Issue: Prescription Drug Pricing

Understanding Prescription Drug Pricing

Summary

The system setting the price a patient pays for a prescription drug is a rat's nest of regulations, exorbitant profit margins, and what the industry calls "formularies"— lists compiled by a committee of doctors and pharmacists consisting of both brand-name and generic drugs used by practitioners to identify drugs with the greatest overall value to patients. The companies involved are almost all national—if not global—making state-level improvements difficult, but not impossible. To change the system at a state level, one must first understand the key players, the paths of product creation, capital investment and regulatory formulas, and the actions of other state legislatures. America has some of the highest prescription drug prices in the world; they represent nearly 20 percent of health care costs.[1] That hurts everyone.

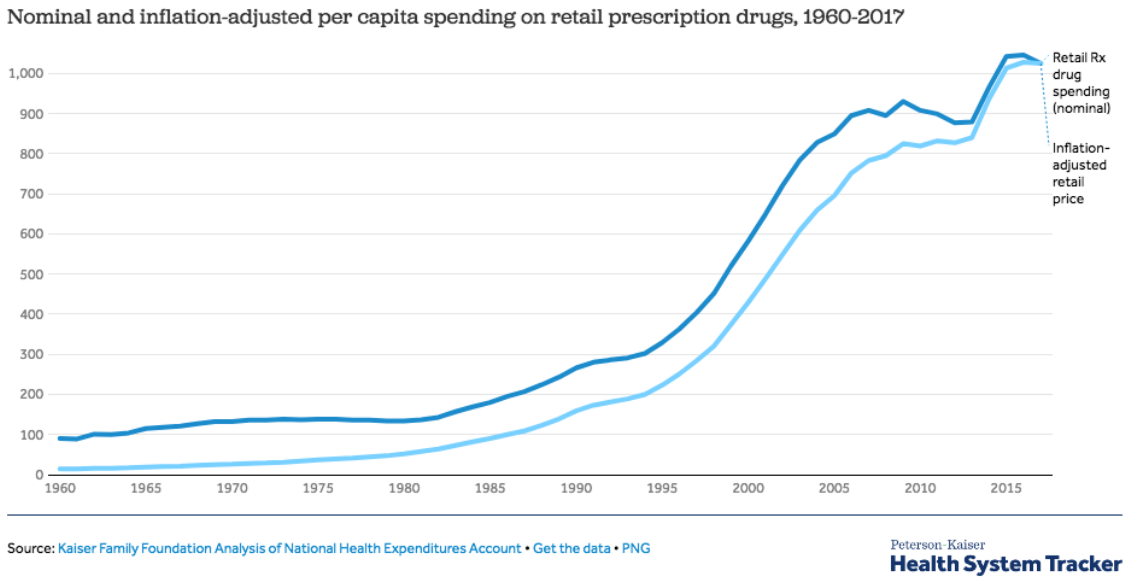

Fig. 1 Source: Kaiser Family Foundation Analysis of National Health Expenditures

The expenditures by the State of Virginia on prescription drugs totaled $707 million in FY 2015.[2] These included purchasing through Medicaid, corrections departments including jails and juvenile justice facilities, state employee health plans, local health departments, and community services. Eighty-two percent of the expenditures came primarily from the state's Medicaid program ($577 million). As more of Medicaid is shifted to managed care programs ($309 million), it's even more difficult to negotiate prices. Virginia has little impact on the cost and choice of drugs as rebates are negotiated at the federal level. The second largest expenditure for Medicaid is from Medicare Part D for dually-eligible recipients ($188 million). Similarly, Virginia has no control over the state share of Medicare Part D since it is also mandated by the federal government.

Commercial health plans paid $2.0 billion in Virginia alone for prescription drugs in 2015 on behalf of consumers. A report by IMS Health found that prescription drug prices rose an average of 12% in 2015 with similar rate increases for the past several years.

The Key Players

Pharma Companies

Pharmaceutical companies research, test, and seek federal approval for prescription drugs, and when they are approved, manufacture and market them. Of the key players in prescription drug pricing, pharma companies take the most capital risk. Only five out of every 5,000 tested drugs make it to human trials, and only one out of those five makes it to market.[3] This risk is part of the reason why the wholesale acquisition cost (WAC) of any brand name drug—the price set by the pharmaceutical company—is set so much higher than the manufacturing price. Patent protections give the company a few years of exclusive profit before the drug formula becomes public and generic.

Under US patent law, pharma companies hold patents for their drug for 10 to 20 years[4] —longer for drugs meant to treat diseases that affect fewer than 200,000 American residents, which are called "Orphan Drugs."[5] Once a drug goes generic it is more difficult for the company that developed it to make a profit, so many resort to drastic price hikes.[6] Generic drugs have the same active ingredients, dosage, and the U.S. Food and Drug Administration's (FDA) approval as name-brand drugs,[7] and these price hikes of name brand drugs raise the cost passed on to insurance companies, further raising prices for everyone covered.

Increasing transparency for disclosure of the drugs' wholesale costs at the pharmaceutical company level, as attempted in 2018 by Virginia as well as several other states, is unlikely to be successful.[8] All publicly traded drug companies are required to disclose their research and development costs, and focusing exclusively on drug companies as the sole scapegoat neglects some egregious practices of other actors. Attempts to pass such legislation against pharma companies have been met with a powerful lobbying force. An alternative solution would be setting regulations to limit drastic price hikes, which would help to control drug pricing. For more examples of proposed bills, search under the "Rx Price Gouging" tag in this interactive map produced by the National Academy for State Health Policy: https://nashp.org/rx-legislative-tracker-2019/ .

In Virginia, SB1308 was introduced by Sen. John Edwards (D-Roanoke) to prevent price gouging for prescription drugs. The bill would prohibit "unconscionable price increases in the price of essential off-patent or generic drugs, authorize the Secretary of Health and Human Resources to designate drugs as essential drugs, and establish an enforcement mechanism." The bill failed in committee with no further information provided.

In addition to the above, the U.S. Congress has taken recent steps to curb drug price growth, introducing several new bills which would "allow for the legal importation of cheaper drugs from Canada and to allow Medicare to negotiate drug prices and apply penalties to drug companies whose U.S. prices far exceed the prices in other developed countries."[9] One would hope that the new Democratic-controlled House would also look into the increasing lack of competition in the industry after more and more pharmaceutical companies merge into market behemoths.

Pharmacy Benefit Managers (PBMs)

PBMs, such as CVS Health, Express Scripts, and UnitedHealth Group's OptumRx, can best be described as middlemen between pharma companies, insurance companies, and pharmacies. They negotiate rebates and the contents of the official list of drugs—or "formulary"— so that insurance companies get the best prices and highest quality prescriptions and pharmaceutical companies can get the largest number of their prescriptions into the market. Those savings should get passed on to the pharmacies and ultimately the consumer. Private insurance companies don't have the time or means to negotiate with every drug company and pharmacy, so there is a place for a legitimate negotiator in the current prescription drug system. Unfortunately, PBMs who play that role have proved to be more profit-driven than consumer-protection-driven.

On top of the administrative fees they charge everyone they work with, PBMs have come under scrutiny for a practice called "spread pricing." When a patient buys a drug from a pharmacy, the pharmacy then turns to the PBM to ask for a refund for the drug they just sold. This refund is slightly higher than the price the patient paid so the pharmacy can make a reasonable profit. The PBM then turns to the insurance company and asks for a refund of the refund the PBM just gave the pharmacy. The problem occurs when the PBM asks for a significantly higher refund than they paid the pharmacy. They take the difference as their profit.[10] As shown in Fig. 2, in 2014, the patient paid $8 for the prescription, but the insurance company gets charged $16, resulting in a spread of $8. (For an interactive version of the chart, visit https://www.bloomberg.com/graphics/2018-drug-spread-pricing/). The PBM receives 200% profit on each prescription, which raises the price of insurance, copays, and deductibles for patients.

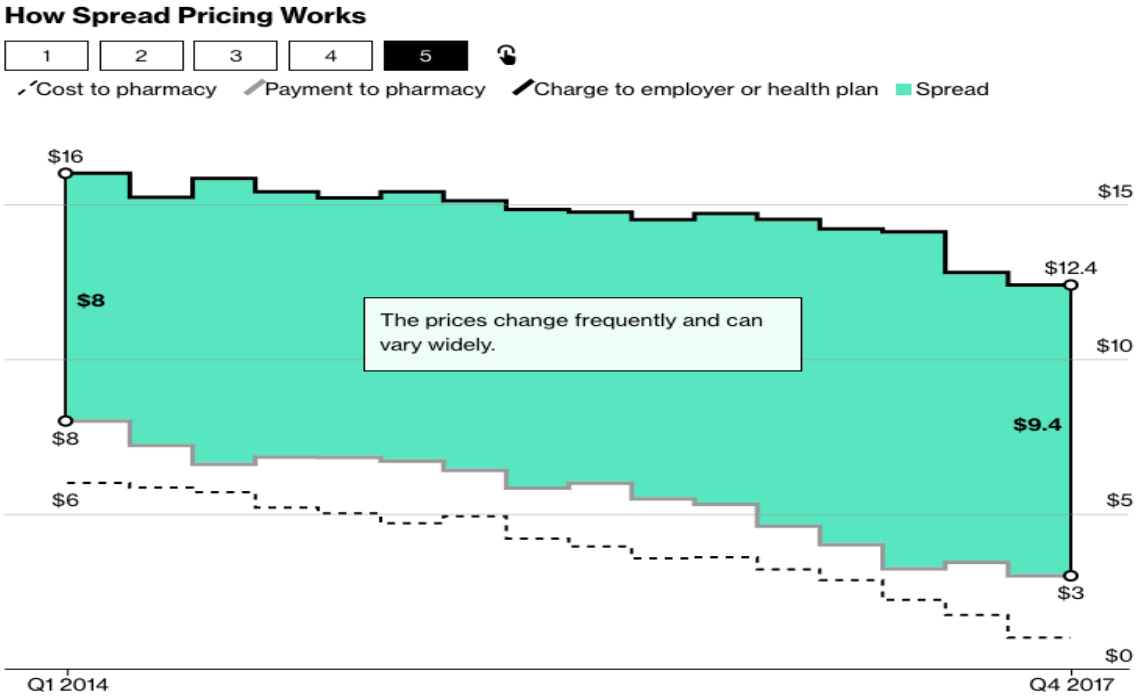

Fig. 2 https://www.bloomberg.com/graphics/2018-drug-spread-pricing/

Shown in Fig. 3 is a real-life example of spread pricing on a drug meant to treat hepatitis B in Indiana:

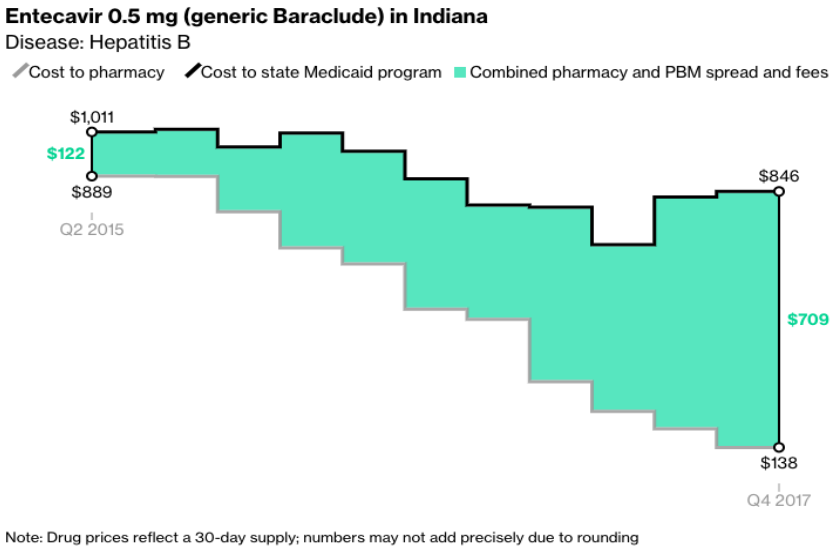

Fig. 3 https://www.bloomberg.com/graphics/2018-drug-spread-pricing/

PBMs claim that spread pricing is an alternative to making profit through administrative fees, and that the option is up to their customer: the pharmacies and insurance companies.[5] They also claim that reports like the Bloomberg article[5] cited in this paper are cherry-picking examples of spread pricing, that the PBMs make money off some drugs, lose money on others. A study done in Ohio on generic drugs found that counterclaim to be questionable. Figure 4 is the chart Bloomberg made of their findings.

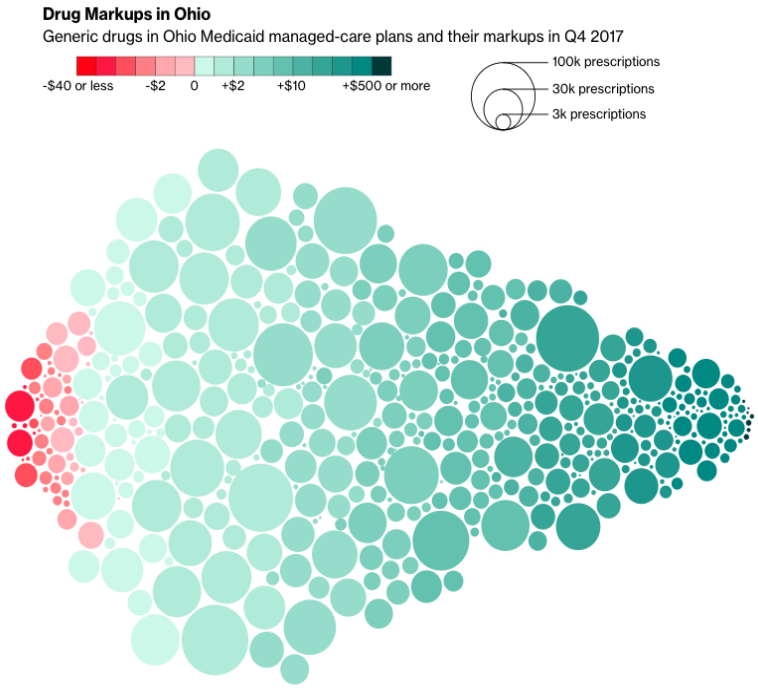

Fig. 4 https://www.bloomberg.com/graphics/2018-drug-spread-pricing/

Unfortunately, transparency regarding PBM's spread pricing fees and other practices is lacking. For an actor that takes very little risk in the system, it is difficult to determine where their money goes. Any attempt to change or regulate these fees and profits is, again, met with a powerful lobbying force. While it is difficult to find effective solutions for the lack of accountability of PBMs, it is simple to see that when the Department of Veterans Affairs negotiates directly with pharmacies and drug manufacturers they save a lot of money doing so.[11] In West Virginia, they cut PBMs out of their state Medicaid program. They had estimated savings for the state of $30 million in the first year alone. By the end of the year, they found that the change had actually saved the state Medicaid program $54.4million.[12] Despite the difficulties of passing legislation increasing PBM transparency, it is worth pursuing, keeping in mind that cutting them out of the equation completely has proven to be economically beneficial for states that succeeded.

In Virginia Del. Keith Hodges (R) introduced bill HB2516 in an attempt to regulate the PBM spread by not allowing insurance companies to calculate future insurance premiums including the PBM spread as a benefit. Instead the bill required the spread to be treated as an administrative cost. The bill was left on the table in the Republican-controlled Labor and Commerce Committee and postponed from consideration.

Insurance Companies

Insurance companies help patients pay for prescriptions and medical treatments. Without them patients would be required to pay for every treatment out of pocket and would likely go into debt as a result. Insurance companies work by taking the periodic payments and co-pays of their customers and making careful calculations and risk assessments to ensure the costs of sicker patients are covered by the payments from healthier patients. For large insurance companies, this works well and they can make high profits while still providing necessary services to customers.

Delegates introduced a couple of bills to regulate insurance companies in Virginia in 2018. These included HB 1445 (Del. Hope-D), which would have prohibited insurance companies from denying services based on cost and other factors and HB 1478 (Del. Roem-D13), which would have required insurance companies to cover prosthetics. Both were killed by Republicans in the Commerce and Labor Committee. Arguments should be made regarding the moral compass of insurance companies that consider it ethical to deny coverage of medically-necessary prosthetic devices for amputees.

As mentioned above, insurance companies are also complicit in negotiating fixed-cost copays with PBMs. "Under the guise of providing "rebates" to patients, PBMs in effect push the cost of drugs higher in order to garner larger commissions. It is important to remember that in addition to benefitting PBMs, these 'rebates' benefit both insurance companies and drug makers by allowing them to charge even higher prices – leaving patients and taxpayers ultimately to foot the bill."[13] The best solution to gain insight into the behemoth insurance company-related challenge, which could apply across the board, is to legislate increased transparency within the companies. If it were clear where the money goes, solutions can only be easier to find.

Pharmacies

In a market that rewards efficiency, small pharmacies struggle to keep up. Pharmacies are responsible for acquiring products from a wholesaler, filling prescriptions, filing for refunds from PBMs, and making enough profit to pay employees and keep the lights on. Locally-owned businesses are being pushed to invest in faster software, more efficient prescription turn-around, and keeping prices low.[14] This is why consolidation is a growing issue in the industry; demand is increasing and large

companies have the required resources to operate efficiently. The past two decades have seen the field narrow to three leading national pharmacies: CVS, RiteAid/Albertsons, and Walgreens.[15]

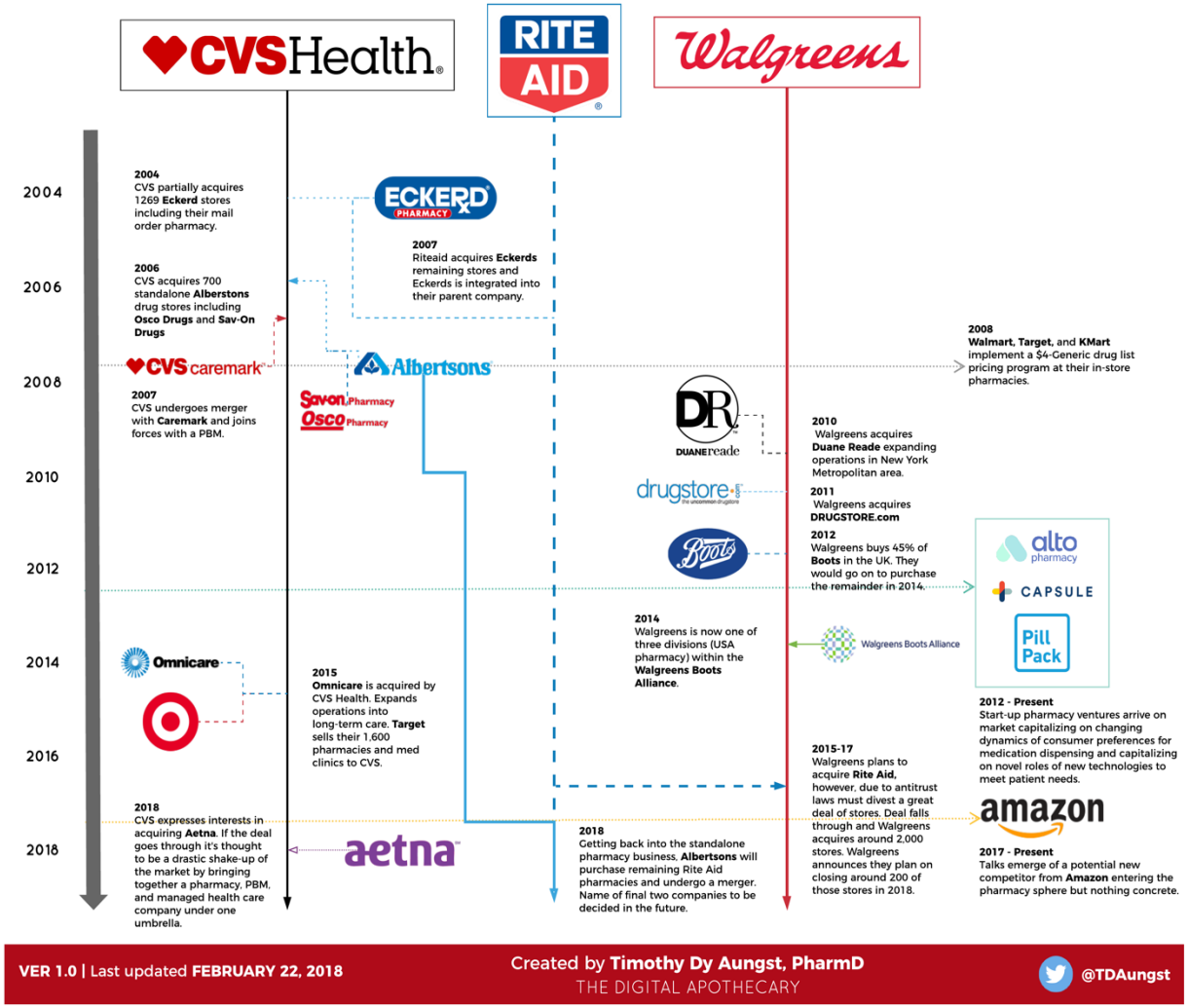

Fig. 5 https://www.pharmacytimes.com/contributor/timothy-aungst-pharmd/2018/03/pharmacy-wars-an-era-of-acquisition-mergers-and-losses

As seen in Fig. 5, from Timothy Aungst of *Pharmacy Times*, the field keeps changing, not always to the patient's benefit. As with any industry, consolidation of competition increases the power to the remaining business to control prices. This was the fear of the American Antitrust Institute (AAI) during the recent merger between CVS and Aetna,[16] two major players in the pharmacy/PBM industry. Thanks to its oversized power in both the pharmacy and PBM industries, CVS has more control than ever over formularies and pricing negotiations, without the fear of competition cutting prices for patients.

Vertical integration, similar to the intra-industry mergers, gives the appearance of increased efficiency and lower prices as a result of increased negotiating power, but this is not always the case. Pharmacies and PBMs have been consolidating more and more but the mergers don't eliminate PBMs, they simply remove the accountability provided when the pharmacy is a separate entity.

Is there anything a state legislature can do to improve the situation? Little can be done about national mergers other than filing complaints with the Department of Justice. States can provide increased oversight into mergers done within the state, with attention being paid to how it will affect patients' costs and competition in the market. The State of California, for example, recently passed Assembly Bill 595, instituting stronger oversight for health care mergers in a state where five insurers cover 90 percent of the market.[17] Similarly, in Virginia, 82 percent of the individual healthcare market was controlled by three companies in 2017,[18] a strong indicator that the market might benefit from more oversight.

Process Flows

Drug Product Flow

Compared to the financial and contractual process flows, the product flow of outpatient drugs is relatively easy to track and explain. The pharmaceutical company—the manufacturer— makes and sends them to the wholesaler to be distributed. The wholesaler sends the drugs to the pharmacy, which then dispenses them to patients. This is the basic aspect of prescription drug production.

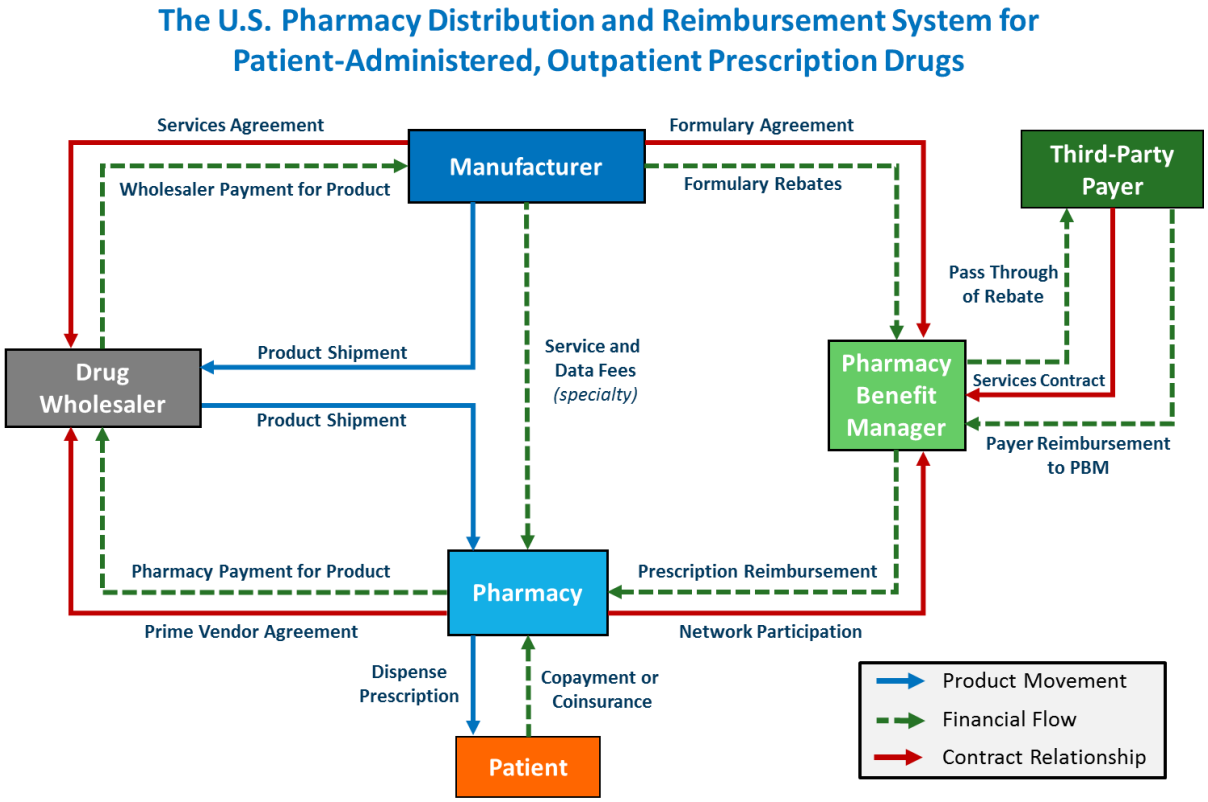

Chart illustrates flows for patient-administered, outpatient drugs. Please note that this chart is illustrative. It is not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace.
Source: Fein, Adam. J., *The 2016 Economic Report on Retail, Mail and Specialty Pharmacies*, Drug Channels Institute, January 2016.
(Available at http://drugchannelsinstitute.com/products/industry_report/pharmacy/)

Fig. 6

Financial Transactions

Financial transactions are more complicated. The wholesaler will buy the drug from the pharmaceutical company (the manufacturer) based on the wholesale acquisition cost (WAC). The pharmacy will then buy the drug from the wholesaler.

Rebates come into play after the manufacturer negotiates with insurance companies (the third-party player) through PBMs in order to set the price the manufacturer will then repay to cover the costs of unsold prescriptions. Insurance companies will agree to purchase a certain number of prescriptions, but if they don't sell that many prescriptions to patients, the manufacturer will agree to "buy back" the unsold prescriptions for a percentage of the original price. The size of the rebate helps to influence insurance companies to encourage doctors to prescribe more brand-name or generic versions of the drug in question. Of course, the rebate goes through the PBM before reaching the insurer, and the PBM takes a percentage of it before passing it along.

As briefly explained when talking about spread pricing, when a patient pays for their prescription, the amount they pay is not equal to what the pharmacy, PBM, or insurance company receives. If the patient is uninsured, the amount they pay is determined by the pharmacy. If the patient is insured, the amount they pay is determined by the insurance company. For an insured patient, the patient pays the pharmacy for the drug. The pharmacy then gets reimbursed by the PBM for the drug, plus a small percentage for profit. The PBM then gets reimbursed by the insurance company, plus a percentage for profit. The insurance company, therefore, is covering a lot of profit by the time it gets the bill, and that is reflected in coverage rates and patient copayments.

Contract Relationships

The wholesaler has direct contracts with the pharmaceutical company and pharmacy to ensure supplies, storage, and deliveries are managed. PBMs, however, are central to all other relationships in the field. They negotiate with pharmaceutical companies about formularies, rebates, and prices. They negotiate with pharmacies about reimbursements and products. They negotiate with insurance companies about fees. For an industry so intertwined in the pricing and negotiating aspect of prescription drugs, PBMs should be held accountable for the fees and profits they take in every one of their interactions. Complete oversight and transparency would assure fair pricing by all parties involved.

Medicare Part D

Medicare Part D is the branch of Medicare that covers prescription drugs. In 2017, Medicare Part D came into play in 1.5 billion prescriptions nationally,[19] meaning it has significant power in pricing negotiations with pharmaceutical companies. Unfortunately, Medicare Part D is currently required by law to use the services of PBMs and cannot negotiate directly with drug companies. This is a huge loss for Medicare as 14 percent of Medicare payments went to outpatient prescription drugs, as shown in Fig. 7 created by the Kaiser Family Foundation.[20]

One solution would be to have Medicare negotiate directly with drug companies, just as Veterans Affairs does, which would have saved Medicare an estimated $14.4 billion in 2016.[21] That change plus a further expansion of Medicare could improve and save the lives of tens of thousands in the Commonwealth, many of whom are struggling to pay for life-saving medications—all due to out-of control drug prices. But that issue is for Congress to decide.

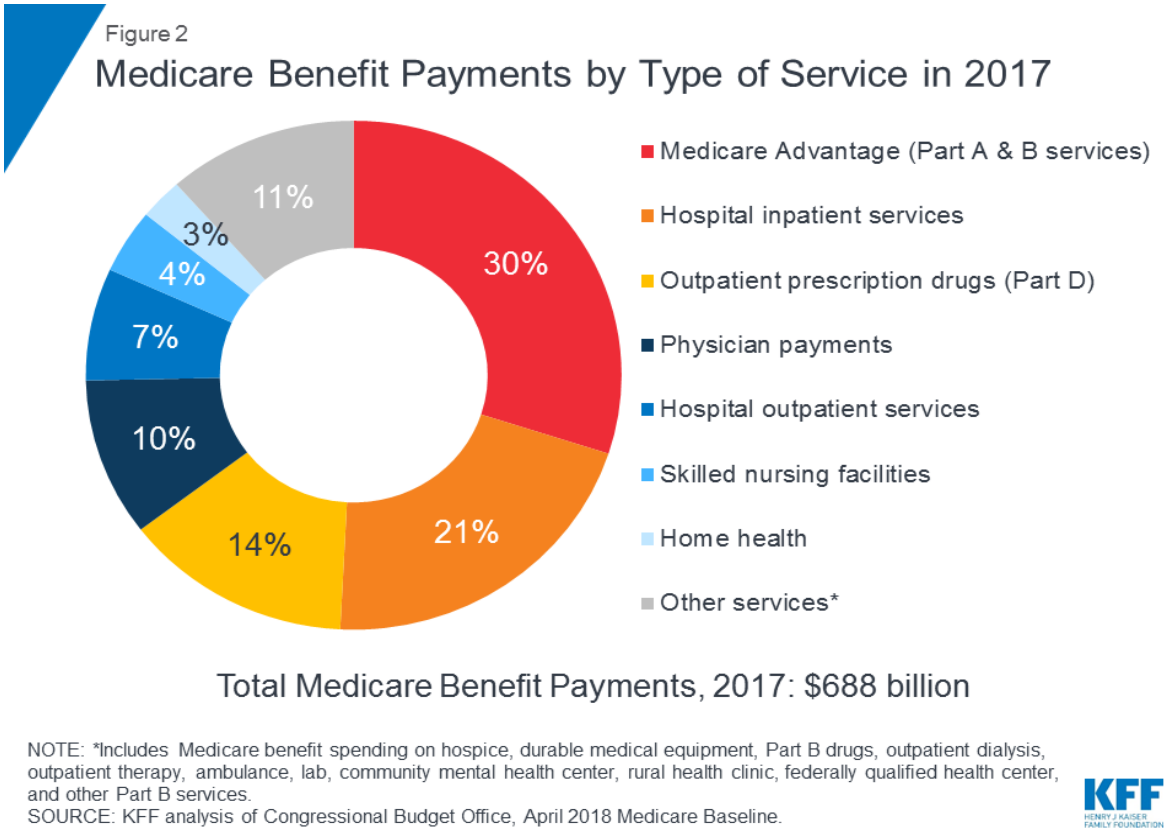

Figure 7: https://www.kff.org/medicare/issue-brief/an-overview-of-medicare/

Solutions

The National Academy for State Health Policy (NASHP) identified options for states to help to lower or reduce healthcare costs. They reported their recommendations in a report (http://nashp.org/wp-content/uploads/2016/10/Rx-Paper.pdf) released in October 2016.[22]

These options included:

- Increase price transparency to create public visibility and accountability;
- Create a public utility model to oversee in-state drug prices;
- Purchase in bulk and distribute high-priced, broadly-indicated drugs that protect public health;
- Use state unfair trade and consumer protection laws to address high drug prices;
- Seek the ability to re-import drugs from Canada on a state-by-state basis;
- Pursue Medicaid waivers and legislative changes to promote greater purchasing flexibility;
- Enable states to operate as pharmacy benefit managers to broaden their purchasing and negotiating powers;
- Pursue return on investment pricing and forward financing approaches to allow flexible financing based on long-term, avoided costs;
- Ensure state participation in Medicare Part D through Employer Group Waiver Plans;
- Protect consumers against misleading marketing; and
- Use shareholder activism through state pension funds to influence pharmaceutical company actions.

Virginia

In the regular session of 2016, the legislature approved the appropriation for a workgroup to study potential solutions. The workgroup released a report detailing a number of ways that Virginia could reduce or control the costs of prescription drugs.[23] Some of the strategies are discussed below.

Transparency

It cannot be stressed enough how vital transparency is in holding the drug industry and all related players accountable. By making records public, finances can be tracked. PBMs can show where they spend their money and the various ways they profit, alongside everyone else in the field.

Regulate Spending

A major reason it has proven nearly impossible to pass legislation regulating drug-related industries is their daunting lobbying power. One way to address this and help keep costs down would be to introduce legislation prohibiting—or at least limiting—nonessential spending including: lobbying, political contributions, and compensating any employee more than $5 million per year. A similar action was suggested for the electric utility industry in House Bill 2645 in Virginia's 2019 legislative session, introduced by Sam Rasoul (D-Roanoke) and fourteen co-patrons.[24] Unfortunately, that bill died in committee, along with most other Democratic-initiated bills of that session. With future Democratic control over the House, a regulatory bill could conceivably pass and help millions of patients.

Create a Statewide Formulary and Develop a Statewide Pharmacy Benefit Manager

"A standard formulary in the Commonwealth's Medicaid program would streamline drug coverage policies for one million Medicaid members and thousands of providers, improving the continuity of care for members and decreasing the administrative burden to providers."[25]

The development of a statewide Pharmacy Benefit Manager would coordinate pricing negotiations and payments for all healthcare purchasing entities in Virginia, including local and regional jails and community services boards (agencies that provide services for people with mental illness, substance use disorders, and/or intellectual disability as well as infants and toddlers who have developmental delays). The PBM would negotiate with pharmaceutical companies, require full pricing transparency of pharmacy reimbursements as well as provide increased clinical and financial information for better decision making about the preferred drug formulary.

Maximize Group Purchasing Mechanisms including Re-creation of a State Pharmacy

Prior to 2010 Virginia operated the Community Resource Pharmacy which bought and distributed prescription drugs to community services boards. Using its volume, it negotiated prescription purchasing. The pharmacy was closed in 2010 due to budget cuts leaving health boards to negotiate pricing on their own. The Virginia Department of Health operates a central pharmacy and a mail order program to support its operations but has limited scope. Providing a unified purchasing model to support all the statewide prescription drug purchasing would enable Virginia to leverage volume for greater negotiation power as well as provide more efficiency and reduced administrative burden.

Conclusion

Prescription drug pricing is incredibly complicated and is made all the more so by the lobbying power of the multiple major players involved. There is no single scapegoat for the skyrocketing prices of life-saving medications—there is plenty of blame to spread around. A long process is needed to get things under control, and the process needs to begin by taking back Democratic control of the State House and State Senate so that regulatory bills can make it out of committee. To learn more about state legislative bills introduced across the United States, the National Academy for State Health Policy has created an interactive map showing every bill introduced related to drug pricing as well at their contents and fate.[26] In the meantime, anything that legislators and legislative candidates can do to understand the complexities and opportunities for improvement in this vast issue can only increase the likelihood of it being ameliorated over time—something surely not for the faint-hearted.

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