Report of Governor Gretchen Whitmer's Prescription Drug Task Force

December 31, 2020

Table of Contents

Executive Summary **4**

Task Force Membership 5

Presenters 6

Task Force Meetings 7

I. The High Cost of Prescription Drugs **7**

Causes of High Prescription Drug Costs 8

II. Federal Legislative and Administrative Action **12**

Lower Drug Costs Now Act (H.R. 3 of 2019) 12

Most Favored Nation Model Interim Final Rule 12

Rebate Rule 12

Drug Importation Rule 13

The Public Disclosure of Drug Discounts and Real-Time Beneficiary Drug Cost Act (H.R. 2115 of 2019) 13

Summary of Federal Legislative and Administrative Actions 13

III. State Legislative and Administrative Action Recommendations **13**

Transparency 13

Affordability 15

Accountability 17

Accessibility 20

IV. Future Considerations **22**

Rate Setting and Spending Targets 22

Prescription Drug Tax Credits 22

Taxing Drug Price Increases that are Greater than the Rate of Inflation 22

Value-Based Contracting 23

Prohibit Pay for Delay 23

Expand the Use of Medication Therapy Management 23

License Pharmaceutical Sales Representatives 23

Repeal Drug Industry Immunity Law 23

Prohibit Spread Pricing 24

State Accountability Review Board 24

Empower the Department of Attorney General to Take Action 24

Challenge Monopoly Power 24

Encourage Public Production of Drugs 24

Prescription Drug Importation from Canada 25

Waste Free Formularies (Public Entities) 25
Drug Spending Cap 25
Additional Legislator Considerations 25
V. Conclusion 26
Appendix 27

Executive Summary

On February 21st 2020, Governor Whitmer signed Executive Order 2020-01 creating the Prescription Drug Task Force as an advisory body within MDHHS.[1] The Task Force is charged with the following:

1. Analyze the scope and causes of the problem of high-cost prescription drugs in Michigan and the impact of this problem on this state's residents, communities, and businesses.
2. Analyze the way prescription drug prices are set in Michigan and identify strategies for increasing the transparency of that process.
3. Recommend legislative and administrative actions that can be taken, and policy-related changes that can be implemented by governmental and non-governmental agencies, relevant to lowering prescription drug prices for consumers in Michigan.
4. Recommend legislative and administrative actions that can be taken, and policy-related changes that can be implemented by governmental and non-governmental agencies, relevant to increasing transparency in the pricing of prescription drugs in Michigan.
5. Provide other information or advice or take other actions as requested by the governor.

The Task Force heard input from health policy experts and stakeholders to obtain an understanding of the factors that influence drug pricing and to discuss legislative and administrative solutions to lower the cost of prescription drugs for consumers. There are several policy recommendations that would provide cost savings as well as transparency and accountability to the system. Those recommendations include:

- Requiring manufacturer, Pharmacy Benefit Manager (PBM), and hospital chargemaster transparency reports;
- Setting price controls, such as copay caps and applying rebates to consumer cost-sharing;
- Licensing PBMs and registering them under the Third-Party Administrator Act;
- Penalizing unsupported price increases;
- Using International Reference Rate pricing; and
- Restricting the use of gag clauses in PBM contracts with pharmacies.

This report includes both policy recommendations and ideas that warrant further consideration.

The report is split into four main sections: first, a section describing the problem associated with high-cost prescription drugs in Michigan; analyzing the prescription drug distribution chain, a description of how drug prices are set, and some of the causes of high prescription drug costs; second, a section describing some of the action to address the problem at the federal level; third, a section describing recommended state actions that could be taken to lower prescription drug prices and increase transparency in the pricing of prescription drugs in Michigan; and fourth, a section outlining additional ideas that merit future consideration.

In developing the state legislative and administrative actions for the report, the Prescription Drug Task Force based its recommendations on four opportunity areas: Transparency, Affordability, Accountability, and Accessibility. The policy options described in this report are organized according to those four principles.

The Task Force met four times from October through December of 2020. Members heard presentations from health policy experts and stakeholders, including entities within the prescription drug supply chain, to gain an understanding of the role and the impact that each entity's practices have on the prices consumers ultimately pay for prescription drugs.

[1] http://www.legislature.mi.gov/documents/2019-2020/executiveorder/pdf/2020-EO-01.pdf

Task Force Membership

Robert Gordon, Director
Department of Health and Human Services (DHHS)

Anita G. Fox, Director
Department of Insurance and Financial Services (DIFS)

Orlene Hawks, Director
Department of Licensing and Regulatory Affairs (LARA)

Winnie Brinks
State Senator
District 29

Curt VanderWall
State Senator
District 35

Angela Witwer
State Representative
District 71

Hank Vaupel
State Representative
District 47

Padma Kuppa
State Representative
District 41

Presenters

- Melissa Seifert, Associate State Director Government Affairs, AARP Michigan
- Larry Wagenknecht, Chief Executive Officer, Michigan Pharmacists Association
- Laura Appel, Senior Vice President and Chief Innovation Officer, Michigan Health and Hospital Association
- Jane Horvath, Principal, Horvath Health Policy
- Timothy J Antonelli, R.Ph. Manager, Pharmacy Policy, Health Reform and Strategic Programs, Blue Cross Blue Shield of Michigan
- Kristen Kraft, Director of State Relations for Governmental Affairs, Blue Cross Blue Shield of Michigan
- Dominick Pallone, Executive Director, Michigan Association of Health Plans
- Scott Pace, Partner, Impact Management Group
- Heather Cascone, Senior Director of State Affairs, Pharmaceutical Care Management Association
- Mathew DiLoreto, Vice President, State Government Affairs, Healthcare Distribution Alliance
- Peter Fotos, Senior Director of State Advocacy, Pharmaceutical Researchers and Manufacturers of America
- Shauna Gardner, Director of State Policy, Pharmaceutical Researchers and Manufacturers of America
- Jennifer Reck, Project Director, The National Academy of State Health Policy (NASHP)
- Andrew Gattine, Senior Policy Fellow, The National Academy of State Health Policy (NASHP)

Task Force Meetings

Meeting #	Date	Presenters
Meeting #1	October 20, 2020	
Meeting #2	November 16, 2020	• AARP • Michigan Pharmacists Association • Michigan Health and Hospital Association
Meeting #3	November 20, 2020	• Horvath Health Policy • Blue Cross Blue Shield of Michigan • Michigan Association of Health Plans • PSAO Coalition • Pharmaceutical Care Management Association • Health Distribution Alliance • Pharmaceutical Research and Manufacturers of America
Meeting #4	December 7, 2020	• Hank Vaupel, State Representative • National Academy for State Health Policy

I. The High Cost of Prescription Drugs

Over the past six years, the average price of drugs prescribed to treat diabetes, heart disease, depression, and other common conditions has more than doubled. These prices are set with little transparency but with tremendous consequence. The high cost of prescription drugs is a national problem, but it is also a Michigan problem. Prices for the most commonly prescribed drugs for older patients have increased at more than 10 times the rate of inflation within five years, and the average cost of prescription drugs increased nearly 60% between 2012 and 2017, while Michiganders' incomes have increased only 11%.[2]

Another reason that the high cost of prescription drugs affects Michigan residents more than those of other states is because we take more prescription drugs than the national average. According to 2019 data from the IQVIA Nation Prescription Audit, Michigan ranks 14th among all 50 states and the District of Colombia with $1,914 per capita prescription drug spending. The same data has Michigan ranked 13th with 13.38 prescriptions filled per capita.

The high cost of prescription drugs can be devastating. Prescription drug prices have been rising at unsustainable rates. Among Michigan residents ages 19-64, 32% stopped taking their medication as prescribed due to cost in 2017.[3] Residents across Michigan must often choose between filling life-saving prescriptions and paying rent, buying food, or obtaining other critical essentials.

[2] https://www.aarp.org/politics-society/advocacy/info-2019/prescription-drugs-state-fact-sheets.html

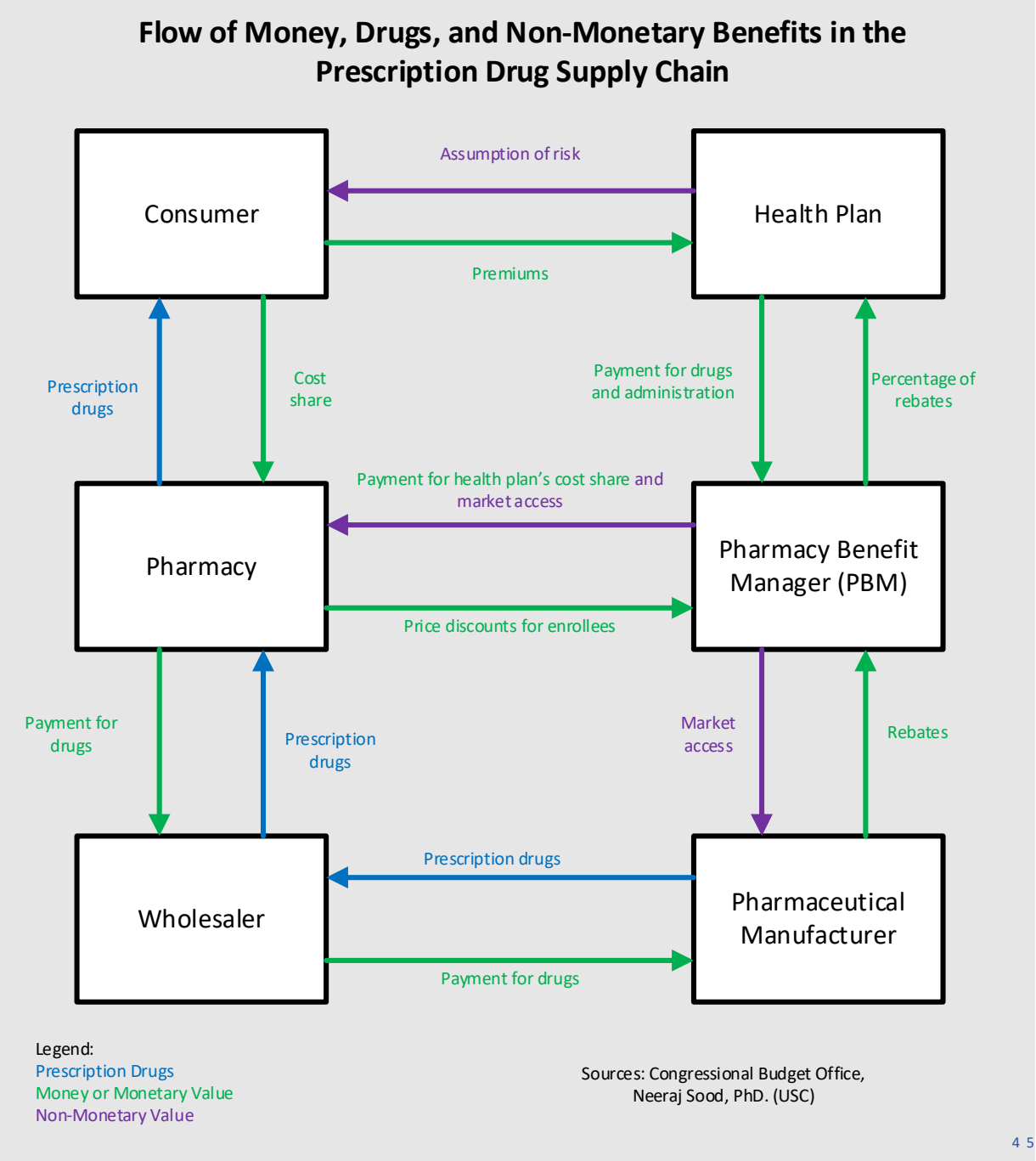
[3] State Health Access Data Assistance Center (SHADAC) analysis of National Health Interview Survey data, State Health Compare, SHADAC, University of Minnesota, statehealthcompare.shadac.org.

Causes of High Prescription Drug Costs

To understand how drug prices are set requires an understanding of the entire prescription drug supply chain and the flow of money between the different actors in the supply chain.

Interactions Between Market Participants

The following diagram illustrates how different actors in the market for prescription drugs interact with each other.



[4] https://www.cbo.gov/sites/default/files/107th-congress-2001-2002/reports/10-30-prescriptiondrug.pdf
[5] https://content.naic.org/sites/default/files/inline-files/Sood-NAIC-August2019.pdf

Prescription Drug Market Participants

The following chart broadly summarizes the role of each participant in the prescription drug distribution chain.

Participant	Role
Consumer	Pays premium to health plan in exchange for a transfer of risk; pays out-of-pocket cost sharing amounts to pharmacy for covered prescription drugs.
Health Plan	Contracts with Pharmacy Benefit Managers (PBMs), sets overall premiums for enrollees, and handles grievances and appeals.
Pharmacy	Buys drugs from wholesalers, dispenses drugs to enrollees, receives payment from PBMs and enrollees. Pharmacies can be independent, or a regional or national chain; they may also be linked to a PBM or a wholesaler.
Pharmacy Benefit Manager (PBM)	Develops and maintains drug formulary (list of medicines approved for coverage, by cost-sharing tier, under a health plan), contracts with pharmacies, negotiates discounts and rebates with drug manufacturers, and processes and pays prescription drug claims. They may also perform drug utilization reviews, manage clinical programs, and operate pharmacies.
Wholesaler	Purchases drugs from manufacturer; sells drugs to pharmacy.
Manufacturer	Brings drugs to market, sets the price of drugs, can lease a drug's license, are involved in sales, marketing, and the drug's "life cycle management." Sells drugs to wholesaler; provides rebates to defray the cost of prescription drugs to PBM; inadvertently gains market access through PBM.

Some relationships between market participants are relatively simple in that they are just the payment of money in exchange for something and have limited downstream effects. However, the interplay between manufacturers, PBMs, and health plans is less straight-forward and requires further examination as these three actors have a substantial impact on the end price of a given prescription drug.

Nuances to the Flow of Prescription Drugs

There are some nuances that can be important to understanding the flow of prescription drugs.

First, there are four PBMs that administer drug benefits for a large majority of covered individuals in the United States.[6] This gives each of the four dominant PBMs a substantial amount of negotiating power in the market. For example, a pharmacy that is not contracted with one of the largest PBMs could be limiting their ability to sell drugs in their community. Covering many individuals may also improve a PBM's market power when it comes to negotiating rebates with a drug manufacturer as they can boast a larger volume of drug sales than could a smaller PBM.

Second, not all health plans are created equal, and thus there is no uniformity in prescription drug coverage across health plans. Larger health plans tend to have more negotiating power with their PBM, can set their own formularies, and could ensure that 100% of manufacturer rebates flow from the manufacturer to the health plan. Smaller health plans may have to accept a PBM's national drug formulary, which the PBM controls, and they may be more likely to allow a PBM to retain a larger percentage of manufacturer rebates. A smaller health plan may be more likely to be at a disadvantage in negotiations with a PBM and is less likely to have the resources to hire a consultant to assist with PBM selection.

[6] https://khn.org/morning-breakout/dr00016900/

Third, not all pharmacies are created equal, which results in differing levels of negotiating power. A small, community pharmacy may have less negotiating power in comparison to a national pharmacy chain. A group of pharmacies may choose to band together to form a Pharmacy Services Administrative Organization (PSAO) to increase their market power. However, members of a PSAO are not bound to a PSAO's decisions, which may limit the PSAO's overall success in negotiations. For example, if a PSAO did not agree to a PBM's contract terms, each individual pharmacy could disregard the PSAO and contract with a PBM.

Fourth, there are some companies that hold patents for drugs, but do not manufacture the drugs for which they hold a patent. For simplicity, these companies are considered manufacturers in this report.

Finally, there exists a degree of vertical integration (where one company performs two or more stages of production) within the prescription drug market. For example, an insurer, a PBM, and a pharmacy could all be affiliated businesses.

The Role of Manufacturers in Prescription Drug Costs

Drug manufacturers are granted market exclusivity to sell a drug that is protected under patent. This market exclusivity essentially gives a manufacturer a monopoly over the sale of the drug, and the resultant monopoly pricing power provides an immense financial incentive for manufacturers to continue developing new and innovative medications.

When a drug's patent expires, generic versions of that drug can be sold. Drug patent expiration is a substantial boon to consumers because the price of the drug tends to drop significantly, making it available to consumers who could not previously afford the drug. However, drug patent expiration is likely to have a negative impact on a manufacturer's profits.

Misaligned Incentives

Though pharmaceutical manufacturers serve an important role in creating medications to treat illnesses, they also have a financial incentive to sell as many drugs at the highest price possible. This is naturally at odds with a consumer's preferences, which are to have necessary medications available to them at low costs. The following list contains drug manufacturer practices that may be detrimental to the consumer.

- **Extending patents.** There are several ways that a manufacturer could extend the life of a patent to maintain market exclusivity. Here are some examples:
    - Producing a new formulation of the drug that is clinically superior or that can be administered differently;
    - Finding a new use for an existing drug;
    - Combining two or more successful drugs into one tablet and marketing it as a new product.
- **"Pay-for-delay".** Some drug manufacturers have been able to sidestep competition by offering patent settlements that pay generic companies not to bring lower-cost alternatives to market.
- **Financial incentives for prescribers.** Paying prescribers to prescribe a drug is illegal. However, a manufacturer can pay a prescriber to talk about their drugs in speaking engagements and pay for consulting work and conference attendance. These incentives may make the prescriber more likely to prescribe a particular drug.
- **Price and rebate setting.** A drug manufacturer can increase the rebate on a drug to incent PBMs and health plans to place them more favorably on a formulary, possibly bumping off cheaper alternative drugs.

- **Direct-to-consumer advertising.** A manufacturer can also engage in direct advertisement to consumers to boost demand for a particular drug, which may influence the prescribing of drugs that, in some cases may not be medically necessary.

The Role of Pharmacy Benefit Managers in Prescription Drug Costs

PBMs have three main sources of income: health plans, pharmaceutical manufacturers, and pharmacies.

First, PBMs receive payments from health plans. Health plans pay PBMs to manage their prescription drug benefits. This includes developing and maintaining drug formularies and negotiating prices with pharmaceutical companies on behalf of the health plans, as well as paying the insurance share of a drug's cost.

Second, PBMs receive rebates from pharmaceutical companies. Rebates are the difference between the negotiated price and the list price of a drug. Pharmaceutical companies pay the rebates to the PBM. The PBM passes the rebate on to the health plan according to their shared contract, which may allow the PBM to keep a percentage of the rebate.

Third, PBMs receive income through price discounts at pharmacies. Unlike pharmaceutical manufacturer rebates, pharmacy discounts are often not paid back to the health plan. Some PBMs also own pharmacies, so they may make money through the profit of the pharmacy services instead of through discounts.

Misaligned Incentives

Though PBMs are contracted by the health plan (and, by extension, work for the consumer), their potential revenue streams from pharmaceutical companies and pharmacies can incentivize them to act in ways that can be detrimental to the consumer. The following list contains PBM practices that may be detrimental to the consumer.

- **Rebate retention.** The result of a PBM-drug manufacturer negotiation is a rebate, which is the difference between the list price of a drug and the negotiated price. A PBM may retain a percentage of the rebate, which provides incentive for the PBM to favor whichever drug is most profitable for them. This may include the elimination of comparable and less expensive medication from a formulary.
- **Spread pricing.** Spread pricing is the PBM practice of charging a plan sponsor a higher amount for a drug than they will reimburse the pharmacy and keeping the difference. Contracts between pharmacies and PBMs are not transparent so plan sponsors may not be unaware if there is a difference between the amount they are billed and the amount the PBM has been reimbursed by the pharmacy.
- **Gag clauses.** The term "gag clause" refers to a stipulation in a contract between a PBM and a pharmacy that prohibits the pharmacy from informing consumers of an alternative option when purchasing a drug. For instance, a gag clause may prohibit a pharmacist from telling a consumer about a generic version of a drug that would be less expensive or telling a customer if a drug could be purchased at a lower price out-of-pocket than through their insurance plan.
- **PBM-owned pharmacies.** Some PBMs are affiliated with pharmacies, which creates several incentives for PBMs to act against the best interests of the consumer. PBMs can insert language into pharmacy benefit contracts that requires enrollees to use PBM-owned mail pharmacy services for long-term (90 days or longer) maintenance medications. This eliminates any competition to fill these prescriptions and could allow the pharmacy to charge higher prices to the consumer. An affiliation with a pharmacy may also incentivize a PBM to do any of the following, which are all contrary to the best interests of consumers:

- Complete fewer generic substitutions;
- Switch patients to higher-cost therapeutic alternatives ("therapeutic interchange"); or,
- Repackage drugs in a manner that could lead to increased costs to plan sponsors, while maximizing revenue for the PBM ("package size pricing").

The Role of Health Plans in Prescription Drug Costs

Like PBMs, a health plan's profit incentive may incent them to hold on to a drug rebate instead of passing it on to enrollees in the form of a smaller deductible or a smaller premium. Health plans are also in charge of contracting with PBMs, which leaves them somewhat responsible for any actions a PBM might take that are detrimental to their enrollees.

Some large health insurers also own a PBM, and those that do may share the same misaligned incentives of their PBM.

II. Federal Legislative and Administrative Action

While this report focuses on legislative and administrative actions that can be taken at the state level, there has been recent activity on prescription drug pricing at the federal level that are worth noting. The Task Force identified the following recent potential federal actions that could help reduce prescription drug costs in the state of Michigan.

Lower Drug Costs Now Act (H.R. 3 of 2019)

The Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3) would have required the federal government to establish prices for selected drugs that have little competition and account for substantial spending. The bill would require a drug's price to be set between the lowest price in six high-income countries and 120 percent of the average price across those countries. These prices would apply not only to Medicare but to private insurance and, indirectly, to Medicaid as well. However, the price reductions would not apply to uninsured individuals.[7]

Most Favored Nation Model Interim Final Rule

On November 20, 2020, the federal government issued the Most Favored Nation Model Interim Final Rule (CMS-5528-IFC). Under this rule, healthcare providers would be reimbursed for Medicare Part B drugs based on the lowest price available internationally. However, there is a concern that if providers cannot purchase these drugs at international drug prices, they may decline to take the financial risk of acquiring these drugs at all, which would mean that their patients will not have access to them.[8]

Rebate Rule

The federal Anti-Kickback Law prohibits anyone knowingly or willfully offering, paying, soliciting, or receiving remuneration to induce or reward referral of business under federal health programs like Medicare and Medicaid. However, there is a current safe harbor for certain "discounts" which include drug rebates negotiated by PBMs and Medicare Part D plans. The Rebate Rule (85 FR 76666) ends the safe harbor protection for rebates, with the intent to have these savings passed directly to patients for Medicare Part D drugs at point-of-sale.[9]

[7] https://www.congress.gov/bill/116th-congress/house-bill/3
[8] https://www.cms.gov/newsroom/fact-sheets/fact-sheet-most-favored-nation-model-medicare-part-b-drugs-and-biologicals-interim-final-rule
[9] https://www.healthaffairs.org/do/10.1377/hblog20201122.985836/full/

Drug Importation Rule

Under the Drug Importation Final Rule (85 FR 62094), states may develop a program to import drugs from Canada. Certain categories of drugs will be excluded, such as controlled substances, biological products, infused drugs, and drugs injected intravenously and intrathecally. The drugs may be imported by a drug wholesaler or pharmacist. Drugs that are imported must be approved by the Health Products and Food Branch of Health Canada and meet FDA requirements. In addition, the importer or manufacturer must arrange for the drug to be tested by a U.S. laboratory for compliance with established specifications and standards. States that are considering developing drug importation programs include Florida, Vermont, Maine, Colorado, New Mexico and New Hampshire.[10]

The Public Disclosure of Drug Discounts and Real-Time Beneficiary Drug Cost Act (H.R. 2115 of 2019)

This legislation would have required the Secretary of Health and Human Services to make public certain aggregate information regarding rebates, discounts and price concessions that PBMs negotiate with prescription drug manufacturers. The stated purpose of the provision is to compare this information with the costs and price concessions that are passed on to plan sponsors.[11]

Summary of Federal Legislative and Administrative Actions

Legislation cited in both the federal and state action sections will expire with the end of the U.S. Congressional/Michigan legislative term. As federal legislation to address prescription drug prices stalls, states can test many of these ideas such as price caps, industry reporting requirements and international pricing benchmarks on a smaller scale. States can also learn from federal efforts to advance these concepts and anticipate legal challenges. Michigan should continue to pursue these options at a state-level, and its successes may help inform future federal initiatives in drug pricing.

III. State Legislative and Administrative Action Recommendations

Transparency

Prescription drug pricing transparency refers to seeking to understand the factors that influence drug pricing. The following are policy solutions aimed to provide more transparency.

Require Drug Manufacturer Transparency Reports

Legislative action requiring additional reporting for prescription drug manufacturers could lead to a greater understanding of what is causing the increase in prescription drug costs in the manufacturing space. This could allow government and other interested parties to have more information so they can effectively respond to rising prices and possibly even decrease drug costs through increased scrutiny.

A manufacturer transparency report could include a broad range of reporting requirements including the following financial information:

- Explanations or notifications for price increases;
- Total cost of manufacturing;

[10] https://www.federalregister.gov/documents/2020/10/01/2020-21522/importation-of-prescription-drugs
[11] https://www.congress.gov/bill/116th-congress/house-bill/2115?q=%7B%22search%22%3A%5B%22hr2115%22%5D%7D&s=1&r=1

- Clinical trial costs paid by the manufacturer;
- Cost of research and development;
- Costs associated with coupons, discounts, and rebates;
- Financial incentives used;
- Whether the manufacturer has contracted with a PBM for exclusive provision of a drug; and
- Marketing and advertising costs.

State Legislative Action

House Bill 5937 of 2020 would have established transparency reporting requirements for drug manufacturers in certain circumstances. An example of this is the requirement of the bill for a drug manufacturer to submit a report to the Director of the Department of Insurance and Financial Services (DIFS) within 30 days of increasing the Wholesale Acquisition Cost (WAC) of certain prescription drugs by 15% or more in a year or 40% or more over a 3-year period. House Bill 5937 would have also required Department of Insurance and Financial Services (DIFS) to prepare an annual report based on the information received in the required transparency reports.[12]

Disclosure requirements such as those in House Bill 5937 could bring transparency to drug pricing to ensure a fair market for consumers and may lead to lower drug prices over time.

Pharmacy Benefit Manager Transparency Reports

Legislative action requiring additional reporting for PBMs could lead to a greater understanding of PBM business practices and potential causes of increased prescription drug costs in the PBM space. This could allow government and other interested parties to obtain more information so they can effectively respond to rising prices and possibly even decrease drug costs through increased scrutiny.

A PBM transparency report could include a broad range of reporting requirements including the following information:

- Payments collected from manufacturers by the PBM;
- Payments collected from manufacturers by the PBM that were passed through to insurers or carriers;
- Payments collected from manufacturers by the PBM that were passed through to enrollees at the point of sale;
- Payments collected from manufacturers by the PBM that were retained as revenue by the PBM;
- The aggregate Wholesale Acquisition Costs from a drug manufacturer or wholesaler for each therapeutic category of drugs across all plan sponsors, net of rebates and other fees and payments;
- The aggregate amount of all rebates received by the PBM from all manufacturers and all plan sponsors;
- The aggregate amount of fees the PBM received;
- The aggregate amount of all rebates the PBM received that were not passed on to health plans or insurers;
- The aggregate amount of all fees that the PBM received from all manufacturers that were not passed through to health plans;
- The aggregate retained rebate percentage (rebates not passed through divided by all rebates received); and

[12] http://legislature.mi.gov/(S(zdbpmlsk51z1lcufcgrgtfx0))/mileg.aspx?page=getObject&objectName=2020-HB-5937

- The use of spread pricing.

PBM transparency reporting could also be a requirement included in PBM licensure which is discussed later in this report.

State Legislative Action

House Bill 5938 of 2020 would have required a PBM to file an annual transparency report with DIFS containing some of the information listed in the previous section. DIFS would have been required to provide a report on the information received from the PBMs.[13] The disclosure of PBM payment information could ensure a more fair and transparent prescription drug market.

Hospital Chargemaster Transparency

Hospitals use their chargemaster prices to negotiate reimbursement rates with private payers. As a result, their chargemaster prices are usually significantly higher than the actual cost of care. Most patients are not charged the chargemaster price unless they are uninsured. While the Centers for Medicare and Medicaid Services (CMS) already require hospitals to publicly post their chargemasters, state legislative action could be taken to expand upon this requirement. Hospital chargemaster transparency could ensure patients are better informed of their potential prescription drug costs so the consumer is better informed regarding the cost of care.

State Legislative Action

House Bill 5945 of 2020 sought to bring transparency to hospital rate-setting practices, including prescription drug pricing in a hospital setting. The bill would have required any hospital that maintains a chargemaster, or a list of standard charges for each service, item, and service package, to publish an electronic version of the information conspicuously on its website and post a clear and conspicuous notice regarding how to access the chargemaster in its emergency department, admissions office, and billing office where applicable. The chargemaster would have been required to include a notice that explains the standard charges on the chargemaster may not reflect the actual charge billed to a patient and that the patient is responsible for understanding what items are covered by their health insurance policy.[14]

Affordability

Prescription drug affordability refers to seeking policy solutions aimed at improving affordability, such as through creating price controls.

Copay Cap for Insureds

A copay cap is a price control measure that limits the out-of-pocket cost for a prescription drug. Legislative action can require that insurers not exceed a set maximum copayment cap that an insured would be required to pay to acquire a certain drug within a specified time period. Copay caps could provide immediate relief to patients who struggle to pay their out-of-pocket costs and could ensure patients have continued access to crucial medications.

State Legislative Action

House Bill 4701 of 2019 would have established a cost sharing cap that health insurers can place on prescription insulin. The amount an insured would be required to pay could not exceed $100 per 30-day supply of insulin, regardless of the amount or type of insulin needed to fill the insured's prescription.[15]

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[13] http://legislature.mi.gov/(S(zdbpmlsk51z1lcufcgrgtfx0))/mileg.aspx?page=getobject&objectname=2020-HB-5938
[14] http://legislature.mi.gov/(S(zdbpmlsk51z1lcufcgrgtfx0))/mileg.aspx?page=getobject&objectname=2020-HB-5945
[15] http://legislature.mi.gov/(S(yhs1ovcxc3hfc2fnlyzqwuah))/mileg.aspx?page=getObject&objectName=2019-HB-4701

This price control measure could be an effective means to reduce out-of-pocket costs for insulin and ensure that patients have continued access to insulin.

Drug Rebate Application to Cost Sharing

Drug manufacturers issue rebates to PBMs to lower the actual price of purchasing the drug. Depending on a PBM's contract with a plan sponsor, the entire rebate could be passed on to the health plan sponsor or a percentage of the rebate could be kept by the PBM. The health plan can currently choose how to spend the rebates it receives. In other words, it can choose to absorb the cost savings for itself or pass the rebate savings on to the insured through lower premiums. Legislative action could be taken to require that health plans with prescription drug coverage apply those drug rebate cost savings to an insured's out-of-pocket maximum or any cost sharing requirement. This would ensure that manufacturer rebates are directly benefiting the customer and that the cost savings are not being absorbed by other entities within the supply chain.

State Legislative Action

House Bill 5944 of 2020 would have required all health plans providing prescription drug coverage to apply both of the following to an insured's overall contribution to an out-of-pocket maximum or any cost sharing requirement:

- Amounts paid by the insured; and
- Amounts paid on behalf of the insured by another person.

This bill would have ensured that customers receive the benefit of the rebates on the prescription drugs they purchase instead of having the savings retained by the health plan or the PBM.[16]

International Reference Rates

Other countries pay a fraction of what Americans pay for prescription drugs, often because they effectively negotiate drug prices. For this reason, many policymakers have embraced Canadian drug importation, though this design can be complex to implement as described above.[17] As an alternative, legislative action could be taken to establish a process for setting an upper payment limit for certain prescription drugs based on rates set by other countries, such as Canada, as a reference. This legislation would put a limit on what purchasers pay, producing cost savings throughout the supply chain and for the insured.

Prescription Drug Emergency Fund

Legislative action could be taken to establish a Prescription Drug Emergency Fund to assist consumers with out-of-pocket expenses related to purchasing prescription drugs in an emergency. The fund could be financed through fines assessed for failing to file transparency reports, PBM and pharmaceutical representative licenses, or through other funding sources. The fund could be utilized by consumers who need immediate relief from an out-of-pocket cost they are unable to afford in an emergency setting.

Prohibit Price Gouging

Legislative action could be taken to prohibit manufacturers from hiking prices for generic and off-patent drugs. Price increases that surpass a specific threshold identified in the law could trigger the state's Attorney General to take investigative and enforcement action. Manufacturers that price-gouge could face fines and could be required to stop charging the excessive price. This price threshold could dissuade

[16] http://legislature.mi.gov/(S(zdbpmlsk51z1lcufcgrgtfx0))/mileg.aspx?page=getObject&objectName=2020-HB-5944

[17] https://www.nashp.org/an-act-to-reduce-prescription-drug-costs-using-international-pricing/

manufacturers from implementing sudden price increases for a prescription drug and help ensure price stability throughout the prescription drug supply chain and for the consumer.[18]

State Legislative Action

House Bill 5109 of 2019 would have prohibited manufacturers from charging excessive prices, stopped unconscionable increases in Wholesale Acquisition Costs, and required the Attorney General to investigate such violations.[19] The bill was specifically aimed at helping prevent price increases that cannot be justified by the cost of production of the drug or in situations where consumers have no choice but to purchase the drug due to insufficient competition in the market for the drug. This consumer protection would help prevent manufacturer price gouging.

Accountability

Prescription drug accountability refers to seeking policy solutions aimed at regulating certain practices that can raise prices. The following are policy solutions to consider when seeking greater accountability.

Pharmacy Benefit Manager Licensure

Legislative action could be taken to establish licensure requirements for PBMs. This could allow the state to have greater regulatory authority over PBMs and define new standards for PBM business practices to keep PBMs accountable. Most states have gone about licensing PBMs in two ways: by regulating PBMs under a Third-Party Administrator (TPA) law and/or by establishing a standalone license for PBMs. Without licensing PBMs as a TPA or creating a standalone PBM license, a state may have little regulatory authority over a PBM. PBM licensure legislation could contain the following provisions to improve the behavior of PBMs in the prescription drug market:

- Require certain network adequacy requirements;
- Pharmacy affiliation limitations;
- Gag clause prohibitions;
- Transparency reporting;
- Establish a fiduciary relationship between the PBM and insurer;
- Prohibit spread pricing;
- Prohibit “copay clawbacks”; and
- Require rebates and coupons savings be passed on to the consumer.

State Legislative Action

House Bill 5938 of 2020 would have amended the Michigan Insurance Code to create a license for all PBMs that provide services within Michigan. For a PBM to be licensed, they would be required to submit an application prescribed by DIFS. The Director of DIFS would be able to suspend, deny, or place a restriction on a PBM for a violation of their licensure or violations of state or federal laws.[20] The Director could also examine or audit a PBM’s records and books.

The bill would have also required the following of licensed PBMs:

- Disclosure to health insurers of PBM ownership or affiliation with pharmacies;
- Prohibition of imposing limits on an insured’s access to medication that differ based on a PBM’s ownership in a pharmacy;

[18] https://www.nashp.org/an-act-to-prevent-excessive-and-unconscionable-prices-for-prescription-drugs/
[19] http://legislature.mi.gov/(S(zdbpmlsk51z1lcufcgrgtfx0))/mileg.aspx?page=getObject&objectName=2019-HB-5109
[20] http://legislature.mi.gov/(S(zdbpmlsk51z1lcufcgrgtfx0))/mileg.aspx?page=getobject&objectname=2020-HB-5938

- Prohibition from steering business toward an owned pharmacy through a penalty, requirement, or other financial incentive;
- Prohibition of a PBM from discriminating against a 340B Program entity within their pharmacy network and requires that the 340B program entity be reimbursed similar to other pharmacies;
- Prohibit PBM gag clauses;
- Require a PBM transparency report; and
- Disclosure of their Maximum Allowable Cost list to pharmacies.

Include Pharmacy Benefit Managers and Carriers Under the Regulatory Authority of the Third-Party Administrator Act

Under the Michigan Third-Party Administrator Act, a Third-Party Administrator (TPA) is a person who processes claims and provides services pursuant to a service contract.[21] Requiring PBMs and carriers to be licensed as TPAs would give the Department of Insurance and Financial Services (DIFS) greater statutory authority over PBMs. The Third-Party Administrator Act requires the following of TPAs:

- Apply for a TPA Certificate of Authority; and
- Prove financial viability each year.

These procedures require TPAs to submit affiliation statements, financial statements, fees, and other informational documentation to DIFS.

State Legislative Action

HB 5941 of 2020 would have amended the Third-Party Administrator Act to specifically include PBMs and health insurance carriers in the definition of a TPA and would prohibit PBMs from engaging in certain conduct.[22]

Copay Clawback Prohibition

A "copay clawback" is a practice employed by PBMs when an enrollee's cost sharing amount is larger than the actual cost of the drug. The PBM retains the difference between the copay and the actual price of the drug, which often occurs for generic drugs.[23] Prohibiting copay clawbacks could pass down cost savings to the consumer by allowing them to retain the savings from generic medications.

The limits to the practice could be established through specific legislative prohibition or could also be established through PBM licensure, which was discussed earlier in this report.

State Legislative Action

House Bill 5941 of 2020 would have established additional regulatory requirements for PBMs under the Third-Party Administrator Act. The bill would require that patient copays cannot be higher than the cost of the drug, and carriers cannot exclude or discriminate against pharmacies in which they do not have some sort of financial interest.[24]

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[21] http://www.legislature.mi.gov/(S(suyksbkg4blgln0ka10qfivn))/mileg.aspx?page=getobject&objectname=mcl-act-218-of-1984

[22] http://www.legislature.mi.gov/(S(kabzgr0d1pitp0oicz2pbdlc))/mileg.aspx?page=getObject&objectName=2020-HB-5941

[23] https://healthpolicy.usc.edu/wp-content/uploads/2018/03/2018.03_Overpaying20for20Prescription20Drugs_White20Paper_v.1-2.pdf

[24] http://legislature.mi.gov/(S(5k3nhjzo2c051gdzv3lpho2c))/mileg.aspx?page=getObject&objectName=2020-HB-5941

Penalizing Unsupported Price Increases

Unsupported price increases can be defined as an increase in the price for a prescription drug for which there was no, or inadequate, new clinical evidence to support the price increase. Legislative action could be taken to place fines on pharmaceutical manufacturers whose drug price increases are unsupported by clinical evidence. Data on unsupported price increases is publicly available through independent institutions such as the Institute for Clinical and Economic Review (ICER), which produces an annual report identifying drugs with unsupported price increases outpacing medical inflation. State tax authority could be used to assess penalties on the manufacturers identified in the report. Because ICER's analysis targets drugs with the greatest impact on net spending, penalties could result in millions in revenue for a state, which would be used to offset costs to consumers. Unlike other policy options to review drug prices, such as establishing a drug affordability review board, this option provides industry accountability while keeping administrative costs minimal.[25]

Fair Pharmacy Audits

Pharmacy audits are conducted to ensure that pharmacies are complying with regulations or other contractual agreements. Concerns have been raised that PBMs and health plans have used the pharmacy auditing process as a revenue stream by charging fees to avoid paying for legitimate claims that were previously approved for reimbursement. The practice of extrapolation is where a simple error on one prescription is extrapolated to all similar claims during a pharmacy audit, resulting in revocation of funds on all similar claims.[26] Legislative action could be taken to ensure that PBMs are held accountable for these practices and to ensure that pharmacies are also held to a fair and reasonable standard of accountability.

Generic Equivalent Rebates

A PBM often retains some percentage of a drug rebate from a drug manufacturer. This provides an incentive for the PBM to steer covered individuals toward drugs that will result in a higher rebate share for the PBM. The PBM-preferred drug is often a brand name drug and could be more expensive for the consumer. Legislative action could be taken to prohibit a PBM's ability to accept rebates on prescription drugs when a cheaper generic equivalent exists. This type of legislation may realign a PBM's incentives in a way that benefits consumers and could result in fewer circumstances of consumers paying more than what is necessary for the prescription drugs.

State Legislative Action

House Bill 5943 of 2020 would have provided further clarification regarding which prescription drug rebates would be considered "kickbacks" under the Health Care False Claims Act[27] to realign PBM incentives that negatively impact consumers.

The bill would have limited which prescription rebates would not be considered kickbacks to prescriptions that meet both of the following criteria:

- The rebate is not for a drug with a lower-cost generically equivalent drug covered under the insured's policy; and
- The rebate is available to all "eligible individuals" regardless of how the drug is paid when provided to the consumer.

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[25] https://www.nashp.org/an-act-to-protect-name-of-state-consumers-from-unsupported-price-increases-on-prescription-drugs/

[26] https://www.michiganpharmacists.org/Portals/0/advocacy/priorities/fairaudits.pdf

[27] https://www.legislature.mi.gov/(S(unycbgi2ce1meyzxrk1vf1xi))/mileg.aspx?page=getObject&objectName=mcl-Act-323-of-1984

"Eligible Individual" meant an individual not prohibited under state or federal law from receiving or using a rebate. PBMs in violation of this provision would be subject to penalties under the Health Care False Claims Act.[28]

Limit Drug Manufacturer Gifts to Prescribers

Drug manufacturers and wholesalers often attempt to incentivize prescribers to prescribe a certain drug through various means such as providing samples, educational materials, and other gifts. These practices can result in worse patient outcomes through unnecessarily prescribed medications and higher drug costs to the consumer. Limiting this practice could result in improved patient outcomes and cost savings for consumers.

State Legislative Action

House Bill 5940 of 2020 aimed to limit the gifts a manufacturer can give to a prescriber of medications as gifts can incent prescribers into prescribing certain medications that may not be in the best interest of the consumer, financially or otherwise.

HB 5940 would have prohibited a pharmaceutical manufacturer or wholesaler from offering a gift to a prescriber when selling, promoting, or engaging in any other marketing activity for a prescription drug. A "gift" in this section refers to payment, advance, forbearance, or the rendering or deposit of money, services, or anything else of value, exceeding $63 for any one-month period.

The bill also would have required the manufacturers and wholesalers to ensure its employees comply with the following requirements:

- If the employee provides information about a prescription drug to a prescriber, that the employee provides to the prescriber, in writing, the Wholesale Acquisition Cost of the drug.
- That the employee does not engage in deceptive or misleading marketing of a prescription drug, which would include knowingly leaving out, misstating, or making a misleading representation of a material fact.
- That the employee does not attend a patient examination without the prior consent of the patient.[29]

Accessibility

Prescription drug accessibility refers to efforts to increase the supply of and access to prescription drugs. The following are policy solutions to consider when seeking greater accessibility.

Restrict Gag Clauses

A gag clause is a stipulation in a contract between a PBM and a pharmacy that prohibits the pharmacy from informing consumers of an alternative option when purchasing a drug. Gag clauses can be used by a PBM to steer business to a certain type of drug that they prefer even if there are lower cost alternatives for the patient. Prohibiting gag clauses could increase access to certain drugs and decrease drug costs by giving consumers the option to choose a generic alternative they would not have otherwise known was available. Types of gag clauses that have been prohibited by states include:

- Clauses that prohibit a pharmacist from informing a patient of a generic alternative;
- Clauses related to informing a patient if paying out-of-pocket would be less expensive; and,

[28] http://legislature.mi.gov/(S(zdbpmlsk51z1lcufcgrgtfx0))/mileg.aspx?page=getObject&objectName=2020-HB-5943

[29] http://legislature.mi.gov/(S(zdbpmlsk51z1lcufcgrgtfx0))/mileg.aspx?page=getobject&objectname=2020-HB-5940

- Clauses related to the information a pharmacy can provide a governing body about a process or procedure.

State Legislative Action

House Bill 5938 of 2020 would have prohibited a PBM from entering into a contract that prohibits a pharmacy or pharmacist from doing any of the following:

- Providing a covered person the retail price or the cost share amount for a drug;
- Discussing the retail price or the cost share amount for a drug;
- Selling a more affordable substitute if one is available.[30]

House Bill 5941 of 2020 would have required that a contract between a PBM and a pharmacy include a clause allowing a pharmacy to disclose the current selling price of a drug. This was meant to prevent a gag clause in the contract.[31]

House Bill 5942 of 2020 would have allowed pharmacists to share more information openly with patients regarding prescription drug alternatives and would prohibit pharmacists from entering into a contract that limits their ability to share price and alternative drug information with a patient. This consumer protection increases the amount of information a pharmacist can give a patient, specifically regarding things like cheaper generic drug alternatives.

The bill would have also added "biosimilar drug products" to this list of prices a pharmacist must provide when asked by a consumer. This bill would have also allowed a pharmacist to offer all of this pricing information without being asked and would prohibit a pharmacist from entering into a contract that limited their ability to provide such pricing information.

Additionally, a pharmacy or pharmacist would have been prohibited from entering into a contract with a PBM that prevents or interferes with a patient's choice to receive an eligible prescription drug from a 340B Program entity or a pharmacy when dispensing a 340B drug. The 340B Program is a federal program that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices.[32]

Limit Prescription Drug Formulary Changes (Non-Medical Switching)

A formulary is a list of prescription drugs that a health plan will cover. As new drugs become available to consumers or the price of existing drugs change, health carriers may update their formulary by adding or removing drugs or moving drugs to different cost tiers. Drugs placed in a higher tier may require an enrollee to pay a higher out-of-pocket cost or try a lower tiered drug first before insurance covers the higher tiered drug. This may cause consumers to face unexpected out-of-pocket costs or interrupt access to current medications they are taking. Legislative action could be taken to limit formulary changes to protect consumers and keep health plans accountable.

State Legislative Action

House Bill 5939 of 2020 would have restricted the ability of health plans from removing prescription drugs, reclassifying them to a more restrictive drug tier, or adding utilization restrictions. Doing so could increase consumer protection by limiting when a health plan can change the prescription drug

[30] http://legislature.mi.gov/(S(zdbpmlsk51z1lcufcgrgtfx0))/mileg.aspx?page=getobject&objectname=2020-HB-5938
[31] http://legislature.mi.gov/(S(zdbpmlsk51z1lcufcgrgtfx0))/mileg.aspx?page=getobject&objectname=2020-HB-5941
[32] http://legislature.mi.gov/(S(zdbpmlsk51z1lcufcgrgtfx0))/mileg.aspx?page=getobject&objectname=2020-HB-5942

formulary, and therefore lowering the frequency with which patients need to search for alternative medications.

The bill would have restricted the ability of a health plan that offers prescription drug coverage from doing either of the following:

- Removing a covered prescription drug from its list of prescription drugs or adding utilization management restrictions; or
- Reclassifying a drug to a more restrictive drug tier or a higher cost-sharing drug tier.

Under other certain circumstances where a prescription drug can be removed from the formulary, the insurer would be required to provide the affected insured notice in writing 90 days before the change. Under certain circumstances when a drug can be reclassified in the formulary, the insurer must provide the affected insured notice in writing 60 days before the change.

The bill did not try to prohibit the addition of prescription drugs to a health plan's list of covered drugs during the plan year and would not impact or limit a generic or biosimilar substitution. The bill would also not have limited the ability of an insurer to require a pharmacist to supply generic substitutions of prescription drugs.

Lastly, the bill would have required a health plan to treat an insured who currently uses a medication that was reclassified or removed from the formulary as if it had not been changed if their prescriber determines that the medication is medically necessary.[33]

IV. Future Considerations

The following are policy proposals that have been raised and discussed by Task Force members for potential consideration. These proposals are not necessarily Task Force recommendations; however, these proposals may merit further discussion and consideration in the future.

Rate Setting and Spending Targets

Legislative or administrative action could be taken to establish drug affordability review boards – impartial entities made up of multiple stakeholders that would give the state the ability to establish certain rates, set spending targets, and limit how much its residents may pay for certain high-cost drugs.[34]

Prescription Drug Tax Credits

The federal government allows all taxpayers to deduct the total qualified unreimbursed medical care expenses that exceed 7.5% of their adjusted gross income for insulin. Michigan could develop a similar state tax credit to help consumers afford insulin and other high cost prescription drugs. This could provide financial relief for consumers paying high out-of-pocket costs for certain prescription drugs.

Taxing Drug Price Increases that are Greater than the Rate of Inflation

Private insurers and Medicaid require manufacturers to pay rebates on price increases greater than inflation. Michigan could use this model to levy a similar tax on price increases. This could disincentivize

[33] http://legislature.mi.gov/(S(zdbpmlsk51z1lcufcgrgtfx0))/mileg.aspx?page=getobject&objectname=2020-HB-5939
[34] https://www.nashp.org/policy/prescription-drug-pricing/administrative-actions/#toggle-id-3

entities from raising prices and incentivize measures to keep price increases below or at the rate of inflation. This could provide price stability for entities throughout the supply chain and for consumers.

Value-Based Contracting

Value-based contracting requires drug manufacturers to be accountable for the prices they set. Under a value-based pricing arrangement, the manufacturer pays a partial or full refund to the payer when the drug does not work as advertised. Michigan Medicaid has executed its first outcomes-based contract for the drug Zolgensma, which at $2.125 million is currently the most expensive drug approved by the FDA. Private payers should be encouraged to enter into these types of value-based agreements with drug manufacturers. An executive budget recommendation included $5 million to transform how the state pays for health services to reward quality and positive outcomes.

Prohibit Pay for Delay

Drug manufacturers of brand name prescription drugs have been able to limit competition from generic drugs by offering patent settlements that pay generic drug manufacturers not to bring lower-cost alternatives to market. These "pay-for-delay" patent settlements effectively block all other generic drug competition for a growing number of branded drugs. Legislative action could be taken in Michigan to prohibit the practice.[35] This could keep drug manufacturers accountable for anticompetitive behavior and could result in cost savings for consumers by encouraging competition in the market for prescription drugs with more generics.

Expand the Use of Medication Therapy Management

Medication Therapy Management (MTM) services are face-to-face consultations provided by pharmacists or other healthcare providers to optimize drug therapy and improve therapeutic outcomes for beneficiaries. The healthcare provider may create a comprehensive, reconciled list of all the patient's medications for the patient and other clinicians for self-management, care coordination, and continuity.[36] By expanding or encouraging MTM services for commercial, self-funded, or public employee plans through legislative or executive action, the cost savings associated with MTM services may be extended to more patients.

License Pharmaceutical Sales Representatives

Pharmaceutical sales representatives play a major role in marketing high-cost drugs to providers. While they may provide useful information to clinicians, they can influence spending by encouraging clinicians to prescribe high-cost brand-name drugs when there are equally effective, less costly options available.[37] Legislative action could be taken to give the state the authority to license pharmaceutical sales representatives to increase transparency and accountability surrounding their activities and influence.

Repeal Drug Industry Immunity Law

The 1995 Michigan Product Liability Act gives pharmaceutical companies immunity from lawsuits filed by consumers. Michigan is the only state in the country that gives pharmaceutical companies complete immunity from prosecution. Repealing this law would allow manufacturers to be held accountable for

[35] https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay
[36] https://www.ncsl.org/research/health/medication-therapy-management.aspx
[37] https://www.nashp.org/a-model-act-to-license-pharmaceutical-representatives/

their actions and would provide Michigan residents with just legal recourse. Senate Bill 457 of 2019 would have rescinded such limitations on liability for drug manufacturers.[38]

Prohibit Spread Pricing

Spread pricing is the PBM practice of charging a health plan sponsor a higher amount than they will reimburse a pharmacy for a prescription drug and keeping the difference. Legislative action could be taken to limit or prohibit this PBM practice. This could reduce the cost of prescription drugs within the supply chain and help reduce costs for consumers. Some states have chosen to specifically prohibit spread pricing, which is meant to end the practice completely. Limits to the practice could also be established through PBM licensure.

State Accountability Review Board

Legislative or administrative action could be taken to establish drug accountability review boards – impartial entities made up of multiple stakeholders that would give a state the ability to establish certain penalties, prohibitions, or requirements upon certain entities in the prescription drug supply chain. This could ensure certain entities are kept accountable while also ensuring input and participation from stakeholders. House Bill 5108 of 2019 would have created a 'Prescription Drug Consumer Protection Board' to require drug manufacturers to justify increases for prescription drugs and impose penalties.[39]

Empower the Department of Attorney General to Take Action

The investigatory and enforcement powers of the state Department of Attorney General (AG) could be leveraged to scrutinize certain entities in the prescription drug supply chain to ensure those entities are held accountable for certain business practices and price increases. Legislative action could be taken to allow the AG to take investigatory action and to ensure consumer protection. House Bill 4702 of 2019 would have required the AG to investigate pricing of prescription insulin drugs to ensure adequate consumer protections in pricing and whether additional consumer protections are needed.[40]

Challenge Monopoly Power

Throughout the prescription drug supply chain, certain entities have consolidated considerable market power and are not subject to a high degree of market competition. In order to ensure that drugs are affordable and accessible, the state could encourage action, either directly or indirectly, that increases competition in the marketplace.

Encourage Public Production of Drugs

To increase the supply of prescription drugs in the market to ensure affordability, the state could take legislative action to encourage the public production of prescription drugs. Michigan, or a public institution in Michigan, could publicly produce drugs that could be sold to Medicaid, other states, and in the private insurance market. Michigan could produce drugs through a corporation, quasi-public corporation like the Michigan Economic Development Corporation (MEDC), or with a public university.

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[38] http://www.legislature.mi.gov/(S(m44ztofstc3avpprzux451g0))/mileg.aspx?page=getObject&objectName=2019-SB-0457

[39] http://legislature.mi.gov/(S(p4qmds0oywujar1zn4kvz4am))/mileg.aspx?page=getObject&objectName=2019-HB-5108

[40] http://legislature.mi.gov/(S(opcchhsi5o32aqhi4zz1vemu))/mileg.aspx?page=getObject&objectName=2019-HB-4702

Prescription Drug Importation from Canada

Legislative action could be taken to create a state wholesale importation program to purchase lower-cost drugs from Canada and make them available to state residents through an existing supply chain that includes local pharmacies.[41] This would ensure prescription drugs are accessible and affordable to Michigan residents. House Bills 5107,[42] 4978,[43] and 4979[44] of 2019 and Senate Bill 525 of 2019[45] could have established an importation program in the state.

Waste Free Formularies (Public Entities)

The formulary is the list of prescription drugs that a health plan will cover. Creating a waste free formulary means removing wasteful drugs from a formulary and replacing them with drugs that offer the same benefit at a lower cost. Wasteful drugs could include high-priced brand-name drugs, combination drugs, drugs with over-the-counter substitutes, or drugs with little clinical value.[46] Legislative or administrative action could be taken to review the formularies of public entity health plans to reduce wasteful spending and ensure accessibility to quality prescription drugs.

Drug Spending Cap

New York Medicaid implemented a Drug Spend Cap, which produced $55 million in savings in Fiscal Year 2018 and $85 million in Fiscal Year 2019. Under this approach, the Medicaid program sets an aggregate ceiling for drug costs that is the ten-year rolling average of the medical component of the consumer price index plus four percent, and minus a pharmacy savings target. This approach gives Medicaid additional authority and leverage to negotiate deeper discounts on certain high-cost drugs.

Medicaid would negotiate supplemental rebates with manufacturers of drugs that are projected to cause this ceiling to be exceeded. Medicaid retains all supplemental rebates that it negotiates, including those that are based on managed care drug utilization. If negotiations are unsuccessful, Medicaid's Drug Utilization Review Board would review the drug in question and recommend a target rebate amount. If Medicaid is still unsuccessful in securing the target rebate amount after applying the recommendations made by the Board, Medicaid may place prior authorization requirements on the drug or remove it from the formulary.

Additional Legislator Considerations

Overall legislators participating in the task force noted an appreciation for all of the discussions and sincere work towards finding ways to lower the costs of prescription drugs for the citizens of Michigan.

One legislator urged legislative and administrative action on this complex and important segment of health care.

Another legislator outlined several additional considerations they believe will help Michigan move closer to lowering drug costs. First, find the right amount of transparency for the entire supply chain. Second, look for ways to get most, or ideally all, drug rebates and coupons directly to the consumers. Third, ensure clear and easy to understand disclosures of prescription drug coverages for consumers. Fourth,

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[41] https://www.nashp.org/wp-content/uploads/2019/12/Wholesale-Importation-Act-Dec-19-2019.pdf
[42] http://legislature.mi.gov/(S(agxrs4bftt1s2eifidcjddxn))/mileg.aspx?page=getObject&objectName=2019-HB-5107
[43] http://legislature.mi.gov/(S(j4ibh53kgdtlcjlqf4ycjxjs))/mileg.aspx?page=getobject&objectname=2019-HB-4978
[44] http://legislature.mi.gov/(S(1eer5fcwv3lm30ta2ddw1smx))/mileg.aspx?page=getobject&objectname=2019-HB-4979
[45] http://legislature.mi.gov/(S(o5z2e4vd1x4sk153m5fyawrc))/mileg.aspx?page=getObject&objectName=2019-SB-0525
[46] https://www.nashp.org/how-waste-free-formularies-create-savings-on-prescription-drugs/

examine the use of drug samples as marketing tools by prescription drug companies and the impact on the system. This legislator believes it is important to find the right balance for controlling the costs and giving the best possible care to patients.

V. Conclusion

The Task Force worked with great diligence alongside stakeholders to understand the complexity of the problem of high-cost prescription drugs and its impact on the state's residents. This report reflects the contributions and the meaningful discussion among task force members and stakeholders on various recommendations and policy proposals surrounding the four opportunity areas of Transparency, Affordability, Accountability, and Accessibility. The report can serve as a policy guide for actions that can be taken toward lowering prescription drug costs in Michigan.

Appendix

Stop Rx Greed: Cut Drug Prices Now

AARP is Fighting to Make Prescription Drugs More Affordable

STOP Rx GREED
CUT DRUG PRICES NOW

AARP® Real Possibilities

A G E N D A

- High Cost of Prescription Drugs
- Impact on Real People
- How AARP is Fighting to Lower Drug Costs
- Solutions at the Federal & State Level
- How You Can Join the Fight and Take Action

STOP Rx GREED
CUT DRUG PRICES NOW

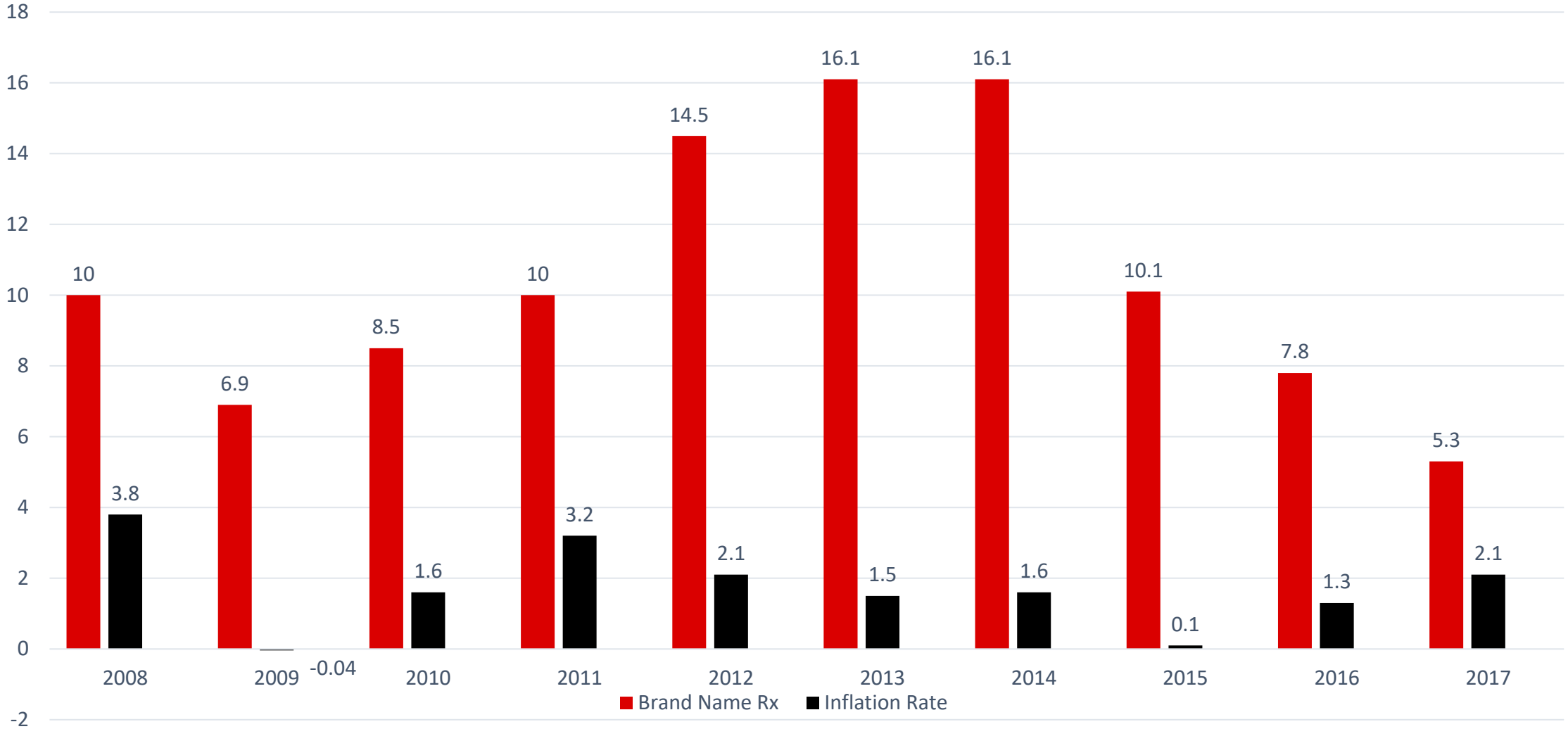
AARP® Real Possibilities

DRUG PRICES ARE GOING UP

while seniors struggle
to afford Medicare.

- Average Medicare Part D enrollee takes 4.5 meds/month
- Over two-thirds of seniors have two or more concurrent chronic illnesses
- Median income for a Medicare beneficiary is $26,000/yr.

COSTS KEEP RISING FOR BRAND NAME RX



A4

ANNUAL RETAIL PRICES

Lantus

$4,703/yr.

$1,792/yr.

Xarelto

$4,688/yr.

$2,769/yr.

Advair

$4,370/yr.

$2,239/yr.

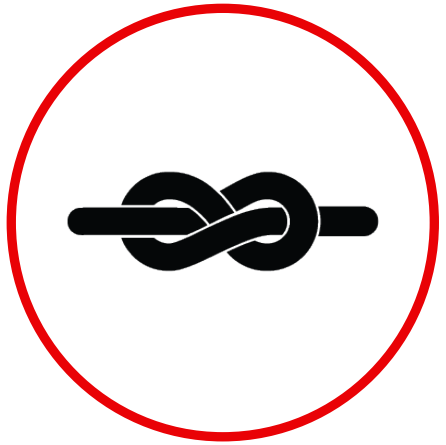
Wondering **why** our prescription drugs costs so much?

- Drug companies set their own prices
- Drug companies hold the patent rights
- Money spent on advertising
- Medicare blocked from negotiating prices

AARP IS FIGHTING TO

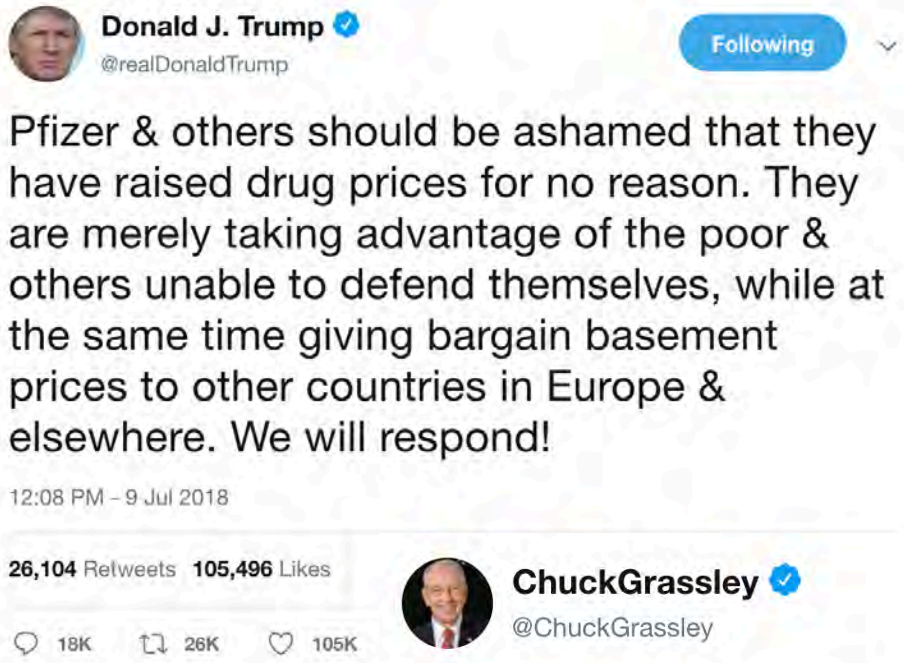
PROTECT SENIORS
and all taxpayers from *price gouging* by drug companies.

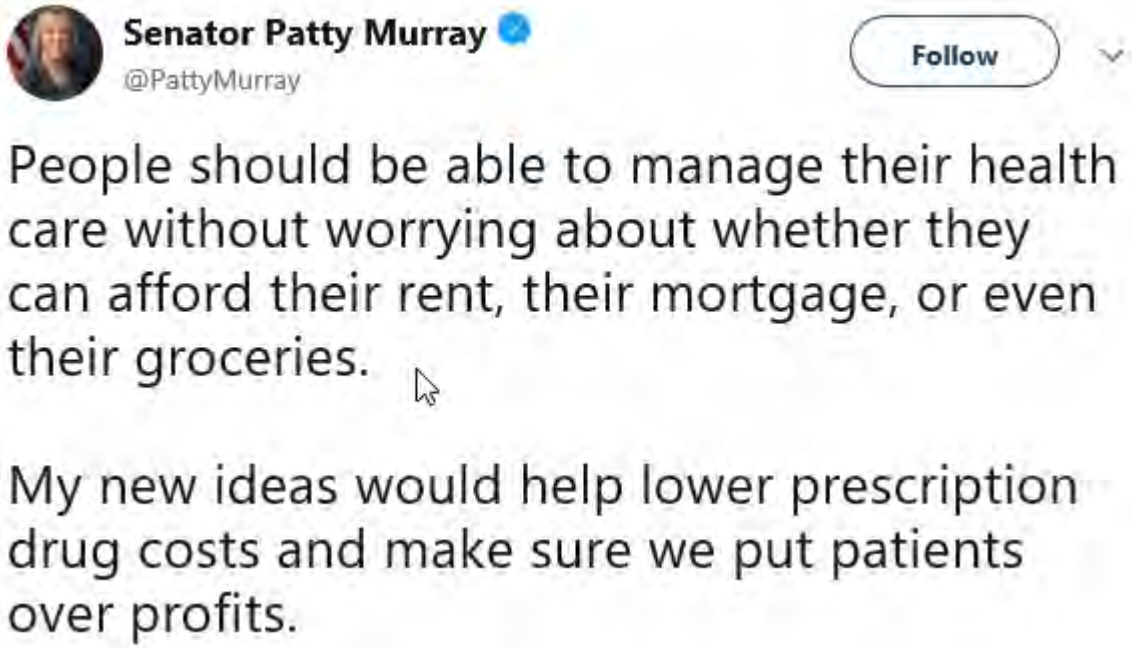
HELP PEOPLE
get the drugs they need at a price they can afford.

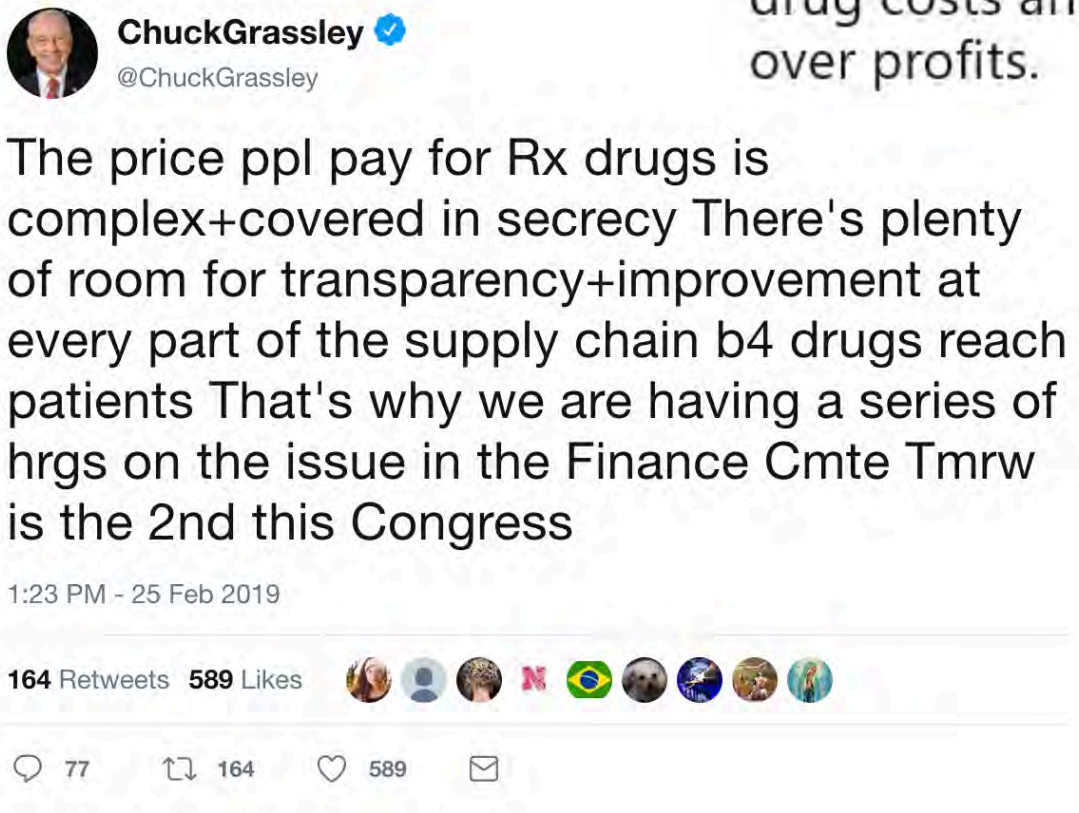


CLOSE LOOPHOLES
to stop brand-name drug companies from blocking access to lower cost generic drugs.

BRING TRANSPARENCY
in drug pricing to make easier to understand.


Donald J. Trump
@realDonaldTrump
Following
Pfizer & others should be ashamed that they have raised drug prices for no reason. They are merely taking advantage of the poor & others unable to defend themselves, while at the same time giving bargain basement prices to other countries in Europe & elsewhere. We will respond!
12:08 PM - 9 Jul 2018
26,104 Retweets 105,496 Likes
18K
26K
105K

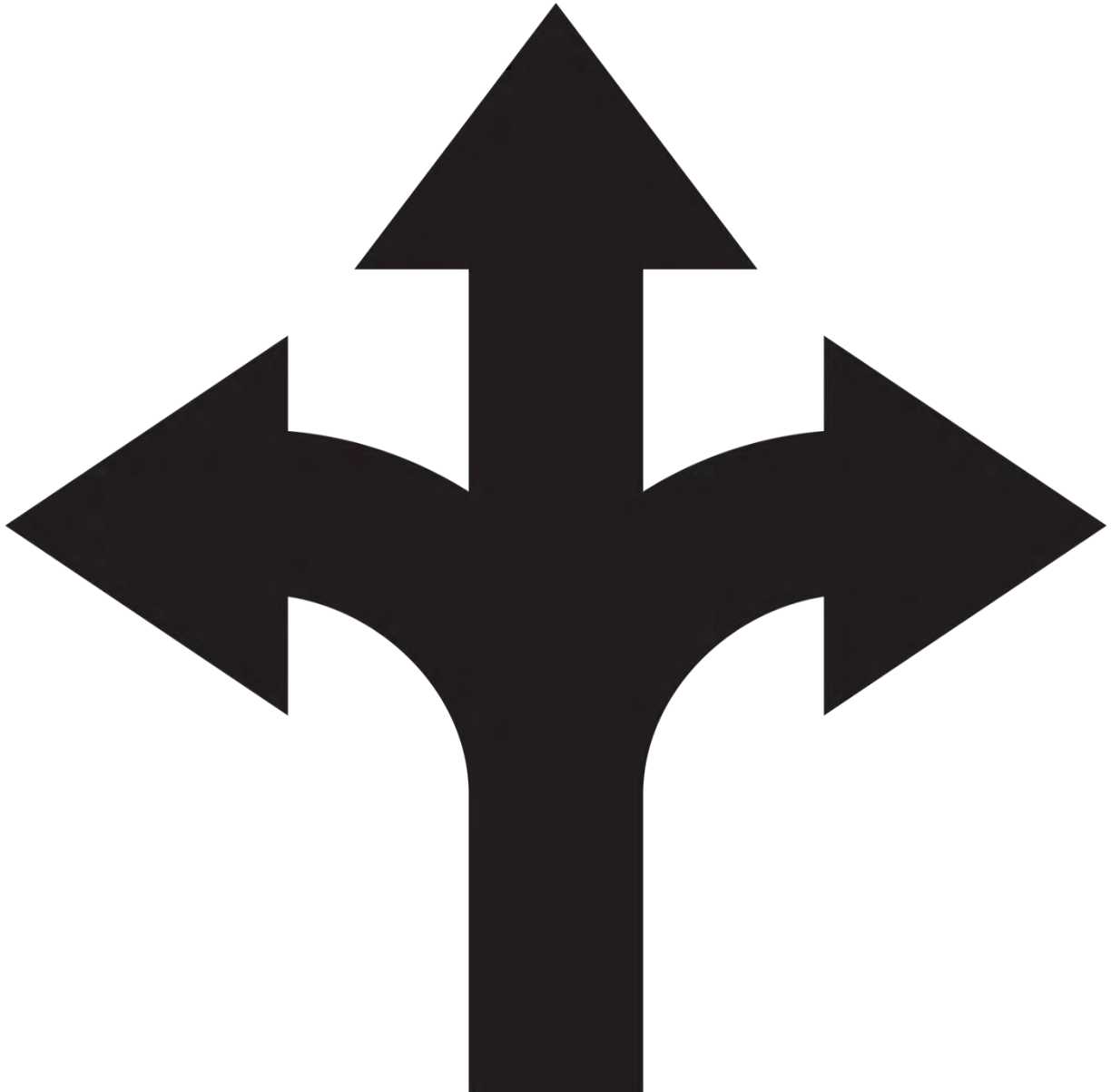

Senator Patty Murray
@PattyMurray
Follow
People should be able to manage their health care without worrying about whether they can afford their rent, their mortgage, or even their groceries.
My new ideas would help lower prescription drug costs and make sure we put patients over profits.


ChuckGrassley
@ChuckGrassley
The price ppl pay for Rx drugs is complex+covered in secrecy There's plenty of room for transparency+improvement at every part of the supply chain b4 drugs reach patients That's why we are having a series of hrgs on the issue in the Finance Cmte Tmrw is the 2nd this Congress
1:23 PM - 25 Feb 2019
164 Retweets 589 Likes
77
164
589

WHAT ARE SOME SOLUTIONS?

We understand **no one solution** will make prescription drugs more affordable.

Therefore, the broadest possible advocacy effort is necessary.



WHAT ARE SOME SOLUTIONS?

Lowering prices through Medicare negotiation

1

Improving access to lower cost generic drugs through competition

2

Capping out of pocket costs on prescription drugs for Medicare enrollees

3

WHAT ARE SOME SOLUTIONS?

State importation from other countries. 1

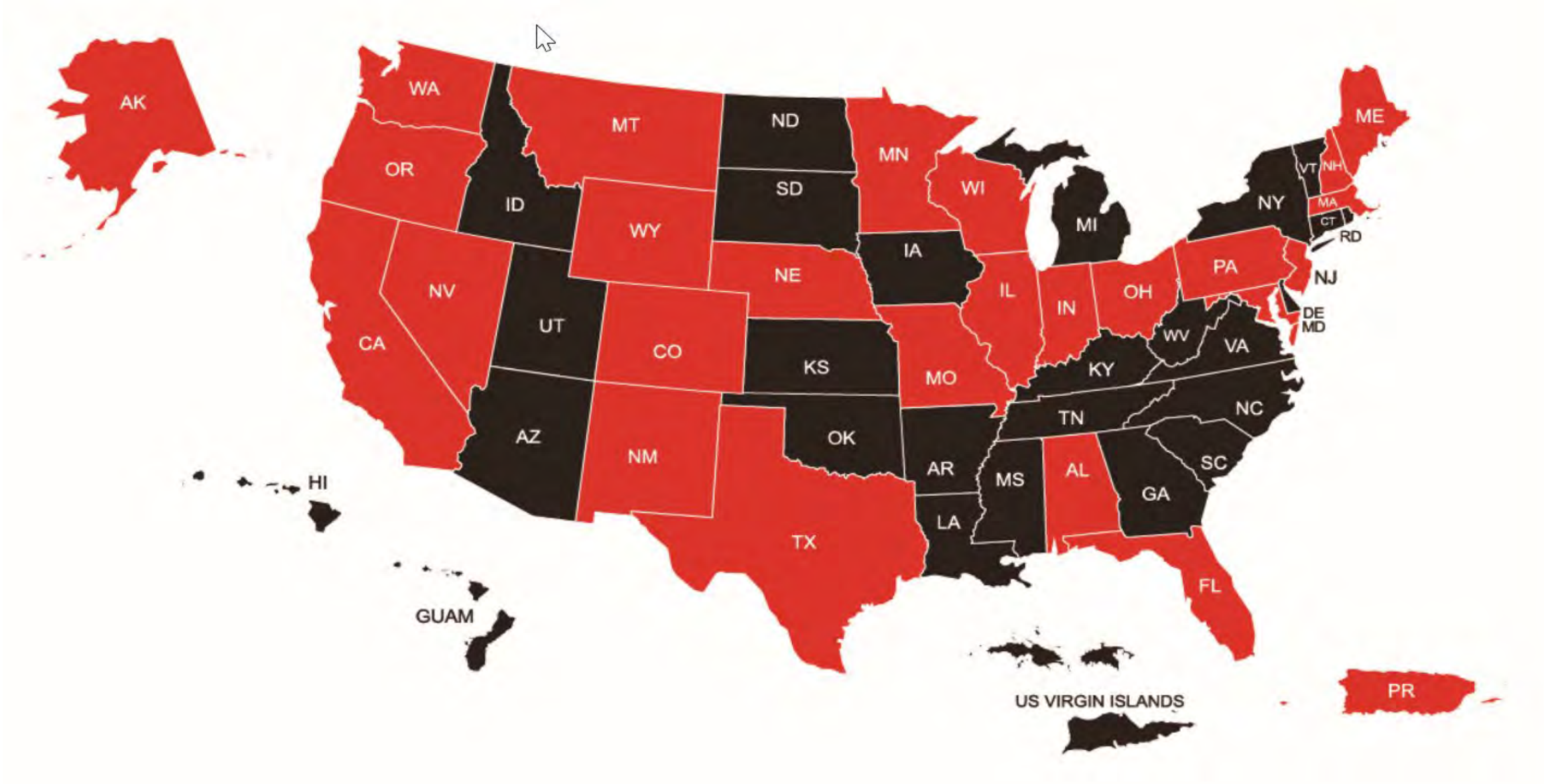
Bulk purchasing of Rx 2

Drug Affordability Commissions 3

Transparency behind dramatic price increases in Rx costs. 4

Setting caps on out of pocket costs for prescription drugs 5

STATE LEGISLATIVE WINS



Updated as of February 4, 2020

KEY **Rx State Wins**

JOIN THE FIGHT TO STOP RX GREED

Sign Petition telling Congress to Cut Drug Prices Now!

Share Your Story with AARP
www.action.aarp.org/rx-stories

STOP Rx GREED
CUT DRUG PRICES NOW

Engage with AARP Advocates on FB and Twitter - #StopRxGreed

STOP Rx GREED
CUT DRUG PRICES NOW

Contact your Elected Officials and Candidates to Urge them to Take Action

Q & A

STOP GREED
CUT DRUG PRICES NOW

STOP GREED
CUT DRUG PRICES NOW

AARP Real Possibilities

Insert State Contact Info

MICHIGAN PHARMACISTS ASSOCIATION

December 3, 2020

Michigan Prescription Drug Task Force
State of Michigan

Members of the Michigan Prescription Drug Task Force:

The Michigan Pharmacists Association (MPA) would like to thank the Michigan Prescription Drug Task Force for allowing us to present to the committee and submit MPA's suggestions for lowering the cost of prescription drugs and healthcare in the state. As residents ourselves, we are strong proponents of saving Michiganders as much money as possible, while also expanding access to care to as many individuals as possible.

Pharmacy Benefit Managers (PBMs) are the middlemen in the healthcare system, as we explained to the Taskforce during our presentation on Nov. 16. These middlemen adjudicate pharmacy claims in a quick and efficient way. However, the PBMs also contribute to the high cost of prescription drugs in the state and nation. Currently Michigan is one of 23 states that have not enacted PBM transparency requirements, thus PBMs are able to operate without any type of regulation. Because of the lack of transparency and other regulations, PBMs have been very successful in benefiting financially from their policies and procedures at the expense of patients and employers.

PBMs have become more than they were originally intended for the health care system and are poorly regulated. From their actions, they appear to be only concerned about their bottom line. The PBMs use tactics such as spread pricing, mandatory name brand usage and pharmacy clawbacks to increase their profits on the backs of patients (through higher copays and decreased access) and employers providing health care benefits.

Through spread pricing, PBMs reimburse a pharmacy one amount for a prescription drug but charge the insurer a higher amount. This is known as the "spread." The spread is the amount that the PBM benefits in the transaction. Spread pricing increases the cost to the insurer who then passes the cost on to the insured. The Michigan Pharmacists Association conducted a study on the impact of spread pricing on the state's Medicaid program, and the report estimated that this practice by PBMs costs the state $64 million per year. Thankfully, spread pricing has recently been prohibited by the Centers for Medicare and Medicaid Services (CMS); however, it is still present in commercial insurance.

Requiring mandatory use of certain brand name medications when a generic is available drives up the cost to the pharmacy, as well as the patient's copay. We frequently see PBMs require the use of brand names when a new authorized generic is available. The manufacturer agrees to pay a rebate to the PBM if they will give their drug a priority status on the formulary. The insurer and patient will still pay the full price of an expensive brand medication while the PBM takes home rebate dollars and is not required by any law to pass them on to the patient or the insurer.

Using pharmacy clawbacks, PBMs reimburse the pharmacy an inflated amount at the point of sale, requiring the patient to pay higher co-pays. Then months later, the PBM will "claw back" the money it paid to the pharmacy for reasons not explained to the pharmacy. The clawbacks are not shared with the patient or employer, but rather go in the pockets of the PBMs. The national clawback average per pharmacy is $100,000[1] per year. One of MPA's members testified in the Michigan House Health Policy Committee (Sept. 1, 2020) that he is on track to reach $120,000 in clawback fees this year. For a small rural, independent pharmacy, this can be disastrous.

The MPA recommends that the deceptive practices described should be combatted through comprehensive PBM reform. House Bill 5938 would help decrease health care costs for patients and employers, as well as decrease unnecessary fees on Michigan pharmacists and pharmacies. The bill would increase PBM transparency, prohibit the use of clawbacks, force PBMs to register with the state and penalize those who do not, and it would require them to report, among other things, any spread pricing in which they participate to the Department of Insurance and Financial Services (DIFS). By taking these simple steps and increasing transparency, the state of Michigan would be able to reduce the cost of health care and prescription drugs.

Again, the Michigan Pharmacists Association would like to thank the Task Force for taking time to review our comments and suggested plan of action. If you have any additional questions, I can be reached at the contact information below.

Sincerely,

Larry Wagenknecht, Pharmacist
Chief Executive Officer
Michigan Pharmacists Association
larry@michiganpharmacists.org
517-377-0226

[1] https://ncpa.org/newsroom/news-releases/2020/04/27/front-line-pharmacies-struggling-pay-unfair-clawback-fees-even

MICHIGAN PHARMACISTS ASSOCIATION

Medication Costs
Prescription Drug Task Force

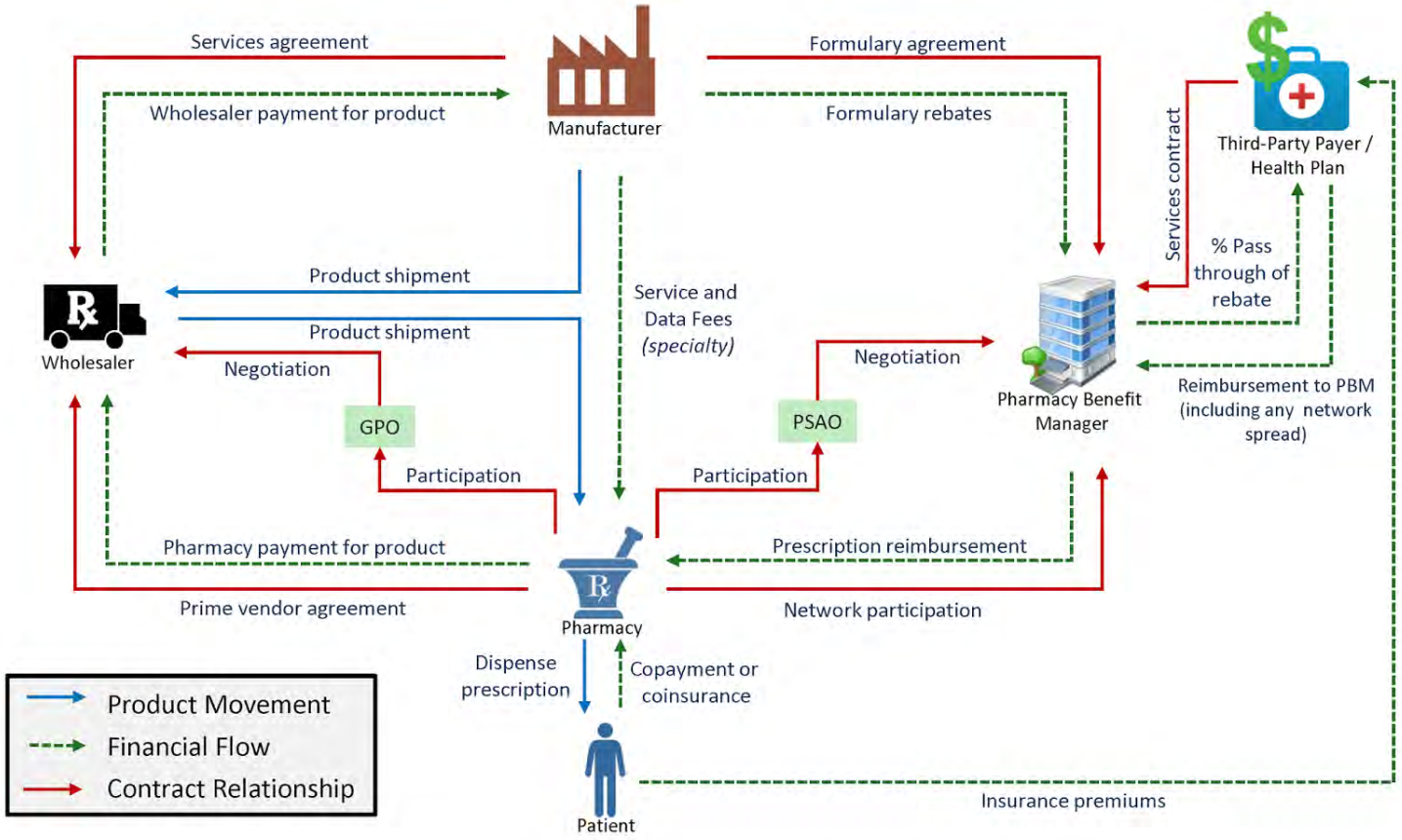
Larry Wagenknecht, Pharmacist
Chief Executive Officer
Michigan Pharmacists Association

MICHIGAN PHARMACISTS ASSOCIATION

Extremely Complex Drug Distribution Process

1. Difficult for EVERYONE to understand – including pharmacists!
2. Difficult to make a change – because of the complexity and the stakeholders involved – the three largest players are the drug manufacturers, third party payers/health plans and pharmacy benefit managers (PBMs)
3. Extremely difficult to influence at the state level – could (should?) be handled at the federal level

U.S. Distribution and Reimbursement System: Patient-Administered, Outpatient Drugs



Source: Fein, Adam J., *The 2017 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute, 2017. Chart illustrates flows for **Patient-Administered, Outpatient Drugs**. Please note that this chart is illustrative. It not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace.
GPO = Group Purchasing Organization; PSAO = Pharmacy Services Administrative Organization

DRUG CHANNELS INSTITUTE

Scope of the Problem…

"Drugs don't work on patients that don't take them."

"The biggest waste in the health care system is when a patient does not take their medication or does not take it as prescribed."

"The estimated annual cost of prescription drug-related morbidity and mortality resulting from nonoptimized medication therapy was $528.4 billion in 2016 US dollars, with a plausible range of $495.3 billion to $672.7 billion." Watanabe JH, McInnis T, Hirsch JD. Cost of Prescription Drug-Related Morbidity and Mortality. Ann Pharmacother. 2018 Sep;52(9):829-837. doi: 10.1177/1060028018765159. Epub 2018 Mar 26. PMID: 29577766.

MICHIGAN PHARMACISTS ASSOCIATION

Actions to Date

1. Advocate for PBM reform – Michigan is one of only 13 states that have NOT implemented PBM transparency or similar reform
2. Supported Pharmacist Gag Clause legislation at federal level – S. 2253 – Know the Lowest Price Act of 2018 – Sen. Stabenow – Oct. 9, 2018
3. Supported the House Health Transparency Bills – specifically HB 5938 (PBMs) and HB 5942 (pharmacist gag clause)

Actions - continued

4. Advocate for increase use of pharmacists to assist with providing patient care – pharmacists are the most underutilized member of the health care team
5. Worked with Medicaid in 2016 to implement Medication Therapy Management (MTM) Program - eliminates poly-pharmacy and identifies lower cost medications
6. I Vaccinate Program

MICHIGAN PHARMACISTS ASSOCIATION

Potential Solutions

1. PBM Transparency – HB 5938 (Rep. Liberati)
2. Pharmacist Gag Clause – HB 5942 (Rep. Kahle)
3. Eliminate rebates from the drug distribution equation – a rebate is just an "overcharge"
4. Expand Medication Therapy Management beyond Medicaid and Medicare - for commercial and self-insured plans
5. Address prior authorizations – SB 612 (Sen. VanderWall)

Potential Solutions - continued

6. Codify parts of the COVID Executive Orders – vaccinations, emergency refills, modification of existing therapy and therapeutic interchange
7. Increase the utilization of pharmacists in patient care – pharmacists are the most accessible member of the health care team – including the treatment of opioid use disorders, diabetes, asthma and hypertension
8. Importation from Canada is NOT the answer

MICHIGAN PHARMACISTS ASSOCIATION

QUESTIONS?

Larry Wagenknecht, Pharmacist
CEO, Michigan Pharmacists Association
larry@michiganpharmacists.org
517-377-0226

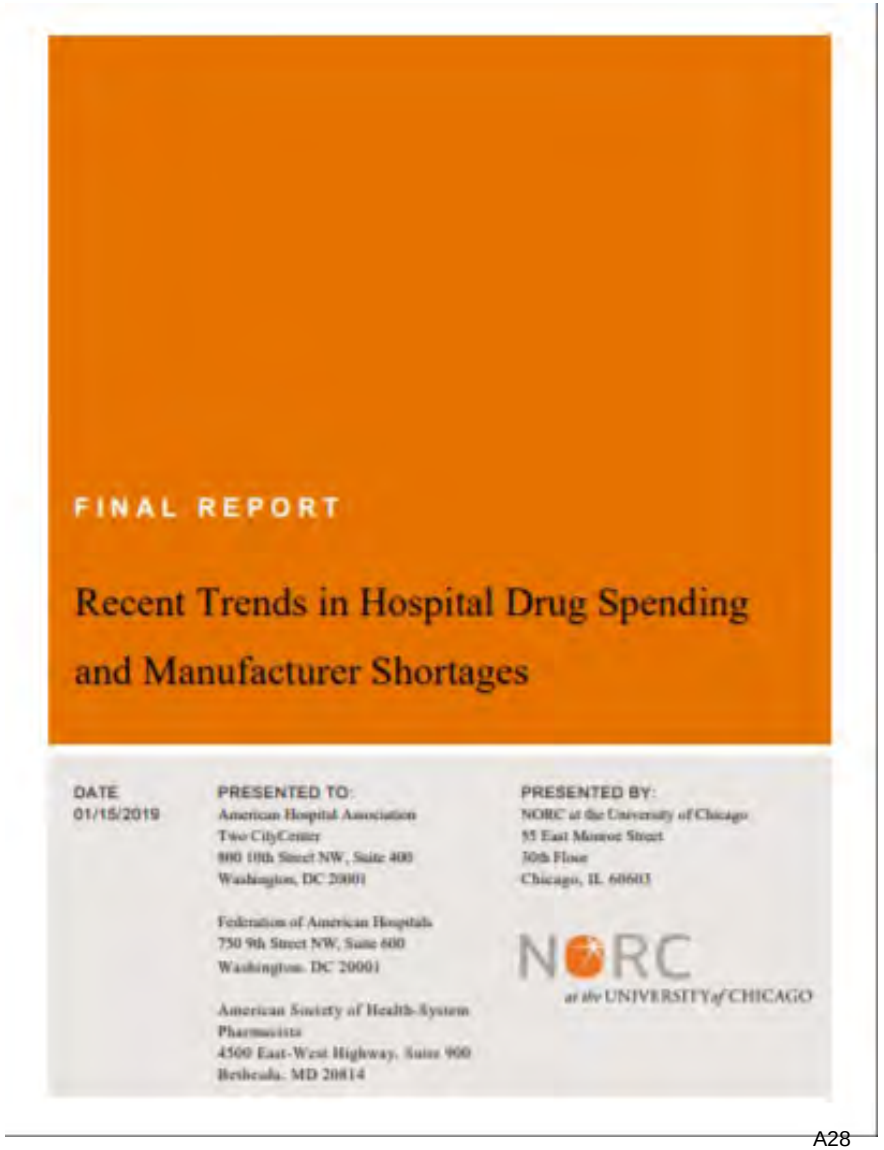
MHA
Michigan Health & Hospital Association

Leading Healthcare

Hospital Prescription Drug Pricing Pressure

Key Findings

- Average total drug spending per hospital admission increased 18.5 percent between FY 2015 and 2017
- Outpatient drug spending per adjusted admission increased 28.7 percent
- Inpatient drug spending per admission increased 9.6 percent
- Inpatient drugs exceeded the Medicare reimbursement update five-fold during the study period.
- Hospitals experienced price increases in excess of 80 percent for anesthetics, parenteral solutions, opioid agonists, and chemotherapy.
- Over 90 percent of surveyed hospitals reported identify alternative therapies to mitigate the impact of drug price increases and shortages.
- One in four hospitals had to cut staff to mitigate budget pressures.


FINAL REPORT

Recent Trends in Hospital Drug Spending and Manufacturer Shortages

DATE
01/15/2019

PRESENTED TO:
American Hospital Association
Two CityCenter
800 10th Street NW, Suite 400
Washington, DC 20001

Federation of American Hospitals
750 9th Street NW, Suite 600
Washington, DC 20001

American Society of Health-System Pharmacists
4500 East-West Highway, Suite 900
Bethesda, MD 20814

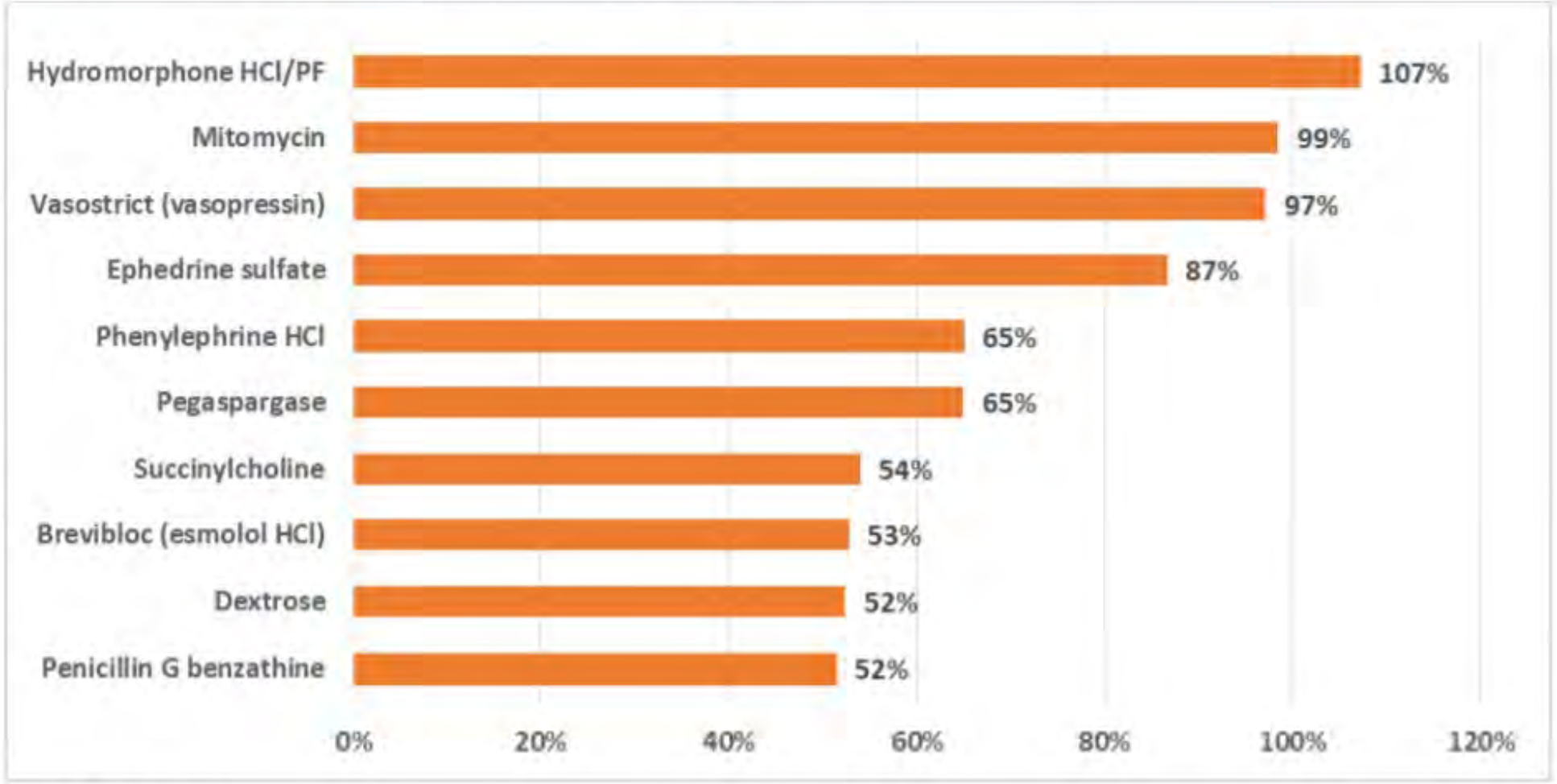
PRESENTED BY:
NORC at the University of Chicago
55 East Monroe Street
30th Floor
Chicago, IL 60603

NORC at the UNIVERSITY of CHICAGO

A28

Drugs with Highest Percentage Change in Price

Figure 4a. Drugs with the Highest Percentage Change in Price per Unit between CYs 2015 and 2017 (for drugs with total CY 2017 spending > $1M)

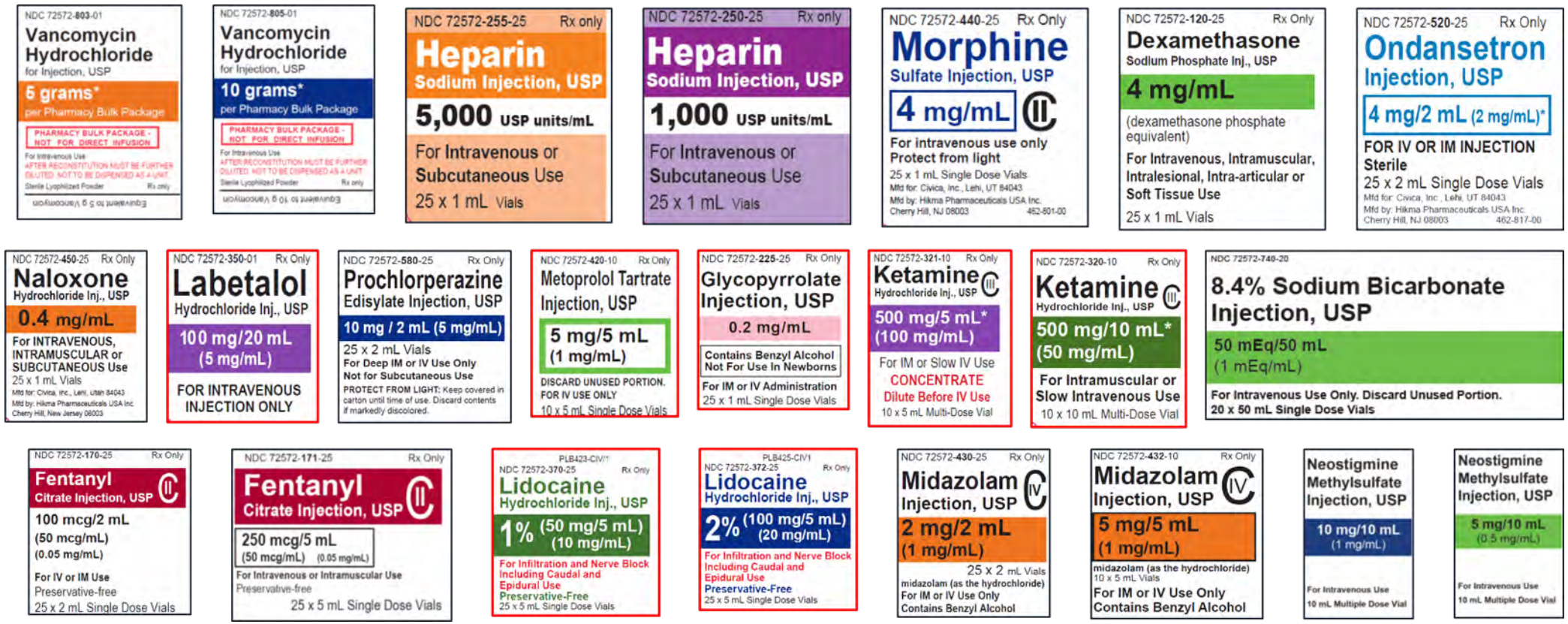


Source: GPO Rx Data

Civica Rx—Established September 2018

- Serving in the public interest as a non-stock, non-profit corporation to address shortages of generic drugs while lowering their cost
- Founded by leading health systems concerned about generic drug shortages, and philanthropic members passionate about improving healthcare
- Committed to transparency, a one-price-for all model, and its membership is open to all

CivicaRx Medications



A31

2020—Entering Retail Field

- Civica Rx created a new entity focused on development and manufacturing of high-cost generic drugs in the retail space
- Intent: Continue disruptive innovation to meet the needs of patients

A32

Partnership with Blue Plans

CIVICA™ + BlueCross BlueShield Association + **Lower costs** for select high-cost generics for consumers

With BCBS companies, Civica Rx is creating a new entity open to other health plans, employers, retailers and other health care innovators who will pass along savings to consumers.

A33

MHA
Michigan Health & Hospital Association

Leading Healthcare

2112 University Park Drive | Okemos, MI 48864

(517) 323-3443 | www.mha.org

Laura Appel
Senior Vice President
lappel@mha.org
517-285-2962
@lauradianeappel

Key Players and Key Issues

Pharmaceutical Market Overview

November 20, 2019
Michigan Governor's Task Force
Jane Horvath Presentation

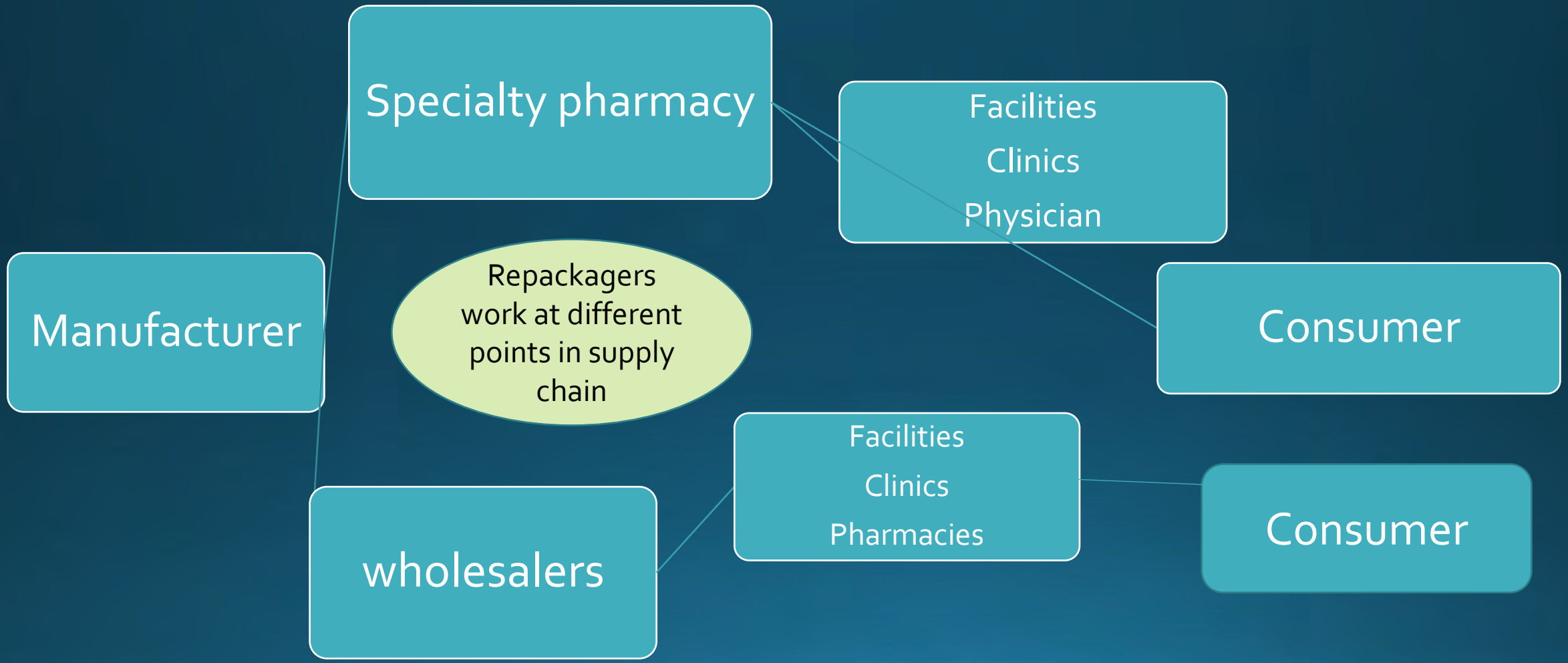
Pharmaceutical Sector

BACKGROUND

Rx Industry Legal and Regulatory Framework

- **Food and Drug Administration, Health and Human Services Department**
  - Licenses prescription drug products
    - New Drug Application (small molecule)
    - Abbreviated New Drug Application (AND, generics small molecule
    - Biologics License Application (large molecule, biologics and biosimilars)
  - Monitors Safety
    - Adverse Events Database
    - Sentinel System
    - Good Manufacturing Practices/physical plant inspections
  - Regulates Drug Advertising
  - Wholesalers must also register
- **Centers for Medicaid and Medicare Services, HHS**
  - Drug Payment Amounts (Medicare Part B)
  - Anti kickback – Medicare and Medicaid (no drug-specific patient discounts or coupons…no inducement to use more services)
  - Coverage Policy (Medicare B and D)
  - Medicaid Drug Rebate Program
- **States license supply chain -- wholesaler to end purchasers**
  - Not all states regulate PBMs

Basics of Product Supply Chain



Rx Purchase/Payment Terminology

- **List Price – manufacturer catalogue price**
  - Often conflated with wholesale price
- **Wholesale Acquisition Price (WAC)**
  - Average of discounts provided to wholesalers purchasing the drug
- **Average Wholesale Price (AWP)**
  - Average of wholesaler prices to retail pharmacies and other direct purchasers
  - Sometimes used by payers to reimburse for drugs dispensed
    - Often thought to be overstated so payers reimburse @ AWP minus some %
- **Maximum Allowable Cost (MAC)**
  - Payer algorithm used to average prices for multi-source products used to reimburse pharmacies
  - MAC formula and Rx to which it applies varies by payer
- **Average Manufacturer Price (AMP)**
  - Average manufacturer sales price to wholesalers and retail pharmacies
  - For Medicaid use only
  - Confidential

Who Does What? Manufacturers

- Bring Drugs to Market
  - Buy promising molecules from research centers (Universities) that do the 'bench science'
    - Outright purchase and/or pay royalties if/when molecule is commercialized
  - Apply for patent (20 years)
  - Conduct R&D on molecules through Phase 1-3 clinical trials
  - Submit to FDA for approval
  - Manufacturer R&D can take 10 or 13 years, so 7-10 years left on patent at FDA approval
- federally regulated and may be state-licensed
- Set the price
  - Often years before a drug reaches the market
- Can lease the drug license to another company to sell
- Sales and marketing, life cycle management
  - Price changes, price concessions, patient assistance

Horvath Health Policy, *Innovations in Healthcare Financing Policy*

Who Does What? Wholesalers

- Buy in large quantity from manufacturers
  - Manufacturers can create 'tie-ins'
- Store Rx
- Sell and Ship to
  - large purchasers
  - regional distributors
  - pharmacies (local distributors)
  - can create sales 'tie-ins'
- A wholesaler can have several roles
  - Specialty Pharmacy - McKesson administers the Vaccine for Children supply to pediatrician offices
  - Pharmacy Services Admin Org (PSAO) -- negotiates with manufacturers and PBMs on behalf of pharmacies and administrative services
  - Fulfill manufacturer price concession agreements with *purchasers (hospitals for example)*

Who Does What? PBMs (or Insurers without PBM)

- Create pharmacy networks for health plans
  - Negotiate pharmacy professional (aka dispensing) fees
  - Set drug reimbursement amounts
  - Pay pharmacy claims, bill insurers for reimbursement of paid claims
  - Align with/operate mail order pharmacy (does not apply to health plan)
- Design and managed health plan formulary
  - Small plans take PBM national formularies, large plans may design their own
  - Negotiate manufacturer rebates based on formulary placement
  - Decide pharmacy utilization management strategies
- Reimburse pharmacies and providers for drugs dispensed or administered to health plan enrollees
- Collect manufacturer price concessions based on paid Rx claims
- Many states license PBMs

Who Does What? Insurers

- Contract with PBMs
  - Scope of PBM role depends on insurer, usually size of insurer
  - Reimburse PBM for pharmacy 'claims paid'
- Why contract with PBMs?
  - Running pharmacy benefit has become complex
    - Response to rising prices (utilization management)
    - Negotiate and manage manufacturer rebates
    - Negotiate with pharmacies and create pharmacy networks
- Set overall premiums based on expected medical and pharmacy costs
  - Rx costs are increasing share of premium (27% or so)
- Run grievance and appeals for pharmacy benefit
- Are state licensed (other than ERISA plans)

Who Does What? Pharmacies

- Retail pharmacies – open to public
  - Purchase drugs from wholesalers and distributors
  - Hire administrative services companies to handle claims wrangling and often to group purchase negotiations (PSAOs, which can be wholesalers)
  - Counsel patients
  - Can't drive brand name market share but can drive generic market share (for volume discounts)
- Specialty pharmacies – may or may not be open to public
  - Contract with manufacturers to handle specific, 'specialty' drugs
  - Work with administering providers to get product to offices as needed
  - Case management for patients on the drug
  - Administrative assistance to administering providers (handling, billing etc.)

Who Does What? PSAOs

- **Pharmacy Services Administration Organization**
  - Target client is independent pharmacies
  - Independent pharmacies make ~90% of their revenue from dispensing
  - PSAO market increasingly dominated by large wholesalers – McKesson, Amerisource Bergen, Cardinal (See next slide)
- **PSAO Services**
  - Network contracting with PBMs and health plans
  - Discount negotiations with Manufacturers and Suppliers for Rx purchase/acquisitions
  - Claims processing/dispute resolution and other administrative services
  - Performance monitoring in compliance with health plan/PBM contracts
  - Regulatory updates on pharmacy or durable medical equipment (DME) provider rules
- **Regulatory Framework**
  - State and federal regulation of pharmacies
  - State and federal regulation of wholesalers

Largest Pharmacy Services Administrative Organizations, by Members and Ownership, 2017

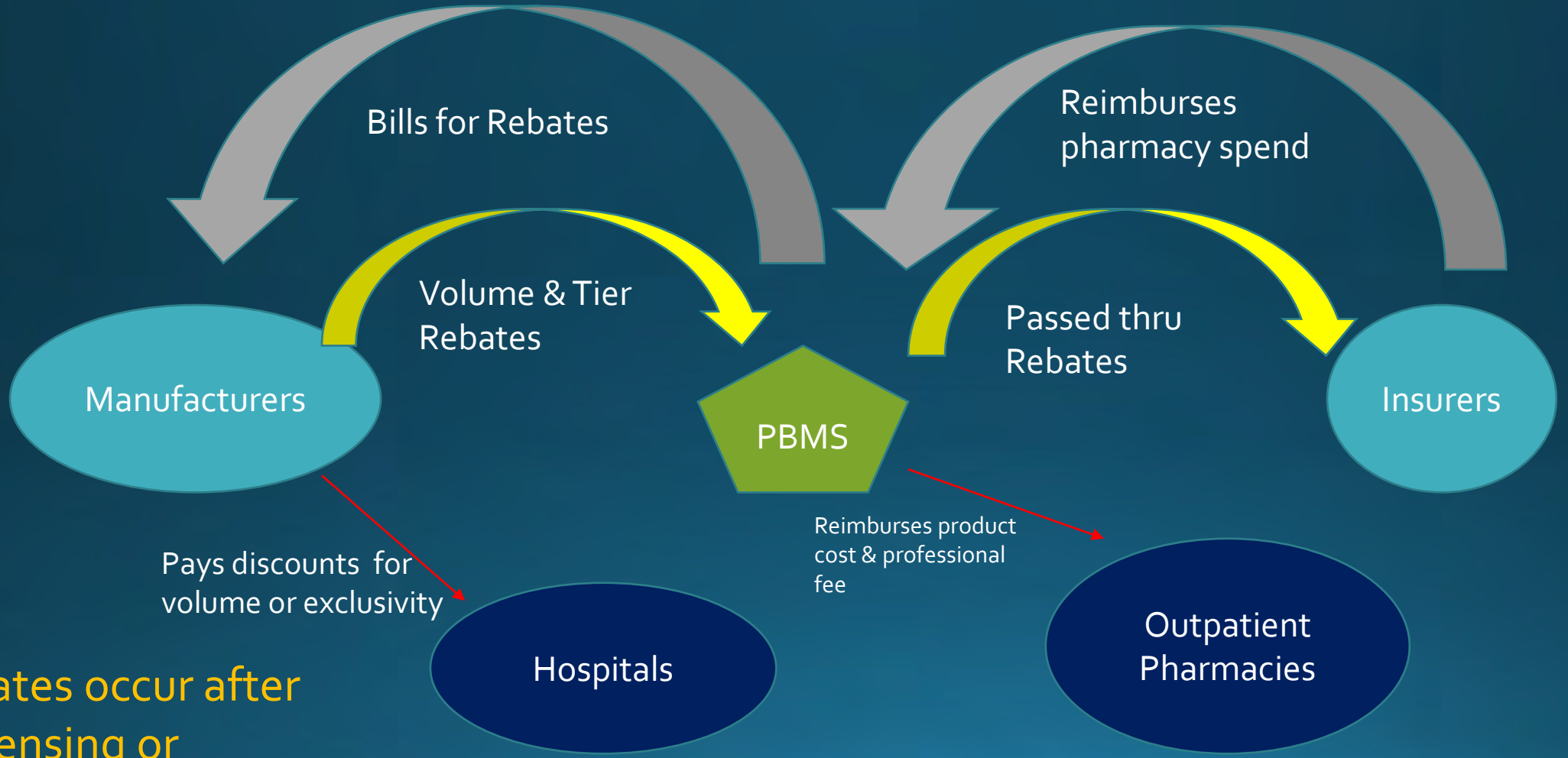
Pharmacy Services Administrative Organization (PSAO)	Participating Pharmacies	Ownership	Wholesaler Ownership?
AccessHealth	5,900	McKesson	Y
LeaderNET / MSInterNet / Managed Care Connection	5,600	Cardinal Health	Y
Elevate Provider Network[1]	4,500	AmerisourceBergen	Y
Arete Pharmacy Network	2,500	H.D. Smith[2]/AAP[3]	Y
Third Party Station	2,100	Wholesale Alliance LLC[4]	Y
EPIC Pharmacy Network, Inc.	1,700	Member-owned	N
Unify Rx	1,200	PBA Health/PPOK[5]	N
American Pharmacy Network Solutions	700	American Pharmacy Cooperative	N

Sources: Drug Channels Institute research and estimates
1. ABC's PSAO was previously called the GNP Provider Network
2. In November 2017, AmerisourceBergen announced its acquisition of H.D. Smith's drug wholesaling business. Arete was not included in the transaction.
3. Arete was formed in 2016 by the merger of H.D. Smith's Third Party network and United Drugs' American Associated Pharmacies. The participating pharmacies figure includes the members of RxPride, which Arete acquired in December 2016.
4. Wholesale Alliance LLC is jointly owned by the following wholesalers: Burlington Drug, Dakota Drug, NC Mutual Drug, Rochester Drug, Smith Drug, and Value Drug.
5. Unify Rx figures include the estimated PSAO members from TriNet Third Party Network (PBA Health) and RxSelect Pharmacy Network (PPOK).

This table appears as Exhibit 87 in *The 2018 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Drug Channels Institute*. Available at http://drugch.nl/pharmacy

DRUG CHANNELS INSTITUTE

Basics of Manufacturer Rebates



Rebates occur after dispensing or sale

Potential Areas of Focus

Key Issues in Pharmaceutical Market

Specialty Drugs

- Definition
  - Costly and/or
  - Requires special handling and/or
  - Requires provider training and/or
  - Requires patient case management or education
- Startling Pricing
  - Triage therapies become first line therapies
  - Rare disease treatment becomes chronic care treatment but pricing based on rare disease or salvage therapy (example: cystic fibrosis).

More Costly Treatments Get Expedited Review/Less Data Required

- FDA fast track/reduced data approval paths 2019 48 NME Rx*
  - 13 – Breakthrough – substantial treatment improvement
  - 28 – Priority Review – FDA decision within 6 months
  - 17 – Fast track – Rx treats serious conditions with unmet medical need
  - 9 – Accelerated Approval – serious medical condition with unmet medical need using surrogate clinical trial endpoints
  - 21 – Orphan Drug NMEs – treat patient populations of <200,000 people
- Expedited drug products may then be used for additional illnesses but pricing remains the same

* NMEs qualified in more than 1 category

Horvath Health Policy, *Innovations in Healthcare Financing Policy*

Industry Move to Small Population Treatments

- Industry R&D focus in treatment areas where insurer cost containment power is reduced and patient need and advocacy is high. Examples
  - Rare diseases – 25M people/330M total population (rare disease affects <200000 people)
  - Cancer – 1.7M people
  - COPD – 16M people
  - Lupus – 1.5M people
  - MS -- 1M people
  - Epilepsy – 3M people
  - Sickle Cell – 1M people
- **49M/330M = >15% of population and counting**
- Pricing model will generate phenomenal/unaffordable costs

Horvath Health Policy, *Innovations in Healthcare Financing Policy*

Key Policy Issues in Rx Supply and Financing

Insurer / Patient

- Insurer mergers
- Insurer/PBM mergers
- Rise of costly breakthrough/fast track drugs on patient costs and access
- All the price-protected programs (Medicaid, VA, 340B, Medicare D…) limit commercial insurer price negotiation ability

PBM

- PBM/Chain Drugstore Mergers
- Treatment of independent pharmacies
- How rebates are used
- Lack of transparency/transparency laws

Mfr

- Corporate Mergers
- Focus on oncology and rare diseases (high priced biologics)
- Focus on Wall Street
- Profits from price and price increases rather than sales
- Political Power
- Gross to Net Bubble
- Patent extensions

Provider

- 340B Program creates market inequities between eligible providers and ineligible providers
- 340B Program driving some provider consolidation, which raises other costs depending on the consolidation

Thank You!

Jane Horvath

Horvath Health Policy, *Innovations in Healthcare Financing Policy*

Linkedin.com/in/horvathhealthpolicy

HorvathHealthPolicy@gmail.com

202/465-5836

600 E. Lafayette Blvd.
Detroit, MI 48226-2998
bcbsm.com

Blue Cross Blue Shield Blue Care Network of Michigan

Michigan Task Force on Prescription Drug Cost
235 S. Grand Avenue
Lansing, MI 48933

Nov. 30, 2020

Leaders of the Task Force –

Thank you for serving on Governor Whitmer's Prescription Drug Task Force and for your efforts to address increasing drug costs.

We share your concerns over the ever-increasing cost of prescription drugs. Our top priority is ensuring that prescription drugs are available when our members need them. Prescription drugs are the single highest expense for Blue Cross Blue Shield of Michigan – higher than hospital stays or doctor visits. These costs are rising and are a significant factor in increasing premium costs and lack of access to necessary medication.

A study by the Peterson Center on Healthcare and Kaiser Family Foundation indicates that drug costs account for approximately 21% of employer insurance benefits. According to Good Rx, drug prices have increased 33% since 2014, outpacing price increases for any other medical service or commodity. This affects us all, as one in four adults taking a prescription drug state that they have difficulty affording their prescription medicine.

These price trends are concerning and demand public policy solutions. As Michigan's largest insurer, our customers look to us to address this problem. We have several efforts in place, such as partnering with Civica Rx to manufacture lower cost generics, contracting with a pharmacy benefit manager to negotiate drug rebates, offering programs that limit member out-of-pocket costs, making real-time drug pricing available to patients and physicians along with information about lower cost alternatives. In addition, utilization management programs such as prior authorization or step therapy ensure the clinically appropriate use of select prescription drugs and encourage the use of cost-effective therapies.

However, state and federal law changes are necessary to address this crisis and curb the cost trend. We offer the following state policy solutions to help increase access to necessary medication by decreasing costs:

1. Require prescription drug price and cost transparency
2. Limit gifts from drug companies to prescribers
3. Limit coupons for drugs when a generic-equivalent drug exists
4. License drug company sales representatives
5. Allow pharmacists to provide cost information to consumers

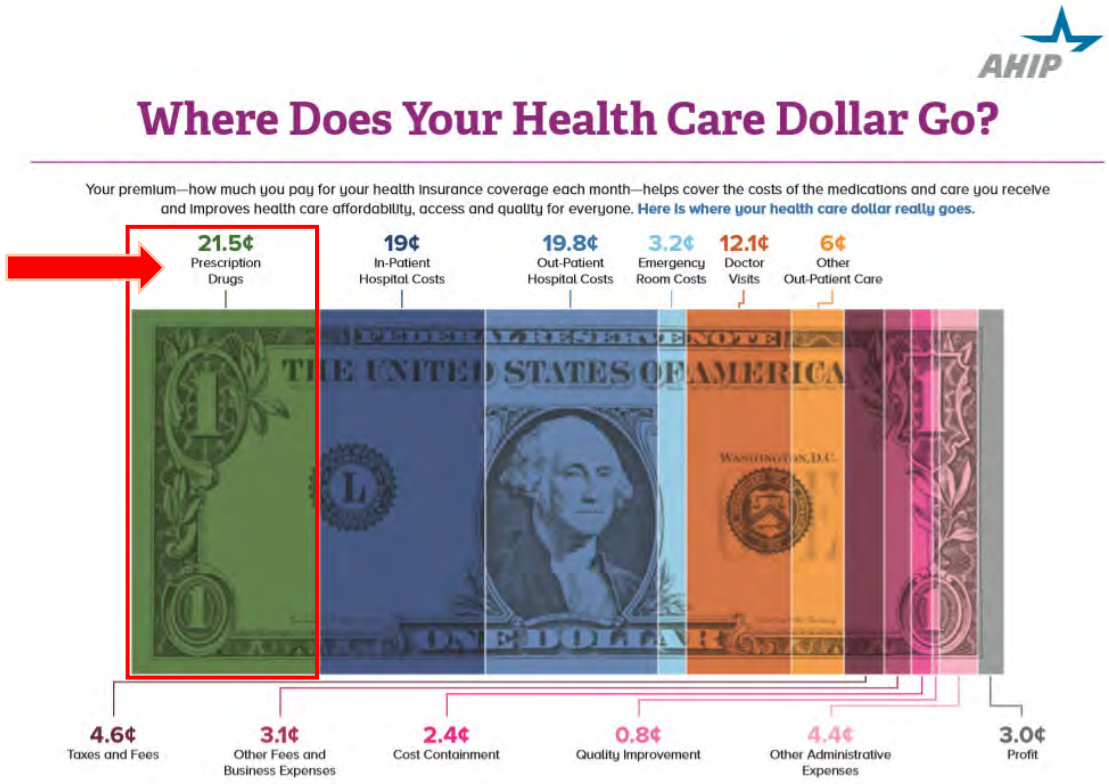
600 E. Lafayette Blvd.
Detroit, MI 48226-2998
bcbsm.com

Blue Cross Blue Shield Blue Care Network of Michigan

You will find more information on why these changes are crucial to lowering drug costs in the appendix. Thank you for considering these important changes.

Kristen Kraft
Director, State Government Affairs

Appendix – The Growing Cost of Prescription Drugs



*Prescription Drugs: Represents payments for outpatient prescription medications, mostly self-administered drugs, as well as payments for prescription medications administered in the physician's office or clinic. For both of these drug categories the prescription drug spending was calculated net any estimated prescription drug rebates paid by the drug company.

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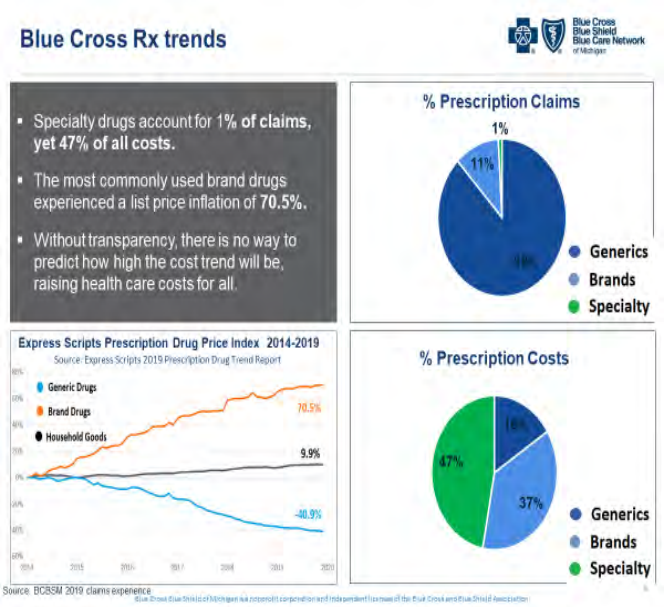

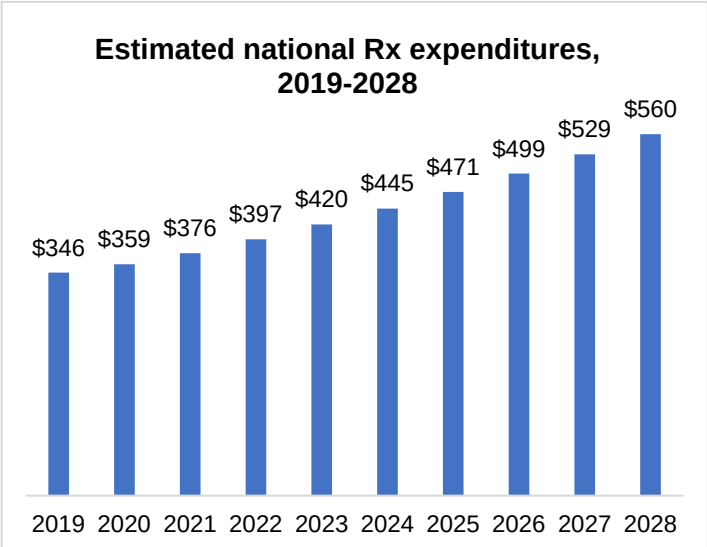

Appendix – additional information regarding policy suggestions

1) **Require Rx price and cost transparency**
State legislation to require the disclosure of prescription drug costs and price increases. Various bills have been considered by the legislature. House Bills 4154 or 5937 are good examples of potential legislation.

Why it is necessary:

- Without transparency, there is no ability to predict how drug prices are set, or how high the cost trend will be - raising health care costs for all.
- Transparency simply offers a window into the cost drivers associated with prescription drug pricing. It doesn't require a pharmaceutical company to disclose information that is proprietary or confidential in nature, nor does it aim to regulate prices, profits or advertising dollars spent.
- Until actual costs related to research and development, manufacturing and sales and marketing are known, honest and productive conversations about how to address ever-increasing prices cannot occur.
    - Drug costs can seemingly increase inexplicably overnight (example A).
- Transparency is a common-sense concept that levels the playing field, placing many of the regulatory reporting requirements health insurers and other industries must meet on drug pharmaceutical manufacturers.

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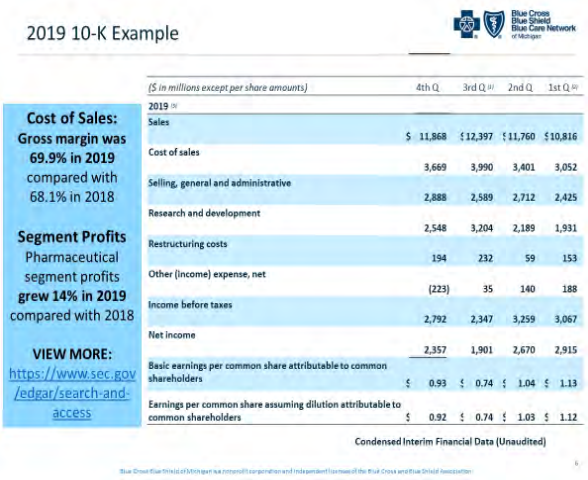
- Health insurers are statutorily required to report financials to state and federal regulators, including all health insurer costs and rate information. This information is publicly available.
- There is no oversight of pharmacy manufacturer profits (example B). The 10-k filings are not specific enough to determine what factors contribute to the cost.

(example A)



(example B)

2) Limit gifts from drug companies to prescribers

State legislation to place restrictions on how much a drug maker can give to a prescriber in the form of meals, conferences and consulting fees. Other states have adopted similar statutory guidelines. House Bill 5940 offers model language.

Why is it necessary:

If enacted, this concept would block pharmaceutical sales representatives from providing gift incentives for favorable prescribing trends, which can easily distort the market and increase costs. At least four states (Minnesota, Vermont, New Jersey, and Massachusetts) have adopted restrictions on what drug reps can give as gifts to prescribers. The level of limits and the complexity of the laws vary by state, but all place limits on what can be given to a prescriber to influence their prescribing habits. A recent study found gifts of any size had some effect and larger gifts elicited a larger impact on prescribing behaviours.

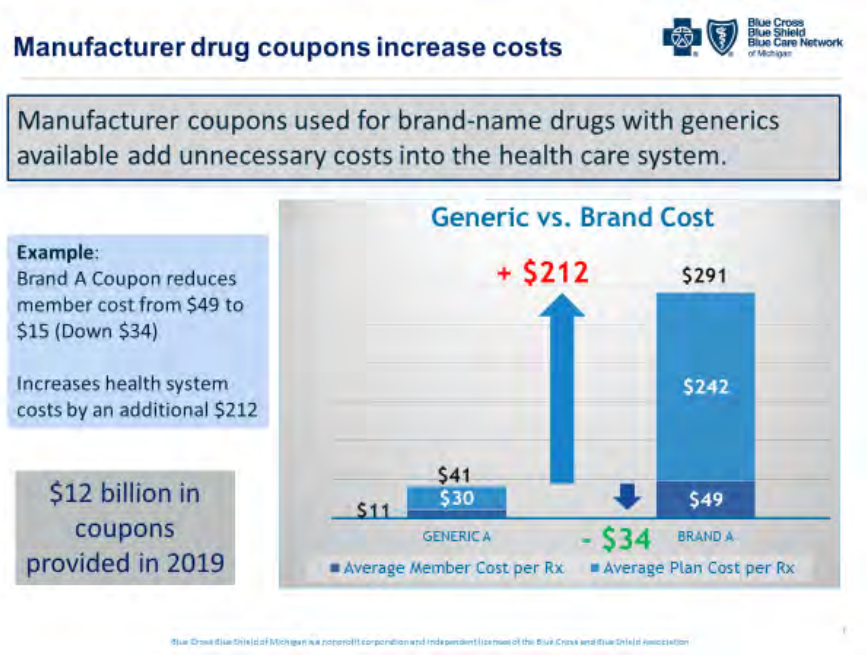
3) Limit coupons for drugs when a generic equivalent drug exists

If not adopted this year, HB 5943 offers model legislation that should be adopted. Manufacturer coupons are used to incent the purchase of brand-name drugs, even if generic drugs are available, adding unnecessary costs into the health care system. It is already illegal to use coupons while on Medicare, as coupons are considered a remuneration offered to consumers to induce the purchase of specific drugs.

600 E. Lafayette Blvd.
Detroit, MI 48226-2998
bcbsm.com

Why is it necessary:

- Drug coupons seem like a consumer-friendly approach, yet they drive up the overall cost of care (see example A). They disincentivize the use of lower cost drugs, driving consumers to often significantly higher priced options.
- Coupons are only available for individuals with private health insurance – it is actually illegal to provide a coupon to individuals on Medicare– and are not available for uninsured individuals.
- We think it is a common sense and fair approach to prohibit coupon use when a less expensive generic option is available. These less expensive options not only save an individual out-of-pocket costs, they also save costs for employers and the entire health care system.



(example A)

4) **License drug company sales representatives**

Laws in Colorado and the City of Chicago serve as models for legislative action to license drug company sales representatives. These laws help ensure pharmaceutical sale representatives have the proper training and oversight to ensure fair, accurate information is provided to prescribers.

Licensure would include annual professional continuing education as well as training in ethical standards, whistleblower protections, and laws and regulations applicable to pharmaceutical marketing.

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Why is it necessary:
Pharmaceutical companies use strategies marketing brand name drugs over generics. Brand name drugs significantly increase drug prices and the cost of health care.

Licensing also verifies adequate training and professional ethical standards to ensure health professionals are provided the best information when being "sold" on a drug by a sales rep. As health care professionals are subject to medical licensure, a sales force focused on influencing health care professionals' prescribing decisions should be subject to licensure.

5) Allow pharmacists to provide cost information to consumers

State legislation that aligns with federal law on what information can be given to consumers to help them find the best price for their medications. Under federal law, pharmacists are allowed to provide cost information; however, adopting similar provisions in state law strengthens consumer protections and provides an additional avenue for enforcement by state regulatory authorities. The state legislature currently has a few examples under consideration, including HB 5938, HB 5941 and HB 5942.

Why is it necessary:

This increased transparency measure could help consumers save costs. Existing gag clauses restrict what pharmacists can tell customers about what they could pay for a prescription. This hides the full price of the drug cost if paid out-of-pocket rather than using their insurance.

Blue Cross Blue Shield of Michigan

Governor's Prescription Drug Task Force
November 20, 2020

Kristen Kraft, Director State Government Relations
Tim Antonelli, Pharmacy Services

A60

About Blue Cross Blue Shield of Michigan

- A **nonprofit mutual insurance** company founded in 1939
- The largest nonprofit mutual health insurer in Michigan, serving more than **6 million people nationwide**
- Headquartered in Detroit, with more than 8,100 Michigan employees across the state
- Provided more than **$90 million in 2019** to improve health across Michigan
- Maintained **average operating margin of less than 1 percent for more than 10 years**

Nearly 100 million health care claims processed, with an average claims expense of $72 million per day

28.7 million prescriptions processed, totaling over $3.7 billion

Partnership with Civica Rx, a nonprofit generic drug manufacturer with a mission to ensure that essential generic medications are accessible and affordable CIVICA™

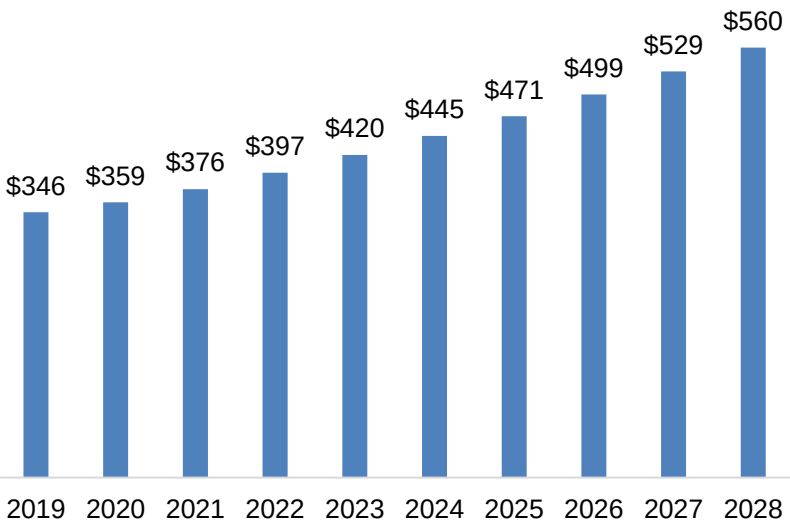
A61

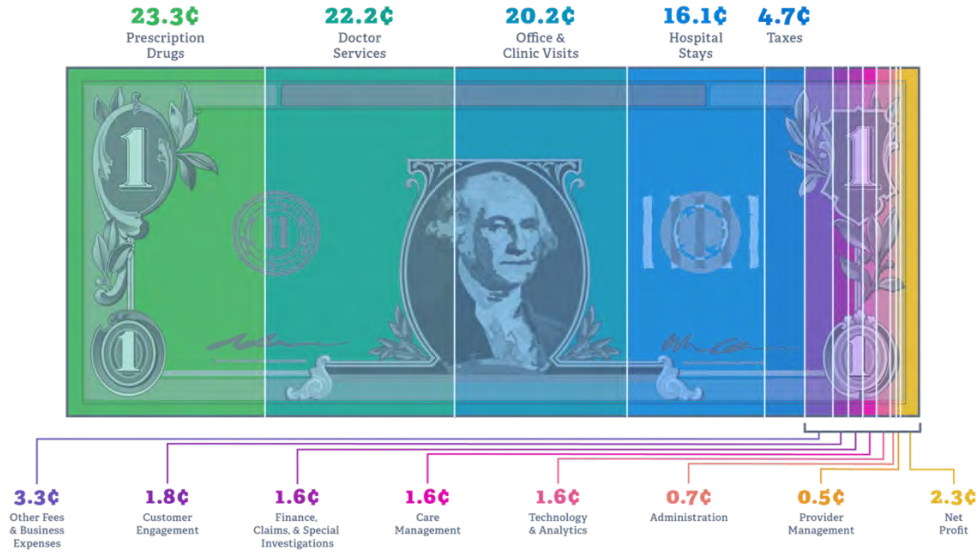
Payer perspective

- Prescription drug costs are the fastest growing consumer health expense and will continue that path without action
- Rx costs even exceed the cost of hospital stays
- Branded and specialty drugs, which will include an influx of new and expensive and innovative drugs into the market, will drive up this trend

Our **top priority** is making prescription drugs available when our members need them.

Estimated national Rx expenditures, 2019-2028





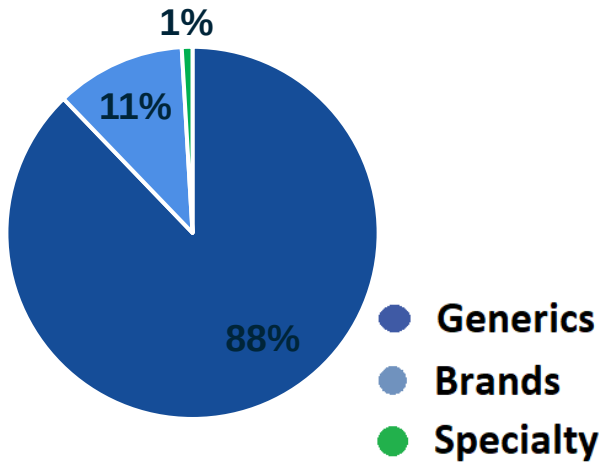
A62

Source: CMS Office of the Actuary, "Projections of National Health Expenditures – 2020; AHIP, "Where Does Your Health Care Dollar Go?"

Payer perspective

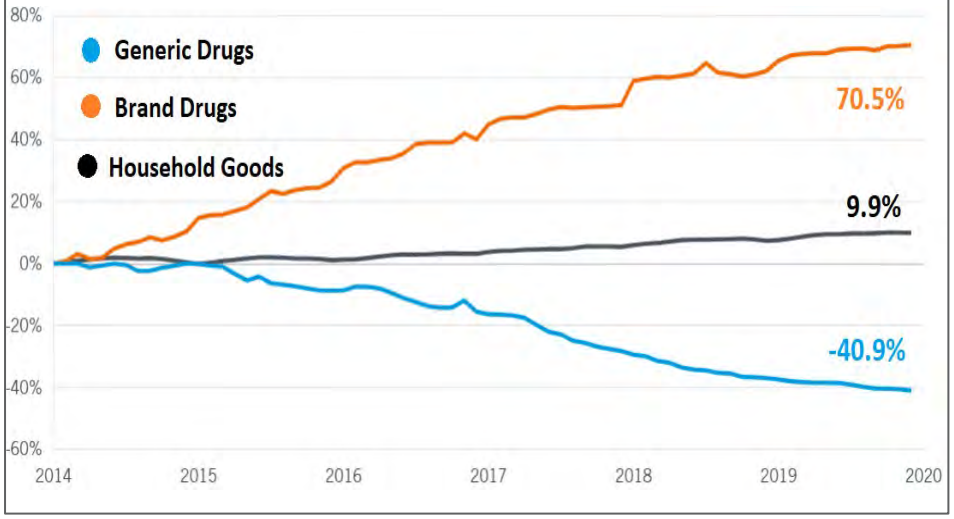
- Specialty drugs account for 1**% of claims, yet 47% of all costs.**
- The most commonly used brand drugs experienced a list price inflation of **70.5%.**
- Without transparency, there is no way to predict how high the cost trend will be, raising health care costs for all.

% Prescription Claims

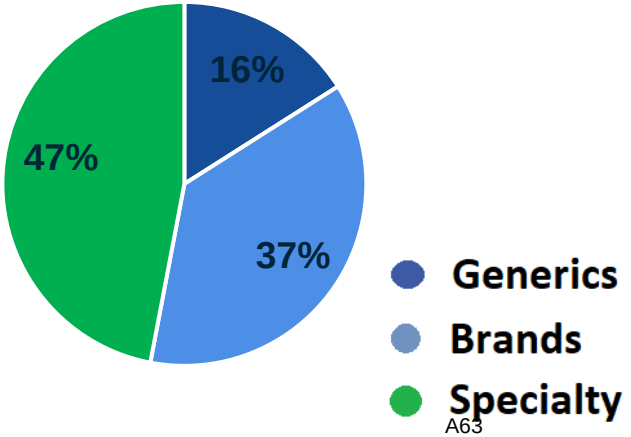


Express Scripts Prescription Drug Price Index 2014-2019

Source: Express Scripts 2019 Prescription Drug Trend Report



% Prescription Costs



A63

Source: BCBSM 2019 claims experience

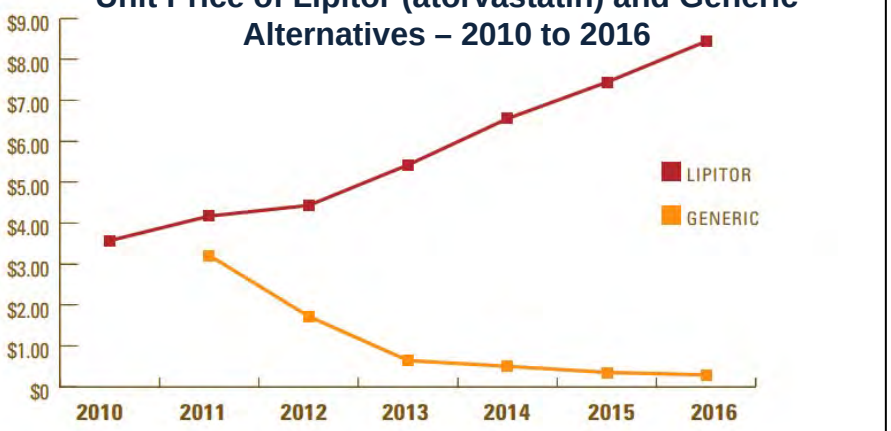
Generics and Biosimilars

Generics

- Create competition
- Result in cost savings
- Example: Lipitor generics resulted unit cost to decrease below **$1** from **>$4**

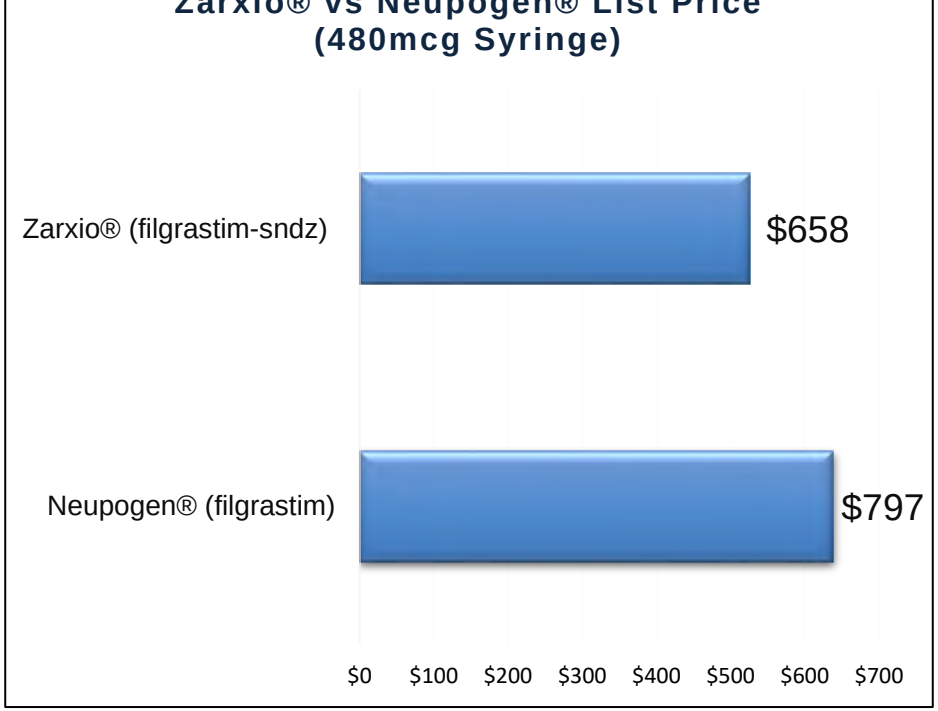
Biosimilars

- Create competition
- Result in cost savings
- Example: First biosimilar approved and marketed in the US is **17.4%** below innovator price



Market Share of Generic Alternatives by Year and Number of Manufacturers of Generics[6]

	2010	2011	2012	2013	2014	2015	2016
GENERIC SHARE	0.0%	8.0%	88.4%	96.3%	98.0%	98.8%	99.3%
MANUFACTURERS		2	11	14	16	16	15
SPENDING YEAR OVER YEAR	–	12%	–32%	–49%	–8%	–18%	–15%



Source: BCBSA Health of America: Rising costs for patented drugs drive growth of pharmaceutical spending in the U.S. Available online @ www.bcbs.com

A64

Manufacturer strategies to prevent competition

Blue Cross Blue Shield Blue Care Network of Michigan

Analysis of the twelve best selling drugs in the US in 2017 revealed the following:

- Averaged **71** patents issued
- Averaged **15** years on the market
- Average list prices increased **68%** since 2012

Source: I-MAK Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices. Available online @ www.i-mak.org

Top 12 grossing drugs of 2017

	AVG/DRUG	TOTAL	RANGE
NUMBER OF PATENT APPLICATIONS	125	1498	48–247
PATENTS ISSUED	71	848	27–132
PRICE CHANGE SINCE 2012	+68%	N/A	-58%–163%
YEARS BLOCKING COMPETITION	38	456	31–48
YEARS ON THE U.S. MARKET	15	176	6–21

HUMIRA

CONDITION(S) TREATED	Arthritis
NUMBER OF PATENT APPLICATIONS	247
NUMBER OF PATENTS ISSUED	132
PRICE CHANGE SINCE 2012	+144%
YEARS BLOCKING COMPETITION	39
ON THE U.S. MARKET SINCE	2002

ENBREL

CONDITION(S) TREATED	Arthritis
NUMBER OF PATENT APPLICATIONS	57
NUMBER OF PATENTS ISSUED	41
PRICE CHANGE SINCE 2012	+155%
YEARS BLOCKING COMPETITION	39
ON THE U.S. MARKET SINCE	1998

REVLIMID

CONDITION(S) TREATED	Multiple Myeloma
NUMBER OF PATENT APPLICATIONS	106
NUMBER OF PATENTS ISSUED	96
PRICE CHANGE SINCE 2012	+79%
YEARS BLOCKING COMPETITION	40
ON THE U.S. MARKET SINCE	2005

XARELTO

CONDITION(S) TREATED	Blood Clots
NUMBER OF PATENT APPLICATIONS	49
NUMBER OF PATENTS ISSUED	30
PRICE CHANGE SINCE 2012	+87%
YEARS BLOCKING COMPETITION	31
ON THE U.S. MARKET SINCE	2011

A65

Manufacturer strategies to prevent competition

Blue Cross Blue Shield Blue Care Network of Michigan

Sovereign Immunity

- Allergen transferred patents for Restasis to the St. Regis Mohawk Tribe in 2017
- St. Regis Mohawk Tribe exclusively licensed the rights back to Allergan
- Intent was to invoke sovereign immunity to dismiss patent challenges filed by generic makers
- U.S. Supreme Court denied Allergan petition and upheld lower court ruling

Pay for Delay

- Settlements between brand and generic drug makers to delay generic competition
- Supreme Court affirmed that settlements where brand manufacturers pay generics to settle patent litigation and delay entering the market could have "significant anticompetitive effects" and violate the antitrust laws
  (Actavis vs FTC 2013)

REMS*

- Intended to help ensure that new drug benefits outweigh their risks
- Brand manufacturers have used REMS to block potential generic applicants from accessing product samples needed to create a generic or biosimilar
- FDA published a list of manufacturers
- CREATES Act established a process for obtaining samples

Citizen Petitions**

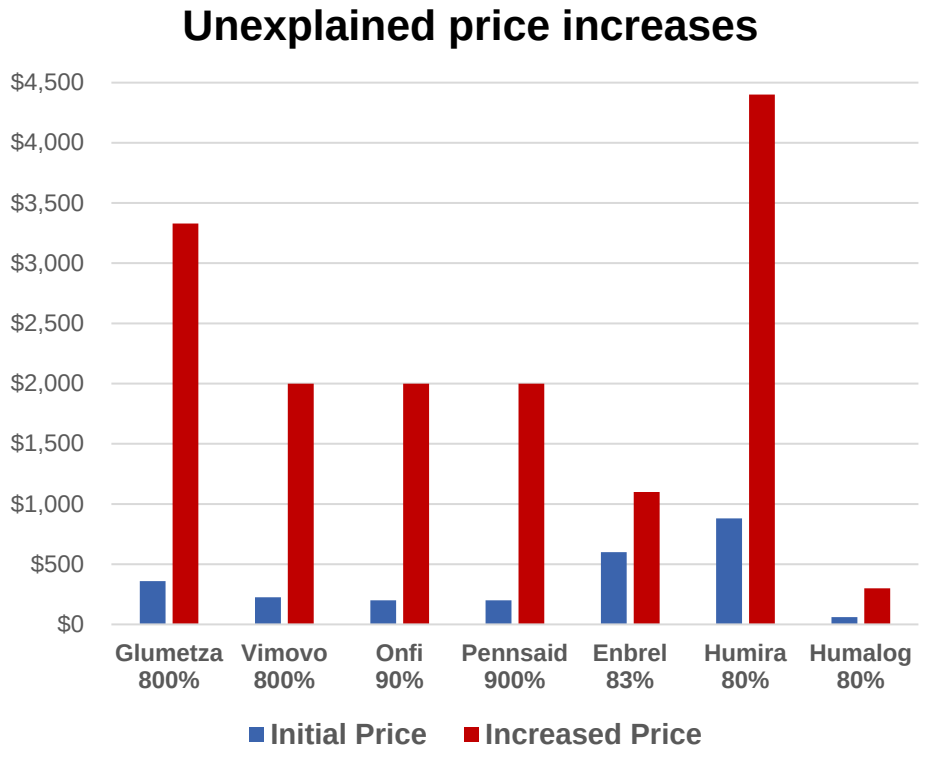
- Intended to allow citizens to raise concerns on FDA policy
- Brand manufacturers have used to raise frivolous/questionable claims to prevent competition
- Roughly 40% filed a year or less before generic approval
- FDA denies the requested action for approximately 80% of petitions filed by drug companies

* Risk Evaluation and Mitigation Strategy (REMS)

** Feldman R, A Citizen's Pathway Gone Astray — Delaying Competition from Generic Drugs, N Engl J Med. 2017 Apr 20;376(16):1499-1501. doi: 10.1056/NEJMp1700202. Epub 2017 Mar 1

A66

Prescription drug pricing is unpredictable



AG Nessel joins coalition filing third complaint into antitrust, price-fixing investigation of generic drug industry, WLUC, 6/10/2020

No end in sight to rising drug prices, study finds, NBC News, 5/31/19

Drug prices in 2019 are surging, with hikes at 5 times inflation
CBS News July 1, 2019

Drug price hikes are back for 2020, Axios, January 6, 2020

FDA approves a generic version of the drug Martin Shkreli monopolized

Damian Garde

February 28, 2020

The Food and Drug Administration on Friday approved a generic version of Daraprim, the anti-infective treatment made famous when Martin Shkreli's company raised its price by more than 5,000%.

The approval means Shkreli's company, now called Phoenixus, will no longer have a monopoly on Daraprim, which lost patent protection years ago. Cerovene, a U.S. generics company, will market an identical product. *Source: STAT News*

A67

High-cost drug examples

Blue Cross Blue Shield Blue Care Network of Michigan

Drug	Cost per patient per Year*
Zolgensma™	$2,100,000
Luxturna ™	$850,000
Exondys 51™	$800,000[1]
Ravicti®	$790,000
Spinraza®	$750,000[2]
Brineura ™	$702,000
Soliris®	$540,000
Hemlibra®	$500,000
Kymriah®, Yescarta®, Tecartus ™ (CAR-T)	$373,000 – $475,000[3]
Vitrakvi®	$393,000
Cuprimine®	$380,000
Kalydeco®	$307,000

*Annual cost estimates are based on wholesale acquisition cost (WAC), average dosing and rounded; Zolgensma™, Luxturna™ and CAR-T are given as one-time treatments

1. Based on average weight; costs could exceed $1 million per patient per year
2. For first year, then $375,000 annually
3. Yescarta, Kymriah and Tecartus drug costs; Total medical costs could exceed $1 million

A68

High-cost drug examples

Blue Cross Blue Shield Blue Care Network of Michigan

New Cancer Medications Approved in First Half 2020

(Average cost per year of treatment is $246,000)

Drug Name	Manufacturer	Approval Date	Route	Estimated Monthly Cost	Estimated Annual Treatment Cost
Ayvakit (Apalutamide)	Blueprint Medicines	January 2020	Oral	$32,000	$384,000
Tazverik (Tazemetostat)	Epizyme	January 2020	Oral	$15,499	$185,990
Sarclisa (Isatuximab)	Sanofi	March 2020	Intravenous	$20,800	$249,600
Tukysa (Tucatinib)	Seattle Genetics	April 2020	Oral	$18,500	$222,000
Pemazyre (Pemigatinib)	Incyte Corporation	April 2020	Oral	$17,000	$204,000
Trodelvy (Sacituzumab Govitecan)	Immunomedics	April 2020	Intravenous	$16,096	$193,152
Tabrecta (Capmatinib)	Novartis	May 2020	Oral	$19,232	$230,784
Retevmo (Selpercatinib)	Lilly	May 2020	Oral	$20,600	$247,200
Qinlock (Ripretinib)	Diciphera Pharmaceuticals	May 2020	Oral	$32,000	$384,000
Zepzelca (Lurbinectedin)	Jazz Pharmaceuticals	June 2020	Intravenous	$13,266	$159,192

Consumer protections that improve care, address costs

Blue Cross Blue Shield Blue Care Network of Michigan

Prescription Drug Benefits

- Coverage of prescription medications
- Access to a nationwide network of pharmacies
- Preventive medications at $0 cost
- Real-time drug pricing information
- Drug formulary listing all drugs covered
- Prior authorization and step therapy

Member Protections

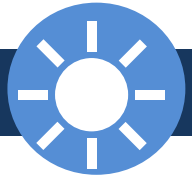
- Medical loss ratio
- Out-of-pocket maximums
- Drug safety programs

Regulatory Compliance

- Network adequacy
- Drug formulary coverage standards
- Utilization management standards
- Rate approvals

Pharmacy Benefit Manager Contracting

- Lower drug costs
- Increase access to drugs
- Claims processing
- Broad pharmacy networks
- Negotiate prescription drug rebates
- Improved medication adherence



Transparency

- Real-time electronic tools with cost, benefit design
- Highly regulated at the state and federal level

A70

Questions?

Kristen Kraft, Director State Government Relations
Tim Antonelli, Pharmacy Services

A71


mahp
Michigan Association
of Health Plans

MAHP: Who We Are

- The Michigan Association of Health Plans is a nonprofit corporation established to promote the interests of member health plans.

- MAHP's mission is "to provide leadership for the promotion and advocacy of high quality, accessible health care for the citizens of Michigan."

- Represents 10 health plans and their subsidiary licensed health plans, covering all of Michigan and more than 45 related business and affiliated organizations. Our member health plans employ about 8,000 persons throughout the state.

- Member health plans provide coverage for more than 3 million Michigan citizens – nearly one in every three Michiganders.

- Member health plans collect and use health care data, support the use of "evidence based medicine", and facilitate disease management and care coordination in order to provide cost-effective care.

mahp
Michigan Association of Health Plans

MAHP VISIONS

- *MAHP members expand coverage access for Consumers. Michigan will provide should be a national leader in providing health insurance coverage options to the State's population.*

- *Michigan's health insurance industry improves value, affordability, choice and competition. By fostering competition, Michigan will become one of the top 25 competitive states for health insurance.*

- *MAHP members will advocate for the improved health status of Michigan consumers. MAHP members will work with partners in government, the provider community, community organizations, and business leaders to improve the health status of Michigan residents in areas that MAHP members serve through meaningful transparency and a focus on integrating benefits.*

What Health Plans Do

Utilization Management:

- Techniques that provide safeguards against inappropriate care
- Prior authorization
- Claims review to identify inappropriate care

Disease & Case Management:

- Early identification of high-risk patients for early intervention
- Focus attention on individuals based on indicators (use of analytics)

Network Design:

- Carefully pooling providers who provide excellent care at lower costs
- Tiered networks

Benefit Design:

- Cost sharing through copays and deductibles
- Saving/spending accounts (HSAs, FSAs)
- As requested by the market

mahp
Michigan Association of Health Plans

Prescription Drug Task Force 2020

1. Analyze the **scope and cause** of the problem **of high-cost prescription drugs** in Michigan and the impact of this problem on this state's residents, communities, and businesses.

2. Analyze the way prescription **drug prices are set** in Michigan **and identify strategies for increasing the transparency** of that process.

3. Recommend legislative and administrative actions that can be taken, and policy-related changes that can be implemented by governmental and non-governmental agencies, relevant to **lowering prescription drug prices for consumers** in Michigan.

4. Recommend legislative and administrative actions that can be taken, and policy-related changes that can be implemented by governmental and non-governmental agencies, relevant to **increasing transparency in the pricing of prescription drugs** in Michigan.

mahp
Michigan Association of Health Plans

Scope and Cause of High-Cost Prescription Drugs

Market-based system where the **Manufacturer sets the list price**, arguably at a price point "the market can bear."

Prescription drugs are then discounted throughout the supply chain. Wholesaler, PBM, PSAO, Pharmacy, all take a margin.

List price matters to those who pay full price, a percentage of the list price, or pay insurance premiums:

- Uninsured consumers who have to pay full price.
- Insured consumers who haven't met their annual deducible.
- Insured consumers who have co-insurance and other out-of-pocket expenses as part of plan design.
- Employers who provide insurance coverage for their employees (Full and Self Insured).
- Individuals who purchase their own insurance coverage (Individual Market).
- State and Federal Governments who purchase insurance for citizens based on income, age, or disability.

mahp Michigan Association of Health Plans

Where Does Your Health Care Dollar Go?

Your premium—how much you pay for your health insurance coverage each month—helps cover the costs of the medications and care you receive and improves health care affordability, access and quality for everyone. **Here is where your health care dollar really goes.**

This data represents how commercial health plans spend your premiums. This data includes employer-provided coverage as well as coverage you purchase on your own. Data reflects averages for the 2016-18 benefit years. Percentages do not add up to 100% due to rounding.

/ahip @ahipcoverage @ahipcoverage AHIP | www.ahip.org

Prescription Drug Spending Growth Slower but Continues to Rise

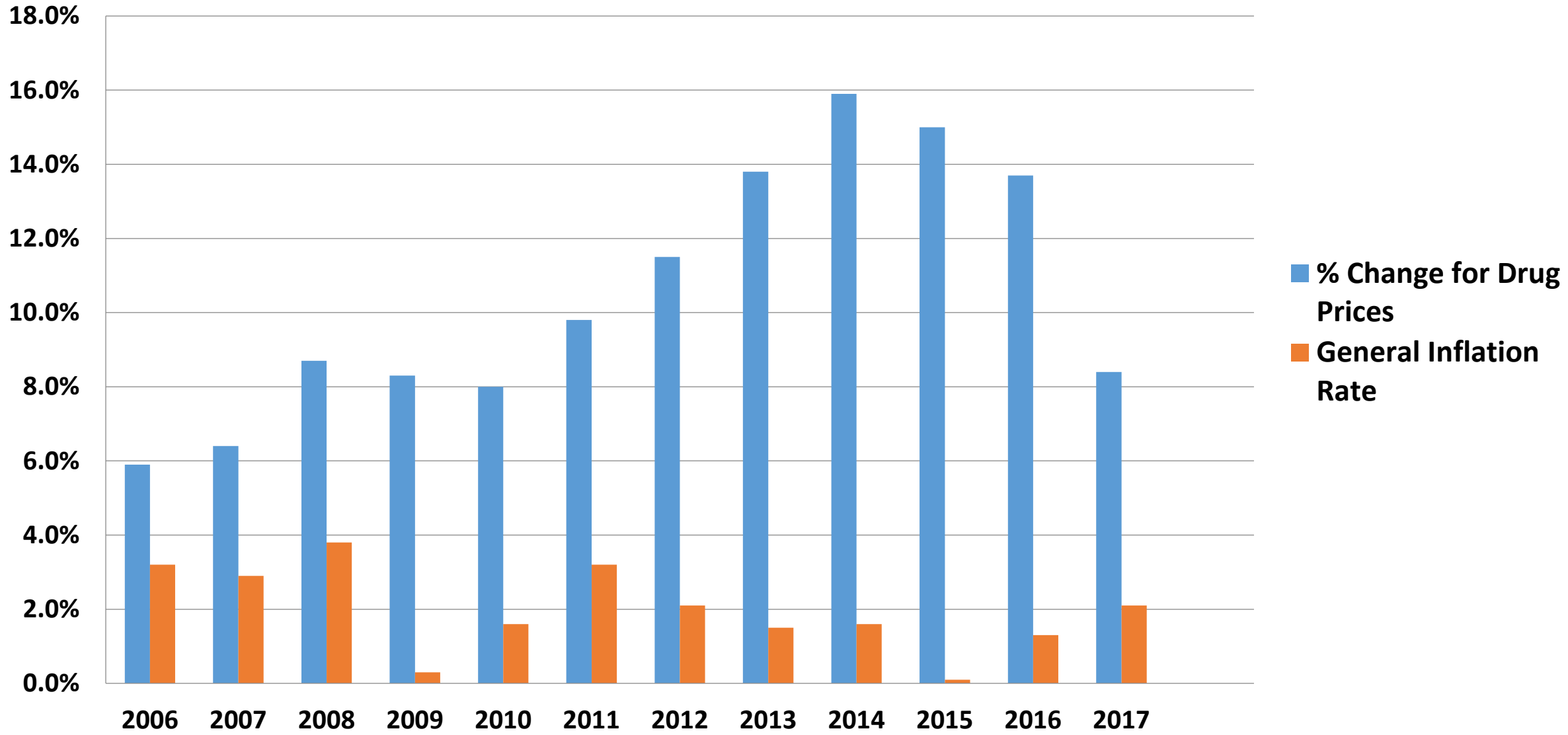
- **U.S. prescription net drugs spending rose to $509 billion in 2109. It has increased at a Cost Adjusted Growth Rate (CAGR) of 4.1% over the past five years. This net spending is calculated after supply chain discounts, manufacturer rebates, patient out-of-pocket costs are deducted, and markups and margins by intermediaries are added.**

- **Total manufacturer net sales in 2019 were $356 billion and increased at a 4.6% CAGR over the past five years. Manufacturer net sales is calculated after deducting negotiated rebates, discounts, coupons, vouchers, and other price concessions.**

- **Manufacturer net sales have increased by $56 billion over the past five years. $68 billion of growth from new branded medicines, and $40 billion of growth from increased use of existing brands. Offset by $70 billion reduction in sales from loss of patent protection.**

source: IQVIA Institute August 2020: Medicine Spending and Affordability in the United States

Change in Drug Costs Compared to Inflation



Source: http://www.aarp.org/rxpricewatch Dec. 2017

MEDICAID DRUGS

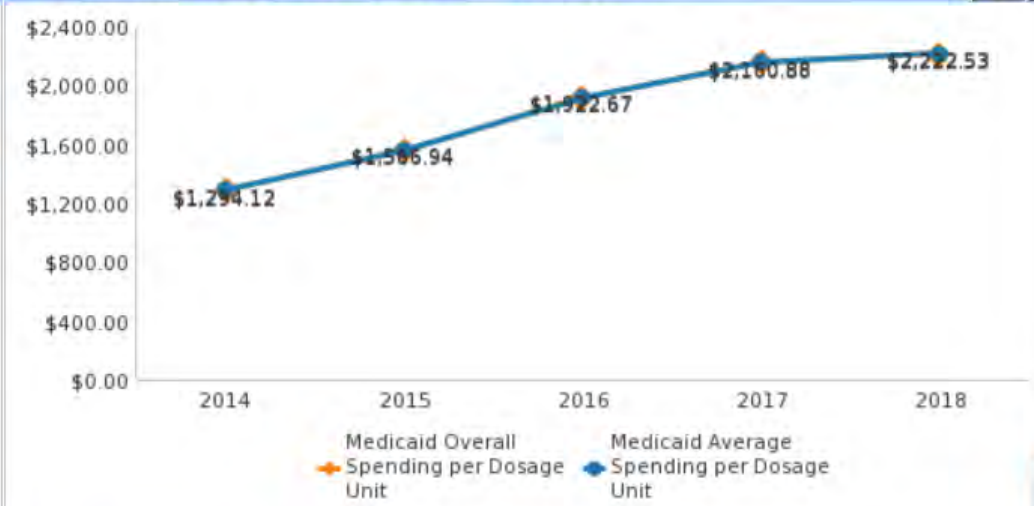
Medicaid Drugs | Information

Brand Name	Generic Name	Number of Manufacturers	Average Spending per Dosage Unit 2017	Average Spending per Dosage Unit 2018	Change in Average Spending per Dosage Unit (2017 - 2018)	Annual Growth Rate in Average Spending per Dosage Unit (2014 - 2018)	Total Spending 2018
Humira Pen	Adalimumab	1	$2,160.88	$2,222.53	2.9%	14.5%	$1,386,718,665
Latuda	Lurasidone HCl	1	$37.30	$40.59	8.8%	13.9%	$1,244,564,745
Mavyret	Glecaprevir/Pibrentasvir	1	$231.04	$239.60	3.7%	3.7%	$1,021,288,242
Vyvanse	Lisdexamfetamine Dimesylate	1	$8.88	$9.46	6.5%	8.8%	$1,015,172,563
Genvoya^	Elviteg/Cob/Emtri/Tenof Alafen	1	$90.55	$86.63	-4.3%	-0.3%	$911,876,985
Invega Sustenna	Paliperidone Palmitate	1	$1,522.21	$1,577.04	3.6%	6.6%	$869,025,167
Suboxone	Buprenorphine HCl/Naloxone HCl	1	$7.88	$7.85	-0.3%	2.1%	$788,866,456
Lyrica	Pregabalin	1	$6.54	$7.07	8.1%	12.9%	$767,025,790
Triumeq^	Abacavir/Dolutegravir/Lamivudi	1	$85.19	$83.32	-2.2%	1.3%	$602,684,956
Flovent HFA	Fluticasone Propionate	1	$19.11	$18.71	-2.1%	4.6%	$584,499,258
Basaglar Kwikpen U-100^	Insulin Glargine,Hum.Rec.Anlog	1	$21.23	$19.98	-5.9%	-3.3%	$580,571,872
Methylphenidate ER	Methylphenidate HCl	10	$6.74	$6.31	-6.4%	6.1%	$561,394,786
Symbicort	Budesonide/Formoterol Fumarate	1	$29.29	$28.50	-2.7%	3.9%	$558,766,605

Manufacturer Information - Humira Pen

Manufacturer Name	Average Spending per Dosage Unit 2017	Average Spending per Dosage Unit 2018	Change in Average Spending per Dosage Unit (2017 - 2018)	Annual Growth Rate in Average Spending per Dosage Unit (2014 - 2018)	Total Spending 2018
Abbvie US LLC	$2,160.88	$2,222.53	2.9%	14.5%	$1,386,718,665

Manufacturer Trend in Spending Per Unit - Abbvie US LLC



*Average spending per dosage unit reflects multiple routes of administration of the drug (e.g., intravenous, subcutaneous) which individually may have different unit pricing. Additional information regarding calculation of spending per unit can be found in the methodology document.

^Drug identified as outlier; use measures based on Average Spending per Dosage Unit with caution. See methodology document for additional details.

CMS

Produced by the CMS/Office of Enterprise Data & Analytics (OEDA), November 2018

MEDICAID DRUG SPENDING DASHBOARD 2015

S - Drug selected due to high total program spending.
F - Drug selected due to high annual spending per presc
U - Drug selected due to large increase in average cost p

	Brand Name	G
S	Abilify	A
S	Adderall XR	D
S	Advair Diskus	F
F	Advate	A
U	Anucort-HC	H
S	Aripiprazole	A
U	Ativan	L
S	Atripla	E
F	Avastin	E
U	Carbamazepine	C
U	Clindamycin Phos-Benzoyl Perox	C
U	Clobetasol Propionate	C
F	Complera	E
F	Copaxone	C
U	Daraprim	P
U	Demerol	M
U	Econazole Nitrate	E
S	Enbrel	E
U	Epitol	C
F	Epzicom	A
U	Fentanyl Citrate	F
S	Flovent HFA	F
F	Gleevec	I
U	Glumetza	M
U	Granisetron HCl	C
F	H.P. Acthar	C

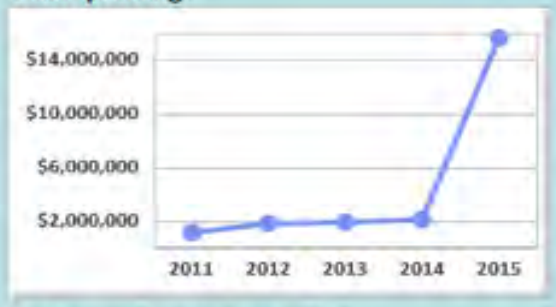
*This measure accounts for unit cost changes for different strengt

DRUG DETAILS

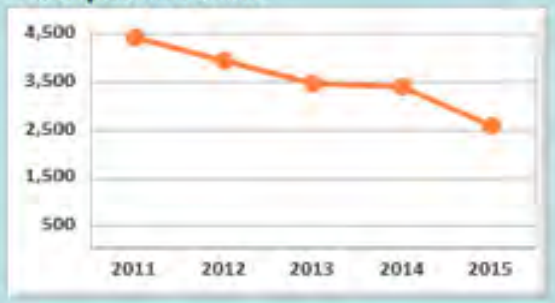
Daraprim

Percent Change from 2014 - 2015	Total Spending	Prescription Fill Count	Avg Spending Per Prescription Fill	Avg Cost Per Unit (Weighted)*
	607%	-24%	831%	874%

Total Spending



Prescription Fill Count



Average Cost Per Unit (Weighted)*

Additional Measures for 2015

Total Spending	$15,704,936.08

Prescription Fill Count	2,585
Total Spending Per Prescription Fill	$6,075.41

Unit Count	118,175
Avg Cost Per Unit (Weighted)*	$132.90

Drug Description

Brand Name	Daraprim
Generic Name	Pyrimethamine
Uses	This medication is used with other medication (such as a sulfonamide) to treat a serious parasite infection (toxoplasmosis) of the body, brain, or eye or to prevent toxoplasmosis infection in people with HIV infection. Rarely, pyrimethamine is used with sulfadoxine to treat malaria. The CDC no longer recommends using pyrimethamine alone to prevent or treat malaria. Pyrimethamine belongs to a class of drugs known as antiparasitics. It works by killing parasites. NOTE: This is a summary and does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.
Manufacturer	Amedra/Turing P

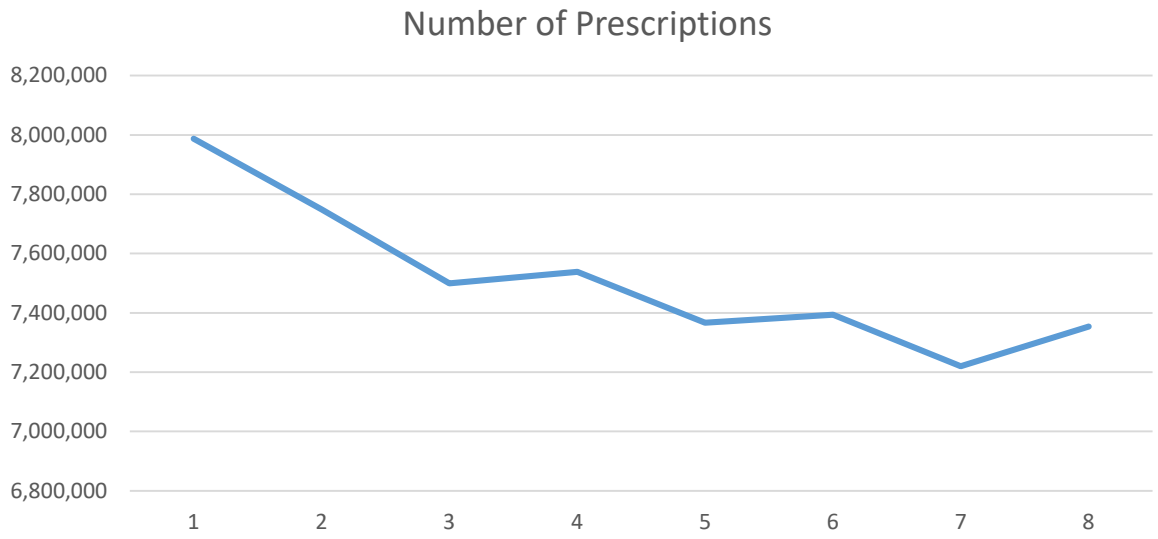
Evidence-based Practice Center (EPC) Reports (see main page for a full list of EPC reports with website links)

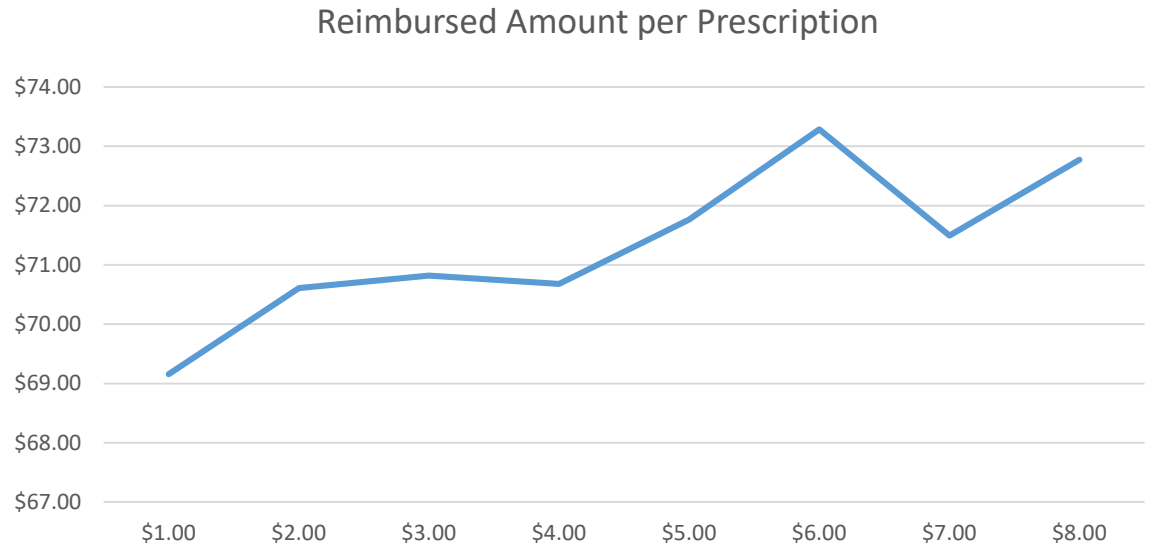
n/a

*This measure accounts for unit cost changes for different strengths and dosage forms of a drug and presents a weighted average.

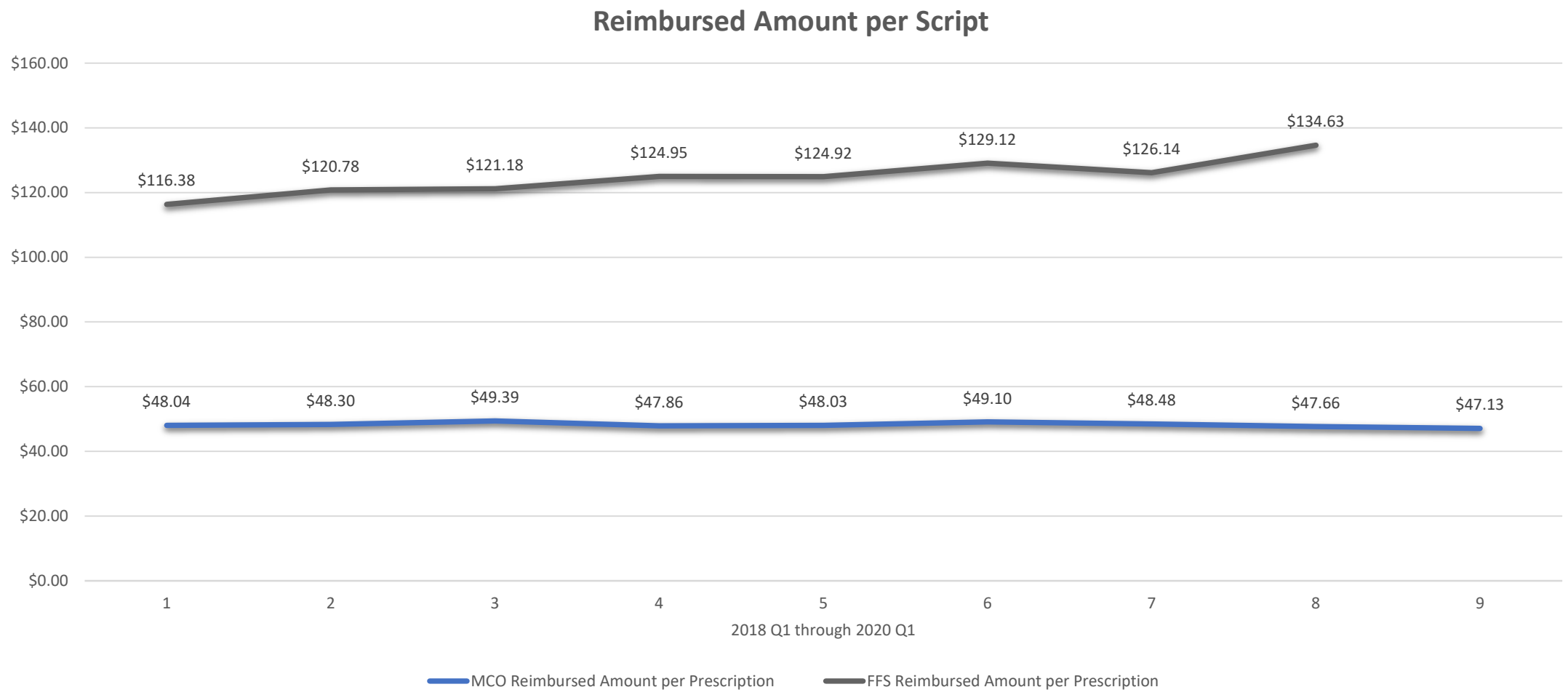
CMS Drug Utilization Data - Michigan

Year	Quarter	Number of Prescriptions	Medicaid Amount Reimbursed	Reimbursed Amount per Prescription
2018	1	7,987,517	$552,401,096	$69.16
2018	2	7,748,523	$547,106,301	$70.61
2018	3	7,499,419	$531,119,642	$70.82
2018	4	7,538,758	$532,821,909	$70.68
2019	1	7,366,819	$528,678,679	$71.76
2019	2	7,393,294	$541,816,054	$73.28
2019	3	7,220,291	$516,206,321	$71.49
2019	4	7,354,277	$535,182,197	$72.77
2020	1	5,290,306	$249,335,914	$47.13
2020	2	5,793,869	$510,130,180	$88.05
Note: 2020 Q1 appears to be missing all FFS claims. Q2 appears incomplete				





CMS Drug Utilization Data - Michigan



2019 EQI Data Project

- The Encounter (data) Quality Improvement (EQI) project is key to supporting MAHP's efforts to develop documentation to assist in shaping the Medicaid rate discussion and results for the coming fiscal year.
- EQI data using the new Milliman Template was collected from all eleven companies and represents 100% of MCOs as of September 2018.
- Data was collected through a data request and receipt of EQI templates submitted by plans to the state :
  - Monthly data was collected from Oct. 2013-Dec. 2016, paid through Feb. 2017
  - October 2016 to January 2018, paid through Jan. 2018
  - February 2017 to May 2018, paid through July 2018
  - January 2019 Files: June 2017 to September 2018, paid through November 2018
  - We reviewed enrollment and paid claims for reasonability compared to financials (EXHIBIT OF PREMIUMS, ENROLLMENT AND UTILIZATION from snl.com)
- The data periods have been adjusted for completion in the analysis.
- Completion factors have been revised with 1/2019 data.

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EQI Data:TANF Historical Trend Comparison

Total Med/Rx Trend	Service Category Weight*	Milliman FY2019 Rate Development			EQI Data Annual Changes		
		Trend	Management Savings	Combined (Trend/Savings)	FY2017/ FY2016	FY2018/ FY2017	FY2018/ FY2016
Inpatient Hospital	21%	1.5%	-0.7%	0.8%	6.7%	0.3%	3.5%
Outpatient Hospital	26%	1.5%	-0.2%	1.3%	5.1%	12.8%	8.9%
Physician	34%	2.0%	0.0%	2.0%	-0.3%	-9.4%	-4.9%
Other Ancillary	3%	2.0%	0.0%	1.9%	10.5%	-4.6%	2.7%
Total (Excl. Rx)	84%	**1.7%**	**-0.2%**	**1.5%**	**3.2%**	**-0.7%**	**1.2%**
Pharmacy	16%	7.1%	-0.7%	6.4%	-1.7%	5.1%	1.7%
Total (Incl. Rx, LTSS)	100%	**2.6%**	**-0.2%**	**2.4%**	**2.3%**	**0.2%**	**1.2%**

*Service category weight based on FY2018 EQI PMPMs.

EQI Data: Duals Historical Trend Comparison

Total Med/Rx Trend	Service Category Weight*	Milliman FY2019 Rate Development			EQI Data Annual Changes		
		Trend	Management Savings	Combined (Trend/Savings)	FY2017/ FY2016	FY2018/ FY2017	FY2018/ FY2016
Inpatient Hospital	15%	4.0%	-1.4%	2.6%	26.2%	-47.2%	-18.3%
Outpatient Hospital	16%	4.0%	0.0%	4.0%	9.8%	-35.0%	-15.5%
Physician	27%	3.0%	0.3%	3.2%	24.1%	-29.6%	-6.6%
Other Ancillary	29%	4.0%	0.0%	4.0%	11.9%	0.0%	5.8%
Total (Excl. Rx)	86%	**3.7%**	**-0.2%**	**3.4%**	**18.3%**	**-27.8%**	**-7.6%**
Pharmacy	11%	8.2%	-0.1%	8.0%	87.3%	-60.0%	-13.4%
Total (Incl. Rx, LTSS)	100%	**4.3%**	**-0.2%**	**4.1%**	**27.3%**	**-33.9%**	**-8.2%**

*Service category weight based on FY2018 EQI PMPMs.

EQI Data: Disabled Historical Trend Comparison

Total Med/Rx Trend	Service Category Weight*	Milliman FY2019 Rate Development			EQI Data Annual Changes		
		Trend	Management Savings	Combined (Trend/Savings)	FY2017/ FY2016	FY2018/ FY2017	FY2018/ FY2016
Inpatient Hospital	30%	2.5%	-1.2%	1.2%	4.1%	7.5%	5.8%
Outpatient Hospital	18%	3.0%	-0.1%	3.0%	8.0%	6.8%	7.4%
Physician	18%	2.0%	0.1%	2.1%	1.0%	-4.7%	-1.9%
Other Ancillary	6%	3.0%	0.0%	2.9%	17.9%	-8.0%	4.1%
Total (Excl. Rx)	72%	**2.5%**	**-0.5%**	**2.0%**	**5.2%**	**2.6%**	**3.9%**
Pharmacy	27%	8.2%	-0.2%	7.9%	5.4%	9.1%	7.2%
Total (Incl. Rx, LTSS)	100%	**4.0%**	**-0.4%**	**3.5%**	**5.4%**	**4.0%**	**4.7%**

*Service category weight based on FY2018 EQI PMPMs.

EQI Data: CSHCS Historical Trend Comparison

Total Med/Rx Trend	Service Category Weight*	Milliman FY2019 Rate Development			EQI Data Annual Changes		
		Trend	Management Savings	Combined (Trend/Savings)	FY2017/ FY2016	FY2018/ FY2017	FY2018/ FY2016
Inpatient Hospital	41%	1.0%	-1.1%	-0.1%	-4.5%	-18.9%	-12.0%
Outpatient Hospital	12%	1.0%	-0.1%	0.9%	7.3%	4.8%	6.0%
Physician	11%	1.0%	0.1%	1.0%	3.4%	-14.2%	-5.8%
Other Ancillary	8%	1.0%	0.0%	1.0%	0.5%	-8.5%	-4.1%
Total (Excl. Rx)	72%	**1.0%**	**-0.7%**	**0.3%**	**-1.3%**	**-13.8%**	**-7.8%**
Pharmacy	28%	7.1%	-1.1%	5.9%	6.6%	3.3%	4.9%
Total (Incl. Rx, LTSS)	100%	**2.4%**	**-0.5%**	**1.9%**	**0.4%**	**-9.7%**	**-4.8%**

*Service category weight based on FY2018 EQI PMPMs.

EQI Data: HMP Historical Trend Comparison

Total Med/Rx Trend	Service Category Weight*	Milliman FY2019 Rate Development			EQI Data Annual Changes		
		Trend	Management Savings	Combined (Trend/Savings)	FY2017/ FY2016	FY2018/ FY2017	FY2018/ FY2016
Inpatient Hospital	24%	2.0%	-0.9%	1.1%	9.1%	4.9%	6.9%
Outpatient Hospital	21%	1.0%	-0.1%	0.9%	1.4%	7.8%	4.6%
Physician	24%	0.5%	0.1%	0.6%	-4.6%	-6.6%	-5.6%
Other Ancillary**	3%	1.0%	0.0%	1.0%	9.7%	-7.0%	1.0%
Total (Excl. Rx)	72%	**1.1%**	**-0.3%**	**0.8%**	**1.7%**	**1.1%**	**1.4%**
Pharmacy	23%	6.1%	-0.9%	5.1%	10.9%	4.9%	7.9%
Total (Incl. Rx)	95%	**2.2%**	**-0.2%**	**2.0%**	**3.7%**	**1.9%**	**2.8%**
Dental	5%	1.0%	0.0%	1.0%	-24.6%	-36.6%	-30.9%
Total (Incl. Dental, Rx, LTSS)	100%				**0.9%**	**-0.8%**	**0.1%**

*Service category weight based on FY2018 EQI PMPMs.
**HMP Dental experience was excluded from the "Other Ancillary" service category.

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Prescription Drug Task Force 2020

1. Analyze the **scope and cause** of the problem **of high-cost prescription drugs** in Michigan and the impact of this problem on this state's residents, communities, and businesses.

2. Analyze the way prescription **drug prices are set** in Michigan **and identify strategies for increasing the transparency** of that process.

3. Recommend legislative and administrative actions that can be taken, and policy-related changes that can be implemented by governmental and non-governmental agencies, relevant to **lowering prescription drug prices for consumers** in Michigan.

4. Recommend legislative and administrative actions that can be taken, and policy-related changes that can be implemented by governmental and non-governmental agencies, relevant to **increasing transparency in the pricing of prescription drugs** in Michigan.

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Policy Considerations

- **Evaluate the cost of recent transition to Single Preferred Drug List (SPDL) for the Medicaid managed care program:**
  - Per prescription costs before and after transition should be evaluated.
  - Amount of aggregate rebates received by the State before and after transition should be transparent.
  - Evaluation of prescription drug utilization before and after transition.

- **Streamline Medicaid prescription drug coverage policies and enhance medical management of complex drugs:**
  - Policy 1918-Pharmacy, proposed on 7/18/2019 should be advanced.
  - Carve-in remaining prescription drugs for management by Medicaid Health Plans

- **Opposed SB 1036:**
  - Proposed legislation would prohibit Prior Authorization of prescription drugs under specific circumstances. If enacted, this legislation would limit the ability of Medicaid Health Plans to ensure immediate use of costlier drugs is clinically appropriate.

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Policy Considerations

- **Approach PBM regulation with caution:**
  - State oversight through licensure and registration of PBMs should be achieved without hindering the ability of PBMs to negotiate lower costs for the enrollees they serve.

- **Consider prohibitions on manufacturer coupons and vouchers:**
  - Coupons reduce the rate of generic utilization by incentivizing use of higher cost brand drugs. When the temporary discount is removed by the manufacturer, the patient is often left with higher out of pocket costs.
  - Medicaid and Medicare prohibit this practice.

- **Adopt manufacturer transparency legislation:**
  - 19 States have adopted laws governing drug price transparency.
  - Meaningful transparency is key. Payments to patient advocacy organizations should also be disclosed.

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Dominick Pallone
Executive Director
Michigan Association of Health Plans
Dpallone@mahp.org
www.mahp.org

Pharmacy Services Administrative Organization (PSAO) Coalition

SCOTT PACE, PHARM.D., J.D. – CHAIR
PARTNER, IMPACT MANAGEMENT GROUP
NOVEMBER 20, 2020

Governor's Task Force on Prescription Drug Prices

Background on PSAOs

- *Voluntary* service organization that provides back office services to independent pharmacies and small chains. These services include executing contracts with payers and PBMs on behalf of independent community pharmacies in their PSAO network;
- PSAOs often get access to networks that are not offered to pharmacies who contract directly with PBM (i.e. preferred Medicare Part D, some Medicaid Managed Care, etc.)
- PSAOs help pharmacies obtain access to more patients in their communities through their contracting;
- Creates administrative efficiency for the pharmacy to not have to wade through contractual terms and make individual evaluations about each PBM contract, addendum or network addition;
- PSAOs charge a flat monthly fee for their service.

Core Services that PSAOs Provide to Independent Pharmacies

- Evaluation and execution of PBM contracts by experienced teams;
- Access to preferred Part D networks unavailable to individual stores;
- Support with interactions between the pharmacy and PBM;
- Central payment services that make PBM payments faster and delivery of claims data more efficient;
- Reconciliation and business support tools;
- Patient data tools to improve performance for Medicare and some Private Health Plans;
- Customer support to assist with resolving PBM issues;
- In short, the services offered by PSAOs are to help pharmacies interact with the PBMs;

What PSAOs in the PSAO Coalition Do ***Not*** Do

- Dictate reimbursement rates (this is determined by the PBMs in their contractual offerings);
- Set Maximum Allowable Cost (MAC) rates for generic medications;
- Retain *any* portion of pharmacy reimbursement, DIR fees or any dispensing fees. **PSAOs charge a flat monthly fee for their service.** Reimbursements are passed through, in their entirety, from PBM to pharmacy;
- PSAOs do not sign every contract presented by the PBMs;
- Determine formulary selections or patient coverage;
- Create networks or plan designs;
- Create Direct and Indirect Remuneration (DIR) Fees;

What PSAOs in the PSAO Coalition Do ***Not*** Do - continued

- PSAOs do not provide access to pooled purchasing power;
- PSAOs do not sell or distribute drugs or negotiate with manufacturers;
- Do not provide inventory functions for pharmacies;
- PSAOs do not have an improved negotiation position based on the affiliation with their parent companies and their respective size in other lines of business;
  - The three largest PSAOs represent approximately 25% of the total number of retail pharmacies, but only less than 13% of the total retail pharmacy prescription volume;
  - Compare this with the three largest PBMs (CVS/Caremark, OptumRx, and Express Scripts/Cigna) who collectively have 80% of the total PBM marketplace;
  - Creates inequitable contracting positioning;

PSAO Benefits for Pharmacies

- Provide back office functions related to contract evaluation, reconciliation services to ensure accurate payment, and tools to improve patient outcomes that can help to reduce DIR fees;
- Keep pharmacies up-to-date on industry contracting changes and evolution;
- Utilize contracting expertise and resources to provide pharmacists access to patients that they might not be able to serve by contracting directly with PBM;
- The back office solution helps to provide pharmacists more opportunity to focus on other areas of their business and to work on other patient-focused activities;

Wrap up

- PSAOs are voluntary entities that charge a flat fee for their service;
- PSAOs assist with executing contracts, they DO NOT negotiate with manufacturers and DO NOT sell medications to pharmacies;
- PSAOs provide administrative simplification for pharmacies;
- The PSAO Coalition is here to help answer your questions and help educate on PSAO issues that you may have related to pharmacy contracting and payment;
- My contact info is pace@impactmanagement.com or 501-690-8735.

The Role of Pharmacy Benefit Managers in the Health Care System

Heather Cascone
Senior Director, State Affairs
Pharmaceutical Care Management Association

November 20, 2020

hcascone@pcmanet.org
(202) 756-5729

What Is a PBM?

- PBMs administer the prescription drug portion of the health care benefit

- PBMs perform a variety of services to ensure high-quality, cost efficient delivery of prescription drugs to consumers

- PBMs provide lower costs for prescription drugs.

Who Are PBM Clients?

Why Do Plans Hire PBMs?

Drive Cost Savings for Patients and Payers

PBMs help save patients and payers 40–50% on their annual drug and related medical costs compared to what they would have spent without PBMs.[1]

Improve Health Care Quality and Patient Outcomes

- Reduce medication errors through use of drug utilization review programs.
  - PBMs will help prevent 1 billion medication errors.[2]
- Improve drug therapy and patient adherence, notably in the areas of diabetes and multiple sclerosis.[3]
- Manage programs to address opioid use issues.

[1] Visante, Return on Investment on PBM Services, February 2020.
[2] Visante estimates based on IMS Health data and DUR programs studies.
[3] Visante estimates based on CDC National Diabetes Statistics Report 2017 and studies demonstrating improved adherence by 10+%).

PCMA

Pharmacy Benefit Management Services

Claims Processing

Price, Discount and Rebate Negotiations with Pharmaceutical Manufacturers and Drugstores

Formulary Management

Pharmacy Networks

Mail-service Pharmacy

Specialty Pharmacy

Drug Utilization Review

Disease Management and Adherence Initiatives

The Patient Value of PBMs

Avoid adverse drug-to-drug interactions

Real time benefit tools like E-prescribing (opioids)

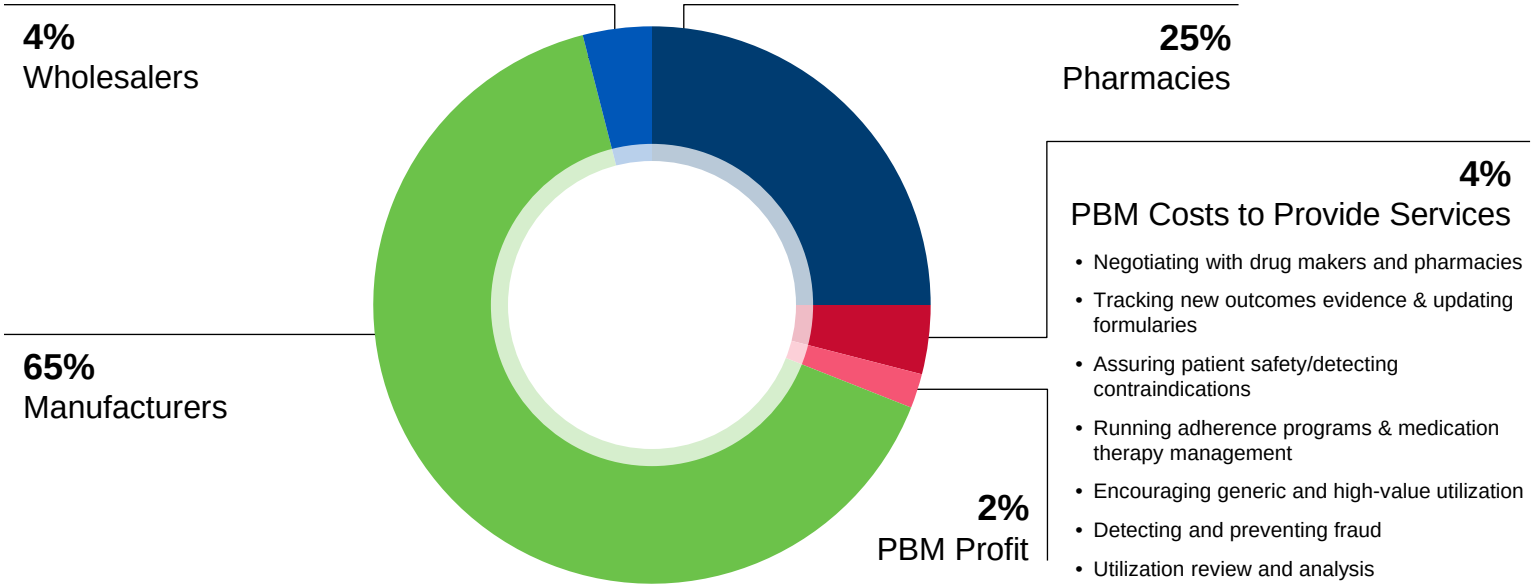
Step therapy (the right Rx for the right patient at the right time)

Mail order (24/7 access to pharmacists)

Specialty pharmacy (hands on virtual help)

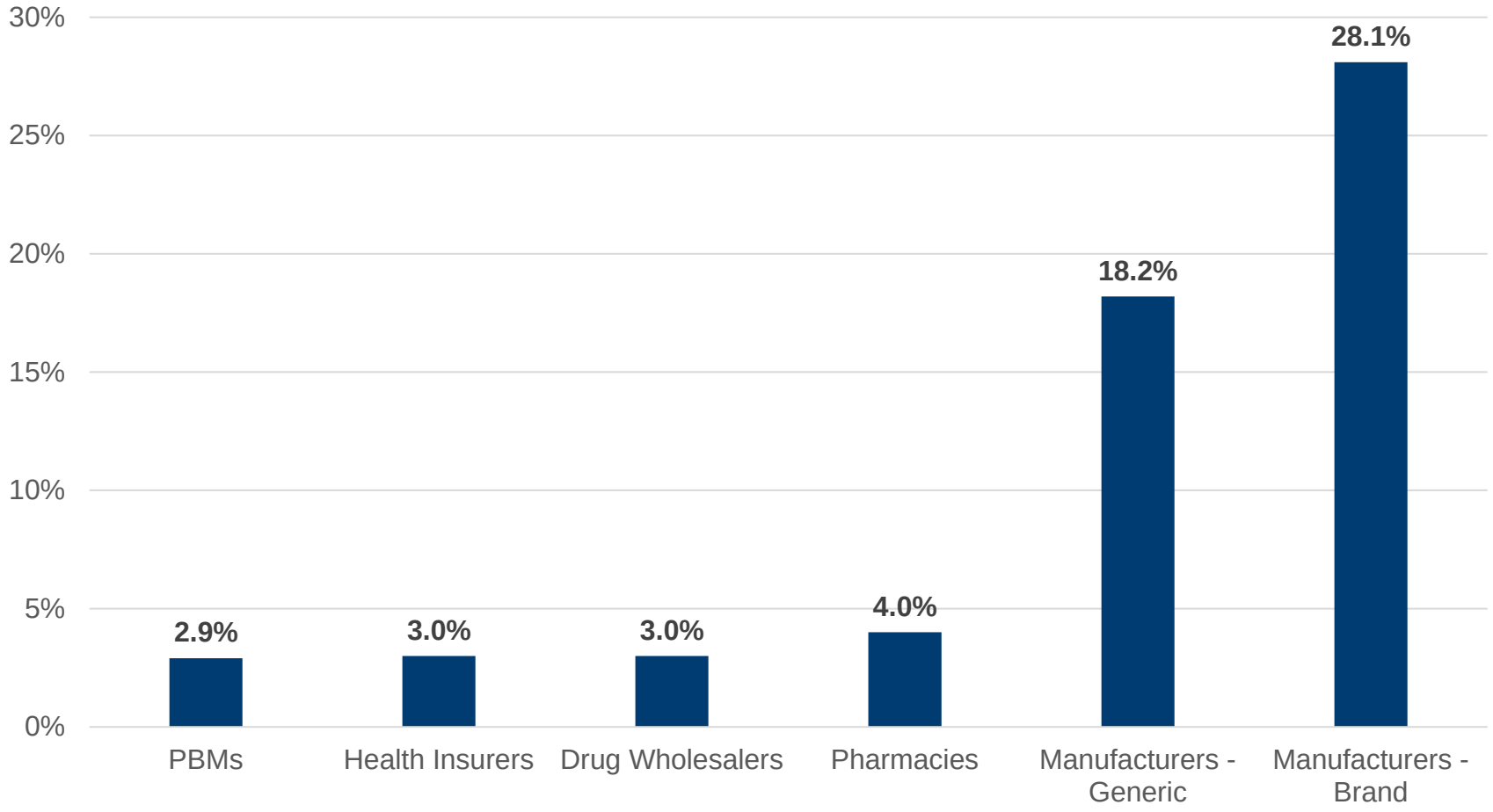
PBMs Take Only 6% of Rx Drug Dollar: 4% Pays for PBM Services, 2% Profit

Share of Drug Dollar Retained by Drug Supply Chain Participants



Source: Visante estimates, 2019; based on data published by IQVIA, Pembroke, Altarum, USC Schaeffer, and Health Affairs. Figure displays estimated total net expenditures (after rebates), both brands and generics. Includes only traditional PBM services, and excludes prescriptions filled by PBM-owned mail/specialty pharmacies, which cost less than retail but provide added margins to PBMs who own mail/specialty pharmacies.

Pharmaceutical Supply Chain Profit Margins



Source: *The Flow of Money Through the Pharmaceutical Distribution System.* Schaeffer Center for Health Policy & Economics, University of Southern California. June 2017

Tackling High Drug Costs

- Patient cost-sharing

- Brand drug manufacturers establish prices within a monopoly established by federal patent law.

- Manufacturers have little incentive to reduce their prices.

- **Insurance carriers and PBMs do not have any control over the price the manufacturer sets for a drug —**

A Plan Sponsor Is the PBM's Client

- The plan sponsor always has the final say when creating a drug benefit plan.
- There is no one-size-fits-all model because each plan sponsor has unique needs.

Value-Based Purchasing Program

Formulary Management

Preferred Pharmacy Networks

Negotiation of Rebates

Mail-order/ Specialty Pharmacy

PBM Innovations

For Physicians

- ePrescribing
- ePrior Authorization

For Patients

- Real-time benefit checks and drug prices
- Mail delivery
- 24/7 pharmacists via phone or chat
- App to check on Rx status

Thank you!

HDA
Healthcare Distribution Alliance
PATIENTS MOVE US.

December 3, 2020

Michigan Prescription Drug Task Force
Michigan Department of Health and Human Services
333 S. Grand Ave
Lansing, Michigan 48909

Re: HDA Comments for Final Report to Governor Whitmer

Dear Members of the Michigan Prescription Drug Task Force,

On behalf of the Healthcare Distribution Alliance (HDA), the national trade association representing healthcare wholesale distributors ("distributors" or "wholesale distributors"), we would like to thank you for the opportunity to present during the November Task Force meeting. We look forward to continued collaboration with the state of Michigan and its policymakers as it relates to the healthcare wholesale distribution industry. As the taskforce prepares its final policy recommendations for the Governor, we want to provide this letter as a resource reiterating the role wholesale distributors play within the healthcare supply chain and their impact on drug pricing.

Role of Wholesale Distributors:

HDA members work around-the-clock to safely and efficiently ship pharmaceutical and healthcare related products to pharmacies, hospitals and other healthcare providers nationwide. In their role as wholesale distributors, HDA members do not conduct research, manufacture, promote or prescribe medications, nor do they influence prescribing patterns, the demand for specific products or patient-benefit designs. Their primary role is to ensure that medicines travel from manufacturers to dispensing locations safely, securely and efficiently.

Wholesale distributors save our healthcare system approximately $33 billion each year[1], and their logistical expertise is paramount to the security and support on which providers rely daily. Without wholesale distributors, pharmacies and providers would be forced to acquire large warehouses, carry weeks of inventory while also managing the impossible task of placing orders from thousands of pharmaceutical manufacturers. By working with wholesale distributors, who provide logistical, inventory, and other service support, providers can maintain a one-stop-shop for all medical products, which creates efficiency, reliability and security within our healthcare supply chain.

Role in Drug Pricing:

It is critical for members of the task force to understand the role wholesale distributors play in pricing pharmaceuticals. The healthcare wholesale distribution industry has a very high-volume, low-profit margin model –

[1] HDA Research Foundation and Deloitte Consulting LLP. 2019. *The Role of Distributors in the US Health Care Industry*. https://www.hda.org/resources/the-role-of-distributors-in-the-us-health-care-industry

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like most wholesale industries. In fact, overall industry profitability for the wholesale distribution sector shows little notable change over the past several years, even during recent market volatility.

Wholesale distributors purchase brand pharmaceuticals based on a manufacturers' list price, or Wholesale Acquisition Cost (WAC). Wholesale distributors may purchase generic drugs at a manufacturer's list price, but they are often able to use their market power to negotiate discounted prices on generic drugs with pharmaceutical manufacturers. In 2019, nine out of every ten prescriptions in the U.S. were dispensed using generic medicines. However, generics account for only 22% of prescription drug spending.[2] Wholesale distributors are uniquely positioned to continue negotiating discount arrangements on generic drugs with pharmaceutical manufacturers further lowering the cost of generic drugs. This, and the other non-medication related services wholesale distributors provide, result in some medications being sold at discounted rates and lower-than-list price to dispensing locations.

Since wholesale distributors purchase and subsequently sell pharmaceuticals from manufacturers based on their list price, or a discounted negotiated price in the case of generic drugs, wholesale distributors will charge manufacturers distribution fees related to their services. These fees, which are not passed on to the customer, represent a fair market value for a bona fide service - an itemized service performed on behalf of the manufacturer that the manufacturer would otherwise need to perform (or contract for) in the absence of a distributor.

As reported by numerous industry studies, wholesale distributors retain approximately one percent of total drug expenditures on brand name medications[3]. You can look at a wholesale distributors role like this: once a drug reaches the dispensing location, their job is generally done in the supply chain and the provider and insurance benefit market takes over. To that end, a recent bill in Michigan, House Bill 5940, mischaracterized wholesale distributors' role by assuming they interact directly with prescribers and healthcare providers. On average, HDA members work with 1,400 manufacturers worldwide to ensure customers can access a full range of products for each of their patients and do not market or promote one particular product.

HDA supports the state's efforts to better understand the prices that consumers pay at the pharmacy counter. However, as noted previously, wholesale distributors do not have direct influence into the pricing of dispensable units, pharmacy benefit design or the ultimate price that consumers pay to fill their specific prescriptions. Wholesale distributors are not a part of negotiations on the "pay side" of the supply chain. Rather, this is the role of health insurers and pharmacy benefit managers (PBMs). Wholesale distributors simply purchase medical products in bulk, not per pill or per dose, and sell to hundreds of thousands of points of care across the country.

Certain Prescription Drug Pricing Data is Publicly Available:

The state already has full access to publicly available, pharmacy invoice level, pricing information reported to the Centers for Medicare and Medicaid Services (CMS) that would obviate much of the need for wholesale distributors to report pricing data. The National Average Drug Acquisition Cost (NADAC) data is determined for virtually every drug in the marketplace through a nationwide, pharmacy survey process and is the invoice price pharmacies pay to wholesale distributors for their medication products. This information is updated weekly and is not proprietary. It is available immediately to benchmark pharmaceutical prices in Michigan against national drug pricing trends while at the same time creating a certain level of pricing transparency

[2] Tracking Who Makes Money on Brand-Name Drug, Kaiser Health News, October 2016. https://khn.org/news/little-known-middlemen-save-money-on-medicines-but-maybe-not-for-you/

[3] Revisiting the Pharmaceutical Supply Chain: 2013-2018, BRG, January 9, 2020. https://www.thinkbrg.com/pp/publication-1090.pdf

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with little concern for building out and managing data systems and contending with numerous confidentiality concerns.

In addition to NADAC, each pharmaceutical manufacturer also reports a list price for all products sold in the U.S. The WAC, set by the manufacturer of a drug product, is the base price that wholesale distributors are charged for the purchase of all drugs. WAC is reported in various published compendia, such as First DataBank and Medi-Span, that the state likely already has access to. Each WAC is specific to the drug, strength, dosage form, package size and manufacturer. A manufacturer choosing to increase the published WAC drives marketplace price increases for brand and generic drugs alike. When the WAC of a product is increased by a manufacturer, the wholesale distributor will likely pay more to purchase the product. In turn downstream customers may pay more to the wholesale distributor for that product.

Both of these indexes are readily available and searchable by National Drug Code (NDC). As such, officials have the manufacturer pricing (WAC), wholesale distributor pricing and pharmacy acquisition costs (NADAC) and by a simple process of deduction, the margin between the two.

Model Legislation:

In recent years, state legislatures and organizations such as the National Academy for State Health Policy (NASHP) have pursued model legislation that fundamentally mischaracterizes the role of wholesale distributors. Specifically, drug price transparency legislation that has been modeled in states, such as Maine, places reporting mandates and other requirements on wholesale distributors that does not provide the state with useful data for analyzing and lowering drug prices, or requests data that a wholesale distributor simply does not have altogether. New Hampshire's recent drug price transparency law took some limited measures to correct such flaws, but certain inaccuracies remain. These are some examples of states that HDA has worked with to help educate legislators about the unique position of HDA members with respect to drug pricing. It is critical that the Michigan Prescription Drug Task Force understand the importance and role of HDA member companies, which in turn should help eliminate negative outcomes for any proposed legislation.

Conclusion:

On behalf of HDA's members, we ask that the task force consider these factors when developing the final report of policy recommendations for consideration by Governor Whitmer. Again, thank you for your time during the November meeting, we hope this letter serves as a resource as the Task Force determines policy recommendations and seeks to address drug pricing in Michigan during the next legislative session.

Sincerely,

Roxolana Kozyckyj
Director, State Government Affairs
Healthcare Distribution Alliance

901 North Glebe Road, Suite 1000, Arlington, VA 22203 • Main (703) 787-0000 • Web www.hda.org

Healthcare Distribution Alliance: An Introduction

Matthew J. DiLoreto
Vice President, State Government Affairs
Healthcare Distribution Alliance

Prescription Drug Task Force
November 20, 2020

Healthcare Distribution Alliance HDA

Association:

- National association representing primary wholesale distributors.
- Founded in 1876
- Headquartered in Arlington Virginia.
- The mission has remained consistent since 1876: Protect patient safety and access to medicines through safe and efficient distribution; advocate for standards, public policies and business processes that enhance the safety, efficiency and value of the healthcare supply chain; and, create and exchange industry knowledge and best practices.

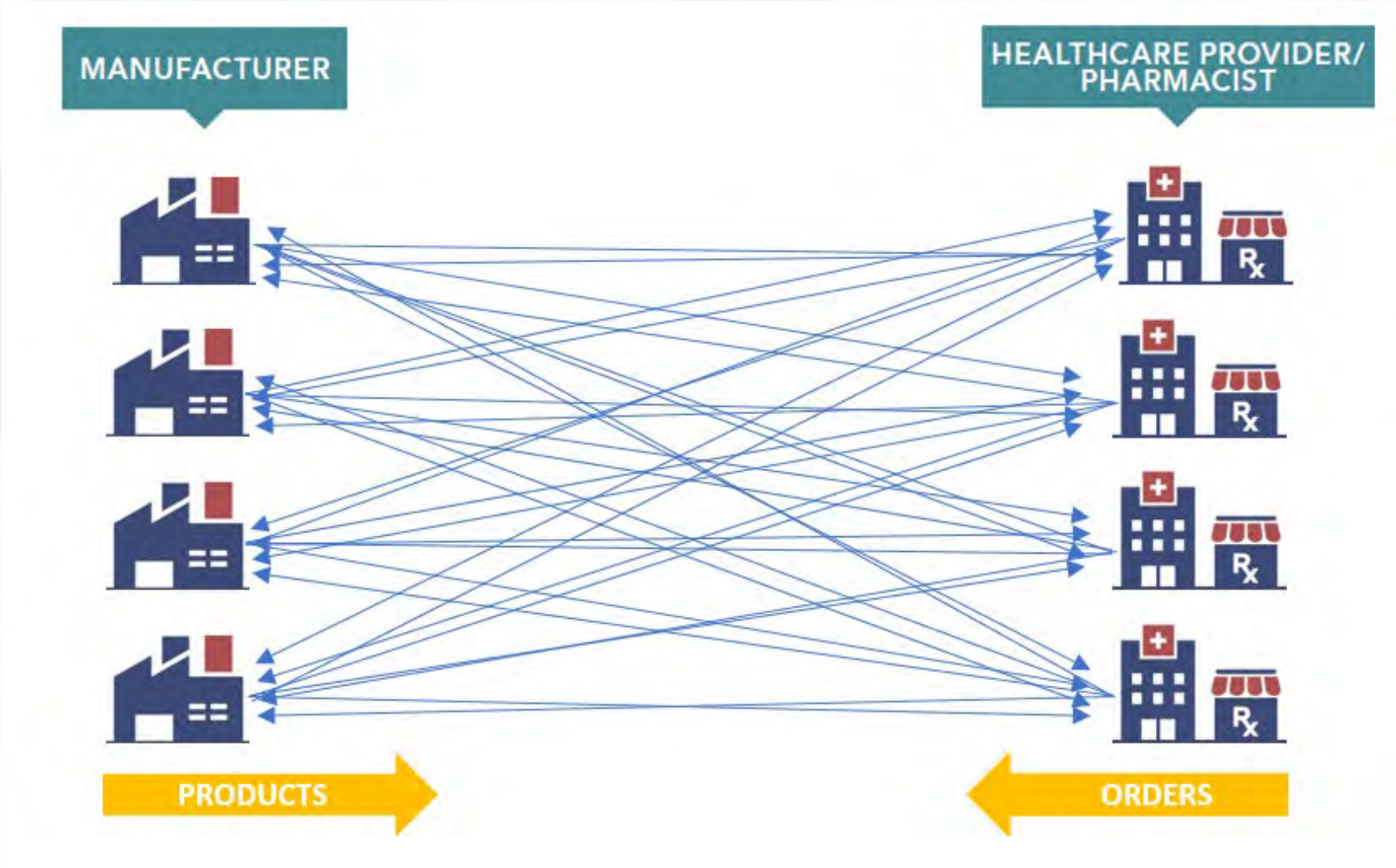
Member Companies:

- Currently represents the distribution interests of 36 member companies.
- Companies include large publicly traded corporations to smaller regionally based, privately held companies.
- Companies serve roughly 200,000 licensed healthcare providers.
- Ship and distribute nearly 15 million lifesaving products to providers each day.

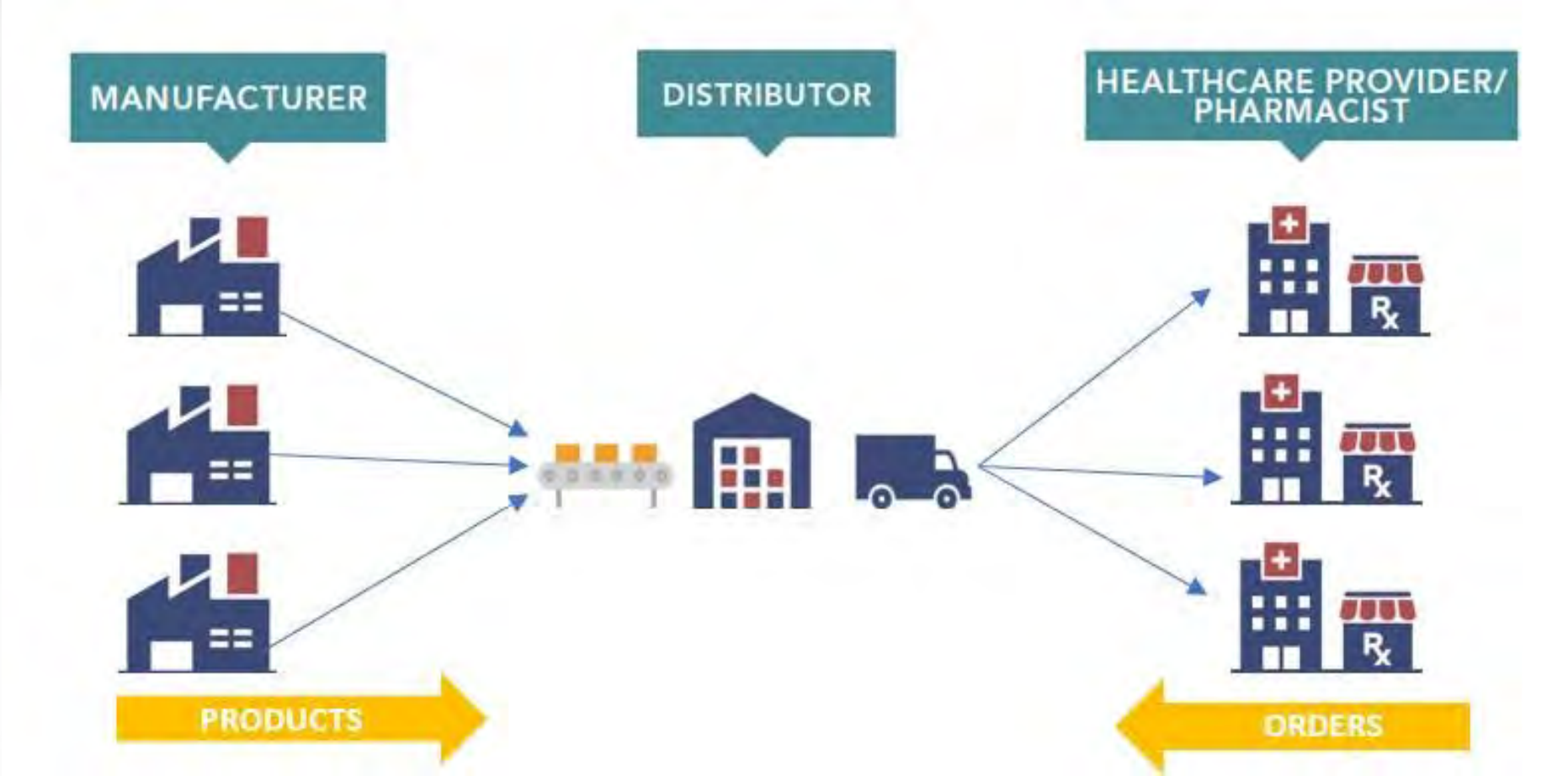
HDA
Healthcare Distribution Alliance
PATIENTS MOVE US.

WHAT IS THE ROLE OF A WHOLESALE DISTRIBUTOR

Supply Chain Without Pharmaceutical Distributors

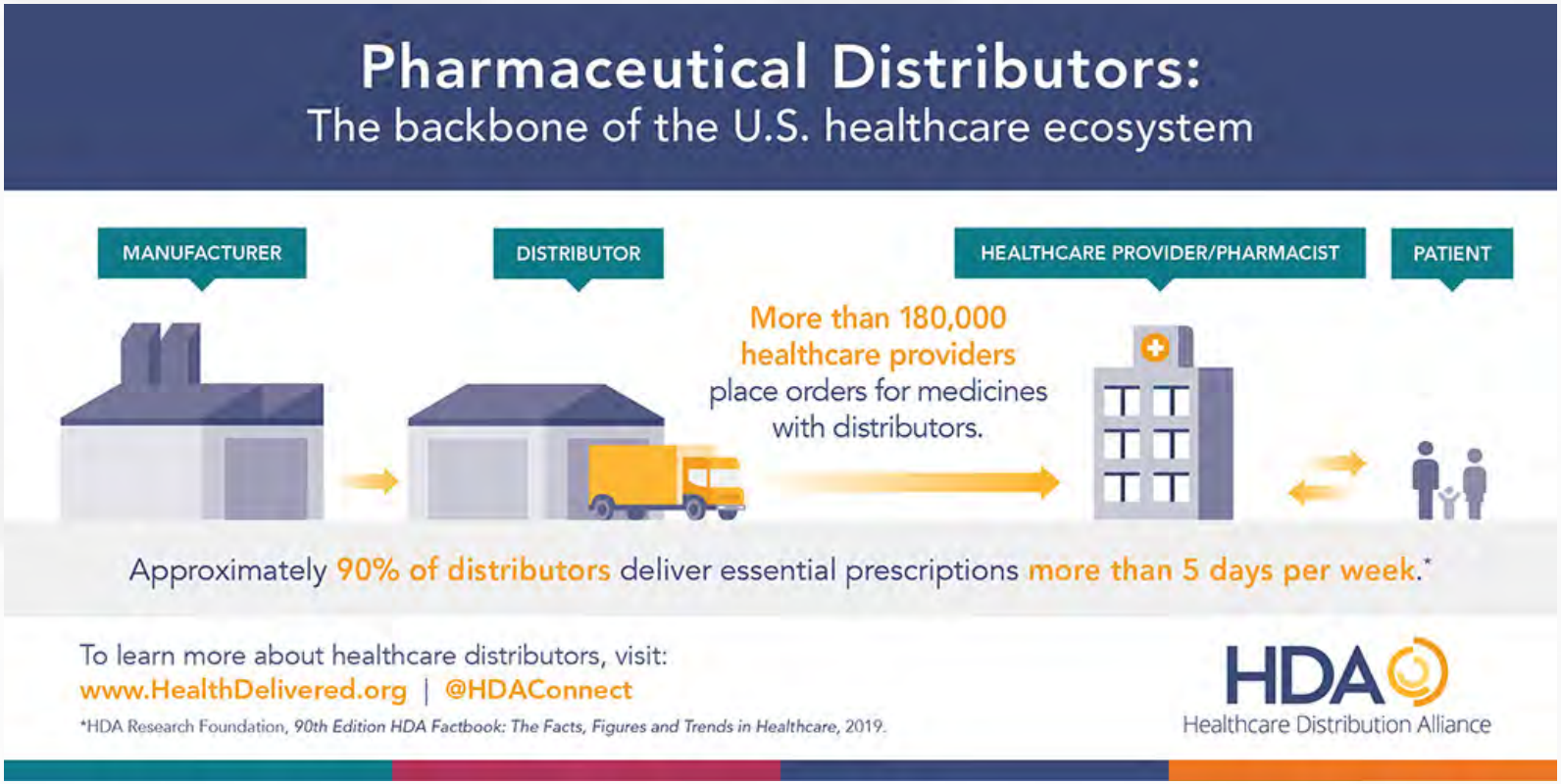


Supply Chain With Pharmaceutical Distributors



Pharmaceutical Distributors:

A vital link in the healthcare supply chain



DISTRIBUTORS ARE LOGISTICS EXPERTS

They do not manufacture, prescribe or promote medicines.

Delivering Savings & Efficiencies

Distributors provide between $33 and $53 billion in savings each year.

Providing core benefits to the pharmaceutical supply chain by:

- Consolidating orders
- Delivering products
- Processing returns
- Maintaining infrastructure to manage customer relationships

Amplifying value across the healthcare ecosystem by:

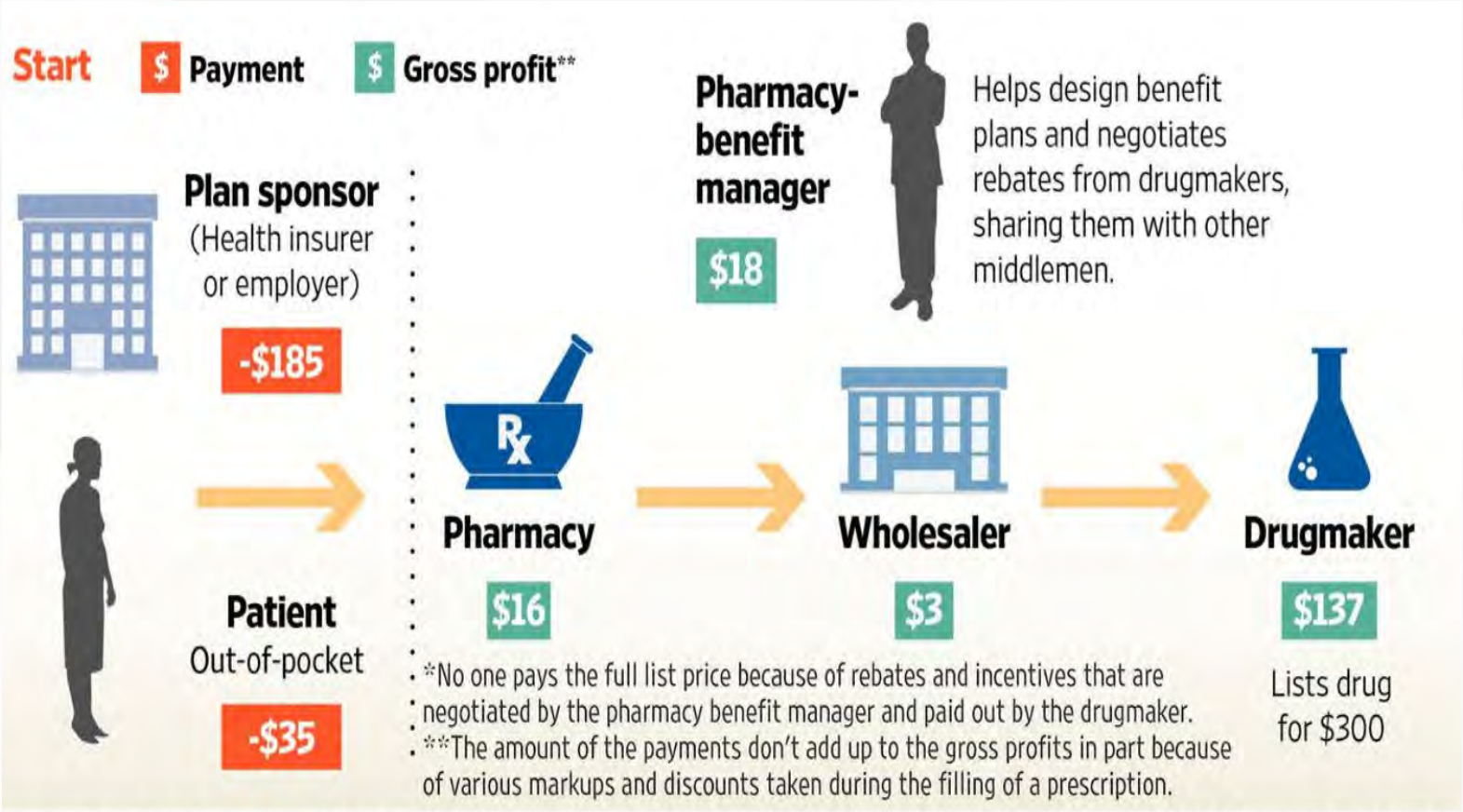
- Increasing operational efficiency
- Providing inventory management
- Bearing financial risk

Delivering Savings & Efficiencies

- Pharmaceutical wholesale distributors primarily utilize a **fee-for-service model**.
- The pharmaceutical distribution model is a high value, high volume but low profit margin industry. A recent analysis from Berkeley Research Group (BRG) shows the profit margin for a wholesaler is **approximately one percent** of the cost of brand medicines. These findings are consistent with other reports, including analyses done by the *USC, PhRMA, Wall Street Journal* and *Kaiser Health News*.

Supply Chain Profits Example

$300 Brand Name Drug



Sources: Pembroke Consulting; WSJ staff reports

THE WALL STREET JOURNAL.

Wholesale Distributors' Role

- Purchase pharmaceuticals from manufacturers based on the Wholesale Acquisition Cost ("WAC"), a publicly available figure.
- Manufacturers set WAC, distributors are not privy to how WAC is set.
- Charge manufacturers distribution fees related to their services, **these fees are not passed on to the customer or impact drug cost**.
- Typically sell branded drugs based on WACs or often WAC – a %.
- May purchase generic drugs at a manufacturer's list price but often are able to use market power to negotiate discounted prices on generic drugs.
- Market power allows wholesalers to offer discounted pricing on generic drugs.

Wholesale distributors do not have any insight into pricing of dispensable units, or the prices that consumers pay based on what it costs them to fill their specific prescriptions. Distributors are not a part of any negotiations on the "pay side" of the supply chain, rather this is the role of health insurers and pharmacy benefit managers (PBMs). Wholesale distributors do not have data on a per pill or per dose basis seen at the pharmacy cash register.

Pharmaceutical Distributors Delivering Solutions Nationwide

VALUE-ADDED SERVICES TO ENSURE THE SAFE AND TIMELY DELIVERY OF

MEDICINES & HEALTHCARE PRODUCTS > TO **200,000 SETTINGS**

91% OF U.S. PRESCRIPTION **DRUG SALES** ARE HANDLED BY PRIMARY DISTRIBUTORS

PROVIDE BETWEEN **$33 AND $53 BILLION** IN SAVINGS ANNUALLY.

AND EACH BUSINESS DAY, NATIONAL AND SPECIALTY DISTRIBUTORS DELIVER

15 MILLION PRESCRIPTION MEDICINES & HEALTHCARE PRODUCTS

TO HEALTHCARE PROVIDERS AND PHARMACIES IN **ALL 50 STATES**

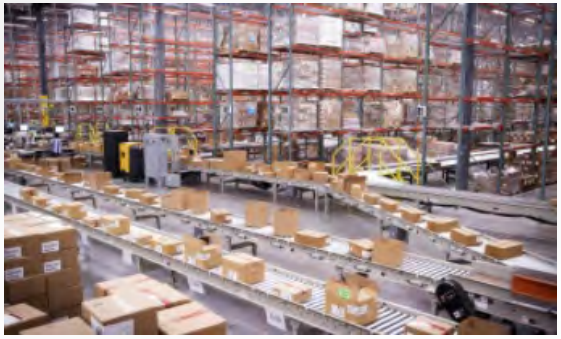
COVID-19: Responding to An Unprecedented Crisis

While this is not the first emergency that America's pharmaceutical distributors have faced, COVID-19 has presented unique supply chain challenges. Wholesalers are striving to rise to these challenges and mitigate supply chain disruptions.

During the COVID-19 pandemic, HDA members are:

- **Working around-the-clock to increase medical capacity** and enhance our national supply of critical medications and healthcare supplies.
- **Coordinating with manufacturers worldwide** to anticipate changes in demand, mitigate disruptions and ensure healthcare providers everywhere have access to available medicines.
- **Maintaining active business continuity plans** to protect essential workers and prevent any disruptions to operations.
- **Working in partnership with federal and state officials** to facilitate information sharing and coordination.

Conclusion



- Wholesalers plan a critical, logistics focused role within the supply chain.
- As reported by numerous, supply chain and independent studies, wholesalers operate on the smallest profit margin on products.
- In their role as wholesaler distributors, HDA members do not determine or influence the list price of pharmaceutical products.
- Wholesalers do not develop or determine patient's benefit design.

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LEARN MORE

www.hda.org

PhRMA
RESEARCH • PROGRESS • HOPE
950 F STREET, NW, SUITE 300 • WASHINGTON, DC 20004 • 202-835-3400 • PhRMA.org

December 4, 2020

TRASMITTED VIA EMAIL
MDHHS-RxTaskForce@michigan.gov

Re: Request for Comment to the Michigan Prescription Drug Task Force created by Executive Order 2020-01

Dear Task Force Members:

On behalf of the Pharmaceutical Research and Manufacturers of America's (PhRMA) 34 member companies and the patients we serve, thank you for allowing us the opportunity to present to the Task Force on Friday, November 20, 2020 as well as submit the following comments for your consideration. We hope that the information is both informative and helpful.

The responsibility of the Task Force to examine and provide recommendations to the Governor, administration and legislature on prescription drug spending and affordability is critically important. No patient should have to worry about whether they can afford the health care they need. However, the notion that spending on medicines is the primary driver of health care cost growth is false and ignores cost savings that medicines provide to the health care system overall. Medicines lead to fewer physician visits, hospitalizations, surgeries and other preventable procedures – all of which translate to lower health care costs. New medicines are making crucial contributions to medical advances, changing the direction of health care as we know it. With more than 4,500 medicines in the pipeline[1] (74% which have the potential to be first in class medicines and 42% of which could be personalized medicines)[2], patients have greater hope than ever before.

Prescription medicines have also transformed the trajectory of many debilitating diseases and conditions, including HIV/AIDS, cancer, and heart disease, resulting in decreased death rates, improved health outcomes, and better quality of life for patients. Better use of medicines could eliminate up to $213 billion in US health care costs annually, which represents 8% of the nation's health care spending.[3] Better use of medicine yields significant health gains by avoiding the need for other, more costly, medical services.

We request the Task Force's consdideration of the following proactive policy solutions to help patients pay less by lowering cost-sharing obligations and out-of-pocket costs to ensure patient access to life saving medicines and treatments:

[1] Adis R&D Insight Database
[2] Analysis Group[3]
[3] IMS Institute for Health Care Informatics

1). Share the Savings: Michigan should enact a law that would require health insurance companies and Pharmacy Benefit Managers (PBMs) to share at least part of their negotiated savings with patients at the pharmacy counter.

Many patients with commercial health insurance are required to share in the cost of their prescription medicines. The cost to patients is often much higher than the cost to their insurance company – for the same medicine on the same prescription. That's because health insurance companies and PBMs negotiate significant rebates and discounts on the cost of the medicine and do not share these savings with patients. On average, manufacturers rebate 40 percent of a medicine's list price back to health insurers, PBMs, the government and other entities in the pharmaceutical supply chain. In 2018, these rebates and discounts totaled $166 billion.[4]

At the same time, patients are being forced to pay more out-of-pocket for their medicines due to an increase in deductibles and the use of coinsurance. Deductibles require patients to pay in full for their medicines before insurance coverage kicks in. And unlike copays, which are a fixed dollar amount charged per prescription, coinsurance requires patients to pay a percentage of the medicine's price.

For example, for a drug with a $100 list price, a health insurance company or PBM may negotiate a discount or rebate of $40, for a net cost to them of $60. But a patient still in her deductible pays the full $100. A patient with a 25% coinsurance pays $25 for a medicine with a $100 list price (.25X100), rather than the $15 (.25X60) she would pay if the coinsurance was based off the discounted amount being paid by her insurance company. That extra money collected from the patient may go to the health insurance company or the PBM. It does not go to the manufacturer of the medicine.

Despite what health insurance companies claim, this will not drastically increase premiums. One study demonstrated that, even if health insurance companies were required to share all the negotiated rebates with patients, premiums would increase at most 1%, while patients could save up to $800 each year on their medicine costs.[5] Fixing this broken part of the system and sharing these savings will give patients immediate relief and help them better afford the medicines they desperately need.

2). Make Coupons Count: Michigan should enact a law that protect third-party cost-sharing assistance, including copay coupons, to help protect patients and enable them to better afford their medicines.

For patients with commercial health insurance, the amount they pay for their medicines is determined by health insurance companies and pharmacy benefit managers (PBMs). New tactics by these companies to block manufacturer cost-sharing assistance, as also known as copay

[4] Drug Channels Institute
[5] Milliman

coupons, threaten to make it harder for patients to get important treatments for chronic illnesses such as asthma, diabetes, HIV, arthritis, hemophilia and others.

When patients are facing their deductible or paying high coinsurance, they will often have higher out-of-pocket costs than when their plan requires a copay because deductibles and coinsurance are often based on the list price of the medicine and not the discounted amount the insurance company and PBM have negotiated to pay. This higher cost sharing can impact patients' ability to adhere to their prescribed treatment, which can be devastating for patients with chronic conditions who rely on medicines to keep their symptoms in check.

To help patients better afford their medicine and stay adherent, many third-party entities, including pharmaceutical manufacturers, offer cost-sharing assistance such as copay coupons. Historically, commercial health insurance plans have counted these coupons towards a patient's deductible and maximum out-of-pocket limit, providing relief from high cost sharing and making it easier for patients to get their medicines.

Unfortunately, health insurance carriers and PBMs have adopted policies, often referred to as "accumulator adjustment programs," that block manufacturer coupons from counting towards deductibles and maximum out-of-pocket limits. This means patients could be paying thousands more at the pharmacy than they should be.

Many patients who have relied on this assistance to afford their medicines have no idea that health insurers and PBMs are no longer counting coupons toward their out-of-pocket limits. This can result in unpleasant surprises at the pharmacy counter, where patients may face thousands of dollars in charges because manufacturer coupons don't count towards their deductible and maximum out-of-pocket limit.

Five states – Illinois, Georgia, Virginia, West Virginia and Arizona -- have already enacted legislation to address this issue, and we encourage Michigan to follow their lead to help patients pay less.

3). Offer Lower, More Predictable Cost Sharing Options and Cover Medicines from Day One: Michigan should enact laws to lower patient out-of-pocket costs.

Between 2012 and 2017, the percentage of health insurance plans that employed deductibles for prescription drugs almost doubled from 23% to 52%.[6] In addition to employing deductibles for prescription drug coverage, insurers have increasingly replaced fixed-dollar copays with percentage-based coinsurance, which requires patients to pay a percentage of the medicine's price.

Compounding the challenge, these deductibles are usually structured to reset at the beginning of each calendar year, when Americans face post-holiday financial stress, tax bills and winter

[6] PwC

utility costs. This burden is further exacerbated by the fact that, while health insurance companies receive substantial discounts from prescription drug manufacturers, the amount patients subject to a deductible must pay is often based on a drug's list price, not the discounted price being paid by their health insurance company.

For prescription drugs, these increasing out-of-pocket costs are further exacerbated by the fact that, while health insurance companies often receive substantial rebates and discounts from prescription drug manufacturers, the amount patients subject to a deductible or coinsurance must pay is typically based on a drug's list price, not the discounted price being paid by their health insurance company.

What we can do at PhRMA

At PhRMA, we will continue to research and develop therapies that save lives and improve quality of living for patients and their families. Our researchers are working around the clock to bring new treatments and cures to market. Now, especially during the time of this pandemic, our industry is working tirelessly to develop COVID-19 vaccines and treatments to preserve the health and wellness of the residents of Michigan and those around the world. We also would like to partner and continue to work with the Governor and Task Force to develop and promote policy and solutions to lower health care costs for all Michiganders.

Thank you again for allowing us to present in November and for your consideration. Please do not hesitate to contact us if you have further questions or inquiries.

Sincerely,

Peter Fotos
Senior Director, State Government Affairs, PhRMA
pfotos@phrma.org

Shauna Gardner
Director, State Policy, PhRMA
sgardner@phrma.org

CC: Members of Governor Whitmer's Prescription Drug Task Force

Value of Medicines

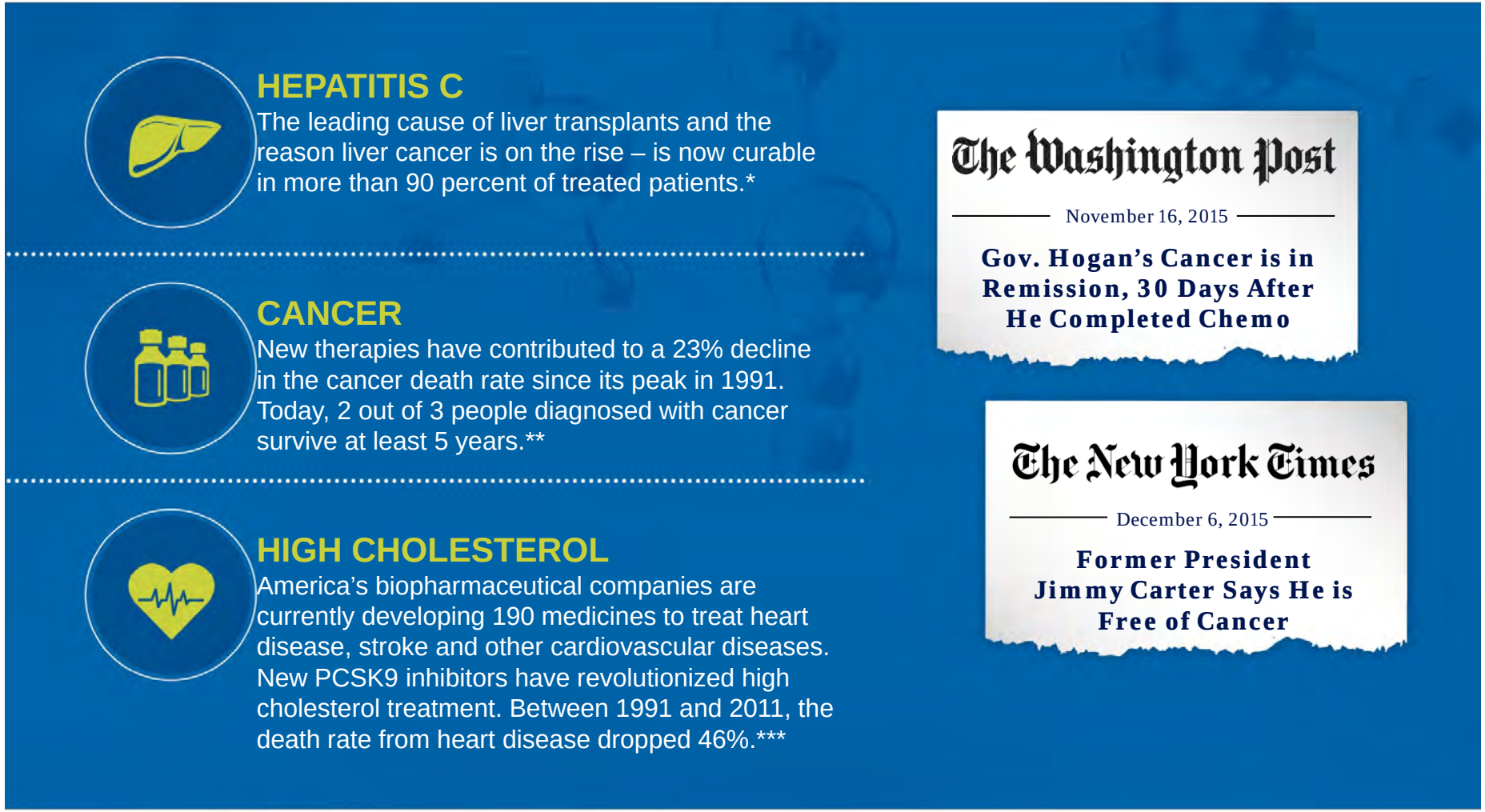
Prescription Drug Price Task Force – Michigan

November 20, 2020

Shauna Gardner, State Policy, Director

PhRMA
RESEARCH • PROGRESS • HOPE

Medicines Are Transforming the Treatment of Devastating Diseases



PhRMA RESEARCH · PROGRESS · HOPE

*Source: U.S. Food and Drug Administration.
**Source: American Cancer Society.
***Source: Pharmaceutical Research and Manufacturers of America (PhRMA) and the Association of Black Cardiologists (ABC), "Medicines in Development for Heart Disease and Stroke," December 2015.

Prescription Medicines: Costs in Context www.phrma.org/cost

R&D is risky and expensive

On average, it takes more than
10 years and $2.6B to research and develop a new medicine.

BETWEEN 1998 AND 2014

Unsuccessful Attempts

123
Alzheimer's Disease

96
Melanoma

167
Lung Cancer

Just
12%
of drug candidates that enter clinical testing are approved for use by patients

Successful Attempts

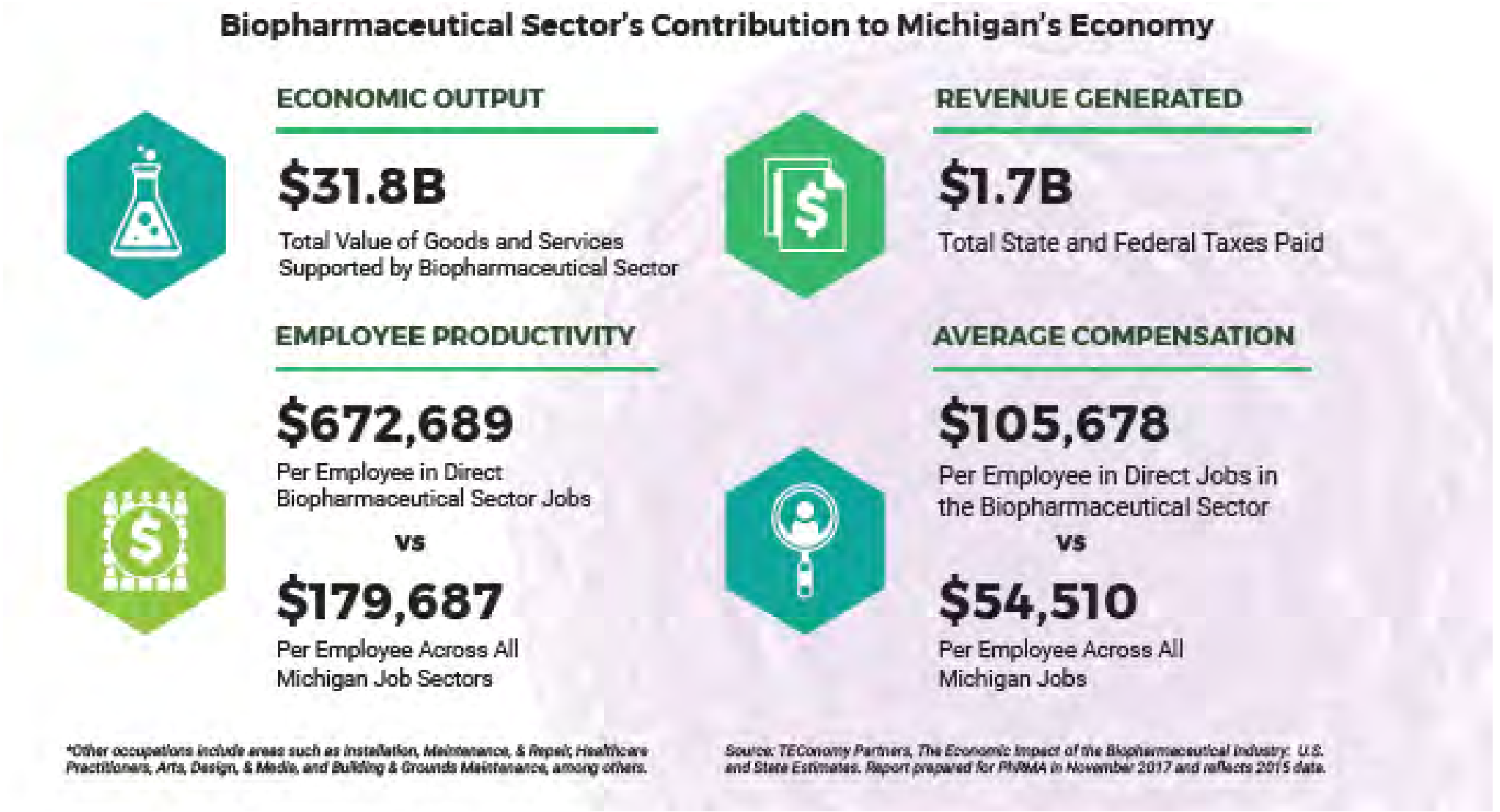
4
Alzheimer's Disease

7
Melanoma

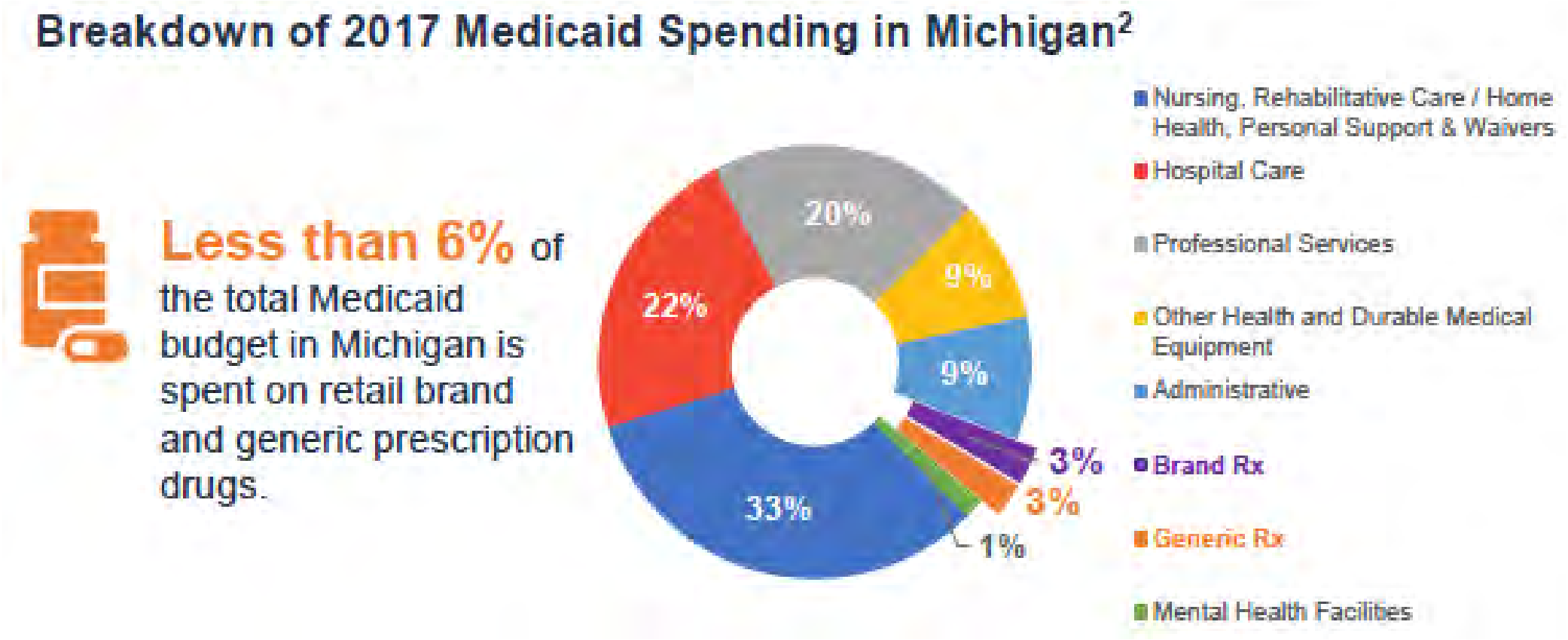
10
Lung Cancer

Source: Tufts Center for the Study of Drug Development (CSDD).
Source: Pharmaceutical Research and Manufacturers of America (PhRMA), "Researching Alzheimer's Medicines: Setbacks and Stepping Stones," 2015.
Source: Pharmaceutical Research and Manufacturers of America (PhRMA), "Researching Cancer Medicines: Setbacks and Stepping Stones," 2014.

Economic Impact of Pharmaceutical Industry in MI



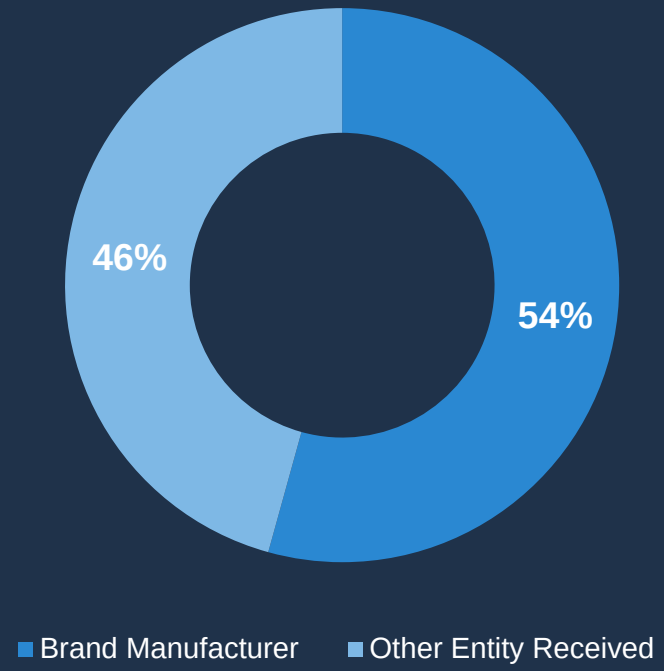
Medicaid Drug Spend in Michigan



Source: The Menges Group analysis of FY2016 CMS 64 reports and State Drug Utilization datafiles.

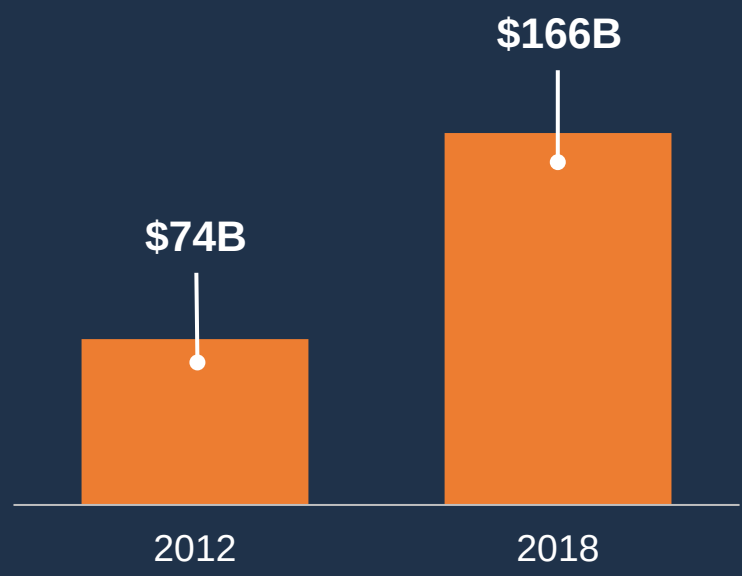
Nearly half of spending on brand medicines goes to entities other than the manufacturers who developed them.

Percent of Total Spending on Brand Medicines Received by Manufacturers and Other Entities, 2018



Source: Berkeley Research Group, 2020.

Rebates, discounts, fees and other price concessions have more than dodoubled since 2012

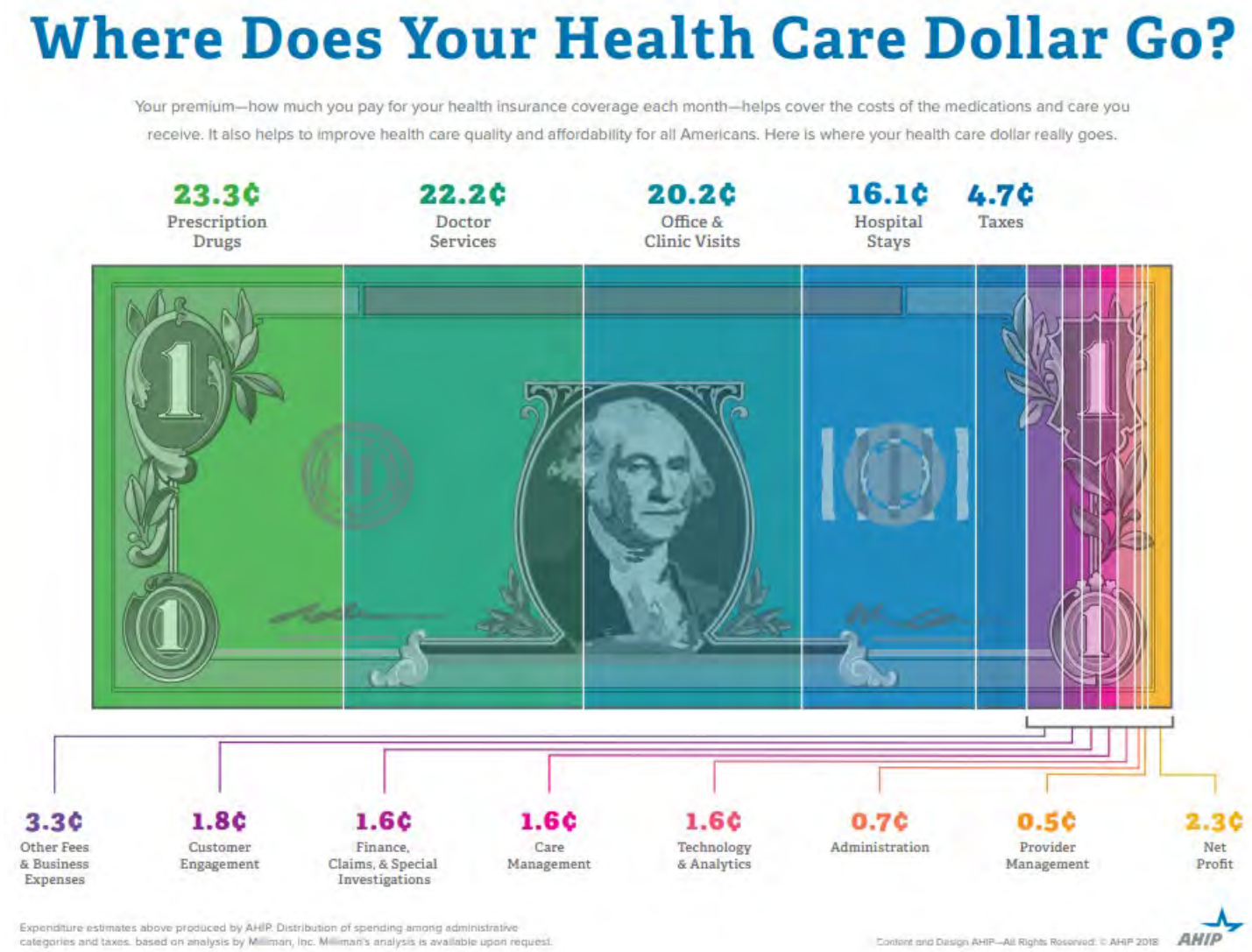


Source: Drug Channels Institute, 2019.

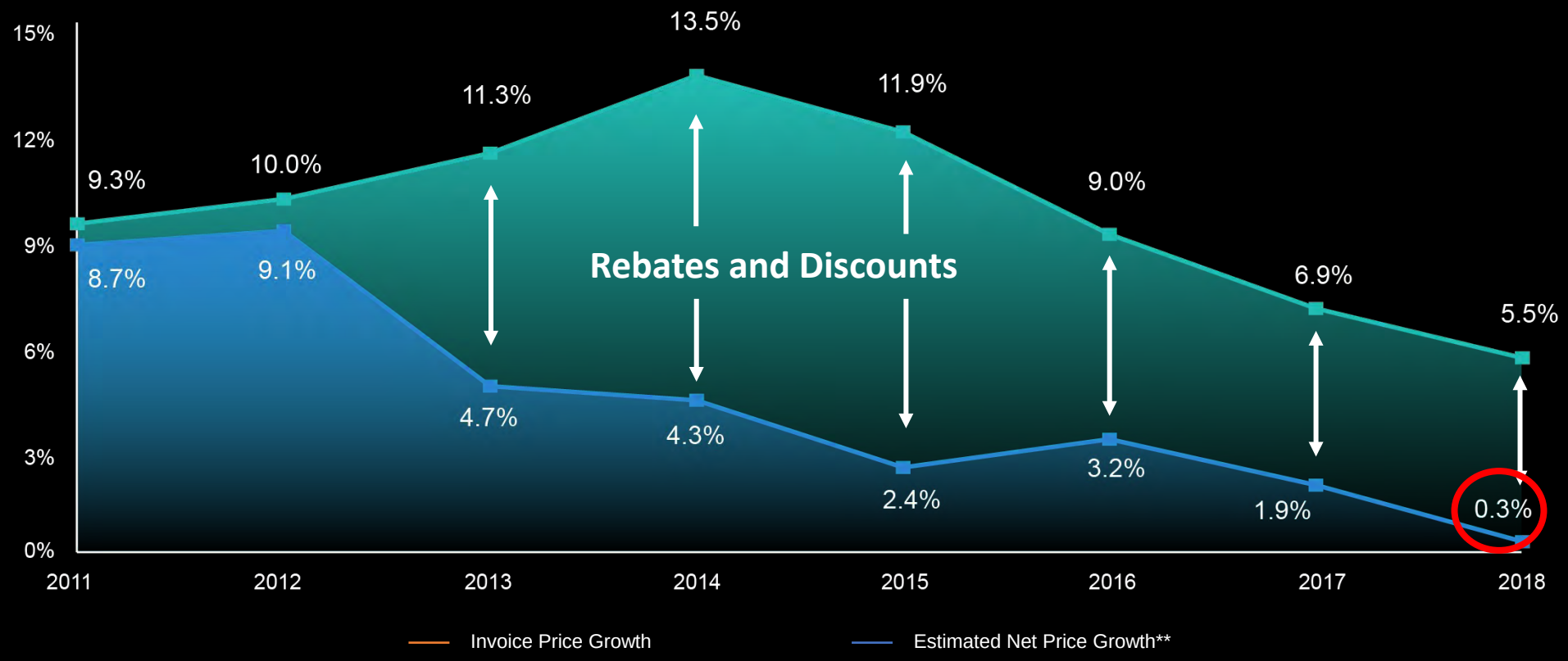
AHIP Premium Infographic

- AHIP focuses only on the list price of medicines, which does not account for the sizable rebates and discounts paid by biopharmaceutical companies, even though those rebates and discounts significantly reduce the amount that health plans actually spend on medicines.
- Based on patients younger than 65, with lower hospital spend
- AHIP presents its data in a way that overemphasizes the role of prescription medicines, while minimizing the contribution of other sectors

-



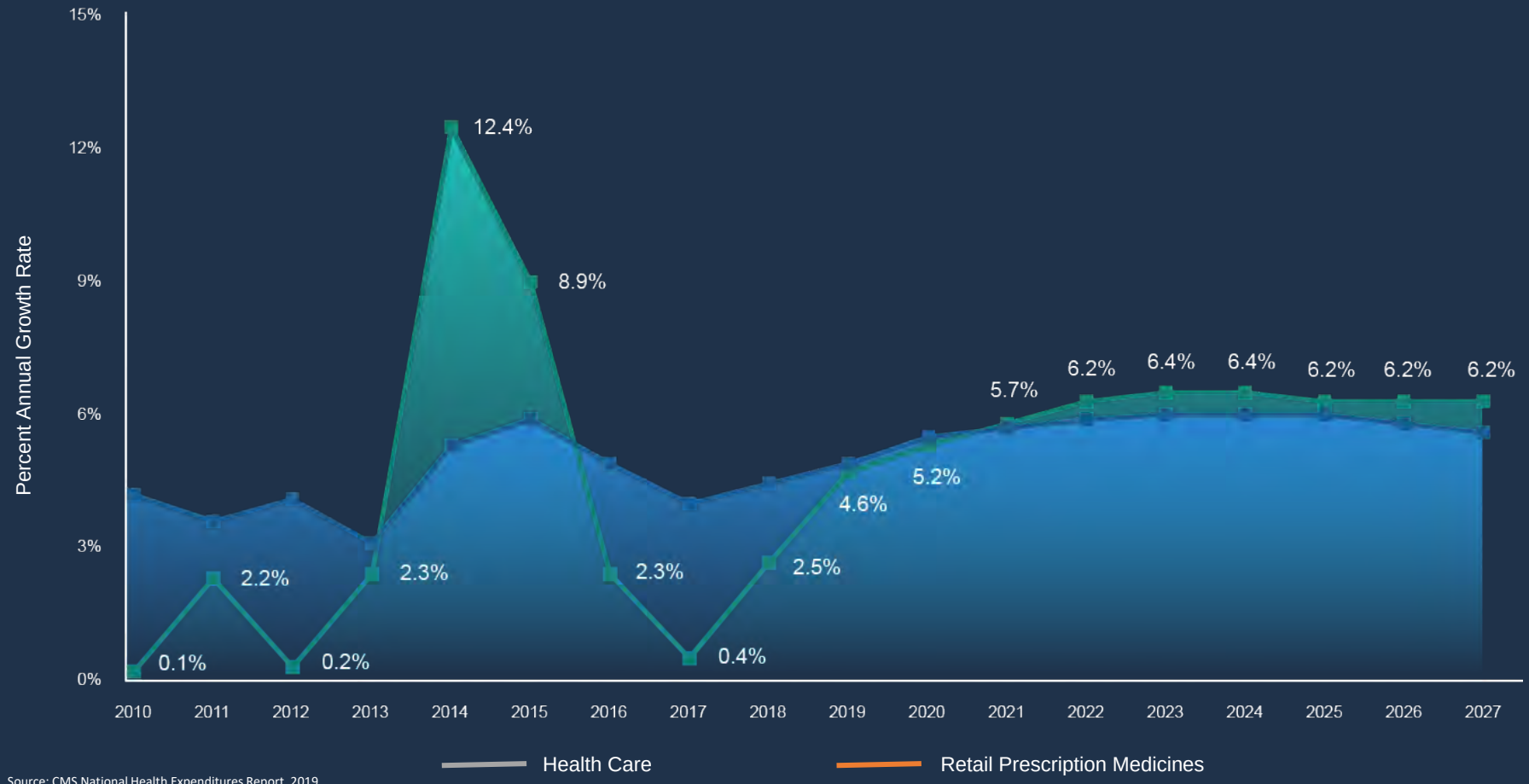
After discounts and rebates, brand medicine prices grew just 0.3% in 2018



Source: IQVIA, January 2019.
*Includes protected brand medicines only (ie, brand medicines without generic versions available in the year indicated).
**Net price growth reflects impact of off-invoice rebates and discounts provided by manufacturers.

8

...and is projected to grow in line with health care spending through next decade.



Source: CMS National Health Expenditures Report, 2019.
Note: Total retail sales include brand medicines and generics.

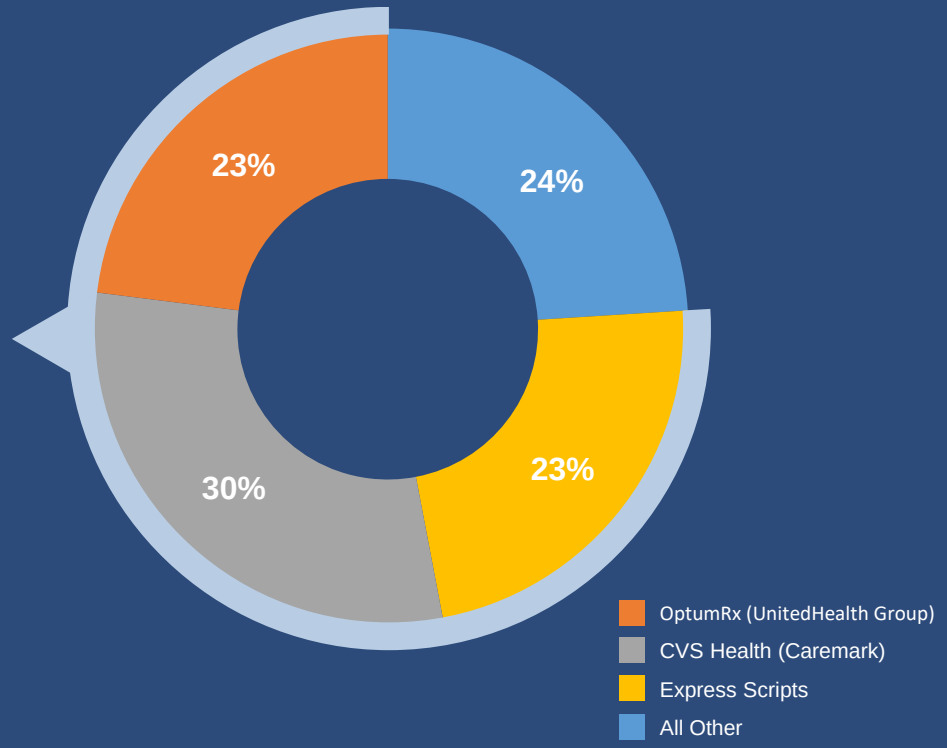
A143

Insurers and PBMs have a lot of leverage to hold down medicine costs.

- Negotiating power is increasingly concentrated among
  - fewer pharmacy benefit managers (PBMs).

Top 3
Market Share:

76%



Source: Drug Channels Institute, March 2019.

Insurers determine:

FORMULARY
if a medicine is covered

TIER PLACEMENT
patient cost sharing

ACCESSIBILITY
utilization management through prior authorization or fail first

PROVIDER INCENTIVES
preferred treatment guidelines and pathways

Policies so that *"Patients Pay Less"*

Share the Savings

Make Coupons Count

Offer Lower Cost Sharing Options

Cover Medicines from Day One

Potential Solution: “Share the Savings” – Pass rebates directly onto the patient at the pharmacy counter.

Sharing negotiated discounts with patients would increase premiums about 1%.

Certain commercially insured patients could save $145 to more than $800 annually.

Change in Plan Costs with Shared Rebates

	PLAN TYPE		
	Traditional PPO	**Copay HDHP***	**Coinsurance HDHP**
Net Plan Per Member Per Month Spend	$433.91	$374.41	$372.89
Change in Plan Costs $	$0.82	$2.62	$3.84
Change in Plan Costs %	0.2%	0.7%	1.0%

NOTE: Plan cost includes medical and pharmacy claims
*HDHP = High-deductible health plan

A146

Manufacturer Cost Sharing Assistance Can Help Ease Patients' Out-of-Pocket Costs

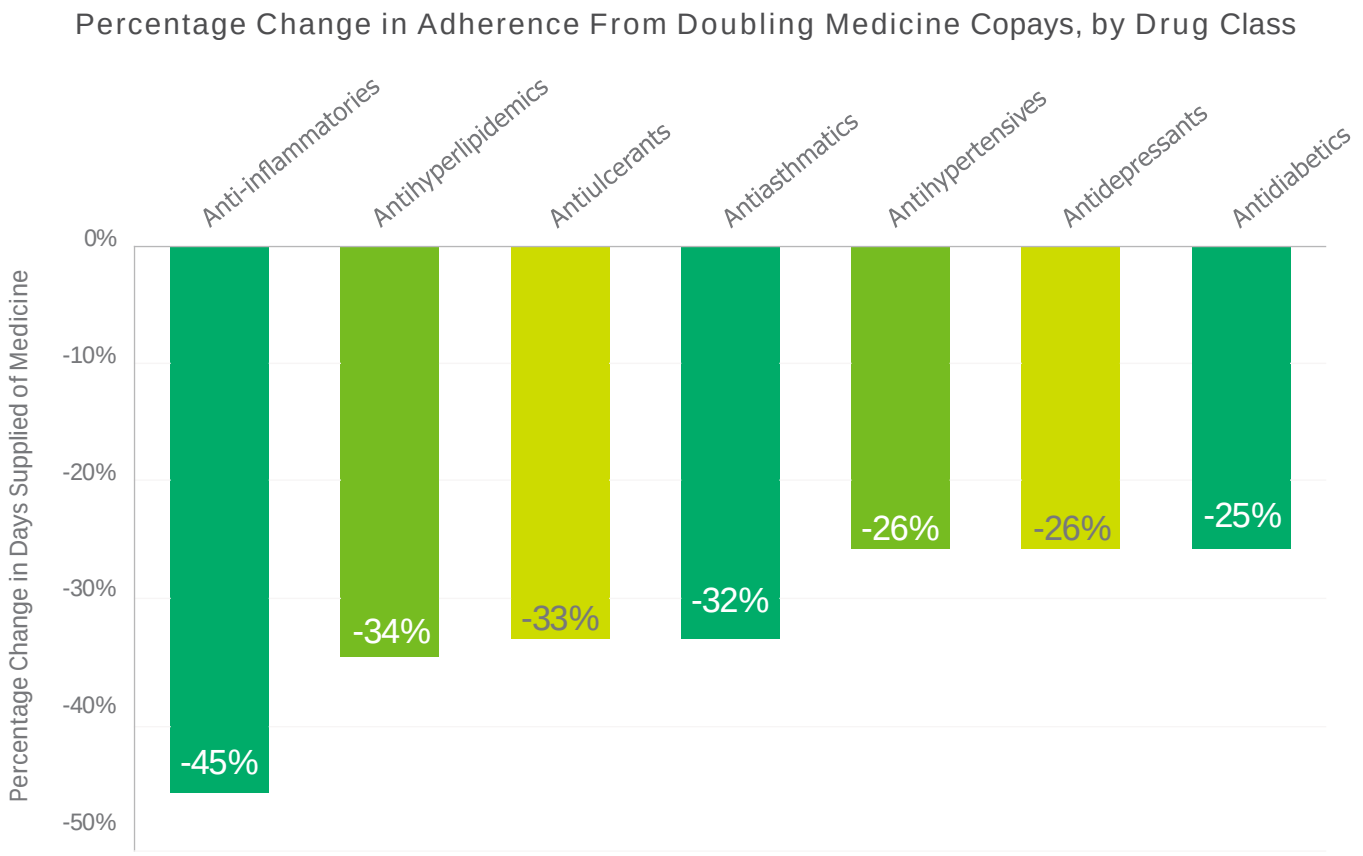
In 2017, just **0.4%** of commercial claims were filled with a coupon for a **brand medicine** that had a generic equivalent.

Programs that do not count manufacturer cost sharing assistance toward a patient's deductible or out-of-pocket maximum hurt the sickest patients, leaving them vulnerable to unexpected out-of-pocket costs as high as **several thousands of dollars** to continue taking their medicine.

Source: IQVIA[15]

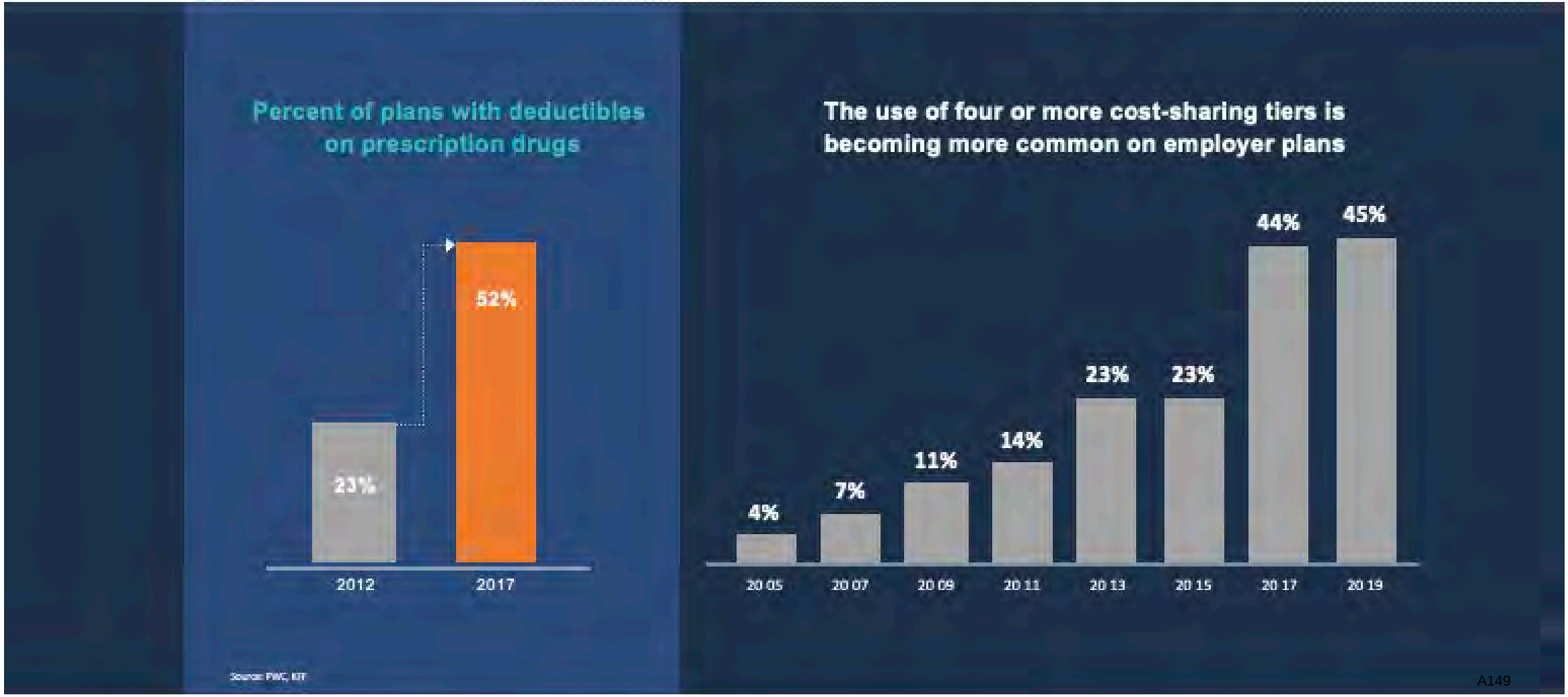
High Cost Sharing Reduces Adherence

RAND researchers found that doubling copays reduced patients' adherence to prescribed medicines by 25%-45% and increased emergency room visits and hospitalizations.

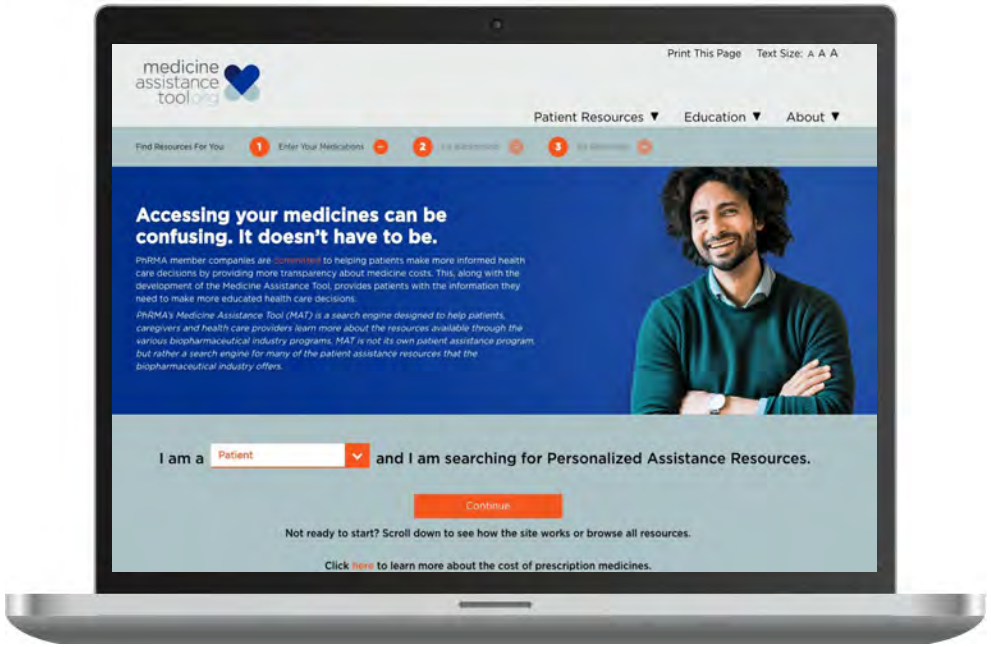


Source: Goldman DP et al.[8]

Patients Face Rising Out-of-Pocket Costs for Medicines and Other Barriers to Care



Many of America's Biopharmaceutical Companies Are Expanding Their Assistance Programs To Help More People



950+ **public and private programs**

The Medicine Assistance Tool (MAT) is a web platform designed to help patients, caregivers and health care providers learn more about some of the resources available to assist in affording their medicines.

www.MAT.org

QUESTIONS AND ANSWERS

Shauna Gardner
Director, PhRMA
sgardner@phrma.org

Peter Fotos
Senior Director, PhRMA
pfotos@phrma.org

November 30, 2019

RE: Patient Prescription Drug Cost and Access Burdens (suggestion of policy solutions)

Dear Legislators,

Our organizations are dedicated to improving access to quality, affordable, and equitable healthcare. We, like many others, are frustrated by how much people are paying for their prescription medications and the rising out-of-pocket costs for certain medications. Now more than ever, as patient advocates and partners interested in quality affordable healthcare, we continue to advocate for solutions that will make prescription drugs affordable to the patient. These solutions must focus on all health care stakeholders, including insurance companies, wholesalers, pharmacy benefit managers, pharmaceutical manufacturers, and others.

A careful examination of drug pricing should be done through the lens of putting patient access and care first. Any legislative effort to address pricing needs to focus on making the health care system work better for patients. We want to make insurance work like insurance again. Solutions should focus on policies that lower out-of-pocket costs for patients while avoiding those that reduce patient access. Michigan should also consider making sure rebates and discounts are shared with patients at the pharmacy counter. As Michigan's legislature begins to take up the issue of affordability, we feel as though the following may be effective legislative solutions that limit patient out-of-pocket cost exposure.

Count Co-Pay Assistance Programs (Coupons) Toward Deductible and Out-of-Pocket Maximums
To help alleviate high out of pocket prescription costs many individuals living with chronic conditions receive co-pay assistance for their specialty medications. This assistance is particularly helpful to those who are required to pay their entire annual deductible or out-of-pocket maximum in the beginning of their plan year.

Recently, we have seen a rise in health plans instituting co-pay accumulator programs. These programs make co-pay assistance and other third-party programs ineligible from counting toward an individuals' deductibles or out-of-pocket maximums., This leaves beneficiaries paying unexpected out-of-pocket costs for their drugs, which can lead to lack of adherence. It is particularly not fair to patients who rely on specialty medications in which there is no generic equivalent.

Reform Prior Authorization and Step Therapy
Prior authorizations for medications are required when a doctor chooses to prescribe a medication not on the insurance company's standard formulary, but that the doctor feels is the best course of therapy for the patient. Step therapy (also known as fail first) requires patients to try, and fail, on one or more prescription drugs chosen by their insurance company – not their healthcare professional - before gaining access to the drug that was recommended to treat their health condition. This one-size-fits-all approach to controlling health care costs undermines and burdens providers, and may lead to unnecessary delays, even denials, of care. This often causes Michigan patients' health to deteriorate as

they await authorization or try and fail on medications that don't work for them. In some circumstances, delays to the appropriate care can even increase costs. Prior authorization and step therapy protocols need to provide for timely appeals and necessary exemptions to ensure patients are not denied lifesaving medical treatments.

Ensure Non-Medical Switching is no longer an issue for patient affordability

Non-medical switching occurs when an insurer requires a patient to switch from his or her current medication to an alternative drug by excluding the original medication from coverage, elevating the drug to a higher cost tier, or otherwise increasing the patient's out-of-pocket costs. Many times, these changes occur in the middle of the plan year leaving a patient unable to seek out a different plan that would cover the medications they need. Legislation should support patients by further preventing health insurance plans from making benefit, coverage, utilization management or access switches in the middle of the plan year without the consent of the patient and his or her provider.

Directly Address Patient Out-of-Pocket Costs (OOP)

Patients' out-of-pocket costs for prescription drugs in the form of high deductibles and co-insurance have continued to create critical access and affordability challenges for those with chronic conditions. Repeated studies have verified that high OOP costs are a significant barrier to treatment and often lead to skipped doses or outright abandonment of treatment. Some legislative policy ideas that would help patients include:

- Promoting predictability be ensuring patients have access to plans with fixed copays across all prescription drug tiers rather than using high co-insurance levels.
- Increasing choice in the insurance marketplace by ensuring that some plans offer benefit designs with no prescription drug deductible.
- Ensure non-discrimination by prohibiting plan designs that discriminate against individuals based on health status or claims experience and place all medicines used to treat a condition on the highest cost-sharing tier.

Eliminate Drug Rebates or Pass the Savings to Patients

On average, pharmaceutical companies rebate about 40 percent of a medicine's list price back to health insurance companies and pharmacy benefit managers. Currently, these rebates and discounts are not reaching patients at the pharmacy counter. They stay with the health insurers and pharmacy benefit managers. That's not right and it needs to change. If insurance companies and pharmacy benefit managers do not pay the full price for medicines, patients shouldn't have to either. These rebates and discounts should be shared with patients at the pharmacy counter or used to lower patient premiums.

In closing, we share your desire to lower health care costs for all Michiganders; however, we feel as though there are certain legislative solutions that will directly reduce prescription costs for patients. Discussions about the affordability of drugs are important, however, capping drug prices while failing to address affordability for patients could limit the availability of prescription options to patients in Michigan. Should you have any questions, please contact either Andrew Schepers at andrew.schepers@cancer.org or Carl Schmid at cschmid@hivhep.org.

Sincerely,

Andrew Schepers
Michigan Government Relations Director
American Cancer Society Cancer Action Network

Carl Schmid
Executive Director
HIV + Hepatitis Policy Institute