorization is required. Drugs not on the list require prior authorization for reimbursement.

^{29.} Katherine Young and Rachel Garfield, "Snapshots of Recent State Initiatives in Medicaid Prescription Drug Cost Control" (Kaiser Family Foundation, February 21, 2018), https://www.kff.org/.

^{30.} Medicaid and CHIP Payment and Access Commission, "Medicaid Payment for Outpatient Prescription Drugs," May 2018, 2, https://www.macpac.gov.

^{31.} Department of Health and Human Services, "2016 Medicaid Final Rule" 42 CFR § 447.502 (2016), https://www.gpo.gov.

^{32.} Centers for Medicare and Medicaid Services, "Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State," June 2018, https://www.medicaid.gov.

^{33.} See: Centers for Medicare and Medicaid Services, "Methodology for Calculating the National Average Drug Acquisition Cost (NADAC) for Medicaid Covered Outpatient Drugs" (2013), https://www.medicaid.gov.

same service when provided to non-Medicaid patients."³⁴ If the NADAC information required for Wisconsin's lowest-cost comparison is not available, the state's reimbursement method also includes fallback options that take other costs into consideration instead.

Dispensing fees are meant to cover labor, record keeping, and other overhead costs needed to dispense a drug—essentially, costs other than for purchasing the drug itself. In Wisconsin, Medicaid dispensing fees are calculated based on the pharmacy's annual prescription volume:³⁵

- Under 35,000: \$15.69 per member, per service, per month, per provider
- Equal to or over 35,000: \$10.51 per member, per service, per month, per provider

Some pharmacy services can qualify for additional allowances. For example, compounding drug claims (claims for drugs specially prepared in exact strengths and doses for a specific patient) qualify for an additional \$7.79, and certain other drugs that need to be repackaged into special doses can qualify for additional allowances of \$0.015/unit added to the dispensing fee.

State-level legislation and policy options

Broadly speaking, state-level policy levers for cutting prescription drug costs tend to use one of three major strategies: boosting industry transparency, implementing statutory price controls, or reducing costs by making drug acquisition and distribution more efficient. Each of these approaches can be applied at multiple levels in the prescription drug supply chain.

Across the states, these approaches have been considered and implemented in a range of forms. The National Academy for State Health Policy (NASHP) maintains lists of prescription drug related bills for 2018, 2017, and 2015–2016. While they do not use the three strategies described above, the NASHP lists categorize and summarize each proposed bill, including status and sponsor information. According to NASHP records, states' 2018 drug legislation included:

- Ninety-two proposed bills related to PBMs; thirty-five of these were enacted.
- Thirty proposed bills related to increasing drug price transparency from manufacturers; four of these were enacted.
- Thirteen proposed bills related to penalties for "price gouging" by manufacturers; none passed.

^{34.} ForwardHealth Wisconsin, "Changes to Billing and Reimbursement Policy for Covered Outpatient Drugs," March 2017, 20, https://www.forwardhealth.wi.gov.

^{35.} ForwardHealth Wisconsin, "Covered Outpatient Drug Reimbursement: Professional Dispensing Fees," October 1, 2018, https://www.forwardhealth.wi.gov.

- Nine proposed bills related to drug imports from Canada; one of these was enacted.
- Seven proposed bills creating state drug task forces, commissions, or study committees; one of these was enacted.
- Four proposed bills to combine purchasing negotiations across state agencies; none passed.
- Nineteen other proposed bills that do not fit the categories above.36

While PBM-related legislation was by far the most successful, counting the full range of proposals can provide a helpful sense of the types of legislative efforts taking place across the country.

Based on the bills on the NASHP lists, examples of legislative efforts related to the three strategies of increasing transparency, implementing price controls, and boosting efficiency are listed below.

- Transparency. Requiring that certain information be made public applies pressure on various actors to keep costs and price increases under control.
 - Manufacturers. Mandatory disclosure of costs or wholesale prices can encourage manufacturers to keep their own prices under control. For example, a state might require a manufacturer to publically disclose ingredient cost data for drug price increases over a certain threshold, such as 10 percent. These mandatory disclosures can put pressure on manufacturers to keep price increases more closely in line with their actual costs.
 - Insurers. Mandatory disclosures can require that insurers make information about their prescription drug-related costs and contracts public. Because drug costs can be major drivers of premium increases, this information can help patients and employers keep abreast of the factors underlying the costs of coverage and might help them negotiate policies that deliver higher value to patients.
 - PBMs. Mandatory state licensure, audits, or pricing and contract-related disclosures can require PBMs to make information about profits, pricing practices, and contractual relationships public. These disclosures can help patients and insurers track PBMs' profit motives.
- Price controls. While transparency legislation can put public pressure onto various actors, this pressure does not necessarily translate to lower prices. In some cases, therefore, states take direct action to control prices, often for specific drugs or drug types. As with transparency legislation, these controls are applied at multiple levels.
 - Manufacturers. Bills in this category often define sets of essential drugs and then place limits on manufacturers' abilities to increase the price of those drugs above a certain threshold without regulatory approval. For example, single-year price

^{36.} National Academy for State Health Policy (NASHP), "State Legislative Action to Lower Pharmaceutical Costs," September 5, 2018, https://nashp.org.

increases of more than 100 percent could require review and approval by the state attorney general.

- **Insurers.** Regulations can limit costs by mandating certain formulary placement or otherwise limiting patients' costs for certain crucial drugs. For example, some bills place limits on the allowable out-of-pocket cost an insurer can charge an enrollee, such as a cap of \$100/month for a 30-day supply of certain drugs.
- PBMs. Limits on PBMs' ability to set per-transaction charges, substitute higher-cost drugs for lower-cost options, or perform drug or pharmacy steering based solely on profitable contracts can all help keep costs down by reducing PBMs' profits. For example, regulation might prohibit PBMs from charging patients more to get drugs from pharmacies with which the PBMs do not have favorable contracts.
- **Efficiency.** Legislative efforts in this area are often specific to the processes and markets of the state in which they occur, but two major themes do emerge across states.
 - Collective action. A number of states are considering consolidating purchasing and price negotiating power across state agencies or other entities subject to some degree of state control. For example, unifying the drug purchases of Medicaid programs, public pensions, and state educational institutions can allow for a significant boost in negotiating power, leading to lower costs than could be achieved separately.
 - Study and information sharing. A number of states considered new committees or task forces to study and report on various aspects of prescription drug costs, generally with the goal to inform targeted legislation in a future session. In a similar vein, some state legislation sought to empower educational campaigns to help stakeholders—typically prescribers—do their part to keep costs low.

Conclusion

Prescription drugs go through a complex and variable series of movements, processes, services, and purchases on their path to a patient. Each of these can be governed by various authorities, including private corporations, state regulatory authority, and federal regulatory authority. Most often they encounter a combination of all three. This complexity can make it all the more difficult to develop targeted measures aimed at simplifying processes or reducing costs. However, as costs continue to rise, so too may the demand for legislative action. \blacksquare

Appendix 1. Stages and money flow in the prescription drug supply chain

Stage	Description	Money flow	
Manufacturing	The drug is manufactured and packaged.	WAC:	
	The manufacturer sets a wholesale sales price, also known as the wholesale acquisition cost (WAC). This is meant to cover the costs of research, production, and some profit. Before discounts, this is the price of the drug to the wholesaler.	Internal manufacturer calculation \$100	
	Almost no one pays the WAC: ³⁶ • Uninsured patients pay based on wholesale prices, but often with a self-pay discount from the manufacturer or pharmacy.		
	• Insured patients pay a patient portion (copay or coinsurance), and all of the other actors involved in getting the drug from the manufacturer to the patient all negotiate contracts to pay other prices.		
Wholesale distribution	Wholesalers buy large amounts of drugs from the manufacturer. The contract between the manufacturer and wholesaler offers the wholesaler some discount from the WAC (e.g., 5% off). ³⁷	Wholesaler pays manufacturer: WAC (\$100) – discount (5%) \$100 – 5% = \$95	
	There may be multiple wholesale steps between the manufacturer and the pharmacy, with contracts between wholesalers as well.		
Stocking at pharmacy	Pharmacies buy drugs from the wholesaler(s).	Pharmacy pays wholesaler:	
	The contract between pharmacy and wholesaler sets a price, typically lower than the WAC (e.g., 3%	WAC (\$100) – discount (3%) \$100 – 3% = \$97	
	off). ³⁸	Wholesaler net income:	
	The net to the wholesaler is the difference between the contracted manufacturer sales price and pharmacy purchase price.	Incoming pharmacy payment (\$97) – outgoing manufacturer payment (\$95) \$97 – \$95 = \$2	

^{36.} See, e.g., Academy of Managed Care Pharmacy (AMCP), "Guide to Pharmaceutical Payment Methods," Executive Summary, 2013, 5, http://www.amcp.org; Neeraj et al., "Flow of Money through the Pharmaceutical Distribution System," 1,"Pipeline to Profits."

^{37.} Academy of Managed Care Pharmacy (AMCP), "Pharmaceutical Payment Methods," 5.

^{38.} Academy of Managed Care Pharmacy (AMCP), 4–5.

Appendix 1. Stages and money flow in the prescription drug supply chain, continued

Stage	Description	Money flow	
Negotiation by insurer or PBM	The insurer contracts with a PBM to manage prescription drug benefits, setting reimbursement rates based on the average wholesale price (AWP), which is calculated by marking up the WAC (e.g., an added 20%). ³⁹	AWP: WAC (\$100) + extra percent (20%) \$100 + 20% = \$120	
	PBMs negotiate to receive drug-based payments directly from manufacturers in exchange for preferable tier placement for that manufacturer's drugs. ⁴⁰ A PBM's contract with an insurer determines what portion of the payment the PBM keeps and how much passes back to the insurer.	Insurer pays PBM: AWP (\$120) – discount (30%) \$120 – 30% = \$84 Manufacturer pays PBM: Negotiated rate per fill \$30	
	The manufacturer makes whatever is left from the wholesaler's payment after the PBM payments are made. If this amount is higher than the unit cost of R&D, production, and distribution, the manufacturer makes a profit.	PBM shares with insurer: Manufacturer payment (\$30) * negotiated portion (50%) \$30 × 50% = \$15 Manufacturer net income: Incoming wholesaler payment (\$95) – outgoing PBM payment (\$30) – production cost (\$20) \$95 - \$30 - \$20 = \$45	
Prescription	A medical practitioner writes a prescription for the patient. The prescription indicates (among other things) the drug, preparation, quantity, and directions for use. Assuming they use a PBM, insurers' only income related solely to prescription drugs comes from	Patient & employer pay insurer Monthly employee payment (\$240) + monthly employer contribution (\$480) \$240 (pt.) + \$480 (emp.) = \$720/mo.	
	PBM-shared manufacturer payments. The insurer profits from prescription drug coverage as long as the total of PBM-shared manufacturer payments and whatever portion of premiums it allocates for prescription drugs (e.g., 10%) is higher than what it pays out to the PBM. The rest of insurers' profit is unrelated to prescription drugs.	Insurer net income: Portion of premiums + rebate shares – PBM payment (\$720 × 10%) + \$15 – \$84 = \$3 Note: The patient and insurer pay the prescriber for the visit where the prescriber writes the prescription. This payment is for general healthcare services, and is not a significant element of the prescription drug supply/payment chain.	

^{39. &}quot;Pipeline to Profits." Note that public insurers have different contracts and use different contract terms according to relevant statutes that apply only to them, such as the <u>Affordable Care Act requirements</u> for Medicaid drug rebates (42 U.S.C. 1396r–8).

^{40.} Academy of Managed Care Pharmacy (AMCP), "Pharmaceutical Payment Methods," 9.

Appendix 1. Stages and money flow in the prescription drug supply chain, continued

Stage	Description	Money flow
Dispensing to patient	The patient pays the patient portion (copay or coinsurance according to formulary tier) at the pharmacy. This payment is passed through to the	Patient portion (to PBM): According to copay tier \$10
	PBM.	PBM pays pharmacy:
	To cover the rest of the non-patient portion, the	AWP (\$120) – discount (15%)
	PBM pays a negotiated amount to the pharmacy. These contracts are typically based on either the	\$120 - 15% = \$102
	WAC or AWP minus some discount (e.g., 15%).	PBM gross income: Incoming insurer payment
	The PBM's net income is the total of the contracted amount from the insurer, any manufacturer	(\$84) + incoming manufacturer payment (\$30) + patient copay
	rebates, and the patient's copay, minus the payment	(\$10)
	to the pharmacy and any rebates passed to the	\$84 + \$30 + \$10 = \$124
	insurer.	PBM net income:
	The pharmacy's net income is the difference between what they receive from the PBM and what they pay the wholesaler.	Gross income (\$124) – outgoing pharmacy payment (\$102) – outgoing manufacturer payment share to insurer (\$15) \$124 – \$102 – \$15 = \$7
		Pharmacy net income: Incoming PBM payment (\$102) – outgoing wholesale payment (\$97) \$102 - \$97 = \$5

Appendix 2. Actors' roles: supply chain, services, and payments

Actor	Supply chain	Services	Payments 41
Manufacturer	Manufactures drugs. Sells to wholesalers.	Researches and develops new drugs.	To PBMs: drug rebates To patients: copay assistance/coupons
Wholesaler	Buys from manufacturers. Sells to pharmacies.	Repackages drugs. Distributes drugs to dispensers.	To manufacturers: for drug stocks
Employer	N/A	Sponsors insurance for employees.	To insurers: insurance premiums
Insurer	N/A	Covers members' prescriptions.	To PBMs: drug reimbursement To prescribers: visit reimbursement
Pharmacy benefit manager (PBM)	N/A	Manages insurers' drug benefits. Places manufacturers' drugs on formularies.	To pharmacies: drug reimbursement To insurers: portion of drug rebates
Pharmacy	Buys from wholesalers. Sells to patients.	Stocks drugs. Educates patients.	To wholesalers: for drug stocks
Patient	Consumes drugs.		To insurers: insurance premiums To PBMs (via pharmacy):

N/A—not applicable

^{41. &}quot;Payments" here include major purchases and overarching reimbursement models. There are many other transactions that might also take place, such as fees for drug distribution, dispensing, e-prescribing, or administrative costs. Because of the diversity and inconsistency of other such transactions, they are omitted for the sake of clarity.

Appendix 3. sample prescription drug formulary

Tier	Scope	Description	Patient cost ⁴²
1	Generic drugs	Inexpensive drugs identical to the branded version in effectiveness.	Very low (e.g., \$5 ¹⁰)
2	Preferred branded prescription drugs	Brand-name drugs with low list prices or favorable manufacturer/PBM contract prices.	Low-medium (e.g., 20% coinsurance)
3	Non-preferred branded prescription drugs	Brand-name drugs more expensive than those in Tier 2 (often without a favorable contract/rebate for the insurer).	Medium-high (e.g., 40% coinsurance)
4	Specialty drugs (Might be split into preferred and non- preferred tiers)	Drugs not covered by Tiers 1–3, used outside their standard purpose, or with other special considerations.	Variable (e.g., \$50 copay)
[protected]	Specific special cases listed in the formulary.	Drugs with special requirements and/ or cost limits.	Low (e.g., \$0 for specific preventative drugs)
[not covered]	Everything else	Drugs that do not fall into any of the categories above.	Variable (list price)

 $^{42. \,} Sample \, amounts \, from \, 2018 \, \, Wisconsin \, Group \, Health \, Insurance \, benefits: \\ \underline{\text{`Comparison of Pharmacy Benefits'}}, \, May \, 31, \,$ 2018, https://www.wisconsin.edu.

Appendix 4. Glossary¹

- actual acquisition cost (AAC). A calculated (or hypothetical) estimate for what a pharmacy actually paid to a wholesaler to stock a drug, sometimes called "ingredient cost." Typically lower than AWP and WAC. AAC is required to be used to set Medicaid reimbursement rates, but insurers or PBMs might also negotiate the use of the AAC rather than AWP/WAC in contracts with pharmacies, since this substitution would require them to pay the pharmacies relatively less based on drug costs.
- average wholesale price (AWP). The "list price" for a drug at retail, much like an MSRP list price for cars. It is used as the basis for some reimbursement/payment contracts, mostly with private insurers, and calculated from the WAC. Calculations are not statutorily defined. Medicare moved from using AWP to ASP for reimbursement formulas in 2003.
- **branded prescription drug.** The initial commercial version of a drug, as opposed to a generic drug. It is licensed by an FDA New Drug Application and is protected (or was formerly protected) by a patent.
- **dispense.** On the basis of a prescription, preparing and providing a drug to the consumer. **dispensing fee.** A fee paid as part of a reimbursement to the dispenser of a drug that is meant to cover costs other than the drug price, such as the pharmacist's labor, record keeping, and other overhead. Medicaid programs include dispensing fees as one portion of their reimbursement calculation for prescription drugs. Some private insurance and PBM contracts also include these fees.
- **formulary.** The list of prescription drugs an insurance plan covers, also called "drug list." A formulary is created by either an insurance company or a contracted PBM. Within the formulary, a formulary tier is a set of drugs with specific reimbursement policies. Examples include generic drugs, which often have no or very low copays, and various levels of branded or specialty drugs with higher amounts of patient responsibility.
- **generic drug.** An identical competing drug manufactured and sold without the brand name after a branded prescription drug's patent expires. It is licensed by an FDA Abbreviated New Drug Application.
- ingredient cost. A calculated portion of some reimbursement rates to approximate what it costs a pharmacy to stock a drug independent of any other costs or overhead. It is often paired with dispensing fees to cover those other costs. A common example is the actual acquisition cost (AAC) reimbursement calculation used by state Medicaid programs.

^{1.} Adapted and paraphrased from sources include "A Glossary of All Terms Pharma," NASHP, June 15, 2018, https://nashp. org; Kaiser Family Foundation, "Follow the Pill"; and other sources previously cited in this paper.

- insurer. An organization or company that takes full or partial financial responsibility for benefits claims by a covered set of members. Examples include private organizations (e.g., Aetna, Cigna), government programs (e.g., Medicare, Medicaid), and employers (under self-insurance).
- manufacturer. The organization that manufactures the drug and offers it for sale, whether directly to pharmacies or through one or more wholesalers.
- member. A person covered by an insurance policy. The insurance field tends to refer to "members" rather than "patients."
- NADAC. The National Average Drug Acquisition Cost formula used to calculate reimbursement rates for some government programs.
- **outpatient drug.** A drug not covered and paid for as part of other services, such as a hospital stay. Most drugs dispensed by retail or mail-order pharmacies are outpatient drugs.
- payer. A company or organization other than the patient that pays for or reimburses some or all of the cost for health services. It is typically an insurer, but may also be a government agency, employer, or other third party.
- pharmacy. The most common dispenser of drugs to patients. "Pharmacy" used alone typically refers to a retail/commercial pharmacy that both fills prescriptions and offers nonprescription over-the-counter drugs (e.g., ibuprofen, Benadryl). Other types include commercial mail-order pharmacies, inpatient hospital pharmacies, and specialty pharmacies. These types can overlap at a single location or organization. For example, CVS offers retail, mail, and specialty pharmacy services.
- pharmacy benefit manager (PBM). Handles some or all pharmacy benefits for insurers or employers. Example services include formulary management, copay/cost-sharing tiers, pharmacy networks and contracts, and manufacturer/wholesaler contracts.
- practitioner. Someone practicing medicine. Sometimes used as shorthand for a person with authority to prescribe drugs (e.g., an M.D. or a dentist), as distinct from those who cannot write prescriptions.
- **preferred drugs.** Drugs reviewed and approved by an insurer or PBM for some special formulary status, such as a lower tier (and hence a lower cost for the patient) or waived prior authorization requirements.
- **prescriber.** A medical professional with authority to write a prescription authorizing a certain strength, form, and quantity of a drug to be dispensed to a patient.
- prescription. An order for the preparation and use of a drug or device for a patient. It is required for a patient to receive prescription drugs from a pharmacy.
- **prior authorization.** A requirement by the insurer to review and approve a drug or other benefit as medically necessary or otherwise appropriate before it will be covered. Sometimes referred to as a "preauthorization requirement."

- **provider.** A professional involved in patients' health care. The term is used more broadly than "practitioner," encompassing not only those with prescribing authority (e.g., physicians) but other clinical staff such as registered nurses, physical therapists, and radiology technicians.
- **rebate.** A discount or payment on the cost of a drug, most often paid by a manufacturer to a PBM. Rebates allow manufacturers to offer confidential contractual discounts without altering the list price of the drug.
- **repackaging.** Changing the unit size, format, or packaging of a drug to be distributed or sold, for example, taking pills from large cartons and creating bottles of 30. It is often offeres as a service by wholesalers.
- **retail drug.** Any kind of drug available from a retail pharmacy counter. Despite the "retail" name, it is typically paid for through pharmacy claims rather than directly and entirely by the patient.
- specialty pharmacy. Pharmacies that dispense and manage drugs with special requirements or complexities. Examples may include very high-cost drugs, drugs with intensive shipping or storage requirements (e.g., heat or cold), or experimental drugs used by specialists for patients with specific rare or difficult-to-treat conditions. The specialty pharmacy handles and dispenses the drugs and often also provides services like home delivery, special administration such as IV infusions, and ongoing checks that the patient follows the prescription instructions correctly.
- **usual and customary.** The price a provider or pharmacy charges a patient without insurance coverage or any other special considerations. It is a factor in some Medicare/Medicaid reimbursement rate calculations.
- wholesale acquisition cost (WAC). The baseline price for wholesale distributors' drug purchasing contracts. Set by drug manufacturers using internal algorithms to cover costs of research, manufacturing, and distribution.
- wholesaler. An organization that buys large amounts of drugs to resell in smaller quantities to pharmacies or other smaller wholesalers. Because they buy very large quantities, wholesalers pay relatively lower prices to manufacturers than a smaller buyer will. Wholesaler contracts with both manufacturers and pharmacies are based on WAC with some negotiated percentage discount. Wholesalers profit from the difference between those discounts (e.g., 10 percent from the manufacturer and 4 percent to a pharmacy).