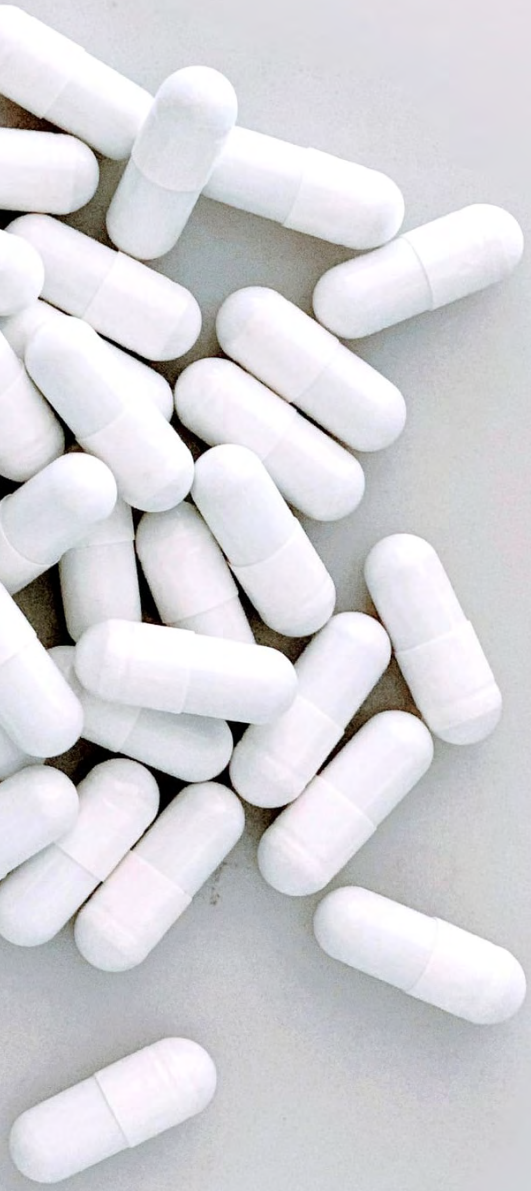
STATE OF WISCONSIN

GOVERNOR'S TASK FORCE ON
REDUCING PRESCRIPTION DRUG PRICES



Governor's Task Force on Reducing Prescription Drug Prices

Meeting Materials

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STATE OF WISCONSIN
GOVERNOR'S TASK FORCE ON
REDUCING PRESCRIPTION DRUG PRICES

GOVERNOR'S TASK FORCE ON REDUCING PRESCRIPTION DRUG PRICES
November 20, 2019
10:00 a.m. – 2:00 p.m.

I. Welcome (15 minutes)
- **Tony Evers, Governor**

II. Video Presentation (5 minutes)
- **Tammy Baldwin, U.S. Senator**

III. Opening Remarks (10 minutes)
- **Nathan Houdek, OCI Deputy Commissioner and Task Force Chair**

IV. Member Introduction (20 minutes)

V. WI Department of Justice Update on Prescription Drug Lawsuits (20 minutes)
- **R. Duane Harlow, Assistant Attorney General**

VI. Understanding the Prescription Drug Supply and Financing Chain (40 minutes)
- **Hemi Tewarson, National Governors Association**
- **Jane Horvath, Horvath Health Policy**
  - **a. Overview of Drug Supply and Financing Chain**
  - **b. Stakeholder Issues and Concerns**

VII. Lunch (25 minutes)

VIII. State and Federal Action Addressing Prescription Drug Access and Affordability (50 minutes)
- **Sandra Wilkniss, National Governors Association**
- **Jane Horvath, Horvath Health Policy**
  - **a. Overview of Federal and Industry Action**
  - **b. Overview of State Action**
  - **c. Overview of Legal Challenges to State Action**

IX. Task Force Member Discussion (40 minutes)

X. Future Meetings (10 minutes)

XI. Adjourn

Meeting Minutes
November 20, 2019
10:00 a.m. – 2:00 p.m.
Hill Farms State Office Building, Room N 108
4822 Madison Yards Way, Madison, WI 53705

Task Force Members Present: Nathan Houdek, Yolanda Tolson-Eveans, Anna Benton, Lara Sutherlin, Brian Stamm, Sen.Tim Carpenter, Rep. Tyler Vorpagel, Lisa Lamkins, Tony Fields, Ian Hedges, Brent Eberle, Robyn Schumacher, Peter J. Fotos, Janet Fritsch, Alan Lukazewski, Sue Wilhelm, Brian Stephens, Josh Bindl, Michael Goldrosen, Duane Harlow (attending in place of Laura McFarlane)

OCI Staff Present: Mark Afable, Jennifer Stegall, Olivia Hwang, Julie Walsh, Megan Aubihl, Jessica Carlson

Public Attendees: Liz Smalley, Denise Tucker, Scott Tyre, Tim Lundquist, John Trochlell, Jane Horvath, Hemi Tewarson, Sandra Wilkniss, Laura Rose, Rebecca Hogan, Ted Osthelder, Karla Ashenhurst, Katie White, Kerry Manion, Jonathan Moody, Melissa Duffy, Dennis Majeskie, Amy Sholis, Chris Mleczko, Lisa Johnson, Mary Haffenbredl, Jordan Lamb, Mollie Zito, Nick Probst, Nancy Wenzel, Jeanine Schneider

Welcome

- Commissioner of Insurance Mark Afable thanked all attendees and members of the task force.

Video from Gov. Tony Evers

- Welcomed and thanked the task force members for the important work the task force is doing.

Video from Sen. Tammy Baldwin

- Thanked the task force members for their efforts to help bring down drug prices and help Wisconsinites with the growing costs of prescription drugs.

Opening Remarks

- Nathan Houdek, OCI Deputy Commissioner and task force chair, thanked the task force members and outlined the two main objectives for the meeting:
    - To provide an opportunity to level set their understanding of pharmaceutical supply chain, what is happening at a federal level, and learn about current legal action; and
    - Get to know each other, and encourage and foster a robust dialog.

Member Introductions

- Task force members introduced themselves, outlining their background, expertise, and current roles.

Wisconsin Department of Justice Update on Prescription Drug Lawsuits

- Assistant Attorney General R. Duane Harlow shared information about the developments in prescription drug lawsuits.
    - He first outlined the antitrust lawsuit against the maker of Suboxone, an opioid replacement therapy, for which Wisconsin is the lead state in the litigation. The State

asserts that the manufacturer sought to extend its period of exclusivity (with monopoly pricing) by manipulating the process, preventing generic drugs to come onto market.
    - Harlow explained litigation that is moving forward against generic drug manufacturers. A lawsuit, which includes 46 states, alleges generic drug manufacturers conspired to fix prices, rig bids, and behave in other anticompetitive conduct.
- He stated that these unlawful practices created higher prices which could negatively affect hospitals and pharmacists, health insurance premiums and plans, Medicare and Medicaid programs, and the individual consumers.

Understanding the Prescription Drug Supply and Financing Chain

- Hemi Tewarson of the National Governors Association and Jane Horvath of Horvath Health Policy gave a presentation providing an overview of the prescription drugs supply and financing chain.
    - Horvath defined the purchase/payment terms in the industry [list price, wholesale acquisition price (WAC), average wholesale price (AWP), maximum allowable cost (MAC), and average manufacturer price (AMP)]
    - Horvath explained the major stakeholders and what each does:
        - *Manufacturers* bring drugs to market, set the price, lease the drug license, manage the drug life cycle, including sales and marketing, and are regulated at the federal level.
        - *Wholesalers* buy in large quantities, store prescription drugs, sell and shop, can serve as a specialty pharmacy on behalf of manufacturers of health plans or as a Pharmacy Services Administration Organization (PSAO), and are regulated by states and federal FDA.
        - *Pharmacy Benefit Managers (PBM)* create pharmacy networks, operate formulary, pay claims, and collect manufacturer price concessions. Not all PBMs are licensed by the State.
        - *Insurers* contract with PBMs, set overall premiums, run grievance and appeals, and are generally state licensed.
        - *Pharmacies* can be retail pharmacies, which are open to the public, or specialty pharmacies, which are generally not open to the public. They are licensed by states and somewhat by federal programs.
        - *Pharmacy Services Administration Organizations* contract with PBMs and health plans, negotiate discounts, process claims/resolve disputes, monitor performance, and update performance monitoring in compliance with health plan/PBM contracts.
    - Horvath noted that the Medicaid rebate program complicates policy decisions.

State and Federal Action Addressing Prescription Drug Access and Affordability

- Sandra Wilkniss of the National Governors Association and Jane Horvath gave an overview of federal and industry action.
    - Wilkniss explained briefly four ways states have tried to combat rising prescription drug prices: importation, public-private group purchasing, price gouging, and pay for delay.
    - She expanded on four additional measures:
        - *Regulation of PBMs* – A prominent area of action in recent years (40 bills addressing PBMs enacted in 2019 in 27 states).

        - *Regulation of insurers* – States are pursuing a variety of approaches to regulate insurer benefit design and limit consumer cost sharing (32 bills addressing insurance design enacted in 2019 across 24 states).
        - *Price transparency* – Transparency is a major focus in recent years regarding both drug prices and PBM behavior (California, Nevada, Vermont).
        - *Affordability boards* – To address prices directly, states (Maine, Maryland, Ohio) enacted laws to establish authorities to review drug pricing and affordability.
- State Example: Massachusetts
    - Accountability for drug manufacturers
    - Increase state oversight of PBMs

- Public programs - States have been active in advancing strategies to improve purchasing and manage access and costs for public programs, including pharmacy benefit management, PBM contracting, reverse auction procurement, 340B oversight, 340B for corrections, alternative payment approaches, affordability approaches, and multi-agency purchasing.

Overview of Legal Challenges to State Action

- Sandra Wilkniss of the National Governors Association and Jane Horvath gave an overview of the legal challenges.
    - Manufacturer challenges are primarily related to efforts to address transparency and price gouging.
    - Manufactures allege violation of trade secret laws, dormant commerce clause, due process, free speech, and federal patent laws.
    - State examples: California (PhRMA v Brown), Nevada (PhRMA and BIO v Sandoval) and Maryland (AAM v Frosh)
- PBM challenges are primarily related to efforts to address transparency and disclosures, fiduciary duty, and MAC pricing. Presenters also discussed the focus on alleged violations of ERISA preemption.

Open Discussion

- Several task force members expressed their desire for a wholistic approach.
- Task force members expressed concerns that transparency needs to be meaningful.
- Some members requested the task force consider making changes that could optimize the current programs with streamlining and standardization.

Other Business

- The next meeting will be held January 22, 2020 in Milwaukee.
- Meetings will be on the third Wednesday of each month starting in February.
- The staff of the task force will distribute a draft of a 2020 work plan.
- The task force website will be live soon.
- Chair Houdek extended an invitation to industry experts, consumer advocates, and stakeholders to continue to participate in the task force.

PRESCRIPTION DRUG LITIGATION

WISCONSIN DEPARTMENT OF JUSTICE

PUBLIC PROTECTION UNIT

- Environmental Enforcement
- Consumer Protection
- Antitrust Litigation

ANTITRUST LAW

- Regulation of business conduct and organization.
- Purpose is to promote competition to protect the free market and benefit consumers.

ANTITRUST LAW – FEDERAL & STATE

- Sherman Act
- Clayton Act
- Federal Trade Commission Act
- Wisconsin's "Little Sherman Act" and "Little Clayton Act."
  - *Wis. Stats. Ch. 133.*

SUBOXONE

- Antitrust Lawsuit filed in 2016.
- Plaintiffs are 42 States and Commonwealths, led by the State of Wisconsin.
- Defendants are involved with the development, manufacture, and sale of Suboxone (buprenorphine/naloxone).

SUBOXONE

- Suboxone is a opioid replacement therapy for the treatment of opioid dependency.
- Until generic buprenorphine/naloxone was introduced to the market in 2013, Suboxone was the only replacement maintenance therapy that could be prescribed in an office setting and taken by patients at home.

SUBOXONE

- 2002 Suboxone introduced as a sublingual tablet and granted "orphan drug" status by the FDA.
- The orphan drug designation provided the defendants with a seven year exclusivity period, expiring on October 8, 2009.
- Exclusivity = freedom to market as a brand-name drug, free from generic competition.
- After the exclusivity period expires, generic drugs may enter the market.

HATCH-WAXMAN ACT

- Federal law passed with the intended purpose of pushing down prescription drug pricing by encouraging the manufacture of generic drugs by the pharmaceutical industry.
- Allows generic drugs to come onto the market more quickly through an Abbreviated New Drug Application. The ANDA process allows generic drug manufacturers to get drugs approved ***without*** replicating the costly and time-consuming clinical trials required of the original drug manufacturer.
- To be approved, an ANDA must demonstrate that the generic drug: (a) has the same active ingredients; (b) is pharmaceutically equivalent (same dosage form and strength); and (c) is bioequivalent (exhibiting the same drug absorption characteristics).

GENERICS

- Oral drugs that are proven to be both pharmaceutically equivalent and bioequivalent to a branded oral drug receive an "AB" rating from the FDA.
- Oral drugs that carry the FDA's AB generic rating in a particular category may be substituted by pharmacists for a physician's prescription for a brand-name drug ***without*** the physician's approval.
- When generic drugs enter the market (typically at lower prices), it is not uncommon for the brand-name manufacturer to lose 80 percent or more of its brand-name sales.
- The entry of generics creates competition and genuine competition results in lower prices.

PRODUCT HOPPING - SUBOXONE TABLETS TO SUBOXONE FILM

- Defendants create Suboxone Film.
- Change to the dosage form (tablets to film) means generic tablets would not be pharmaceutically equivalent. ***No AB rating***. Pharmacist may ***not*** substitute generic tablets if Film is prescribed.
- Film was patented and defendants enjoy a period of exclusivity (NO COMPETITION).

MARKET CONVERSION – TABLETS TO FILM

- Campaign to drive the Film to market before the generic tablets could enter.
  - Promoting superiority of the Film over the Tablets to doctors, payors, and pharmacists.
  - Pricing the Tablets so that they were more expensive than the Film.
  - Hiring and compensating its sales force to incentivize them to sell the Film.
- September 2012, defendants publicly announce that they intended to discontinue Suboxone Tablets due to defendants' concerns regarding the safety of the Tablets. Defendants withdrew the Suboxone Tablets in March 2013.

DELAY OF GENERICS INTO THE MARKET

- Manufacturers of generic drugs filed ANDAs in 2009.
- Generic ANDAs were ultimately approved in February 2013.
- By the time generic tablets were introduced Suboxone Film constituted more than 85% of the market.

DELAY OF GENERICS INTO THE MARKET

- Defendants failed to cooperate in good faith with the generic manufacturers in the submission of a joint Risk Evaluation and Mitigation Strategies (REMS) for the Tablets.
- Defendants filed a Citizen Petition asking the FDA to withhold approval.
- Due in part to the acts of the Defendants, the applications for generics were not approved until February 2013.

SUBOXONE LAWSUIT

- Defendants engaged in an overarching conspiracy to prevent and delay generics to maintain their monopoly profits.
- The lawsuit seeks:
  - Injunctive Relief
  - Disgorgement
  - Penalties

STATES LITIGATION AGAINST GENERIC DRUG MANUFACTURERS

- 2013-14 sudden price spikes in a number of generic drugs.
- Congressional hearings.
- United States Department of Justice Criminal Investigation.
- State AGs' investigation and lawsuits.

STATES LITIGATION AGAINST GENERIC DRUG MANUFACTURERS

- 2016 State AGs' lawsuit:
  - 46 States.
  - 18 Corporate Defendants, and two corporate executives, all who were involved in the manufacture and sale of 15 generic drugs.
- 2018 State AGs' lawsuit:
  - 50 States and Territories.
  - 20 Corporate Defendants, and 15 corporate executives, all who were involved in the manufacture and sale of more than 100 generic drugs.

STATES LITIGATION AGAINST GENERIC DRUG MANUFACTURERS

- Both lawsuits allege the defendants engaged in conspiracies to:
  - Fix prices
  - Rig bids
  - Allocate drug markets
  - Other anticompetitive conduct
- Defendants claim the increased prices are the result of market forces and drug shortages.

STATES LITIGATION AGAINST GENERIC DRUG MANUFACTURERS

- Relief sought:
  - Injunctive remedies
  - Disgorgement
  - Civil Penalties

CONSEQUENCES OF ANTICOMPETITIVE CONDUCT IN PHARMACEUTICAL SALES

- Anticompetitive conduct results in higher prices.
- Affects hospitals and pharmacists.
- Affects health insurance premiums and plans.
- Affects Medicare and Medicaid programs.
- Affects individual consumers.

WISCONSIN DEPARTMENT OF JUSTICE

R. Duane Harlow

Assistant Attorney General

Wisconsin Department of Justice

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Background on NGA Health

Wisconsin Governor's Task Force on Reducing Prescription Drug Prices

National Governors Association
November 20, 2019

National Governors Association

Conference of Governors at the White House, 1908

Over 100 years of serving our nation's governors

Founded in 1908, the National Governors Association (NGA) is the nonpartisan organization of the nation's 55 governors. Through NGA, governors share best practices, address issues of national and state interest and share innovative solutions that improve state government and support the principles of federalism.

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Organizational Structure

The NGA Center for Best Practices is a 501(c)(3) and part of our larger organization.

NGA

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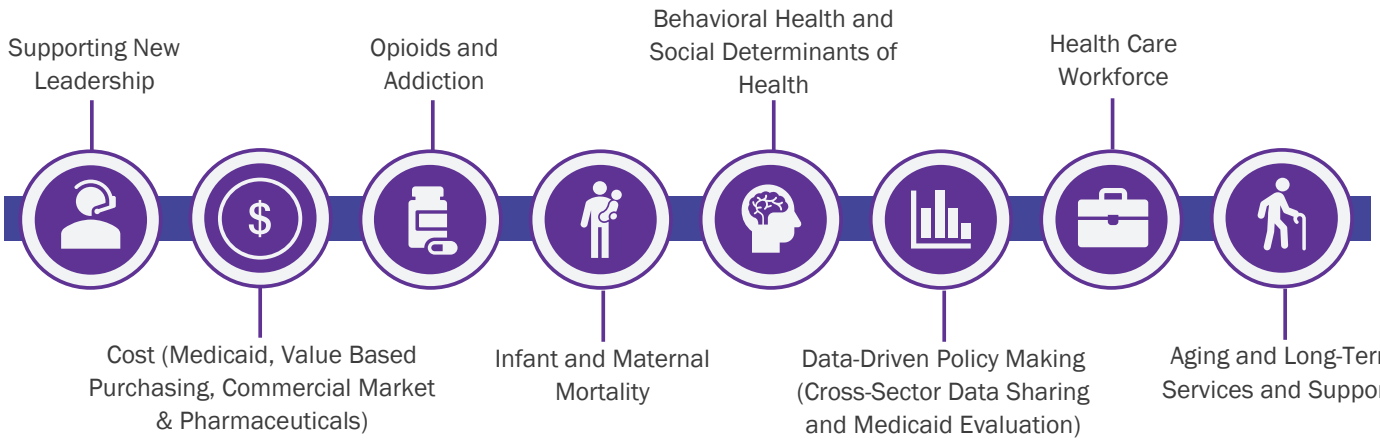
NGA Health – 2019 Focus Areas



NGA

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NGA Health – Recent Work on Pharmaceuticals

NGA Health

- ***Pharmaceuticals and Public Health Crises*** (2017 – 2018)
  - Identify strategies to address public health crises (e.g. opioids, hepatitis C) by increasing access to pharmaceuticals while ensuring fiscal sustainability of public programs
  - Collaborative work with 10 states (Delaware, Louisiana, Massachusetts, New Mexico, New York, Ohio, Oregon, Rhode Island, Virginia and Washington)
  - Publication released August 2018: Public Health Crises and Pharmaceutical Interventions: Improving Access While Ensuring Fiscal Sustainability
- ***Pharmaceuticals Learning Collaborative*** (2019 – 2020)
  - Webinar series and multi-state meetings open to all states
  - Technical assistance with 6 states (Kentucky, Louisiana, Nevada, Ohio, Oregon, Wisconsin)

NGA Advocacy

- 2019 Principles For Federal Action To Address Health Care Costs

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Understanding the Prescription Drug Supply and Financing Chain

Wisconsin Governor's Task Force on Reducing Prescription Drug Prices

Jane Horvath Presentation
November 20, 2019

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Pharmaceutical Market

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 (ANDA, 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 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 or Pharmacy admin service entities

Horvath Health Policy, *Innovations in Healthcare Financing Policy*

Rx Purchase/Payment Terms

- **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
  - Confidential
  - For Medicaid use only

Horvath Health Policy, *Innovations in Healthcare Financing Policy*

Generic Drug Supply Chain

$20 Drug Example

= supply flow
= money flow
= negotiation

DRUG MAKERS

Set Drug List Prices

Wholesale Acquisition Price (WAC) varies $15-$25, from multiple generic drug makers

PBM

Depending on contract, PBM pays:
** FFS $8 ($18 minus $10 copay)*
** avg. price/MAC $10 ($20 minus $10 copay)*
PBM charges insurance $11.50 ($20 avg price plus $1.50 dispensing fee, minus $10 copay).

PSAO/PBM contract determines payment methodology to the pharmacy

PSAO / WHOLESALER

PSAO sells/distributes drug to their pharmacy client for discounted price off the Average Wholesale Price; AWP = $18

HEALTH INSURANCE PROVIDER

Generic drug has $10 copay, insurer pays full amount $11.50, (minus copay of $10).

PBMs/health insurance providers pay pharmacy for drugs dispensed

PHARMACY

Pharmacy buys for $18; charges patient $10 copay

Patient pays $10 copay for drugs

Pharmacy dispenses drugs to patient for copays

PATIENT

Copay of $10 to pharmacy.

4 AHIP

Branded Supply Chain

$10,000 Drug Example

= supply flow
= money flow
= negotiation

DRUG MAKER

Set Drug List Price

Sets list price of $10,000

Drug makers pays rebate to PBM per negotiated agreement

PBM

PBM pays pharmacy $10,925; Negotiated $2000 rebate with Drug Maker, keeps $200, sends $1800 to health insurance provider

PSAO negotiates drug reimbursement on behalf of their pharmacy

PSAO / WHOLESALER

PSAO buys drug at $10,000 WAC; sells/distributes drug to their pharmacy client for $10,500 AWP

PBM/ health insurance provider pays pharmacy for drug dispensed

HEALTH INSURANCE PROVIDER

Pays PBM $10,925; receives $1800 rebate from PBM; records total drug spend of $9,125.

PHARMACY

Pharmacy charges $11,000; charges patient $75 copay

Patient pays $75 copay

Pharmacy dispenses drug to patient for copay

PATIENT

Who Does What? Manufacturers

- **Bring Drugs to Market**
  - Buy promising molecules from research centers (Universities) that do the 'bench science'
  - Outright purchase price and/or contract for royalties if molecule is commercialized
  - Apply for patent (20 years),
    - or purchase patent from original developer, or lease rights from patent holder
  - Generally 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
- **Set the price**
  - Often years before a drug reaches the market
- **Lease the drug license** to another company to market
- **Sales and marketing, life cycle management**
  - Price changes, price concessions, patient assistance
- **Regulated @ federal level**
  - States may license manufacturers whose drugs are sold in-state

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Who Does What? Wholesalers

- **Buy in large quantity** from manufacturers
  - Manufacturers can create 'tie-ins' buy all products direct from manufacturer
- **Store Rx**
- **Sell and Ship**
  - to very large purchasers
  - to regional distributors
  - to large pharmacies (local distributors)
- **A wholesaler can have several roles**
  - Specialty Pharmacy – on behalf of manufacturers or health plans for distribution of specialty drugs
  - Pharmacy Services Administration Organization (PSAO)
- **Regulated by States and Federal Food and Drug Administration (FDA)**

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Who Does What? PBMs (or Insurers without PBM)

- **Create pharmacy networks**
  - Negotiate pharmacy professional (or dispensing) fees
  - Set drug reimbursement amounts
  - Operate mail order pharmacy
- **Operate formulary**
  - Small plans take PBM national formularies, large plans may design their own
  - Negotiate manufacturer rebates based on formulary placement
  - Decide on pharmacy utilization management strategies
- **Claims payment**
  - Reimburse pharmacies and providers for drugs dispensed or administered
  - Bill insurer/client for Rx claims reimbursement
- **Collect manufacturer price concessions** based on paid Rx claims
- **Not all states license PBMs**

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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 managing manufacturer rebates
    - Need to negotiate with pharmacies and create 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 which are federally regulated)

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Who Does What? Pharmacies

- **Retail pharmacies** – open to public
  - Purchase drugs from wholesalers and distributors
  - May hire administrative services companies to handle claims wrangling and group purchase negotiations (PSAOs, see next slide)
  - Counsel patients
  - Can't drive brand name market share but can drive generic market share
- **Specialty pharmacies** – not open to public
  - May contract with manufacturers to handle specific 'specialty' drugs
  - May work with administering providers to get product to offices as needed
  - May provide case management for patients
  - May provide administrative assistance to administering providers (handling, billing etc.)
- **Licensed by States and somewhat by Federal programs** in which they participate

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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

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PSAO Ownership

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

Potential Areas of Focus

Key Issues in Pharmaceutical Market

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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, HIV).

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More Treatments Get Expedited Review/Less Data

- **FDA fast track/reduced data approval paths 2018 ~56 NME Rx**
  - 13 – Breakthrough – substantial treatment improvement
  - 42 – Priority Review – FDA decision within 6 months
  - 24– Fast track – Rx treats serious conditions with unmet medical need
  - 4 – Accelerated Approval – serious medical condition with unmet medical need using surrogate clinical trial endpoints
  - 31 – Orphan Drug – treats patient populations of <200,000 people
- **Expedited drug products may then be used for additional illnesses, but pricing remains the same**

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Key Policy Issues in Rx Supply and Financing

Insurer	PBM	Manufacturer	Provider
• Insurer mergers • Insurer/PBM mergers • Rise of costly breakthrough/fast track drugs on patient costs and access • All the price-protected programs (Medicaid, CA, 340B, Medicare Part D) limit commercial insurer price negotiation ability	• PBM/chain drugstore mergers • Treatment of independent pharmacies • How rebates are used • Lack of transparency/transparency laws	• Corporate mergers • Focus on oncology and rare diseases (high-priced biologics) • Profits from price and price increases rather than sales • Gross to net bubble • Patent extensions	• 340B program creates market inequities between eligible providers and ineligible providers • 340B program driving some provider consolidation

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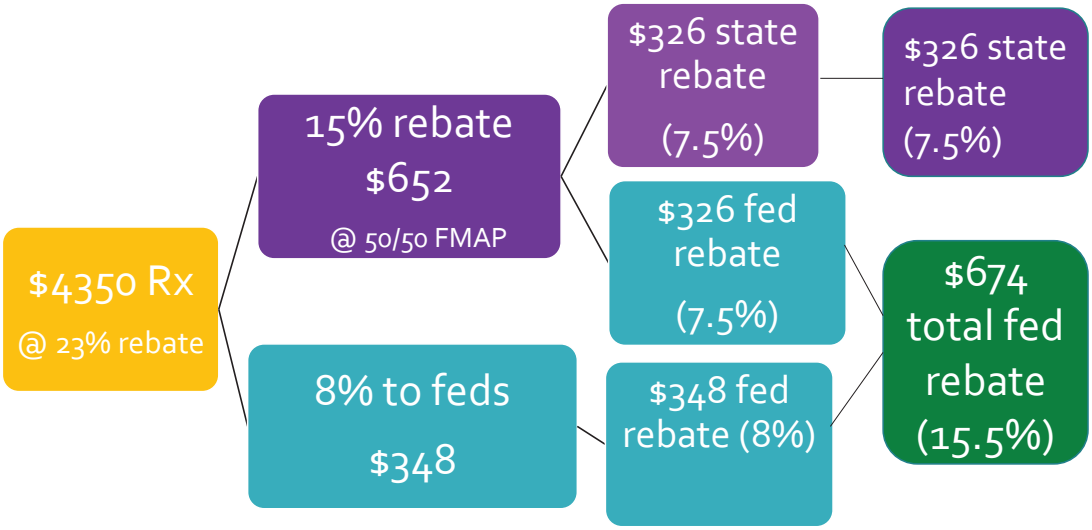
Medicaid Rebates Complicate Policy



(FMAP of 50%, no best price, no CPI penalty in this example)

States tend to think that there is too much $$ at stake for Medicaid to work with other state agencies in joint Rx purchase

State MDRP experimentation has high federal score thus barrier to law changes. CBO assumes joint purchase/waiver of BP experiments undermine 'best price' & federal revenues. Federal share of rebates also affects 1115 waiver federal budget neutrality math.

Horvath Health Policy, *Innovations in Healthcare Financing Policy*

Thank You!

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State and Federal Action Addressing Prescription Drug Access and Affordability

Wisconsin Governor's Task Force on Reducing Prescription Drug Prices

National Governors Association
November 20, 2019

Agenda

01 Overview of State Action

02 Legal Challenges to State Action

03 Overview of Federal Action

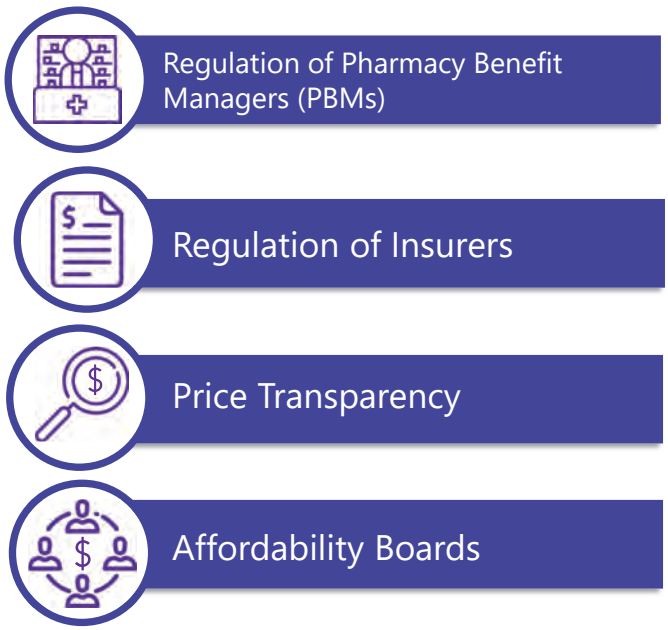
04 Overview of Industry Action

Overview of State Action

NATIONAL GOVERNORS ASSOCIATION

Strategies Across Markets

States are pursuing a variety of strategies that have broad impact on pharmaceuticals access and costs across public, commercial, and self-insured markets:



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Regulation of Pharmacy Benefit Managers (PBMs)

Regulation of PBMs has been the most prominent areas of action across states in recent years (40 bills addressing PBMs have been enacted in 2019 across 27 states):

- Prohibiting gag clauses in pharmacy contracts
- Imposing stronger disclosure and reporting requirements for PBMs
- Requiring PBMs to obtain licensure from the state
- Requiring PBMs to act as a fiduciary
- Regulating or prohibiting spread pricing
- Requiring that rebates and discounts received from manufacturers be fully passed on to the insurer
- Ensuring fair auditing of pharmacies by PBMs
- Prohibiting pharmacy copay clawbacks
- Regulating PBMs Maximum Allowable Cost (or MAC) lists
- Prohibiting PBMs from exclusively requiring mail-order pharmacies

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Regulation of Insurers

States are pursuing a variety of approaches to regulate insurer benefit design and limit consumer cost sharing (32 bills addressing insurance design have been enacted in 2019 across 24 states):

- Restrict charging more than retail price at the point of sale
- Cap copayments for select drugs or drug classes
- Limit coinsurance percentage for specialty tier drugs
- Require prorated daily cost sharing rates for drugs dispensed by network pharmacies
- Limit the number of tiers on a formulary
- Establish step therapy protocol and override processes
- Restrict mid-year formulary changes, with certain exceptions

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Price Transparency

Transparency has been a big focus in recent years regarding both drug prices (launch and increases) and PBM behavior (gag clauses and spread pricing):

- 2017 – 2019, 121 bills introduced across 33 states; 17 bills enacted across 11 states
- Transparency has also been implemented in conjunction with other strategies in some states (e.g., MA, NY)

Price transparency laws have typically included the following elements:

- Require manufacturers to report on and provide justification for drug launch prices and price increases over a certain threshold
- Require health plans to report on which drugs are driving plan spending
- Impose penalties for failure to report
- Publicize information (California, Nevada, Vermont have all released initial reports)

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Affordability Boards

To address prices directly, several states have introduced and a few (Maine Maryland and Ohio) have enacted laws to establish authorities to review drug pricing and affordability:

- Boards or commissions tasked with reviewing and making recommendations regarding pricing, purchasing, and affordability challenges and opportunities in a state
- The charge and authority of affordability boards vary slightly across states
- In some states, these boards would have authority to set “allowable rates” for certain drugs

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State Example: Massachusetts

Massachusetts recently introduced comprehensive health care legislation, which includes provisions related to pharmaceuticals:

- Creates a multi-pronged approach for increasing accountability for drug manufacturers
  - Subjects manufacturers of new, high-cost drugs to accountability reviews similar to existing processes for insurers and providers
  - Imposes a penalty on manufacturers that exponentially increase the cost of drugs which are sold or distributed in the Commonwealth

- Aims to increase state oversight of pharmacy benefit managers
  - Establishes a PBM certification requirement within the Division of Insurance
  - Requires PBMs to report financial data to increase transparency

NGA

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Strategies for Public Programs

In addition to broader market strategies, states have been very active in advancing strategies to improve purchasing and manage access and costs for public programs:

Pharmacy Benefit Management	PBM Contracting	Reverse Auction Procurement	340B Oversight
340B for Corrections	Alternative Payment Approaches	Affordability Approaches	Multi-Agency Purchasing

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Legal Challenges to State Action

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Manufacturer Challenges

- Primarily related to state efforts to address price transparency and price gouging
- Alleged violations of trade secret laws, dormant commerce clause, due process, free speech laws, and federal patent laws
  - Alleged violations of trade secret laws are most compelling

State Examples

California

Lawsuit against California (PhRMA v Brown) is ongoing (lawsuit was dismissed in 2018 then amended and allowed to proceed in 2019)

Nevada

Lawsuit against Nevada (PhRMA and BIO v Sandoval) was dropped after state agreed to trade secret protection regulations

Maryland

Federal appeals court struck down Maryland's law ruling that it violates the dormant commerce (AAM v Frosh)

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PBM Challenges

- Primarily related to state efforts to address transparency and disclosures, fiduciary duty, and MAC pricing
- Largely focused on alleged violations of ERISA preemption
  - Challenges have also included alleged violations to the dormant commerce clause, contract clause (Art 1, Sec. 10), Medicare Part D preemption, takings (5th amendment) and void for vagueness

State Examples

- The Pharmaceutical Care Management Association (PCMA) has challenged 5 state laws regulating PBMs and won three of those challenges (District of Columbia, Iowa, Arkansas)
- Thirty-three states filed an amicus brief with the Supreme Court, detailing that the Eighth Circuit rulings are not consistent with Supreme Court rulings on state authority to regulate payment rates and protect residents.

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How Legal Challenges Affect State Policy

PBMs

- Inconsistent rulings raise questions but have not limited activity
- States can mitigate risk by avoiding explicit reference to "ERISA" in legislation and clarifying that nothing is intended to conflict with existing law

Price Gouging

- Price gouging legislation limited to generics and off-patent brands in response to DC Circuit ruling on supremacy clause/patent law
- But then the 4th circuit found that limiting price gouging to generics was not fair

Affordability Boards

- New legislation has been more limited to state/local government purchasers and payers
- Such limitations protect a state from a dormant commerce clause lawsuit, but undermine the intent and effectiveness of the boards

NGA

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Overview of Federal Action

Federal Action – 116th Congress

- Over 20 hearings
  - Senate: Finance, Health Education Labor and Pensions (HELP), Judiciary, Aging
  - House: Energy and Commerce, Ways and Means, Oversight and Reform

- Over 130 bills have been introduced this Congress
  - At least 60 bills have bipartisan support and approximately 20 of those have support in both chambers
  - Bipartisan bills include those focused on:
    - Generic and biosimilar development (CREATES Act, FAST Act)
    - Pay-for-delay/anti-competitive behavior (Preserve Access to Affordable Generics and Biosimilars Act)
    - Patents and transparency (FAIR Drug Pricing Act, Biologic Patent Transparency Act, Prescription Drug Price Transparency Act, BLOCKING Act)
    - Importation (Safe and Affordable Drugs from Canada Act 2019)

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Federal Action – Bills to Watch

- **S.2543 - Prescription Drug Pricing Reduction Act of 2019**, sponsored by Sen. Chuck Grassley (R-IA)
  - Major ***Medicare*** provisions
    - Impose an inflationary rebate on Part B and Part D drugs
    - Establish a maximum add-on payment for Part B drugs
    - Establish a beneficiary out of pocket maximum for Part D drugs
    - Shift risk during the catastrophic phase to plans and manufacturers
    - Establish new reporting and transparency requirements
  - Major ***Medicaid*** provisions
    - Raise cap on rebates from 100 to 125 percent of the Average Manufacturer Price (AMP)
    - Exclude authorized generics from the calculation of AMP
    - Enable collection of rebates on certain drugs provided as part of outpatient hospital services
    - Prohibit spread pricing by pharmacy benefit managers
    - Permit value based purchasing arrangements for gene therapies
    - Create new standards related to reporting and conflicts of interest

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Federal Action – Bills to Watch

- **S.1895 - Lower Health Care Costs Act**, sponsored by Sen. Lamar Alexander (R-TN) and Sen. Patty Murray (D-WA)
  - Broad package addressing health care costs that includes provisions on pharmaceuticals, such as:
    - Allowing certain generic or biosimilar drugs to enter the market earlier
    - Imposing new rules for insurers' contracts with pharmacy benefit managers and health care providers
    - Imposing new transparency requirements
- **S.1391 - Fair Accountability and Innovative Research Drug Pricing Act of 2019**, sponsored by Sen. Baldwin (D-WI)
  - Reporting and justification for certain drug price increases
- **H.R. 3 - Lower Drug Costs Now Act of 2019**, sponsored by Rep. Frank Pallone (D-NJ)
  - Would establish price negotiation for certain drugs in Medicare
  - Negotiated prices must also be offered under private health insurance unless insurers opt out
  - The negotiated maximum price may not exceed an international benchmark
  - Drug manufacturers that fail to comply would be subject to civil and tax penalties

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Federal Action – Administration

? **International Pricing Index:** Advance notice of proposed rulemaking issued in October 2018 to set target sales prices for certain Medicare Part B drugs using an international benchmark based on prices in select foreign countries.

? **Importation**: Safe importation action plan was announced in July

- Pathway 1: HHS will outline a process for states, wholesalers, or pharmacists to submit plans for approval of demonstration projects to import drugs from Canada
- Pathway 2: Would allow manufacturers to import versions of their drugs sold in other countries if they can ensure it is the same version sold in the U.S. and meet other requirements.

X **Pricing in Television Advertisements**: A rule requiring drug price disclosure in television advertisements was blocked in federal court in July, the U.S. Department of Health and Human Services (HHS) filed a notice of appeal in August.

X **Safe Harbor Proposed Rule**: A proposed rule that would have eliminated safe harbor protection for drug rebates for Medicare Part D plans and Medicaid managed care organizations was withdrawn in July

Overview of Industry Action

Consolidation

Recent Mergers and Acquisitions

Insurers, PBMs, and Pharmacies
- Aetna/CVS
- Cigna/Express Scripts
- Anthem/IngenioRx

Manufacturers
- Takeda/Shire
- BMS/Celgene
- Eli Lilly/ Loxo Oncology

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New and Existing High-Cost Drugs

- Price Increases
  - The costs of oral and injectable brand-name drugs increased annually by 9.2 percent and 15.1 percent, respectively, largely driven by existing drugs
- Pipeline/New Specialty
  - Late stage pipeline growth is mostly driven by specialty and niche therapies across a range of diseases
    - Oncology leads new launches
  - The prices of new drugs entering the market continue to rise, especially for oncology and orphan drugs
- Notable Products Highlight Challenges
  - Naloxone – opioid overdose reversal
  - Insulin - diabetes
  - Zolgensma – spinal muscular atrophy

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GOVERNOR'S TASK FORCE ON REDUCING PRESCRIPTION DRUG PRICES

January 22, 2020
10:00 a.m. – 2:00 p.m.
Milwaukee Area Technical College
Room S120

I. **Welcome/November Meeting Minutes/2019 Task Force Report/2020 Workplan (10 minutes)**
Nathan Houdek, *Deputy Commissioner, Office of the Commissioner of Insurance*

II. **ETF Pharmacy Committee Update (5 minutes)**
Brian Stamm, *Deputy Director, ETF Office of Strategic Health Policy*

III. **Pharmacy Benefit Manager Economics (90 minutes)**
Neeraj Sood, PhD, *Professor and Vice Dean for Faculty Affairs & Research, USC Price School of Public Policy & USC Schaeffer Center*

IV. **Lunch (25 minutes)**

V. **IngenioRx (30 minutes)**
Robert Gallé, *Chief Operating Officer*

VI. **Navitus Health Solutions (30 minutes)**
Brent Eberle, *Senior Vice President and Chief Pharmacy Officer*

VII. **Task Force Member Discussion (50 minutes)**

VIII. **Adjourn**

Meeting Minutes
January 22, 2020
10:00 a.m. – 2:00 p.m.
Milwaukee Area Technical College
700 W State Street, Milwaukee

Task Force Members Present: Nathan Houdek, Anna Benton, Josh Bindl, Sen. Tim Carpenter, Brent Eberle, Tony Fields, Peter Fotos, Janet Fritsch, Michael Goldrosen, Ian Hedges, Nathan Houdek, Lisa Lamkins, Alan Lukazewski (via phone), Laura McFarlane, Robyn Schumacher, Brian Stamm, Brian Stephens, Rep. Lisa Subeck, Lara Sutherlin, Yolanda Tolson, Rep. Tyler Vorpagel, Sue Wilhelm

OCI Staff Present: Jennifer Stegall, Olivia Hwang, Julie Walsh, Megan Aubihl, Jessica Carlson

Public Attendees: Karla Ashenhurst, Mollie Zito, Alex Moe, Sean Kirkby, Nancy McKee, Ramie Zelenkova, Matt McGovern, Larry Lewis

Welcome
Nathan Houdek, OCI Deputy Commissioner and Task Force chair

- Mr. Houdek welcomed Task Force members and public attendees
- Key housekeeping items:
  - Task Force on Reducing Prescription Drug Prices website is live
    - https://rxdrugtaskforce.wi.gov/Pages/Home.aspx
  - November meeting minutes are posted to the Task Force website
    - https://rxdrugtaskforce.wi.gov/Pages/Meetings/MeetingMinutes.aspx
  - 2019 Task Force report was submitted to the Governor and is available on the Task Force website
    - https://rxdrugtaskforce.wi.gov/Documents/122019RxTaskForceReport.pdf
  - 2020 Workplan is available on the Task Force website
    - https://rxdrugtaskforce.wi.gov/Documents/2020Workplan.pdf
  - June meeting will be held Thursday, June 18

ETF Pharmacy Committee Update
Brian Stamm, Deputy Director, ETF Office of Strategic Health Policy

- Mr. Stamm gave an overview and update of the Wisconsin Pharmacy Cost Committee
- ETF was awarded a technical assistance grant from the National Governors Association to develop strategies for saving state dollars on prescription drugs in partnership with other State of Wisconsin agencies.
- Currently working on:
  - Pool/bulk purchasing
  - 340B drug pricing program specifically with the Department of Corrections
  - Specialty drug site of care (can be administered in multiple sites of care) – trying to determine which locations are most and least expensive

Pharmacy Benefit Manager Economics
Neeraj Sood, PhD, Professor and Vice Dean for Faculty Affairs and Research, USC Price School of Public Policy & USC Schaeffer Center

Dr. Sood delivered a presentation focused on two main topics:

1. PBM economics
2. Subscription models for prescription drugs

Dr. Sood's presentation is available on the Task Force website
https://rxdrugtaskforce.wi.gov/Documents/PBMPresentation_1_22_20.pdf

Task Force members took particular interest in the data on slide 12 of the presentation that indicates, "Of $100 spent on drugs, $42 goes to PBMs, wholesalers, pharmacies, and insurers." The study where that data comes from can be found here:
https://healthpolicy.usc.edu/wp-content/uploads/2017/06/USC_Flow-of-MoneyWhitePaper_Final_Spreads.pdf

Transparency and the challenges in understanding which entity in the supply chain is making the most money on a particular drug was an issue of interest.

The concept of a "subscription model" used in Louisiana as a means to address Hepatitis C was discussed, as well as challenges in translating that model to the commercial market with the Medicaid best price rules in place.

IngenioRx Overview
Rob Gallé, PhD, Chief Operating Officer

Mr. Gallé gave an overview of IngenioRx and their vision for a "whole-health approach," transparency and collaborative relationships.

The IngenioRx presentation is available on the Task Force website.
https://rxdrugtaskforce.wi.gov/Documents/PBMPresentation_1_22_20.pdf

Navitus Pharmacy Benefits
Brent Eberle, RPh MBA, Senior Vice President, Chief Pharmacy Officer

Mr. Eberle provided an overview of Navitus; explained the four major areas of PBM business; discussed pharmacy audits; and reviewed legislative activity impacting PBMs in Wisconsin and other states. Additionally, Eberle gave a brief description of Civica, a non-stock, non-profit corporation developed to address shortages of generic drugs while lowering costs.

Eberle's presentation is available on the Task Force website.
https://rxdrugtaskforce.wi.gov/Documents/PBMPresentation_1_22_20.pdf

Task Force Member Discussion
Task Force members shared their thoughts on topics covered during the presentations as well as highlighted issues of interest for future meetings.

Issues raised and Task Force member comments are below. (*Note: these reflect a summary of member comments; not all comments reflect the views of all Task Force members)*

- Direct and Indirect Renumeration (DIR) fees and an interest in understanding the extent to which PBMs are imposing these.
- Contractual agreements between pharmacists and PBMs are not give-and-take negotiations. PBMs set the terms and pharmacies determine whether they can follow them as a condition of being included in the network.
- Flow of dollars and the extent each entity is making a profit within the supply chain was an interesting discussion point from Dr. Sood's presentation.
- Legislative proposals prohibiting certain PBM related practices in the area of pricing, networks and pharmacy audits, and requiring new transparency requirements continues to be an area of interest.
- Per member/per month cost of prescription drugs is of interest.
- Direct manufacturer to consumer marketing is of concern; inflates prices to the consumer so would be interested in understanding more about that marketing.
- Important for the Task Force to include recommendations that lower the cost of prescription drugs for the consumer; even $15 at the counter is very real and matters to the consumer.
- Subscription model is interesting; Medicaid best price rules are an obstacle.
- There may be some duplication in what insurers and PBMs are doing so this may be an area to look at.
- Would like to continue the review of all members of the supply chain before prioritizing what needs to be taken on by the Task Force.
- PBMs serve an important role.

Adjourn
Deputy Commissioner Houdek thanked the Task Force members for their participation and reminded the group that the PBM discussion will continue at the February 18 meeting in Oshkosh. He indicated that insurer and employer issues will also be discussed at that meeting.

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Leonard D. Schaeffer Center for Health Policy & Economics

USC Price
Sol Price School of Public Policy

PBM Economics and New Pricing Models

Neeraj Sood, PhD
Vice Dean for Research and Professor,
USC Price School of Public Policy & USC Schaeffer Center

January 22, 2020
Governor's Task Force on Reducing Prescription Drug Prices
Milwaukee, WI

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PBM Economics and New Models

1. PBM economics

- **What is the role of PBMs in the pharmaceutical supply chain?**
- **How well is the PBM market functioning?**
- **Potential policy solutions**

2. Subscription models for prescription drugs

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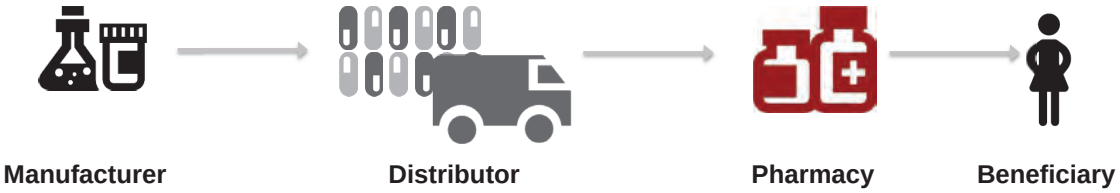
Flow of prescription drugs



PBMs are true middle men, they play no role in the physical distribution of prescription drugs to consumers

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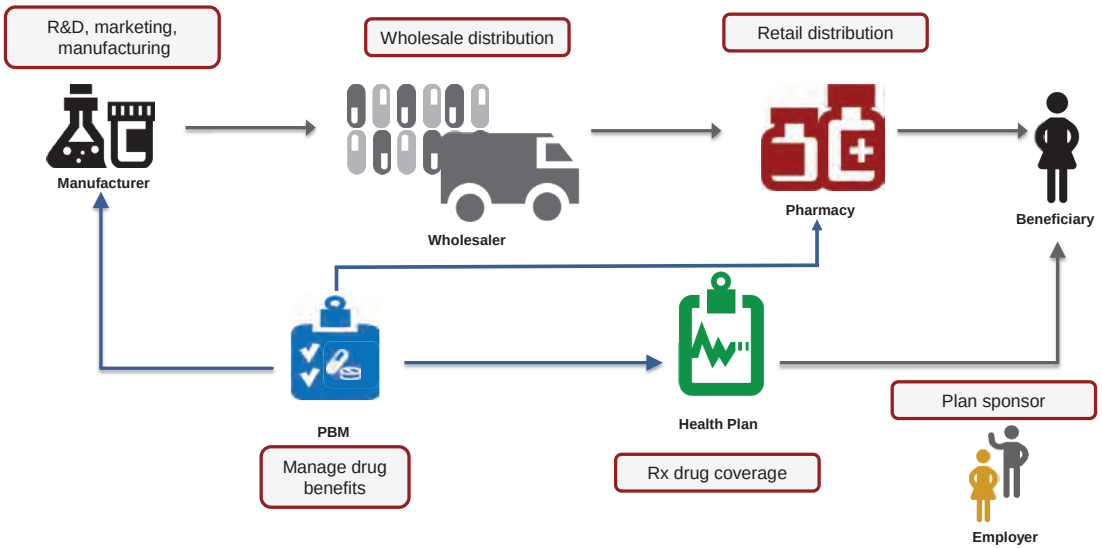
Flow of services



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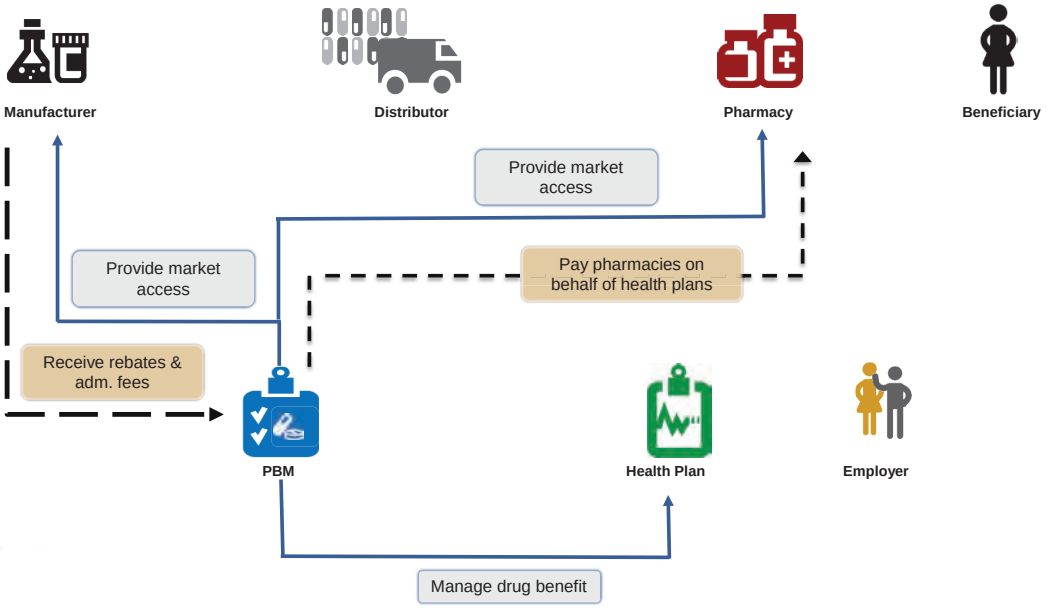
PBM relationship with other supply chain participants



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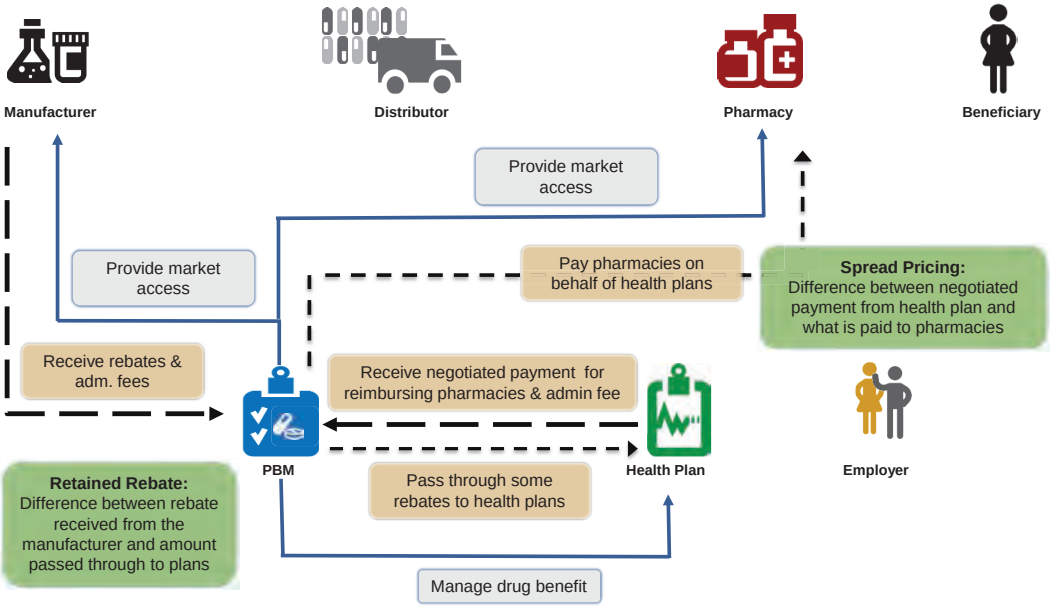
How do PBMs make money?



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PBM Economics

- What is the role of PBMs in the pharmaceutical supply chain
- How well is the PBM market functioning?
- Potential policy solutions

8

Trickle down rebates …

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Buying a house:

- Sally is considering buying a house.
- Her real estate agent is John.
- John negotiates with the seller a $10,000 reduction in the price of the house.
- Sally pays $10,000 less for the house.

Scenario:

- She now has two agents: John & Joe
- John negotiates a $10,000 discount from the seller. The amount is **secret and not disclosed**. He keeps some of the money and passes the rest to Joe.
- Joe keeps some of the **undisclosed** money received from John and passes the rest to Sally.
- How much of the $10,000 did Sally receive?

9

Lack of transparency means consumers might not benefit from higher rebates

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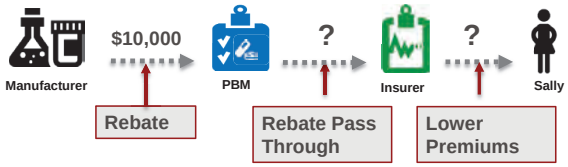

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Rebates misalign incentives: Not choosing cheaper drugs

	PBMs keeps	Cost to health plans	Cost to consumers?
Drug A Retail Price: $200 • rebate of $50	$5 ✓	$155	
Drug B Retail Price: $100 • rebate of $30	$3	$73 ✓	✓ **Uninsured** might pay list price ✓ **Insured consumers below deductible** might pay list price ✓ **Insured** may pay higher premiums

Assume retail and wholesale mark-up is 10%; PBM keeps 10% of rebate

11

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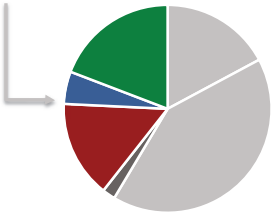
Lack of competition in the supply chain

- Highly concentrated supply chain with few key players controlling large market shares

CVS Health EXPRESS SCRIPTS OPTUMRx

  - Top 3 PBMs account for roughly 75% of covered lives
  - Wholesale, pharmacy and insurer markets are also highly concentrated
  - Of $100 spent on drugs, $42 goes to PBMs, wholesalers, pharmacies, and insurers.



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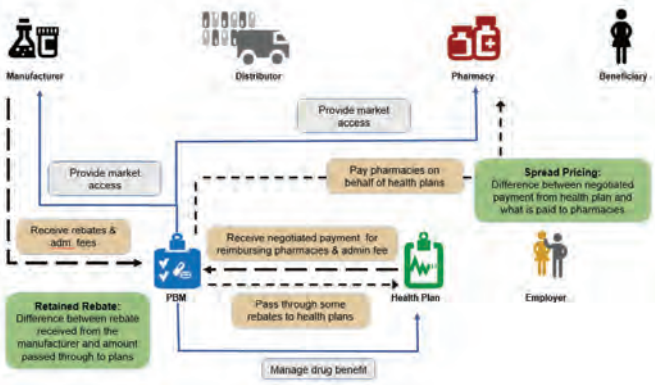
Consolidated PBM markets means higher costs for consumers

- Dominant PBMs might negotiate higher rebates but not pass rebates to health plans
- Dominant PBMs might engage in excessive “spread pricing”



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New wave of vertical consolidation in pharma supply chain might further curtail competition

- Misaligned incentives
  - A PBM that owns a pharmacy might favor its own pharmacy even if rival pharmacies have lower costs
  - A PBM that owns a health plan might try to increase drug costs of rival health plans
- Barriers to entry
  - Need to entry several distinct supply chain markets to effectively compete in the market

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PBM Economics

- **What is the role of PBMs in the pharmaceutical supply chain**
- **How well is the PBM market functioning?**
- **Potential policy solutions**

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Recommendation one:
Improve drug price transparency throughout the supply chain

- Improve drug price transparency throughout the supply chain by following the flow of money for “tracer” drugs.
- Tracer drugs are:
  - Those that account for significant fraction of state/federal spending on drugs
  - Those that have experienced significant increase in list price
- Any firm (manufacturer, wholesaler, PBM, pharmacy etc) that does not participate cannot get state/federal funding

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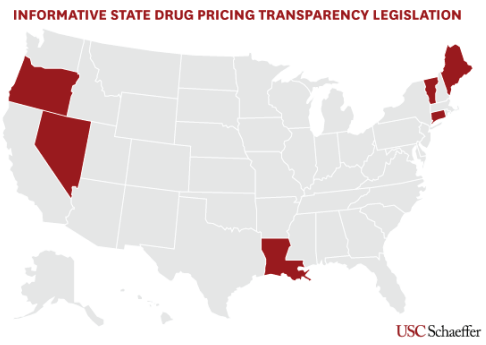
Evaluation of recent state policies show limited improvement in transparency

166 drug pricing bills identified between 2015 and 2018

35 bills passed in 22 states included a transparency component

7 bills were **“informative”**

Informative: reveals previously unavailable information in the form of profits or real transaction prices for supply chain participants



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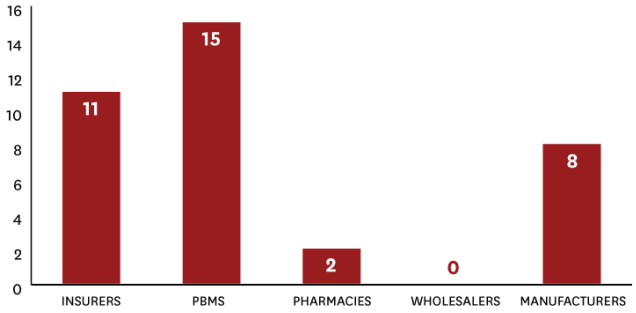
No state targeted all five of the distribution entities

- Vermont requires that insurers report net price
- Maine requires that manufacturers report net price
- Oregon and Nevada require manufacturers report profits
- Connecticut, Louisiana, and Nevada require PBMs report rebates in aggregate (not at the drug level)
- **No state passed laws that together revealed true transaction prices or profits across the system**

Figure 4: Number of States Targeting Each Entity Through Transparency Legislation



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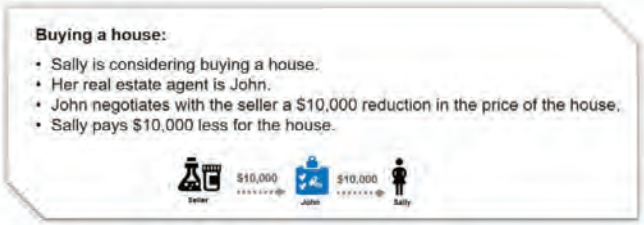
Recommendation two:
Move from a rebate system to a discounts model

- Discount model ensures that price reductions are passed to health plans and consumers
- Discount model better aligns incentives of payers and consumers



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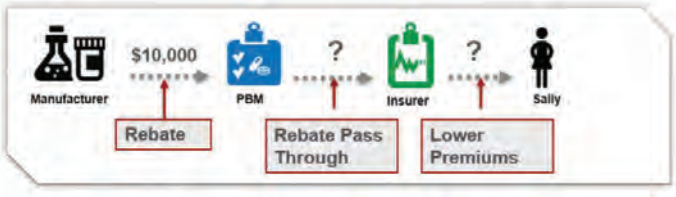
Recommendation three:
Mandate pass-through of rebate to consumers

- Ensures that consumers get the benefits of rebates
- More equitable as sick consumers using drugs are not subsidizing healthy consumers not using drugs



Example:

- Louisiana prohibits PBMs from retaining any rebates or spread pricing if the LA Dept. of Health chooses to not carve out pharmacy services
- New York and Ohio have made recommendations

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Recommendation four:
Outlaw unfair business practices of PBMs

- Limits to spread pricing
- Minimum rebate pass through
- Limits to favorable pricing for affiliated business units such as health plans and pharmacies

Example:

- In some states PBMs can't require use of mail order pharmacies (ostensibly their own)

- More could be done

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Recommendation five:
Reduce barriers to entry in the PBM market

- I do not know how to do this, but it is a good idea!

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PBM Economics and New Models

1. PBM economics

- **What is the role of PBMs in the pharmaceutical supply chain?**
- **How well is the PBM market functioning?**
- **Potential policy solutions**

2. Subscription models for prescription drugs

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My journey into subscription models started in 2015

It was motivated by three facts:

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Fact 1: **According to the CDC 20,000 people die from hepatitis C in the US each year**

More than the combined death toll from 60 other infectious diseases including HIV

More than 6 times the death toll from 9/11

The high death toll would be understandable if there was no cure for the disease

25

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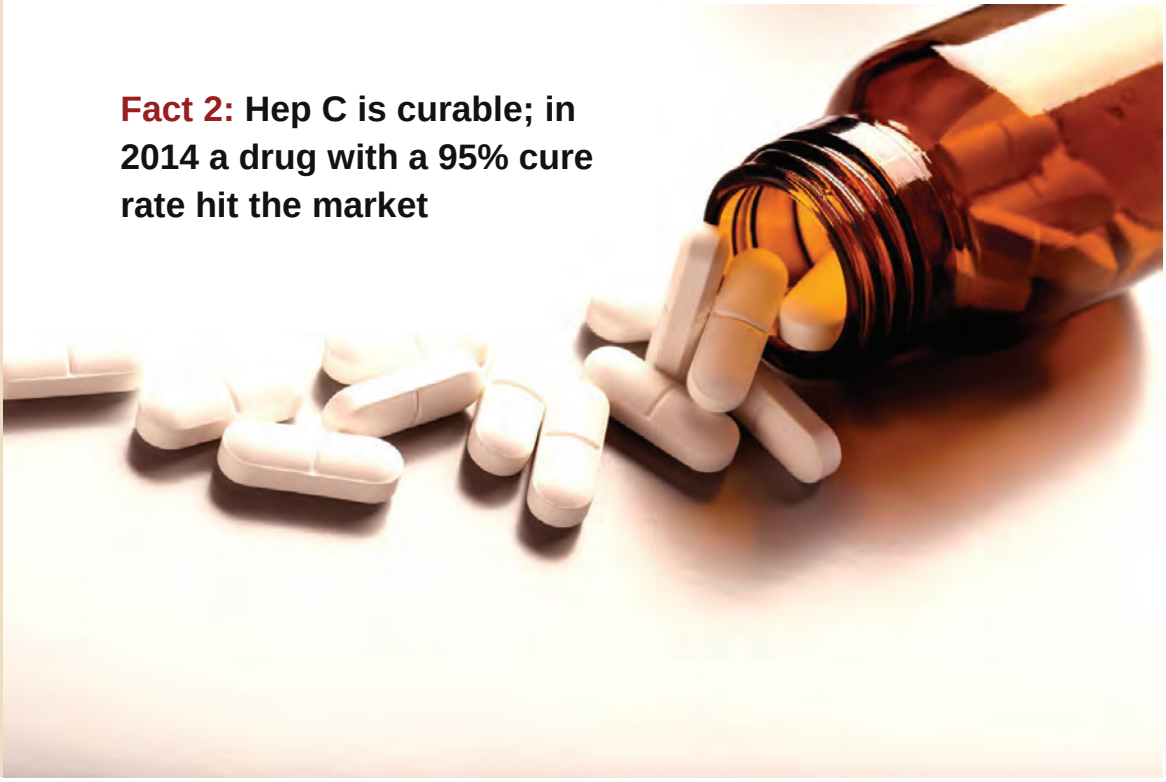
Fact 2: **Hep C is curable; in 2014 a drug with a 95% cure rate hit the market**



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Fact 3: **Populations that are most vulnerable have the least access…**

Less than 3 in 100

Medicaid beneficiaries have received the cure.

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Fact 3: Populations that are most vulnerable have the least access…

Less than 1 in 100

Prison inmates have received the cure.

28

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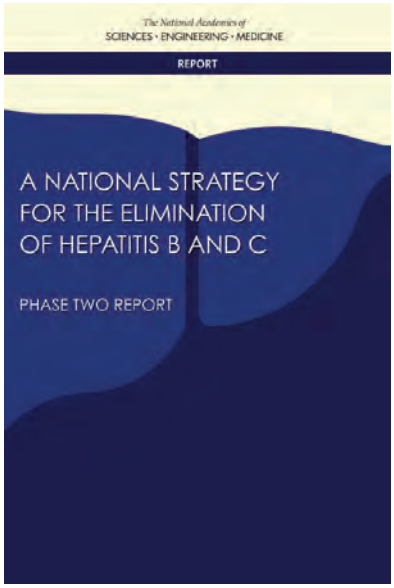
The National Academies of Science proposed a subscription model for Hep C cures in 2017



Key points of National Academies recommendation:

1. Voluntary transaction between companies producing Hep C cures and the federal government
2. The federal government would make a lump sum payment to one company
3. In return, the company would make the cure available free of cost to under served markets such as Medicaid, Indian Health Service and Prisons

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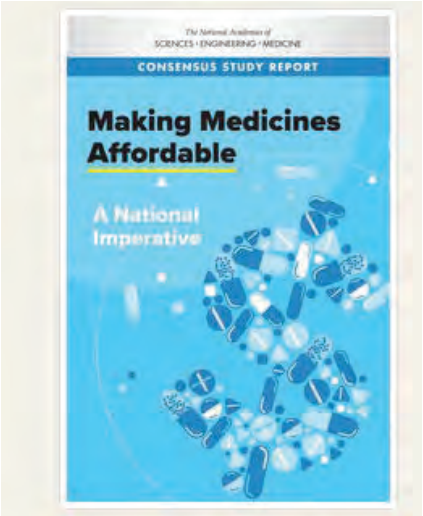
Louisiana is the first state to implement the subscription model



Four other states have also received CMS approval

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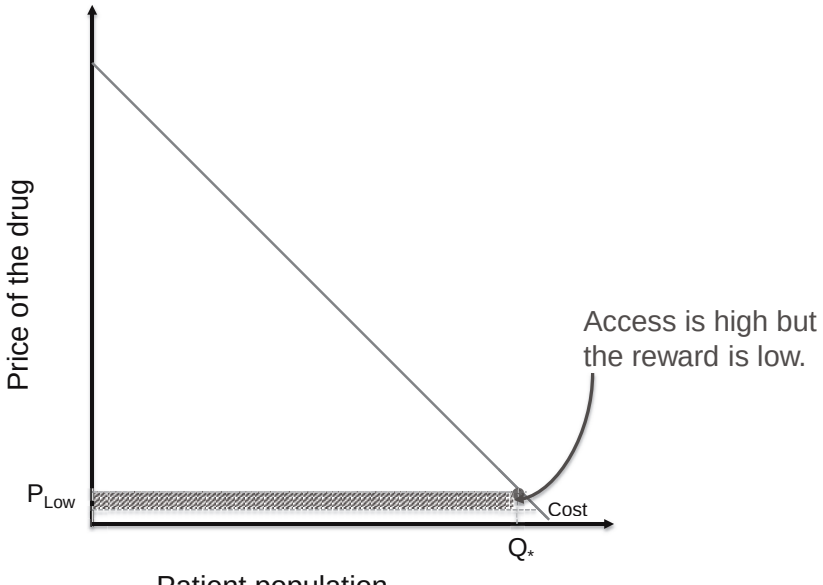
Low prices promote access but do not reward innovation



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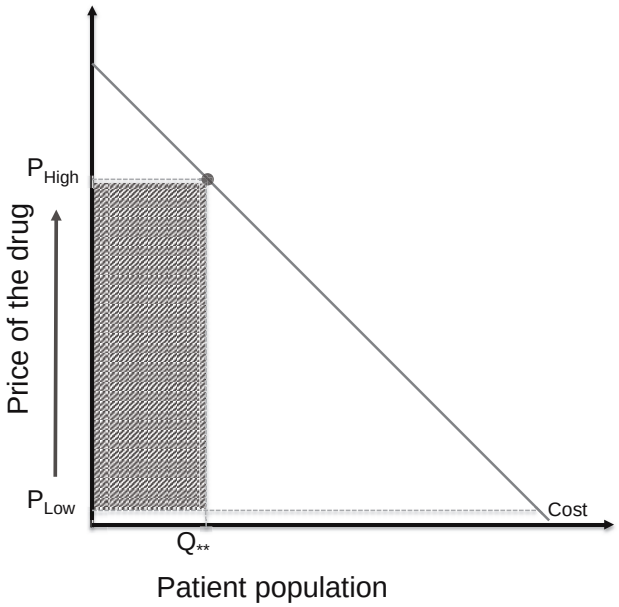
Firms set high prices to make money



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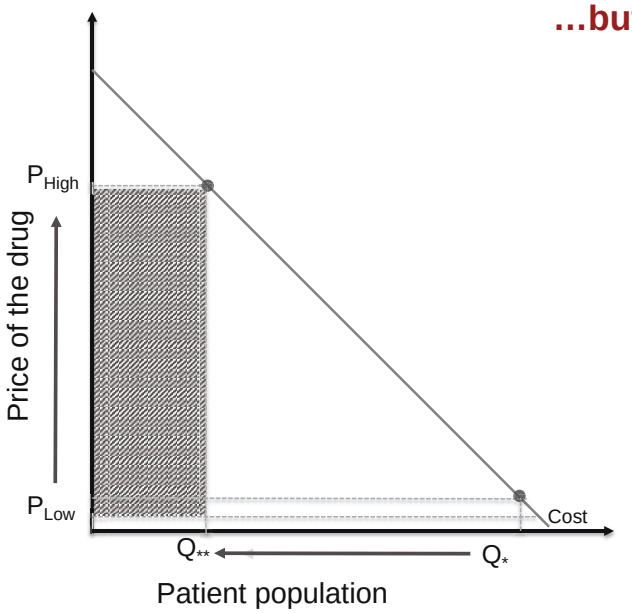
Firms set high prices to make money

…but it limits access



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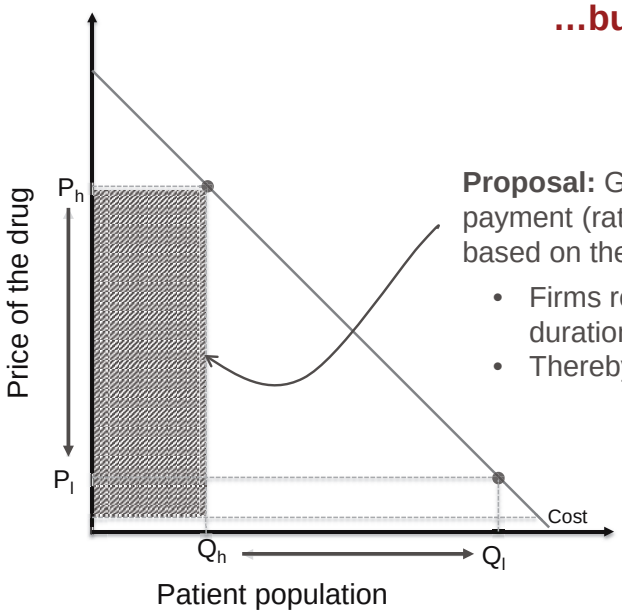
Firms set high prices to make money

…but it limits access



Proposal: Give firms an upfront payment (rather than price) that is based on their expected revenue

- Firms reduce price for contract duration
- Thereby increasing access

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For example

6000 Medicaid patients receive treatment yearly

3 Pharma companies

$40,000 negotiated price

4000 patients get drug A = **$160 Million**

1000 patients get drug B = **$40 Million**

1000 patients get drug C = **$40 Million**

Total cost to the state and federal government: **$240 Million**

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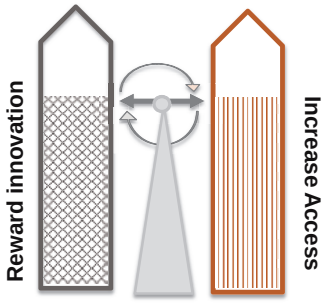
State negotiates with one company on expected revenue instead of price per treatment

$200 Million for one year

Company perspective: **$200M > $160M**

State perspective: **$200M < $240M**



Significantly more patients receive treatment

Incentive to innovate is maintained

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Subscription model is not the same as volume-based discounts

	Subscription model	Modified subscription model	Volume-based discounts model
Description →	Pay a fixed upfront fee for unlimited supply	Pay a fixed price per treatment up to a cap; zero after cap is reached	Price per treatment decrease with volume
Requires upfront payment	Yes ✓	No ✗	No ✗
Marginal cost to payer of treating additional person	0	+ before cap; 0 after cap	+
IMPLICATIONS			
Manufacturer assured fixed revenue	Yes ✓	No ✗	No ✗
Lowest cost for eliminating Hep C	Yes ✓	No ✗	No ✗
Incentive to treat additional people	Maximum	Increases w/volume; Maximum after cap	Increases w/volume
Cost to state with status quo	High	Low	Low

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Can the subscription model work in other markets?

- **Can it work in other states?**
  - Yes, but need the right leadership
  - Need partnership with CMS (Washington, Oklahoma, Michigan, and Colorado are prime examples)
  - Need to make commitment to expand testing and linkage to care
  - Need to steer demand for preferred drug

- **Can it work in the commercial insurance market**
  - Yes, only if we change Medicaid best price rules

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Can the subscription model work for other drugs?

- **Yes, if the following conditions hold**
  1. There is an access problem with status quo pricing model
     - Significant fraction of patients who can clinically benefit from the drug cannot afford the drug even with insurance
  2. The scope for moral hazard is minimal
     - The risk of inappropriate use is minimal even with zero price or copay
  3. There is some competition with several potentially substitutable products

- **For example, insulin meets all these conditions**

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Policy recommendations

- **Make it easier for states to implement the model in Medicaid**
  - Provide technical and monetary resources to implement the model
  - CMS should streamline review
  - Change regulations and laws so that a waiver is not required

- **Change Medicaid best price rules to make an exception for subscription models**

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USC Price
Sol Price School of Public Policy

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Neeraj Sood
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STATE OF WISCONSIN

GOVERNOR'S TASK FORCE ON REDUCING PRESCRIPTION DRUG PRICES

Contact information:
Email: OCIRXDrugTaskForce@wisconsin.gov
Website: RxDrugTaskForce.WI.gov

The market is looking for a better path forward.

Long considered one of the most cost-effective tools in health care, many now view pharmacy care as a runaway train of escalating costs fueled by misaligned incentives.

Our mission is to help our clients and members reclaim the power of pharmacy

As a fully-scaled pharmacy benefits manager (PBM), IngenioRx will deliver the full capabilities of a traditional PBM wrapped in a bold vision to demystify pharmacy and maximize whole health.

Restoring trust and confidence.

Introducing IngenioRx

A new company with an established pedigree

>$18B
pharmacy spend managed annually

#1
Anthem's average C-Sat rating by NCQA[1]

≈1 in 8
Americans are Anthem members[2]

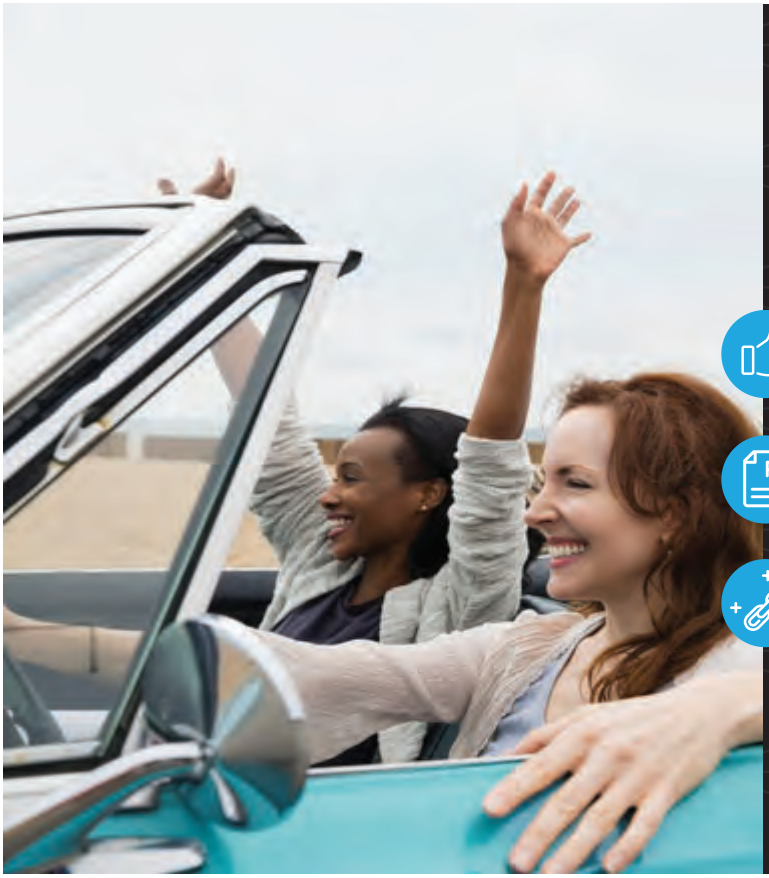
30 years
experience driving pharmacy strategy

≈68,000
network pharmacies[3]

>175MM
pharmacy claims annually[3]

>6,000
wholly dedicated Rx associates

1 *NCQA Health Insurance Plan Ratings 2018–2019 - Private Summary Report* (accessed February 2019): healthinsuranceratings.ncqa.org.
2 Statistic derived by comparing the U.S. census data (census.gov/popclock/) to Anthem current membership (39.5M, internal data accessed December 2018).
3 Anthem, Inc. internal data, January 2020.



Eliminating trade offs, maximizing value

Our promise:

- Steadfast commitment to a whole-health approach
- Demystify and simplify pharmacy
- Create collaborative relationships

A vision for moving pharmacy forward

Solutions today while changing tomorrow

Whole-health approach

FROM
- A focus on optimizing drug price
- Fragmented care & interventions
- Misaligned incentives across the continuum of care

TO
- A focus on optimizing total cost
- A streamlined approach to care
- Innovative partnerships that align around the patient

Demystify and simplify pharmacy

FROM
- Opaque economics
- "Arbitrary" decision-making
- Complicated processes and language

TO
- Clear line of sight into pharmacy cost drivers
- Benefit-agnostic approach focused on simplifying care
- A consumer-centric mentality

Create collaborative relationships

FROM
- Multiple points of contact
- Influencing outcomes by interrupting care

TO
- A single source of truth
- Delivering insights to the exam room

ingenioRx

A whole-health approach with guaranteed impact

What that means	What we do
Singular focus on total cost of care	Plan-specific, total cost guarantees Wholly independent formulary process Consistent approach to cost management
Maximizing value across stakeholders	Optimizing site-of-care decisions Value-based arrangements with providers Holding manufacturers accountable for outcomes
Deep partnership with providers	Consistent clinical criteria across medical and pharmacy Pushing actionable insights to the exam room Thinking nationally, acting locally

ingenioRx

Value of our programs

Disease/ condition	Impact
Asthma	• 14% fewer admissions • 8% lower medical costs • $588 PMPY savings
Kidney Disease	• 13% fewer admissions • 3% lower medical costs • $444 PMPY savings
Coronary Artery Disease	• 13% fewer admissions • 9% lower medical costs • $1,068 PMPY savings
Diabetes	• 7% fewer admissions • 7% lower medical costs • $600 PMPY savings
Heart Failure	• 24% fewer admissions • 19% lower medical costs • $3,552 PMPY savings
Hypertension	• 14% fewer admissions • 6% lower medical costs • $456 PMPY savings

*Outcomes based on 2014 integrated analysis. Savings apply to members with conditions listed. Results shown do not represent a guarantee of outcomes; group-specific results and cost savings will vary.

*Results based on 2018 clinical and cost-of-care programs for enterprise Commercial and Exchange business; medical cost offsets based on Medication Review.

Member and provider engagement

Through different outreach programs — like Medication Review and Pharmacy Outreach — we can help change member behaviors and encourage them to close gaps in care, support cost management programs and stay on track with their medications.

STATE OF WISCONSIN

GOVERNOR'S TASK FORCE ON REDUCING PRESCRIPTION DRUG PRICES

Task Force on Reducing Prescription Drug Prices

Role of PBMs

Brent Eberle, RPh MBA
Senior Vice President, Chief Pharmacy Officer

January 22nd, 2020

N6967-0919P

NAVITUS
PHARMACY BENEFITS REINVENTED™

Agenda

- Navitus Overview
  - SSM Health
- What services does a PBM provide
  - Beyond contracting activities
- PBM Business Models
  - How does a PBM get paid
- PBM Legislative Activity
  - Overview of activity in WI
- Appendix: Civica Overview

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NAVITUS
PHARMACY BENEFITS REINVENTED

Navitus Overview

NAVITUS
PHARMACY BENEFITS REINVENTED

Introducing Navitus Health Solutions

Navitus is an industry leading, pass-through pharmacy benefit manager (PBM) and serves as an alternative to traditional PBMs. We're committed to making prescriptions more affordable for plan sponsors and their members. That's why we've *reinvented pharmacy benefit management* to more effectively reduce costs and improve health.

- Founded in 2003
- Owned by SSM Health in St. Louis, MO
- 6 million members and growing
- Nationwide presence with corporate campuses in Madison and Appleton, WI; Austin, TX; and Phoenix, AZ
- Serves 600+ clients including employers, health plans, government, unions, etc.
- URAC accredited PBM and specialty pharmacy
- 4.5 out of 5 Stars EGWP Rating by CMS, the highest among PBM-sponsored EGWP Plans*

*Medicare evaluates plans based on a 5-star rating system. Star Ratings are calculated each year and may change from one year to the next.

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What does a PBM do?

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What does a PBM do?

Cost Management
- Pharmacy Network Management
  - Retail / Retail-90 / Mail / Specialty
- Formulary & Rebate Management
- Plan Design & Benefit Management

Utilization Management
- Prior Authorization & Step Therapy
- Concurrent & Retrospective Drug Util. Review
- Population Health Programs
  - Medication Therapy Management
  - Adherence & Persistency Programs
  - Appropriate use (Opioid Mgmt. Programs)
- Specialty Pharmacy

Operations
- Member & Pharmacy Call Center
- Eligibility Management
- Plan Builds & Plan Testing
- Government Program Support
  - Medicare Part D
  - Managed Medicaid
  - Healthcare Marketplace (ACA Exchange Plans)

Technology
- 24-7 Sub-second Claims Processing
- Data Security
- Data Analytics & Reporting
- Web and Mobile Applications
- eHealth Services
  - eRx (formulary & benefit info.)
  - ePA (electronic PA)
  - Real Time Benefit Check

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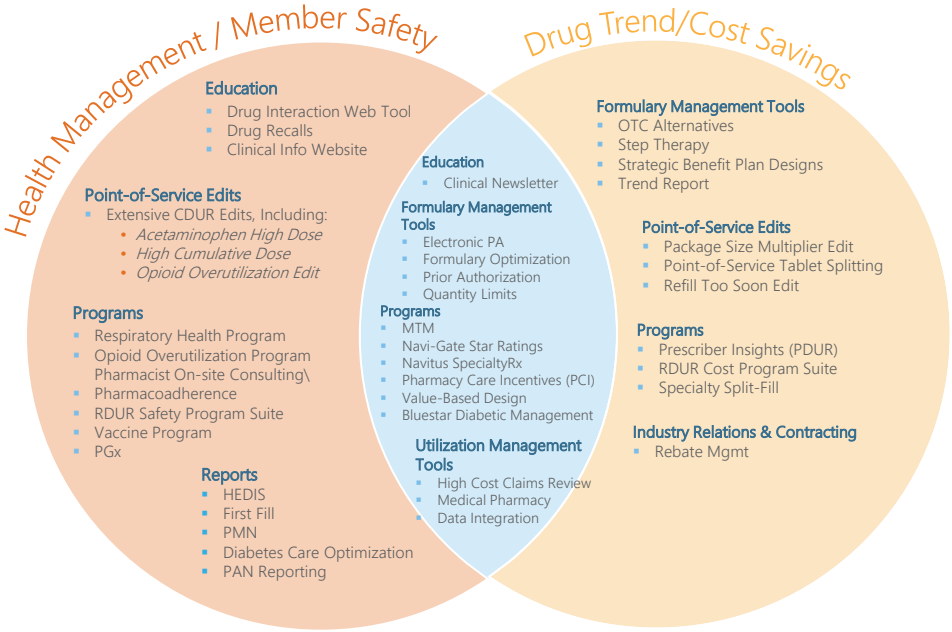
Population Health Overview



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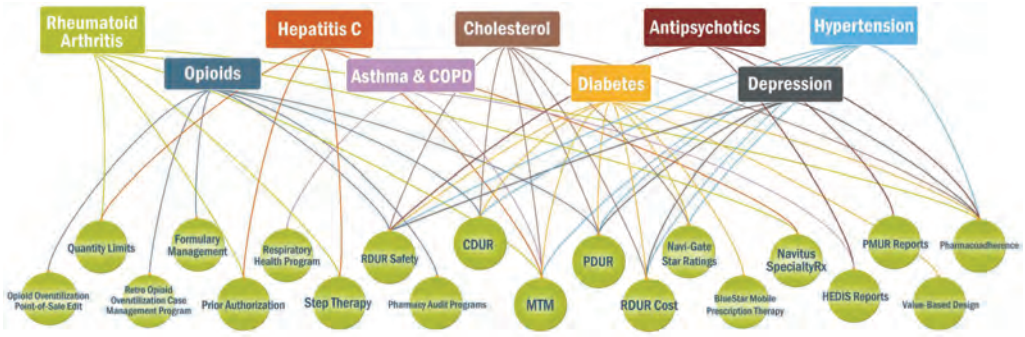
Population Health



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Importance of Pharmacy Auditing

- Common Billing Errors
  - Metric Quantity vs. Unit Quantity
  - Day Supply Errors – Impact Plan & Member Pay Amounts
  - Test Claims Not Reversed
- Questionable Business Practices
  - Pre-printed order forms
    - Leave off lower cost / formulary options
    - Recommend higher than needed quantities
    - "cross out items not needed"
  - Compounding – Experimental & Investigations Therapies
    - "Foot Bath"
    - Topical Pain Relievers
  - Diabetic Supplies / Gray Market
- Heat Zone Activity
  - Pharmacies located in heat zones that are outreaching to prescribers out of State for Medicare members and providing mail order type services without a relationship with those members.

Note: All dollars Navitus recovers in an audit are returned 100% to the plan sponsor

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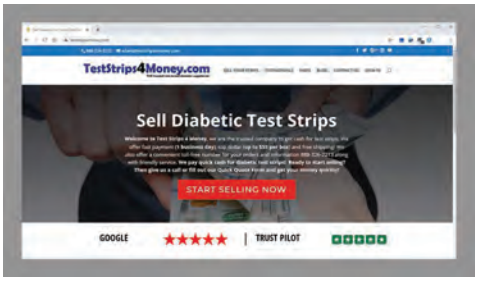
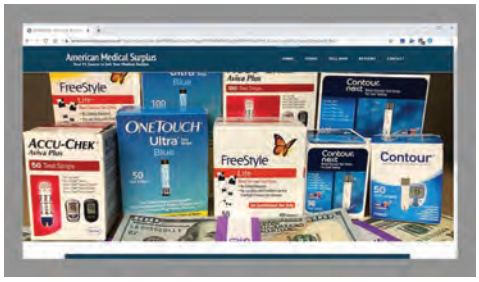
Selling of Diabetic Supplies

"how to sell my diabetic supplies"

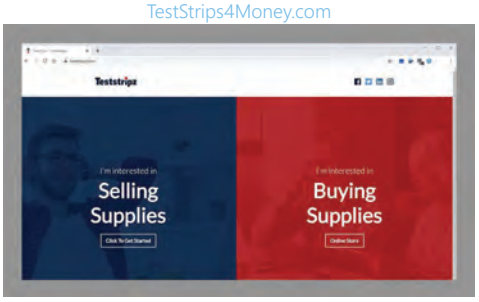
QuickCash4TestStrips.com



TestStrips4Money.com



AmericanMedicalSurplus.com



TestStripz.com

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Preprint Form Example

CATEGORY	DRUG	DIRECTIONS	QTY/DX	REFILL
PAIN	☐ DICLOFENAC 3% GEL	APPLY 1 TO 2 GRAMS TO THE AFFECTED AREA(S) 3 TO 4 TIMES DAILY AS LONG AS DIRECTED BY PHYSICIAN.	300 GRAMS	
	☐ LIDO/TERRACAINE 7%-7% CREAM	APPLY 1 TO 2 GRAMS TO THE AFFECTED AREA(S) 3 TO 4 TIMES DAILY AS LONG AS DIRECTED BY PHYSICIAN.	240 GRAMS	
	☐ DOXEPIN 5% CREAM	APPLY 1 TO 2 GRAMS TO THE AFFECTED AREA(S) 3 TO 4 TIMES DAILY AS LONG AS DIRECTED BY PHYSICIAN.	180 GRAMS	
	☐ DIFLORASONE 0.05% OINTMENT	APPLY 1 TO 2 GRAMS TO THE AFFECTED AREA(S) 3 TO 4 TIMES DAILY AS NEEDED FOR INFLAMMATION (AVOID FACE). USE 2 WEEKS ON, 1 WEEK OFF. USE AS LONG AS DIRECTED BY PHYSICIAN.	120 GRAMS	
SCAR	☐ CALCIPOTRIENE 0.005% CREAM	APPLY 1 TO 2 GRAMS TO AFFECTED AREA(S) UP TO 3 TO 4 TIMES DAILY AS NEEDED FOR SCARS (AVOID FACE). USE 2 WEEKS ON, 1 WEEK OFF. USE AS LONG AS DIRECTED BY PHYSICIAN.	120 GRAMS	
	☐ DIFLORASONE 0.05% OINTMENT	APPLY 1 TO 2 GRAMS TO AFFECTED AREA(S) UP TO 3 TO 4 TIMES DAILY AS NEEDED FOR SCARS (AVOID FACE). USE 2 WEEKS ON, 1 WEEK OFF. USE AS LONG AS DIRECTED BY PHYSICIAN.	120 GRAMS	
TOPICAL ANTIFUNGAL	☐ ECONAZOLE 1% CREAM	APPLY 1 TO 2 GRAMS TO AFFECTED AREA(S) 3 TO 4 TIMES DAILY AS DIRECTED BY PHYSICIAN. USE AS LONG AS DIRECTED BY PHYSICIAN.	120 GRAMS	
	☐ DIFLORASONE 0.05% OINTMENT	APPLY 1 TO 2 GRAMS TO AFFECTED AREA(S) UP TO 3 TO 4 TIMES DAILY (AVOID FACE). USE 2 WEEKS ON, 1 WEEK OFF. USE AS LONG AS DIRECTED BY PHYSICIAN.	120 GRAMS	
FOOTBATH ANTIBIOTIC ANTIFUNGAL	☐ VANCOMYCIN 250mg CAPSULES	EMPTY 6 VANCOMYCIN CAPSULES, ADD THE HALVED CAPSULES TO HOT WATER AND STIR TO DISSOLVE. WAIT UNTIL HOT WATER COOLS TO WARM WATER, THEN SOAK FEET FOR 15 TO 30 MINS, 1 TO 2 TIMES DAILY.	360 CAPSULES	
	☐ ECONOZOLE 1% CREAM	ADD 42.5 GRAMS (HALF A TUBE) TO THE WARM WATER IN THE FOOT BATH SOAKING PAIL AND MIX VIGOROUSLY WITH HAND(S). SOAK AFFECTED AREAS FOR 15 TO 30 MINUTES, 1 TO 2 TIMES DAILY.	2850g OR 30 TUBES	
NSAID	☐ NAPROXEN SOD CR 375mg TABLETS	TAKE 1 TABLET BY MOUTH TWICE DAILY AS NEEDED FOR PAIN.	180 TABLETS	
	☐ FENOPROFEN 400mg CAPSULES	TAKE 1 CAPSULE BY MOUTH THREE TIMES A DAY AS NEEDED FOR PAIN.	90 CAPSULES	
PPI	☐ OMEP SOD-NCARB 40/1100mg TABLETS	TAKE 1 CAPSULE BY MOUTH EVERY MORNING WITHOUT FOOD.	30 CAPSULES	
WELLNESS	☐ MEMOLIC TABLETS	TAKE 1 TO 2 TABLETS BY MOUTH DAILY. (125mg VITAMIN C, 800IU VITAMIN D3, 25mg THIAMINE, 12.5mg VITAMIN B6, 1mg FOLIC ACID, 1mg VITAMIN B12, 5mg NADH, 50mg COENZYME Q-10).	60 TABLETS	
ORAL STEROID	☐ PREDNISOLONE 25mg/5mL	TAKE 1 TSP (5mL) BY MOUTH 3 TIMES DAILY FOR 4 DAYS. THEN TAKE 1 TSP (5mL) BY MOUTH 2 TIMES DAILY FOR 3 DAYS. THEN TAKE 1 TSP (5mL) BY MOUTH ONCE DAILY FOR 2 DAYS OR UNTIL FINISHED.	100 MILLILITER	
MUSCLE RELAXER	☐ CHLORZOXAZONE 250mg TABLETS	TAKE 1 TABLET BY MOUTH 3 TIMES DAILY AS NEEDED FOR MUSCLE SPASMS OR PAIN.	90 TABLETS	
ANTI INFECTIVE	☐ MUPIROCIN 2% CREAM	APPLY 1 TO 2 GRAMS TO THE AFFECTED AREA 3 TIMES DAILY. USE AS LONG AS DIRECTED BY A PHYSICIAN.	60 GRAMS	
STEROID	☐ DIFLORASONE 0.05% OINTMENT	APPLY 1 TO 2 GRAMS TO AFFECTED AREA(S) UP TO 3 TO 4 TIMES DAILY AS NEEDED. USE 2 WEEKS ON, 1 WEEK OFF AS LONG AS DIRECTED BY PHYSICIAN.	120 GRAMS	
MIGRAINE	☐ VANATOL LIQUID SOL'N	TAKE 1 TO 2 TABLESPOONS BY MOUTH EVERY 4 HOURS AS NEEDED FOR MIGRAINE (MAXIMUM 6 TABLESPOONS PER DAY). (50mg/15mL BUTALBITAL, 325mg/15mL ACETAMINOPHEN, 40mg/15mL CAFFEINE)	1419 MILLILITER	
PATCH	☐ LIDOCAINE 5% PATCH	APPLY 1 TO 2 PATCHES TO AFFECTED AREA(S) FOR UP TO 12 HOURS IN A 24 HOUR PERIOD. IF APPLICABLE, ALTERNATE WITH CREAM. USE AS LONG AS DIRECTED BY PHYSICIAN.	60 PATCHES	
PSORIASIS	☐ CALCIPOTRIENE 0.005% CREAM	APPLY 1 TO 2 GRAMS TO AFFECTED AREA(S) TWICE DAILY. USE AS LONG AS DIRECTED BY PHYSICIAN.	120 GRAMS	

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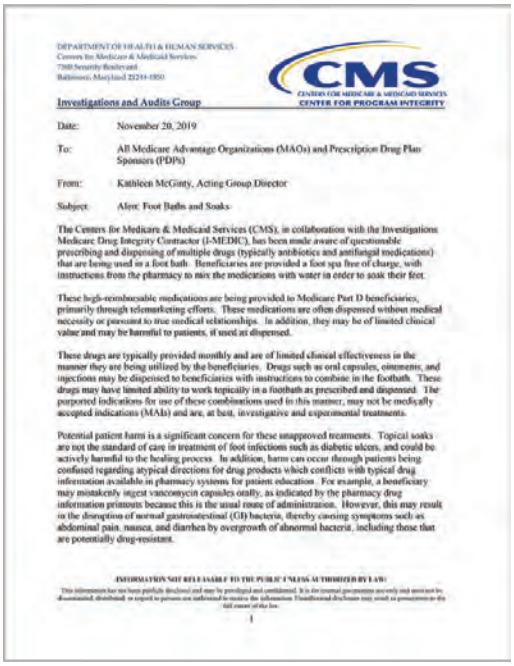
Preprinted Forms



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR PROGRAM INTEGRITY

Investigations and Audits Group

Date: November 20, 2019

To: All Medicare Advantage Organizations (MAOs) and Prescription Drug Plan Sponsors (PDPs)

From: Kathleen McGinty, Acting Group Director

Subject: Alert: Foot Baths and Soaks

The Centers for Medicare & Medicaid Services (CMS), in collaboration with the Investigations Medicare Drug Integrity Contractor (I-MEDIC), has been made aware of questionable prescribing and dispensing of multiple drugs (typically antibiotics and antifungal medications) that are being used in a foot bath. Beneficiaries are provided a foot spa free of charge, with instructions from the pharmacy to mix the medications with water in order to soak their feet.

These high-reimbursable medications are being provided to Medicare Part D beneficiaries, primarily through telemarketing efforts. These medications are often dispensed without medical necessity or pursuant to true medical relationships. In addition, they may be of limited clinical value and may be harmful to patients, if used as dispensed.

These drugs are typically provided monthly and are of limited clinical effectiveness in the manner they are being utilized by the beneficiaries. Drugs such as oral capsules, ointments, and injections may be dispensed to beneficiaries with instructions to combine in the footbath. These drugs may have limited ability to work topically in a footbath as prescribed and dispensed. The purported indications for use of these combinations used in this manner, may not be medically accepted indications (MAIs) and are, at best, investigative and experimental treatments.

Potential patient harm is a significant concern for these unapproved treatments. Topical soaks are not the standard of care in treatment of foot infections such as diabetic ulcers, and could be actively harmful to the healing process. In addition, harm can occur through patients being confused regarding atypical directions for drug products which conflicts with typical drug information available in pharmacy systems for patient education. For example, a beneficiary may mistakenly ingest vancomycin capsules orally, as indicated by the pharmacy drug information printouts because this is the usual route of administration. However, this may result in the disruption of normal gastrointestinal (GI) bacteria, thereby causing symptoms such as abdominal pain, nausea, and diarrhea by overgrowth of abnormal bacteria, including those that are potentially drug-resistant.

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW:

1

Footbath & Soaks Pricing
$200 - $9,000 per Rx
(average $2,000)

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PBM Business Models

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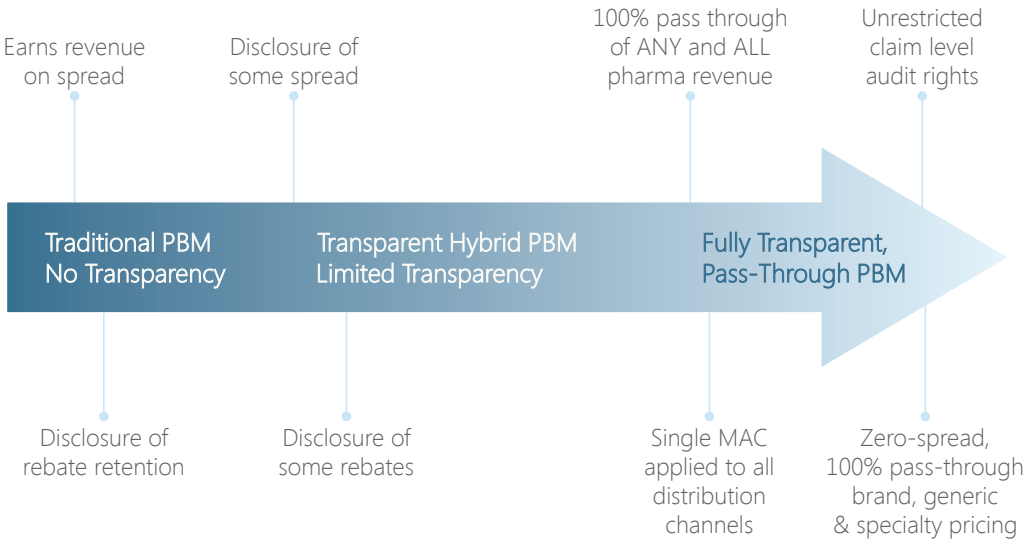
Degrees of PBM Transparency



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PBM Pricing Models

Traditional

MAC Spread | Rebate Maximization | Specialty Spread | Other | Mail Order Spread | Admin Fee | Retail Spread | DIR Fee

Transparent Hybrid

MAC Spread | Rebate Maximization | Specialty Spread | Other | ~~Mail Order Spread~~ | ~~Admin Fee~~ | ~~Retail Spread~~ | ~~DIR Fee~~

Pass-Through

Navitus has a 100% transparent pass-through model and earns revenue only from its PMPM fee

~~MAC Spread~~ | ~~Rebate Maximization~~ | ~~Specialty Spread~~ | ~~Other~~ | ~~Mail Order Spread~~ | ~~Admin Fee~~ | ~~Retail Spread~~ | PMPM Fee

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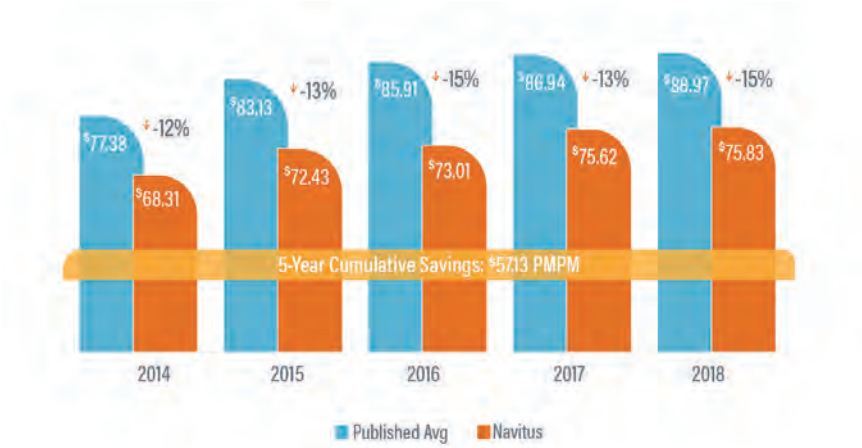
Trend Performance

5-Year Total Net Cost PMPM Comparison – Cumulative Impact



We are generating long-term savings with a 5-year cumulative PMPM of $57.13, which is 14% less than the industry average

Source: Navitus drug trend analysis and published PMPM figures from other PBMs in the industry including Express Scripts and CVS, 2018.

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PBM Legislative Activity

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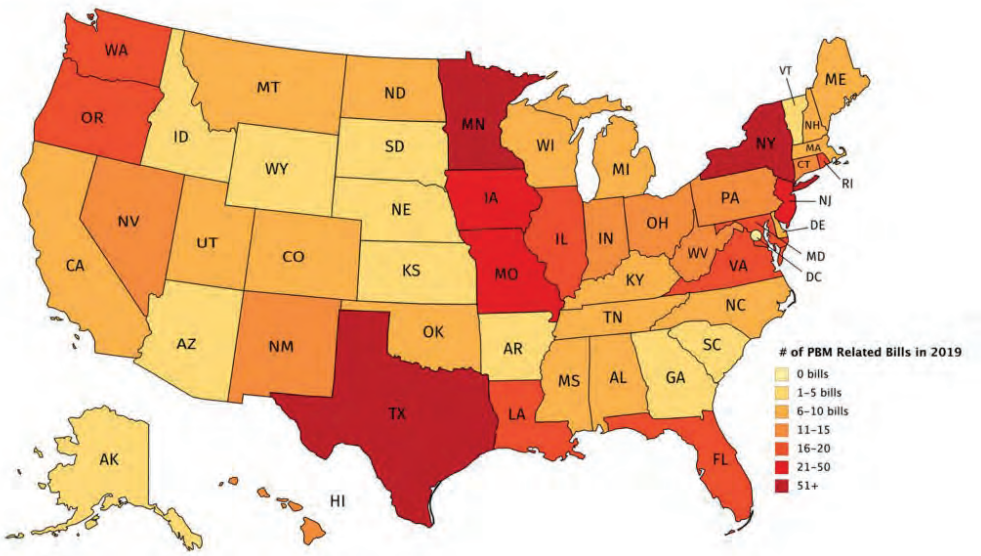
2019 STATE LEGISLATION RELATED TO PHARMACY BENEFIT MANAGEMENT

50 states considered over 650 bills affecting PBMs. More than 150 of these bills were adopted.



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TYPES OF LEGISLATION REGULATING PBMs

States are considering legislation covering a range of topics related to PBMs. Below is an snapshot of the legislation.

1 Drug Price & PBM Transparency

These bills vary from state to state. Some require drug manufacturers to provide notice to payers of WAC increases. Other state cover a broad range of requirements regulating PBMs, including reporting of rebates to the state insurance commissioner.

STATES:

AR, IA, IL, LA, TX, **MA, ME, MN**, MT, NC, **NE, NH**, NJ, NM, **NY**, PA, RI, **SC, TX, UT**, WA, WI, WY

2 Licensure/Registration

Requires licensing or registration of PBMs, license fees, and filing annual reports. Some states also include requirements related to network adequacy, gag clauses, claw backs, and pharmacy audits.

STATES:

AR, **FL**, GA, HI, **IL**, IN, **LA**, TX, **ME, MN**, MO, MT, NC, **NH**, NM, NY, OK, SC, TN, TX, **UT**, WA, WI, **WV**

3 Step Therapy

Legislation related to the use of step therapy protocol that allows patient to have access to an exception process. Other states prohibit use of step therapy in treatment of metastatic cancer or chronic conditions.

STATES:

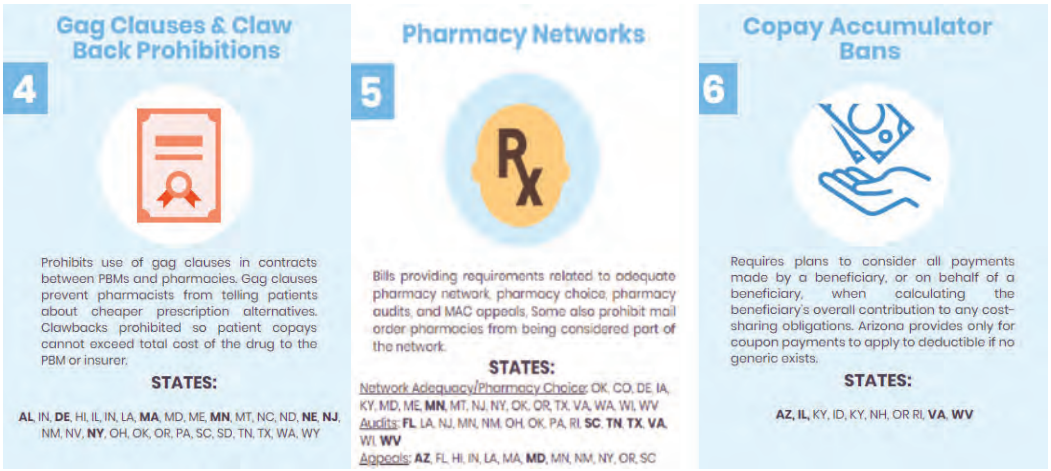
AR, CT, DE, FL, GA, HI, IL, LA, MA, **MD**, ME, MI, **MN**, MO, MT, NC, **ND**, NJ, NM, NY, **OH, OK**, OR, RI, **TX**, UT, VA, VT, WA, **WI**

Note: bolded states indicate adopted legislation

NAVITUS PHARMACY BENEFITS REINVENTED

TYPES OF LEGISLATION REGULATING PBMs

States are considering legislation covering a range of topics related to PBMs. Below is an snapshot of the legislation.



Note: bolded states indicate adopted legislation

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PROPOSED WISCONSIN PBM LEGISLATION

Concepts currently being contemplated

- PBMs to register with the Wisconsin Insurance Commissioner (OIC)
  - Navitus and many other PBMs currently have WI licensure with OCI under current law related to "Employee Benefit Plan Administration"
- Price transparency requirements
  - Submission of annual rebate reports
  - Pharmacies to publish the "cash" pricing of their top 100-150 products
- Prohibit gag clauses and claw backs in pharmacy contracts with PBMs
  - Gag clauses are now prohibited by federal law
  - Prohibit Claw back to prevent the patient from paying more than cost of the drug
- Regulate how a PBM's audit of pharmacists and pharmacies
  - Governed by the contract between the PBM & the pharmacy
  - Many audit elements are dictated to the payors by CMS (Medicare/Medicaid)
- Limits mid-year formulary changes
  - Limits the plans ability to control costs
- Requires adequate pharmacy networks and allows patients to use their pharmacy of choice without penalty
  - Can increase drug costs by eliminating pharmacy competition

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Thank You.

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CIVICA™

Delivering **Quality** Medicines that are
Available and **Affordable**

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

45+ Health Systems Members

1200+ Hospitals

30% of U.S. Licensed Beds

46 States

18 Drugs in production or shipped

76

CIVICA™ @CivicaRx @CivicaRx #CivicaRx

CIVICA™

REDUCING DRUG SHORTAGES THROUGH COLLABORATION

Health Systems

Member health systems prioritize the medications needed to reduce shortages for patients and identify the volume requirements for their hospitals.

Manufacturers

Manufacturers commit their production capacity based on long-term projected volumes of medications identified by the health systems.

Result

Reliable supply of essential generic medications promptly improves patient care.

CIVICA™ @CivicaRx @CivicaRx #CivicaRx

Not-For-Profit	Fair and Sustainable Prices	Transparency and One Price	No Fees or Rebates	Promote Competition
Long-Term Guaranteed Contacts	Redundant Manufacturing	Advanced Manufacturing in Appropriately Regulated Countries	Strategic Stockpiles (Safety Stock)	Transparency Location of Manufacturing Facility

Civica Rx is member-driven and committed to eliminating uncertainty within the supply chain

CIVICA™ @CivicaRx @CivicaRx #CivicaRx

Health Systems continue to join Civica, including:

SSM Health, CommonSpirit, Kootenai Health, Advocate Aurora Health, Hospital Sisters Health System, Intermountain Healthcare, St. Clair Hospital, Steward, New Hanover Regional Medical Center, Mayo Clinic, Memorial Hermann, Spectrum Health, ChristianaCare, MemorialCare, U Health, St. Luke's, Southeast Georgia Health System, ThedaCare, Baptist Health South Florida, Regional One Health, HCA Hospital Corporation of America, UnityPoint Health, Ochsner Health System, Piedmont Healthcare, Aspirus, UHealth, Piedmont Health, Trinity Health, Providence St. Joseph Health, Sanford Health, North Memorial Health, Baptist Health, NYU Langone Health, Allegheny Health Network, The Christ Hospital Health Network, Franciscan Alliance, Integris Health, Griffin Health, NorthBay Healthcare

1. Bring true competition to the generic market, focusing on value (price and quality)
2. Ensure stable and predictable supply of essential generic drugs, correcting shortages
3. Be a conscience of the market, serving as a check against aggressive pricing behavior of generic drug manufacturers

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CIVICA™

- Quality
- Supply
- Sustainability

GOVERNOR'S TASK FORCE ON REDUCING PRESCRIPTION DRUG PRICES
February 19, 2020
10:00 a.m. – 2:00 p.m.
University of Wisconsin Oshkosh
Culver Family Welcome Center
Room 228; The Michael D. Wachtel Room
625 Pearl Ave, Oshkosh

I. **Welcome (10 minutes)**
Nathan Houdek, Deputy Commissioner, *Office of the Commissioner of Insurance*

II. **Consumer Experience (10 minutes)**

III. **Pharmaceutical Care Management Association (PCMA)/America's Health Insurance Plans (AHIP) (60 minutes)**
- **Heather Cascone,** *Senior Director, State Affairs [PCMA]*
- **Kris Hathaway,** *Vice President, State Affairs [AHIP]*

IV. **Lunch (25 minutes)**

V. **MagellanRx Management (30 minutes)**
- **Don Nelson,** *Vice President, Government Affairs-Midwest Region*

VI. **"The High Price We Pay: Employers' Perspectives on The High Cost of Prescription Drugs" (45 minutes)**
- **Paul Meyer,** *COO at The Alliance*
- **Tena Hoag,** *Chief Financial Officer at Advanced Laser*
- **Jerry Ward,** *Executive Vice President at Seats Incorporated*
- **Dan Ludwig,** *Director of Benefits and Safety at Brakebush Brothers, Inc.*
- **Josh Bindl,** *Chief Executive Officer at National CooperativeRx*

VII. **Task Force Member Discussion (60 minutes)**
- Assembly Bill 114/Senate Bill 100 update
- Discuss potential policy options

VIII. **Next Meeting Date/Location**
- March 18, 2020
- Northcentral Technical College
  Professional Conference Center Room (1004A/B)
  Wausau, WI

IX. Adjourn

Meeting Minutes
February 19, 2020
10:00 a.m. – 2:00 p.m.
University of Wisconsin Oshkosh
Culver Family Welcome Center
Room 228; The Michael D. Wachtel Room
625 Pearl Ave, Oshkosh

Task Force Members Present: Nathan Houdek, Anna Benton, Josh Bindl, Brent Eberle, Tony Fields, Peter Fotos, Janet Fritsch, Michael Goldrosen, Ian Hedges, Lisa Lamkins, Alan Lukazewski, Laura McFarlane, Robyn Schumacher, Brian Stamm, Brian Stephens, Rep. Lisa Subeck (remotely), Lara Sutherlin, Yolanda Tolson, Sue Wilhelm

OCI Staff Present: Megan Aubihl, Jessica Carlson, Jennifer Stegall, Derek Spellman, Julie Walsh

Welcome
Nathan Houdek, OCI Deputy Commissioner and Task Force chair

- Deputy Commissioner Houdek welcomed Task Force members and public attendees
    - Mr. Houdek indicated the Task Force would continue discussing PBMs and hear presentations from health insurance providers and self-insured employers.
- Key housekeeping items:
    - Wisconsin Eye filming and live-streaming the meeting
- Consumer experience: two consumers shared their personal experiences in managing high prescription drug costs
    - Kyle Kemp, small business owner in Oshkosh
        - Mr. Kemp has diabetes and manages the expenses of insulin, test strips and other supplies on a limited income.
        - Shared with Task Force members the supplies needed to manage his diabetes (i.e. the cost of medications and supplies as well as how quickly those supplies are used)
    - Kimberly Goffard, public health nursing supervisor – Winnebago County Health Department
        - As the mother of a young adult son recently diagnosed with diabetes, Ms. Goffard explained the medical needs of her son and the expenses that accompany managing diabetes.
        - With health insurance and the use of a Flexible Spending Account, her family is able to cover their prescription drug expenses. However, Ms. Goffard emphasized that while her family is fortunate to be able to cover the expenses, the cost is high.

Health Insurance Plan's Perspective
Kris Hathaway, Vice President of State Affairs – America's Health Insurance Plans (AHIP)

- Ms. Hathaway urged Task Force members to include all partners in the supply chain including PSAOs when reviewing how to contain costs.
- Ms. Hathaway highlighted that she was asked to talk about:
    - Point-of-sale rebates
    - Coupons

    - Capping co-payments
    - Freezing formularies

Ms. Hathaway's presentation is available on the Task Force website:
https://rxdrugtaskforce.wi.gov/Documents/AHIP_Presentation_2_19_20.pdf

- Task Force members expressed interest in understanding the dynamic between reducing the cost to the consumer at the pharmacy counter and the implications for the overall healthcare spend (including impact on premiums, deductibles, copays, etc.)

Pharmacy Benefits Manager Perspective

Heather Cascone, Senior Director of State Affairs – Pharmaceutical Care Management Association (PCMA)

Ms. Cascone's presentation is available on the Task Force website:
https://rxdrugtaskforce.wi.gov/Documents/PCMA_PBM_Presentation_2_19_20.pdf \

- PBMs use tools such as rebates to negotiate price concessions
- Questions surrounding transparency continue to be a concern:
    - Releasing detailed data vs. aggregated data
    - PCMA maintains that rebate negotiations are trade secret
    - Reporting information could, even if unintentionally through mishandling of the data, make proprietary information available to competitors and drive costs up.
    - Insurers report prescription drug rebate data as part of their MLR reporting currently. Data on the portion a PBM retains is not available.

MagellanRx Management Medicaid Pharmacy Trend Report

Don Nelson, MBA, Vice President, Regional Government Affairs

The MagellanRx Management Medicaid Pharmacy Trend Report presentation is available on the Task Force website.
https://rxdrugtaskforce2016-auth-prod.wi.gov/Documents/Magellan_Rx_Presentation_2_19_20.pdf

- Mr. Nelson gave an overview of MagellanRx Management Medicaid Pharmacy Trend Report.

Employers' Perspectives on the High Cost of Prescription Drugs

Paul Meyer, COO at The Alliance

- Outlined the challenges faced in offering health benefits, including prescription drug coverage in the self-insured market

Tena Hoag, Chief Financial Officer at Advanced Laser

- Walked through the process by which Advanced Laser became self-insured; including partnering with other local businesses and creating a near-site clinic (later adding mental health care)

Jerry Ward, Executive Vice President at Seats Incorporated

- Self-funded since 1982; focus on healthcare is important to make sure employees are healthy and at work, and to control the company's third-highest cost
- Onsite clinic available to employees, whether they take their insurance or not
- Controlled prescription drug costs over the past several years
- Joined National Cooperative Rx in 2010 – pass rebate savings on to employer to bring down overall healthcare costs

Dan Ludwig, Director of Benefits and Safety at Brakebush Brothers, Inc.

- Started self-funding 2014; maintained flat costs; onsite health center
- Drug spending increased; cover 90% of the cost of medications but can still be expensive
    - Partnering with National CooperativeRx
    - Onsite clinic and onsite prescribing – seeing higher compliance

    - Work with a compliant and safe international mailorder program
- Started theoretically looking into “medical tourism”

Josh Bindl, Chief Executive Officer at National CooperativeRx

- Provided an overview of the National CoopertiveRx business model

Task Force Member Discussion

The Task Force discussion was limited to 15 minutes due to presentations running longer than anticipated. Deputy Commissioner Houdek asked the Task Force members to weigh in on initial thoughts around rebate reporting and some of the requirements included in Assembly Bill 114/Senate Bill 100. Members engaged in limited discussion around the potential for publicly available rebate information, as well as the idea of a discount model and concerns with discriminatory reimbursement. Mr. Houdek apologized for the limited time for discussion and asked members to think about issues they would like addressed in the form of Task Force recommendations.

Adjourn

The next Task Force meeting will be held on March 18 in Wausau.

Wisconsin Task Force Reducing Prescription Drug Prices

Kris Hathaway
Vice President, State Affairs and Policy
America's Health Insurance Plans

February 19, 2020
Oshkosh, WI

Who is AHIP?

America's Health Insurance Plans (AHIP) is the national association whose members provide coverage and health-related services that **improve and protect the health and financial security of consumers, families, businesses, communities and the nation**.

Agenda

- Drug Cycle
- PBM Partners
- Health Care Dollar
- Pharmaceutical Market
- Point of Sale Rebates
- Coupons
- Medical Management
- What Wisconsin Can Do

Drug Supply Chain

DRUG MAKERS

Set Drug List Prices

Drug Makers negotiate with PSAOs to distribute their drugs to Pharmacies

Drug Makers pays Rebates to PBMs per Negotiated Agreements

PBMS

Negotiates Discounts with Drug Makers on Behalf of their Health Plan Clients or Large Employer Clients

PSAO / WHOLESALER

PSAOs sell/distribute drugs to their Pharmacy Clients

PSAOs Negotiate Drug Reimbursement on Behalf of their Pharmacy Clients with PBMs; PBMs pay pharmacy for drugs dispensed

HEALTH INSURANCE PROVIDERS

Health Insurance Providers Cover our Enrollees Drug Costs

PHARMACY

Pharmacy Sells Drugs To Patient for Copays

PATIENT

PBM Services

- Claims Processing
- Price, Discount and Rebate Negotiations with Drug Manufacturers and Drugstores
- Formulary Management
- Pharmacy Networks
- Mail-service Pharmacy
- Specialty Pharmacy
- Drug Utilization Review
- Disease Management and Adherence Initiatives

PCMA

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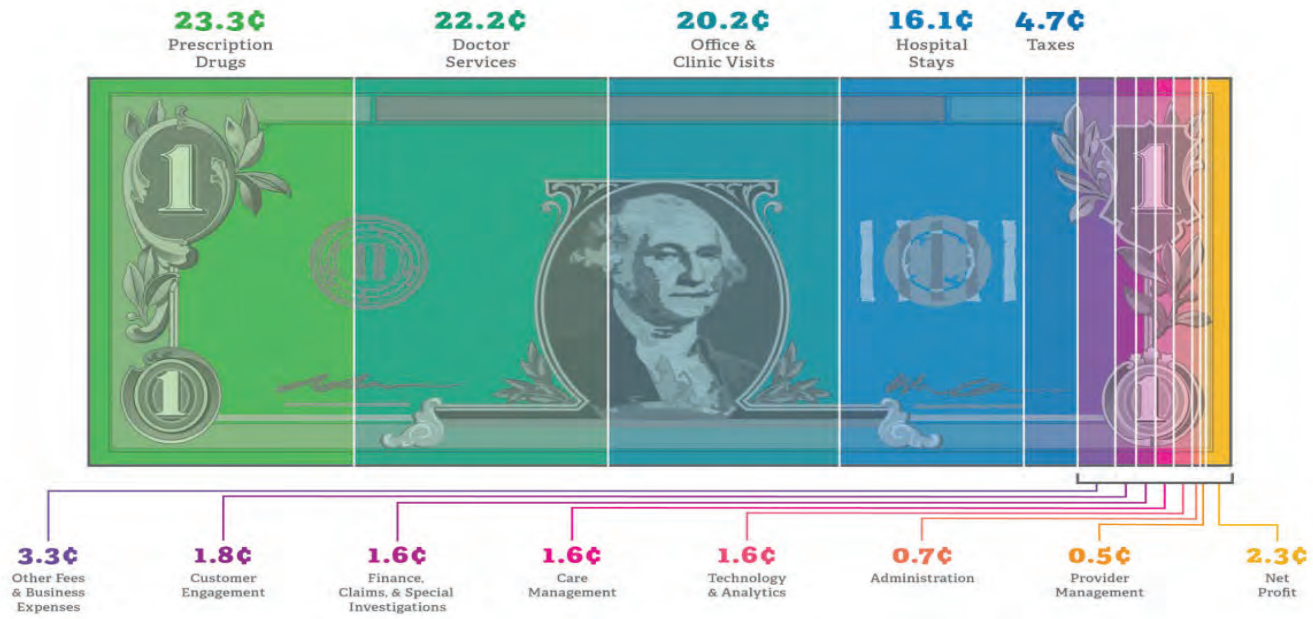
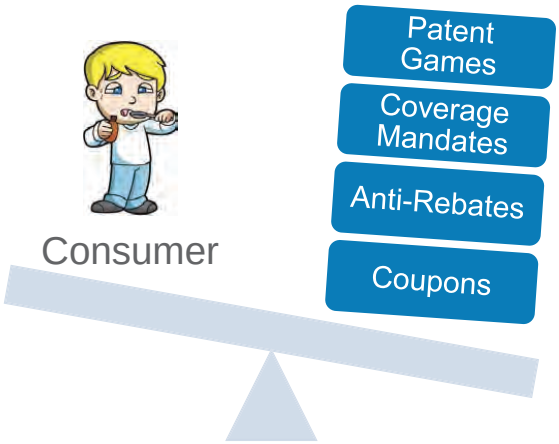
Why Curbing Drugs Costs Is Critical



Source: https://www.ahip.org/wp-content/uploads/2017/03/HealthCareDollar_FINAL.pdf

3 AHIP

Broken Pharmaceutical Market



Patent Games:
- **Off Label Promotion**
- **Orphan Drug Abuses**
- **Pay for Delay**
- **Product Hopping**
- **Dosing Strategies**
- **Generic Barriers**

7 AHIP

A Case Study: Humira

HUMIRA® adalimumab

+6.2%
(Jan 2019)

+9.4%
(Jan 2018)

+8.4%
(Jan 2017)

+7.9%
(Jun 2016)

+9.9%
(Jan 2016)

#1 selling drug in the world with $19.9 billion in sales in 2018*

*Abbvie Financial Results 2018, reported Jan 25, 2019

>$50,000 in annual drug expenses per patient

15+ years with no biosimilar competition (FDA approved in 2002)

Patent settlement blocks biosimilar (until at least 2022)

Source: Bloomberg, EvaluatePharma, US Bureau of Labor Statistics; Statista.com; Medicare/Medicaid Drug Dashboard; Barron's

8 AHIP

Point of Sale Rebates - Not the Solution

- Over 300 million medications* are prescribed annually:
  - 82% generic drugs
  - 18% brand name drugs
- Only 2.4% of brand drugs would be eligible for a discount at the pharmacy counter (i.e. point-of-sale rebate)

* Commercial data only

7 AHIP

What Are Copay Coupons?

- Drug makers will provide a coupon to a patient so they can receive a discount on a specific brand drug:
  - i.e. Mylan offered $300 copay coupon off their EpiPen to some patients after there was a public outcry when they raised their price from $100 to $600
- Drug makers use coupons as an incentive for patients to use branded drugs instead of less expensive generics, as insurance providers still pay for the drug.
- Insurance providers are considering not having the price of a drug used with a coupon go towards their deductible and out-of-pocket maximums to stop the practice if there is a generic equivalent.

9 AHIP

Copay Coupons

- Coupons reduce the use of generic drug competitors and **increase brand drug sales by more than 60%**.

Consumers Pay More $$$ → **Pharma Makes More $$$**

Coupons are prohibited in federal health care programs like Medicare and Medicaid.

- Considered a kickback, because they induce a patient to take a certain drug.
- Studies show they increase use of higher cost drugs, especially when generic or brand alternatives are available.

When Discount Raise Costs: The Effect of Copay Coupons on Generic Utilization.

Massachusetts vs. New Hampshire

In a 2017 study on copay coupons, the researchers took neighboring states that had differing approaches to copay coupons to analyze the impact coupons have on generic utilization and drug spending.†

	Massachusetts	New Hampshire
Coupons Allowed?	**NO** - Massachusetts banned the use of coupons statewide	**YES** - New Hampshire allows coupon use in non-federal programs
Drugs Not Offering Coupons	When branded drugs did not offer coupons, **use of generic alternatives was equivalent** in both states	
Drugs Offering Coupons to All Patients		• When branded drugs offered coupons, **use of generic alternatives was 3.4% LOWER** • This amounted to **$700 million more in drug spending – $2.9 billion over five years**
Drugs That Offer Coupons Among Patients <65 yrs		• When branded drugs offered coupons for this age group, **use of generic alternatives was 6.3% LOWER** • **Increased spending could reach close to $6 billion**

† *When Discount Raise Costs: The Effect of Copay Coupons on Generic Utilization.*

Medical Management Promotes Smart Care

What Are Medical Management Tools?

- Evidence-based medical necessity review
- Formulary and provider tiered network designs
- Prior and concurrent authorization
- Quantity/dosing limits and step therapy approaches

Why Are They Used?

Health insurance providers and government-sponsored health programs use medical management tools to:

- Promote patient safety
- Prevent unnecessary, inappropriate, and potentially harmful care
- Improve and better coordinate care
- Increase health care affordability for consumers

13 AHIP

Medical Management – Specific Tools

Capping Copays

- Places a fixed amount to a consumer's insurance copayment
- Brings temporary release to one patient while raising premiums and costs for all

Frozen Formulary

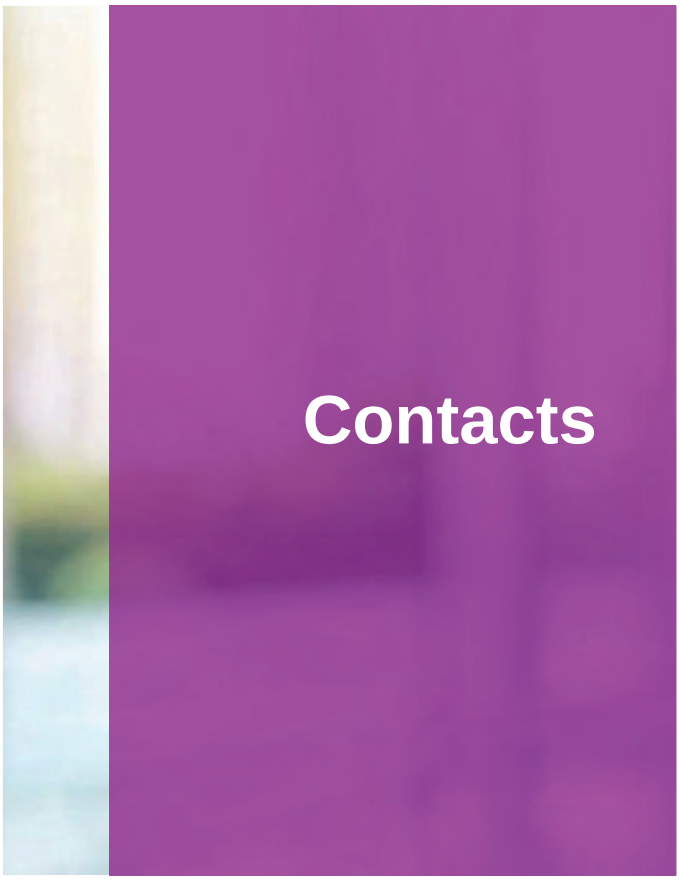
- Disallows removing a drug from a formulary or moving it to a higher cost tier
- Cannot replace drugs with new, clinically appropriate and less expensive alternatives
- Works only if there is a freeze on the cost of existing and new drugs

14 AHIP

Wisconsin Can Make A Difference

- Eliminate Gag Clause & Clawbacks
- Advance notification by manufacturers of drug cost increases & launch prices
- Address Patent Abuses
- Involve & Support Attorney General on Price Anomalies
- Ensure Drug Reps Include Prices When Marketing to Physicians
- Patient Assistance Program Funding Sources

15 AHIP



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AHIP

Wisconsin Task Force Reducing Prescription Drug Prices

The Role of Pharmacy Benefit Managers in the Health Care System

Heather Cascone
Senior Director, State Affairs
Pharmaceutical Care Management Association

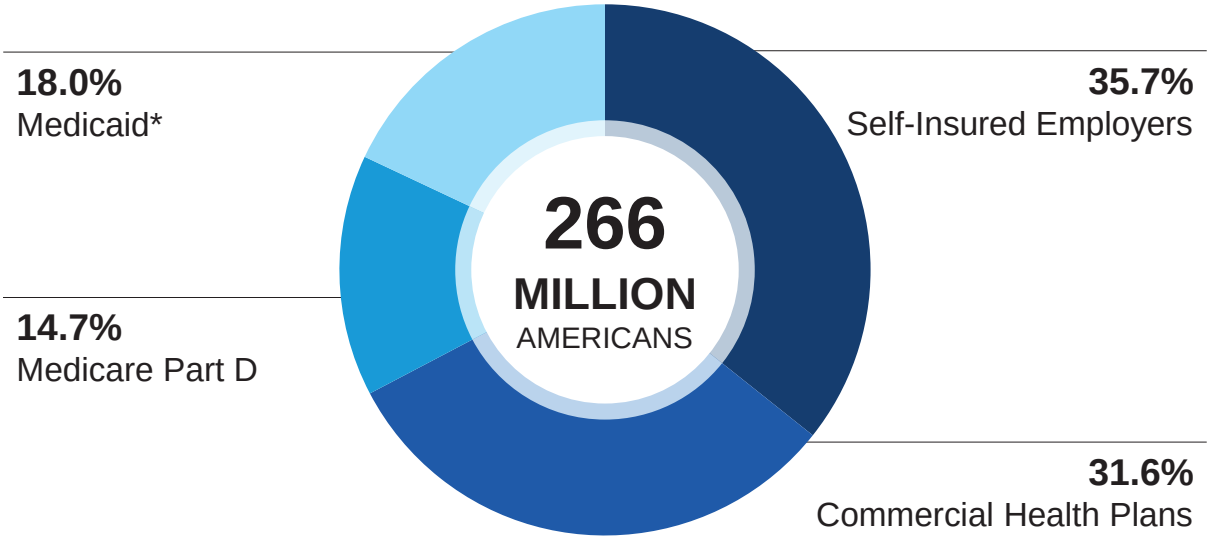
February 19, 2020

What Is a PBM?

- A pharmacy benefits manager (PBM) is a health care company that contracts with insurance carriers, employers, and government programs to administer the prescription drug portion of the health care benefit
- PBMs work with their clients to perform a variety of services to ensure high-quality, cost efficient delivery of prescription drugs to consumers
- PBMs aggregate the buying clout of millions of enrollees, enabling plan sponsors and individuals to obtain lower costs for prescription drugs.

PBMs' National Footprint

More than **266 million Americans** receive pharmacy benefits provided through PBMs



*Excludes Medicare-Medicaid Dual Eligibles where drugs are covered by Medicare Part D.
Source: Visante estimates prepared for PCMA, 2016.

PCMA

Who Are PBM Clients?

3

PCMA

Why Do Plans Hire PBMs?

- PBMs help save plans 40-50% over unmanaged benefit, increase adherence.[1]
- Reduce medication errors through use of drug utilization review programs.
  - Over next 10 years, 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.

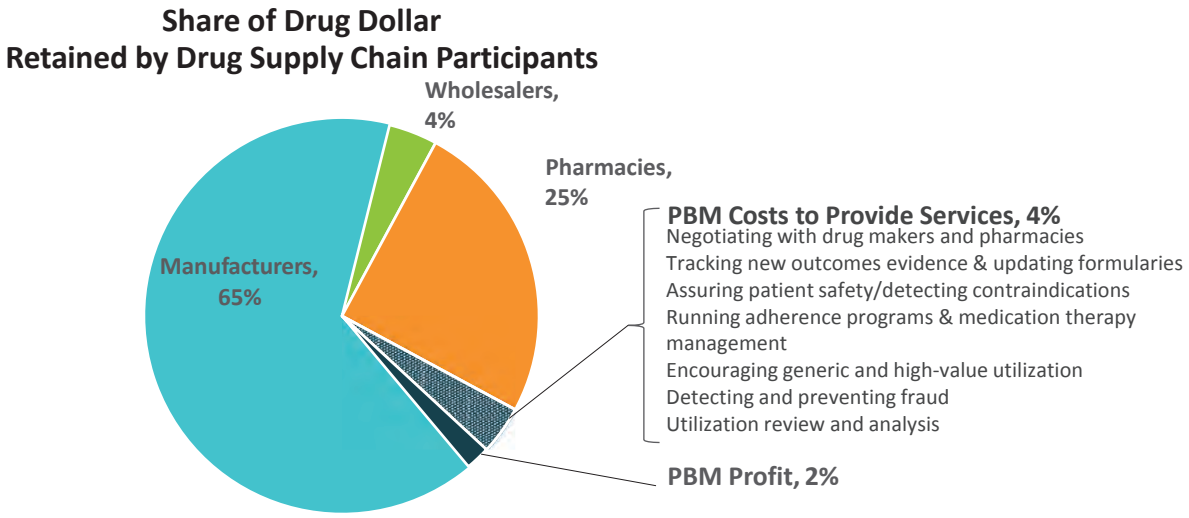
1 Visante, Return on Investment on PBM Services, Nov. 2016.
2 Visante estimates based on IMS Health data and DUR programs studies.
3 Visante estimates based on CDC National Diabetes Statistics Report 2014 and studies demonstrating improved adherence by 10+%).

PCMA

PBM – Plan Contracts

- PBMs offer various design models depending on a plan sponsor's specific needs:
  - Plan sponsors choose how to compensate PBMs.
  - Performance guarantees and audit rights protect plan sponsors and ensure transparency.
- The plan sponsor always has the final say when creating a drug benefit plan.
- Things not determined by a PBM: benefit design, cost sharing levels, deductibles, etc.

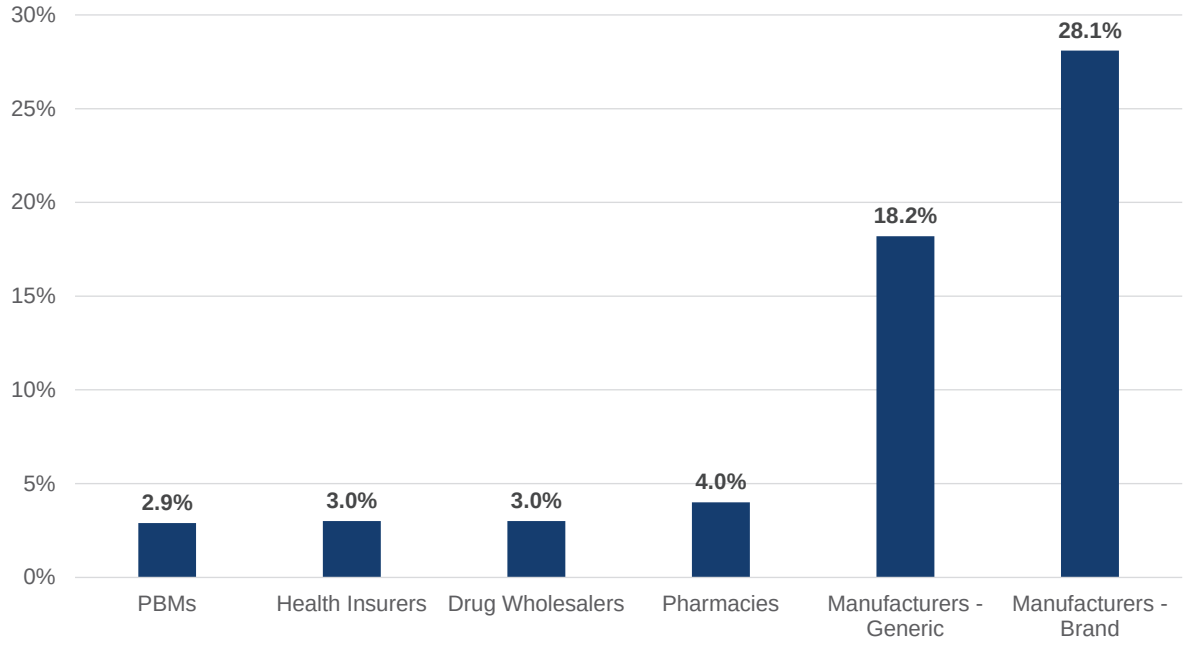
PBMs Take Only 6% Of Rx Drug Dollar: 4% Pays for PBM Services, 2% Profit



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.

Visante
The Business of Pharmacy

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

PCMA

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

- Negotiating with drug makers and pharmacies
- Tracking new outcomes evidence & updating formularies
- Assuring patient safety/detecting contraindications
- Running adherence programs & medication therapy management
- Encouraging generic and high-value utilization
- Detecting and preventing fraud
- Utilization review and analysis

PCMA

Is Drug Pricing a Problem?

PCMA

Tackling High Drug Costs

- Patient cost-sharing often represents only a small fraction of the total cost of the drug.
- Brand drug manufacturers establish prices within a monopoly established by federal patent law.
- Until other drugs are approved for the same disease or condition, 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** — but PBMs have some tools to drive down drug costs.

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PBMs Pass Through Rebates

- In Medicare Part D, rebates must be used to benefit beneficiary
- In Medicaid, states may negotiate above 23.1% statutory rebates and collect supplemental rebates
- In private insurance, disposition of rebates is up to the plan sponsor
  - On average, 90 percent of rebates are passed through to plan sponsor
- Use of rebates by plan sponsor depends on plan design
  - Most use rebates to reduce premiums, cost sharing

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PCMA

No Correlation Between Rebates and Prices

Using commercially available data on gross and net sales for the top 200 self-administered, patent-protected, brand drugs in the United States, Visante estimated annual rebate levels over the 2011-2016 period and compared these against manufacturer list price levels and increases over the same time period.

Major findings:

- No correlation between the size of rebates and price increases
- High price increases in drug categories with low rebates
- Lower price increases in drug categories with high rebates
- Drug prices increasing regardless of rebate levels

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PCMA

Eliminating Rebates Will Lead to Higher Prices

Restricting rebates will introduce the wrong kind of transparency into the program and thus significantly hamper negotiating leverage, leading to **higher drug costs**

- "[i]f pharmaceutical manufacturers learn the exact amount of rebates offered by their competitors … then tacit collusion among manufacturers is more feasible … Whenever competitors know the actual prices charged by other firms, tacit collusion — and thus higher prices — may be more likely." Letter to Assembly Member Greg Aghazarian, U.S. Federal Trade Commission Comments on AB 1960 (September 7, 2004)

13

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PBM Innovations

- For Physicians
  - ePrescribing
  - ePrior Authorization
- For Patients
  - Real time benefit checks

PCMA

How Would the World Look Without PBMs?

- Without management of benefit, 40-50% more in costs[1]
  - No one to make drug manufacturers compete with each other
  - No competition on price or quality in the pharmacy space
  - No auditing of pharmacies for fraud, waste, and abuse
  - No utilization controls that reduce waste and increase adherence
  - Paper claims, longer claims processing times, inability to have real-time reimbursement and coverage information for consumers at the pharmacy counter
  - Less utilization of generic drugs

1 Visante, *The Return on Investment (ROI) on PBM Services.* (November 2016).

PCMA

Thank you!

2019 Magellan Rx Management Medicaid Pharmacy Trend Report

PRESENTED BY

Don Nelson, MBA

Vice President, Regional Government Affairs

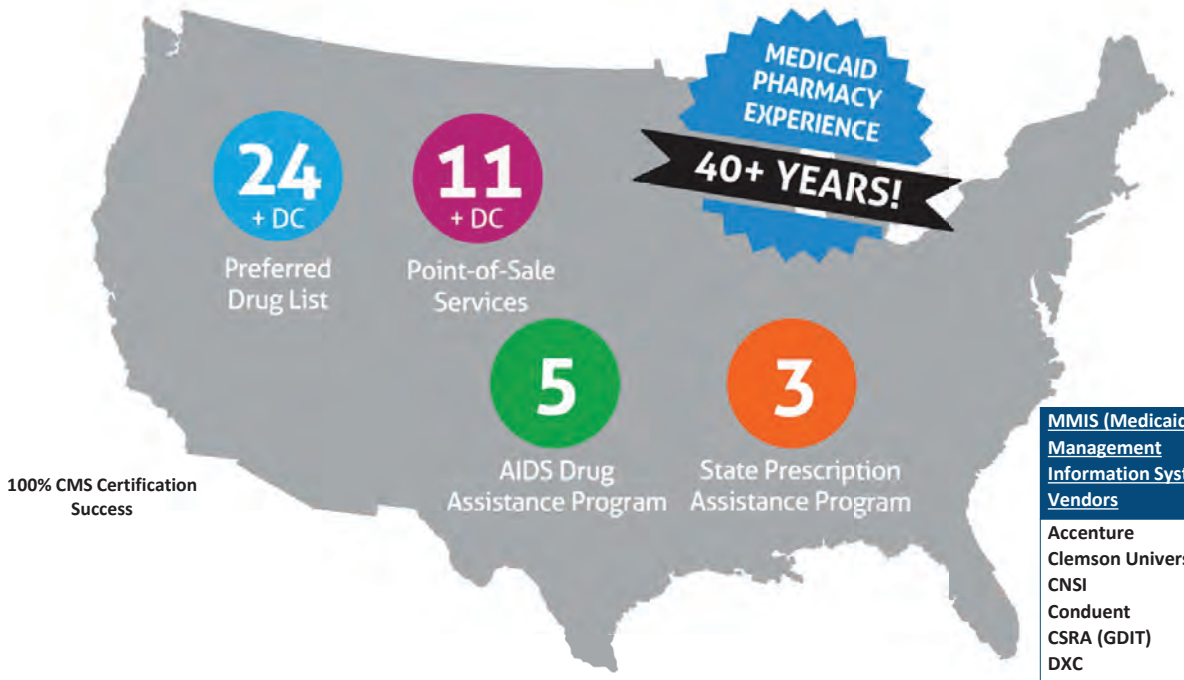
Magellan Rx MANAGEMENT℠

MAGELLAN RX MANAGEMENT

MEDICAID PHARMACY TREND REPORT™

2019 FOURTH EDITION

- Overall trends in the Medicaid data 2017-2018
- Deep dive on brand and generic drug trends
- Trend forecast using MRx Predict
- Key classes driving trend
- New contracting methods in Medicaid



100% CMS Certification Success

MMIS (Medicaid Management Information System) Vendors
Accenture
Clemson University
CNSI
Conduent
CSRA (GDIT)
DXC
State Operated

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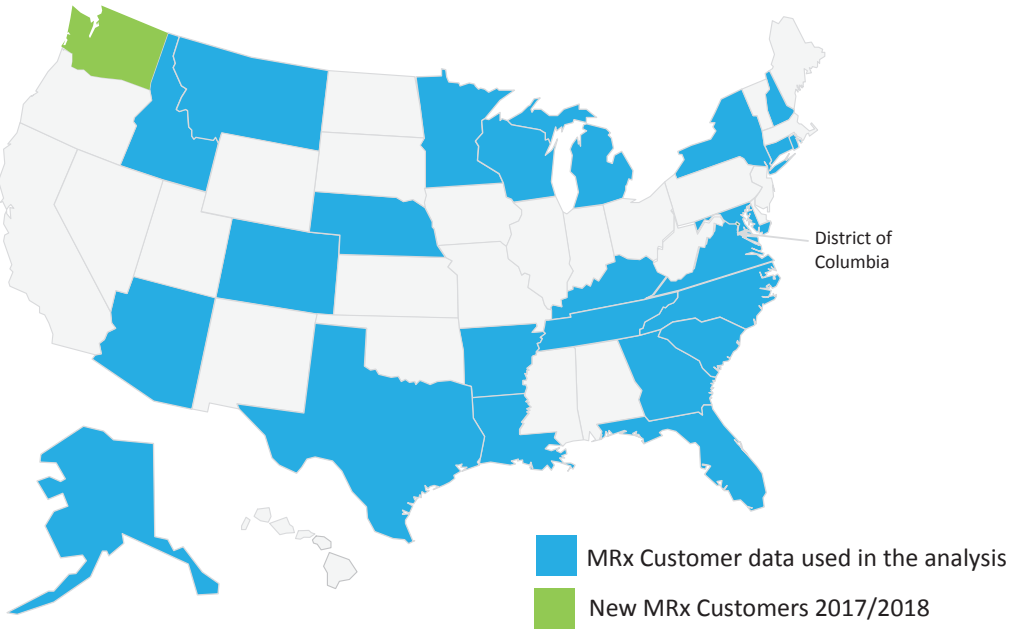
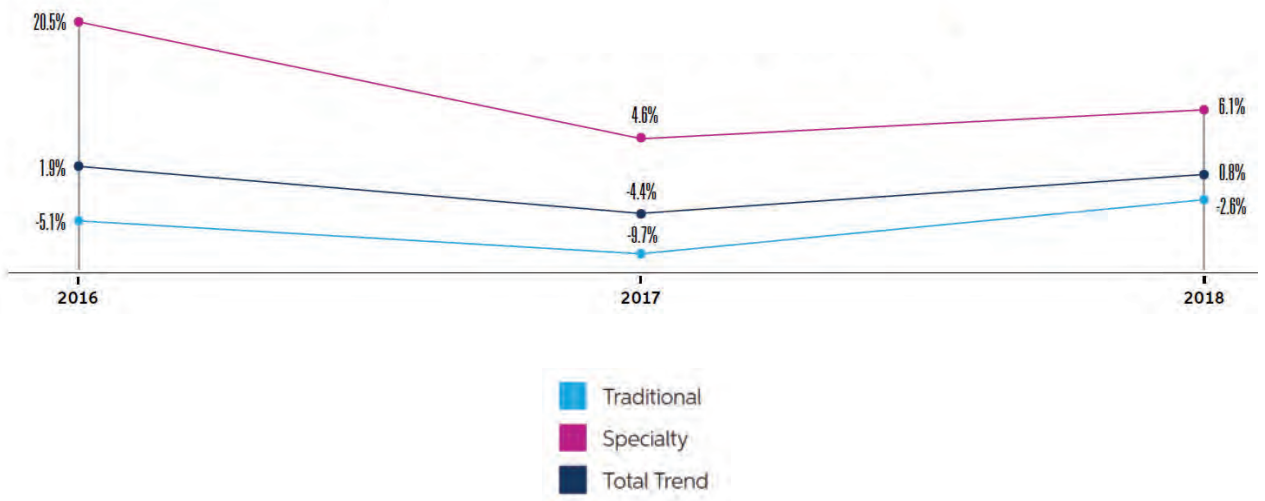
State Experience



Net Cost per Claim Trend 2016-2018



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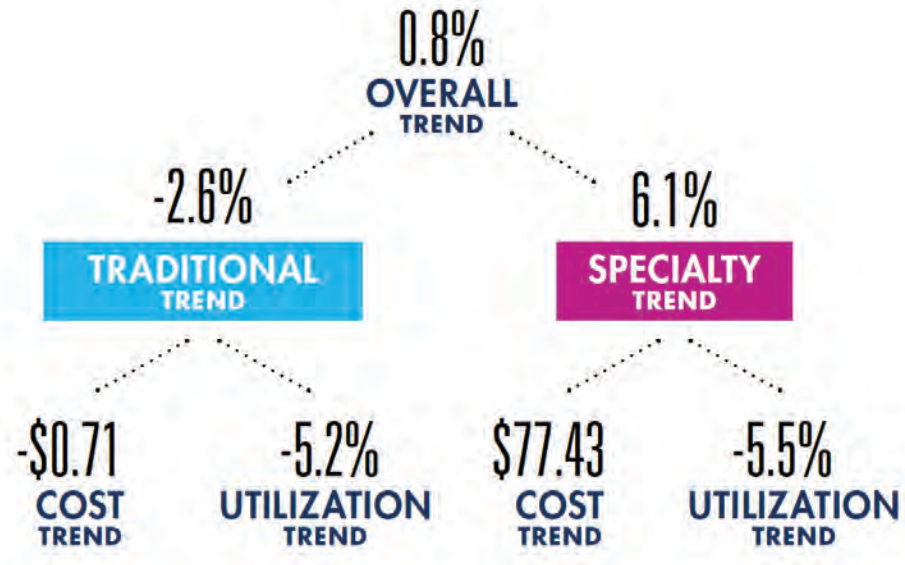
Overall Net Trend



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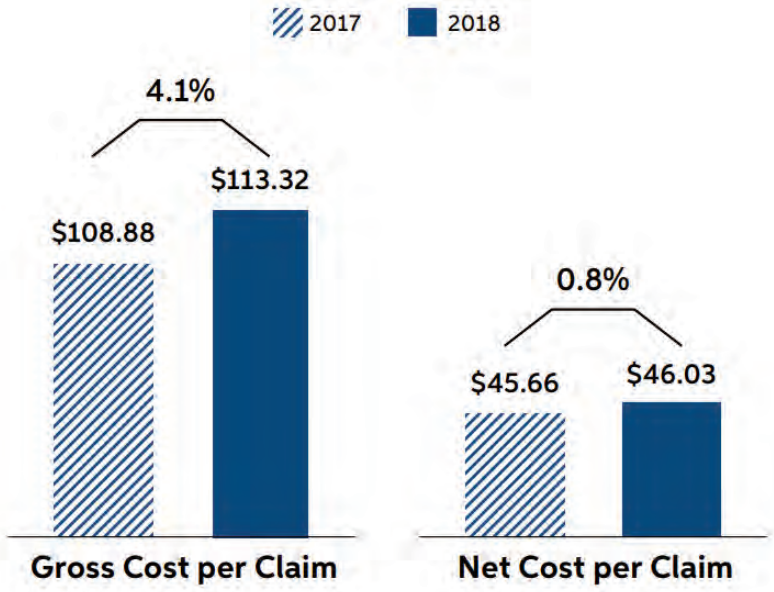
2018 Overall Cost Trend



7

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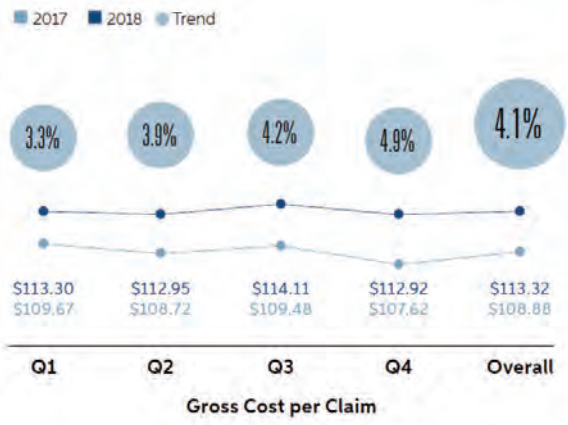
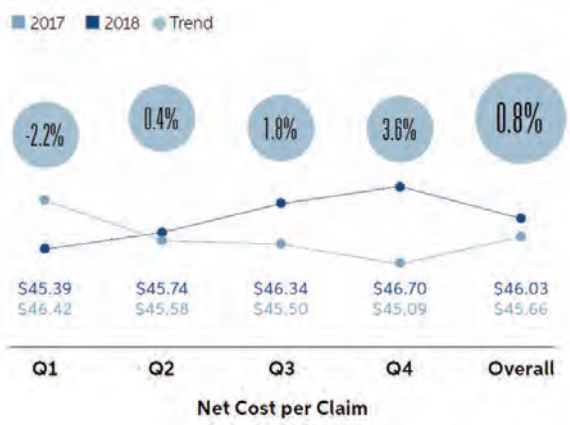
Overall Gross and Net Cost Per Medicaid Claim

2017–2018





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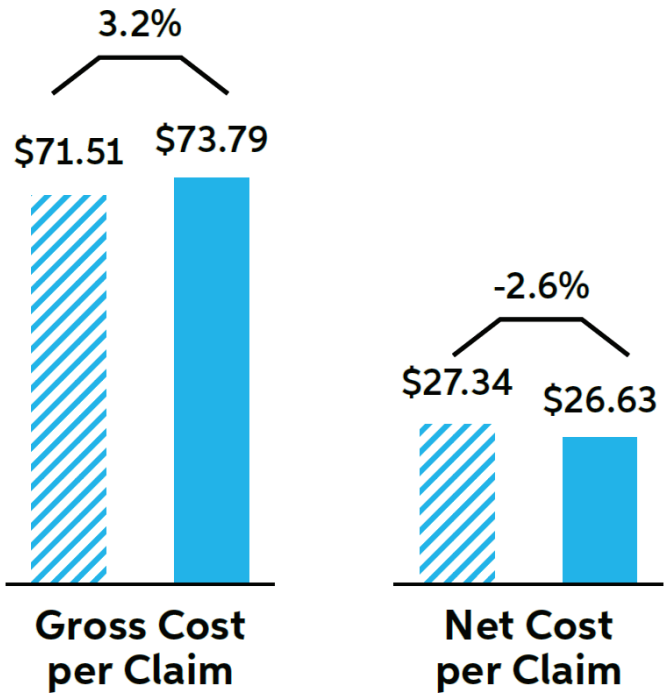
Magellan Rx MANAGEMENT

2018 Traditional Cost Trends



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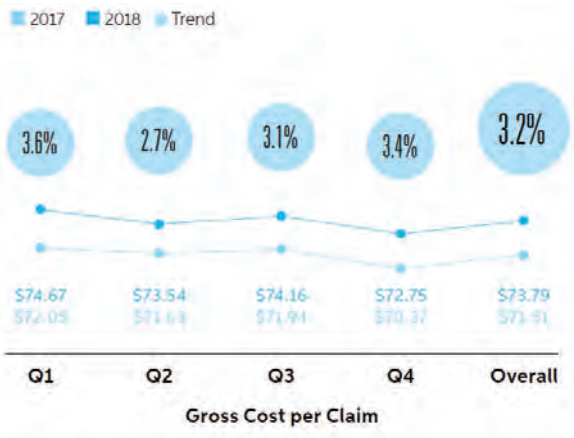
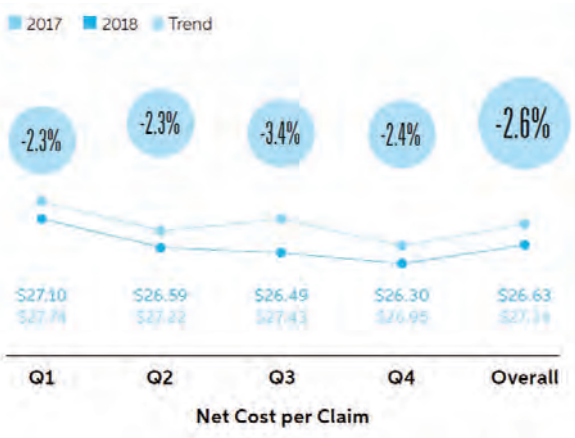
Traditional Gross and Net Cost per Medicaid Claim

2017–2018





10

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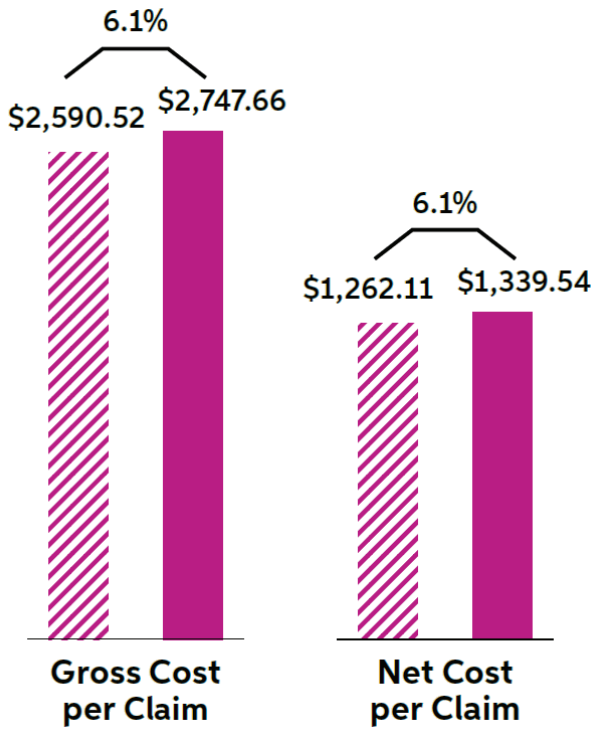
2018 Specialty Cost Trends



11

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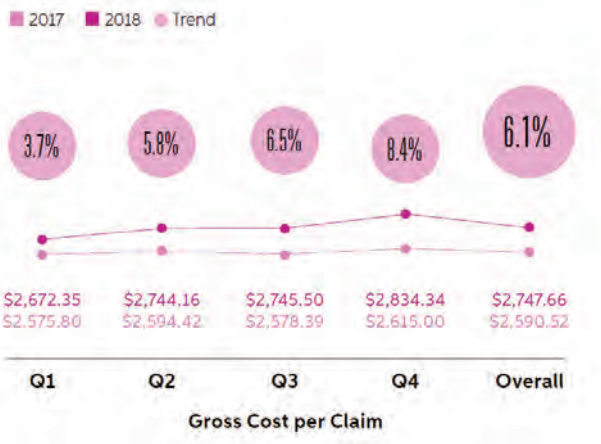
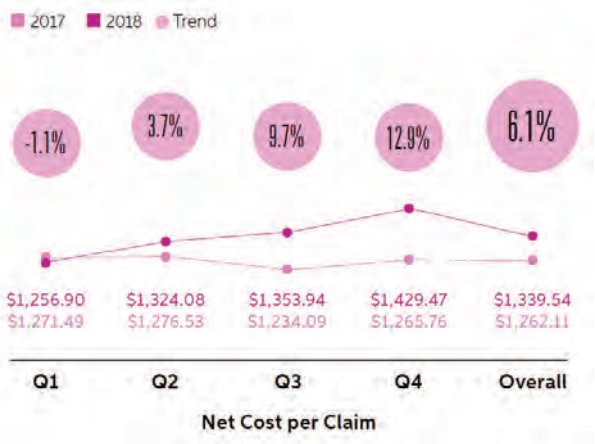
Specialty Gross and Net Cost per Medicaid Claim
2017–2018





12

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Medicaid Federal Rebate 2017-2018

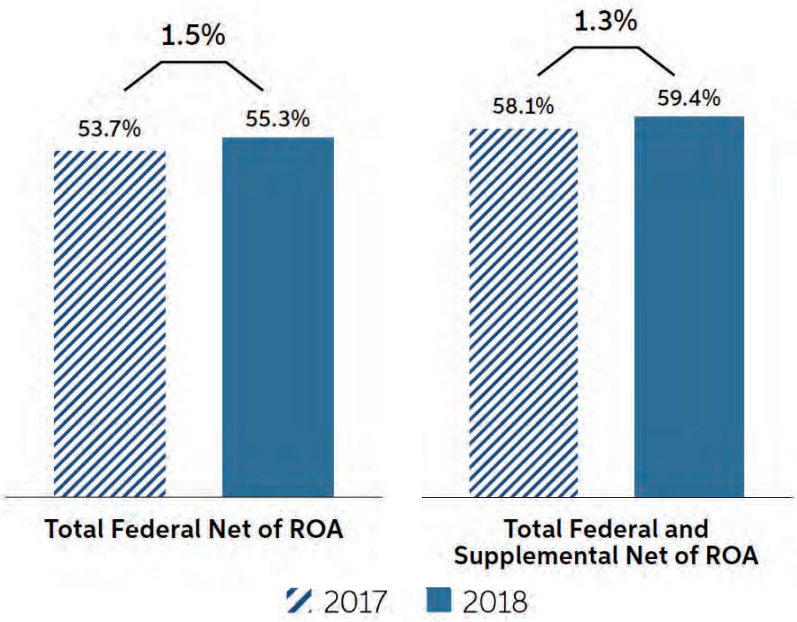

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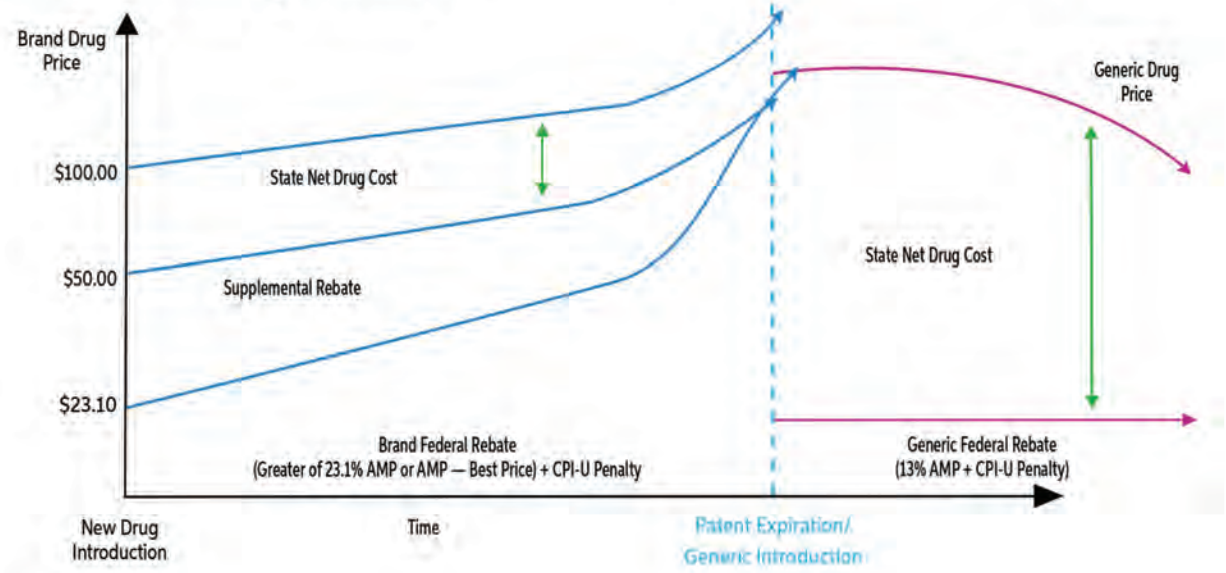
FIGURE 1

Medicaid Pharmacy Economics



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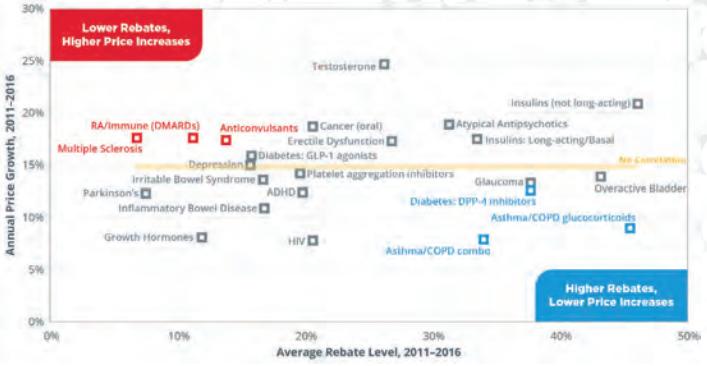
Myth vs. Fact: Rebates
Study of top drugs shows no correlation



Major Findings:

- **No correlation** between drug prices and PBM/payer rebates
- Cases exist of higher-than-average price increases with relatively low rebates
- Cases exist of lower-than-average price increases with relatively high rebates
- Drugmakers are **increasing prices regardless of rebate levels**

Study: Top 200-self-administered, patent-protected, brand-name drugs in 23 major drug categories examined.

Source: Visante, *No Correlation Between Increasing Drug Prices and Manufacturer Rebates in Major Drug Categories*. (April 2017).

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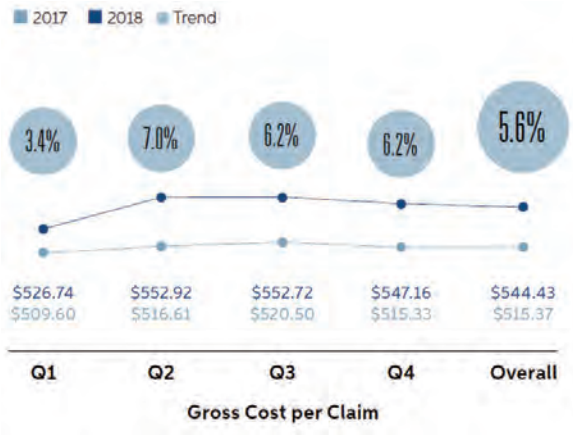
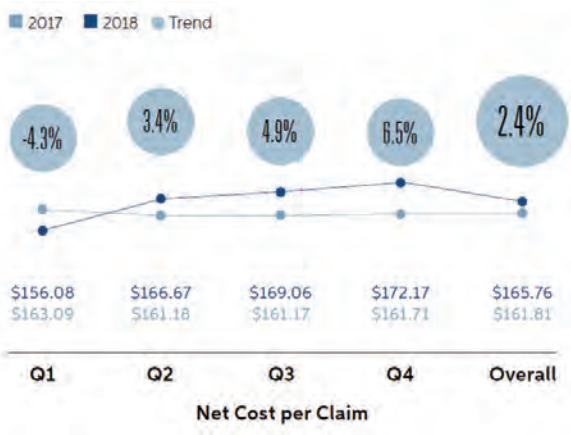
Branded Drug Gross and Net Cost per Medicaid Claim
2017–2018





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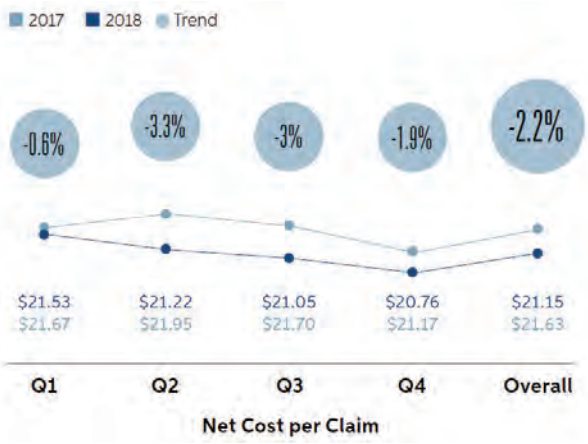
Generic Gross and Net Cost per Medicaid Claim
2017–2018



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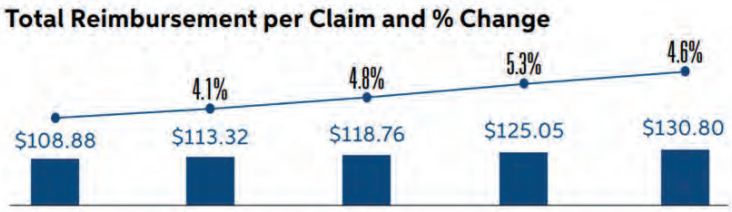
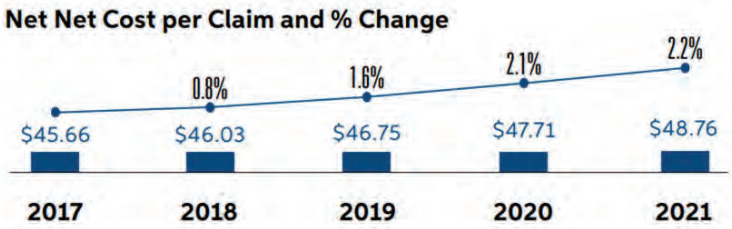
Medicaid Forecasting with MRx Predict





MRx Predict

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Drug Classes Driving Trend

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Traditional Categories Driving Trend

Antipsychotics

CLASS TREND PROFILE

-$51.4m
Net Spend Trend

-10.7%
Total Net Spend Trend

-1.7%
Claim Volume Trend

-9.1%
Net Cost Per Claim Trend

Spend and Utilization Trends

2017 total net spend 2018 total net spend

Invega Sustenna (IM) ▲5.6%
CLAIM VOLUME ▲7.2% NET COST PER CLAIM ▼-1.4%

Invega Trinza (IM) ▲22.4%
CLAIM VOLUME ▲25.5% NET COST PER CLAIM ▼-2.5%

Latuda (oral) ▲14.1%
CLAIM VOLUME ▲4.2% NET COST PER CLAIM ▲9.5%

Aripiprazole tablet (oral) ▼-80.4%
CLAIM VOLUME ▲4.6% NET COST PER CLAIM ▼-62.1%

Abilify Maintena (IM) ▲18.5%
CLAIM VOLUME ▲23.7% NET COST PER CLAIM ▼-4.2%

Chlorpromazine (oral) ▼-8.4%
CLAIM VOLUME ▼-3.0% NET COST PER CLAIM ▼-5.7%

Rexulti (oral) ▲25.4%
CLAIM VOLUME ▲29.3% NET COST PER CLAIM ▼-3.0%

Quetiapine tablets (oral) ▲2.5%
CLAIM VOLUME ▼-0.7% NET COST PER CLAIM ▲3.2%

Vraylar (oral) ▲55.3%
CLAIM VOLUME ▲69.9% NET COST PER CLAIM ▼-8.6%

Risperdal Consta (IM) ▼-15.0%
CLAIM VOLUME ▼-12.0% NET COST PER CLAIM ▼-3.5%

Traditional Categories Driving Trend

Hypoglycemics, Insulin and Related Agents

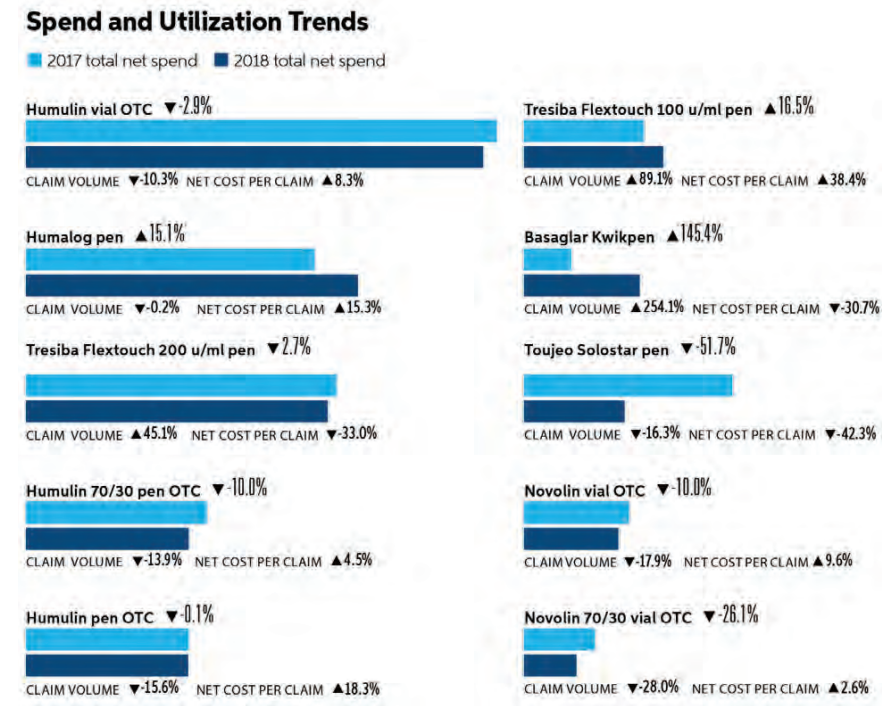
CLASS TREND PROFILE

-$8.3m
Net Spend Trend

-98.9%
Total Net Spend Trend

-2.3%
Claim Volume Trend

-103.5%
Net Cost Per Claim Trend



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Traditional Categories Driving Trend

Opiate Dependence Treatments

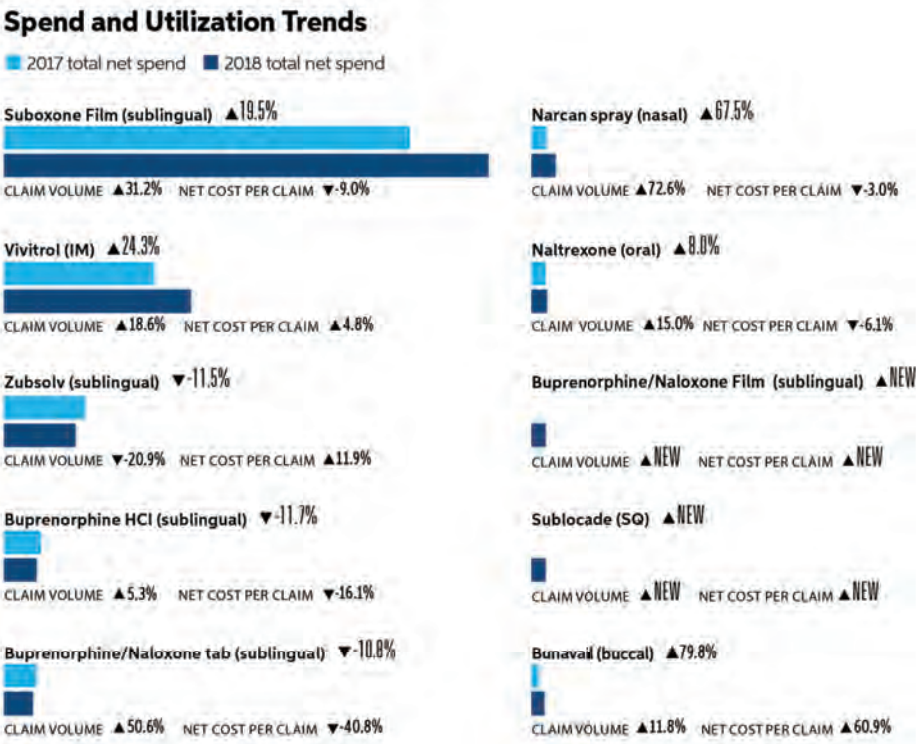
CLASS TREND PROFILE

$17.9m
Net Spend Trend

18.5%
Total Net Spend Trend

24.6%
Claim Volume Trend

-4.9%
Net Cost Per Claim Trend



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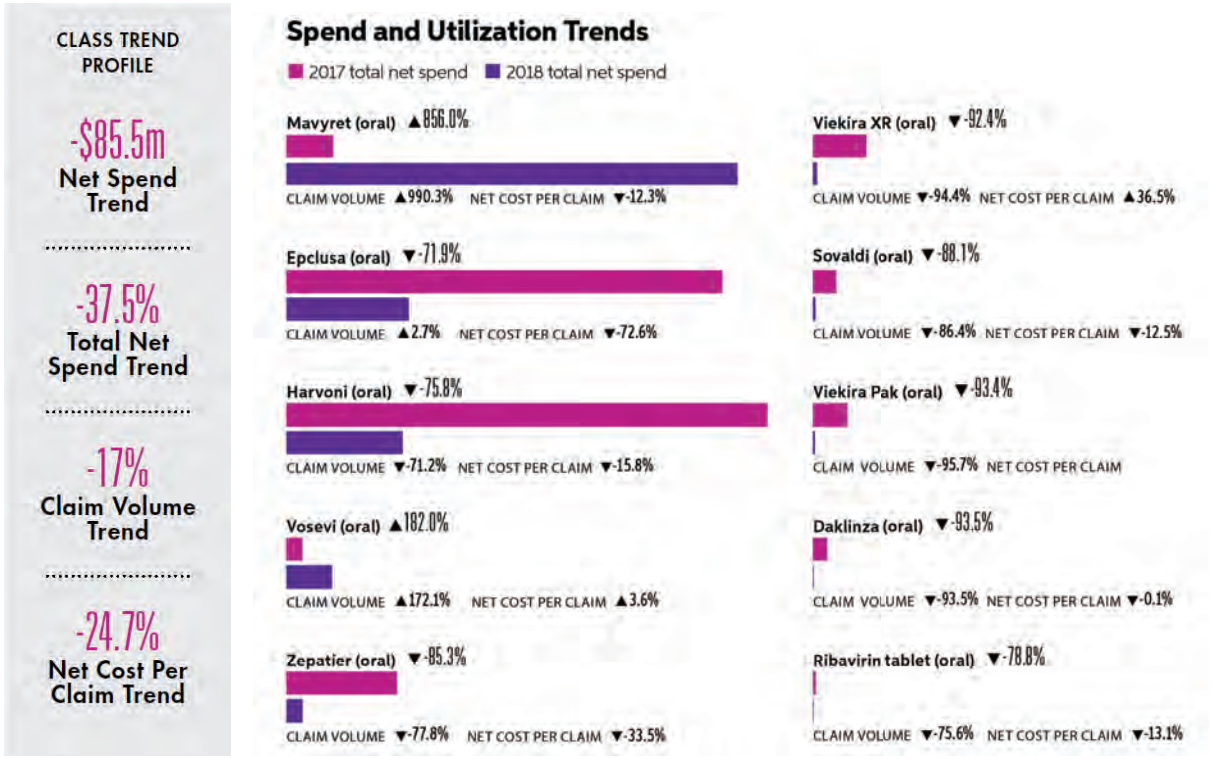
Specialty Categories Driving Trend

Hepatitis C Agents



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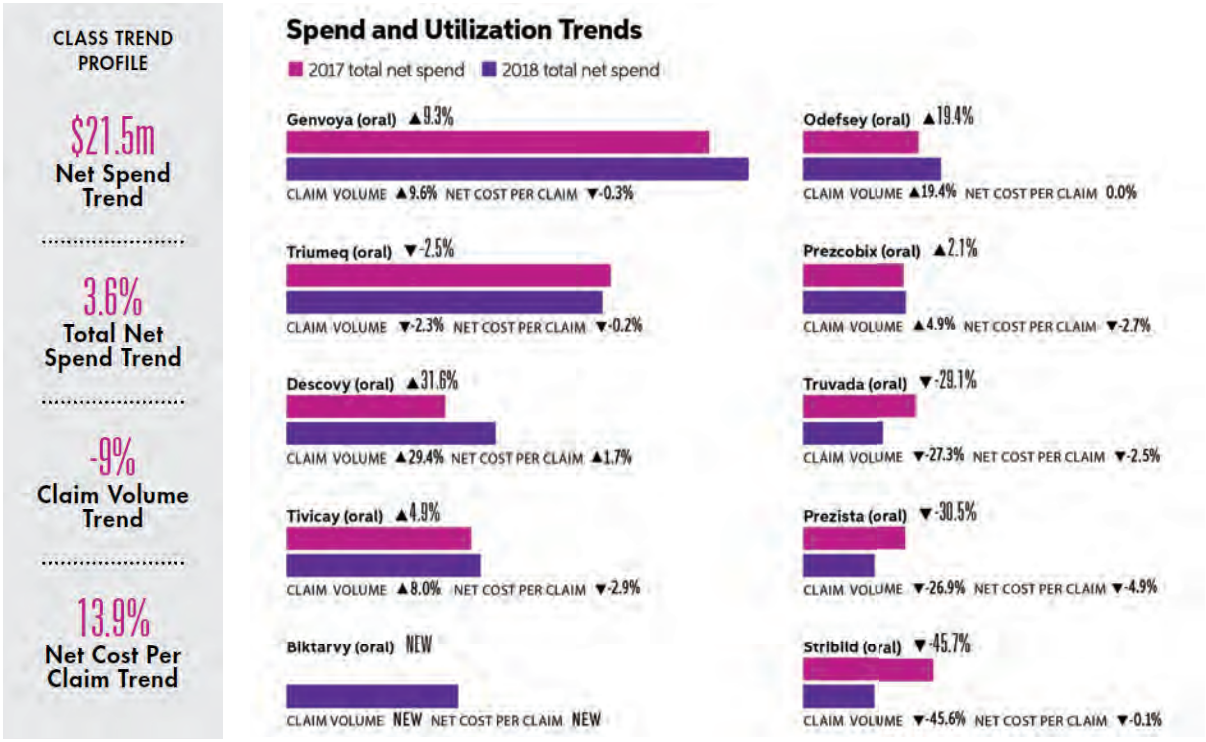
Specialty Categories Driving Trend

HIV/AIDS



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Specialty Categories Driving Trend

Movement Disorders

CLASS TREND PROFILE

$16.8m
Net Spend Trend

173%
Total Net Spend Trend

170.9%
Claim Volume Trend

0.8%
Net Cost Per Claim Trend

Spend and Utilization Trends

2017 total net spend ■ 2018 total net spend

Ingrezza ▲443.0%
CLAIM VOLUME ▲658.3% NET COST PER CLAIM ▼-28.4%

Austedo ▲1,108.4%
CLAIM VOLUME ▲826.8% NET COST PER CLAIM ▲30.4%

Tetrabenazine ▼-26.4%
CLAIM VOLUME ▲11.8% NET COST PER CLAIM ▼-34.2%

Xenazine ▼-28.9%
CLAIM VOLUME ▼-43.1% NET COST PER CLAIM ▲24.8%

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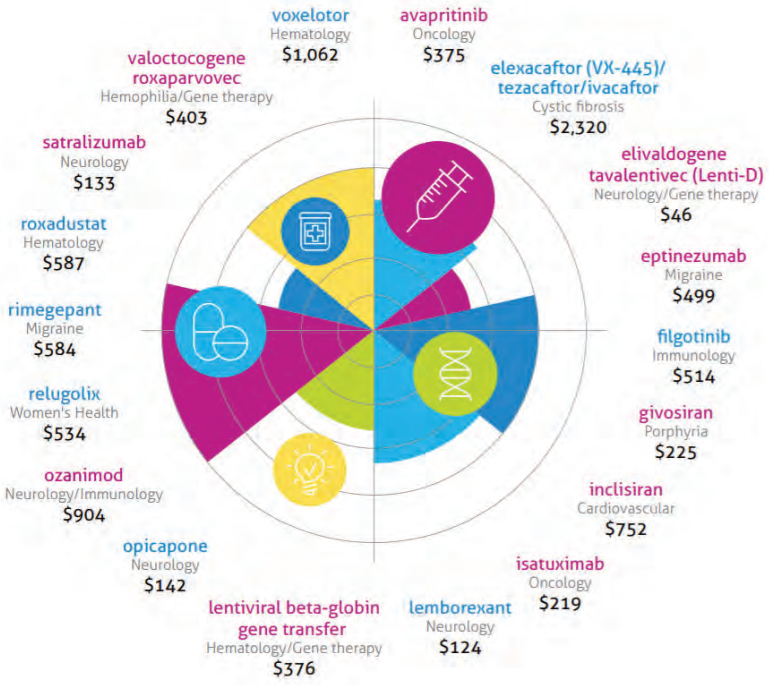
Pipeline and Forecasting



★ Specialty drug names appear in magenta

$ Financials are projected total annual US sales reported in *millions*, for the year 2023

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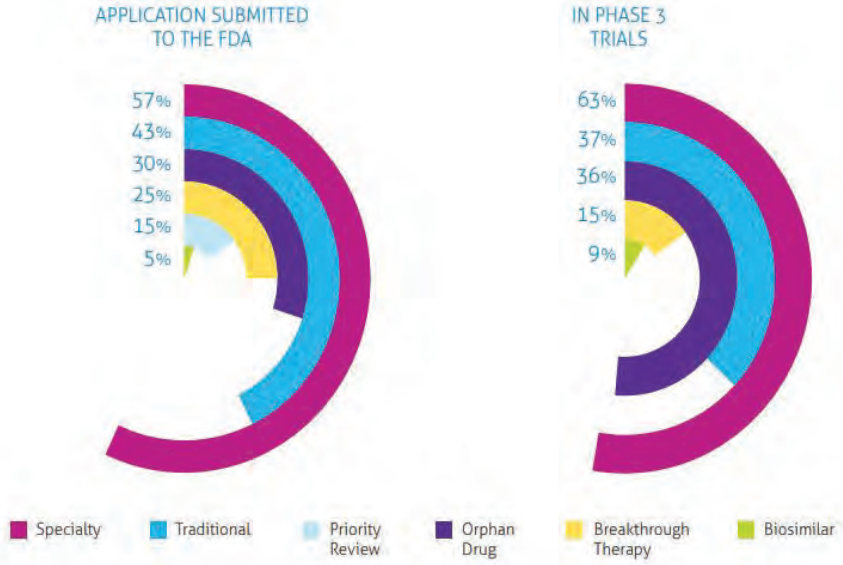
PIPELINE DRUG LIST

The pipeline drug list is an aerial outline of drugs with anticipated FDA approval through 2021. It is not intended to be a comprehensive inventory of all drugs in the pipeline; emphasis is placed on drugs in high-impact categories. Investigational drugs with a Complete Response Letter (CRL) and those that have been withdrawn from development are also noted.



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MRx Pipeline

PIPELINE DRUG LIST

★ Specialty drug names appear in magenta throughout the publication.

NAME	MANUFACTURER	CLINICAL USE	DOSAGE FORM	APPROVAL STATUS	FDA APPROVAL
dulaglutide (Trulicity®)	Eli Lilly	T2DM CV outcomes	SC	Submitted – sNDA	January 2020
peanut protein capsule (AR101)	Aimmune	Peanut allergy (children and adolescents)	Oral	Submitted – BLA; Breakthrough Therapy; Fast Track	January 2020
durvalumab (Imfinzi®)	AstraZeneca	SCLC (1st-line, extensive-disease)	IV	Submitted – sBLA; Orphan Drug; Priority Review	Jan–Mar 2020
osilodrostat	Novartis	Cushing's syndrome	Oral	Submitted – NDA; Orphan Drug	Jan–Mar 2020
rimegepant	Biohaven	Migraine treatment	Oral	Submitted – NDA; Priority Review (ODT only)	Late February 2020
paclitaxel injection concentrate for suspension	Sun Advanced Research	Breast cancer	IV	Submitted – 505(b)(2) NDA	Feb–Mar 2020
empagliflozin (Jardiance®)	Boehringer Ingelheim	T1DM	Oral	Submitted – sNDA	Feb–May 2020
ethinyl estradiol/ levonorgestrel	Agile	Contraception	Transdermal	Submitted – 505(b)(2) NDA	02/16/2020
pembrolizumab (Keytruda®) - 6-week dosing regimen	Merck	Melanoma; Classical Hodgkin lymphoma; Primary mediastinal large B cell lymphoma; Gastric cancer; HCC; Merkel cell carcinoma	IV	Submitted – sBLA; Breakthrough Therapy; Orphan Drug	02/18/2020

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Biosimilars Pipeline

To date, a total of 26 biosimilars have received FDA approval. Of these, only 13 have entered the market.

APPROVED BIOSIMILARS				
Brand Name (Nonproprietary name)	Manufacturer	Approval Date	Commercially Available	Originator Product (Manufacturer)
Zarxio® (filgrastim-sndz)	Sandoz	March 2015	✓	Neupogen® (Amgen)
Inflectra® (infliximab-dyyb)	Pfizer/Celltrion	April 2016	✓	Remicade® (Janssen)
Erelzi™ (etanercept-szzs)	Sandoz	August 2016	–	Enbrel® (Amgen)
Amjevita™ (adalimumab-atto)	Amgen	September 2016	–	Humira® (Abbvie)
Renflexis® (infliximab-abda)	Samsung Bioepis/ Merck	May 2017	✓	Remicade (Janssen)
Cyltezo® (adalimumab-adbm)	Boehringer Ingelheim	August 2017	–	Humira (Abbvie)
Mvasi™ (bevacizumab-awwb)	Amgen	September 2017	✓	Avastin® (Genentech)
Ixifi™ (infliximab-qbtx)*	Pfizer	December 2017	–	Remicade (Janssen)
Ogivri™ (trastuzumab-dkst)	Mylan	December 2017	✓	Herceptin® (Genentech)
Retacrit® (epoetin alfa-epbx)	Pfizer/Hospira	May 2018	✓	Epogen® (Amgen) Procrit® (Janssen)
Fulphila® (pegfilgrastim-jmdb)	Mylan	June 2018	✓	Neulasta® (Amgen)
Nivestym® (filgrastim-aafi)	Pfizer	July 2018	✓	Neupogen (Amgen)
Hyrimoz™ (adalimumab-adaz)	Sandoz	October 2018	–	Humira (Abbvie)

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Magellan Rx MANAGEMENT

Notable Developments in Medicaid

OUTCOMES-BASED CONTRACTING

A real-world opportunity for drug manufacturers to demonstrate a product's value.

SUBSCRIPTION PAYMENT MODEL

States are incentivized to engage in a broad and far-reaching public health campaign to promote screening, diagnosis, and treatment referral for the identified condition(s).

30

Magellan Rx MANAGEMENT

31

Magellan Rx MANAGEMENT

GOVERNOR'S TASK FORCE ON REDUCING PRESCRIPTION DRUG PRICES

May 20, 2020

10:00 a.m. – 2:00 p.m.

I. Welcome (10 minutes)
- **Nathan Houdek, Deputy Commissioner**, *Office of the Commissioner of Insurance*

II. Consumer Experience (5 minutes)

III. Pharmacy Society of Wisconsin (40 minutes)
- **Paul Cesarz, RPh,** *Manager Community Pharmacy Professional Services; Mercy Health Pharmacy*

IV. Hometown Pharmacy (40 minutes)
- **Dan Strause,** *Managing Partner, Hometown Pharmacy*

V. Break (15 minutes)

VI. Free and Charitable Clinics (40 minutes)
- **Ian Hedges,** *Chief Executive Officer at HealthNet of Rock County*
- **Yolanda Tolson-Eveans,** *Pharmacist in Charge at St. Vincent de Paul Charitable Pharmacy*

VII. Task Force Member Discussion (90 minutes)
- Discuss potential policy options

VIII. Next Meeting Date/Location
- June 18, 2020; Sturgeon Bay or Webinar (TBD)

IX. Adjourn

Meeting Minutes
May 20, 2020
10 a.m. – 2 p.m.
Webinar via Zoom

Welcome
Nathan Houdek, OCI Deputy Commissioner and Task Force chair

- Deputy Commissioner Houdek welcomed Task Force members and public attendees and thanked Ms. Aubihl for her work setting up the meeting
- Quick recap of previous meetings:
  - First meeting in November
  - January discussed Pharmacy Benefit Managers (PBMs)
  - February meeting heard more from PBMs and self-insured employers
  - March and April were canceled (postponed)
- Today's meeting will look at pharmacies and pharmacists
- Key housekeeping items
  - Use chat box during the presentation
- Revised 2020 work plan
  - June 18 – wholesalers and pharmacy services administrative organizations (PSAOs), hospital drug dispensing, and drug importation
  - July 21 and July 22 – the plan is to hold those meetings in Madison and/or they will be held virtually

Consumer Experience

- Mark Miller, a resident of North Freedom, Wisconsin in Sauk County
  - Mr. Miller has chronic obstructive pulmonary disease (COPD) and manages the expense of his prescriptions, including costly inhalers, on a limited income.
  - After paying for necessary costs, including housing, utilities, etc., and paying for his inhaler he is often left with less than $50 at the end of the month.

Pharmacy Society of Wisconsin
Paul M. Cesarz, BS Pharm, R.Ph. – Manager System Community Pharmacy Professional Services, Mercyhealth Walworth Pharmacy

- A presentation from Mr. Cesarz is available on the Task Force website: https://rxdrugtaskforce.wi.gov/Documents/PharmacySocietyOfWisconsin.pdf

Pharmacy Perspective
Dan Strause – Managing Partner, Hometown Pharmacy

- A presentation from Mr. Stause is available on the Task Force website: https://rxdrugtaskforce.wi.gov/Documents/HometownPharmacy.pdf

Free and Charitable Clinics and Pharmacies
Ian Hedges, Chief Executive Officer, HealthNet of Rock County
Yolanda Tolson-Eveans, Pharmacist in Charge, St. Vincent De Paul Charitable Pharmacy

- A presentation from Mr. Hedges and Ms. Tolson-Eveans is available on the Task Force website: https://rxdrugtaskforce.wi.gov/Documents/FreeCharitableClinics.pdf

Task Force Member Policy Discussion
Mr. Houdek asked the Task Force members to weigh in on initial thoughts around two documents that outline policy options. The documents reflect issues raised during Task Force meetings and those included in Assembly Bill 114/Senate Bill 100, which failed to advance through the Legislative process due to a shortened floor period resulting from COVID-19. Mr. Houdek pointed out that these bills may be voted on during an extraordinary session or re-introduced next session. The Task Force has not taken a position on the proposals.

Issues raised by Task Force members are reflected in documents for discussion only and are not policy recommendations at this point. Mr. Houdek asked members to look at the two documents and provide feedback via email before the next meeting. These documents will continue to evolve, and policy items will be included as the Task Force moves forward into new topics.

Task Force members briefly discussed the following issues during the last 20 minutes of the meeting:

- Reference to "claw back" on the AB 114/SB 100 document may need to be re-visited. Description in the table is an accurate explanation of a requirement in the legislation, however, there is some question around whether the provision highlighted aligns with the industry-standard explanation of what a "claw back" is. The term "claw back" may need to be dropped or replaced.

- There was much discussion and interest in capping co-payments for insulin. The issue was raised as an option for immediately impacting consumers with diabetes. For the purpose of discussion, not necessarily opposition, a member raised the issue of choosing between disease states. For example, the challenge between determining to cap co-pays for insulin as opposed to inhalers.

- A member indicated an interest in learning more about affordability boards.

- A general question was raised about whether PBM transparency has lowered costs to consumers in any other states. Mr. Houdek reminded the group that this question was asked by the Task Force at the last meeting. Presenters at that meeting indicated transparency efforts were too recently started to know an impact on cost and that it isn't necessarily trackable. It was also noted that the intent was more to increase access to the data and bring attention to certain drug prices and practices.

- A Task Force member would like to go back to the National Governor's Association (NGA) and ask about: (a) the potential impact of Haven Healthcare on the pharmaceutical industry; (b) the barriers to and benefits of a government based universal purchaser; and (c) what innovative programs or solutions pharmaceutical manufacturers have in progress to lower prescription drug prices. It was noted that the pharmaceutical manufacturer role and efforts will be discussed in detail at the July 21, 2020 meeting.

Adjourn

Pharmacy Society of Wisconsin

Governor's Task Force on Reducing Prescription Drug Prices

Pharmacists and Pharmacies

Paul Cesarz, BS Pharm, R.Ph.
Manager System Community Pharmacy Professional Services
Mercyhealth Walworth Pharmacy

TODAY'S SPEAKER

Paul Cesarz, BS Pharm, R.Ph.
Manager Professional Services
Community Pharmacy
Mercy Walworth Pharmacy

DISCLOSURE

Pharmacist Paul M. Cesarz declares no conflicts of interest.

MERCYHEALTH HOSPITAL AND MEDICAL CENTER - WALWORTH

- Critical Access Hospital and Clinics
- Mercy Walworth Community Pharmacy
  - N2950 State Road 67
  - Lake Geneva, WI 53147

MERCYHEALTH REGIONAL HEALTH SYSTEM

- 7 Hospitals
- 85 Primary and Specialty care sites
- 48 Community clinics
- 7 Outpatient Pharmacies

OVERVIEW

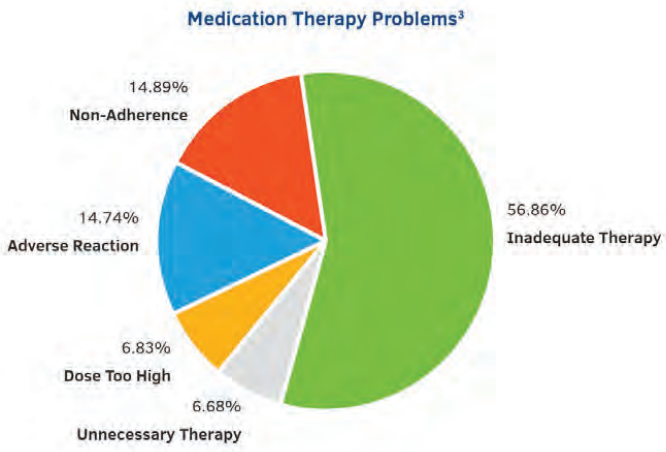
- Pharmacy practice
- Pharmacist services provide value
- Pharmacy supply chain within and outside of health systems
- Pharmacy interactions with PBMs and payers.

"About **30% of older adults** in the U.S. and Canada **filled a prescription** in the last few years for one of many medications that the **American Geriatrics Society recommends they avoid**."

$561 billion in annual spending on prescription drugs which is among the fastest growing elements of healthcare spending.

"**66% of older adults** take **5 or more drugs** per day, and **27% take 10 or more** per day."

"**Inclusion of clinical pharmacists** in physician–pharmacist collaborative care-based patient-centered medical home model was associated with **significant improvements** in patients' medication-related **clinical health outcomes** and a **reduction in hospitalizations**."

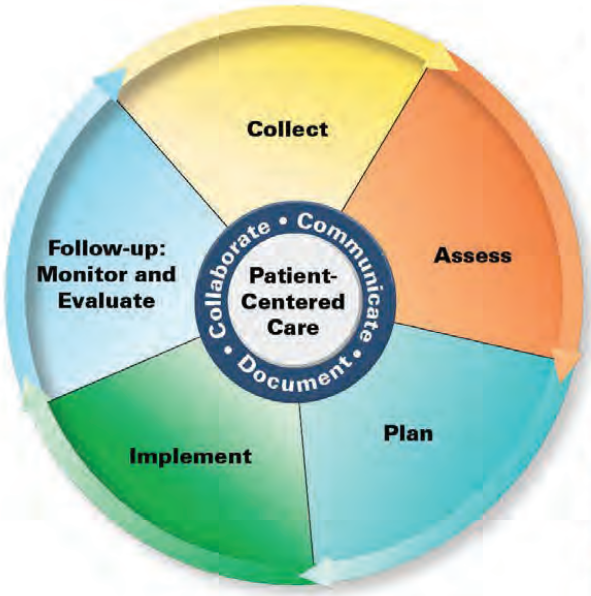


Comprehensive Medication Management in Team-Based Care Brief, American College of Clinical Pharmacy

1/3 of medication related admissions are linked to poor adherence

Approximately ¼ of 1st fill medications are not picked up in the outpatient setting

PHARMACISTS' PATIENT CARE PROCESS[4]



Pharmacists' Patient Care Process

Pharmacists use a patient-centered approach in collaboration with other providers on the health care team to optimize patient health and medication outcomes.

Using principles of evidence-based practice, pharmacists:

Collect
The pharmacist assures the collection of the necessary subjective and objective information about the patient in order to understand the relevant medical/medication history and clinical status of the patient.

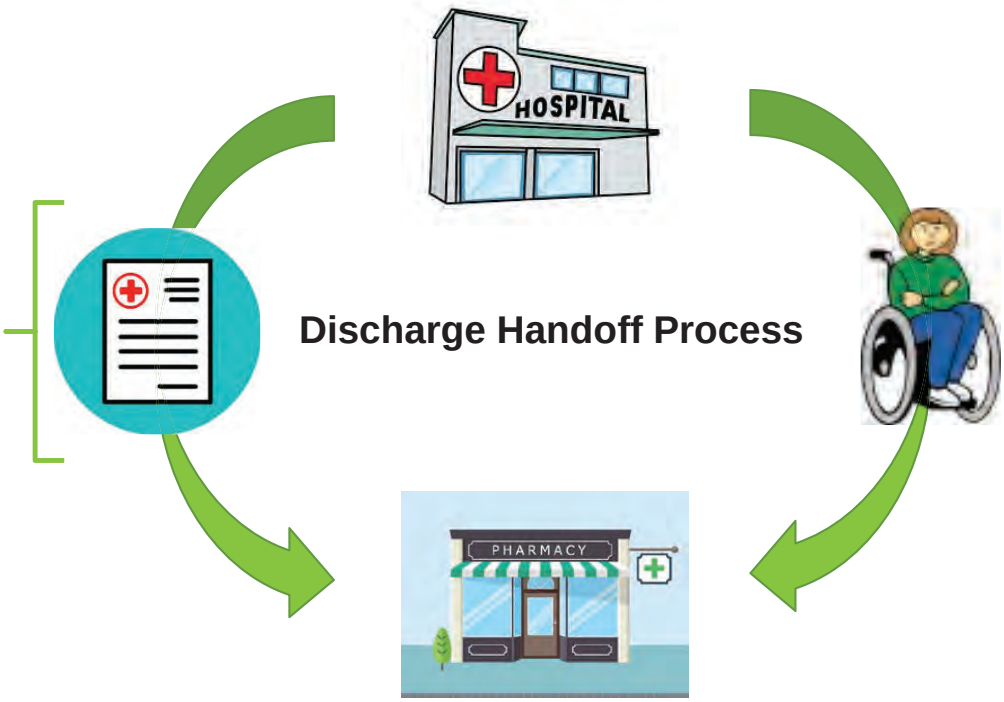
Assess
The pharmacist assesses the information collected and analyzes the clinical effects of the patient's therapy in the context of the patient's overall health goals in order to identify and prioritize problems and achieve optimal care.

Plan
The pharmacist develops an individualized patient-centered care plan, in collaboration with other health care professionals and the patient or caregiver that is evidence-based and cost-effective.

Implement
The pharmacist implements the care plan in collaboration with other health care professionals and the patient or caregiver.

Follow-up: Monitor and Evaluate
The pharmacist monitors and evaluates the effectiveness of the care plan and modifies the plan in collaboration with other health care professionals and the patient or caregiver as needed.

<u>Discharge Handoff Summary</u>
PCP/Unit Contact Info
Patient Chief Complaint
Summary of the Admission
Discharge Diagnoses
Complete Medication List
Vital Signs/Lab Results
Prescription Benefit Eval.
Follow-up appointments



Discharge Handoff Process

VALUE-BASED PAYMENT MODELS: WHERE DOES THE PHARMACIST FIT IN?

Examples of Alternative Payment Model (APM) Programs:

- Medication Therapy Management (MTM)
- Population Health Management/CPESN
- Medication Adherence Programs
- Comprehensive Medication Reviews
- Immunizations
- Pharmacogenomics
- Disease Management Services (diabetes, hypertension, hyperlipidemia)
- Transitions of Care Management
- Comprehensive Primary Care Plus (CPC+)
- Part D Enhanced Medication Therapy Management Model

COLLABORATIVE PRACTICE AGREEMENTS[3]

- Formal Relationship between Pharmacists and Physicians
  - Allows for expansion of services
  - Autonomous changes Pharmacists can make under specified situations and conditions, as outlined in the agreement
  - Wis. Act 294
  - 48 States, including the District of Colombia utilize CPA's
- Goal
  - "To develop consensus recommendations that provide principles and strategies for effectively implementing healthcare changes"

INSTITUTIONAL PROTOCOL

- Therapeutic drug monitoring
  - Anticoagulation
  - Pharmacokinetics for vancomycin and aminoglycosides
- Ordering of tests and labs to monitor drug therapy for appropriateness
- Medication formulary management
- Immunizations

PHARMACIST IMPACT

- Pharmacists and Immunizations in the community setting
  - Prior to 1994- RPh did not exist as immunizers
  - 1996- APhA releases universal pharmacists vaccination training program
  - 1998- WI law allows pharmacists to provide immunizations
  - Fast forward to 2014- Reported ~15% of all flu doses in WI
    - Milwaukee county- >25% of all doses
    - Subset of patients aged 65 years and older- **Approximately 1/3rd of all influenza doses reported to WIR were from community pharmacies.**
  - Community Pharmacies increase access to vaccines!

immunize Milwaukee!

MEDICATION COSTS

- Medication cost management is a critical concern for pharmacy leaders and healthcare leaders
- Specialty pharmaceuticals have seen 17-22% spending growth per year and are expected to comprise 50% of U.S. drug expenditures in 2019
  - Health-systems are centralizing prior auth. processes to support clinicians on the healthcare team
  - ASHP strategic recommendation to have pharmacists take ownership of central prior-authorization management and all aspects of the medication-use system

MAC – MAXIMUM ALLOWABLE COST

- Means the unit price established by the PBM for a multisource drug included on PBM's MAC drug lists for clients.
- The payment schedules specify the maximum unit ingredient cost payable by client for drugs on the MAC list. The MAC list and payment schedules are frequently updated.

CONTROL OF THE ABOVE DEFINITIONS

- Allows PBMs to manipulate the MAC concept in whatever ways they choose
- PBMs pricing formulas
- Generic guarantees

- See: Managed Care, Don't Get Caught By PBMs' MAC Mousetraps
- www.managedcaremag.com/archives accessed May 5, 2020

MAC EXAMPLE CONTRACT DEFINITION

Community Pharmacy	MAC + $1.00 dispensing fee
Mail Order	MAC – 20% plus no dispensing fee

MAC EXAMPLE CONTRACT FORMULA

- Retail generic drugs:
  - The lowest of (i) PBMs MAC or
  - (ii) the retail pharmacys' U&C [usual and customary] or
  - (iii) AWP minus 18 percent [82 percent of the average wholesale price.

MAC EXAMPLE OTHER PRICING FORMULAS

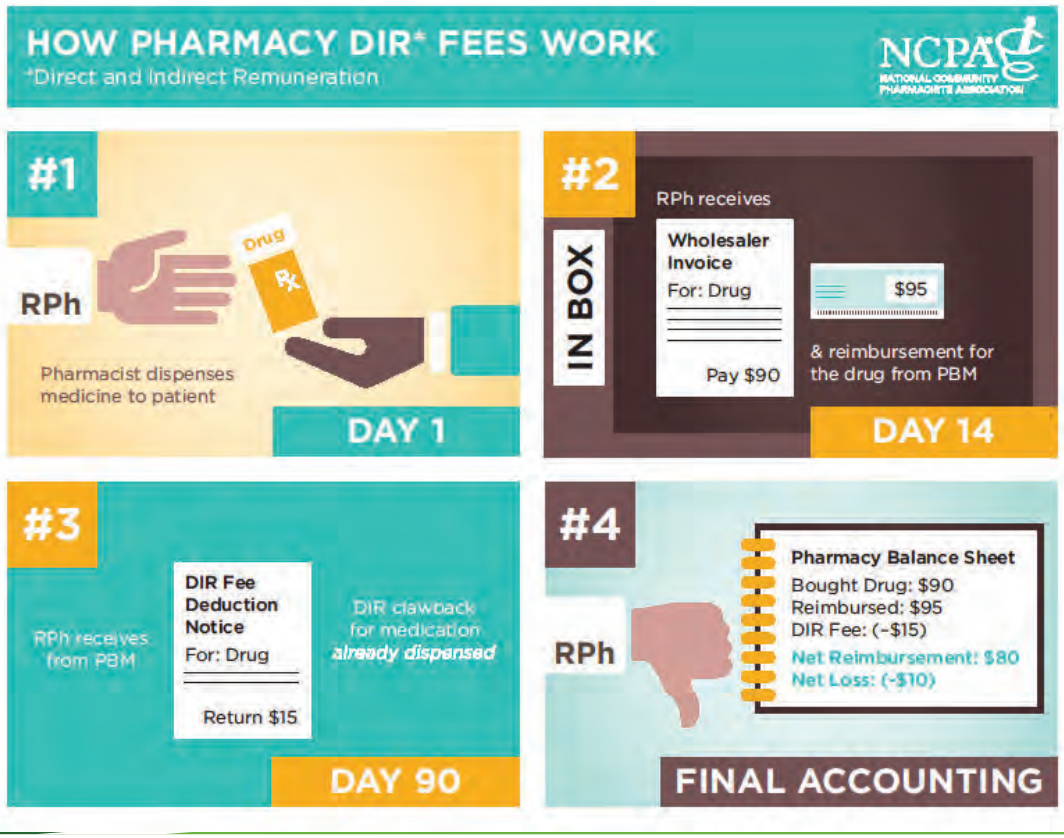
- Mail generic drugs:
  - AWP minus 50 percent or PBMs MAC

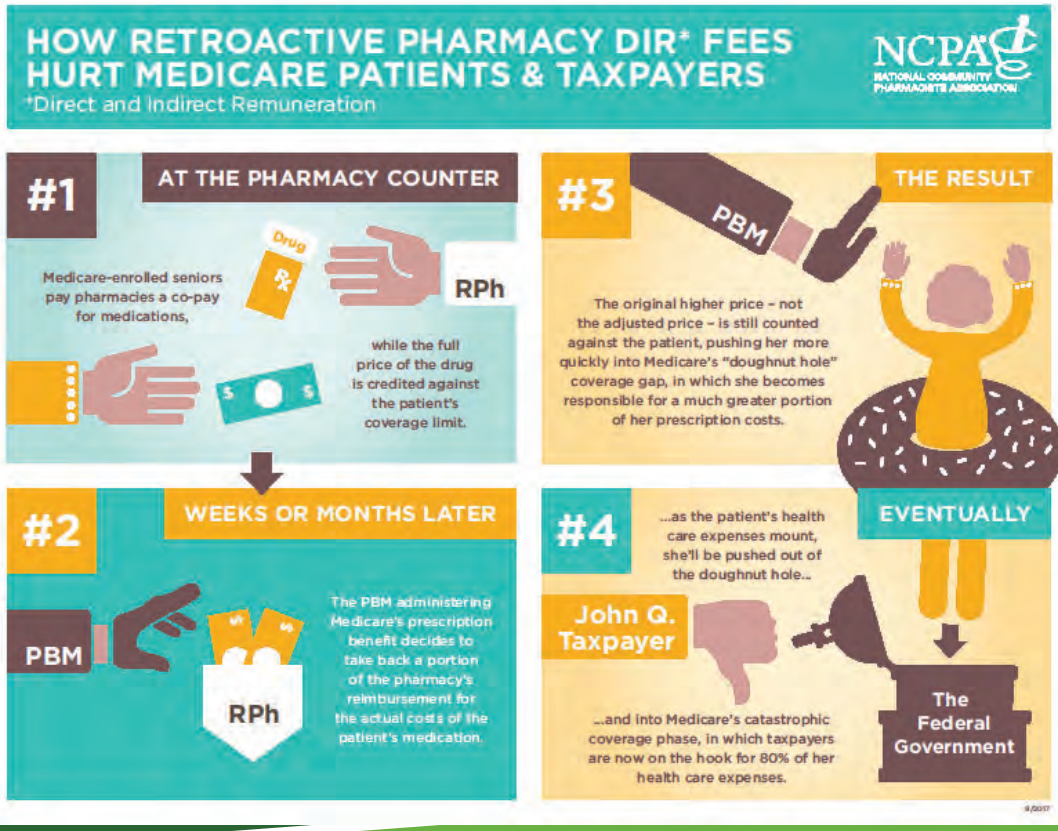
MAC EXAMPLE GENERIC GUARANTEES

- Generic guarantee: PBM warrants that all drugs on PBMs MAC list will be guaranteed to have an average annual discount of AWP minus 64 percent.

PBM MAIL-ORDER WASTE

- An example of Express Scripts overutilization of the healthcare system. The patient has since deceased and his spouse … tried to get Express Scripts to stop sending items. … over $6,000 that Express Scripts charged the patients plan."
- http://www.ncpa.co/pdf/waste-not-want-not---examples-of-mail-order-pharmacy-waste.pdf


HOW PHARMACY DIR* FEES WORK
*Direct and Indirect Remuneration
NCPA
#1
RPh
Drug
Rx
Pharmacist dispenses medicine to patient
DAY 1
#2
RPh receives
IN BOX
Wholesaler Invoice
For: Drug
Pay $90
$95
& reimbursement for the drug from PBM
DAY 14
#3
RPh receives from PBM
DIR Fee Deduction Notice
For: Drug
Return $15
DIR clawback for medication already dispensed
DAY 90
#4
RPh
Pharmacy Balance Sheet
Bought Drug: $90
Reimbursed: $95
DIR Fee: (-$15)
Net Reimbursement: $80
Net Loss: (-$10)
FINAL ACCOUNTING


HOW RETROACTIVE PHARMACY DIR* FEES HURT MEDICARE PATIENTS & TAXPAYERS
*Direct and Indirect Remuneration
NCPA
#1
AT THE PHARMACY COUNTER
Drug
Rx
RPh
Medicare-enrolled seniors pay pharmacies a co-pay for medications,
while the full price of the drug is credited against the patient's coverage limit.
#2
WEEKS OR MONTHS LATER
PBM
RPh
The PBM administering Medicare's prescription benefit decides to take back a portion of the pharmacy's reimbursement for the actual costs of the patient's medication.
#3
PBM
THE RESULT
The original higher price – not the adjusted price – is still counted against the patient, pushing her more quickly into Medicare's "doughnut hole" coverage gap, in which she becomes responsible for a much greater portion of her prescription costs.
#4
EVENTUALLY
...as the patient's health care expenses mount, she'll be pushed out of the doughnut hole...
John Q. Taxpayer
...and into Medicare's catastrophic coverage phase, in which taxpayers are now on the hook for 80% of her health care expenses.
The Federal Government

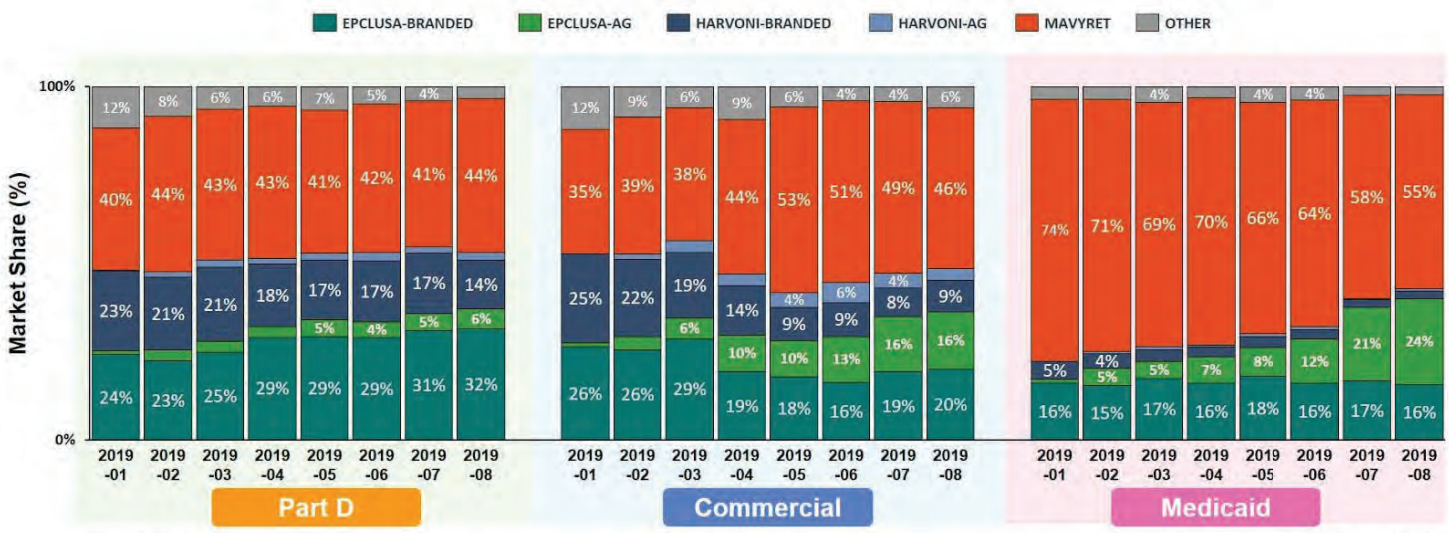
WARPED INCENTIVES

EXPRESS SCRIPTS®

CVS caremark®

OPTUMRx®

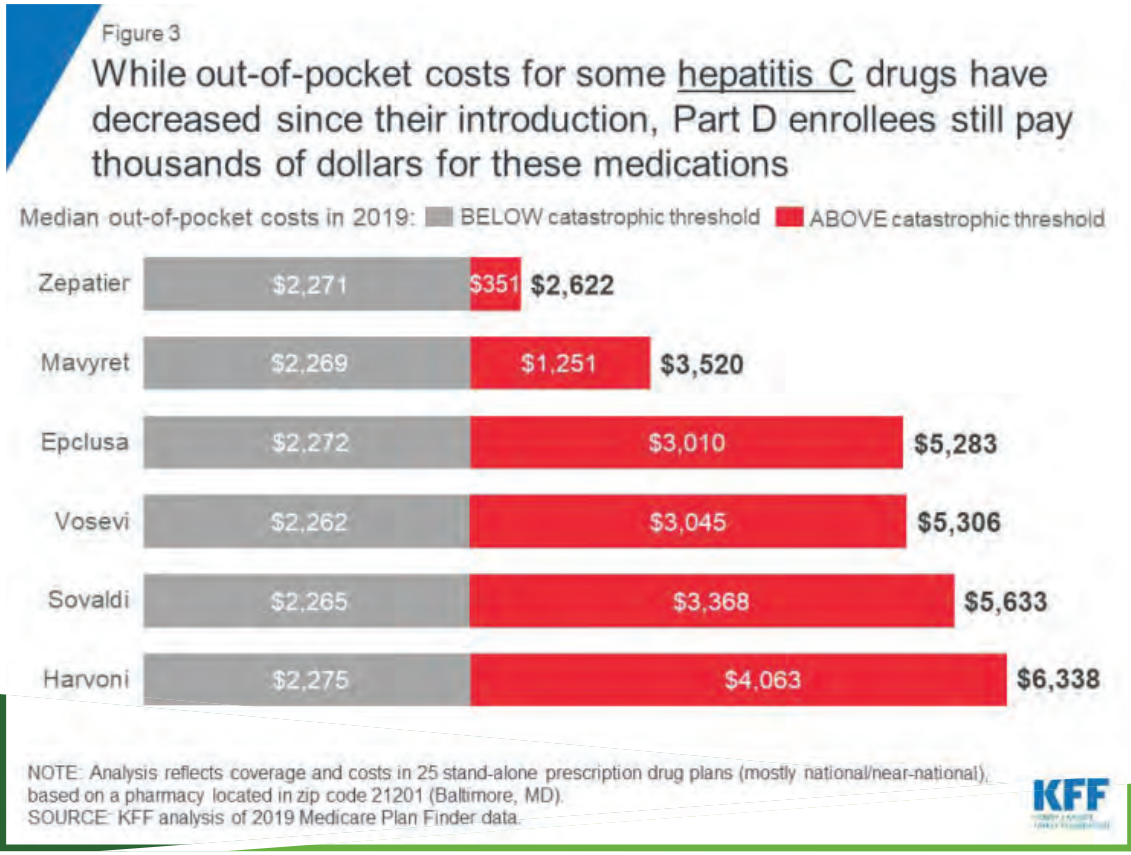
Market Share for Hepatitis C Therapies, New-to-Class Patients, 2019



AG = authorized generic

Source: IQVIA US Market Access Strategy Consulting analysis. New-to-Class patients have not previously initiated therapy on any HEP-C product in the prior year. Data show paid claims.

IQVIA™



NET DRUG COST HAS DECREASED

2001-2003 WISCONSIN BUDGET

- Manufacturer Rebate Provision
  - 2001 Act 16, section 1838gb (see pages 313 – 315 or this 789-page law)
  - Budget passed Senate and House, signed by Governor 8/31/2001

DRUG COST TREND 2012 TO 2016

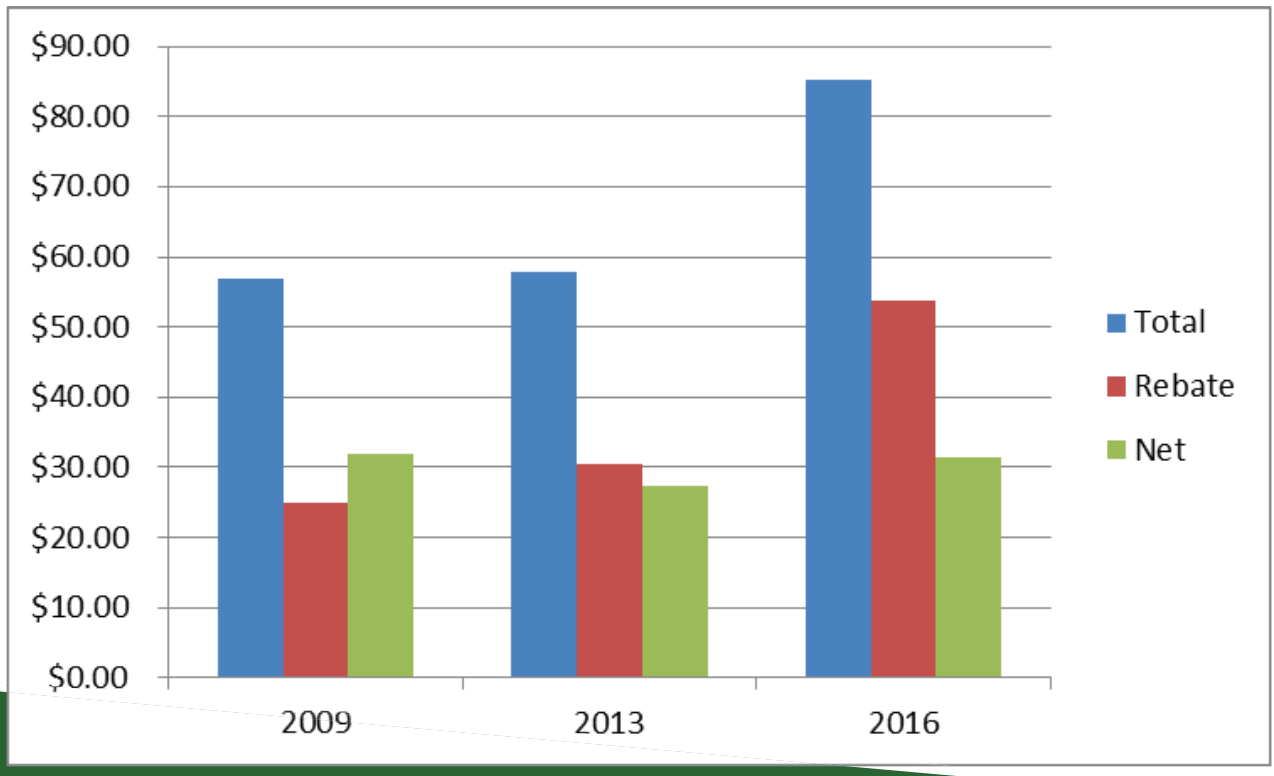
- WI Medicaid Pharmacy Utilization Data
- "In the last five years Total gross paid costs have increased 13%, while net costs decreased 4% due to growth in rebate collection of 20% over the same time period. This also resulted in a net decrease in price per member per month (PMPM)."
  - Minutes of the Drug Utilization Review (DUR) Board Meeting
  - Wednesday, June 7, 2017, page five, paragraph one

NET DRUG COST IN MILLIONS

	Total	Rebate	Net	Rebate %
2009	$ 722.6	$ 316.4	$ 406.2	43.8
2013	$ 822.0	$ 433.2	$ 388.8	52.7
2016	$ 1,238.4	$ 781.8	$ 456.6	63.1

NET DRUG COST PER MEMBER PER MONTH (PMPM)

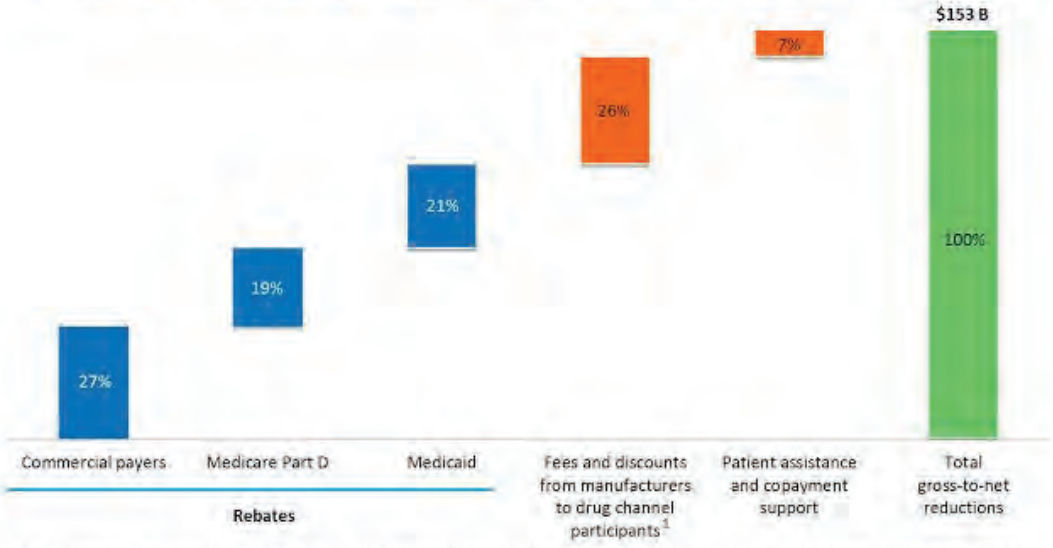
	Total	Rebate	Net	Rebate %
2009	$ 56.86	$ 24.90	$ 31.96	43.8
2013	$ 57.76	$ 30.44	$ 27.32	52.7
2016	$ 85.12	$ 53.71	$ 31.41	63.1



GROSS TO NET PRICE REDUCTIONS

- 2018 Total Value of gross-to-net reductions for brand-name drugs was $166 Billion
- 27% Commercial payers
- 19% Medicare Part D
- 21% Medicaid
- 26% Drug channel participants
- 7% Patient assistance and copayment support

Total Value of Pharmaceutical Manufacturers' Gross-to-Net Reductions for Brand-Name Drugs, by Source, 2017

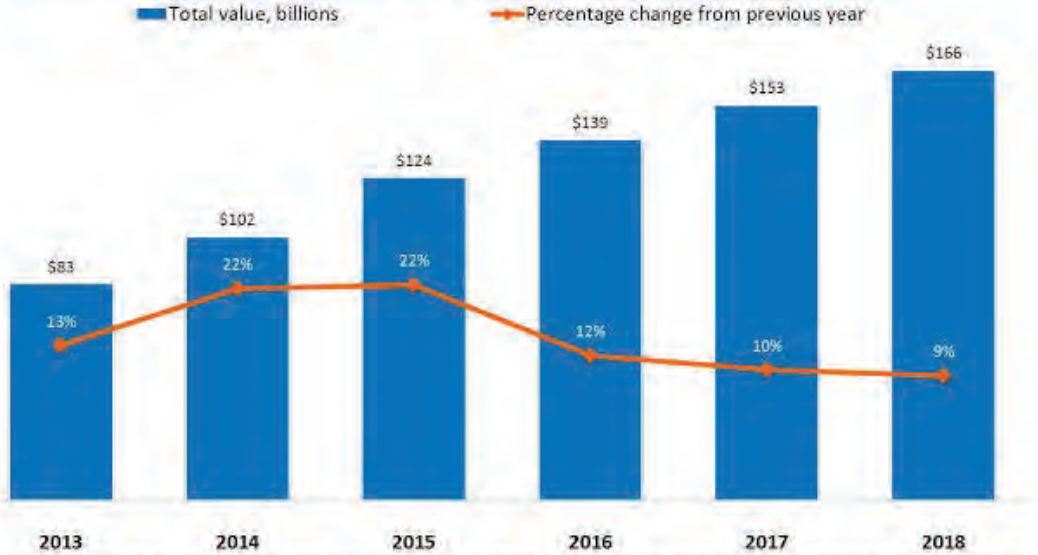


1. Payments by manufacturers include: admin fees to PBMs; discounts to providers under the 340B Drug Pricing Program; fees and discounts to pharmacies and wholesalers; and all other off-invoice discounts and rebates.
Source: Drug Channels Institute estimates. Percentage figures show each category's share of total gross-to-net reductions.

This chart appears as Exhibit 142 in *The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute. Available at http://drugch.nl/pharmacy

DRUG CHANNELS INSTITUTE

Total Value of Pharmaceutical Manufacturers' Gross-to-Net Reductions for Brand-Name Drugs, 2013 to 2018



Source: Drug Channels Institute analysis of IQVIA Institute data; Drug Channels Institute estimates. Gross-to-Net Reductions include the total value of rebates, off-invoice discounts, copay assistance, price concessions, and such other reductions as distribution fees, product returns, the 340B Drug Pricing Program, and more.

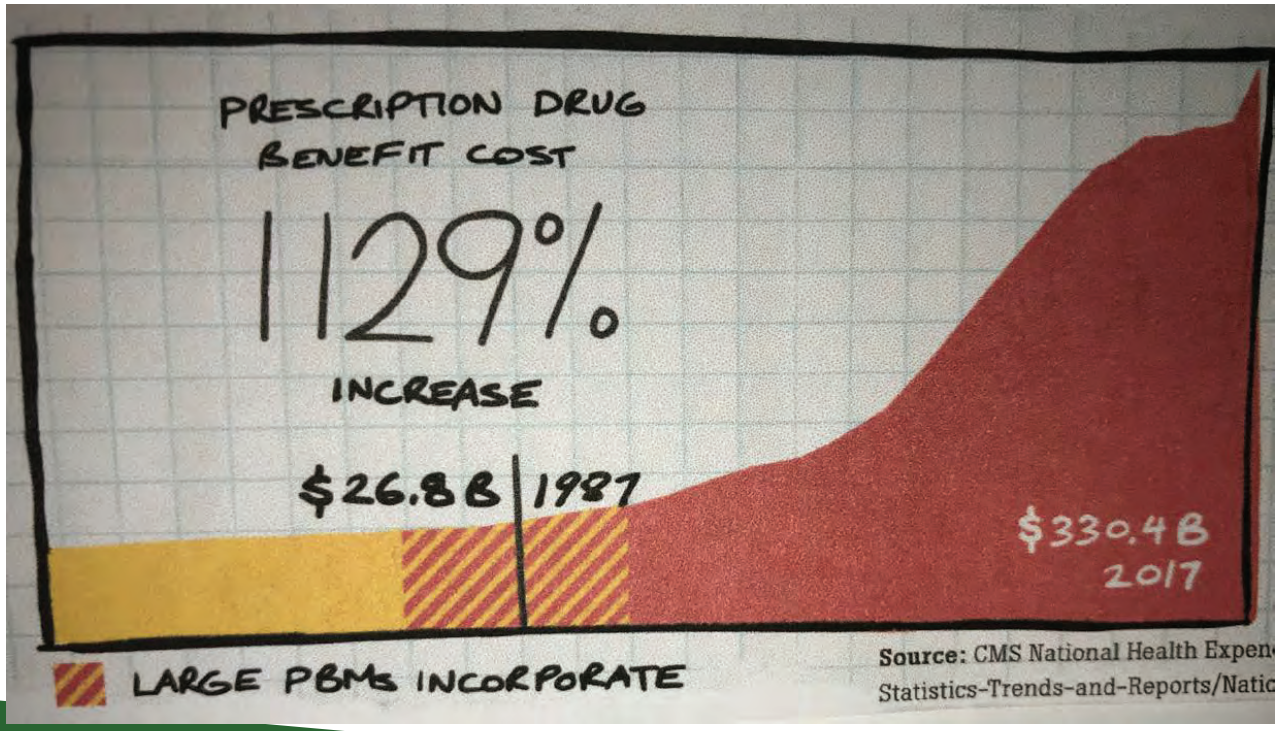
This chart appears as Exhibit 141 in *The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute. Available at http://drugch.nl/pharmacy

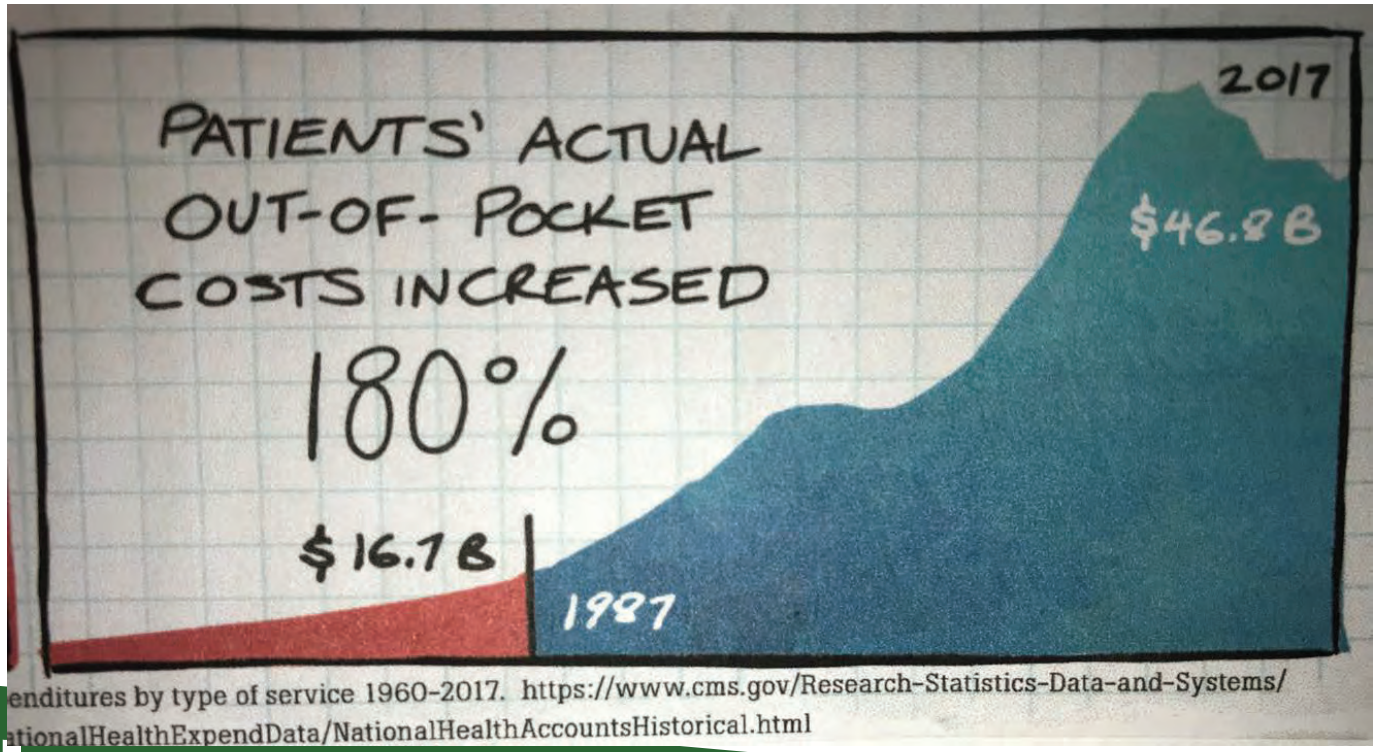
DRUG CHANNELS INSTITUTE

AS OF 2017

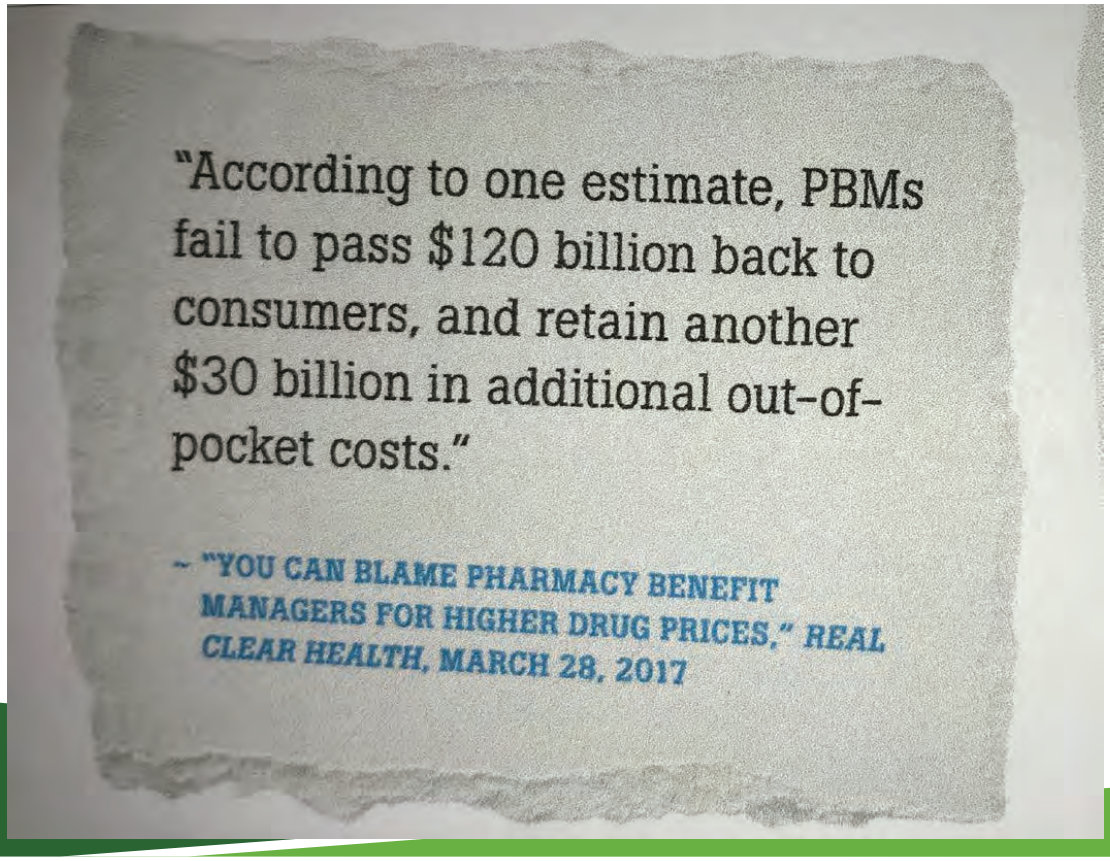
- PBMs control the pharmacy benefits of more than 266 Million Americans.
- Just 3 PBMs – Express Scripts, CVS Caremark, Optum – control as much as 89% of prescription drug benefit transactions in the U.S.

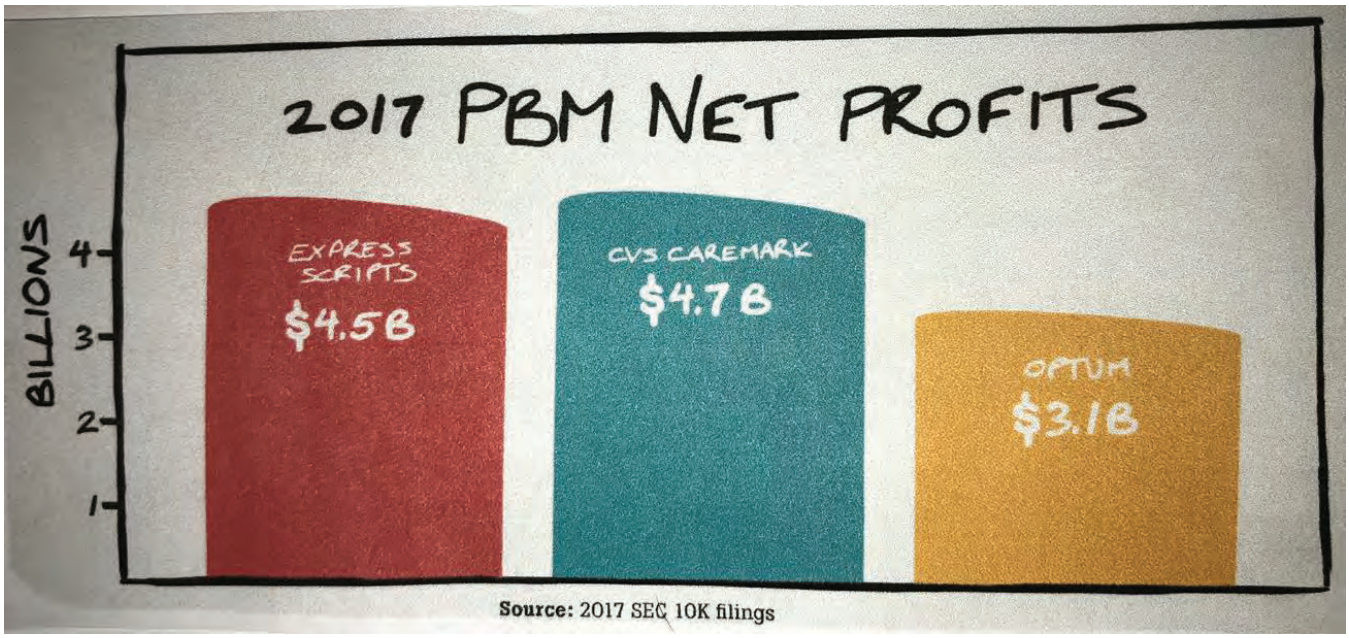
- Council of Economic Advisers, Reforming Biopharmaceutical Pricing at Home and Abroad. Feb 2018, available at https://www.whithouse.gove/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf; see also testimony pf PCMA CEO Mark Merritt before the U.S. House of Representatives Energy & Commerce Committee Subcommittee on Health, December 13, 2017.





enditures by type of service 1960-2017. https://www.cms.gov/Research-Statistics-Data-and-Systems/
ationalHealthExpendData/NationalHealthAccountsHistorical.html





POLICY PROBLEMS THAT INCREASE COSTS

- PBMs use spread pricing by charging health plans more than they reimburse pharmacies, and pocketing the difference
- PBMs promote drugs based on the rebate the PBM obtains, not on the patients' best interest
- PBMs classify certain generic drugs as brand drugs and charge brand prices

POLICY SOLUTIONS TO REDUCE PATIENT OUT OF POCKET COSTS

- Transparent PBMs report all of their financial data, which means they are no longer able to charge significantly higher prices to health plans than the costs that they reimburse pharmacies in order to benefit from a pricing "spread"

POLICY SOLUTIONS TO REDUCE PATIENT OUT OF POCKET COSTS

- When rebates are obtained, transparent PBMs pass along the savings to health plans, rather than hiding it and pocketing the money themselves

POLICY SOLUTIONS TO REDUCE PATIENT OUT OF POCKET COSTS

- Transparent PBMs can't hide the rebates they receive from manufacturers--which means they don't promote expensive brand name drugs over equivalent generic drugs merely to profit from a rebate

POLICY SOLUTIONS TO REDUCE PATIENT OUT OF POCKET COSTS

- Nontransparent PBMs can use their mail-order pharmacies to repackage drugs and inflate their costs. Transparent PBMs--most of which don't own their own mail-order pharmacy--disclose their pricing data to employees and therefore don't attempt such deceptive behavior

Support Commonsense PBM Reform in Wisconsin

Promoting Transparency and Accountability - AB 114 / SB 100

PBM Middle-Men Drive Up Drug Costs

Pharmacy benefit managers, or PBMs, manage plans for nearly 95% of Americans with prescription drug coverage by serving as a "middle-man" between health plans and pharmacies. Operating with limited government oversight, some PBMs have utilized tactics such as "gag clauses" and "copay clawbacks" to drive up costs for customers. Tactics such as pharmacy steering, deceptive advertising, and mandatory mail-order have reduced patient access to pharmacy and complementary health care services at the pharmacies of their choice.

More than 30 states, including Arkansas, Kentucky, and Louisiana have passed PBM reforms. Similar to Wisconsin's proposed legislation, these states have tackled transparency, clawbacks, and gag orders in order to increase access, lower costs, and improve transparency and accountability.

Ensuring the Best Price for Patients

When PBMs charge patients co-pays that are more expensive than the pharmacy's price for the same medication, pharmacists have been banned by contract from informing the patient of the lower cost option. Practice such as these force patients to spend more money out-of-pocket when using insurance than they would spend without using insurance.

Support Commonsense PBM Reform Solutions

- **Prohibiting Gag Clauses:** PBMs may not ban or penalize pharmacists from informing patients of a lower-cost option to purchase medications – for example, if paying with cash is less expensive than the patient's copay.
- **Clawbacks:** PBMs cannot require a patient to pay an amount that is greater than the cost of the drug or the amount the pharmacy is to be reimbursed for the drug.
- **Drug Substitution:** If a PBM changes their formulary mid-year, the patient cannot be required to pay more for their medication or be required to change their medication.
- **False Advertising:** Prohibit PBMs from the use of false, deceptive, or misleading advertising intended to reduce choice of pharmacy.

PHARMACISTS PROVIDE CARE

Wisconsin

A Campaign from the American Pharmacists Association

Access to health care is a serious issue in Wisconsin

53 of 72

Wisconsin counties include areas designated as

"medically underserved"

Source: U.S. Department of Health and Human Services

Currently most Wisconsin residents on Medicare do not have access to important services provided by pharmacists, including:

- Chronic Disease Management (e.g. Diabetes, Heart Disease)
- Drug Therapy Management
- Preventive Screenings & Related Counseling and Education
  - Glucose Testing
  - Blood Pressure
  - Cholesterol

Over 5,500 Pharmacists Licensed in Wisconsin

Source: National Association of Boards of Pharmacy & State Boards of Pharmacy data

If H.R.592/S.109 becomes law, pharmacists - a qualified and underutilized health care provider - can help address the needs of Wisconsin's medically underserved.

THANK YOU!

Special thanks to the following for their contributions on this presentation:
PSW, Sarah Sorem, Danielle Womack

QUESTIONS

Paul M. Cesarz, BS Pharm, R.Ph.

Manager Professional Services Community Pharmacy

Mercyhealth Walworth Pharmacy

pcesarz@mhemail.org

HOMETOWN PHARMACY

Governor's RX Pricing Task Force Presentation

1

HOMETOWN PHARMACY

What does AB 114 do?

- Helps patients:
  - Gag clause; Allows pharmacists to advise patients on the most cost-effective treatments for themselves.
  - Clawbacks; Prohibits PBM from making a consumer pay a higher cost sharing than the cash price
  - Requires 30 days' notice for formulary removal or tier elevation

- Protects pharmacists;
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- Creates a regulatory framework for PBMs;
  - Requires PBMs to be licensed by OCI. Begins a regulatory framework and provides consumers and providers a vehicle to share business practice concerns.
  - requires PBM's to submit annual transparency reports to OCI.

What is missing?

- Disclosure of conflicts of interest?
- mid-year non-medical switching protections for patients, allowing patients the security of knowing their treatment plans would not be changed mid-year for reasons unrelated to health or safety.
- Protection from predatory audits
- ***Transparency for patients, taxpayers, employers, and citizens***

2

HOMETOWN PHARMACY

Hometown Pharmacies

Family of Independent Pharmacies (67 Wi and 3 in Upper Michigan)

- High patient care levels - we know our patients and have high levels of personal interaction and information sharing
- Built to be a high service level to patients and very cost efficient for employers and patients
- We worked hard and took the risk of filling some of the voids of the Shopko departure

Hometown Innovation:

- Vivitrol protocols to help opioid problem
- Drug neutralization pouches for safe opioid disposal
- Proactive healthcare initiatives

3

HOMETOWN PHARMACY

5 Costs to Deliver Prescription Services	Compared to Big chains	Comments
1. Cost of Drug	-$1.86	We combine with largest independents and grocery store chains (7 billion) We still don't get to big 3 chain level (oligopsony/ monopsony) but we are closer than most people anticipate
2. Cost of labor to dispense the RX	-$2.00	We spend more time with the patient - it costs us more - we do this with purpose and intent as we believe patient interaction is very important and leads to better health outcomes and lower overall costs - we actually work to help people move away from prescriptions when possible
3. Cost of local overhead	$3.84	We are more efficient as our stores are on main street versus most expensive corner in town - they have more costs to heat, cool insure
4. Cost of corporate overhead	$9.32	We run an efficient operation - we have no need for an army of attorneys and accountants to answer to Wall Street Our CEO makes the same as a pharmacist
5. Ownership expectations (Profit)	$10.00 +++	Main street dividend versus Wall Street Extrapolation
Total:	$19.32 +++	

Point of slide is to give evidence that independent pharmacies can compete in a normal unbiased free market environment.

4

HOMETOWN PHARMACY

Summary

We are built to be sustainable - except we didn't foresee the market not having checks and balances - preferred networks and exclusionary contracts effectively exclude patients and employers from the most cost effective pharmacy solution.

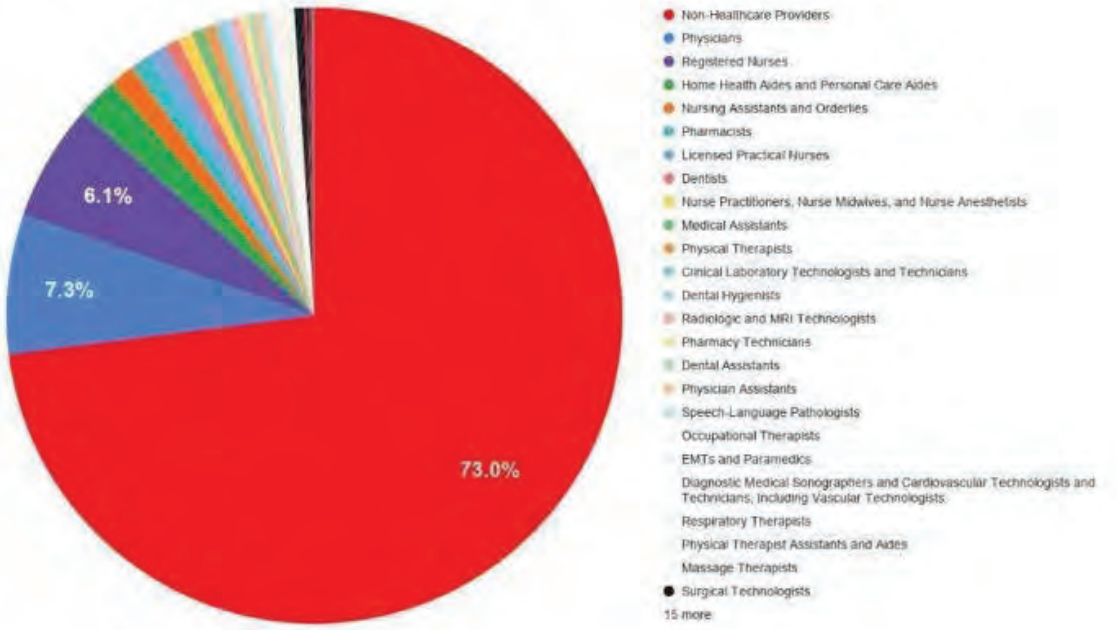
Smoke and mirror communications about chain pricing being better is refuted multiple times by reviewing available data.

Chains have a lower limit (WAC - 72) and when PBMs offer WAC -80 - they pay Independents less (Wac - 90). In essence we are their safety net.

5

HOMETOWN PHARMACY

2018 National Health Expenditure: $3.6 Trillion



SOURCE: Professionally active physician data found at https://www.kff.org/state-category/providers-service-use/physicians/. Aggregate median salaries for healthcare providers found at https://www.bls.gov/ooh/healthcare/. Total National Health Expenditure found at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.

Created by Citizen Health. Help us fix this mess @ HQ.CitizenHealth.io

6

HOMETOWN PHARMACY

UNITED STATES PHARMACEUTICAL SYSTEM

	MANUFACTURERS		WHOLESALERS		PBMS		RETAIL	
	RISK	REWARD	RISK	REWARD	RISK	REWARD	RISK	REWARD
RESEARCH & DEVELOPMENT	✓	✓	✗	✗	✗	✓	✗	✗
MANUFACTURERS	✓	✓	✗	✓	✗	✓	✗	✗
DISTRIBUTION & LOGISTICS	✓	✓	✓	✓	✗	✓	✗	✗
PATIENT INTERACTION & RETAIL	✗	✗	✗	✗	✗	✓	✓	✓
WHO IS REGULATED	YES		YES		NO		YES	
WHO CREATES REGULATION	NO		NO		YES		NO	

HOMETOWN PHARMACY

HUMALOG
Where the Money *Really* Goes

Pharmacists United for **TRUTH & TRANSPARENCY**

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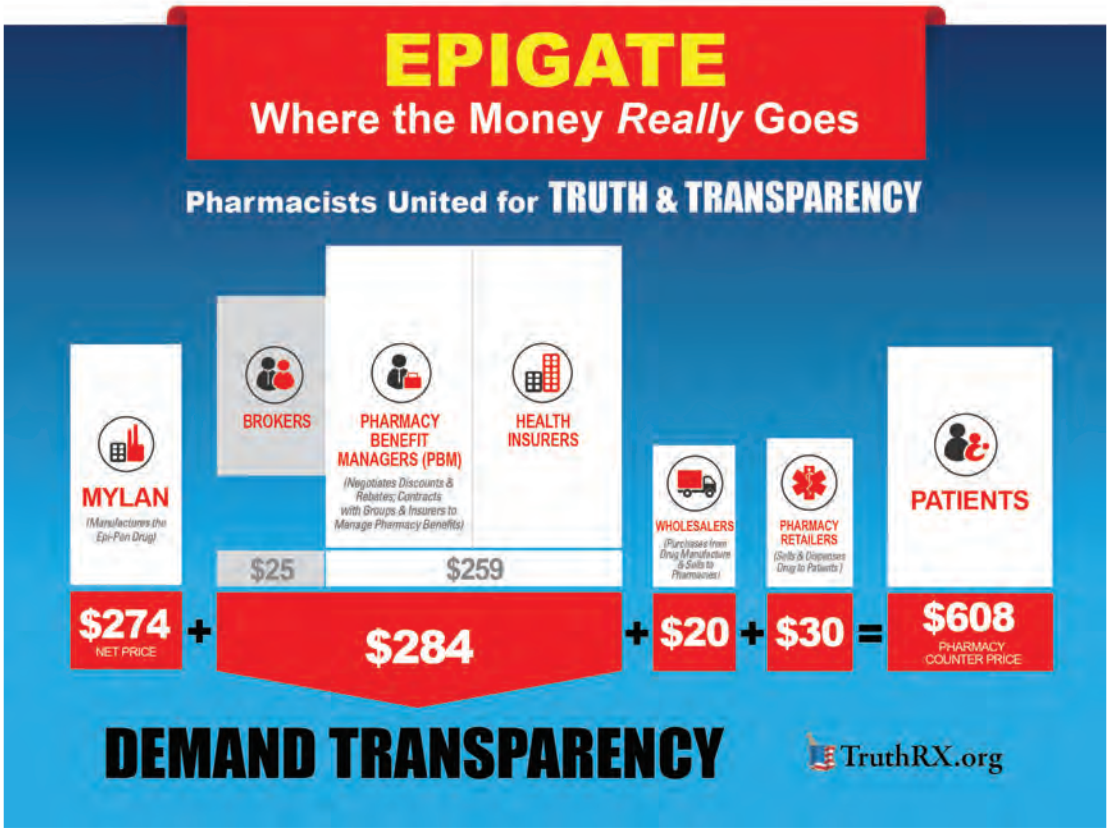
HOMETOWN PHARMACY



9

HOMETOWN PHARMACY

5.2 Fiduciary Acknowledgements. ESI offers pharmacy benefit management services, products and programs ("PBM Products") for consideration by all clients, including Sponsor. The general parameters of the PBM Products, and the systems that support these products, have been developed by ESI as part of ESI's administration of its business as a PBM. The parties agree that they have negotiated the financial terms of this Agreement in an arm's-length fashion. Sponsor acknowledges and agrees that, except for the limited purpose set forth in Section 2.3(c), neither it nor the Plan intends for ESI to be a fiduciary (as defined under ERISA or state law) of the Plan, and, except for the limited purpose as set forth in Section 2.3(c), neither will name ESI or any of ESI's wholly-owned subsidiaries or affiliates as a "plan fiduciary." Sponsor further acknowledges and agrees that neither ESI nor any of ESI's wholly-owned subsidiaries or affiliates: (a) have any discretionary authority or control respecting management of the Plan's prescription benefit program, except as set forth in Section 2.3(c), or (b) exercise any authority or control respecting management or disposition of the assets of the Plan or Sponsor. Sponsor further acknowledges that all such discretionary authority and control with respect to the management of the Plan and plan assets is retained by Sponsor or the Plan. Upon reasonable notice, ESI will have the right to terminate PBM Services to any Plan (or, if applicable Members) located in a state requiring a pharmacy benefit manager to be a fiduciary to Sponsor, a Plan, or a Member in any capacity.

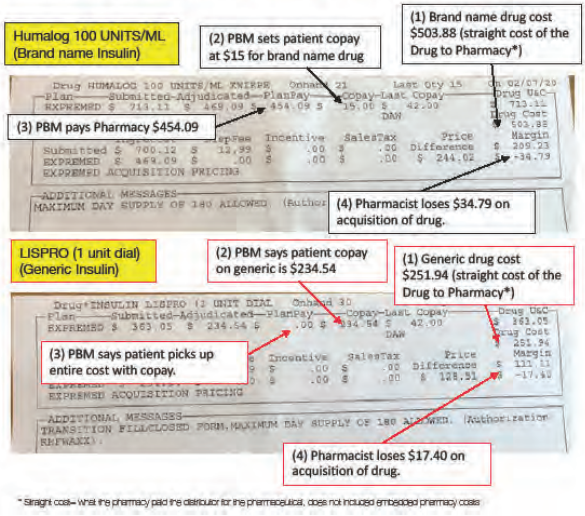
10

HOMETOWN PHARMACY

PATIENT LOSES- PLAN SPONSOR LOSES-PHARMACIST LOSES
PBM WINS

PBM, because of rebates, disincentivizes the patient from choosing the Generic ($235 copay) for the more expensive brand name ($15 copay);

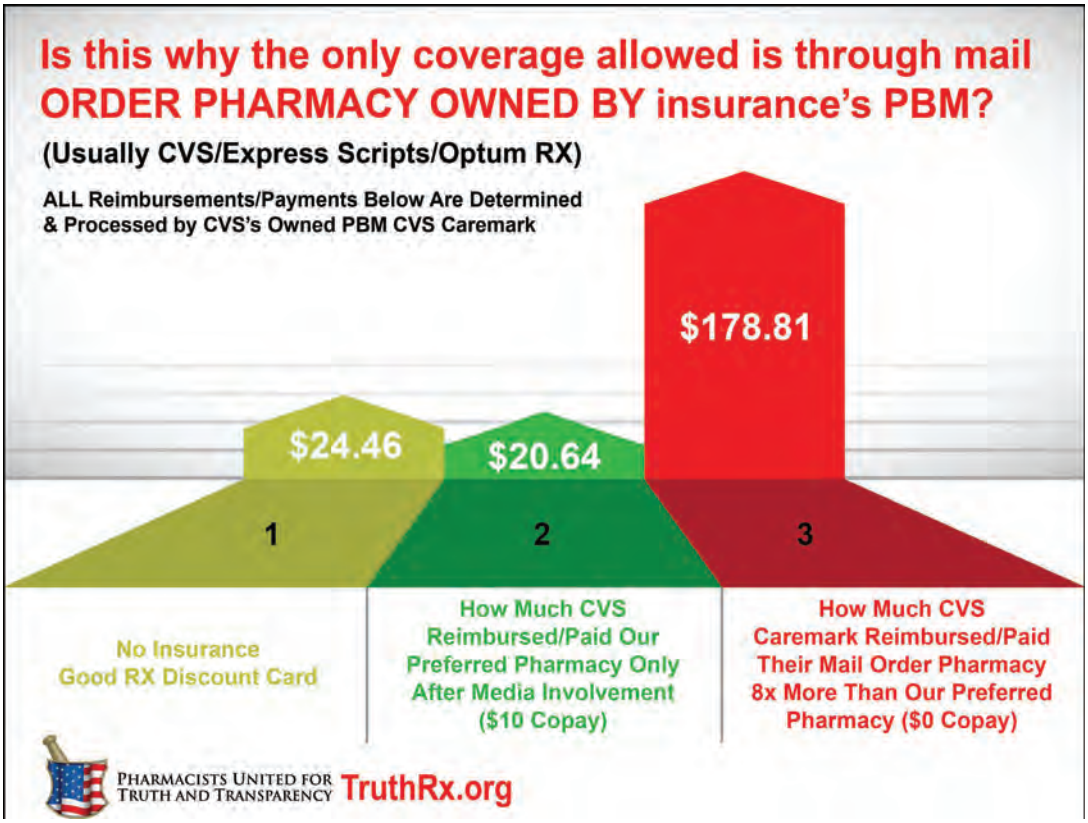
- Plan sponsor loses because they are paying nearly double for the more expensive drug.
- Patient loses because the cost will eventually show up in the premium.
- Pharmacist loses because they aren't being fully reimbursed for the cost of the drug in either scenario, let alone covering dispensing.



* Straight cost– what the pharmacy paid the distributor for the pharmaceutical, does not included embedded pharmacy costs

HOMETOWN PHARMACY

HOMETOWN PHARMACY



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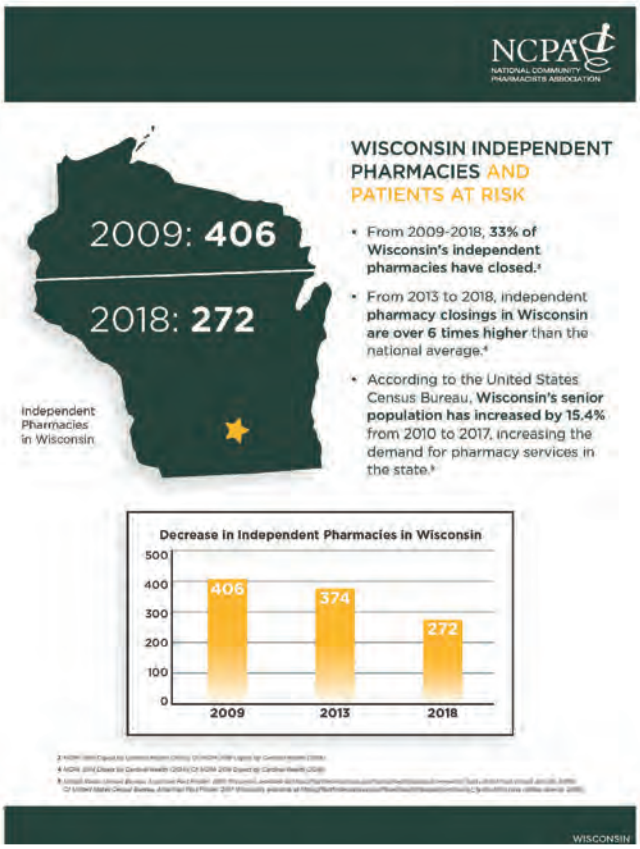
HOMETOWN PHARMACY



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HOMETOWN PHARMACY

All PBMs are Not Created Equal

"...that current PBM models lack transparency and are overly complicated."

Transparency & Pass-Through are not the same.

PBM Model	Revenue Streams	Disclosure
Traditional	No limits	None
Transparent	Some limits	Required
Pass-Through	Strict limits	Required
Hybrid	Varies	Sometimes

Traditional
PBM retains a network spread, rebates, and other revenues streams as compensation.

Pass-Through
PBM charges client the exact amount it pays pharmacies. PBM is compensated with an agreed upon fee for service.

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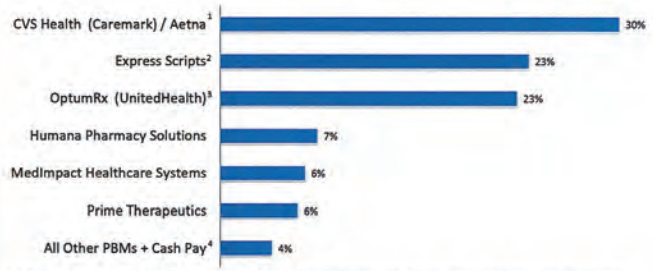
HOMETOWN PHARMACY

Who are PBMs?

76% of the all prescription claims are processed by the "Big 3"

PBM Market Share, by Total Equivalent Prescription Claims Managed, 2018



1. Includes pro forma combination of claims processed by Aetna. Excludes double counting of network claims for mail choice claims filled at CVS retail pharmacies.
2. Includes Anthem. During 2019, Anthem claims will be transitioning to IngenioRx.
3. Includes Cigna. By the end of 2020, Cigna claims will transition to Express Scripts.
4. Figure includes some cash pay prescriptions that use a discount card processed by one of the 6 PBMs shown on the chart.

Source: Drug Channels Institute research and estimates. Total equivalent prescription claims includes claims at a PBM's network pharmacies plus prescriptions filled by a PBM's mail and specialty pharmacies. Includes discount card claims. Note that figures may not be comparable with those of previous reports due to changes in publicly reported figures of equivalent prescription claims. Total may not sum due to rounding.

This chart appears as Exhibit 76 in *The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Drug Channels Institute.* Available at http://drugch.nl/pharmacy

DRUG CHANNELS INSTITUTE

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HOMETOWN PHARMACY

"Drug channel companies are MUCH bigger than Manufacturers."

Adam Fein, PhD

DRUG CHANNELS INSTITUTE

Drug Channel Companies on the 2018 *Fortune* 500 List

Company (stock symbol)	2018 *Fortune* 500 Rank	Revenues ($B)	Revenues, % vs. 2016	Market Value (as of 3/29/18)	Revenue per Employee ($M)	Profit as % of Revenues	Profit as % of Assets	Annualized Return to Investors (2007-2017)	Total Return to Investors (2017)	Employees (000s)
McKesson (MCK)	6	$198.5	3.1%	$29.1	$3.1	2.6%	8.3%	10%	11.9%	64.5
CVS Health (CVS)	7	$184.8	4.1%	$63.1	$0.9	3.6%	7.0%	8%	-5.7%	203.0
AmerisourceBergen (ABC)	11	$153.1	4.3%	$18.9	$7.9	0.2%	1.0%	17%	19.4%	19.5
Cardinal Health (CAH)	14	$130.0	6.9%	$19.7	$3.2	1.0%	3.2%	6.0%	-12.8%	40.4
Walgreens Boots Alliance (WBA)	19	$118.2	0.7%	$64.9	$0.4	3.4%	6.2%	8.8%	-10.5%	290.0
Express Scripts Holding (ESRX)	25	$100.1	-0.2%	$38.8	$3.8	4.5%	8.3%	7.4%	8.5%	26.6
Rite Aid (RAD)	94	$32.8	6.9%	$1.8	$0.5	0.0%	0.0%	-3.4%	-76.1%	70.4
Average	25	$131.1	3.7%	$33.8	$2.8	2.2%	4.9%	7.6%	-9.3%	102.1
Median	14	$130.0	4.1%	$29.1	$3.1	2.6%	6.2%	7.7%	-5.7%	64.5

Source: Drug Channels Institute analysis of 2018 *Fortune* 500 list
Published on Drug Channels (http://www.DrugChannels.net) on June 12, 2018.

DRUG CHANNELS INSTITUTE

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HOMETOWN PHARMACY

PBM Average Wholesale Prices: A Non-Constant

There are 40 total AWP's for Nexium 40mg ranging in price from $78 - >$10,000

Fallacy of Average Wholesale Price (AWP) Contracting

AWPs have no relevance in projecting final client costs from PBM to PBM; therefore, the intent of any employer should be to procure medications at the lowest cost per pill.

Nexium 40mg (AstraZeneca)			Quantity: 30 Pills			
PBM	NDC Code	AWP	AWP for 30	Discount	Disp. Fee	Total Rx Cost
PBM A	00440786190	$10.51	$315.30	-15%	$1.50	$269.51
PBM B	54868451003	$8.60	$258.00	-16%	$1.00	$217.72
PBM C	50436312101	$13.25	$397.50	-17%	$0.75	$330.68
PBM D	68115086730	$9.52	$285.60	-24%	$0.00	$217.06
PBM E	47463054030	$14.13	$423.90	-40%	$0.00	$254.34
ASTRAZENECA	00186504225	$7.52				
Fiduciary PBM	00186504225	$7.52	$225.60	-15%	$3.00	$194.76

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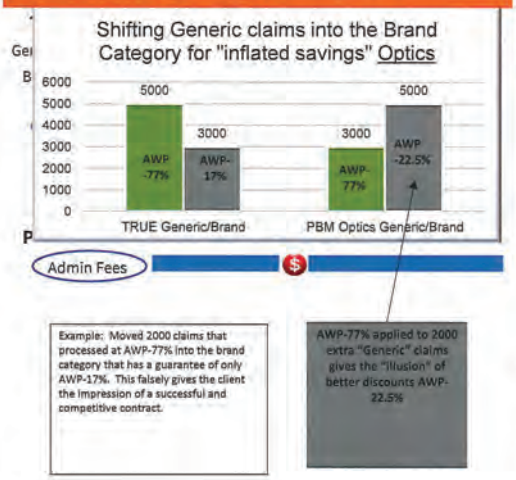
HOMETOWN PHARMACY

What will you pay your PBM for brand and generic drugs?

PBM Profit Levers



"Brand Drug" means a prescription drug identified as such in [redacted]'s master drug file using indicators from First Databank (or other source nationally recognized in the prescription drug industry used by [redacted] for all clients) on the basis of a standard Brand/Generic Algorithm utilized by [redacted] for all of its clients, a copy of which may be made available for review by Administrator, Client, or its Auditor upon request. Notwithstanding the foregoing, certain prescription drug medications that are licensed and then currently marketed as brand name drugs, where there exists at least one (1) competing prescription medication that is a generic equivalent and interchangeable with the marketed brand name drug, may process as "Generic Drugs" for Prescription Drug Claim adjudication and Member Copayment purposes.

Beware of this contract language!

- First, the pricing source is very open ended and allows PBM to pick the better unit cost price between the various providers (MediSpan and FDB).
- This allows PBM to move a large number of claims of generic claims (AWP -7.50%) to be moved to the brand category (AWP- 17.00%) for guarantee purposes. This falsely "inflates" the brand category and provides the appearance that brands are achieving a higher discount when in reality PBM is moving generic claims that processed at AWP-77% to the brand category which raises the overall effective rate.
- The line that states "There exists at least one competing medication" is not in the clients' best interest. This is allowing PBM to move the majority of medication to another category for guarantee purposes, many other PBMS have language that states medication must be produced by more than 2 manufacturers.
- The last line indicates that the adjudication logic is not consistent with the guarantee logic.

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HOMETOWN PHARMACY

Pharmacy Benefit Managers

Wall Street darlings with Deep Pockets

Source: Factset, as of 4/30/2007.
PBM includes: CMX (white actives), ESRX, MHS, and ADVP (white actives).
CLINICAL LABS includes: BRL, DGX, LH, SP, and LABS (white actives).
MANAGED CARE includes: AET, WLP, CI, UNH, CVH, HNT, HUM, PHS, SE, and WC.
RENAL DIALYSIS includes: RCI (White Active) and DVA.
HOME RESPIRATORY includes: LNCR and AHG.
SKILLED NURSING includes: BEV, EKE, GHCI, KND, HCR, and NHC.
WHOLESALE DISTRIBUTION includes: ABC, CAH, and MCK.
LARGE CAP PHARMA includes: ABT, AZN, BMY, LLY, GSK, Pharmia, MRK, NVS, PFE, RHHBY, SNY, SGP, and WYE
MED TECH includes: MDT, BSX, GDT, STJ, ZMH, SYK, and BMET.
HOSPITALS includes: CYN, HCA, HMA, UPHT, THC, TRI, and UHS.

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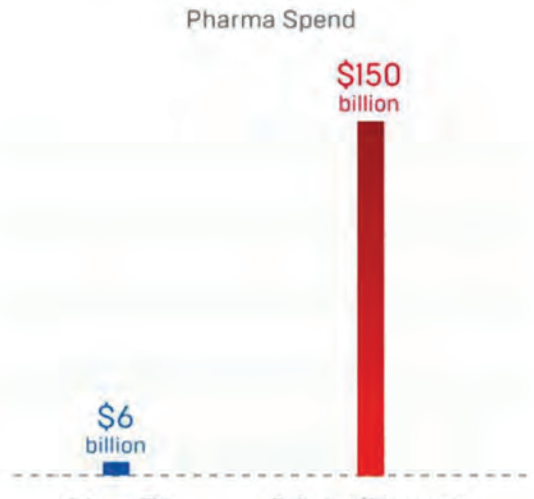
HOMETOWN PHARMACY

Pharmacy Benefit Managers

Who's Paying? The Hidden Business

1/3 OF WHAT WE SPEND ON DRUGS **GOES TO MIDDLEMEN**



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HOMETOWN PHARMACY

Pharmacy Benefit Managers

What's Now - New Alignment

Corporations are assuming multiple roles in the pharma supply chain

	CVS Health	UnitedHealthcare	Cigna	Anthem	Walmart	McKesson		
Payer	aetna (Pending)		Cigna	Anthem	Humana (Rumored)		Centene	
						McKesson	AmerisourceBergen	
PBM	CVS caremark	Optum	(Pending)	(Planned)	Humana (Rumored)	RelayHealth	RAdvance	
Pharmacy	CVS pharmacy		medco (Pending)		Walmart			
Specialty Pharmacy	CVS specialty	briova	accredo (Pending)				alliance Rx	

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HOMETOWN PHARMACY

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- Protection from predatory audits
- ***Transparency for patients, taxpayers, employers, and citizens***

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Free and Charitable Clinics and Pharmacies Task Force on Reducing Prescription Drug Prices

Ian Hedges, Chief Executive Officer, HealthNet of Rock County
Yolanda Tolson-Eveans, Pharmacist in Charge, St. Vincent De Paul Charitable Pharmacy

Isaac's St. Vincent de Paul Story

We are the Safety-Net…

- Last year, more than 150,000 Wisconsinites used more than 99 free and charitable clinics
- Individuals who need this service include:

- ❑ Finding premiums too high; deductibles too high
- ❑ Make too much for Medicaid; do not qualify for other identifiers
- ❑ Missed Open Enrollment
- ❑ Exempt from mandate; qualify for waiver
- ❑ File taxes separately from their spouse
- ❑ Have a change in life circumstances
- ❑ Individuals who are undocumented
- ❑ Waiting for insurance to kick-in
- ❑ Unable to quit, or choose to smoke, and are penalized up to 50% higher premiums
- ❑ Do not have dental/vision insurance
- ❑ Bouncing between marketplace/Badger Care due to income.

But who might need it now?

- Roughly 27 million people have likely lost job-based health coverage since Covid-19 shocked the economy.
- 80% of those 27 million have other options:
  - ➢ More than half qualify for Medicaid
  - ➢ More than a third are eligible for subsidies on the exchange
  - ➢ ~20% are out of luck because their state did not expand Medicaid or because they are ineligible for some subsidized coverage

Federal Poverty Level*

Effective February 1, 2020

Family Size	Annual	100% FPL	120% FPL	135% FPL	150% FPL	185% FPL	200% FPL	250% FPL	300% FPL
1	$12,760	$1,063.33	$1,276.00	$1,435.50	$1,595.00	$1,967.16	$2,126.66	$2,658.33	$3,189.99
2	$17,240	$1,436.67	$1,724.00	$1,939.50	$2,155.01	$2,657.84	$2,873.34	$3,591.68	$4,310.01
3	$21,720	$1,810.00	$2,172.00	$2,443.50	$2,715.00	$3,348.50	$3,620.00	$4,525.00	$5,430.00
4	$26,200	$2,183.33	$2,620.00	$2,947.50	$3,275.00	$4,039.16	$4,366.66	$5,458.33	$6,549.99
5	$30,680	$2,556.67	$3,068.00	$3,451.50	$3,835.01	$4,729.84	$5,113.34	$6,391.68	$7,670.01
6	$35,160	$2,930.00	$3,516.00	$3,955.50	$4,395.00	$5,420.50	$5,860.00	$7,325.00	$8,790.00
7	$39,640	$3,303.33	$3,964.00	$4,459.50	$4,955.00	$6,111.16	$6,606.66	$8,258.33	$9,909.99
8	$44,120	$3,676.67	$4,412.00	$4,963.50	$5,515.01	$6,801.84	$7,353.34	$9,191.68	$11,030.01
9	$48,600	$4,050.00	$4,860.00	$5,467.50	$6,075.00	$7,492.50	$8,100.00	$10,125.00	$12,150.00
10	$53,080	$4,423.33	$5,308.00	$5,971.50	$6,635.00	$8,183.16	$8,846.66	$11,058.33	$13,269.99
Each additional person	$4,480	$373.33	$448.00	$504.00	$560.00	$690.66	$746.66	$933.33	$1,119.99
Program Limits		QMB	SLMB	SLMB+	MAPP Premium		QDWI and Lower	MAPP	

*https://www.dhs.wisconsin.gov/medicaid/fpl.htm

Pharmaceutical Landscape

- Free and charitable clinics provide medications to patients in a variety of ways:
  - In house pharmacy
  - Provider dispensing
  - Stand alone-***St. Vincent de Paul is the only stand-alone pharmacy in the state***
- Drug Repositories*: pharmacies or medical facilities that collect unused or discontinued medications and supplies from patients to pass them onto other consumers who may need them.
- 7 free and charitable clinics/pharmacies are listed as drug repositories in WI

* https://www.dhs.wisconsin.gov/guide/cancer-drugrepo.htm

Each has a standard formulary, but some drugs cannot be provided…

The Society of St. Vincent de Paul Charitable Pharmacy is a fully licensed pharmacy operating on a stand-alone basis and providing prescribed medications at no charge to those low-income individuals who qualify for the pharmacy's services. The pharmacy stocks low-cost drugs for common conditions such as heart disease, diabetes, infections, and other types of illnesses. The Prescription Program is designed to provide up to a 30-day supply per prescription.

Contact
(608)-442-7200

Address
2033 Fish Hatchery Rd
Madison, WI 53725-9686

Hours of Operation
Monday: 11 AM-2 PM
Tuesday: 1-4PM
Thursday: 3-6PM

Note: This list is not an all-inclusive list. If the medication you are taking is not on the list, we still may be able to assist.

GENERIC NAME	BRAND NAME	CLASSIFICATION
benzonatate 100mg	TESSALON	Allergies/Cold/Flu
benzonatate 200mg	TESSALON	Allergies/Cold/Flu
cetirizine 10mg	ZYRTEC	Allergies/Cold/Flu
fexofenadine 180mg	ALLEGRA	Allergies/Cold/Flu
fluticasone 27.5mcg spray	VERAMYST	Allergies/Cold/Flu

Complete Formulary List:
https://svdpmadison.org/wp-content/uploads/2018/07/FormularyUpdated-06_21_18.pdf

Inventory Landscape

WISCONSIN DEPARTMENT of HEALTH SERVICES
Drug Repository Site

Direct Relief
Deliver a world of good.

Samples

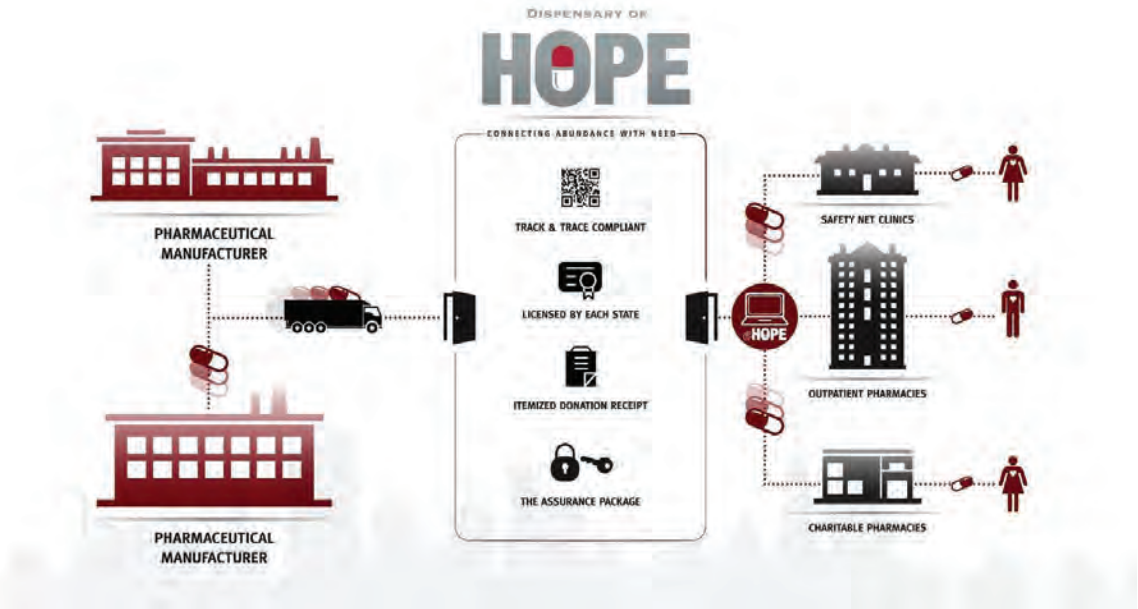
DISPENSARY OF HOPE
CONNECTING ABUNDANCE WITH NEED

americares

MERCK
Be well

RxOutreach

Charitable Medication Distribution Process



What do databases look like?

- Gain access to manufacturers' (AbbVie, Novartis, Johnson & Johnson) brand medications at no cost
- Start-up inventory and continuous replacement of medications saves time and money
- Medications are available to eligible patients without delay and thus improves patient care
- An alternative to navigating the numerous individual patient assistance programs (PAPs) operated by separate healthcare companies
- Weekly inventory list sent out, and clinics can dispense (very similar to how foodbanks have regional partnerships)

Direct Relief
Deliver a world of good.

Policy Recommendations

- More funding for free and charitable clinics and pharmacies, esp. as we cover the costs of prescription drugs for the neediest patients
  - Huge ROI on care – volunteer hours/goods means that a dollar of funding translates into five to ten dollars worth of care.
- Modifications to laws governing drug repositories, and ability to have drugs donated across state lines.
- Allowing 1/3 of CEUs to be dedicated towards volunteerism for healthcare professions such as doctors, pharmacists, etc.
- Creation of real-time; live inventory for sharing between repositories in state of Wisconsin.
- Consider group purchasing options for FCCs and pharmacies with state support like MMCAP

Funding Formula

- Virginia has an annual appropriation for free and charitable clinics
  - Administered by state association
  - $6.7 million appropriation, dividends from tobacco litigation
- State of Wisconsin has a biannual $ 1 million appropriation, but more funding is needed to expand access
- Settlements from active litigation can be possible route for funding

Modifications to Drug Repository Law

- DHS – Division of Quality Assurance has stated that

WI Stat 255.056 and under DHS 148 Administrative Code must be changed for out of state coordination in order to have out-of-state pharmacies participate in WI Drug Repository Program.

Modifications to CME/CPE Requirements

- Ohio currently has a law in place that allows 1/3 of CME to be completed through volunteerism.
  - *Ohio Statute 4729:1-5-02 Continuing education requirements for pharmacist:* A pharmacist may satisfy up to one-third of the pharmacist's continuing education requirements by providing health care services as a volunteer in accordance with section 4745.04 of the Revised Code. The location where health care services are provided shall be an approved in-state provider of volunteer healthcare services
- More pathways for pharmacists and other hcps to volunteer encourages more opportunities for services to be provided for uninsured patients and builds capacity

News > Medscape Medical News > Oncology News

Text #FlipYourScrip to Easily Donate Unused Drugs

Special Interest In Cancer Therapies

Nick Mulcahy
March 10, 2020

41 Read Comments

#FlipYourScrip, a first-of-its-kind national program for donating unused prescription drugs, is now open for business and accepting unexpired bottles of pills or capsules in order to pass them along to needy patients. The program is administered by Remedichain.org, a nonprofit based in Memphis, Tennessee.

Donation involves a simple process that uses a smartphone text to initiate the transaction.

"We've made it as easy as possible for clinicians or any individual to donate a prescription," said Phil Baker, PharmD, president of Remedichain.org.

The organization attempts to match the donation to a financially needy patient in their database, and eventually puts any matched donation (delivered free via FedEx) through a multi-step inspection to ensure safety.

Questions?

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STATE OF WISCONSIN
GOVERNOR'S TASK FORCE ON
REDUCING PRESCRIPTION DRUG PRICES

GOVERNOR'S TASK FORCE ON REDUCING PRESCRIPTION DRUG PRICES

June 18, 2020

10:00 a.m. – 2:00 p.m.

I. Welcome (5 minutes)
- **Nathan Houdek, Deputy Commissioner, Office of the Commissioner of Insurance**

II. Consumer Experience (5 minutes)

III. Department of Justice Update: AG Kaul Joins Coalition of 50 States in Filing 3rd Complaint in Ongoing Antitrust Price-Fixing Investigation into Generic Drug Industry (10 minutes)
- **Laura McFarlane, Assistant Attorney General, WI Department of Justice**

IV. Wholesalers (40 minutes)
- **Roxy Kozyckyj, Director, State Government Affairs – Midwest, Eastern Region, Healthcare Distribution Alliance**

V. Pharmacy Services Administrative Organizations (40 minutes)
- **Scott Pace, Pharm. D., J.D., Partner, Impact Management Group**

VI. Hospitals (40 minutes)
- **Mark Howell, Senior Associate Director, Standards and Drug Policy, American Hospital Association**
- **Aaron Wesolowski, VP, Policy Research, Analytics, and Strategy, American Hospital Association**
- **Brian Stephens, Chief Executive Officer, Door County Medical Center**
- **Dr. Jim Heise, Chief Medical Officer, Door County Medical Center**
- **Amy Konop, Pharmacy Director, Door County Medical Center**
- **Carrie Peterson, Certified Pharmacy Technician, Door County Medical Center**

VII. Break (10 minutes)

Meeting Minutes
June 18, 2020
10 a.m. – 2 p.m.
Webinar via Zoom

Welcome
Nathan Houdek, OCI Deputy Commissioner and Task Force chair

- Deputy Commissioner Houdek welcomed Task Force members and public attendees.
- Key housekeeping items
    - A reminder that this is a public meeting.
    - The meeting is being live-streamed through Wisconsin Eye and will be available on the Task Force website: https://rxdrugtaskforce.wi.gov/Pages/Meetings/WatchPreviousMeetings.aspx
    - July 21 and 22 meetings will be in a virtual format.
    - August 25 is tentatively scheduled for an additional meeting.
    - Task Force members will have use of their microphones/the public does not.
- Seeking feedback from members on the document with possible policy recommendations.

Consumer Experience
The Herrick family, of Cushing, Wisconsin, shares their experience with the cost of prescription medication to treat diabetes in their family.

- There were technical difficulties with the audio and the video was not played during the meeting. The video link is now available on the Task Force website and was sent to Task Force members: https://rxdrugtaskforce.wi.gov/Pages/Meetings/MeetingMinutes.aspx or directly at https://youtu.be/KHd5I7Q3kME

Prescription Drug Litigation Update
Laura E. McFarlane – Assistant Attorney General, Wisconsin Department of Justice

- AG Kaul joined a coalition of 50 States in filing a 3rd complaint in an ongoing antitrust price-fixing investigation into the generic drug industry. A link to the presentation is available on the Task Force website: https://rxdrugtaskforce.wi.gov/Documents/Prescription_Drug_Litigation_Update.pdf

Wholesalers
Roxolana Kozyckyj – Director, State Government Affairs, Healthcare Distribution Alliance

- A presentation from Ms. Kozyckyj is available on the Task Force website: https://rxdrugtaskforce.wi.gov/Documents/HDA.pdf

Pharmacy Services Administrative Organization (PSAO)
Scott Pace, Pharm.D., J.D. – Chair, Partner, Impact Management Group

- A presentation from Mr. Pace is available on the Task Force website: https://rxdrugtaskforce.wi.gov/Documents/PSAO_Coalition.pdf

Trends in Hospital Drug Spending and Manufacturer Shortages
Mark Howell – Senior Associate Director, Standards and Drug Policy, American Hospital Association
Aaron Wesolowski – VP, Policy Research, Analytics, and Strategy, American Hospital Association

- A presentation from the American Hospital Association is available on the Task Force website: https://rxdrugtaskforce.wi.gov/Documents/AHA.pdf

Wisconsin Hospital Perspective
Dr. Jim Heise – Chief Medical Officer, Door County Medical Center
Brian Stephens-Chief Executive Officer, Door County Medical Center
Amy Konop – Pharmacy Director, Door County Medical Center
Carrie Peterson – Certified Pharmacy Technician, Door County Medical Center

- A presentation from the Door County Medical Center is available on the Task Force website: https://rxdrugtaskforce.wi.gov/Documents/DoorCountyMedicalCenter.pdf

Haven Healthcare, Importation, and Accountability Board Update *(Note: NGA provided an update on these issues based on Task Force member requests at a previous meeting)*
Kate Johnson – NGA Senior Health Policy Analyst, NGA Center for Best Practices
Jane Horvath – Horvath Health Policy
Representative Norm Thurston – Utah House of Representatives

- A presentation from the National Governors Association is available on the Task Force website: https://rxdrugtaskforce.wi.gov/Documents/NGA.pdf

Task Force Member Policy Discussion
Mr. Houdek asked the Task Force members to weigh in on the document that was distributed to the Task Force members outlining policy options.

There was a general agreement among members that the Task Force be supportive of the policy provisions included in 2019 Assembly Bill 114/Senate Bill 100, which failed to advance through the Legislative process due to a shortened floor period resulting from COVID-19. Those policy provisions will be set aside and the ongoing focus will be on new policy options that have been raised by the Task Force.

Task Force members discussed spread pricing.

<u>Spread Pricing</u>

- The question was asked whether anyone can state that the elimination of spread pricing will drive a certain level of saving to consumers. Responses from members included:
    - Independent audits have been done by state pharmacist associations that have found spread pricing to actually cost states money. Not saying it's a huge problem in WI but it may be worth exploring further. *(Later noted that the audits relate to Medicaid)*

  - PBMs have seen significant savings by taking spread out, keeping margin out of claims, but it is an insurer/employer decision to make, not necessarily one that requires government regulation. There is value in a plan electing to prohibit spread, but it should be a contractual decision.
  - What do the numbers/savings look like? Let's see and look at this issue with an analysis on where there would be savings.

- Additional comments around whether to eliminate spread pricing include the following:
  - PBMs need to get paid for their services and one model allows for more information about how PBMs are getting paid and the other model (the model allowing spread pricing) does not provide that level of transparency.
  - The state employee plan does not allow spread. The state pays an administrative fee on a per member basis and knows exactly what they are paying for. Having that transparency built into their model has offered savings.
  - A concern is that if the only model is a complete transparent model then the PBMs are incented to be only as good as their peers. With spread, it serves as an incentive to drive down cost.
  - Some members could support the Louisiana model. That model prohibits spread pricing unless the PBM provides written notice to the policyholders of each health insurer in which the PBM engaged in spread pricing. The notice must include the aggregate amount of spread pricing charged by the PBM.
  - Another member questioned how the Louisiana model lowers cost and noted that the notification requirement could be a costly administrative burden.
  - It was noted that the level of spread pricing does not impact the amount the PBM pays the pharmacy.
  - A member pointed out the need for additional transparency and that there is a broader objective of understanding the industry and move forward with more information.

Mr. Houdek asked for feedback on what topics and policy options should be elevated in priority for additional, meaningful discussions. A couple members expressed interest in reviewing the concept of an affordability board. Another member indicated discriminatory reimbursement (relating to the 340B drug purchasing program) should be discussed.

Next Meetings

- July 21 – Scheduled presenters include representatives from the manufacturers, GoodRx and CivicaRx.
- July 22 – Scheduled presenters include representatives from AARP, the American Diabetes Association, the Aids Resource Center of Wisconsin, the Northwest Prescription Drug Consortium, and the Department of Employee Trust Funds (update on the Wisconsin Pharmacy Cost Study Committee).
- August 25 – Discussion about policy recommendations

Adjourn

Prescription Drug Litigation - Update

Laura E. McFarlane
Assistant Attorney General
Wisconsin Department of Justice

Background

- 2013-14 sudden price spikes in generic drugs
  - Congressional hearings
  - United States Department of Justice Criminal Investigation
  - State AG's investigation and lawsuits
- 2016 State AGs' lawsuit - Heritage
  - 46 States
  - 18 Corporate Defendants and two corporate executives, all who were involved in the manufacture and sale of 15 generic drugs
- 2019 State AGs' lawsuit - Teva
  - 50 States and Territories
  - 20 Corporate Defendants, and 15 corporate executives, all who were involved in the manufacture and sale of more than 100 generic drugs

USDOJ Settlements

- **Apotex Corp.**
  - Admitted to fixing prices of Pravastatin, a popular cholesterol drug
    - Worked with other drug companies to inflate and maintain the price of the drug from 2013 - 2015
  - Agreed to pay $24.1 million
- **Sandoz Inc.**
  - Pleaded guilty to four counts of bid rigging and price fixing as part of a deferred prosecution agreement.
  - Agreed to pay $195 million
- **Rising Pharmaceuticals**
  - Admitted to fixing prices and allocating customers for Benazepril HCTZ
  - Agreed to pay more than $3 million in criminal penalty, restitution, and civil damages – subject to bankruptcy court approval
- **Heritage Pharmaceuticals**
  - Admitted that it conspired to fix prices, rig bids, and allocated customers for glyburide
  - Agreed to pay more than $7 million

State of Connecticut, et al. v. Sandoz, Inc., et al. - Dermatology

- 51 States and Territories
- 26 Corporate Defendants and 10 Individuals
  - Sandoz, Inc.
  - Actavis Holdco US, Inc.
  - Actavis Elizabeth LLC
  - Actavis Pharma, Inc.
  - Amneal Pharmaceuticals, Inc.
  - Amneal Pharmaceuticals, LLC
  - Aurobindo Pharma U.S.A., Inc.
  - Bausch Health Americas, Inc.
  - Bausch Health US, LLC
  - Fougera Pharmaceuticals Inc.
  - Glenmark Pharmaceuticals Inc., USA
  - Greenstone LLC
  - G&W Laboratories, Inc.
  - Lannett Company, Inc.
  - Lupin Pharmaceuticals, Inc.
  - Mallinckrodt Inc.
  - Mallinckrodt LLC
  - Mallinckrodt plc
  - Mylan Inc.
  - Mylan Pharmaceuticals Inc.
  - Perrigo New York, Inc.
  - Pfizer Inc.
  - Sun Pharmaceutical Industries, Inc.
  - Taro Pharmaceuticals USA, Inc.
  - Teligent, Inc.
  - Wockhardt USA LLC

Allegations

- Overarching conspiracy among manufacturers of generic topical products to unreasonably restrain trade in the generic pharmaceutical industry
    - Going back from at least 2009 through early 2016
        - Size and frequency of price increases grew exponentially in 2013 and 2014
    - Concept of "fair share"
    - Fix and raise prices
    - Rig bids
- Agreements constitute unreasonable restraints of trade that are *per se* illegal under Section 1 of the Sherman Act, 15 U.S.C. § 1. Also Wis. Stat. § 133.03.

Healthcare Distribution Alliance: An Introduction

Roxolana Kozyckyj
Director, State Government Affairs
Healthcare Distribution Alliance

Wisconsin Governor's Rx Pricing Task Force
June 18, 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 more than 200,000 licensed healthcare providers.
- Ship/Distribute 15 million lifesaving products to those providers each day.

HDA Antitrust Statement

It is the unqualified policy of HDA and all of its operating committees to conduct their operations in strict compliance with the antitrust laws of the United States.

HDA's antitrust policy prohibits any discussions which constitute or imply an agreement or understanding concerning: 1) prices, discounts, or terms or conditions of sale; 2) profits, or profit margins or cost data; 3) market shares, sales territories or markets; 4) allocation of customers or territories; 5) selection, rejection or termination of customers or suppliers; 6) restricting the territory or markets in which a company may resell products; 7) restricting the customers to whom a company may sell; or 8) any matter which is inconsistent with the proposition that each member company of HDA must exercise its independent business judgment in pricing its services or products, dealing with its customers and suppliers and choosing the markets in which it will compete.

HDA membership, Board of Directors and committee meetings shall be conducted pursuant to agendas distributed in advance to attendees; discussions shall be limited to agenda items which have been reviewed by HDA legal counsel; there shall be no substantive discussions of HDA matters other than at official meetings; and minutes shall be distributed to attendees promptly upon review by HDA legal counsel.

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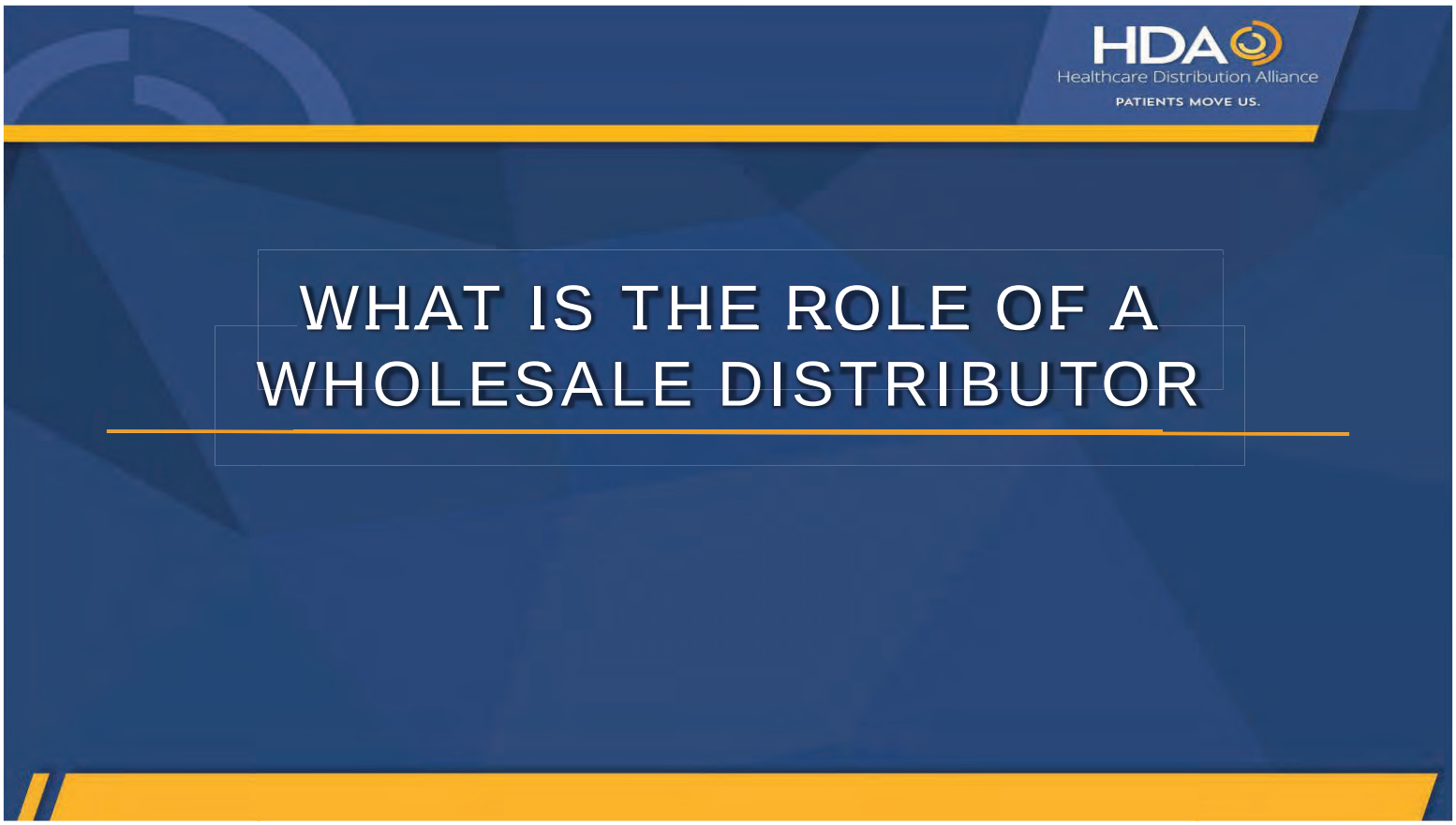
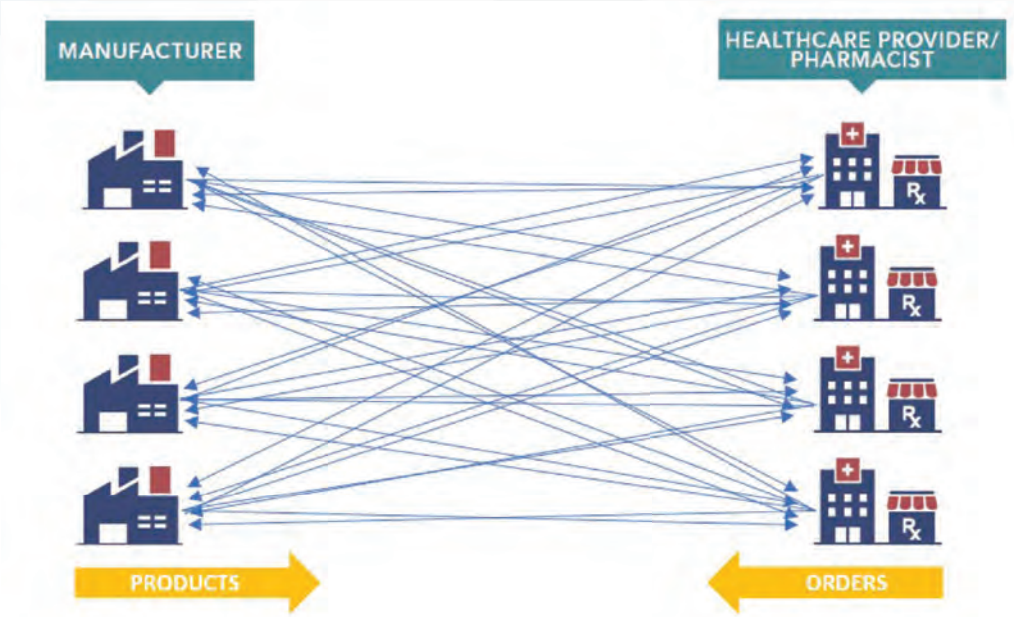


Supply Chain Without Pharmaceutical Distributors



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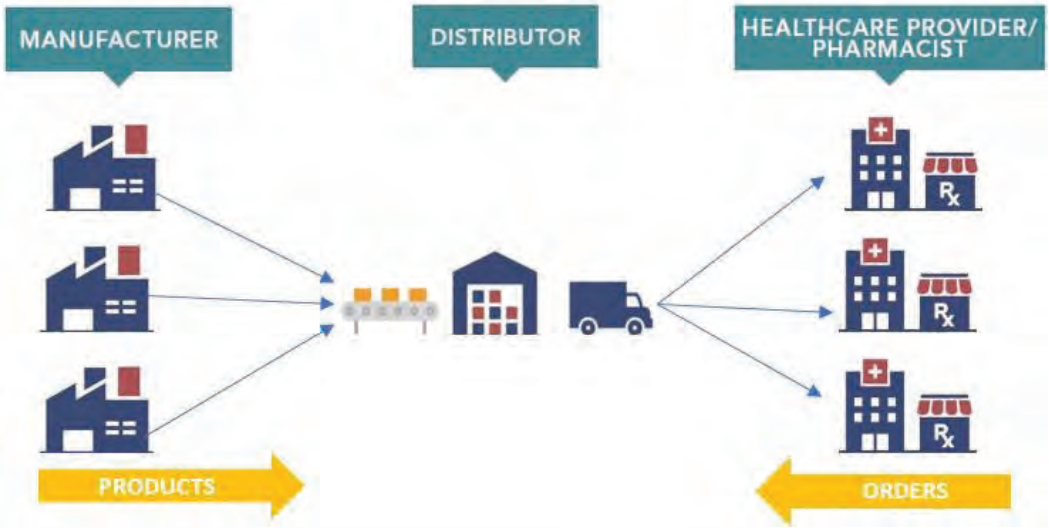
Supply Chain With Pharmaceutical Distributors



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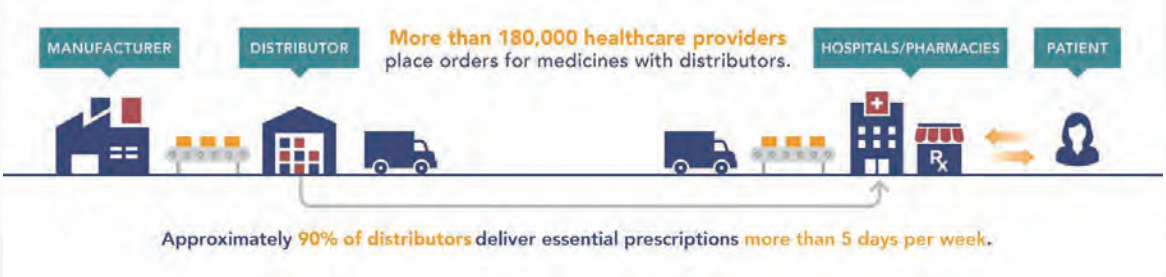
HDA

Pharmaceutical Distributors:

A vital link in the healthcare supply chain



DISTRIBUTORS ARE LOGISTICS EXPERTS.
Distributors provide a one-stop-shop for dispensing locations to acquire product from any licensed manufacturer. Wholesale distributors do not **manufacture**, **prescribe** or promote medicines or **impact patients benefit design or out of pocket costs**.

HDA

Wholesale Distributors in Wisconsin

- HDA members operate **2 facilities** in the state, each licensed by the state Board of Pharmacy:
  - Cardinal Health, Hudson
  - McKesson, Windsor

HDA

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

HDA

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*.

HDA

Wholesale Distributors' Role

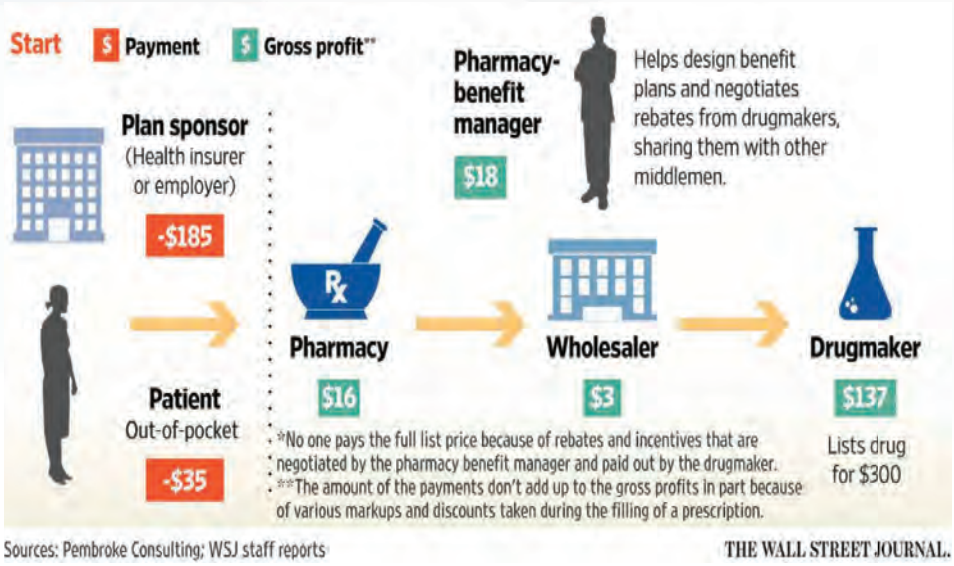
- Purchase pharmaceuticals from manufacturers based on the Wholesale Acquisition Cost ("WAC"), a publicly available figure.
- Manufacturers set WAC, distributors are not privy to how WAC is set.
- Charge manufacturers distribution fees related to their services, these fees are not passed on to the customer 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.

HDA

Supply Chain Profits Example

$300 Brand Name Drug



HDA


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
HDA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Healthcare Distribution Alliance
PATIENTS MOVE US.
LEARN MORE
www.hda.org

Pharmacy Services Administrative Organization (PSAO) Coalition

SCOTT PACE, PHARM.D., J.D. – CHAIR
PARTNER, IMPACT MANAGEMENT GROUP
JUNE 18, 2020

Governor's Task Force on Reducing Prescription Drug Prices

Summary of PSAO Coalition

- Developed in 2020 by the three largest PSAOs that are owned by pharmaceutical wholesalers (AmerisourceBergen – Elevate, Cardinal Health – LeaderNET, & McKesson – Health Mart Atlas)
- Collectively, the Coalition's members provide administrative services related to contracting with PBMs to over 17,000 of the 22,000 independent pharmacies and small chain pharmacies across all 50 states
- Despite the large market share amongst the independent pharmacies in the US, the three largest PSAOs *combined* only represent less than 13% of the total prescription drug market share

Background on PSAOs

- *Voluntary* service organization that independent pharmacies and small chains use to execute 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;

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 typically 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 specific 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

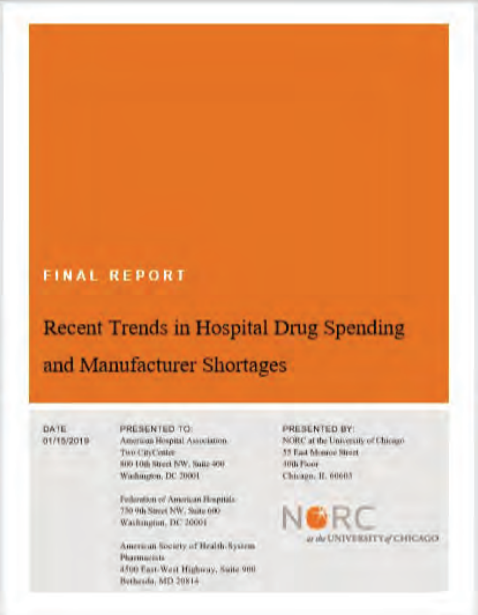
- PSAOs are voluntary entities that charge a flat fee for their service;
- PSAOs assist with executing contracts, they DO NOT negotiate with manufacturers and DO NOT sell medications to pharmacies;
- PSAOs provide administrative simplification for pharmacies;
- The PSAO Coalition is here to help answer 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.

American Hospital Association™
Advancing Health in America

Recent Trends in Hospital Drug Spending and Manufacturer Shortages

June 2020

Background



- In January 2019, the AHA, the Federation of American Hospitals (FAH), and the American Society of Health-System Pharmacists (ASHP) released a report finding that continued rising drug prices, as well as shortages for many critical medications, are impacting patient care and putting strains on hospital budgets and operations.
- The report was prepared based on analysis conducted by NORC at the University of Chicago, an independent research institution.
- The report updated and expanded on a previous AHA/FAH report from 2016 on skyrocketing inpatient hospital drug cost increases by also analyzing outpatient drug costs and the impact of drug shortages.

American Hospital Association™
Advancing Health in America

Key Findings

- Average total drug spending per hospital admission increased by **18.5 percent**
  - Outpatient drug spending per adjusted admission increased 28.7 percent
  - Inpatient drug spending per admission increased 9.6 percent
- Increases continued even after spending on drugs in the inpatient setting shot up **38.7 percent** from FY13-15 as a result of high prices.
- Hospitals experienced price increases in excess of 80 percent across different classes of drugs, including those for anesthetics, opioid agonists and chemotherapy

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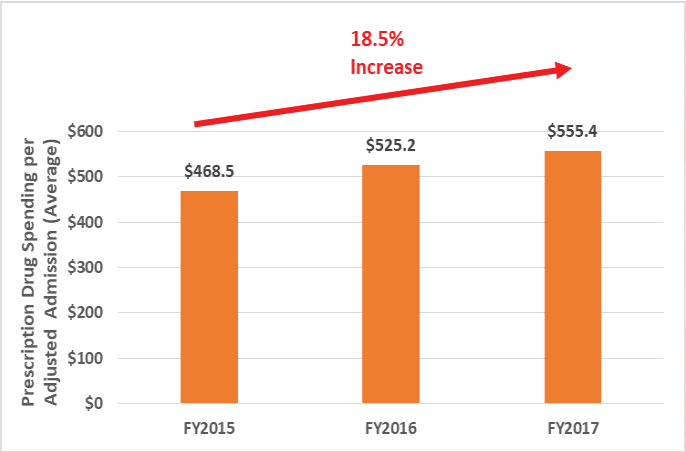
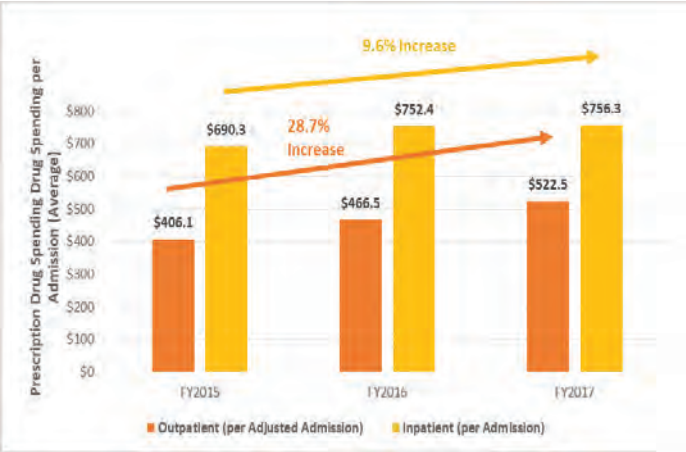
Spending Increases Continue After Historic Spikes





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Impact of High Drug Prices

- Hospitals and health systems continued to experience high annual growth in drug spending that far exceeds medical inflation and Medicare payment updates
- Over 90 percent of surveyed hospitals reported having to 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

American Hospital Association™
Advancing Health in America

EXAMPLES OF SIGNIFICANT CHANGES IN DRUG PRICES:

- **Activase®** (alteplase) – A widely used drug to treat persons with heart attack (acute myocardial infarction) and stroke. Unit prices for Activase **increased by 18.8 percent from $3,486 in CY 2015 to $4,143** in CY 2017.

- **Immunosuppressants** – Three of the top 10 drugs by total spending are immunosuppressants (Remicade®, Humira®, Enbrel®) used to treat rheumatoid arthritis and other auto-immune conditions. The unit prices for these drugs **increased between 15 and 21 percent** from CY 2015 to 2017.

- **Orphan Drugs** – Five of the top spending drugs for hospitals (Remicade®, Humira®, Riuxan®; Prolia®; and Procrit®) have orphan drug status for at least one of their indications and thus receive additional patent protections, as well as other benefits under the Orphan Drug Act. In the case of Humira, a patent settlement between AbbVie and Amgen has **extended the exclusivity of the drug until 2023**.

- **Hepatitis C** – Notably, market competition may have reduced unit prices for Harvoni®, which is used to treat Hepatitis C. In CY 2015, the unit price for Harvoni® was $84,000 for a 12-week course of treatment. Entry of a new competitor drug – Zepatier® by Merck - may have led to a decrease in the price of Harvoni® in CY 2017 of 15 percent

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2020 Survey and Next Study (Tentative):

- Survey Covers 2017-2019 Data
  - Continued focus on inpatient, outpatient and drug shortages
  - PLUS new focus on high launch prices, patient impact and potential COVID additions
- COVID-19 Pandemic Impact on Survey and Study Timeline
- Goals:
  - Continue to highlight the impact of high drug prices on hospitals and health systems
  - Increased focus on impact on patient access to care

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Moving Forward

- Access to high quality, affordable health care remains our highest priority
- And lowering the price of prescription drugs remains the top health priority for patients.
- This means lowering Rx prices for consumers at the pharmacy counter as well as for hospital purchasers.
- While there is not a single policy that will solve the prescription drug pricing crisis…
- There are a number of sensible solutions that, working together, would help rein in the price of prescription drugs

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Solutions

- Ever-Greening
  - In some instances, drug manufacturers attempt to “ever-green” a product when they apply for patent and market exclusivity protections for a “new” product that is essentially the same as the original product. In order to combat Congress give the FDA the ability to deny patents for products that are simply modifications of existing products.
- Pay-for-Delay
  - Pay-for-Delay continues to present significant barriers to affordable drug prices. We recommend that the Federal Trade Commission (FTC) clarify that these practices are presumptively illegal, and urge the inclusion of additional resources for the FTC to investigate these and other settlements.
- Expedite Entry of Generic Competitors
  - The FDA voluntarily undertook this approach, which we believe this approach should be codified in law. Additionally, we support ensuring that the FDA has the resources it needs to continue this effort.
- Limit Orphan Drug Incentives to True Orphan Drugs
  - In some instances, manufacturers have received orphan drug status for drugs that they subsequently marketed for other, non-rare indications. In these cases, manufacturers are receiving the incentives for drugs that are broadly used.

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STATE OF WISCONSIN
GOVERNOR'S TASK FORCE ON
REDUCING PRESCRIPTION DRUG PRICES

Drug Pricing: The Hospital Experience

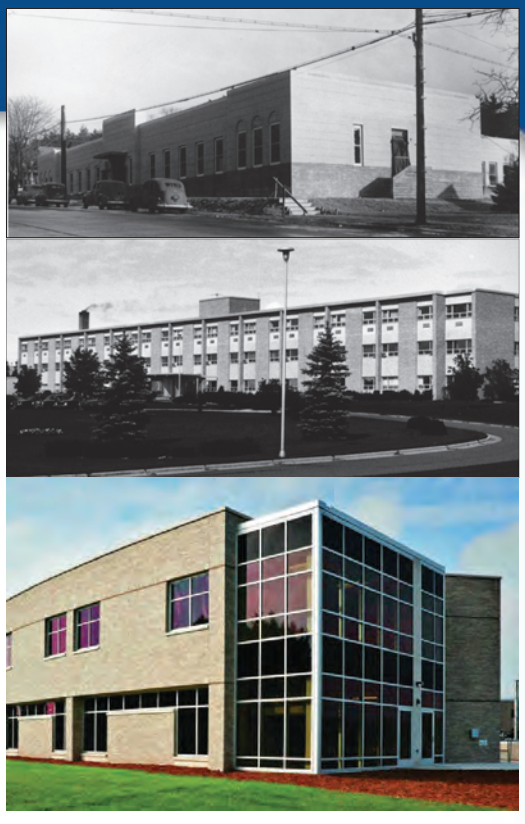
Brian Stephens, Chief Executive Officer
Dr. Jim Heise, Chief Medical Officer
Amy Konop, Pharmacy Director
Carrie Peterson, Certified Pharmacy Technician

Door County Medical Center
IN PARTNERSHIP WITH HOSPITAL SISTERS HEALTH SYSTEM
Trusted team. Close to home.

75 Years of Service

Door County Medical Center (DCMC) has provided 75 years of quality health care to residents of Door County & northern Kewaunee County

- Established as a non-profit hospital organization in 1944
- Became part of Ministry Health Care in 1999
- Ministry Health Care became part of Ascension Health in 2013
- Established formal partnership with Hospital Sisters Health System in November 2016



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IN PARTNERSHIP WITH HOSPITAL SISTERS HEALTH SYSTEM
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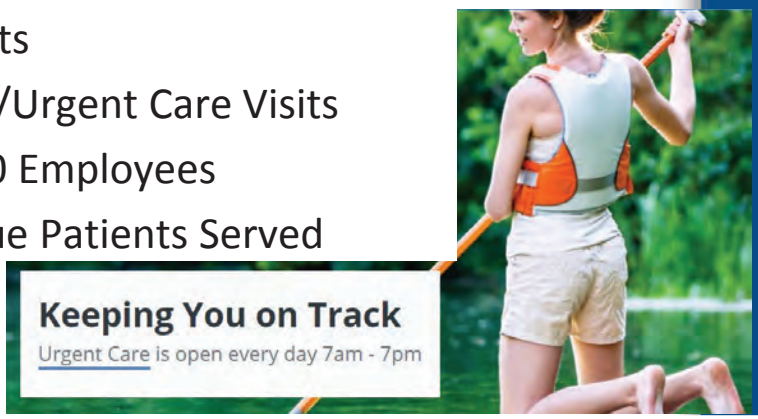
DCMC Today

- FY 2019 Statistics
  - $89 Million in Net Operating Revenue
  - 1,278 Inpatient Admissions
  - 8,771 ED Visits
  - 76,330 Clinic/Urgent Care Visits
  - 563 FTEs/670 Employees
  - 25,000 Unique Patients Served



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Drug Spend

	FY17	FY18	FY19
Drug Spend	$2.6M	$2.6M	$4.1M
Total Expenses	$80.8M	$82.1M	$88.3M
% Increase		0.0%	4.7%
Ratio	3.2%	3.1%	4.7%

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High Cost Drugs

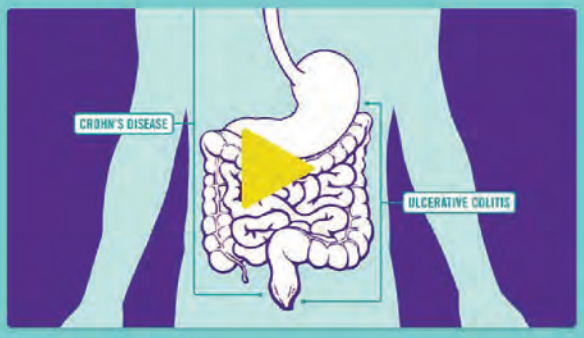
What is STELARA® and how does it work?

- STELARA® is a prescription biologic medicine
- Many biologics are made from proteins, genes, or antibodies
- Some biologics target enzymes or proteins that may cause inflammation—like the inflammation thought to cause Crohn's disease symptoms

STELARA® works differently

There are many different naturally occurring proteins in the body that contribute to inflammation. Patients with Crohn's disease are found to have elevated levels of two of these proteins, IL-12 and IL-23.

STELARA® is the only FDA-approved medicine that targets IL-12 and IL-23, which are thought to be associated with gastrointestinal inflammation in Crohn's disease.



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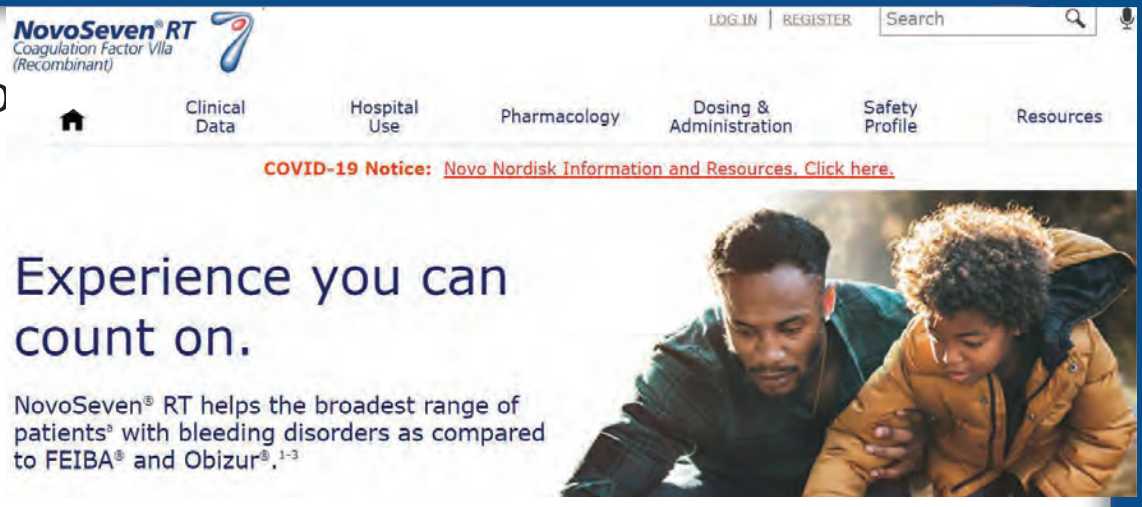
High Cost Drugs

- No



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High Cost Drugs

- Na

Naloxone
Common brands: Evzio, Narcan

Narcotic

It can treat narcotic overdose in an emergency situation.

Brands: Evzio and Narcan

Availability: Prescription needed

Pregnancy: Consult a doctor

Alcohol: No known interactions with light drinking

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High Cost Drugs

Epinephrine
Common brands: EpiPen, EpiPen Jr 2-Pak, Adyphren

Blood pressure support and vasoconstrictor

It can treat severe asthma attacks and allergic reactions (including anaphylaxis) in an emergency situation.

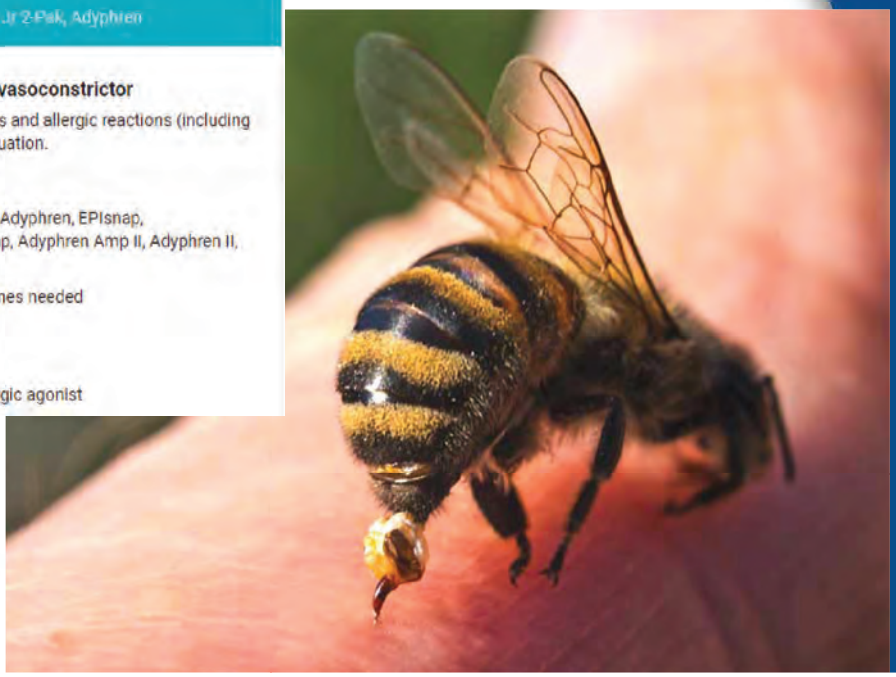
Brands: EpiPen, EpiPen Jr 2-Pak, Adyphren, EPIsnap, EpinephrineSnap-V, Adyphren Amp, Adyphren Amp II, Adyphren II, Auvi-Q, and Bronchial Mist Refill

Availability: Prescription sometimes needed

Pregnancy: Consult a doctor

Alcohol: Interactions can occur

Drug class: Nonselective adrenergic agonist



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The Art of Sourcing Drugs

- Drug availability is the priority with affordability as a second priority
- Attention to it every day
- Recalls
- Working with partner facilities
- Communication with 3rd party buyers

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Questions?

Brian Stephens, CEO
Door County Medical Center
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brian.stephens@dcmedical.org

Door County Medical Center
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State Efforts to Design and Implement Drug Importation Programs

Wisconsin Governor's Task Force on Reducing Prescription Drug Prices

National Governors Association
June 18, 2020

Agenda

- **Introductions, Haven Healthcare and Overview of Drug Importation Landscape**
  - Kate Johnson, NGA Health
- **Federal Regulations and State Drug Importation Efforts**
  - Jane Horvath, Horvath Health Policy
- **Utah Perspective on Drug Importation**
  - Rep. Norm Thurston, Utah House of Representatives
- **Prescription Drug Affordability Boards**
  - Jane Horvath, Horvath Health Policy

2

Haven Healthcare

- Non-profit established by Amazon, Berkshire Hathaway, and JPMorgan Chase in January 2018
  - Focus on improving health outcomes, patient experience, and lowering costs for U.S.-based employees and families from the three companies
  - Objectives include:
    - Easier access to primary care
    - Simpler and more user-friendly insurance benefits
    - Affordable prescription drugs
    - Effective use of data and technology
- Amazon and JPMorgan Chase piloting new health plans for employees in select states
- Atul Gawande, recently stepped down as CEO, now Chairman

3

Drug Importation Landscape

Federal Action

- Current law allows for wholesale importation of certain drugs from Canada if certain conditions are met, including certification by the Secretary of the U.S. Department of Health and Human Services (HHS), no additional risk to health and safety and significant reduction in cost to the consumer.
- July 2019 – Safe Importation Action Plan
  - Pathway 1: States, wholesalers, or pharmacists can submit plans for importation of Health-Canada approved drugs for HHS
  - Pathway 2: Manufacturers may import versions of drug products that they sell in foreign countries that are the same as the U.S. approved versions
- December 2019 – Notice of Proposed Rule Making (Pathway 1)

State Action

- Bills introduced in 23 states in 2020

Laws Enacted (2018 – 2020)	Concept Papers Submitted to HHS
• Colorado • Florida • Maine • New Mexico • Vermont	• Colorado • Florida • Maine • Vermont

4

6/18/2020

Jane Horvath

With Support of Arnold Ventures

WI Governor's Task Force

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Importation: Federal Law

- **In general,** importing Rx into the US is not legal except under the control of the original manufacturer, except as follows:
- **Personal:** The FDA does not enforce the law for importation of drugs for individuals when quantity ≤ 90 pills
- **Wholesale:** With Federal DHHS Secretarial approval, allows importation of wholesale quantities of drugs from Canada by wholesalers or pharmacies if safe and consumer savings are guaranteed
  - Biologics (including insulin and vaccines) excluded from importation
  - Imports only from Canada allowed

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Importation: Proposed Regulation

- Federal Proposed Rule, December 2019.
  - Rule would effectuate the federal law that permits wholesale importation. Unclear when final rule will be published.
  - Several barriers for state wholesale importation under NPRM (list not exhaustive)
    - Imported product will be in finished packaging when imported, rather than large container shipments.
    - Number of Canadian suppliers will be limited which could complicate or stymy importation.
    - Product to be held at facility near a Customs office until tested
      - Unclear how many warehouse facilities are available at the US side of the border
  - In general, ~70% of US Rx supply is imported already by manufacturers. Federal law and regulation establish a safe, transparent, global supply chain that state wholesale import programs would use. Proposed regulation tries to add more requirements to wholesale importation that are not needed and make state importation very difficult on several levels.

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Importation: State and Local Activities

- Enacted Wholesale Importation Laws: VT, FL, CO, ME, NM
  - Submitted Proposals: FL, VT, CO, ME
- Without change in federal law, state importation is unlikely to be very effective as more states attempt it.
  - Expand countries from which to import EU, United Kingdom, Japan
  - Permit wholesale importation of biologics (insulins, vaccines, other biologics)
- CanaRx: 500 US Employers (including state and local governments)
- Utah: to be discussed

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State Importation Law and Bills

- VT, FL, CO, ME, NM have laws
- VT, ME, NM follow NASHP model act – statewide access to imported Rx through state-designated, limited number of wholesale importers
- FL – focus on government payers initially, then statewide. Law allows individual pharmacies to import (order and receive).
- CO- statewide and allows health plans and pharmacists to import.
- The proposed regs may not permit the FL or CO models as enacted. Proposed regs would allow one Canadian exporter, 1 state importer (that then distributes product)

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Utah Perspective on Drug Importation

Prescription Drug Affordability Board

- Enacted in MD and ME – basically to help state and local government purchase and/or negotiate for lower costs
  - MD Board has open option to go statewide in several years with upper payment limits for some high cost drugs
  - Governor vetoed Board funding bill – assessment on plans, pbms and pharma companies
- WA Board bill vetoed by Governor
- States may not need legislation to create inter-departmental PBM contracts or multi-agency consolidated purchasing
- Rx Board bills introduced in ~11 other states in 2020

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11

STATE OF WISCONSIN

GOVERNOR'S TASK FORCE ON REDUCING PRESCRIPTION DRUG PRICES

Contact information:
Email: OCIRXDrugTaskForce@wisconsin.gov
Website: RxDrugTaskForce.WI.gov

GOVERNOR'S TASK FORCE ON REDUCING PRESCRIPTION DRUG PRICES

July 21, 2020

10:00 a.m. – 2:00 p.m.

I. Welcome (5 minutes)
- **Nathan Houdek, Deputy Commissioner**, *Office of the Commissioner of Insurance*

II. Governor Tony Evers (10 minutes)

III. Consumer Experience (5 minutes)

IV. Pfizer (40 minutes)
- **Dr. Robert Popovian,** *Pharm.D., MS., Vice President, US Government Relations, Pfizer Inc.*

V. The Pharmaceutical Research and Manufacturers of America (PhRMA) (60 minutes)
- **Peter Fjelstad, JD**, *Senior Director, PhRMA State Policy*
- **Sharon Lamberton, MS, RN**, *Deputy Vice President, PhRMA State Policy*
- **Saumil Pandya, MHS**, *Deputy Vice President, PhRMA Advocacy*

VI. Break (10 minutes)

VII. GoodRx (40 minutes)
- **Elizabeth Morton***, Sr. Partnership Manager, Pharmacy Strategy*

VIII. Civica Rx (40 minutes)
- **Heather Wall, MBA,** *Chief Commercial Officer, Civica, Inc.*
- **Mohammad (Mo) Kharbat, MBA, B.Sc.,R.Ph.,BCPS,** *Vice President - Pharmacy Services and Health Research, SSM Health – Wisconsin Region*

IX. Task Force Member Discussion (30 minutes)
- Discuss potential policy options

X. Next Meeting Date via Webinar
- July 22, 2020

XI. Adjourn

Meeting Minutes
July 21, 2020
10 a.m. – 2 p.m.
Webinar via Zoom

Welcome
Nathan Houdek, OCI Deputy Commissioner and Task Force chair

- Deputy Commissioner Houdek welcomed Task Force members and public attendees.
- Key housekeeping items
    - A reminder that this is a public meeting.
    - Task Force members will have use of their microphones; the public does not.

Address from Governor Tony Evers

- Thank you to the Task Force members for their hard work and dedication.
- The cost of prescription drugs is a serious concern facing countless people across Wisconsin.
- Appreciate the task force staying focused on consumers and patients.

Consumer Experience
Dr. Barbara Horner-Ibler, Medical Director, Bread of Healing Clinic in Milwaukee shared her experience working with patients struggling to afford the cost of prescriptions. It is a free clinic for adults with chronic illnesses.

- Long-time patient with two prescriptions for inhalers to control her asthma who recently purchased health insurance. When she filled that script it was going to cost her over $500 a month – the full cost of the prescription. She was forced to allow her insurance to lapse so that she could continue to afford her vital prescription drugs. This creates an untenable position and is common in the patients that Dr. Horner-Ibler sees.

Pfizer
Dr. Robert Popovian, Pharm.D., MS – Vice President, US Government Relations, Pfizer Inc

- A presentation from Dr. Popovian is available on the Task Force website: https://rxdrugtaskforce.wi.gov/Documents/Pfizer.pdf

Issues raised by task force members:

- Other players in the drug supply chain claim that it is ultimately the drug manufacturers that set the list price, which drives increased drug prices. But, the manufacturer is saying that they are forced to increase prices because of rebates.
    - Rebate contracting creates misaligned incentives for more expensive medicines to be pursued over lower cost drugs.
    - The Kaiser example was highlighted as a no rebating contract model.
- How is the list cost of a drug price determined?
    - What goes into the price is more than just R&D, but also the cost of all the failures and future research, market dynamics, and portfolio pricing (vs individual pricing).

- As a consumer, and from a policy decision-making process, it would be helpful to see on a given prescription what percentage goes to each entity in the supply chain.
    - Texas passed a bill to increase transparency and the market is moving toward more transparency regarding what goes back to each entity. There still is a limit to the transparency to ensure there is still blind bidding.
- What is driving utilization? Does PhRMA marketing drive utilization?
    - People getting older and Americans becoming less healthy drives utilization.
    - It is ultimately the plan design and formulary decisions made by insurance companies that determine a drug's accessibility.

The Pharmaceutical Research and Manufacturers of America (PhRMA)
Peter Fjelstad, JD – Senior Director, PhRMA State Policy
Sharon Lamberton, MS, RN – Deputy Vice President, PhRMA State Policy
Saumil Pandya, MHS – Deputy Vice President, PhRMA Advocacy

- A presentation from PhRMA is available on the Task Force website: https://rxdrugtaskforce.wi.gov/Documents/PhRMA.pdf

Issues raised by task force members:

- A task force member questioned the dollar figure presented of $2.6 billion to get a drug to market. Doesn't think that is representative of the average.
    - Other figures don't factor in failures – only 1 in 10 drugs in the pipeline get to market. The costs need to cover those 9 drugs that didn't make it to market.
- The rate of getting a molecule to market is 1 in 5,000 and it used to be 1 in 10,000. There is more effiency but no more cost savings there.
- There were some discontent expressed around direct to consumer advertising.

Civica Rx
Heather Wall, MBA – Chief Commercial Officer, Civica, Inc.
Mohammad (Mo) Kharbat, MBA, B.Sc., R.Ph., BCPS – Vice President, Pharmacy Services and Health Research, SSM Health, Wisconsin Region

- A presentation from PhRMA is available on the Task Force website: https://rxdrugtaskforce.wi.gov/Documents/CivicaRx.pdf

Task Force Member Discussion

Continue questions to PhRMA/manufacturers:

- Why does it matter to PBMs or health insurers if coupons are used toward deductible?
    - Some discussion about IRS implications.
    - What counts toward a member's contract obligation?
    - First mover penalty – get kicked off formulary.
- If prices are higher in the US than other countries, does it have to do with PBMs and rebates?

- Prices are lower because those are single-payer systems where the government sets the price. The downside is the innovation, access to fewer medications, and slower access.

Next Meetings

- July 22 – Scheduled presenters include representatives from AARP, the American Diabetes Association, Vivent Health, the Northwest Prescription Drug Consortium, and the Department of Employee Trust Funds (update on the Wisconsin Pharmacy Cost Study Committee).
- August 25 – Discussion about policy recommendations

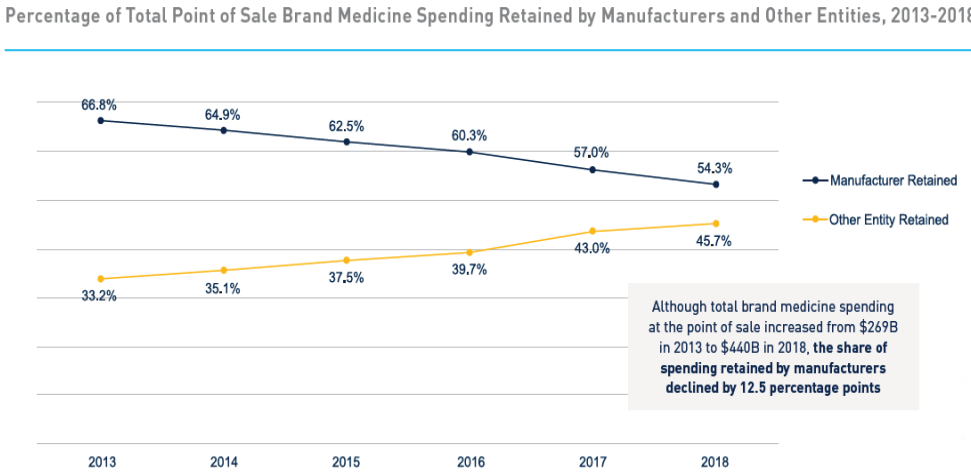
Adjourn

Examining the Landscape of Drug Pricing, Spending and Affordability

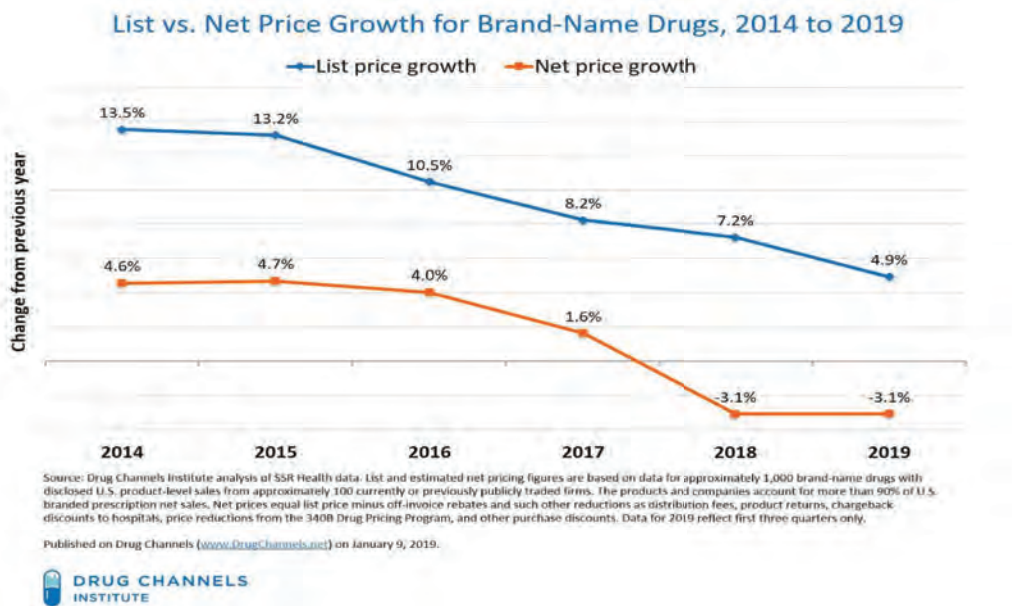
Robert Popovian, Pharm.D., MS
Vice President, US Government Relations
Pfizer Inc

A Lot of Healthcare Players Have Their Hand in the Drug Pricing/Spending Cookie Jar!

Almost 50% of Brand Name Spending is Retained by the Supply Chain



List to Net Price Differential



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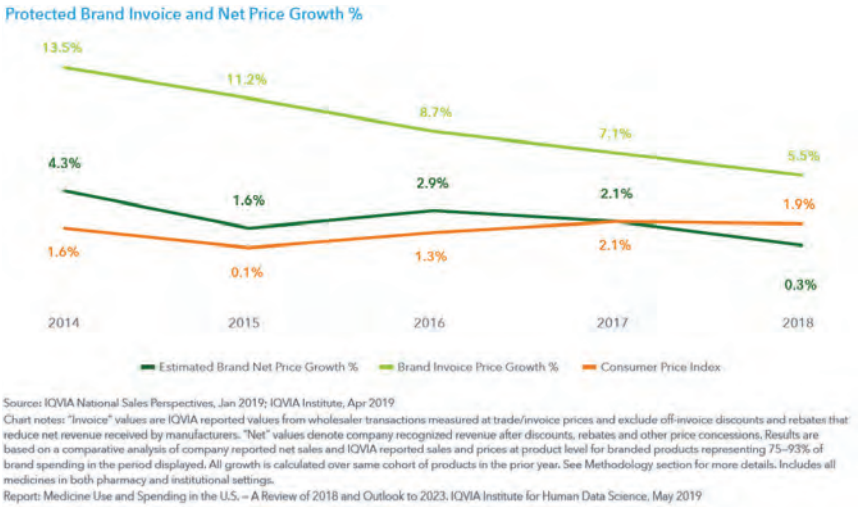


Source: IQVIA National Sales Perspectives, Jan 2019; IQVIA Institute, Apr 2019
Chart notes: "Invoice" values are IQVIA reported values from wholesaler transactions measured at trade/invoice prices and exclude off-invoice discounts and rebates that reduce net revenue received by manufacturers. "Net" values denote company recognized revenue after discounts, rebates and other price concessions. Results are based on a comparative analysis of company reported net sales and IQVIA reported sales and prices at product level for branded products representing 75–93% of brand spending in the period displayed. All growth is calculated over same cohort of products in the prior year. See Methodology section for more details. Includes all medicines in both pharmacy and institutional settings.
Report: Medicine Use and Spending in the U.S. – A Review of 2018 and Outlook to 2023. IQVIA Institute for Human Data Science, May 2019

"Average price growth for 2019 was 0.2% compared to 1.6% in 2018; 2019 showed the slowest price growth since 1972."

https://altarum.org/sites/default/files/uploaded-publication-files/January%202020%20Price%20Brief.pdf

"2.3% , trend for commercial plans in 2019, driven by a 1.4% increase in utilization and a 0.9% rise in unit cost"

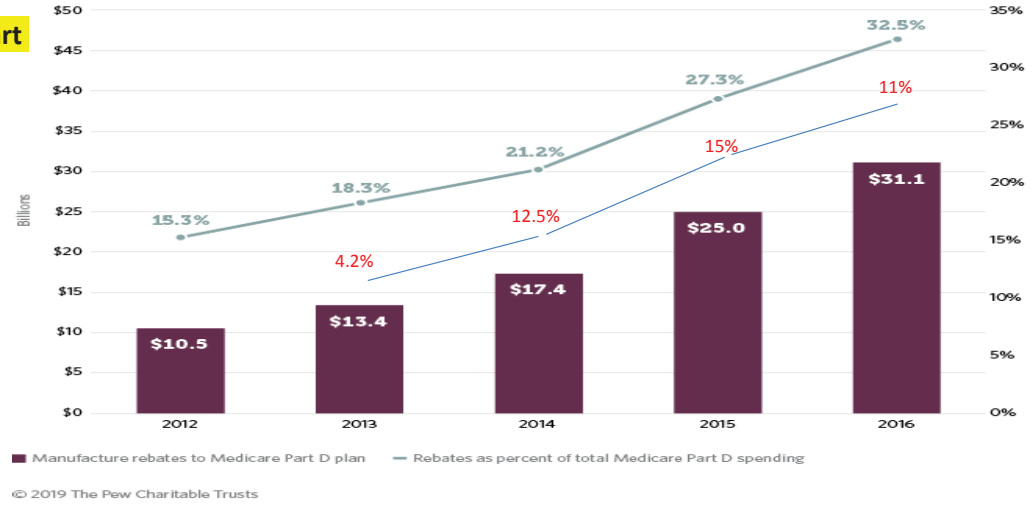
"<1%, increase in unit cost for commercial plans, even as list prices for brand drugs jumped 5.2%"

https://www.express-scripts.com/corporate/drug-trend-report#2019-by-the-numbers

Rebates Growing Faster than Medicare Part D Spending

Growth in Medicare Part D Spending From 2017-2018 = - 5%

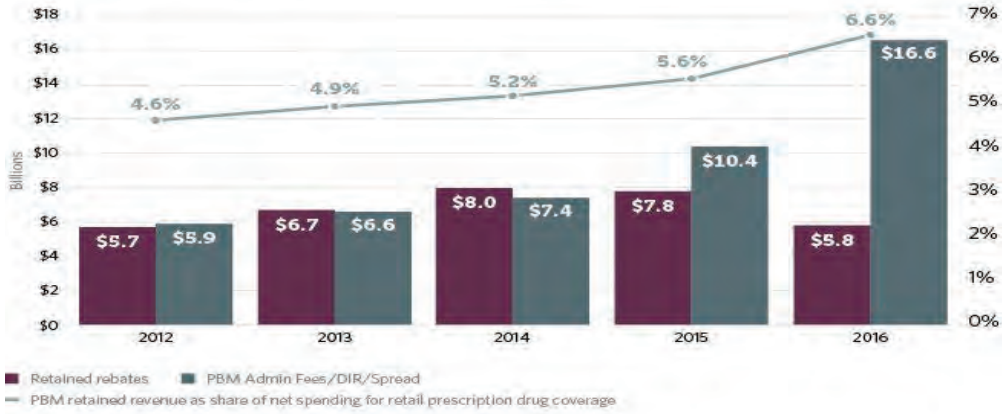
Figure 7
Manufacturer Rebates in Medicare Part D, 2012-16



https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2019.pdf Table III D3

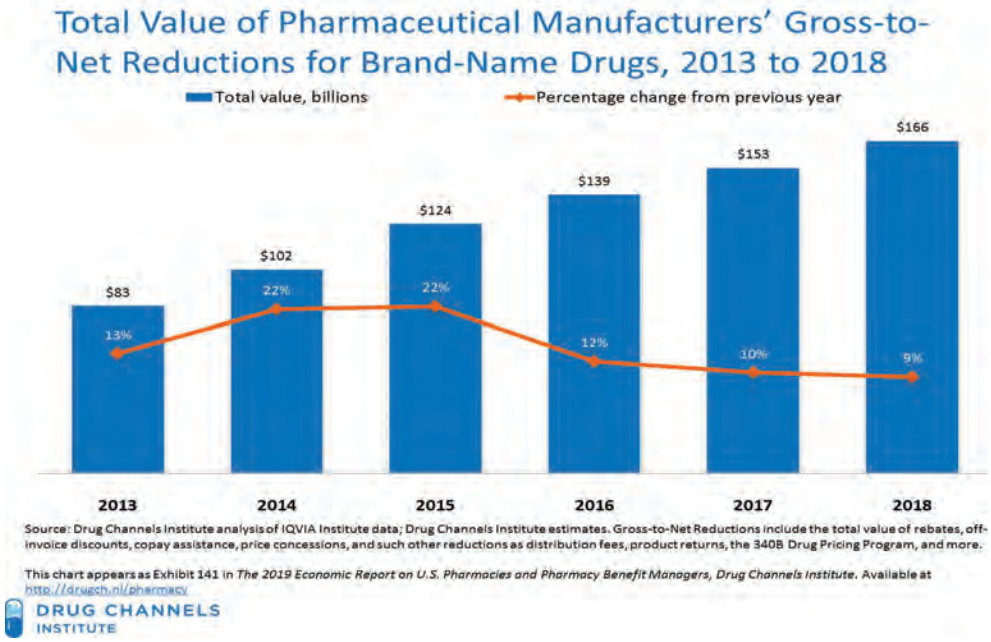
It's Not Just About Rebates!

Figure 9
PBM Retained Revenue on Retail Prescription Drugs by Source and Share of Net Spending for Retail Prescription Drug Coverage, 2012-16

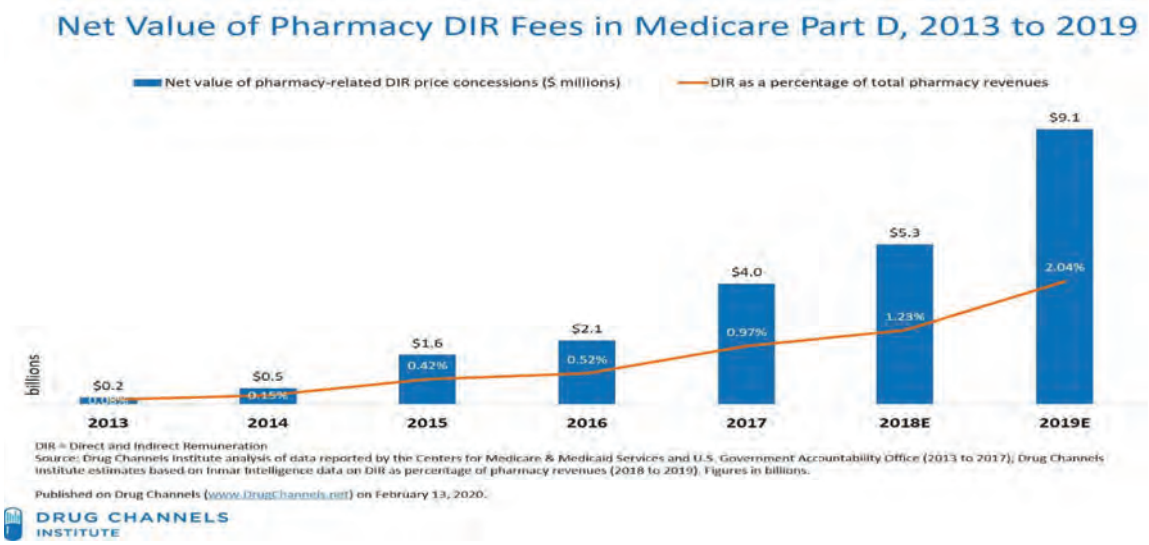


Concessions Paid to the Middlemen

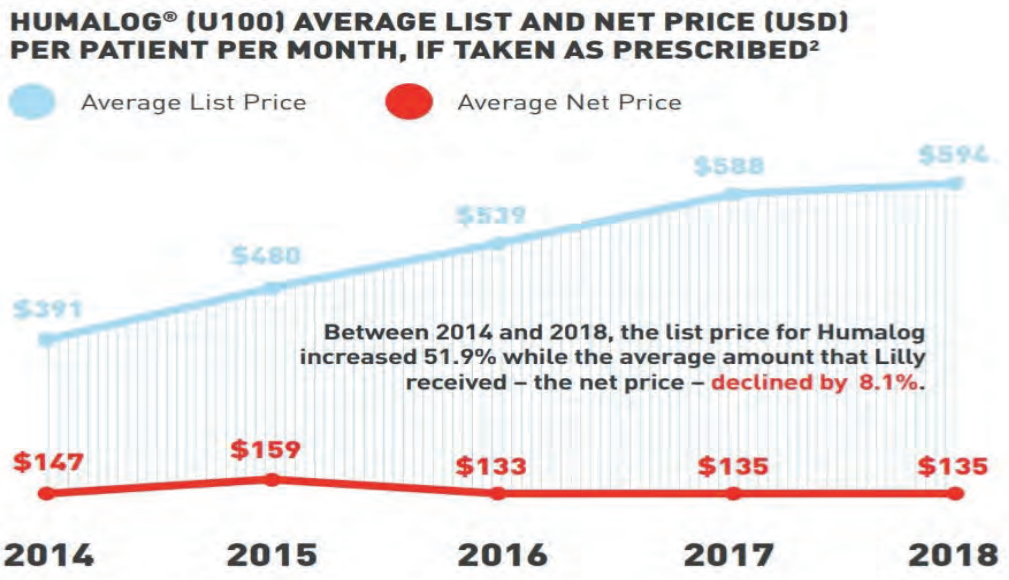
From 2013– 2018 rebates/fees paid by biopharmaceutical companies has increased by ~100%



Concessions Paid to the Middlemen by Pharmacies

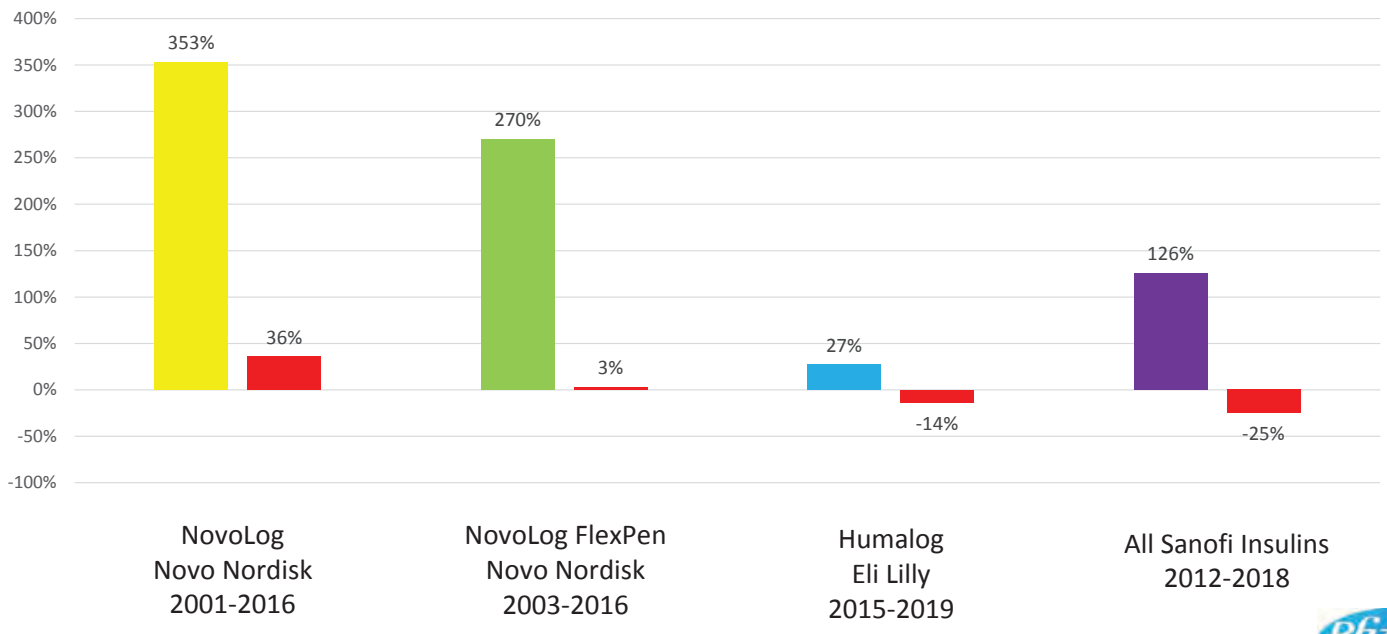


List Prices GO UP – Net Prices GO DOWN Who Benefits? Where Does the $ Go?



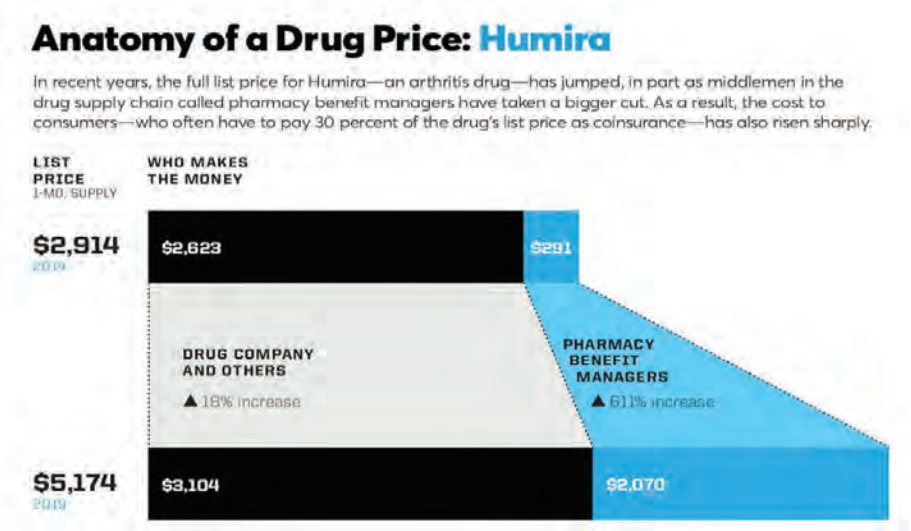
Source: Eli Lilly and Company, 2018 Integrated Summary Report. Available at https://investor.lilly.com/static-files/ae580ba4-5d84-4862-a5d2-99a1d784d7a8.

More Insulin Price Distortion



https://www.americanactionforum.org/research/insulin-cost-and-pricing-trends/

List Prices GO UP – Net Prices GO DOWN
Who Benefits? Where Does the $ Go?



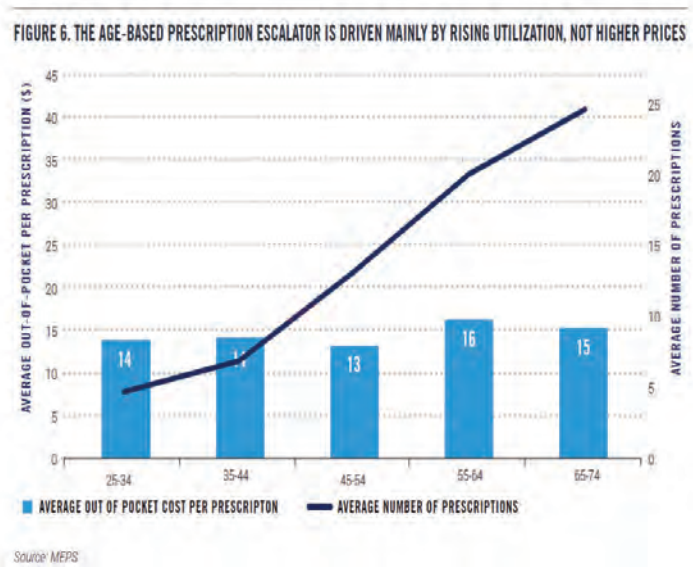
Source: Eric Topol, Twitter (https://twitter.com/EricTopol/status/1200850777524166658/photo/1)

13

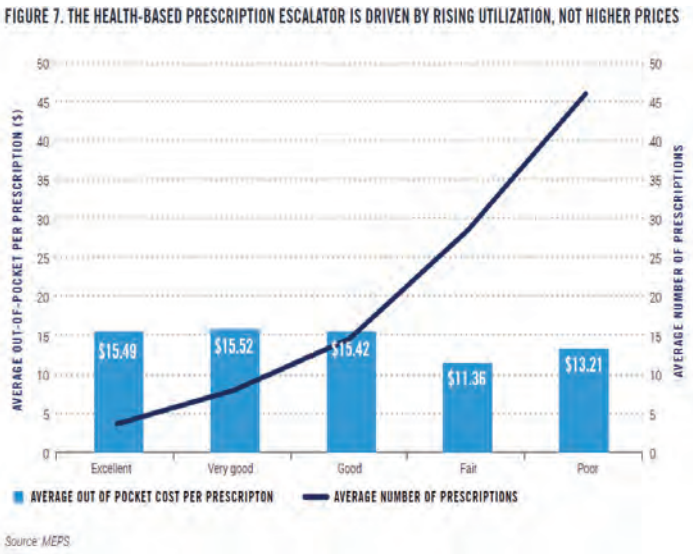
Questions of Interest

What Drives OOP Spending?

UTILIZATION

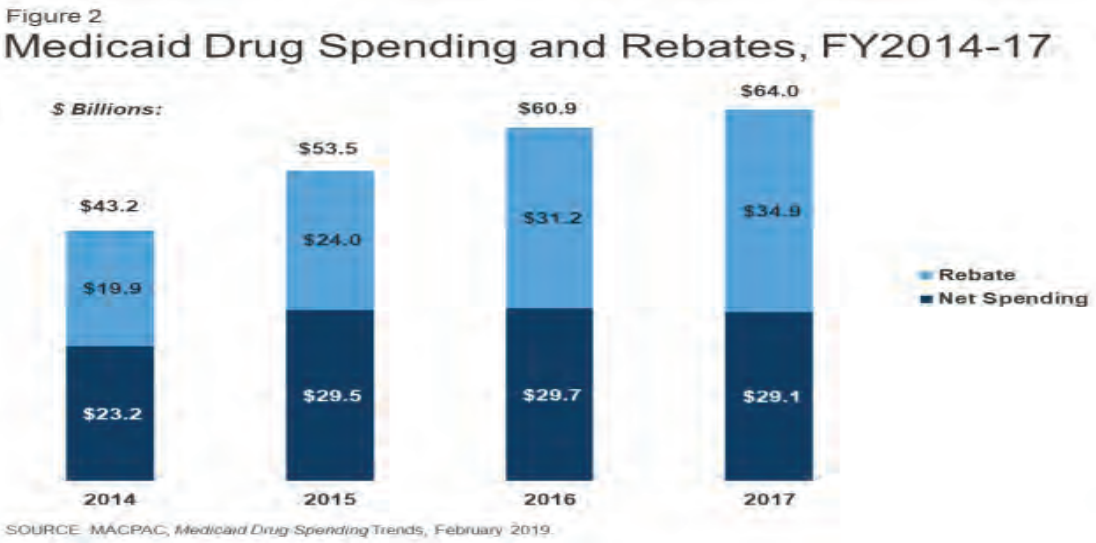


POOR HEALTH



https://www.progressivepolicy.org/issues/the-prescription-escalator-the-real-reason-why-americans-pay-more-for-drugs-eachyear-why-they-are-so-upset-and-what-can-be-done-about-it2/

Is Medicaid Spending for RX Drugs Out of Control?



Do Rebates Impact List Prices?

- Drug rebates and list prices are positively correlated: On average, a $1 increase in rebates is associated with a $1.17 increase in list price.
- Rebates play a role in increasing drug prices, and reducing or eliminating rebates could result in lower list prices and reduced out-of-pocket expenditures for some patients.

https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/

What is the Impact of Biopharmaceutical Spending on Healthcare Premiums?

The California Department of Managed Healthcare (DMHC) via Senate Bill (SB) 17 requires health plans and health insurers that file rate information with the DMHC or the California Department of Insurance (CDI) to annually report specific information related to the costs of covered prescription drugs.

Table 1
Impact of Prescription Drugs on Premiums *(in millions)*[11]

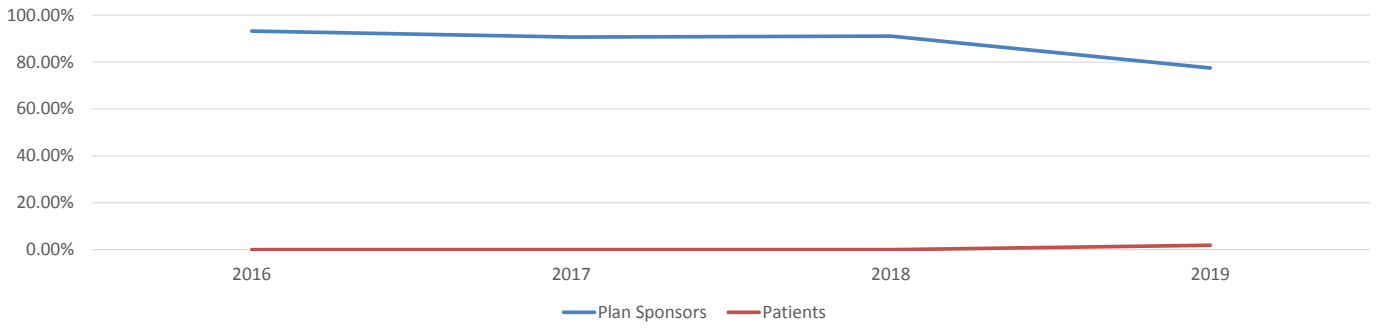
Category of Premium Payment	2018	Percentage of Premium	2017	Percentage of Premium	YOY[12] Percentage Change
Prescription Drug Expenses	$9,051	12.7%	$8,646	12.9%	4.7%
Medical Expenses	$52,993	74.3%	$51,578	76.8%	2.7%
Manufacturer Drug Rebates	($1,058)	(1.5%)	($922)	(1.4%)	14.8%

https://www.dmhc.ca.gov/Portals/0/Docs/DO/sb17.pdf

DO NOT DISTRIBUTE

What % of All Concessions Do PBMs Pass Back to the Plan Sponsors or Patients?

Aggregate data from 19 PBMs the data was collected under House Bill 2536, passed by the 2019 Texas Legislative Session. The Texas Department of Insurance did not audit the data; instead, the agency is reporting the data as reported by the PBMs.



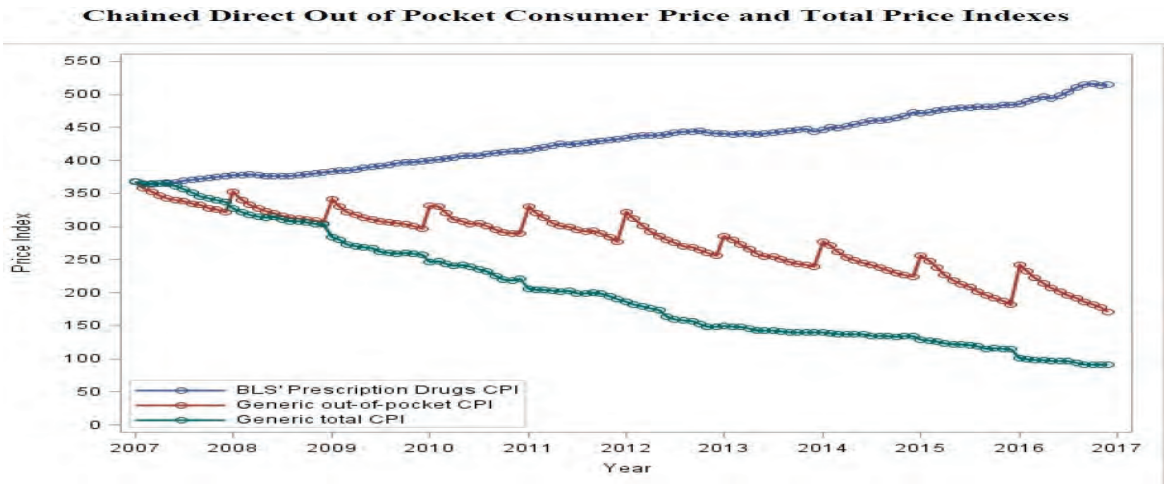
https://www.tdi.texas.gov/reports/documents/drug-price-transparency-PBMs.pdf

How Much Do Patients Save if PBMs Share the Savings?

- ***Consumers already seeing average savings of $130 per eligible prescription in 2019***
- ***Programs strengthen prescription drug adherence by up to 16%, lead to improved patient health***

https://www.optum.com/about/news/successful-prescription-drug-discount-program.html

Are Generic Prices Increasing In the U.S.?



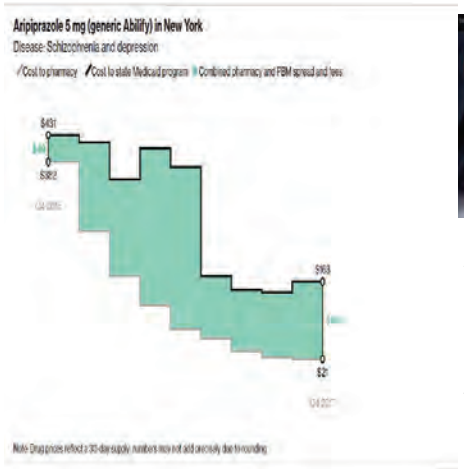
Observations:

- 2007-16 prices for generic RX drugs fell by nearly 80%, same period, consumer out of pocket CPI for generics fell roughly 50% - IOW, consumers didn't fully benefit from generic price declines
- 2007-16 according to BLS, the drug CPI increased by 44% - from 2013-16 concessions paid to middleman by Pharma increased by 56% - IOW based on conservative estimation rebates/fees/concessions outpaced RX pricing CPI

https://www.nber.org/papers/w26120?utm_campaign=ntwh&utm_medium=email&utm_source=ntwg30

Do Patients and States Overpay for RX Medicines?

Spread Pricing



A report commissioned by Ohio Medicaid showed the spread between what the state paid the PBMs and what they paid pharmacies added up to $224 million in 2017

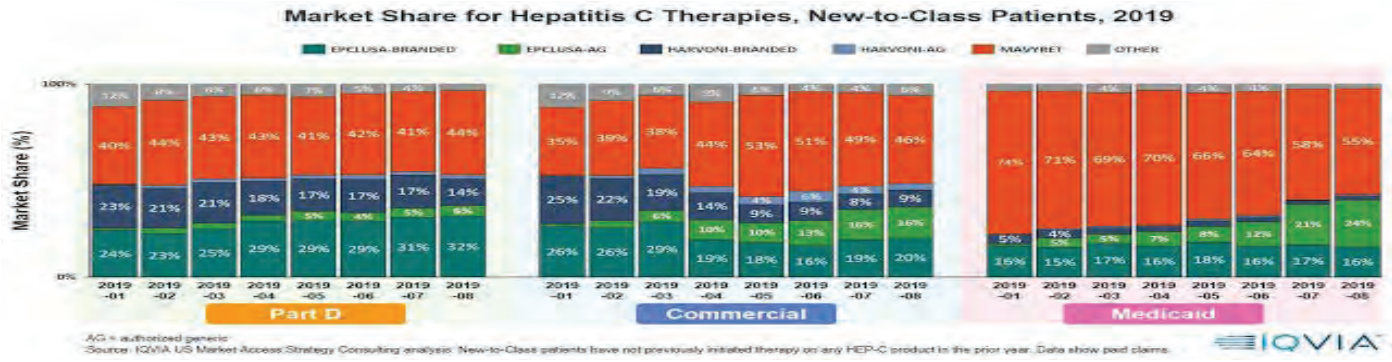
Claw back

Almost one quarter of filled pharmacy prescriptions (23%) involved a patient copayment that exceeded the average reimbursement paid by the insurer

Total overpayments amounted to $135 million

1. http://www.dispatch.com/news/20180610/side-effects-series-on-prescription-drugs
2. https://www.bloomberg.com/graphics/2018-drug-spread-pricing/?srnd=premium
3. https://healthpolicy.usc.edu/wp-content/uploads/2018/03/2018.03_Overpaying20for20Prescription20Drugs_White20Paper_v.1-4.pdf

Does Rebate Contracting Create Mis-Aligned Incentives?



"17 of the largest health plans covered biosimilars as preferred in only 14% of formulary decisions. In 33% of cases, biosimilars were designated as "non-preferred" by the insurer."

https://jamanetwork-com.eu1.proxy.openathens.net/journals/jama/article-abstract/2766151

"72% of Part D formularies had a lower cost-sharing tier and 30% of Part D formularies had fewer utilization controls on branded drugs for at least one multisource drug."

https://jamanetwork-com.eu1.proxy.openathens.net/journals/jamainternalmedicine/fullarticle/2728446

Do PBMs Control Coverage, Access and Distribution?

Prescription Revenues and Market Share from Specialty Pharmaceuticals, by Company, 2019

Pharmacy Name	Parent Organization	Estimated 2019 U.S. Prescription Revenues from Specialty Drugs ($ billions)	Change in Revenues vs. 2018	Share of Prescription Revenues from Specialty Drugs
CVS Specialty[1]	CVS Health	$43.9	+19%	27%
Accredo / Freedom Fertility	Cigna (Express Scripts)[2]	$32.1	+5%	20%
AllianceRx Walgreens Prime / Walgreens stores[3]	Walgreens Boots Alliance	$21.2	+8%	13%
Optum Specialty Pharmacy[4]	UnitedHealth Group (OptumRx)	$17.8	+6%	11%
Diplomat Pharmacy[5]	n/a[5]	$4.5	-6%	3%
Humana Specialty Pharmacy	Humana	$3.6	+11%	2%
Kroger Specialty Pharmacy / Kroger stores	Kroger	$3.4	+21%	2%
Specialty Pharmacy Solutions[6]	McKesson	$1.7	+8%	1%
US Bioservices	AmerisourceBergen	$1.5	+9%	1%
AHF Pharmacy	AIDS Healthcare Foundation	$1.2	+10%	1%
PANTHERx Rare	n/a	$1.2	+65%	1%
Walmart Specialty Pharmacy	Walmart Stores	$1.1	+5%	1%
SenderraRx	n/a	$0.9	+15%	1%
BioPlus Specialty Pharmacy Services	n/a	$0.7	+4%	0%
Onco360 / CareMed	BrightSpring Health Services[7]	$0.7	+8%	0%
All other retail, mail, long-term care, and specialty pharmacies	n/a	$25.7	n.a.	16%
Total		**$161.1**	**+9%**	**100%**

Source: Drug Channels Institute research and estimates. Includes revenues from retail, specialty, and mail pharmacies. Includes specialty revenues from retail locations, where relevant. Excludes revenues from network pharmacies of PBM-owned specialty pharmacies and infusion services covered by medical benefit. Totals may not sum due to rounding.
1. Includes CVS Caremark Specialty Pharmacy, CVS retail pharmacies, and Drug Channels Institute estimated pro forma full year revenues from acquisitions completed in 2019. Includes annualized pro forma specialty revenues from Anthem and Coventry, which transitioned from Express Scripts during 2019.
2. In 2018, Cigna acquired Express Scripts. Excludes Drug Channels Institute-estimated revenues from clients that transitioned from Express Scripts during 2019: Anthem and Coventry Health Care.
3. Includes pro forma full-year revenues from acquisitions completed in 2019.
4. Formerly known as BriovaRx. Note that growth rate is based on Drug Channels Institute-estimated 2018 revenues, which included pro forma revenues from Avella Specialty Pharmacy and Genoa Healthcare.
5. In 2020, Diplomat was acquired by OptumRx.
6. Includes Biologics by McKesson and the Patient Assistance Pharmacy (formerly known as Care Advantage).
7. In 2019, PharMerica merged with BrightSpring Health Services.

This table appears as Exhibit 48 in *The 2020 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute. Available at http://drugch.nl/pharmacy

DRUG CHANNELS INSTITUTE

Summary of Potential Solutions?

- For Immediate Fix: Share the savings directly with the patients at the point of sale at the pharmacy counter
- Long Term Fix: Get rid of contracting via rebates and go to net price contracting
- Longer Term Fix: Mandate fees for services instead of % of retail price (ensure fees are for legitimate services)
- Ensure lower priced alternatives are preferred and not the other way around
- Beware of monopolies in the supply chain
- Pay for Outcomes


Value of Medicines
July 21, 2020
PhRMA
RESEARCH • PROGRESS • HOPE
Peter Fjelstad, JD
Sharon Lamberton, MS, RN
Saumil Pandya, MHS

About 4,500 Medicines in Development in the U.S.

Biopharmaceutical researchers are working on new medicines* for many diseases, including:

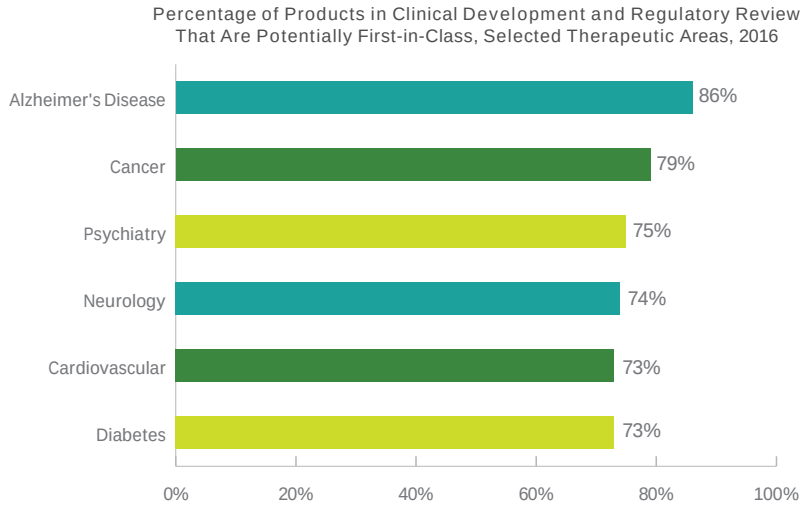
- CANCERS 1,120
- HEART DISEASE &STROKE 200
- HIV 52
- ASTHMA &ALLERGY 130
- SKIN DISEASES 328
- MENTAL DISORDERS 140
- RARE DISEASES 566
- NEUROLOGICAL DISORDERS 537

*Defined as single products that are counted only once regardless of the number of indications pursued

Source: Adis R&D Insight Database[2]

Potential First-in-Class Medicines in the Pipeline

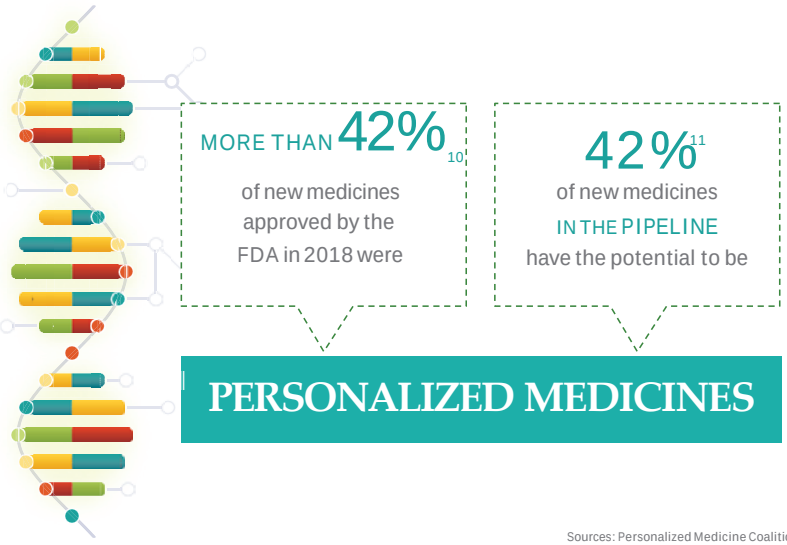
An average of 74% of drugs in the clinical pipeline are potential first-in-class medicines.



Source: Analysis Group[3]

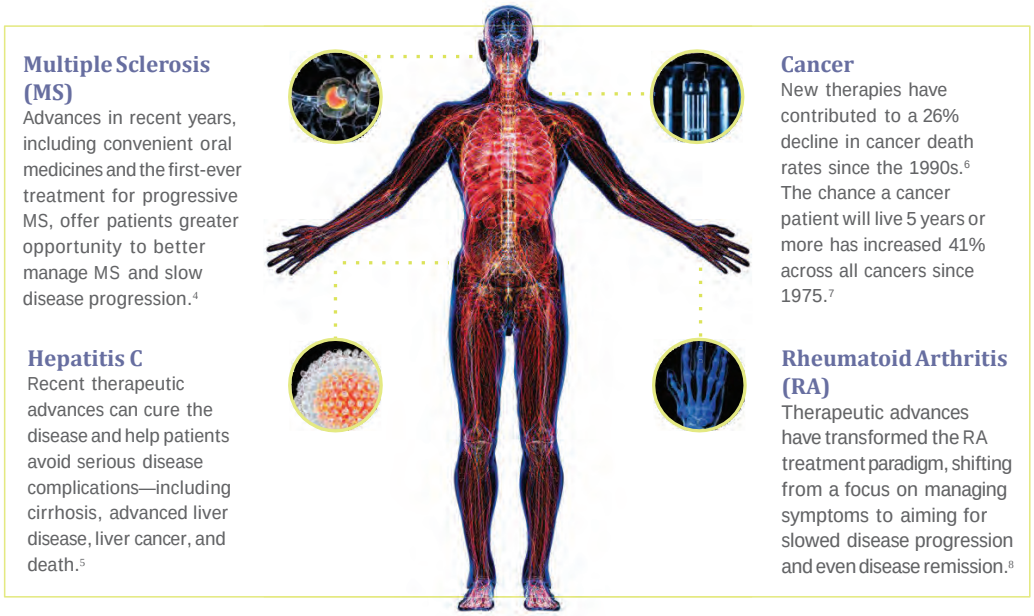
Biopharmaceutical Companies Are Committed to Advancing Personalized Medicine

In recent years, we have seen remarkable advances in targeted therapy, and the R&D pipeline has never been more promising.



Sources: Personalized Medicine Coalition[10]; Tufts CSDD[11]

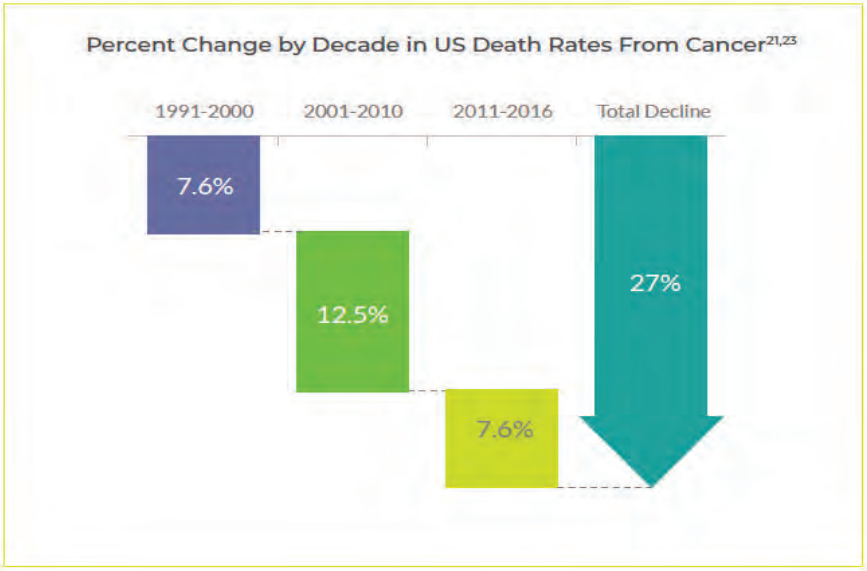
Medicines Are Transforming the Treatment of Many Diseases



Sources: PhRMA[4,5]; Siegel RL et al.[6]; ACS[7]; Boston Healthcare Associates[8]

Cancers: Decline in Death Rates

Since peaking in the 1990s, cancer death rates have declined 27%.[21] Approximately 73% of survival gains in cancer are attributable to new treatments, including medicines.[22]



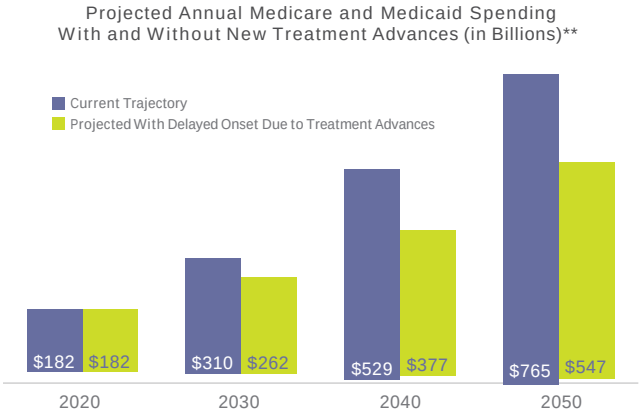
"I think some of the treatments that we have developed over the last half century or so are really starting to pay off and, honestly, [it] seems limitless as to what may pay off in the future."

— William Nelson, MD, PhD, Director, Sidney Kimmel Comprehensive Cancer Center[24]

Sources: Siegel RL et al.[21]; Seabury SA et al.[22]; NCI[23]; Dunellari A[24]

Unmet Need: Future Impact of New Treatments for Alzheimer's Disease

The development of a new treatment that delays the onset of Alzheimer's disease could reduce Medicare and Medicaid spending on patients by $218 billion annually by 2050.*

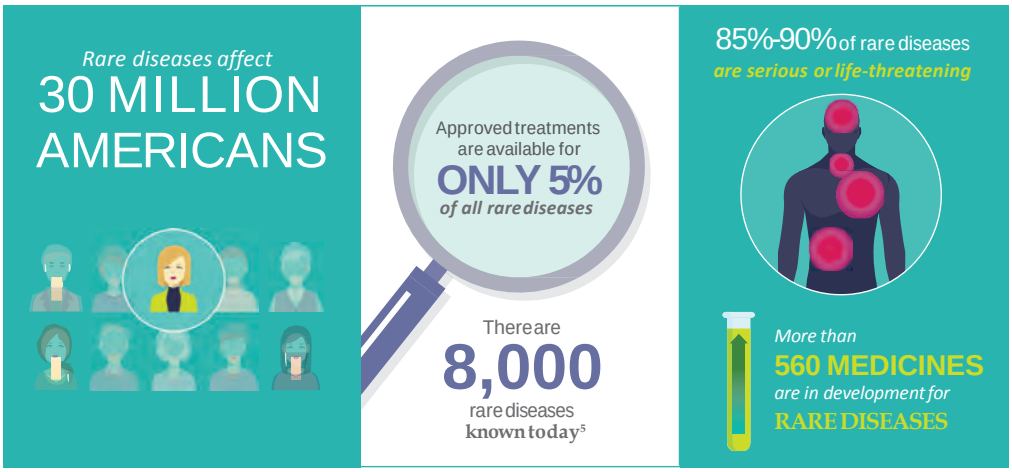


*Assumes research advances that delay the average age of onset of Alzheimer's disease by 5 years beginning in 2025.
**Projected savings to Medicare and Medicaid assume research breakthroughs that slow the progression of Alzheimer's disease. This would dramatically reduce spending for comorbid conditions and expensive nursing home care.

Source: Alzheimer'sAssociation[39]

Harnessing Innovation in Rare Diseases

Since the passage of the Orphan Drug Act in 1983, we have seen tremendous advances in treatments for rare diseases,* with more than 770 orphan drug approvals (compared with fewer than 10 in the decade before passage).[4]



*Rare diseases are defined as conditions for which there are fewer than 200,000 patients diagnosed in the United States.

Sources: FDA[4]; Danese E et al.[5]; PhRMA[6]

Medicines Are Transforming Treatment of Many Rare Diseases

Collectively, rare diseases affect 30 million Americans. Treatments are available for only 5% of rare diseases, but recent advances are providing important new options to many patients for the first time.[9]

Fabry Disease[10]

Fabry disease is a genetic disorder that can cause fat buildup in blood vessels, nerves, and other organs and slowly progress to kidney disease, abnormal heart rhythm, stroke, and early death. The first treatment for adults was approved in 2018 and works by increasing the activity of a deficient enzyme.

Primary Hemophagocytic Lymphohistiocytosis (HLH)[11]

Primary HLH is an inherited and life-threatening immune disorder typically affecting children. The disorder causes damage to various organs, including the liver, brain, and bone marrow. The first treatment specifically for HLH was approved in 2018 for adults and children.

Hereditary Transthyretin-Mediated Amyloidosis (hATTR)[12]

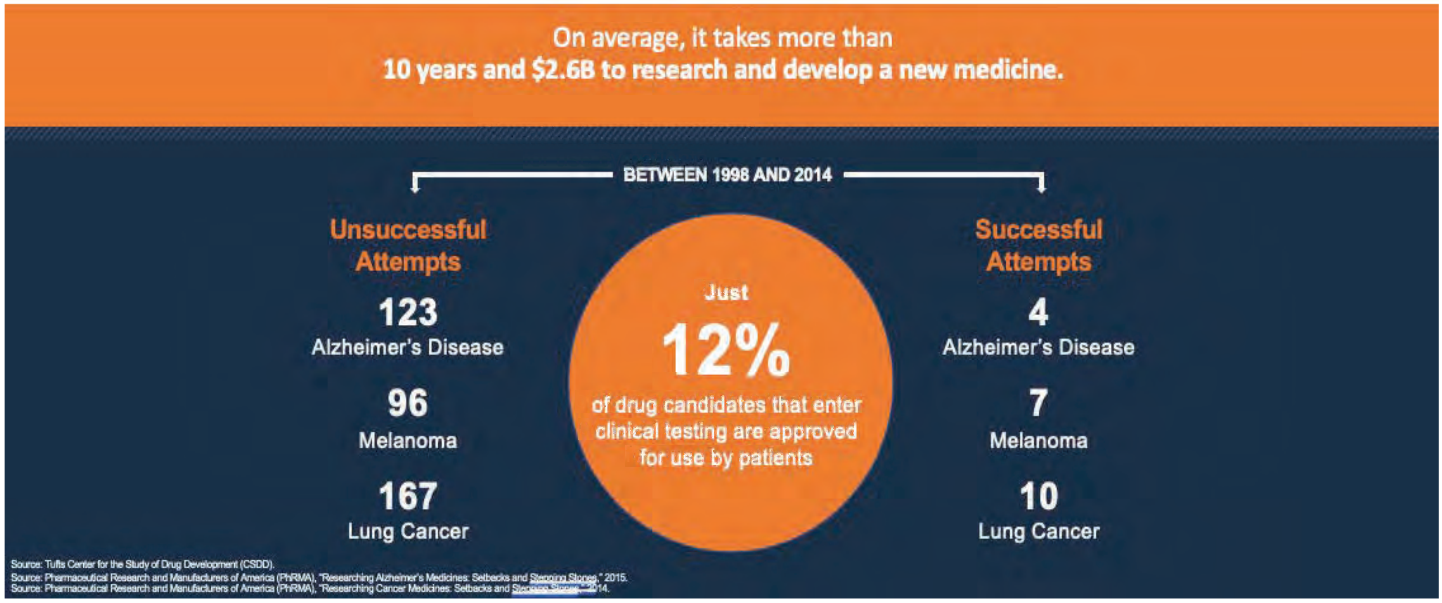
hATTR interferes with the normal functioning of nerves, heart, and other organs and can lead to loss of sensation, pain, or immobility in the limbs. The first treatment for this often fatal genetic disease was approved in 2018 and targets the root cause by interfering with abnormal RNA protein production.

Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)[13]

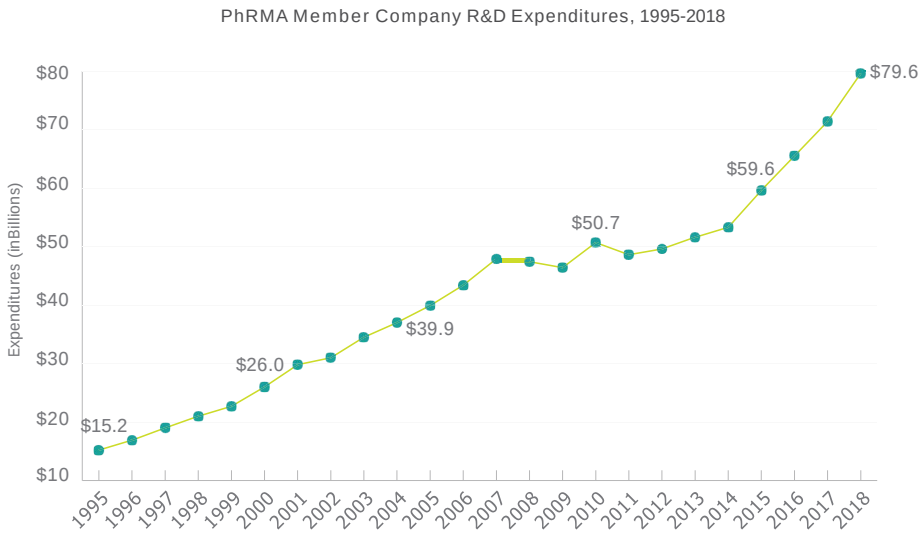
BPDCN is an aggressive blood cancer affecting multiple organs, including the lymph nodes and skin. The first treatment specifically for BPDCN was approved in 2018 for adults and children. Prior to this treatment, intensive chemotherapy and bone marrow transplant had been the standard of care.

Sources: Global Genes[9]; FDA[10-13]

R&D is risky and expensive



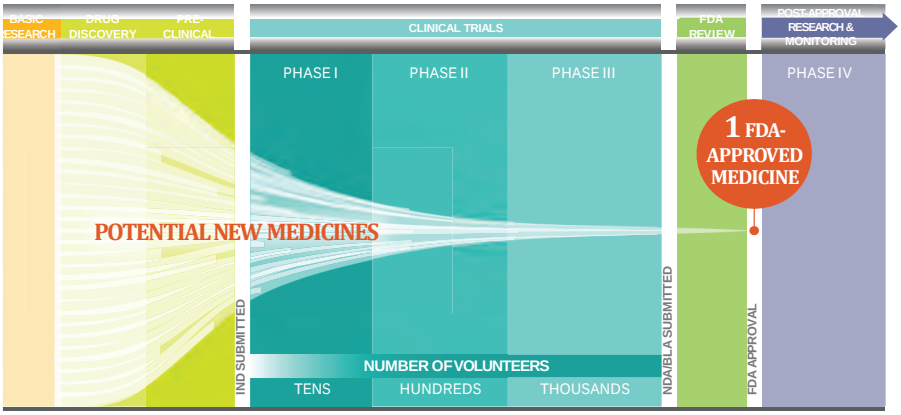
PhRMA Member Company R&D Investment



Source: PhRMA[26]

The R&D Process for New Drugs Is Lengthy and Costly, With High Risk of Failure

From drug discovery through FDA approval, developing a new medicine on average takes 10 to 15 years and costs $2.6 billion.* Less than 12% of the candidate medicines that make it into phase I clinical trials are approved by the FDA.



Key: IND=Investigational New Drug Application, NDA=New Drug Application, BLA=Biologics License Application

*The average research & development (R&D) cost required to bring a new FDA-approved medicine to patients is estimated to be $2.6 billion over the past decade (in 2013 dollars), including the cost of the many potential medicines that do not make it through to FDA approval.

Sources: PhRMA adaptation of DiMasi JA et al.; Tufts CSDD[7]; FDA[8]

Wisconsin Clinical Trials

409 Clinical Trials

6,811 Participants

$90.2 Million invested

$237.4 Million in economic impact to WI

Illustrative Pharmaceutical Lifecycle

New pharmaceutical medicines typically face competition after a relatively short time on the market, first from brand competitors, and eventually from generics

*Brand drug market share generally declines rapidly after generic entry.
**For brand medicines with more than $250 million in annual sales in 2008 dollars, which account for 92% of sales of the brand medicines analyzed

Sources: PhRMA[3]; DiMasi JA et al.[33]; Grabowski H et al.[4]

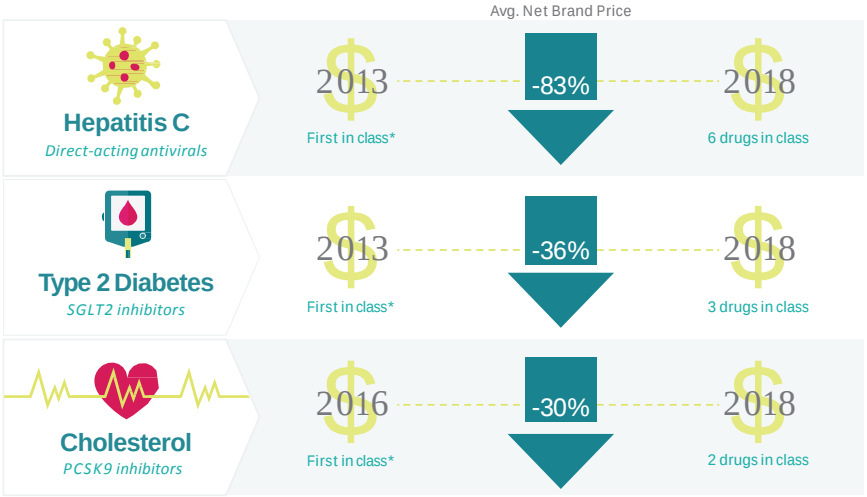
Biopharmaceutical Industry Does the Majority of Research to Translate Basic Science Into New Medicines

While basic science is often initiated in government and academia, it is biopharmaceutical firms that provide the necessary expertise and experience needed to develop new medicines [16]

Sources: Chakravarthy R et al.[34]; Research!America[35]; NIH[36]

Brand-to-Brand Competition Drives Savings in U.S. Market-Based System

Payers leverage purchasing power and competition among brand medicines to negotiate substantial discounts on medicines.



*Indicates launch year of the first drug in this pharmacologic class.

Source: PhRMA analysis of SSR health data[16]

Patent Cliff: Competition from generics and biosimilars is expected to reduce U.S. brand sales by $95 billion from 2019 to 2023…

Biopharmaceutical Profits Are in Line With Those of Other Industries

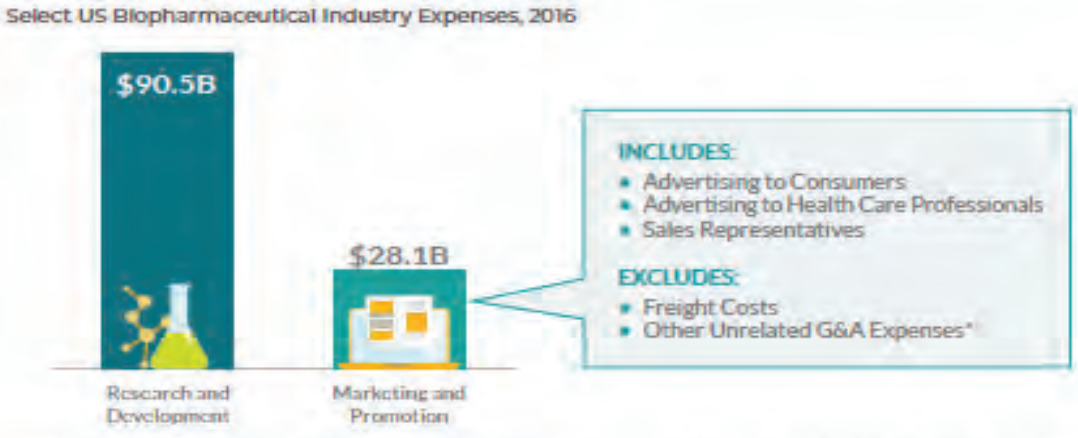
Adjusted for the significant risk and capital investments required to develop medicines, biopharmaceutical industry profits are average among industries.

*Economic profits are accounting profits minus capital expenses.
**Represents the weighted average of pharmaceuticals (8.2%) and biotechnology (2.2%), which are listed as separate industries in the source data.

Source: Adapted from Bates White[10]

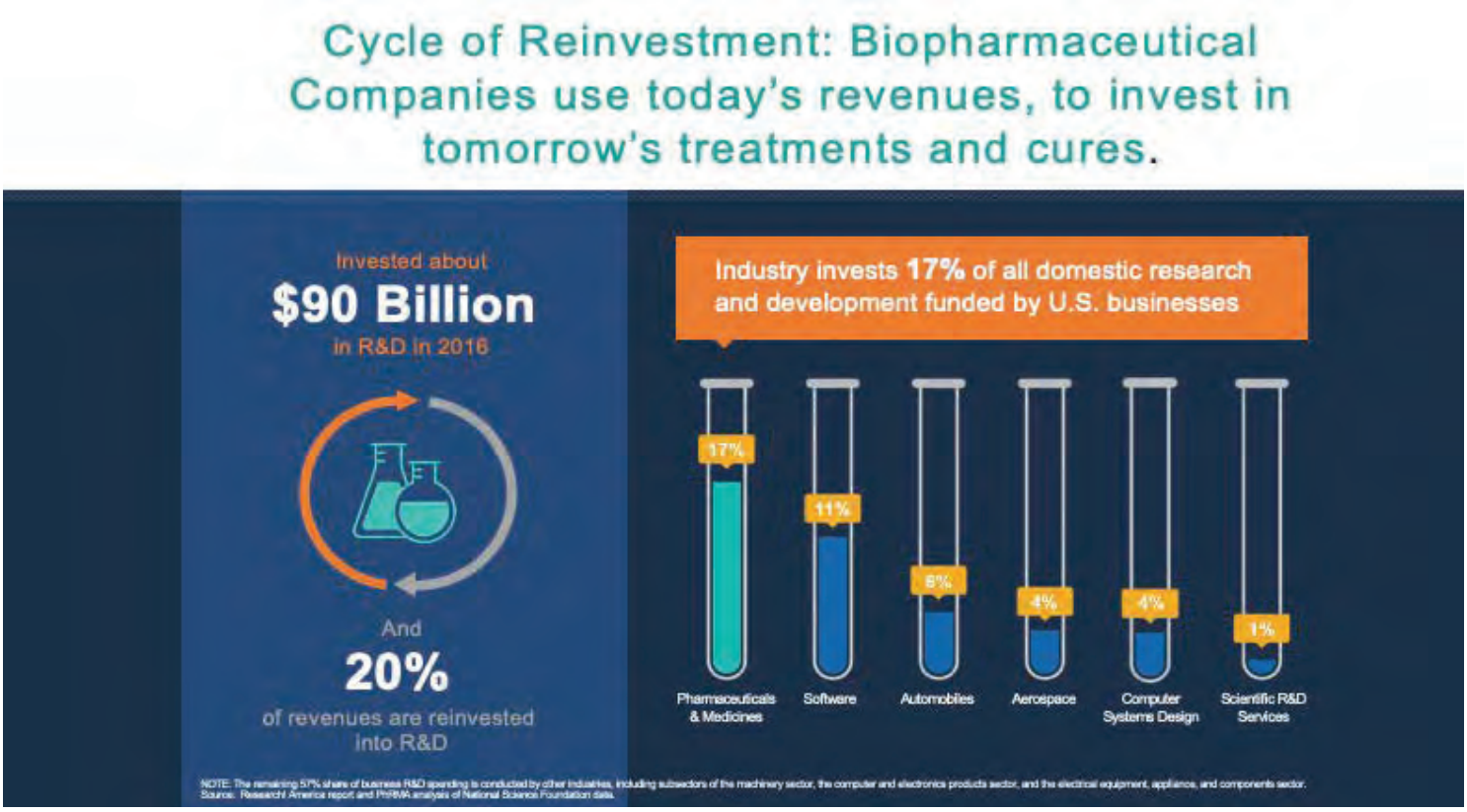
Biopharmaceutical Company Marketing and Promotion Spending in Context

Use of inflated estimates of marketing and promotion spending has created the false impression that the biopharmaceutical industry spends more on marketing than on R&D. More precise estimates show the opposite to be true.



*Indicates general and administrative (G&A) expenses unrelated to marketing and promotion, such as finance and office utility, rent, utilities, and supplies. Some have inaccurately used sales and G&A expenses as a proxy for industry's marketing and promotion expenses.

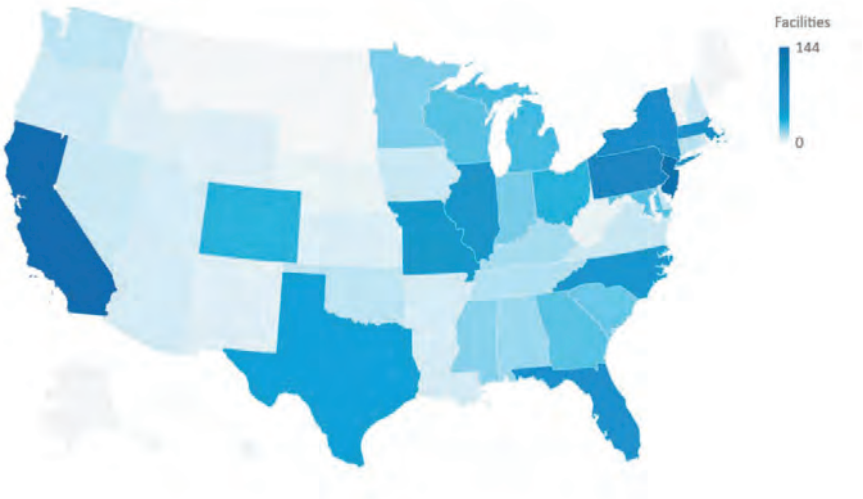
Sources: Schwartz [et al.][11]; Research!America[12]



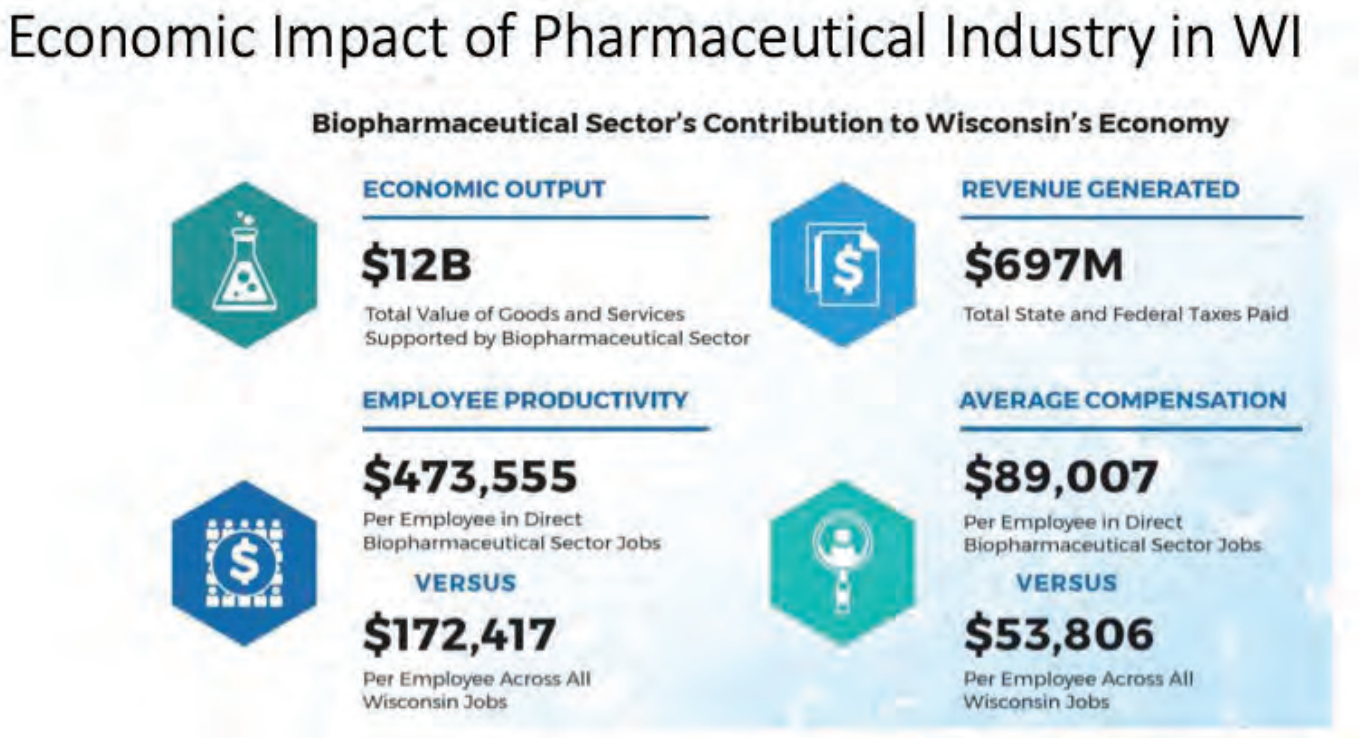
Our Diverse Manufacturing Supply Chain Includes a Significant Presence in the United States

The biopharmaceutical industry:

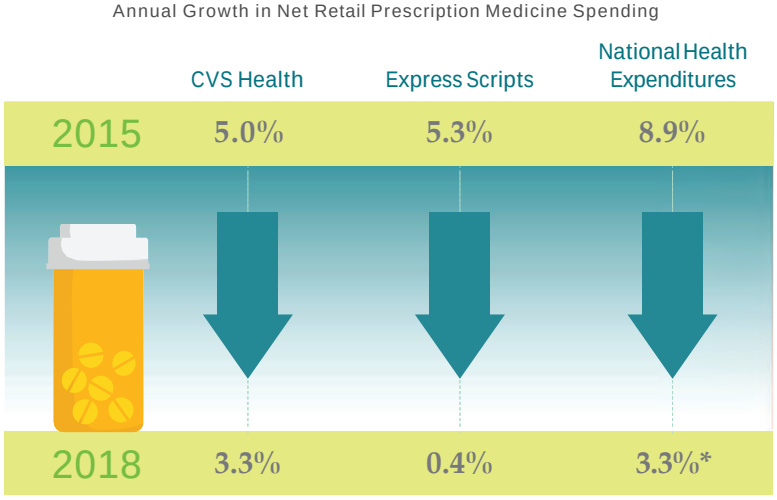
- Has more than 1,300 U.S. facilities involved in the production of human-use medicines located in 45 U.S. states and Puerto Rico compared to fewer than 150 generic manufacturing facilities
- Directly employs nearly 120,000 employees specifically at manufacturing facilities and 811,000 Americans in total
- Supports more than 4 million U.S. jobs across the economy



Source: NDP Analytics, for PhRMA. Analysis of the U.S. Food and Drug Administration's Drug Establishments Current Registration Site. April 2018.

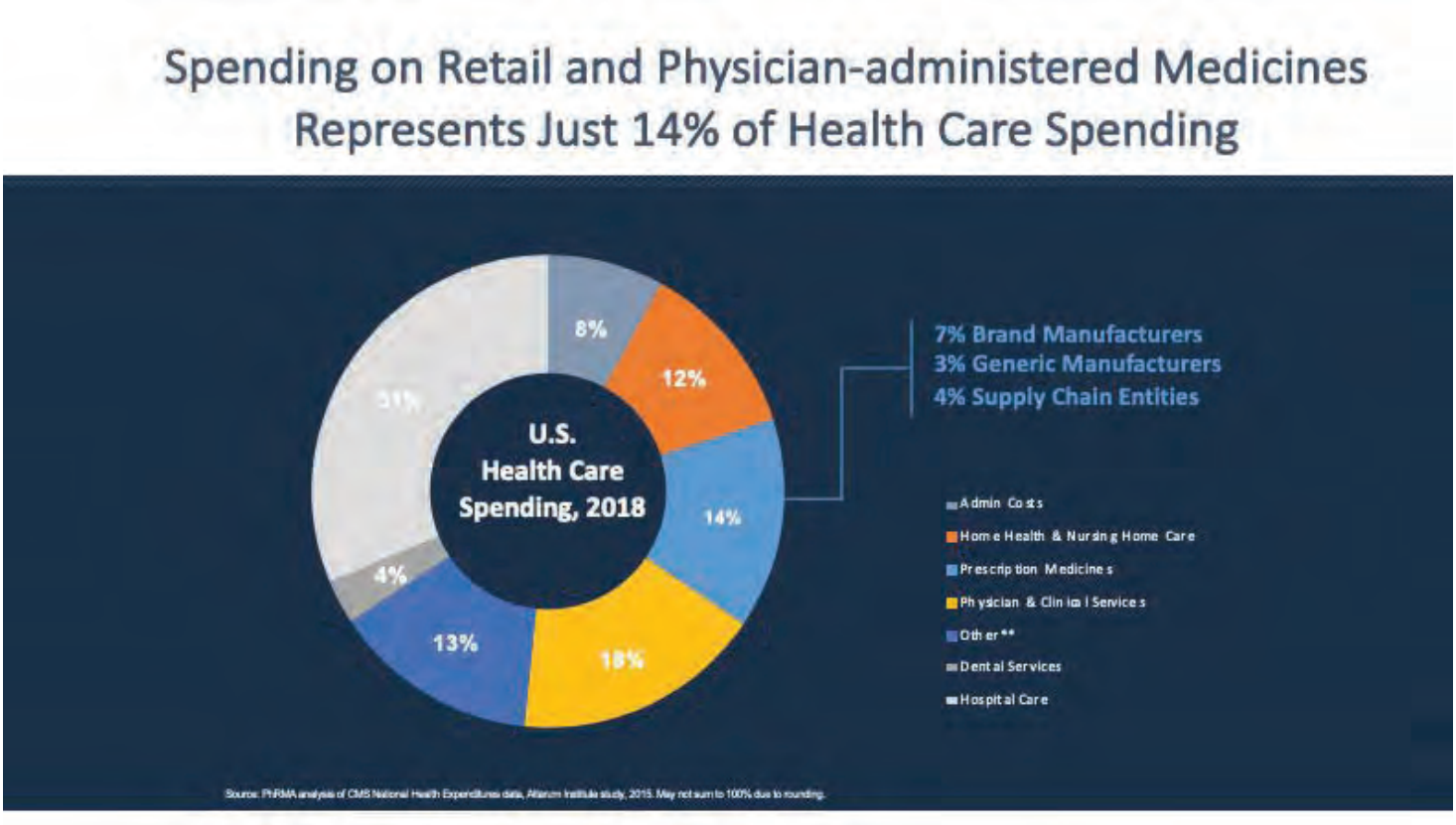


Pharmacy Benefit Managers (PBMs) and Government Actuaries Report Slowing Growth in Medicine Spending



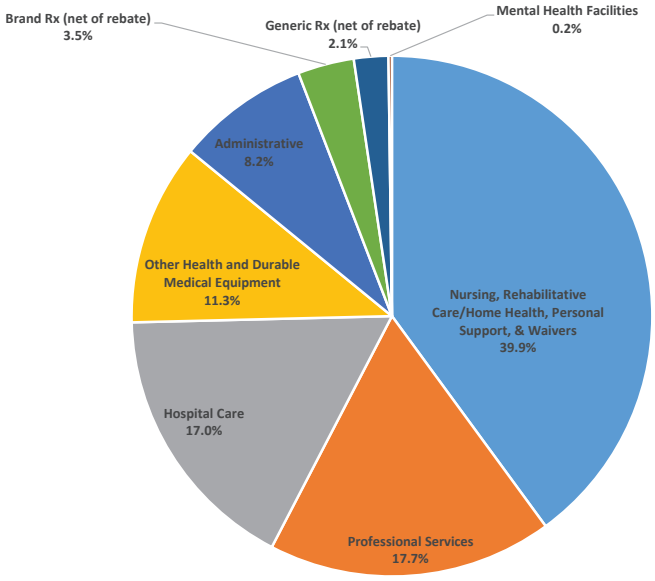
*Projected

Sources: CVS Health[16,17]; Express Scripts[18,19]; CMS[20,21]



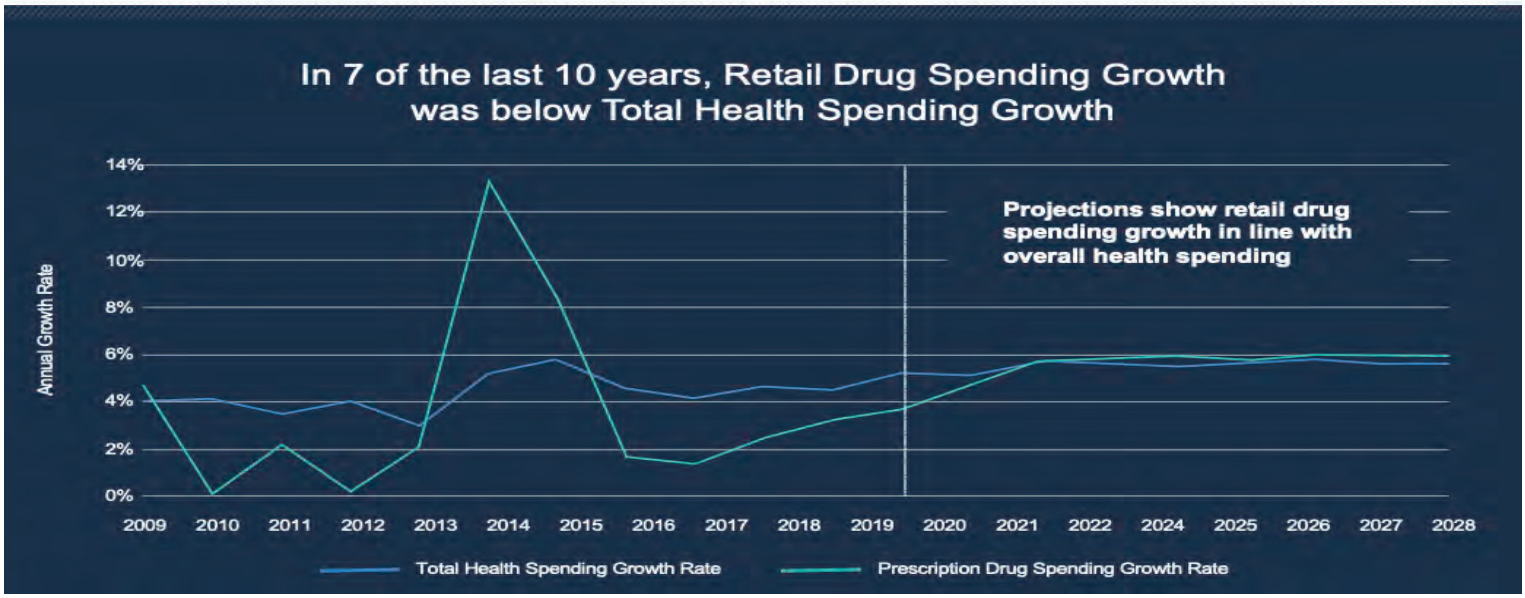
Brand Drugs *Only* 3.5% of WI Medicaid Spend

Wisconsin Medicaid Spending, 2018



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

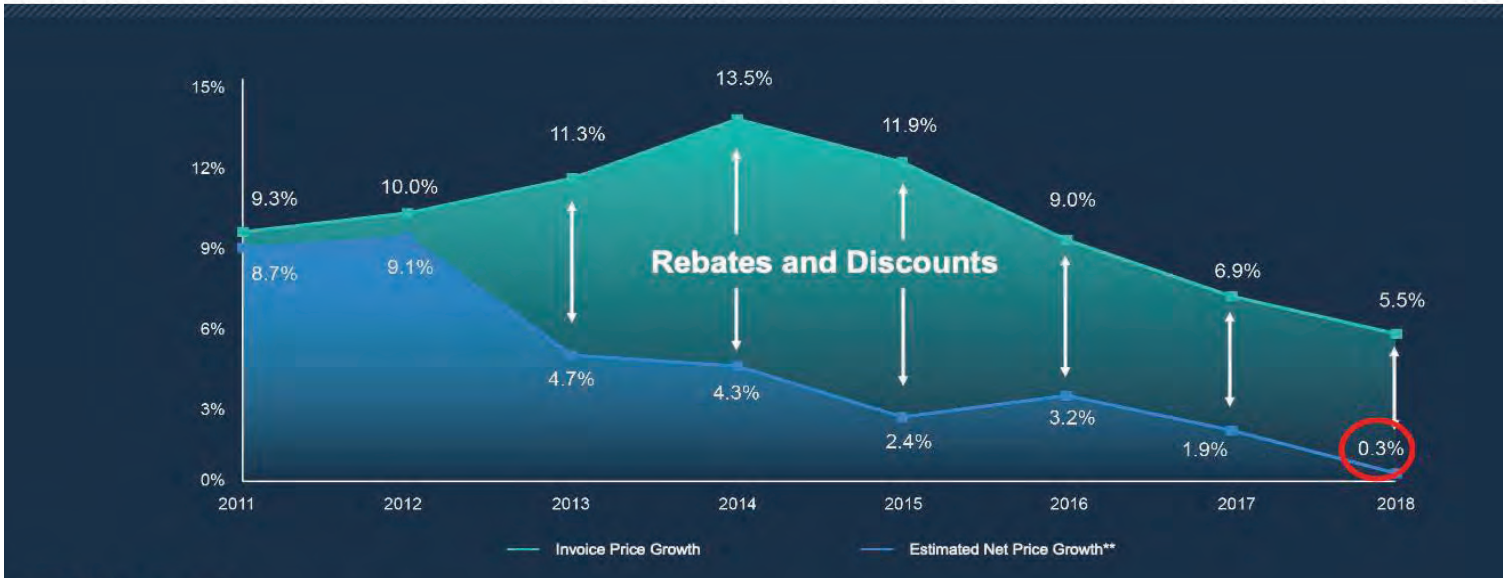
Medicine Spending is Projected to Grow in Line with Health Care Spending Through Next Decade



Note: Total retail sales include brand medicines and genSource: CMS National Health Expenditures Rep

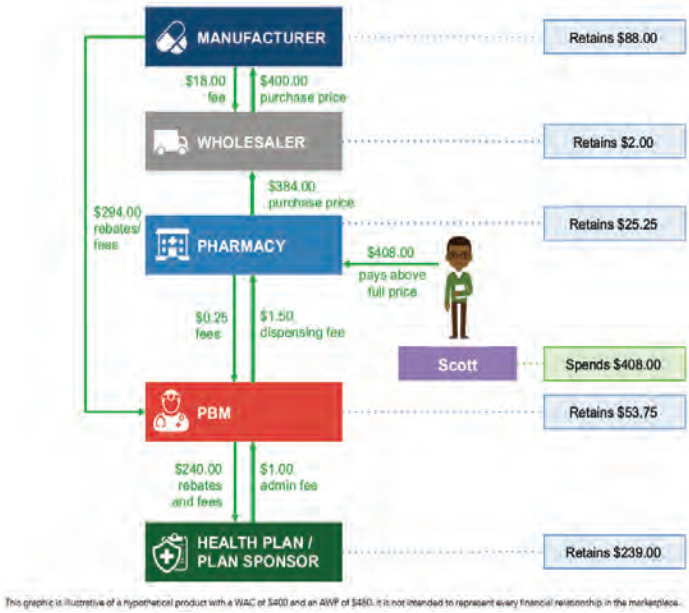
Prescription Medicines: Costs in Context www.phrma.org/cost

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.

Flow of Payment for a $400 Insulin



- Since Scott hasn't reached his deductible, his insurer does not cover any of his costs
- Scott pays more than the list price of his medicine
- The PBM and health plan pay nothing, and actually earn $292.75 on this prescription
- Due to industry consolidation, the PBM, health plan, and even the pharmacy are often part of the same parent company

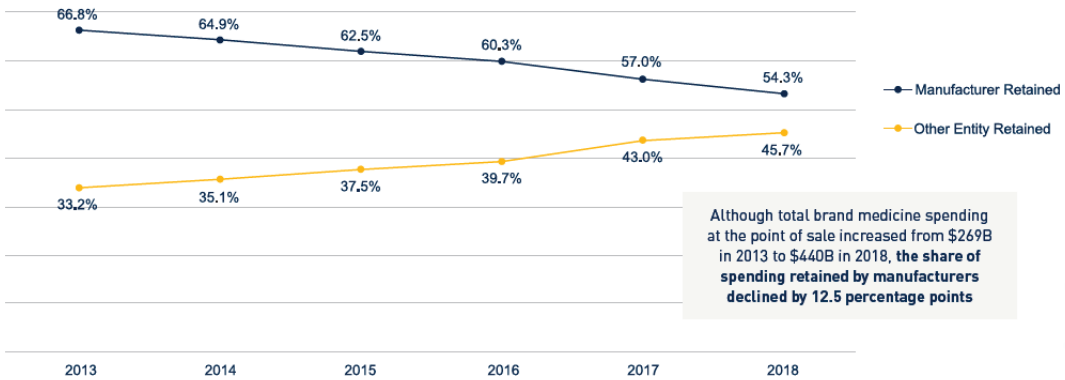
Assumptions:

- $400 list price per prescription
- 65% base rebate
- Patient pays full undiscounted price of medicine

Manufacturers are retaining an increasingly smaller share of total spending on brand prescription medicines

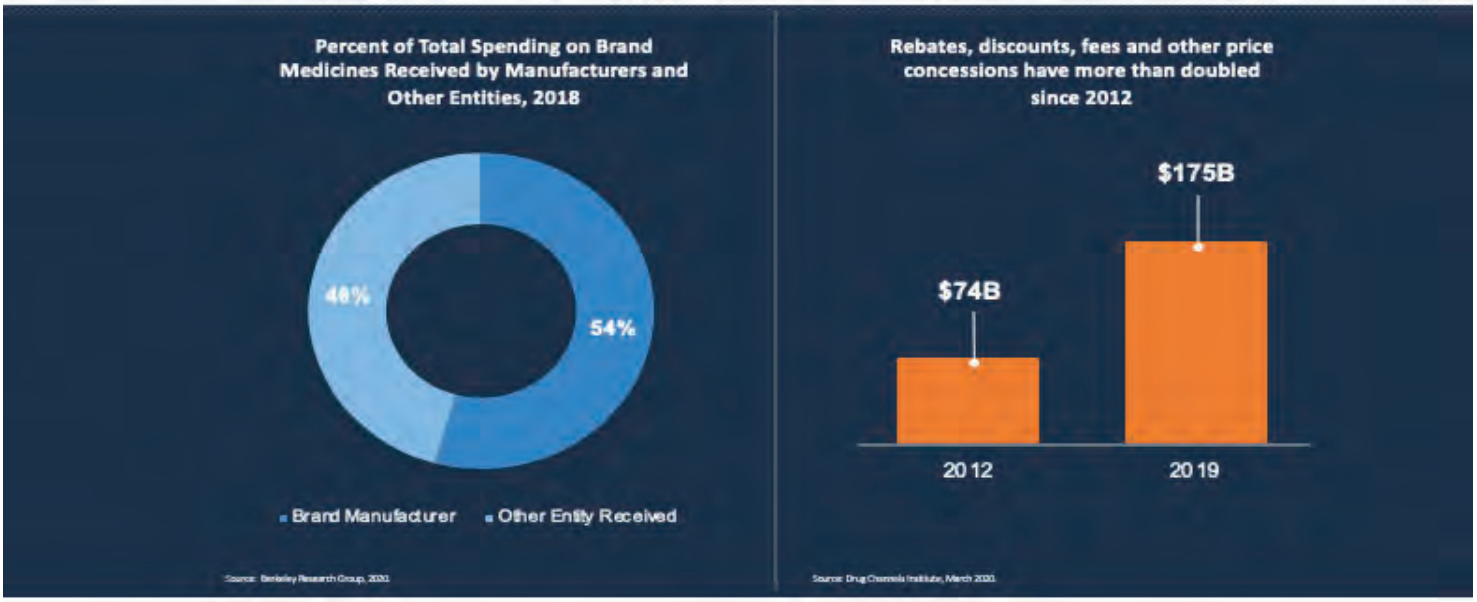
FIGURE 1

Percentage of Total Point of Sale Brand Medicine Spending Retained by Manufacturers and Other Entities, 2013-2018



"A common misconception of the pharmaceutical industry is that manufacturers retain the vast majority of drug spending."

Nearly Half of Spending on Brand Medicines Goes to Entities Other Than the Manufacturers Who Developed Them



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%

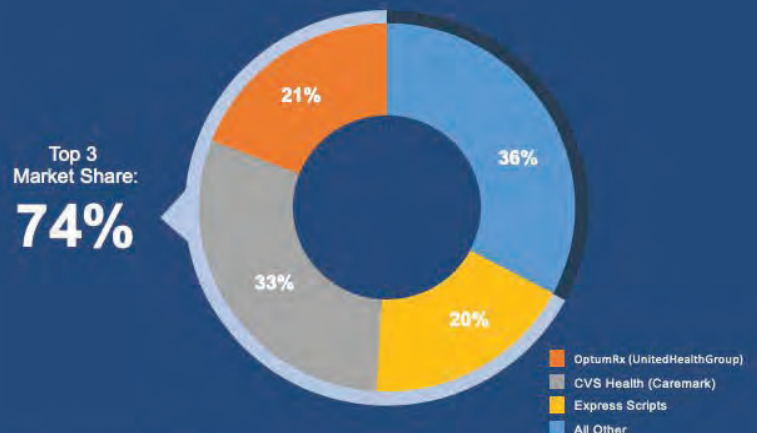
NOTE: Plan cost includes medical and pharmacy claims
*HDHP = High-deductible health plan

Out-of-pocket Costs for the Sickest Continue to Soar Despite a Dramatic Slowdown in Medicine Prices and Spending

Brand Medicine Prices	Retail Medicine Spending
IMS Health & Quintiles are now IQVIA™	CMS CENTERS FOR MEDICARE & MEDICAID SERVICES
0.3%	2.5%
2018	2018

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

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



Insurers determine:

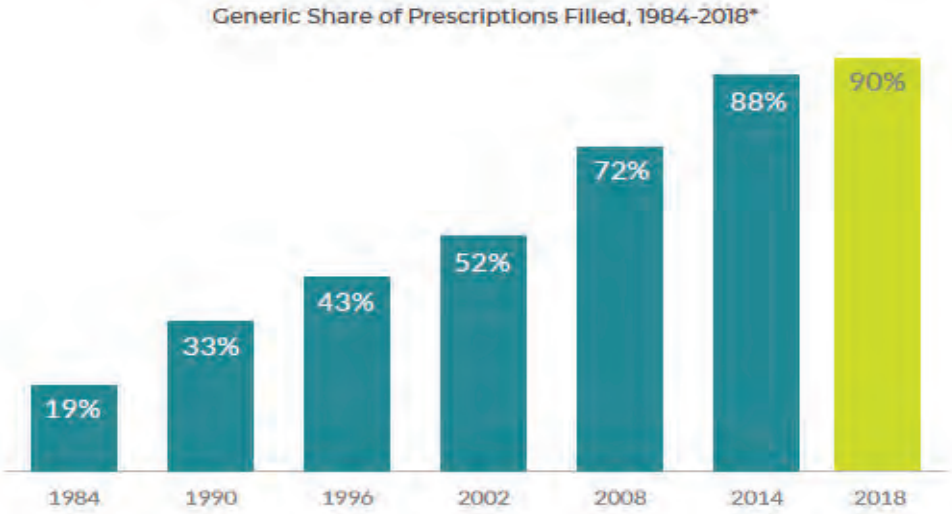
FORMULARY
if a medicine is covered

TIER PLACEMENT
patient cost sharing

ACCESSIBILITY
utilization management through prior authorization or fail first

PROVIDER INCENTIVES
preferred treatment guidelines and pathways

Nine out of Every Ten US Prescriptions Are Filled With Generics

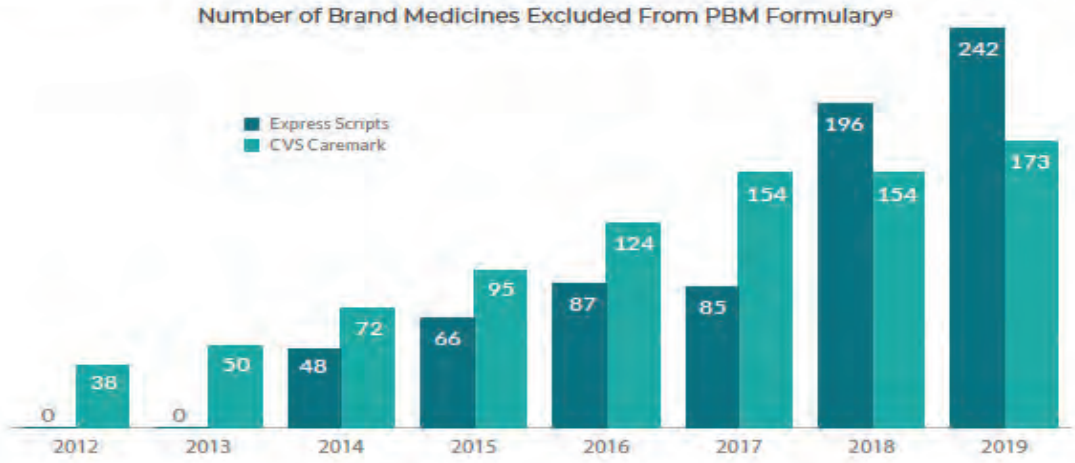


*Generic share includes generics and branded generics. "Other" category from IMS National Prescription Audit™ not included in calculation

Sources: IQVIA Institute[28], Drug Channels Institute[29]

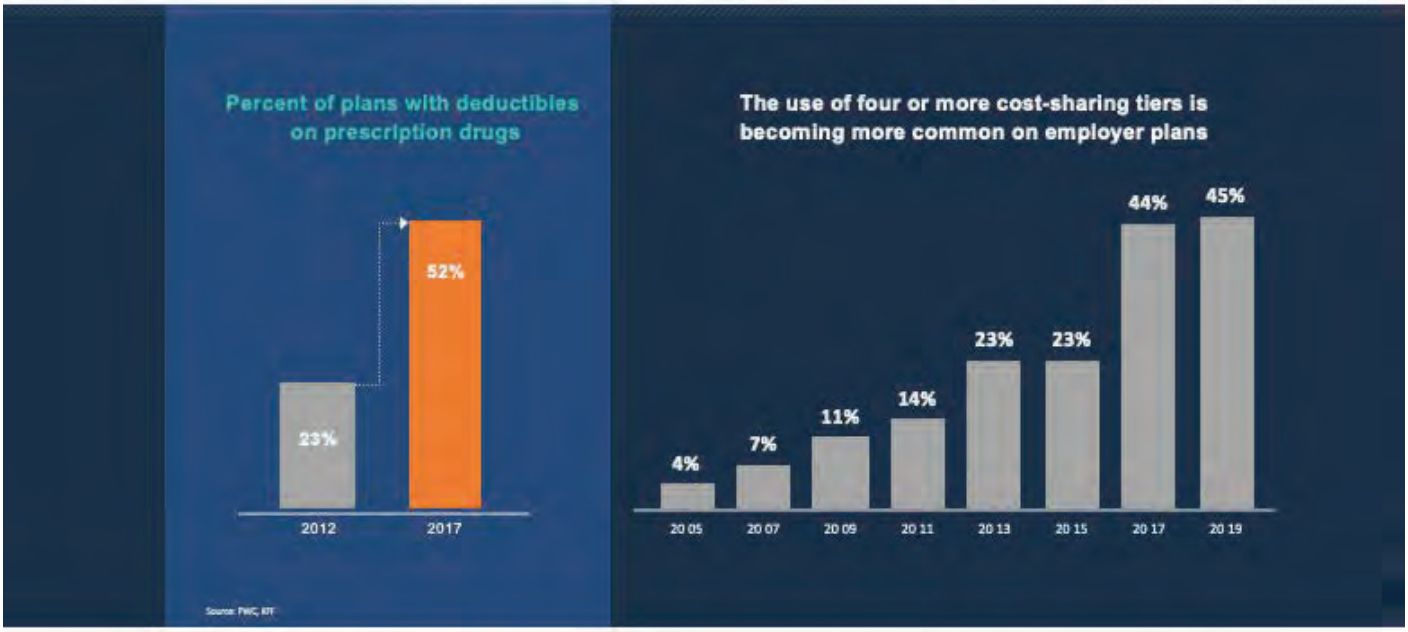
Number of Brand Medicines Excluded From PBM Formularies Has Increased Over Time

When a medicine is excluded from a pharmacy benefit manager's (PBM's) formulary, patients cannot access it without paying the list price. This can interrupt the continuity of a patient's treatment as well as their doctor's ability to make prescribing decisions that best meet their patients' needs.[8]



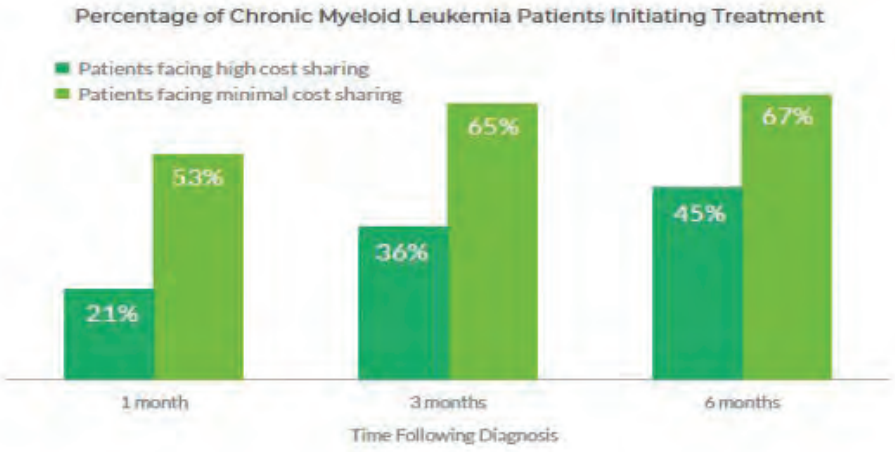
Sources: Tufts CSDD[9], Drug Channels Institute[9]

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



Patients Facing High Cost Sharing Commonly Do Not Initiate Treatment

Chronic myeloid leukemia patients facing high out-of-pocket costs for medicines on a specialty tier are less likely to initiate drug therapy than patients receiving a cost sharing subsidy, and these patients take twice as long to initiate treatment.



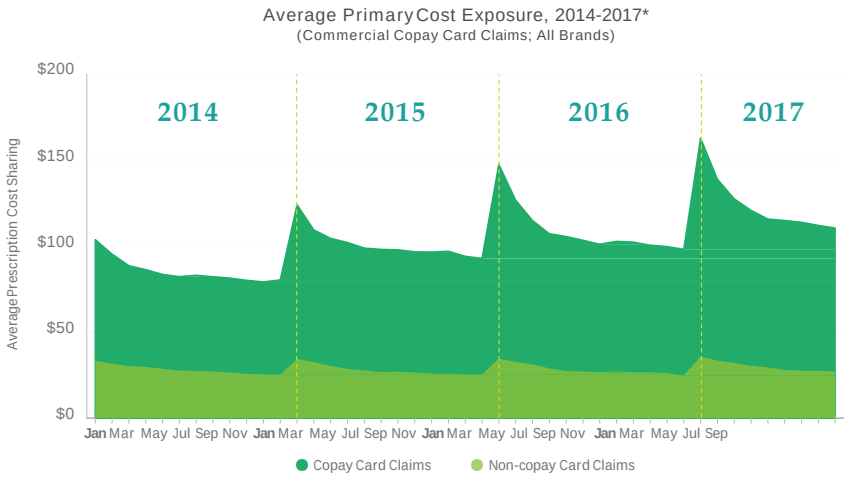
Source: Doshi JA et al.[1]

Policies so that *"Patients Pay Less"*

- Share the Savings
- Make Coupons Count
- Offer Lower Cost Sharing Options
- Cover Medicines from Day One

Without Coupons, Patients Would Face Higher Average Out-of-Pocket Costs per Prescription

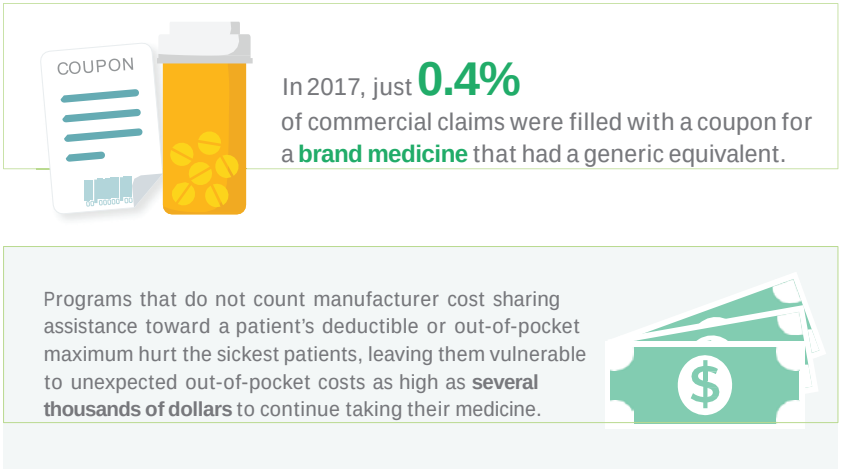
Each January, patients in the commercial market with deductibles face steep increases in out-of-pocket costs for brand drugs.



*Averages are calculated among paid claims where a copay card is used as the secondary payer and normalized to 30 days.

Source: IQVIA[14]

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



Source: IQVIA[15]

Accumulator Adjustment Program (AAP) Ban

- **Manufacturer cost-sharing assistance** is used by patients enrolled in commercial plans to help them pay their out-of-pocket medicine costs. This assistance can help patients afford their prescribed medicines and stay adherent to them.

- **Accumulator adjustment programs (AAPs)** are used by insurers to exclude the value of cost-sharing assistance from patient cost-sharing requirements, including deductibles and out-of-pocket maximums. Excluding this assistance can lead to patients abandoning their medicines due to large surprise costs.

- **AAP bans** can be passed by states to require state-regulated health plans and issuers to count cost-sharing assistance toward patient cost-sharing requirements. Four states have passed such bans (AZ, IL, VA, WV).

Accumulator Adjustment Program (AAP) Ban

- AAP bans would help patients by requiring manufacturer cost-sharing assistance to count. These bans **do not undermine insurers' ability to control costs**. Health plans and issuers are still able to manage costs through utilization management restrictions, such as prior authorization, among other tools.

- HHS's 2021 Notice of Benefit and Payment Parameters (NBPP) gives group health plans and health insurance issuers the flexibility to operate AAPs but **allows states to pass AAP bans for state-regulated insurance markets**.

- HHS suggests that there may be a conflict between manufacturer cost-sharing assistance counting towards high-deductible health plan enrollees' deductibles and IRS rules on health savings accounts, but IRS has not confirmed HHS's interpretation. Even if HHS's interpretation were correct, the conflict would not impact patients unless they are enrolled in HSA-paired HDHPs.

Value-Based Contracts Deliver Results for Patients

Value-based contracts have the potential to benefit patients and the health care system by improving patient outcomes, reducing medical costs, and reducing the costs of medicines.

Outcomes-Based Contracts are associated with **28% lower** patient copayments.

Value-Based Contracts could generate more than **$12 Billion** if they reduced the diabetes burden in the United States by only 5%.

> We've been able to get the best of both worlds. The insurer gets competitive guaranteed discounts on prescriptions, and the manufacturer is aligned and accountable when something doesn't work."
>
> — Chris Bradbury, Cigna[40]

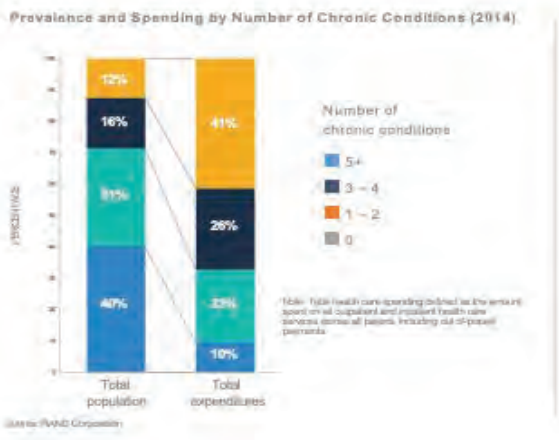
Sources: PhRMA[39]; Hopkins JS et al.[40]

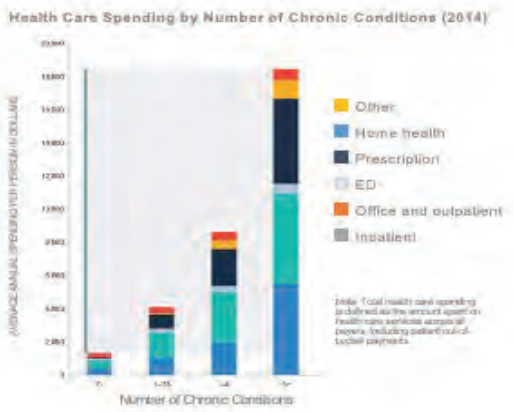
PhRMA Value Assessment Principles

- **Describe a sound process** that is open and transparent, with opportunity for input and a strong role for patients and physicians.
- **Support patient-centered care** by considering patient preferences and heterogeneity, appropriately communicating results, and avoiding misuse.
- **Deliver reliable, relevant information** by using rigorous, transparent methods that rely on the full range of evidence and prioritize longer-term and broader outcomes.
- **Value continued scientific and medical progress** by accounting for personalized medicine, the step-wise nature of progress, and the inherent value of innovation.
- **Take a system-wide perspective** on value by examining the full range of tests, treatments, care management approaches and health care services.

Impact of Chronic Disease on Wisconsin

Treating people with one or more chronic condition consumes 90 cents of every dollar spent on health care.





Impact of Chronic Disease on Wisconsin

Projected total cost of chronic disease 2016-2030 in Wisconsin **$768 BILLION**

In 2015, 3.4 million people in Wisconsin had at least 1 chronic disease, 1.3 million had 2 or more chronic diseases.

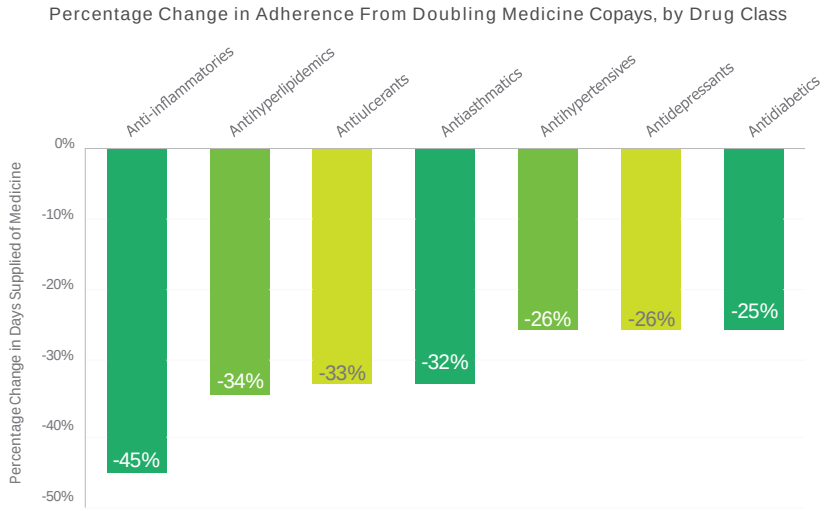
Chronic diseases could cost Wisconsin $37.2 billion in medical costs and an extra $13.9 billion annually in lost employee productivity (average per year 2016-2030).

Medical breakthroughs can and will transform lives and save health care costs over the next 15 years in Wisconsin and across the United States.

	Wisconsin	U.S.
Prevented Cases of Chronic Disease	3.4 Million	169 Million
Total Cost Avoided	$124 Billion	$6 Trillion
Lives Saved	429 Thousand	16 Million

High Cost Sharing Reduces Adherence

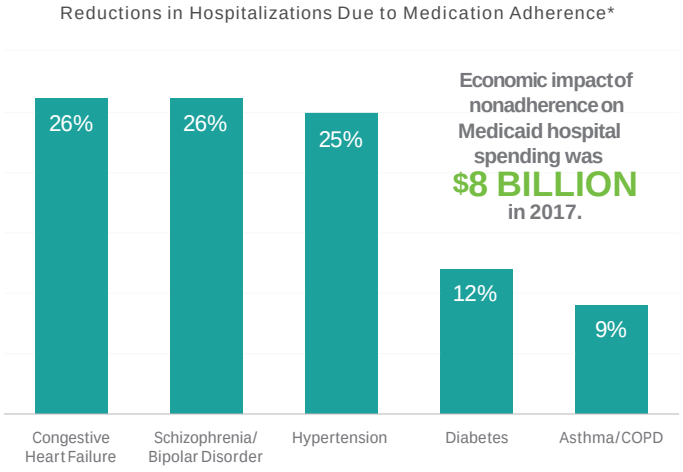
RAND researchers found that doubling copays reduced patients' adherence to prescribed medicines by 25%-45% and increased emergency room visits and hospitalizations.



Source: Goldman DP et al.[8]

Better Adherence Generates Savings in Medicaid

Optimal adherence to medicines for a range of chronic conditions leads to reductions in hospitalizations for many patients enrolled in Medicaid.

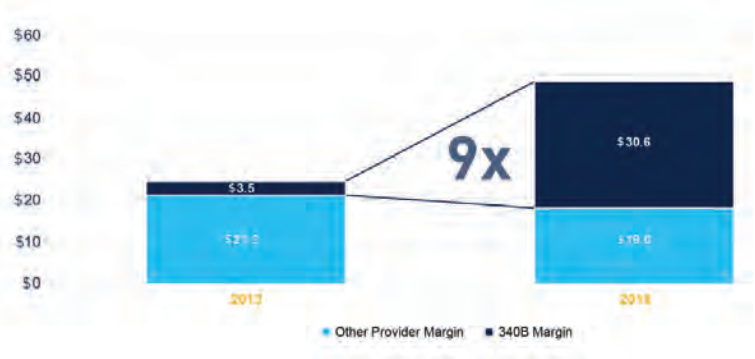


*Results apply to Medicaid populations that are not blind or disabled.

Source: Roebuck MC et al.[12]

340B Program Further Distorts Supply Chain

340B Profits Represent a Growing Share of Provider and Pharmacy Margins



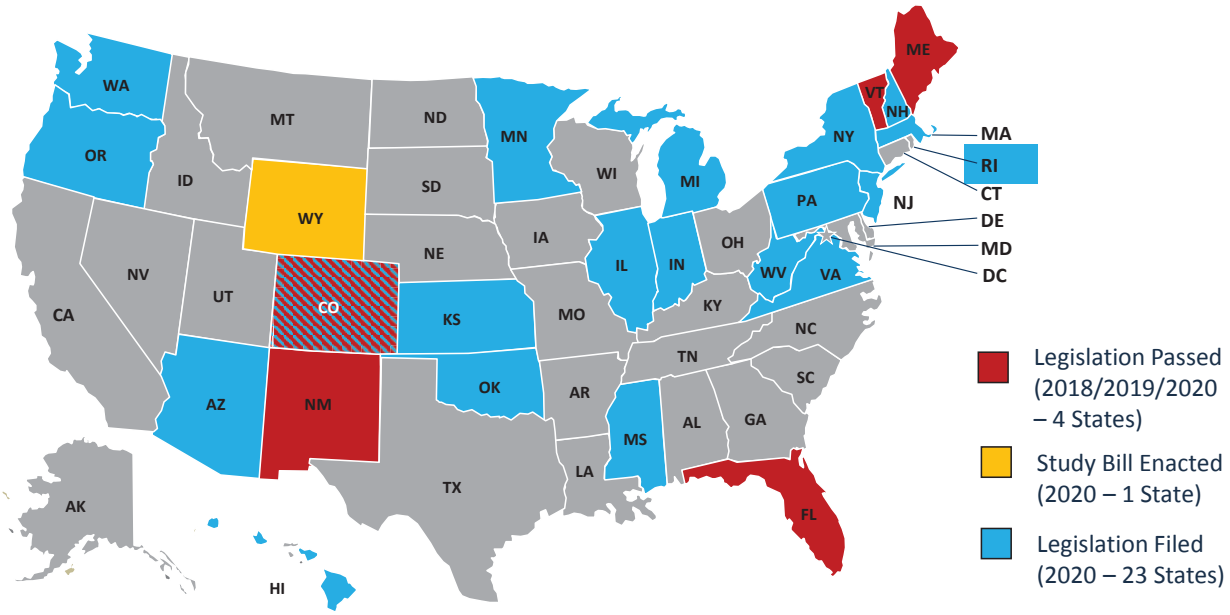
"Unprecedented expansion in the 340B Drug Discount program during this period… was the primary driver of this growth."

Berkeley Research Group. Revisiting the Pharmaceutical Supply Chain: 2013 – 2018.

- 340B discounted purchases were $29.9 billion in 2019*
  - 8% of the total U.S. pharmaceutical market
  - 14% of total U.S. branded outpatient drug sales
- Expansion in 340B program benefits for-profit entities without any guaranteed benefit to patients
- Ways the 340B program distorts supply chain incentives and increases costs:
  - Large 340B discounts create incentives for hospitals to drive up treatment costs
  - Evidence suggests the 340B program shifts care to more expensive and less convenient settings for patients*
- Updated program standards for how 340B discounts are properly applied are necessary to ensure that it continues to serves the needs of safety net providers and patients without creating incentives that contribute to higher costs for the overall health care system

*Drug Channels: https://www.drugchannels.net/2020/06/new-hrsa-data-340b-program-reached-299.html

2020 State Drug Importation Legislative Activity



State Importation Programs Cannot Guarantee Consumer Safety

- The U.S. has one of the most secure supply chains in the world. There is no way to guarantee the safety or integrity of drugs coming from other countries. Importation programs undermine this system.

- Canadian authorities have said they cannot and will not guarantee the safety of medicines imported to the U.S. through Canada.

- In its Comments on the federal Food and Drug Administration's (FDA) Proposed Rule, the Government of Canada expressed concern that any state program could exacerbate Canada's problem with drug shortages and stated that the country will take whatever steps necessary to protect its drug supply for use by its citizens.

- Key stakeholder groups have publicly expressed concern with the safety of importation, including, a Former FDA Commissioners' letter to Congress opposing importation. Others expressing concern are the National Association of Chain Drug Stores, the American Pharmacists Association, the National Sheriffs' Association, and the Western States Sheriffs' Association.

State and Individual Savings Unlikely

- Extensive state resources are required for the implementation and administration of an importation program.
    - Administrative costs; costs of repackaging and re-labeling; law enforcement costs; costs associated with public and stakeholder training and education.

- In public comments to the FDA, states that have passed importation, expressed concern with the ability to recoup state costs, provide significant savings, achieve appropriate levels of access, and operate efficiently under the parameters outlined in the notice of proposed rulemaking (NPRM).

- The Colorado Joint Budget Committee approved the Department of Health Care Policy and Financing's FY 2020-21 recommendation to delay of the implementation of Colorado's Canadian importation program in light of budget concerns.

- The Congressional Budget Office (CBO) estimates a mere 1% reduction in drug spending under importation, and there is not guarantee patients would see any of the potential savings.

Trump Administration Importation Plan

- **Pathway 1:** State demonstration projects under the authority of the Federal Food, Drug, and Cosmetic Act Section 804 to allow importation of drugs from Canada.

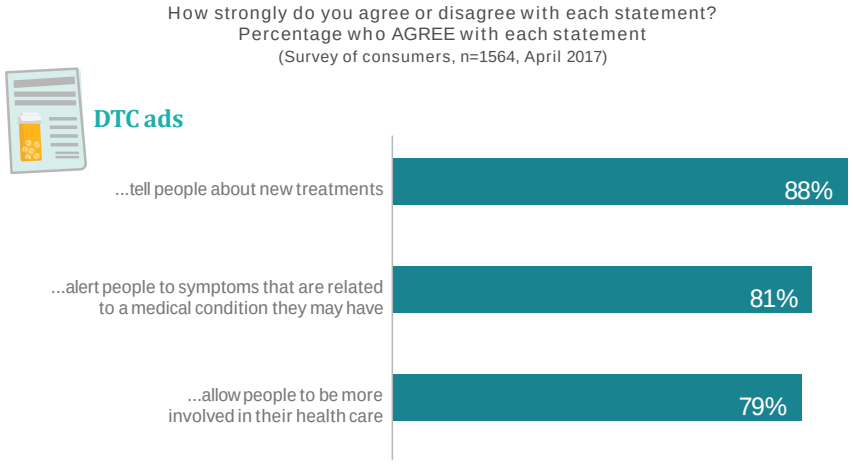
- **Pathway 2:** Manufacturers permitted to import versions of FDA-approved drug products that they sell in foreign countries under a new National Drug Code.

- December 2019: FDA issued NPRM and draft guidance on Pathway 1 and 2 respectively; No final rule or guidance to date.

- State Program Approval: VT, CO, FL, ME, and NM have either submitted, or are in the process of submitting, importation plans to HHS; No federal responses to date.

Direct-to-Consumer Advertising Increases Awareness of Conditions and Treatments

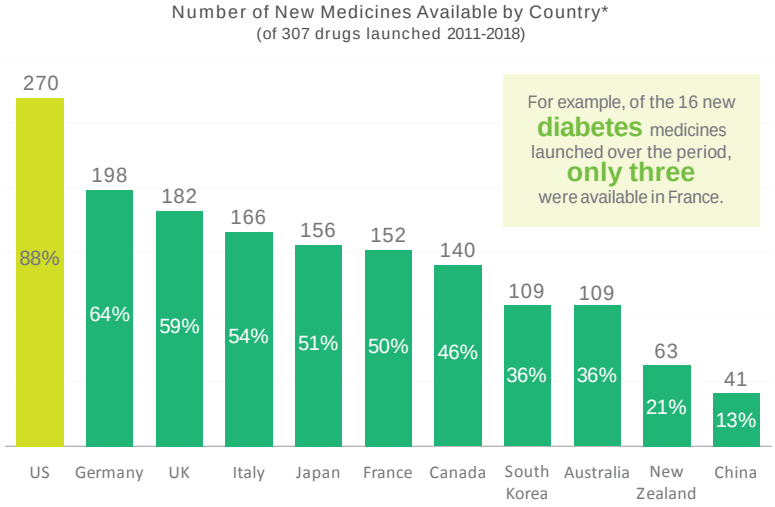
A recent survey of consumers demonstrated the positive contribution of direct-to-consumer (DTC) advertising to patients' knowledge.



Source: Princeton Survey Research Associates International[27]

More Medicines Are Available to U.S. Patients than International Counterparts

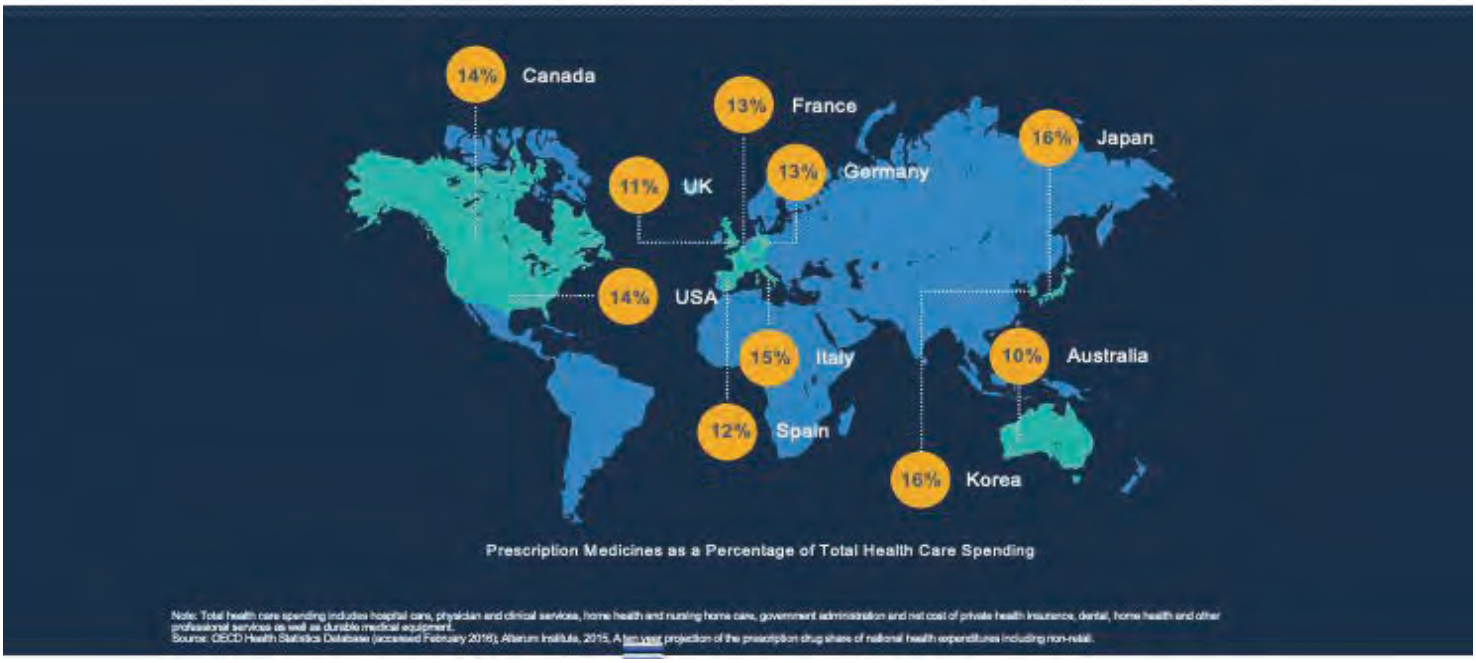
Nearly 90% of newly launched medicines from 2011 to 2018 were available in the United States, compared to just two-thirds in Germany, half in France, and even less in Canada and Australia.



*New Molecular Entities (NMEs) approved by the FDA, European Medicines Agency (EMA), and/or Japan's Pharmaceuticals and Medical Devices Agency (PMDA), and launched in any country between 2011 and 2018.

Source: PhRMA analysis of IQVIA Analytics Link and FDA, EMA, and PMDA data[1]

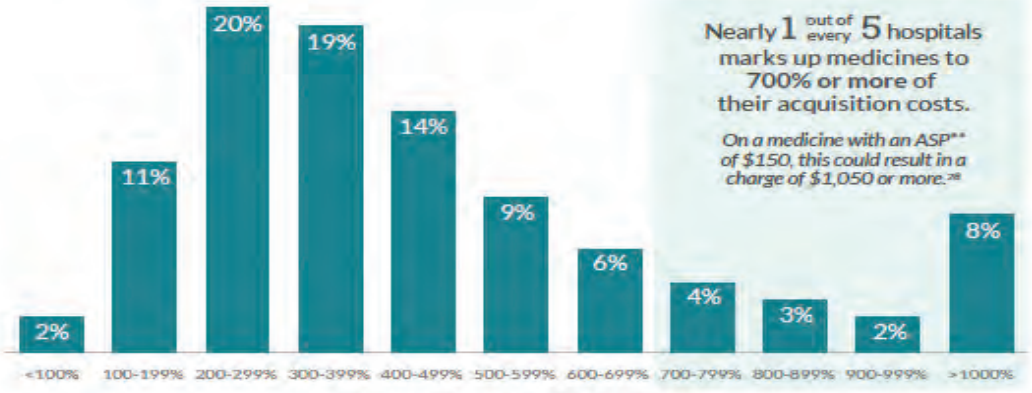
Medicine Spending in the United States is In Line with Spending Around the World



Hospitals Mark Up Medicines in the Outpatient Setting, Driving Up Costs to Patients and the Health System

Hospitals mark up medicine prices, on average, nearly 500%. The amount hospitals receive after negotiations with commercial payers is, on average, more than 250% what they paid to acquire the medicine.[27]

Percentage of Hospitals by Average Level of Markup for Medicines* (3,792 Hospitals)



Nearly 1 out of every 5 hospitals marks up medicines to 700% or more of their acquisition costs.

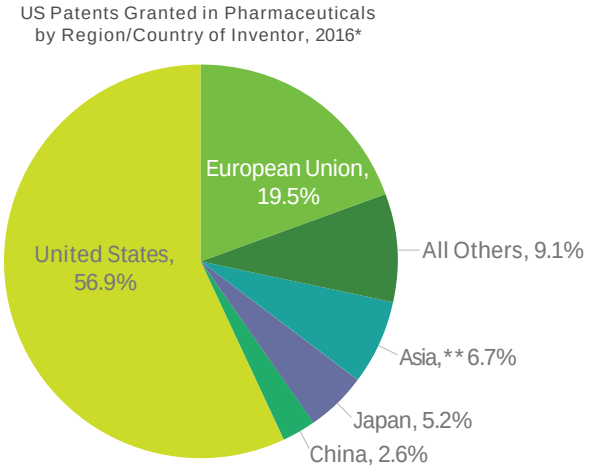
*On a medicine with an ASP** of $150, this could result in a charge of $1,050 or more.[28]*

*Percentages in chart may not add up to 100% due to rounding.
**ASP: Average Sales Price

Sources: The Moran Company[27,28]

The U.S. Leads in Biopharmaceutical Intellectual Property

More than half of the intellectual property related to new medicines was created in the United States.



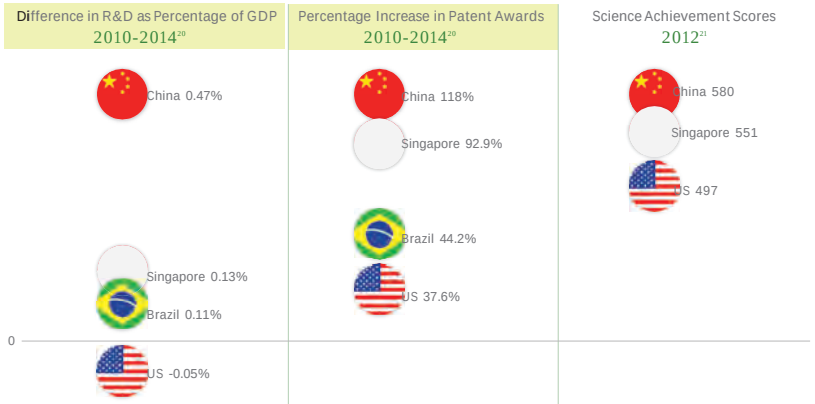
*Percentages may not add up to 100% due to rounding.
**Asia includes India, Malaysia, South Korea, and others.

Source: PhRMA analysis of National Science Foundation data[13]

Other Nations Are Challenging U.S. Leadership in Biopharmaceutical Innovation

Emerging economies are exceeding US performance on key measures related to a robust biopharmaceutical environment.

> The United States is now facing increasing competition to attract and grow a biopharmaceutical presence, not just from developed countries, but also from emerging nations, such as Brazil, China, and Singapore, that are laying the groundwork for future growth."
>
> — TEConomy Partners[20]



Sources: TEConomy Partners[20,21]

Factors Contributing to the Industry's Response

Armed with experience garnered from previous outbreaks and a vast storehouse of knowledge about infectious diseases like influenza, malaria and HIV, researchers are working to develop and deliver diagnostics, treatments and vaccines to save lives and restore the rhythms of daily life for billions of people.

Developing Treatments and Vaccines to Fight COVID-19

There are **1228 clinical trials under way across the globe** for vaccinations and treatments.

1228 Clinical Trials

- **40** Investigating Vaccines
- **1188** Investigating Therapies

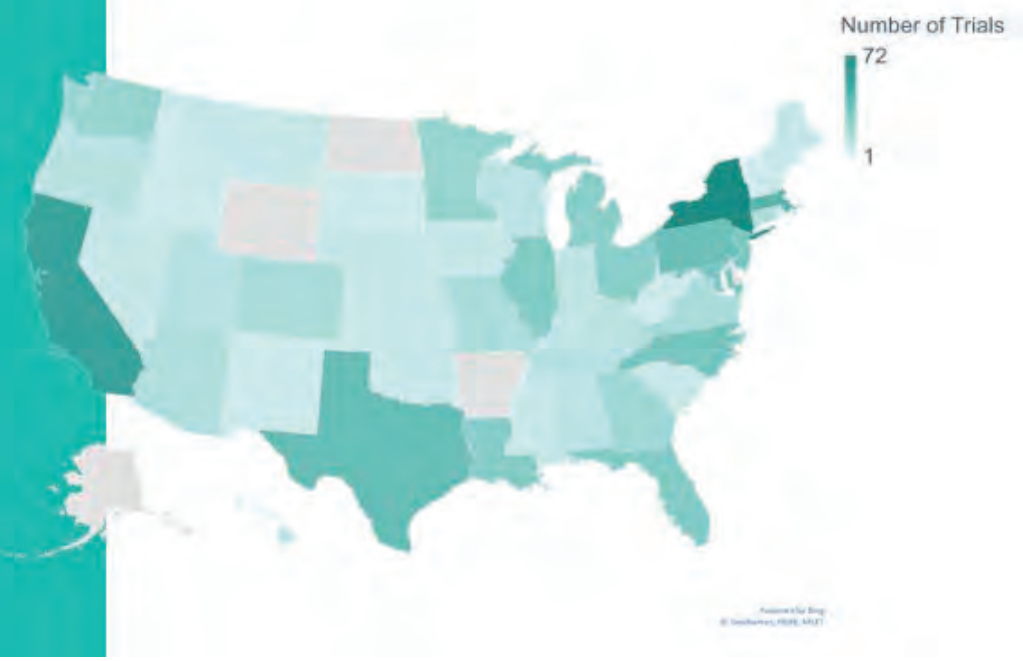
Data as of 6/19/2020

Source: World Health Organization International Clinical Trials Registry Platform (ICTRP)

U.S. Clinical Trials of Investigational Therapies

There are 265 clinical trials investigating therapeutics in 45 states and Washington, D.C.

75 of the 265 clinical trials are being conducted in more than one state



Source: World Health Organization International Clinical Trials Registry Platform (ICTRP)

Diverse, Robust Supply Chains Have Been a Long-Term Priority for the Innovative Biopharmaceutical Industry

Setting up the manufacturing supply chain for a medicine begins years before that medicine is approved for use by patients

Carefully built, robust global supply chains help ensure patients in the United States and around the world have ongoing access to medicines

Building a new biopharmaceutical manufacturing facility can cost between $1 and $2 billion and take 5 to 10 years before it is operational

Companies invest significantly in the design and ongoing maintenance and modernization of manufacturing facilities and their quality systems to help avert disruptions

Facts About the Pharmaceutical Supply Chain

Myth: Changes can quickly be made to supply chains. Moving all manufacturing to the United States would be easy.

- Biopharmaceutical manufacturers must begin setting up the manufacturing supply chain for a medicine years before that medicine is approved for use by patients so changes can't be made quickly.
- Moving all manufacturing to the US would be detrimental to the supply chain because geographic diversity is essential, especially in time of pandemic or natural disaster.
- The US is not overly reliant on any 1 country for APIs.

The APIs Used in Medicines Come From a Diverse Supply Chain

Only 13% of API Manufacturing Facilities Are Located in China

Claims the United States is Highly Reliant on China for API Are Inaccurate

- FDA determined there are **only three medicines** on the WHO Essential Medicines list whose API manufacturers are solely based in China
- FDA has identified **only 20 medicines**[1] that solely source their API or medicine from China, and none of these have been deemed critical medicines
- The FDA is **not aware of any** cellular or gene therapies that are made in China for the U.S. market

Source: FDA, "COVID-19 and Beyond: Oversight of the FDA's Foreign Drug Manufacturing Inspection Process," June 2, 2020. https://www.fda.gov/news-events/congressional-testimony/covid-19-and-beyond-oversight-fdas-foreign-drug-manufacturing-inspection-process-06022020

MAT Can Help Patients Learn More About Their Medicine Costs

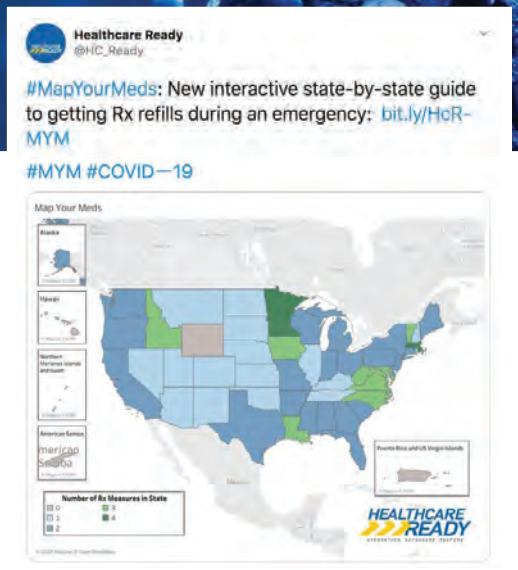
PhRMA member companies are committed to helping patients make more informed health care decisions by providing more transparency about medicine costs. Through MAT.org, we share links to member company websites that include:

- **List Price of a Medicine**
- **Average Estimated or Typical Patient Out-of-pocket Costs**
- **Other Context About Potential Cost of the Medicine**

Each member company has individually and independently determined the content of any cost information provided on their websites.

Healthcare Ready Programs for Constituents

Healthcare Ready Resources



RX OPEN: Provides access to open and closed pharmacies in a disaster-stricken area.

RX ON THE RUN: Personalized wallet card to document prescriptions and other important medical information.

COVID-19 Resource Hub: Resources for individuals and patients including state-level insurance emergency orders on prescription refills and telehealth coverage policies for COVID-19, and relevant pandemic business continuity resources.

HEALTHCARE READY | PhRMA

QUESTIONS AND ANSWERS

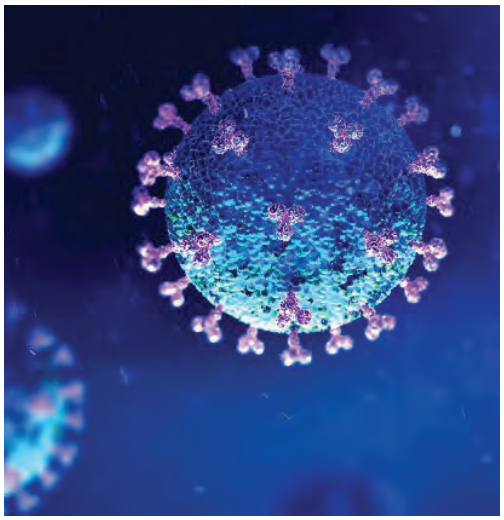
- **Sharon Lamberton, MS, RN**
  - Deputy Vice President, PhRMA
  - slamberton@phrma.org
- **Saumil Pandya, MHS**
  - Deputy Vice President, PhRMA
  - spandya@phrma.org
- **Peter Fotos**
  - Senior Director, PhRMA
  - pfotos@phrma.org
- **Peter Fjelstad, JD**
  - Senior Director, PhRMA
  - pfjelstad@phrma.org

CIVICA™

Delivering **Quality** Medicines that are
Available and **Affordable**

Civica – COVID-19

- Mission of Civica: Provide essential quality medications to the patients who need them.
- Prioritization: From the health systems that utilize the medications.
- 10 of the 19 medications that Civica is currently manufacturing and distributing are being used in clinical protocols to treat COVID-19 patients
- These medications include (but are not limited to):
  - Fentanyl
  - Morphine
  - Midazolam
  - Ketamine
  - Sodium Bicarbonate
  - Vancomycin



CIVICA™ BlueCross BlueShield Association @CivicaRx @CivicaRx #CivicaRx

Civica Rx - Established in 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

~50 Health Systems Members

1200+ Hospitals

30% of U.S. Licensed Beds

50 States

19 Drugs in production or shipped

CIVICA @CivicaRx @CivicaRx #CivicaRx

Civica's Membership Momentum

Governing Board

MAYO CLINIC
CommonSpirit
tjaf laura and john arnold foundation
SSMHealth
HCA Hospital Corporation of America
KAISER PERMANENTE
Providence St. Joseph Health
westfoundation
PETERSON CENTER ON HEALTHCARE
Intermountain Healthcare
Trinity Health

Founding Members

AdvocateAuroraHealth
Hospital Sisters HEALTH SYSTEM
Allegheny Health Network
BaylorScott&White HEALTH
SPECTRUM HEALTH
MEMORIAL HERMANN
Ochsner Health System
NYU Langone Health
Baptist Health South Florida
Steward
StLuke's UNIVERSITY HEALTH NETWORK
SANFORD HEALTH
Franciscan ALLIANCE
UnityPoint Health

Partnering Members

INTEGRIS Health
MemorialCare
ASPIRUS
CHRISTIANA CARE HEALTH SYSTEM
NORTH MEMORIAL HEALTH
NORTHBAY HEALTHCARE
HEALTH UNIVERSITY OF UTAH
Piedmont
Samaritan Health Services
BJC HealthCare
SOUTHEAST GEORGIA HEALTH SYSTEM
Emerson Hospital
BAPTIST HEALTH
Regional One Health
St. Clair Hospital
SCL Health
ThedaCare
MONTAGE Health
KootenaiHealth
Memorial Sloan Kettering Cancer Center
New Hanover Regional Medical Center
CONE HEALTH
Griffin Hospital
The Christ Hospital Health Network
Reid Health

CIVICA @CivicaRx @CivicaRx #CivicaRx

Civica's Role in the Generic Drug Market

1. Bring true competition to the generic market, focusing on value (price and quality)
2. Ensure stable and predictable supply of essential generic drugs, correcting shortages
3. Be a conscience of the market, serving as a check against aggressive pricing behavior o generic drug manufacturers

CIVICA™ @CivicaRx @CivicaRx #CivicaRx

How Civica Works

CIVICA™

REDUCING DRUG SHORTAGES THROUGH COLLABORATION

Health Systems

Member health systems prioritize the medications needed to reduce shortages for patients and identify the volume requirements for their hospitals.

Manufacturers

Manufacturers commit their production capacity based on long-term projected volumes of medications identified by the health systems.

Result

Reliable supply of essential generic medications promptly improves patient care.

CIVICA™ @CivicaRx @CivicaRx #CivicaRx

Civica's Three-pronged Manufacturing Approach

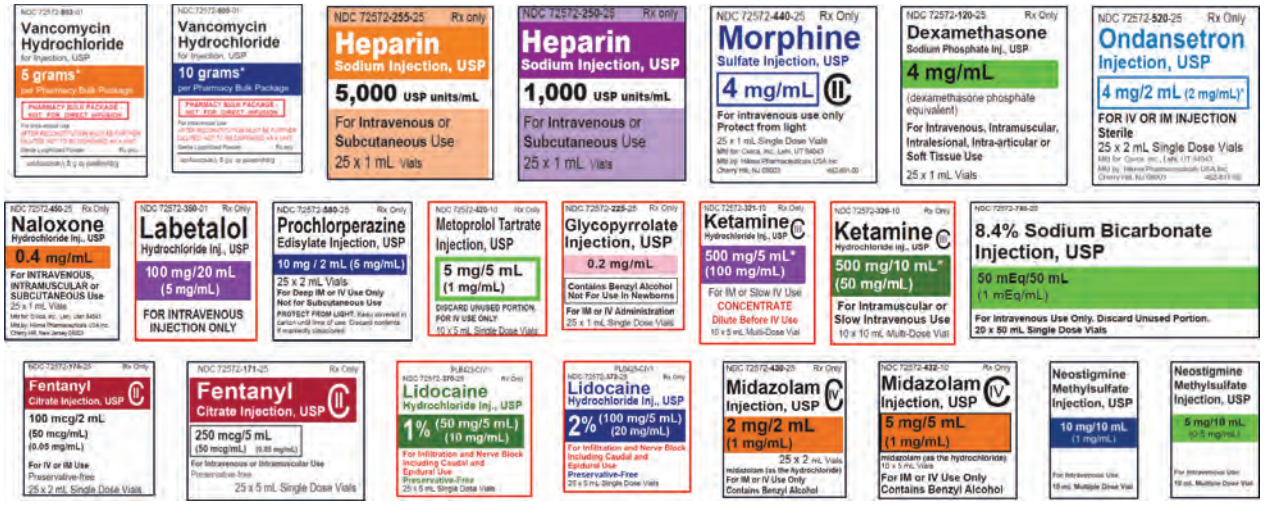
1. Work with generic drug manufacturers that have the US FDA approved manufacturing facilities to produce generic drugs under Civica's National Drug Code, allowing manufacturers to re-enter the market or increase existing capacity.

2. Develop Abbreviated New Drug Applications (ANDAs) for generic drugs and working with contract manufacturing organizations to produce Civica medications.

3. Acquire/build Civica manufacturing facilities using Civica's ANDAs

Progress on partnering manufacturing strategy

19 drugs, prioritized by Civica health systems, either available for delivery to our health system partners or in production including:



Civica's Continuum of Care / Outpatient Retail Strategy

On Jan 23, 2020, a new entity was announced focused on development & manufacturing of high-cost generic drugs in the retail space.

Intent: Continue the Disruptive Innovation to assure we are meeting the needs of patients.

CIVICA @CivicaRx @CivicaRx #CivicaRx

Consistent, Sustainable, Medications at Affordable Prices

To assure healthcare providers can focus on patient care


CIVICA™
Quality
Supply
Sustainability
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GOVERNOR'S TASK FORCE ON REDUCING PRESCRIPTION DRUG PRICES

July 22, 2020

10:00 a.m. – 2:00 p.m.

I. Welcome (5 minutes)
- **Nathan Houdek, Deputy Commissioner**, *Office of the Commissioner of Insurance*

II. Consumer Experience (5 minutes)

III. OptumRx: Real Time Benefit Tools (30 minutes)
- **David Calabrese,** *RPh, Chief Pharmacy Officer, OptumRx*

IV. Wisconsin Pharmacy Cost Study Committee (20 minutes)
- **Renee Walk,** *Lead Policy Advisor, Strategic Health Policy, Department of Employee Trust Funds*

V. Northwest Prescription Drug Consortium (40 minutes)
- **Trevor Douglass,** *DC, MPHOPDP and Pharmacy Purchasing Director, Oregon Prescription Drug Program*
- **Donna Sullivan,** *Pharm D, MSChief Pharmacist Officer, Washington Health Care Authority*

VI. American Association of Retired Persons (AARP) (40 minutes)
- **Leigh Purvis,** *Director of Health Services Research at the AARP Public Policy Institute*

VII. Break (10 minutes)

VIII. American Diabetes Association (40 minutes)
- **Gary Dougherty,** *Director-State Government Affairs, American Diabetes Association*

IX. Vivent Health (40 minutes)
- **Bill Keeton,** *Vice President and Chief Advocacy Officer, Vivent Health*
- **Peggy Tighe,** *J.D., Principal, POWERS, Powers Pyles Sutter & Verville PC*

X. Wrap Up Discussion (10 minutes)
- Discuss potential policy options

XI. Next Meeting Date via Webinar
- August 25, 2020

XII. Adjourn

Meeting Minutes
July 22, 2020
10 a.m. – 2 p.m.
Webinar via Zoom

Welcome
Nathan Houdek, OCI Deputy Commissioner and Task Force chair

- Deputy Commissioner Houdek welcomed Task Force members and public attendees.
- Key housekeeping items:
  - A reminder that this is a public meeting.
  - The meeting is being recorded and live-streamed by Wisconsin Eye which can be found here: https://wiseye.org/player/?clientID=2789595964&eventID=2020071109
  - Task Force members will have use of their microphones; the public does not.

Consumer Experience
The Herrick family, of Cushing, Wisconsin, shared their experience with the cost of prescription medication to treat diabetes in their family.

- In July 2014, Ted Herrick was diagnosed with type 2 diabetes. Several months later, the Herricks' daughter Carly was diagnosed with type 1 diabetes.
- They must first meet a $5,000 deductible, then they pay a coinsurance of 30 percent up to $10,000 maximum out-of-pocket.
- They find the cost of insulin and related diabetes supplies to be a major financial burden on their family.

OptumRx: Real-Time Benefit Tools
David Calabrese, RPh – Chief Pharmacy Officer, OptumRx

- A presentation from OptumRx is available on the Task Force website: https://rxdrugtaskforce.wi.gov/Documents/OptumRx.pdf

Issues raised by task force members:

- Glad to see Optum has the capability to check and interact with EMR. A task force member has access to a program that gives information about the formulary and offers alternative options if something is not on the patient's formulary. The cost information, in terms of the out of pocket to the consumer, is not turned on.
- There was interest in whether the program offers information on the cost of a drug to the provider, so that a decision could be made on the cost to the entire system. It does not at this time, but it is something that is being considered.

Wisconsin Pharmacy Cost Study Committee
Renee Walk – Lead Policy Advisor, Strategic Health Policy, Department of Employee Trust Funds

- A presentation from the Wisconsin Pharmacy Cost Study Committee is available on the Task Force website: https://rxdrugtaskforce.wi.gov/Documents/ETF_Rx_Study.pdf
- The final report of the study is available on the Task Force website: https://rxdrugtaskforce.wi.gov/Documents/WI_Pharmacy_Cost_Study_Committee_Final_Report.pdf

Northwest Prescription Drug Consortium
Trevor Douglass, DC – MPHOPDP and Pharmacy Purchasing Director, Oregon Prescription Drug Program
Donna Sullivan, Pharm D – MSChief Pharmacist Officer, Washington State Health Care Authority

- A presentation from the Northwest Prescription Drug Consortium is available on the Task Force website: https://rxdrugtaskforce.wi.gov/Documents/NW_Rx_Drug_Consortium.pdf

Issues raised by task force members:

- Interest in how the consortium's prescription drug card compares to others offered in the state.
    - Overall, the consortium's card offers the best discounts, with the exception of those entities with a relationship with a manufacturer.
- The program does not allow manufacturer coupons to apply to enrollee deductibles. They will allow adjustments to the enrollee's co-insurance should it be proven that a brand drug is needed over the generic version.
- It was expressed that the coupons are used to get around the plan formulary.
- Spread pricing was raised and the presenters indicated that spread pricing is not allowed in their agreements.
- The consortium is in discussions, at varying levels, with other states about potentially joining the consortium.

American Association of Retired Persons (AARP)
Leigh Purvis – Director of Health Services Research at the AARP Public Policy Institute

- A presentation from AARP is available on the Task Force website: https://rxdrugtaskforce.wi.gov/Documents/AARP.pdf

American Diabetes Association
Gary Dougherty – Director-State Government Affairs, American Diabetes Association

- A presentation from the American Diabetes Association is available on the Task Force website: https://rxdrugtaskforce.wi.gov/Documents/ADA.pdf

Issues raised by task force members:

- There was an interest in what the copay cap covers.
    - It depends on how the law is written. In some states it is a collective cap, meaning if the cap is set at $100, the cost to the enrollee is $100 regardless of the number of scripts

written. In other states, the cap is applied per script. Therefore, if the cap is set at $100, and there are two prescriptions within the month, the cost to the enrollee is $200.

Vivent Health/ 340B Issues

Bill Keeton – Vice President and Chief Advocacy Officer, Vivent Health
Peggy Tighe, J.D., – Principal, POWERS, Powers Pyles Sutter & Verville PC

A presentation from Vivent Health is available on the Task Force website: https://rxdrugtaskforce.wi.gov/Documents/Vivent.pdf

Issues raised by task force members:

- There is "discriminatory reimbursement" occurring where PBMs are not reimbursing covered entities under the federal 340B program at the level they are reimbursing other pharmacies. Concerns were expressed that this practice jeopardizes a covered entities effort to re-invest savings from the 340B program into other community and patient-focused programs.
- The point was made that 340B claims are not rebate eligible.
- There was concern expressed over the growth of the program and whether dollars accrued as hospitals have merged are serving the underserved.

Next Steps

- The next meeting is on August 25. This entire meeting will be a discussion about policy options and recommendations.
- A report summarizing the work of the task force will be compiled to submit to the Governor in September.
- Please send any input and feedback to the task force to be distributed to the members.

Adjourn

Real Time Benefit Tools:

Empowering better choices for members, care providers, and plan sponsors

State of Wisconsin
Governor's Task Force
on Reducing Prescription Drug Costs

OPTUMRx

Agenda

1. Introduction
2. Addressing Affordability
3. Real time benefit tools
4. Questions

David Calabrese, RPh
Chief Pharmacy Officer,
OptumRx

OPTUMRx

We **simplify** the pharmacy experience and provide **access** to **affordable** medications to **champion** healthy lives for **everyone**

AFFORDABILITY

Health for you, healthy for your wallet
Guarantee consumers access to the best cost options for their needs

ACCESSIBILITY

No-stress pharmacy care
Make it easy for consumers to order and receive the medication they need when they need it

ADVOCACY

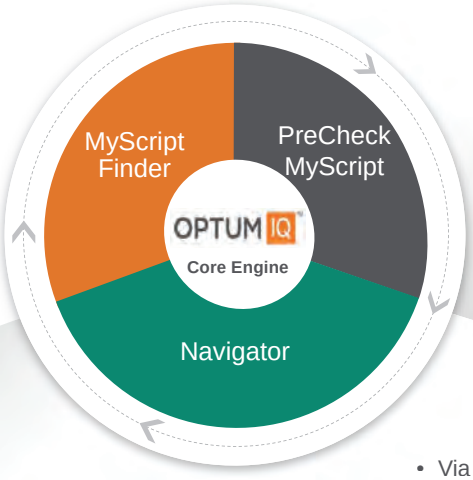
Your advocate in good health
Proactively provide advice and expertise to promote the best health outcomes for consumers

OPTUM Rx

One core engine driving a consistent experience

Member

- With **MyScript Finder*** via portal/mobile app-- the member sees the exact info the Dr. or agent sees, leading to richer discussions & better health engagement



Provider

- With **PreCheck MyScript**, the Dr. will see lower cost, clinically equivalent alternatives better tailored to each member's condition

Customer Service Agent

- Via **Navigator**, pricing and pharmacy information is consistent with what the member is seeing online

OPTUM Rx

MyScript Finder™: Pricing medications has never been so simple

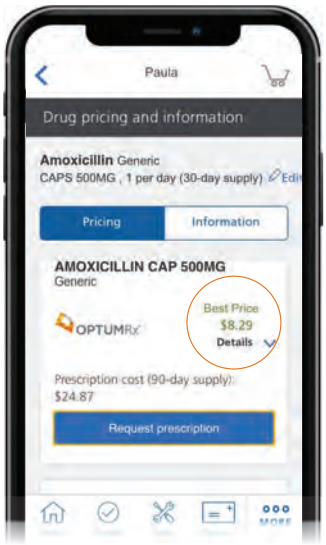
Our digital precision pricing tool delivers greater pricing clarity, consistency, and transparency.

Precision pricing
Members can view targeted pricing specific to their benefits and compare medication options

Pricing transparency
Members know their cost before visiting the pharmacy or other purchasing avenues

Best-price option
To promote savings opportunities the *Best-Price* displays first

Offers savings opportunities
Identifies lower-cost alternatives based on members unique plan



OPTUMRx

Empowering physicians with PreCheck MyScript®

Visibility at the point of care ▶ Cost share | Formulary placement | Clinical alerts

Streamlining prior authorizations

Finding lower cost alternatives

Improving plan performance

>20% of physicians switched to an alternative drug[1]

>30% Prior authorizations were avoided or initiated[1]

OPTUMRx

1. 2017 PreCheck MyScript program results

PreCheck MyScript®

Better clinical decisions which leads to lower costs for patients, better adherence and health outcomes

Member

- $225 per script savings[5]
- Up to 4% higher medication adherence[2]
- 80% shift from 3 tier medications to lower tier[3]

Client

- $415 benefit plan savings per switch[1]
- Higher medication adherence[2] may lead to lower Total Cost of Care

Pharmacist

- $1.78 per script[1]
- 32% pharmacist administrative cost savings with PCMS[1]

Physician

- 50 min time savings per avoided PA[1]
- $41 savings per avoided PA[1]
- Within EMR work stream
- 80% access in 2020[1]

2020 Performance[4]

402K+	Providers Utilizing
>1.5M	Members/month impacted
<2 sec	Application response time

~20% of all transactions with an alternative resulted in a **drug change**[1]

>30% of PreCheck MyScript prior authorizations were **initiated electronically or avoided**[1]

1-5. Full citations in notes

PreCheck MyScript®

Access	Adoption and Utilization	Value Delivery
Expanding real-time benefit-check availability	Delivering relevant workflows in ways users prefer to consume	Implement strategic business enhancements
• Maximize Provider access through EMR partnerships • Broaden provider access to include the Pharmacist	• Add medical diagnosis codes for additional opportunities	• Display pharmacy channel options (home delivery/specialty) • Advance clinical integration and messaging

Better Outcomes

- 20% of scripts with alts switched[3]
- 80% tier 3 shifts to lower tier drugs[3]
- 4% higher adherence[4]
- >30% of PAs initiated or avoided[3]

Thank you

OPTUMRx®

WISCONSIN PHARMACY COST STUDY COMMITTEE

Final Report to the Governor's Task Force on Reducing Prescription Drug Prices

July 22, 2020

WPCSC BACKGROUND

- Inter-agency workgroup began meeting in 2017
- Applied for tech assistance in 2019 and formed the WPCSC
- Committee included representatives from DHS, ETF, OCI, and DOC
- Supported by staff workgroup able to complete deeper cost and policy analysis
- Reviewed options to improve individual agency purchasing arrangements and combined purchasing options

INDIVIDUAL AGENCY OPTIONS

340B CENTERS OF EXCELLENCE

Contracts to direct all patients to a 340B entity in exchange for pass-through of drug acquisition costs

ETF could pursue, but possible conflict with current transparent model

Medicaid would need to pursue a freedom-of-choice waiver; concerns about rural access limiting equitable implementation

DOC has existing contract relationship with UW Hospital, but cost of moving patients to hospital site neutralizes savings

340B ENTITY COST BILLING REQUIREMENT

Adding contract requirements for 340B entities to bill agencies at acquisition cost for 340B drugs

Price confidentiality prevents audit and enforcement of these types of provisions

340B SUBGRANTEE STATUS FOR DOC

Public Health entities receiving funding under Section 317 and 318 of the PHSA can be 340B covered entities

Other state correctional departments have entered into subgrantee arrangements to receive 340B prices for incarcerated populations

DPH favorable to creating relationship

VALUE-BASED CONTRACTING

- Agreements that tie the reimbursement for a drug to patient health
- Includes subscription models (Louisiana & Washington) as well as outcomes-based models (Oklahoma)
- Substantial administrative lift to set up contracts and monitoring
- Challenges in defining meaningful outcomes
- Access to health data limited
- Outcomes from such contracts are still not known

COMBINED AGENCY OPTIONS

POOLED PURCHASING

- Co-negotiated rebates
- DOC does not currently receive rebates beyond discount negotiated by MMCAP
- Medicaid works with TOP$ for supplemental rebates; pooling possibly could increase those rebates
- Lack of transparent data on current pricing makes any combined purchasing effort high risk, and available data indicated limited reward

PREFERRED DRUG LIST / FORMULARY ALIGNMENT

Medicaid uses PDL to encourage members to use lower-cost drugs

ETF and DOC have closed formularies

Alignment of PDL with formularies to create quasi-pooled arrangement

No guarantee of price impact, likelihood of member disruption

COMMITTEE ACTIONS & RECOMMENDATIONS

- Committee recommended DOC pursue 340B arrangement
  - In progress, target 2021
- Other concepts were either not feasible, savings were not significant or unknowable, or disruption and administrative lift would outweigh savings
- Some concepts were ultimately outside the scope of the Committee

ADDITIONAL RECOMMENDATIONS OUT-OF-SCOPE

FOR TASK FORCE CONSIDERATION

Price Transparency

- WPCSC work was limited by ability to analyze costs
- Intra-agency spending transparency is critical to negotiate in good faith
- State-level laws may not be enough

Drug Reimportation

- Appears to be some success in other states (ex: VT, UT)
- Utility could be limited, especially if other states move to this model

FOR TASK FORCE CONSIDERATION

Sole Statewide Purchasing Entity

- Single purchasing authority could have ability to see all purchasing data
- Substantial reorganization of how drugs are purchased by agencies currently
- Possibility to pull in purchasing for the public

Public Health Purchasing of Chronic Disease Drugs

- Model after Vaccines for Children and/or Wisconsin Chronic Disease Program
- State could bulk purchase certain drugs relevant to public health concerns
- Likely considerable cost and administrative challenges

THANK YOU

Renee Walk, MPH

Lead Policy Advisor, Office of Strategic Health Policy

WI Department of Employee Trust Funds

renee.a.walk@etf.wi.gov

Wisconsin Pharmacy Cost Study Committee Report

OPTIONS & OBSTACLES TO LEVERAGING STATE PURCHASING POWER | JULY 2020

Prepared by the

Wisconsin Pharmacy Cost Study Committee

Wisconsin State Agency Pharmacy Cost Study Committee Members

Office of the Commissioner of Insurance
Nathan Houdek, Deputy Insurance Commissioner

Department of Corrections
Daryl Daane, Pharmacy Director

Department of Employee Trust Funds
Eileen Mallow, Strategic Health Policy Director (Project Lead)

Renee Walk, Lead Policy Advisor (Project Coordinator)

Tricia Sieg, Pharmacy Program Manager

Office of the Governor
Noah Roberts, Health Policy Advisor

Department of Health Services
Pamela Appleby, Bureau of Benefits Management Director, Medicaid Services

Dr. Daniel Kattenbraker, Chief Medical Officer, Division of Care and Treatment Services

Table of Contents

Executive Summary

In 2017, staff from the Departments of Corrections (DOC), Employee Trust Funds (ETF), and Health Services (DHS) began meeting to share strategies to address the high costs of prescription drugs and to determine if there were opportunities to collaborate. In 2019, this working group applied for funding from the National Governor's Association (NGA), and with the addition of representatives from the Governor's office and the Office of the Commissioner of Insurance (OCI), formally became the Wisconsin Pharmacy Cost Study Committee (Committee).

The Committee has worked for the last year to develop options that use the joint drug purchasing volume of each agency. The Committee identified three primary approaches that could potentially save money on prescription drugs:

1. DHS & DOC partnership to pass through 340B pricing for medications for inmates;
2. DHS, DOC, & ETF formulary or preferred drug list (PDL) alignment to create pseudo-pooled purchasing; and
3. DHS, DOC, & ETF joint purchasing of certain specialty medications to lower prices for ETF and DOC.

The Committee has facilitated pursuing the first of these three approaches. It further discussed the logistics behind the second two, ultimately determining that they were not feasible to move forward with at the present time. The Committee has also identified several barriers that limit effective pooled purchasing:

- Inability of Medicaid to share net cost of drugs purchased;
- Differing mechanisms or points of purchase and unnecessary complexities built into the supply chain;
- General lack of transparency of costs within the purchasing system;
- Existing contracts that limit the usefulness of carving out one or a handful of drugs;
- Lack of a single purchasing authority amongst State of Wisconsin agencies.

The following paper provides background information on the current state of drug purchasing amongst the agencies working on this project, the relevant statutory provisions that allow for or limit certain activities related to drug purchasing, details on the options and barriers described above, and general Committee recommendations outside of the Committee's scope for how the state might proceed to continue lowering costs for agencies, patients, and taxpayers generally.

Background

Prescription drug spending represents 10% of all healthcare spending in the U.S. While overall growth in prescription drug spending has slowed somewhat in recent

years (0.4% in 2017 versus 12.4% in 2014[1]), increasing prices of brand name drugs and the introduction of new, high-cost specialty drugs continues to drive cost growth.[2]

It was this trend that encouraged several Wisconsin state agencies to begin meeting in late 2017 to discuss how they might align policies and purchasing strategies in order to save money on prescription drugs for the populations they serve. In 2018, ETF, DOC, and two divisions of DHS began meeting monthly to share data and strategies. The agencies applied for and were awarded a technical assistance grant from the NGA in 2019 to support this work, and at that time formally established the Wisconsin Pharmacy Cost Study Committee (Committee).

The Committee's work has generally focused on the purchasing done by three agencies—ETF, DOC, and DHS. Within DHS, the Committee focused its review on drugs purchased by the Wisconsin Medicaid program (Medicaid) and the Division of Care and Treatment Services (DCTS) which manages state-run inpatient facilities. In total, these agencies provide prescription drugs or drug coverage for more than two million Wisconsin residents. In order to identify opportunities to collaborate and save costs, the Committee reviewed the purchasing regulations and current practices of each agency.

Current Agency Purchasing & Regulations

Medicaid

Under Wis. Stats. §49, and DHS 107.10, the DHS provides access to prescription drugs for individuals enrolled in its Medicaid programs, including BadgerCare and SeniorCare. DHS 107.10 and DHS 109 specify the drugs covered under the Medicaid programs, which drugs are subject to prior authorization, any dispensing limitations, and pharmacist drug utilization review requirements. Wisconsin Medicaid is the largest single purchaser of prescription drugs in the state.

In FY2019, DHS spent $1.20 billion, before rebates, for prescription drugs on behalf of Medicaid members. This figure does not include drugs administered in a physician's office or clinic, or drugs received by members while in an inpatient or outpatient facility. DHS contracts with DXC Technology to process claims from retail pharmacies for its Medicaid programs, as well as smaller programs administered by DHS, including the Wisconsin Chronic Disease Program and Ryan White AIDS program.

[1] U.S. Center for Medicare and Medicaid Services, Office of the Actuary, "CMS Office of the Actuary Releases 2017 National Health Expenditures," December 6, 2018, https://www.cms.gov/newsroom/press-releases/cms-office-actuary-releases-2017-national-health-expenditures

[2] Hernandez, Immacula, et al, "The Contribution Of New Product Entry Versus Existing Product Inflation In The Rising Costs Of Drugs," Health Affairs, January 2019, https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.05147

Wisconsin's Medicaid program participates in the Medicaid Drug Rebate Program (MDRP), which is administered by U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) pursuant to Social Security Act §1927. Pharmaceutical manufacturers are required to enter an MDRP agreement to have their drugs covered under state Medicaid programs. If a manufacturer enters into such an agreement, then state Medicaid programs must cover any outpatient drugs produced by that manufacturer. Pharmacy coverage is an optional benefit under federal Medicaid law, but all states currently provide coverage for outpatient prescription drugs.

Under MDRP, rebates are determined based on a statutory formula which requires that Medicaid programs get the best price for a single source or innovator multiple source drug; the best price is the lowest possible price available from the manufacturer during the applicable rebate period, with some exceptions[3]. The MDRP includes the "best price requirement," meaning that the lowest price offered by a manufacturer to any other purchaser must be offered to all state Medicaid programs. The "best price requirement" has been a barrier for non-Medicaid purchasers as well as individual state Medicaid programs in negotiating directly with manufacturers for specific populations because the manufacturer would have to give that same discount to every other state Medicaid program. The Medicaid best price is confidential and cannot be divulged to any third party.

In addition to rebates received under the Medicaid Drug Rebate Program, Medicaid receives supplemental rebates by taking part in The Optimal PDL $olution (TOP$) program, a multistate Medicaid purchasing pool administered by Provider Synergies LLC, an affiliate of Magellan Medicaid Administration. Together, the federal MDRP and supplemental rebates offset about 60% of the costs of payments made to retail pharmacies.

DCTS

DHS also purchases drugs for residents in its care and treatment facilities; the state's two psychiatric hospitals, three centers for individuals with intellectual/developmental disabilities, and two secure treatment centers. In FY2017, the average population in all facilities totaled 1,558. Total spending on drugs for all the facilities totaled $7.8 million in FY2018. The non-secure facilities bill other insurance, including Medicaid, when available.

The table below shows the average population in FY2017 and total spending on drugs in FY2018 by DHS facilities.

[3] 42 U.S.C. 1396r-8 (c)(1)(C)

DHS Division of Care and Treatment Facilities		
Facility Name	FY17 Average Population*	FY2018 Drug Spending
Winnebago Mental Health Institute	187	$1,785,867
Wisconsin Resource Center	376	1,740,716
Mendota Mental Health Institute	282	1,216,533
Sand Ridge Treatment Center	351	836,224
Southern Wisconsin Center**	134	78,000
Northern Wisconsin Center**	13	16,050
Central Wisconsin Center	215	2,158,199
	1,558	$7,831,590
* Based on FY2017 Annual Report		
*Based on Purchase Orders		

Each of these facilities purchase drugs a little differently. Most facilities purchase most drugs using the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP) program; the same program the DOC uses. Whether the drugs are shipped directly to the facility or to a local pharmacy for dispensing depends on whether the facility has an on-site pharmacy. Where the facility does not have an on-site pharmacy, such as Sand Ridge Secure Treatment Center, the facility uses a local pharmacy, which receives the drugs and prepares them for dispensing to individual residents, and incurs an additional dispensing charge from the pharmacy. Southern Wisconsin Center does not use MMCAP but rather purchases its drugs through CVS, the national pharmacy chain.

ETF

Under Wis. Stats. §40, ETF provides access to prescription drugs for employees, retirees, and their dependents participating in the state Group Health Insurance Program (GHIP) for state and participating local units of government, on behalf of the Group Insurance Board (Board). The GHIP prescription drug benefit was first carved out of the medical benefit in 2004 as a self-insured benefit. The Board contracts with Navitus Health Solutions, LLC (Navitus), a pharmacy benefit manager (PBM), to administer the GHIP prescription drug benefit programs. This includes managing drug lists, processing claims, managing pharmacy networks, negotiating drug pricing, and administering clinical programs. In FY2019, the GHIP spent $342.3 million (before rebates) on prescription drugs.

Navitus covers prescription drugs dispensed through retail pharmacies, mail-order services, and specialty pharmacies. It does not include drugs that GHIP participating health insurance plans cover, such as IV-drugs administered in a physician's office or drugs received by members while in an inpatient facility. In addition to managing a pharmacy network, Navitus negotiates rebates with

pharmaceutical manufacturers. All prescription drug related revenues, including rebates are subject to a full-pass-through contracting model, meaning Navitus does not retain any portion of the rebates or other revenues earned from pharmaceutical manufacturers. Retained rebates are used by ETF to lower costs for members. Navitus' sole source of revenue is through the administrative fees ETF pays per member per month.

DOC

Under Wis. Stats §302.38, the DOC is required to provide appropriate care or treatment, "if a prisoner needs medical or hospital care or is intoxicated or incapacitated by alcohol or another drug." Unlike Medicaid and ETF, DOC distributes drugs directly to the inmate population.

In 2018, the DOC spent $33.8 million on prescription drugs for its inmate population. 85% of these drugs were purchased using the MMCAP. Under MMCAP, requests-for-proposal (RFPs) are issued every five years by participating agencies seeking wholesale distributors. Wisconsin has selected Cardinal Health as its wholesaler. The Department of Administration (DOA) is the contracting agency and the DOC accesses the contract through an inter-agency agreement with DOA. A total of 263 Wisconsin state and local government agencies purchase pharmaceutical and medical supplies using MMCAP with sales totaling approximately $57.8 million in FY2018.

Prescription drugs purchased through Cardinal Health are initially distributed to the DOC's Central Pharmacy unit located in Waupun, and then dispense to correctional facilities located across the state. Licensed health care staff located at the facilities then issue the medications as appropriate to patients.

In FY2018, the DOC spent $1.5 million on specialty drugs not available through Cardinal Health and the MMCAP program. Often such drugs are only available through limited channels requiring the DOC to work with multiple wholesalers or specialty pharmacies to procure, and often with minimal discounts. Finally, 2.5% of the DOC's prescription drug budget is spent on medications purchased on state purchasing cards. DOC staff use these purchasing cards only when Central Pharmacy is closed, or a certain medication is out-of-stock. Each facility has an arrangement with a local 24-hour retail pharmacy when a facility does not have a medication an inmate needs.

Other Wisconsin Governmental Purchasers

ETF, functioning as the lead agency for this project, reached out to the Department of Veterans' Affairs (DVA) in 2019 to request information on their purchasing for their veterans' homes. DVA provides both clinical medical services for military servicepeople as well as longer-term care services through three nursing homes

located in Wisconsin. DVA responded to ETF's request indicating that their purchasing was conducted through the US Department of Veterans' Affairs Federal Supply Schedule. The MDRP requires that manufacturers also enter into participation agreements with the Federal Supply Schedule, and this pricing is also confidential under federal law. DVA indicated that their purchasing was very restricted and therefore they would likely not be able to participate in any collaborative purchasing work with the Committee.

Comparison of State Agency Drug Expenditures

To compare the pricing each agency receives under current purchasing arrangements, the Committee compared the top 50 drugs by total expenditures for ETF, DOC, and DHS. The comparisons were based on information provided by each agency for its top 50 drugs based on total spend before rebates. Among the top 50 drugs for each agency, only seven drugs were common across all three agencies. The table in Attachment A shows the common drugs across agencies, including utilization and costs after rebates. The drug mix included in the individual agencies' top 50 lists reflect the clinical needs of their unique populations. ETF's top 50 drugs included many specialty drugs used to treat diabetes, multiple sclerosis, rheumatoid arthritis, and cancer. DOC and DHS populations had more significant use of medications to treat mental health conditions, HIV and Hepatitis C.

The Committee noted several challenges in completing a comparison analysis between agencies. First, as mentioned in the description above of Medicaid regulations, MDRP prevents Medicaid from sharing the actual rebate amounts received for drugs. The amounts shown in Attachment A of this paper are aggregate for the class, but actual rebate amounts can differ based upon which specific form of the drug is being supplied and in what quantity. Defining quantity also presented a challenge. ETF and Medicaid provide coverage for drugs received at retail pharmacies and there are a variety of ways that a drug can be prescribed, both in terms of delivery mechanism and dose. The specifics can be derived from National Drug Codes or NDCs, used to denote what has been prescribed on a drug claim. As mentioned earlier, Medicaid is unable to provide rebate values to this level of specificity, but they can provide this level of unit specificity and pre-rebate costs. DOC, however, purchases drugs differently than Medicaid and ETF, and tracks drugs via a shipped quantity, which may or may not be a comparable dose. Finally, both ETF and Medicaid receive rebates quarterly; this can skew the cost per prescription depending upon the volume of rebates received for the prior quarter versus the volume of prescriptions filled in the present quarter. Any comparisons made of these costs, as well as any proposed solutions for combined purchasing, had to be reviewed with this in mind.

The data available does appear to verify that DHS by and large receives substantial pricing discounts compared to the DOC and ETF. In some instances, particularly for Adalimumab and Albuterol sulfate, it also appears that ETF receives lower pricing

after rebates than DOC does through MMCAP. ETF and DOC also have sufficient volumes of these drugs that combining purchasing efforts could result in additional cost savings to each agency. With advisement from NGA, the agencies began to investigate options for both combining purchasing power as well as individually seeking methods for reducing drug costs.

Individual Agency Purchasing Options

In reviewing current agency purchasing practices versus practices in other states, the Committee identified two options that individual agencies could undertake that could present savings opportunities.

Leveraging 340B Pricing

The 340B Drug Pricing Program, authorized under Section 340B of the U.S. Public Health Services Act, is a drug discount program administered by the Health Resources and Services Administration (HRSA) at the U.S. Department of Health and Human Services. Under the program, eligible safety net providers can purchase drugs at significant discounts if the drug's manufacturer participates in the MDRP. Discounts provided under the 340B program are exempt from the MDRP best price requirements, and so could in theory be lower than the Medicaid best price. 340B prices are also considered confidential under federal law, however, and so cannot be verified.

NGA proposed three options for leveraging 340B pricing for the Committee's consideration[4]:

- Creating hospital centers of excellence with facilities that are 340B entities;
- Requiring 340B entities to bill at acquisition cost; or
- Establishing a Section 318 subgrantee relationship between state Public Health authorities and DOC.

Hospital Centers of Excellence

Under a centers of excellence program, each agency could contract with 340B hospitals to exclusively treat patients who need high-cost drugs that the 340B entity can purchase at a reduced price. 340B-eligible providers may provide 340B drugs to those patients who are considered patients of the 340B provider, as demonstrated by providing a certain amount of care and having medical records documented by the provider. A contract with such entities would stipulate that the 340B entity would pass the acquisition cost back to the agencies in exchange for care and drug reimbursement.

The NGA memo notes challenges for Medicaid programs in executing such contracts due to requirements in the Medicaid program to allow provider freedom of choice.

[4] National Governor's Association. Review of 340B Options. Wisconsin Pharmacy Cost Study Committee Meeting Presentation, October 31, 2020. https://etf.wi.gov/boards/wpcsc/2019/10/31/item3/direct

Some states have sought waivers for these arrangements, but Wisconsin Medicaid has not yet done so in part due to access concerns between rural and urban parts of the state that might limit the ability to implement such waivers equitably.

ETF could pursue this type of arrangement but would face limits under its current pharmacy contracting model. ETF has a fully transparent pharmacy contract, which allows ETF to see all discount contracts between its PBM and manufacturers. ETF's position is that this transparency is critical in order to fulfill its fiduciary duty to members. 340B prices are required to be confidential under federal law, and so ETF could not maintain its fully transparent model for these contract arrangements. ETF may also have to either carve out medical care to ensure that patients become patients of record and that the full savings rate is passed through. This could disrupt continuity of care for other medical services received by the member if the 340B entity is not integrated into the member's regular health plan network.

DOC has an existing contract relationship for some services through the University of Wisconsin Hospitals and Clinics (UWHC), and that contract includes the ability to share access to 340B pricing for inmates who meet the definition of patient of the provider. In the case of DOC, care is provided by in-house medical staff, although some conditions do require inmates to be transported to an off-site facility for consultation and additional care. UWHC's access to 340B pricing is limited to certain conditions; their patient mix does not make them eligible for full 340B pricing. UWHC and DOC have investigated expanding both services and 340B pricing access in the past but determined that logistical challenges would limit this. For UWHC, this would require they hold a separate, secure wing of their facilities to accommodate DOC inmates who are transported for care to provide adequate security. There are generally not enough DOC inmates who would need care that would fully occupy an entire hospital wing, and so these rooms would not be fully utilized. UWHC's other patients would not be able to use those rooms, and so this would result in loss of access to other patients. DOC would also incur costs to transport inmates to and from appointments both in travel costs and staff time. Also, most DOC facilities are outside of Dane County, and so DOC would either need to seek other 340B institutions to partner with or would need to transport inmates a significant distance to bring them to UW Hospital in Madison. The value of transporting inmate patients to UWHC to increase access to a limited set of 340B drugs may be less than the cost of facilitating the transfers over time.

Upon review, the Committee did not recommend this option to any of the three agencies.

340B Entity Billing

The second recommendation provided by NGA was to ensure that 340B entities are billing state programs at acquisition cost for 340B drugs. As stated earlier, 340B pricing confidentiality requirements prevent any of the three agencies from

determining what the true acquisition cost is. ETF's fully transparent model further would require that prices be available to ETF's auditor in order to verify that claims were correctly processed, and this arrangement would likely violate the 340B confidentiality rule. For Medicaid, the Medicaid Average Manufacturer Price (AMP) is confidential to Medicaid and cannot be shared, which further complicates a lower-of pricing requirement. Given the limitations surrounding price-sharing, the Committee also did not recommend that any of the agencies move forward with this option at this time.

Public Health and DOC Partnership

The final option provided by NGA was to investigate partnerships where DOC could access 340B pricing. Most other states who have created these arrangements for the Correctional authorities use some type of partnership with a 340B eligible hospital, but some states entered subgrantee relationships with their departments of public health to access 340B drugs.

As part of the Public Health Service Act (PHSA), 340B statutes allow entities receiving funding under Section 318 for treatment of sexually-transmitted diseases (STDs) and Section 317 for tuberculosis to be considered 340B covered entities if certified by the Secretary of the federal Department of Health and Human Services (HHS). According to CMS, STDs with drugs eligible for 340B treatment include HIV and Hepatitis C treatments, which are often treated with very high cost drugs. To be a subgrantee of a public health entity, an agency would need to establish a treatment relationship with the public health entity. This can be as expansive as full health care provision by the public health entity or as narrow as receiving in-kind materials from the agency related to STD treatment (e.g. test kits). DOC currently receives STD testing kits from the Wisconsin Department of Health Services' Division of Public Health (DPH). DOC pays for these kits currently, but the Health Resources and Services Administration (HRSA), the arm of HHS that administers 340B certification, has indicated that even a discounted payment rate for STD kits can be treated as an in-kind arrangement.

To initiate the subgrantee arrangement, DOC must make its intentions known to DPH and document the nature of their current partnership, adjusting the in-kind relationship if needed. DOC can then apply directly to HRSA for subgrantee status. HRSA will contact DPH to verify the relationship and that DPH is receiving funds under Sections 317 and 318.

Once awarded the subgrantee status, DOC will be able to enroll its institutions as a 340B entities and access 340B drug pricing to fill client prescriptions as long as the client is receiving services that are within the scope of STD or tuberculosis treatments. DOC would need to be able to separately account for drugs that are provided under 340B, either through a separate physical inventory or through software solutions. According to an analysis provided to the state of North Carolina,

who like DOC purchases drugs using the MMCAP enrolling in 340B will not impact the volume discounts received from purchasing through MMCAP. In the same North Carolina analysis, HRSA's vendor, Apexus, indicated that Section 318 grantees can dispense any 340B drug to an individual who is eligible for treatment under the Section 318 subgrantee status. This means that a client who has both an STD and another condition can receive all treatment drugs at 340B prices.

This option was presented to the Committee at their December 2019 meeting, and the Committee recommended that DOC pursue subgrantee status in partnership with DPH. DOC had originally planned to pursue the arrangement for July 1, 2020, but the COVID-19 pandemic has delayed their plans. DOC still intends to implement this arrangement and will seek credentialing in the second half of 2020.

Value-Based Contracting

NGA also submitted an analysis of value-based purchasing approaches[5] to the Committee for consideration, highlighting the approaches taken by two states—Louisiana and Washington. Both models use a "subscription model," wherein the states pay a certain dollar amount to a manufacturer per month for unlimited access to a high-cost medication. Certain drugs, particularly those that are cures rather than maintenance medications, may be better suited to subscription-type arrangements. Likewise, drugs that are either the only treatment available or one of few treatments available in a particular class of medications may be suited to this type of arrangement. For these reasons, the first subscription arrangements implemented in the U.S. have been centered around treatments for Hepatitis C. Louisiana's subscription arrangement is approximately one year old at the writing of this paper, and the term of the subscription contract is five years. Data on the outcomes of this model were not available at the time the committee reviewed the option.

The Committee also discussed an outcomes-based purchasing model that has been undertaken by the state of Oklahoma. Oklahoma has outcomes-based contracts for five different drugs with manufacturers of high-cost, generally sole-source drugs. NGA reported that the number of drug classes for which this approach will work may be limited due to challenges in defining meaningful outcomes and measurement. Often measurement is limited to claims data; electronic health records data can be very hard to access due to the Health Information Portability and Accountability Act (HIPAA) and so clinical outcomes are harder for states to track. In addition, NGA noted that states who are interested in these arrangements should consider the costs of data collection, analysis, and agreement management when looking at outcomes-based arrangements, as these administrative costs may

[5] National Governor's Association. State Value-Based Purchasing Agreements with Biopharmaceutical Manufacturers. Wisconsin Pharmacy Cost Study Committee October 31, 2019 Meeting. https://etf.wi.gov/boards/wpcsc/2019/10/31/item4/direct

overtake much of the additional savings. Finally, as noted, few manufacturers have actively engaged with this type of contracting. Oklahoma has approached 30 different manufacturers to work on such contracts, and the arrangements are very different than those larger manufacturers are accustomed to. They are complex and require a substantial amount of complex analysis to develop.

Due to the inherent complexities of these arrangements, lack of outcomes from states who have tried them, and uncertain savings opportunity, the Committee did not recommend that any of the agencies continue to pursue value-based contracting.

Combined Agency Purchasing Options

The primary driver in the three agencies' convening of the Committee focused on opportunities to pool their purchasing power to leverage better pricing on drugs. Following the review of individual agency options, the Committee refocused its review on opportunities to combine their respective purchasing volume.

Each of the agencies currently participates in some manner of purchase pooling currently, as reviewed above: DOC and DCTS with MMCAP, Medicaid with TOP$, and ETF with Navitus. MMCAP and TOP$ are both inter-state pooling arrangements where multiple states all purchase through the same provider in order to increase either discounts or rebates. The Committee also heard a presentation from another inter-state pooling group, the Northwest Prescription Drug Consortium (NPDC), which Oregon and Washington state both organize and participate in. Similar to MMCAP, NPDC offers group purchasing arrangements for both entities, covering more than 1.1 million members. Benefits to these arrangements include expanding the number of potential lives covered under the group purchasing arrangement. However, the Committee lacks data transparency to complete a full analysis of current drug costs as mentioned earlier in this paper. While the option to combine volume for lower prices is innately attractive, there was hesitance on the part of DOC and ETF to completely move purchasing to a new vendor without being able to verify pricing. In addition, DOC and ETF currently use different statutory purchasing authorities to enter their pharmacy purchasing contracts, and a fuller analysis of purchasing authority would need to be undertaken before such a move could be made.

Another approach would be to create an intra-state purchasing collaborative, where all three agencies combine volume to leverage greater discounts on drugs. Washington state employs this approach through the centralized Washington State Healthcare Authority. A benefit to this type of arrangement includes internal transparency on pricing between the various participating entity contracts, which provides a more holistic picture when negotiating prices. These arrangements may also lower administrative costs. This option was determined to be outside of the Committee's current scope of authority—no single agency involved in this

discussion felt that they could take on purchasing authority for the others, nor did any agency have the authority to create a single, encompassing purchasing authority to govern purchasing across agencies.

Short of fully combining all purchasing for drugs, the Committee also looked at options to pursue combined purchasing arrangements for specific drugs where each agency has common utilization. Returning to the comparison of agency drug expenditures, the Committee focused on three drugs where there appeared to be the most opportunity available both in terms of price reduction and volume of use:

- Adalimumab: Adalimumab is more commonly known by the brand name Humira, and is used to treat arthritis, plaque psoriasis, and Chrohn's disease. Across the agencies, there were 9,715 prescriptions for this drug. The average cost per prescription for ETF was $4,556 and for DOC was $4,848 (Medicaid's price post-rebate was $296, but agencies agreed this price was likely not a good reference due to the best price rule). Conservatively, if DOC were able to simply reduce to ETF's prices, this could save $1.8M over a similar six-month period. Additional savings could also possibly be negotiated for Medicaid through supplemental rebates if they were to be included in pooled purchasing and the additional volume would help their supplemental rebate negotiations.
- Insulin: Insulin in its various forms is used to manage diabetes. Use is common across all agencies (a total of 60,213 prescriptions were recorded during the six-month period of analysis), and diabetes is further known to be a general area of public health concern statewide. In this instance, DOC appears to get a lower price ($146) than ETF ($314). If ETF was able to obtain the lower DOC price, ETF could save $1.4M on insulin over a similar six-month period. Medicaid could also potentially leverage additional supplemental rebates if pooled and negotiated at the same time.
- Albuterol sulfate: Albuterol sulfate is used in inhalers for people with asthma. Many patients across programs use Albuterol sulfate (212,825 prescriptions total), but costs for these drugs is relatively low, ranging among agencies from $30 per prescription to $41. If DOC were able to leverage ETF's $30 price per prescription, their costs would have been approximately $84,000 cheaper over the same six-month period.

In each of these instances, the Committee identified several risks associated with pursuing pooled purchasing. For ETF, removing drugs from manufacturer contracts under the PBM could risk other manufacturer discounts; for DOC, as the largest Wisconsin member of MMCAP, redirecting any large volume of drugs out of the MMCAP arrangement may reduce the discount amounts received by other, smaller municipalities who participate in MMCAP, causing them budget disruption. Also, because the savings that could be generated are relatively small in the overall costs of each agency's programs, the cost to administer the programs should be weighed against the value of potential savings, similar to what is noted in the value-based contracting review above. The DOC savings numbers in particular are not adjusted

for the savings that will result when DOC moves to 340B pricing for higher cost drugs, and so will likely be lower than these initial estimates.

Questions also remained for the committee regarding pricing and pooling arrangements. To determine best pricing, Medicaid prices need to be shared at a granular level that is not currently available, and the delayed rebate values cause some aberrations in the data. For example, the values for Albuterol sulfate made it appear as if ETF receives a better price than Medicaid, an arrangement that is not technically legal.

The other major question that remains concerns contract ownership between independent agencies. The Committee determined that DOA might be the more correct owner for a pooled purchasing arrangement, but assigning that responsibility was deemed outside of the scope of the committee.

Committee Recommendations & Agency Action

Following extensive review with the support of the National Governor's Association, the Committee determined the only appropriate action available under current law and agency structure was to support DOC in pursuing 340B pricing. DOC continues to work on this project as of the drafting of this memo.

While other savings opportunities appear to exist, all were determined to be either beyond the scope of the agencies that formed the Committee, or of uncertain or limited savings value, such that agencies are not comfortable disrupting their existing purchasing arrangements due to downstream impacts.

Additional Recommendations Outside of the Committee's Scope

Throughout their analysis, the Committee continued to encounter roadblocks as well as opportunities that were outside of its scope of control. Following are some of the items of greatest potential for broader intervention at the state or national level.

Price Transparency

In attempting to analyze how much each agency spends on pharmaceuticals in any given period, the Committee continually encountered barriers to sharing cost information, particularly from Medicaid and DVA. Federal law, as mentioned earlier, prohibits the disclosure of Medicaid best price and the Federal Supply Schedule. One unfortunate side effect of DOC moving drugs to 340B is that they may no longer be able to share their costs with the same level of transparency with which they were able to during the course of this project since 340B pricing is also confidential. The Committee and its supporting workgroup repeatedly noted that at the very least, as stewards of state tax dollars, agencies should at least be able to share cost information internally to ensure they were appropriating tax funds responsibly. Unfortunately, confidentiality rules bar even this level of sharing.

Several states have looked to enact some level of price transparency laws to require manufacturers to regularly report drug pricing. The scope of legislation

varies in terms of what reporting is needed and what penalties apply for non-reporting. Such legislation is based on the premise that the process pharmaceutical manufacturers use to price drugs is opaque and that price increases for both brand and generic medications are unsustainable. Requiring manufacturers to report prices would give states a data source from which state purchasers can develop strategies to combat price increases.

The Center for State Drug Pricing at the National Association of State Health Policy (NASHP) has developed model legislation to help guide states.[6] The NASHP model legislation requires manufacturers to report if the Wholesale Acquisition Cost (WAC) of a brand name drug increases by more than 20% in a 12-month period, or if a drug will be introduced with a WAC of $670 per unit or more. Manufacturers would also have to report WAC increases for generic drugs if the current WAC price is $10 or more and the increase is 20% or more in a 12-month period. Notices must be provided at least 30 days prior to the effective date of the increase and must include a justification for the price increase.

The NASHP model legislation would also require manufacturers to report on any price discounts or rebates provided to PBMs. Hospitals participating in the federal 340B drug discount program would also have to report on the margins received under that program and how the margin was spent by the hospital. The legislation would require manufacturers to report on patient assistance programs, including program terms, the number of prescriptions provided to state residents under such programs, and the market value of such programs.

NASHP reports that as of June 2020, 59 total bills have been brought across 23 states related to drug price transparency. Few have passed or been signed, and most have been challenges by pharmaceutical companies or otherwise stalled during the legislative process.[7] In states where bills have passed pharmaceutical manufacturers are litigating efforts to require price reporting, arguing that the legislation violates the Commerce Clause of the U.S. Constitution, since it is attempting to regulate national pricing, not just state pricing. In April of 2019, Maryland's anti-gouging legislation was found unconstitutional by the Fourth Circuit Court of Appeals.[8] Additional appeals are expected. California and Nevada's laws have also been subject to litigation, although the lawsuit against Nevada's legislation was dropped when the state agreed to allow manufacturers to request that certain information be kept confidential because the information is a trade secret.[9]

[6] National Academy of State Health Policy. *Comprehensive Transparency Model Legislation.* https://www.nashp.org/wp-content/uploads/2020/02/revised-transparency-rx-Model-Leg-2.13.20.pdf
[7] NASHP Rx Legislative Tracker. https://www.nashp.org/rx-legislative-tracker/
[8] "Frosh v. Association for Accessible Medicines," U.S. Court of Appeals for the Fourth Circuit
[9] Mahinka, Stephen Paul and Sanchez, Amaru J., "State Drug Price Transparency Laws Present Reporting Issues for Biopharma," November 09, 2018, www.morganlewis.com/pubs/state-drug-price-transparency-laws-present-reporting-issues-for-biopharma

In May of 2018, the Trump administration released the American Patients First blueprint[10], which included some federal level transparency efforts. The Blueprint would have required drug companies to include pricing in their television advertisements. In June of 2020, a federal appeals court upheld a lower court ruling that drug pricing disclosure is outside of the authority of the Department of Health and Human Services to require manufacturers to disclose.[11] The rule to date has not been enacted.

If Wisconsin opted to pursue transparency legislation, it would need to determine which state agency should collect the information reported by manufacturers under the bill. Suggested agencies include the OCI, DHS, the Department of Agriculture, Trade and Consumer Protection, and the DOA. Legislation may specify that the administering agency create rules on the method and format of data to be submitted and that such data be included in a searchable database for use by state and private purchasers of prescription drugs, including health care providers and licensed health insurers. Based on Nevada's experience, the legislation and/or administrative rules could specify what information would be disclosed to hedge against potential lawsuits. Such legislation would likely require additional resources be allocated to the agency managing the collection, including additional staff and software to support data collection.

State-level transparency legislation such as the NASHP model may not provide access to the detailed information needed to compare different bulk purchasing options. For example, such legislation would still not override the Medicaid best price rule, nor would it provide access to the Federal Supply Schedule. A range of additional transparency may be needed to pursue enhancing public policymaking and regulatory oversight, as well as improving bulk purchasing to identify opportunities for cost savings. Some of these changes may be necessary at the federal, rather than state, level.

Drug Reimportation

Some states have identified drug importation from Canada or Mexico as options to combat price increases for select drugs. Federal law allows the importation and reimportation of drugs from other countries as long as certain requirements are met and that the Secretary of the U.S. Department of Health and Human Services certifies to Congress that such a program poses no additional risk to the public's

[10] Department of Health and Human Services. *CMS Drug Pricing Transparency Fact Sheet*. https://www.hhs.gov/about/news/2019/05/08/cms-drug-pricing-transparency-fact-sheet.html

[11] The National Law Review. *Federal Appeals Court Affirms Lower Court Ruling: Drug Pricing Transparency Rule Exceeds HHS's Regulatory Authority*. June 18, 2020. https://www.natlawreview.com/article/federal-appeals-court-affirms-lower-court-ruling-drug-pricing-transparency-rule

health and safety and will result in a significant reduction in the cost of covered products to the American consumer.[12]

In 2018, Vermont became the first state to adopt legislation to authorize importing drugs from Canada. This legislation is designed to provide savings to Vermont consumers. In January 2019, as required by Act 133, the Vermont Agency for Human Services released its report on the initial design of the program. The report estimated that commercial insurers in Vermont could save between $1 - $5 million by importing drugs from Canada.[13]

The report strongly recommends that the state create two new categories of licensure to ensure no additional risk to health or safety: one for Canadian distributors and another for state-based wholesalers that would be allowed to import the drugs. The legislation authorizes the state to become the state-based licensed wholesaler or to contract with a private entity. The legislation allows for a price per drug to be added to the cost of the drugs imported that would pay for the states' costs to administer the drug importation program.

Short of legislation, the Utah state employee health insurance program began to send employees to Mexico and Canada in 2019 to purchase certain high-cost drugs[14]. Utah's program has found that, even inclusive of airfare and lodging costs, it is less expensive to send employees to Tijuana to purchase medications. Employees fly from Salt Lake City to San Diego and then are escorted across the border. There, they have a medical appointment with a doctor in Mexico, receive a prescription, and pick up their medications. After that, they are shuttled back to the airport and return home. Utah has found no reduction in quality effectiveness for drugs purchased this way. The program provides a $500 per-trip bonus to employees willing to make the trip. ETF has discussed this program with Utah in the past, but the longer flights, coupled with the 2020 COVID-19 outbreak, have slowed further discussion.

Legislation could require a state agency to issue a report on the design of a drug importation program, like Vermont's Act 133 did, and/or it could authorize selected state agency to promulgate rules to establish the program, including:

- how the program would ensure that importation would not provide an additional risk to health and safety;
- who would be eligible to purchase the imported drugs;
- what, if any, provisions would ensure that savings are passed along to consumers; and

[12] Vermont Agency for Human Services, "Wholesale Importation Program for Prescription Drugs Legislative Report," December 31, 2018
[13] Ibid.
[14] Whitehurst, Lindsay, "Utah sends employees to Mexico for lower prescription drug prices." February 9, 2020. https://abcnews.go.com/Health/wireStory/utah-sends-employees-mexico-lower-prescription-prices-68861516

- what, if any, additional charges would apply to the drugs to cover the state's operating costs.

The current federal administration has indicated it is researching opportunities to allow for the importation of drugs from other countries and has established a workgroup to study the idea.[15] This suggests that the federal administration could be open to a state-based proposal to do so. It is possible that pharmaceutical manufacturers could respond to such legislation by limiting distribution of drugs to countries exporting drugs to the U.S. making it less likely that distributors in other countries would be willing to export to the United States.

In December 2019[16], the administration, along with the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration, issued a notice of proposed rulemaking (NPRM) that would pave the way for certain prescription drugs to be imported from Canada. Also, draft guidance[17] has been provided for the drug manufacturing industry that describes procedures to assist with the importation of FDA-approved prescription drugs that are, "…manufactured abroad, authorized for sale in any foreign country, and originally intended for sale in that foreign country."

Sole Statewide Purchasing Entity

Another repeated challenge identified by the Committee was determining which agency would have the authority to view pricing across agencies and/or purchase on behalf of all agencies. DOA could potentially do so, but for entities such as ETF that are non-cabinet, the authority may not be as clear. A simpler means of creating the authority as well as ensuring subject matter expertise could be to create a single purchasing entity for the State of Wisconsin. The entity could either provide administrative authority, such as the Washington Health Care Authority, or could even be expanded to provide general pricing oversight as in the review boards currently run in states like Maine and Maryland. The Washington Healthcare Authority can review and make coverage and drug preference decisions for all people in Washington state who are on a government-run health program, including state employees and Medicaid members. Maine and Maryland convene drug affordability review boards that limit how much all state residents may pay for

[15] McGinley, Laurie, "Trump Administration to Explore Drug Imports to Counter Price Hikes," Washington Post, July 19, 2018, https://www.washingtonpost.com/news/to-your-health/wp/2018/07/19/trump-administration-to-explore-drug-imports-to-counter-price-hikes/?utm_term=.75ede28d6e14

[16] Food and Drug Administration. "Trump Administration takes historic steps to lower U.S. prescription drug prices." December 18, 2019. https://www.fda.gov/news-events/press-announcements/trump-administration-takes-historic-steps-lower-us-prescription-drug-prices

[17] Food and Drug Administration. "Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act." December 2019. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/importation-certain-fda-approved-human-prescription-drugs-including-biological-products-under

certain high-cost drugs[18]. These boards have not gone un-challenged and implementing either a statewide authority or an affordability review board may require legislative action.

Public Health Purchasing of Drugs for Chronic Disease

One additional option that could be considered for drugs that address chronic illnesses such as Albuterol sulfate or insulin is a public health purchasing model. In this option, like the Vaccines for Children (VFC) program, a state public health authority would purchase a supply of a medication and distribute it to eligible individuals.

In the case of VFC, the program is federally funded and provides vaccines at no cost to children whose families may be unable to pay for or otherwise obtain vaccinations through insurance. The Centers for Disease Control (CDC) purchases vaccines at a discount and distributes them to grantees such as health departments which then distribute them at no charge.[19] VFC limits eligibility currently to children who are Medicaid or Children's Health Insurance Program (CHIP) eligible, children who are uninsured or underinsured, and to children of American Indian or Alaska Native descent as authorized by the Indian Health Care Improvement Act.[20] This program has generally been deemed effective at providing access to childhood immunizations and reducing the spread of vaccine-preventable disease.

There is no similar federal program currently offered to help adults manage chronic conditions. In Wisconsin, the Wisconsin Chronic Disease Program (WCDP) is funded entirely by the state. WCDP is the payer of last resort for treatments related to chronic renal disease, hemophilia, and adult cystic fibrosis. Members who income up to 300% of the federal poverty level (FPL) do not have copayments or deductibles under the program. Members who make more than 300% FPL must pay a certain amount out of pocket before WCDP coverage begins.[21]

Several states have considered bills to ensure that patient costs for insulin under their health plans stay within limits, but these bills do not control the actual costs of the drugs. This means that insurers assume more of the drug costs, and these costs are ultimately passed back to members in health insurance premiums, or to taxpayers in the cases of public payer programs like Medicaid. Minnesota has pursued a cost control program that limits the costs that individuals pay for emergency insulin supplies at retail pharmacies. Manufacturers must reimburse

[18] NASHP. Administrative Actions. https://www.nashp.org/policy/prescription-drug-pricing/administrative-actions/#toggle-id-3
[19] Centers for Disease Control and Prevention. Vaccines for Children. https://www.cdc.gov/vaccines/programs/vfc/index.html
[20] National Center for Health Research. The Vaccines for Children Program. http://www.center4research.org/vaccines-children-program-vfc/
[21] Department of Health Services. Wisconsin Chronic Disease Program. https://www.dhs.wisconsin.gov/forwardhealth/wcdp.htm

pharmacies for insulin dispensed under the new law or they must send replacement insulin to the pharmacy at no cost. There are also longer-term provisions for manufacturers to provide insulin at copays not to exceed $50.[22]

The utilization levels of drugs to treat asthma and diabetes in ETF, DHS, and DOC populations reflects a high prevalence of these conditions in the Wisconsin population at large. The state may have a population health interest in controlling these conditions in order to promote worker health and productivity. Another option beyond setting cost limits could be for states to negotiate the bulk purchase of insulin or other drugs like Albuterol sulfate through public health entities, who could then provide the drugs to all state residents at either no or very low costs. Drugs could be distributed by local public health authorities who could also provide simple testing and education to patients in how to manage their conditions. The state could also potentially create cooperative arrangements with 340B hospitals to provide drugs and associated care at reduced prices in exchange for passing through the 340B contracted rate for chronic disease management drugs. It should be noted that, similar to the concern described in the Combined Agency Purchasing Options section above, any diversion of these drugs from existing purchasing contracts could affect other discounts provided by those contracts. An extensive review of legal and logistical limitations would need to be conducted on this option.

Other Options Considered but Not Recommended

The Committee reviewed other options for initial consideration as in scope but were ruled out early on as either not feasible or impractical. A list of those proposals and brief descriptions are available in Attachment B.

[22] Walz, Tim. *Governor Walz Signs Alec Smith Insulin Affordability Act*. https://mn.gov/governor/news/?id=1055-428439

Attachment A: Common Drugs Across Agencies

	Department of Employee Trust Funds (ETF)				Department of Health Services, Medicaid Program (Medicaid)			Department of Corrections (DOC)		
Generic Name Group	**Total Cost net of Rebates**	**Total Scripts**	**Cost per Script**	**Cost net of Rebates per Script**	**Estimated Net Paid Amount**	**Total Scripts**	**Net Paid per Script**	**Purchase Dollars**	**Ship Qty**	**Package Price**
ADALIMUMAB	$14,493,762.21	3,181	$5,831.71	$4,556.35	$1,854,850.00	Not Available	Not Available	$2,244,744.43	463	$4,848.26
ALBUTEROL SULFATE	$495,842.40	16,793	$64.64	$29.53	$6,647,556.06	Not Available	Not Available	$307,369.91	7,563	$40.64
BUPRENORPHINE HCL-NALOXONE HCL	$5,950.94	26	$283.18	$228.88	$3,485,622.90	Not Available	Not Available			
ETANERCEPT	$4,812,183.94	1,204	$5,115.95	$3,996.83	$7,504,418.80	Not Available	Not Available	$396,292.08	82	$4,832.83
FLUTICASONE-SALMETEROL	$1,069,725.89	7,063	$470.46	$151.45	$4,033,180.31	Not Available	Not Available			
GLATIRAMER ACETATE	$1,068,154.54	393	$2,945.83	$2,717.95	$2,465,874.00	Not Available	Not Available	$76,595.18	14	$5,471.08
INSULIN GLARGINE	$2,607,308.65	8,308	$586.86	$313.83	$8,831,963.50	Not Available	Not Available	$441,152.17	3,019	$146.13
INSULIN LISPRO	$25,246.22	45	$561.03	$561.03				$43,085.68	209	$206.15
LISDEXAMFETAMINE DIMESYLATE	$1,738,986.20	6,635	$314.03	$262.09	$3,564,582.20	Not Available	Not Available			
LURASIDONE HCL	$576,950.73	475	$1,326.49	$1,214.63				$214,042.87	215	$995.55
METHYLPHENIDATE HCL	$1,419,678.19	10,005	$141.90	$141.90						
PREGABALIN	$1,570,560.30	2,469	$687.47	$636.11	$0.00	Not Available	Not Available	$311,434.46	475	$655.65
RIVAROXABAN	$1,651,645.55	3,192	$685.35	$517.43	$0.00	Not Available	Not Available	$48,256.14	119	$405.51

Notes: Incurred 1/1/2019 through 6/30/2019, Medicaid Estimated Net Paid Amount is an approximate calculation based upon the pre-rebate values and proportion of rebates reported as collected for the class of drugs at the time of this report. Total Medicaid prescriptions and net paid cannot be reported. For DOC, rebates do not apply. Only matching data for Medicaid and DOC are provided. Only matched cost information provided for Medicaid and DOC.

Attachment B: Other Options

The Committee considered other approaches to reducing drug costs across state agencies early in the process that were ruled out early on as not feasible or as having limited savings potential. Below are descriptions of the approaches considered but not being recommended at this time.

Mail Order RFP

DHS and ETF could release a joint request-for-proposal for a vendor to administer mail order prescriptions for both the DHS and ETF programs. The vendor would have to integrate with both DHS and ETF systems and vendors but could be structured to not pose a risk to Medicaid's existing rebates. DOC, DVA, and DHS facilities were not considered for this approach since such a model would not work with their dispensing models. The Committee is not recommending this approach because several federal and state Medicaid regulations make this approach unlikely to generate savings for the Medicaid program.

Orphan Drug Direct-to-Manufacturer Purchasing

DHS, ETF and DOC could work directly with orphan drug manufacturers to obtain orphan drugs at extremely reduced prices. In exchange for these savings, the departments would make data available for the subset of patients who take the medication or may request study participation of the patient on behalf of the manufacturer. This data would help the manufacturer gain access to a larger study population for drugs that are only available to a small population. The Committee is not recommending this approach because of a lack of proof of concept and significant concerns over the sharing of patients' data with pharmaceutical manufacturers.

Specialty Drugs Site of Care

DHS and ETF could research which sites of care are the least expensive to provide specialty drugs and direct members to purchase drugs through those sites of care through the benefit design. Currently, many specialty drugs are dispensed by physician clinics and billed through the medical benefit. Often, these same drugs could be purchased through a specialty pharmacy for a better price and ensuring manufacturer rebates are available to offset costs. The DOC, DVA and the DHS facilities are not likely candidates for participation unless on-site infusions were available at every location, which would likely make it cost prohibitive for facilities. While the members of the Committee agree that the differences in the costs of drugs depending on the site of care is an important issue to address, the Study Committee is not recommending this approach at this time because it could not identify a benefit to working together on such an approach. Both ETF and Medicaid

will continue to focus on making sure that patients are receiving their drugs in the most cost-effective and proper setting.

NW Consortium Overview

- An inter-state agreement between the States of Oregon and Washington
- Designed to meet the broad and unique pharmacy program needs of public and private entities
- Enabling legislation:
  - Oregon: ORS 414.312
  - Washington: RCW: Chapter 70.14.060

NW Consortium Services

- Group pharmacy benefit management
- Managed Medicaid pharmacy benefit administration
- Discount Card Program
- GPO (facilities and public health) program offerings
- Voucher program
- 340B program administration
- Rebate administration services only
- Medicaid supplemental drug rebate program coordination
- Fee-for-Service Medicaid pharmacy administration (coming)

NW Consortium History

2003
Oregon Prescription Drug Program (OPDP) was established by the Oregon State legislature.

2005
Washington Prescription Drug Program (WPDP) was established by the Washington State legislature.

2006
Northwest Prescription Drug Consortium (NW Consortium) created to pool purchasing and bring the best drug prices to program participants.

State of Oregon competitive procurement developed with State of Washington to select Program Administrator.

2007-08
Moda Health selected as Program Administrator for the NW Consortium program and expand participation.

NW Consortium launches with Washington's Public Employees and Oregon's Educators Benefits Boards.

2010
2nd RFP completed by State of Oregon in partnership with State of Washington. Scope of services expanded to include Medicaid, Medicare, GPO and 340B programs.

Moda Health renew as Program Administrator.

2013
OPDP launches GPO program to include Traditional and Non-Traditional non-profit entities.

2015
Through passage of Oregon House Bill 2638, Medicaid received authorization to join OPDP. Any Medicaid Health Plan can elect to use OPDP's programs and contracts to better manage their program costs.

2016
3rd RFP released by State of Oregon in partnership with State of Washington to select new Program Administrator.

Moda Health renewed as Program Administrator.

2017
Eastern Oregon Coordinated Care Organization joins NW Consortium, adding Managed Medicaid as a participant in program.

2018
NW Consortium facilitates more than $800 million in annual drug purchases for over 1 million people in participating groups and facilities.

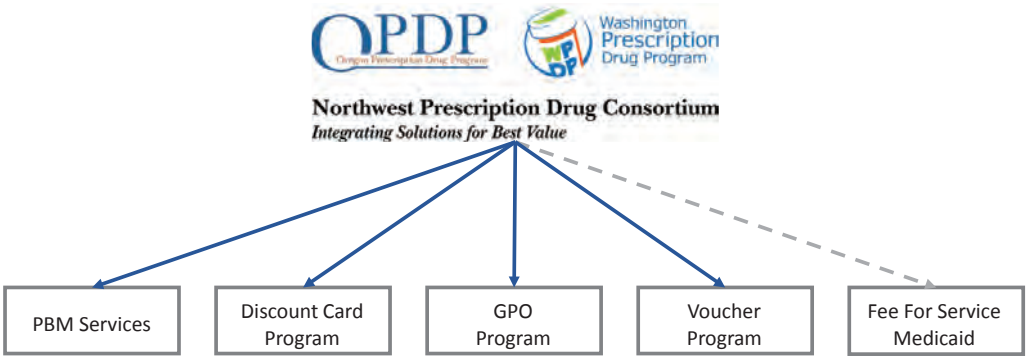
2019
Oregon's Coordinated Care Organization (CCO) RFA solicits PBM's demonstrating pass-through transparency. OPDP offered as an option for CCOs to use for their PBM programs.

WA SEBB elects to join NW Consortium.

2020
4th RFP released by State of Oregon in partnership with State of Washington to select new Program Administrator. Contract discussions expect to be finalized in July. FFS Medicaid platform development started.

Discussions with others states about joining.

NW Consortium Program Elements

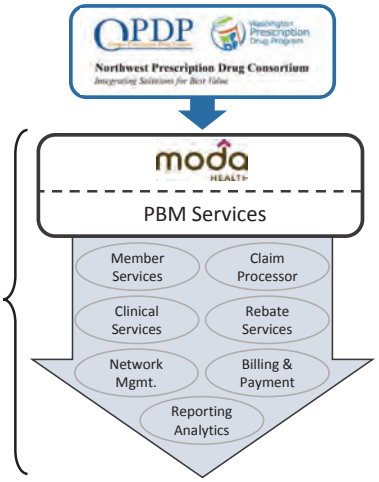


Pharmacy Benefit Management Services

A fully transparent PBM service that focuses on eliminating spread.

Benefiting Agencies: oversee program

Administrator: provides services & manages subcontractors

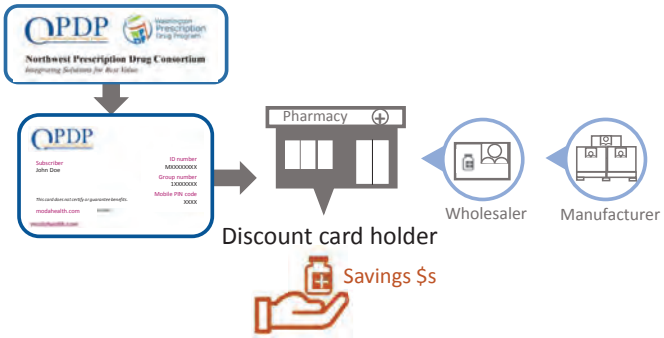


Groups Participating Programs

- Pure pass-through pricing from pharmacies
- 100% pass-through of all manufacturer rebates and fees
- Full audit rights
- Annual market checks

Prescription Discount Card Program

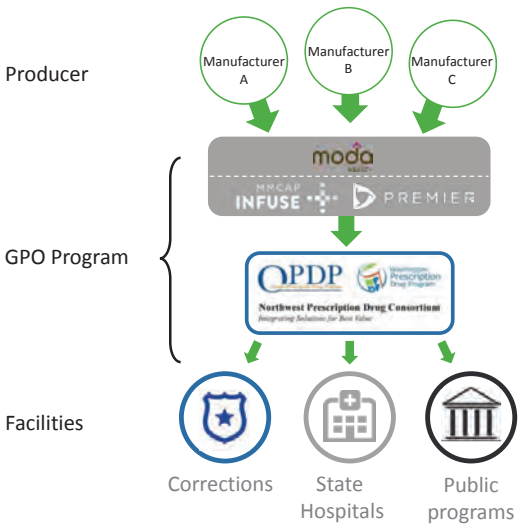
A free state-sponsored prescription drug discount card for under or un-insured individuals.



- Purchases <u>are not</u> subsidized by state funds
- Offers individual consumers pricing comparable to participating groups under the NW Consortium
- Over 55,000 pharmacies participate nationwide

Group Purchasing Option Program

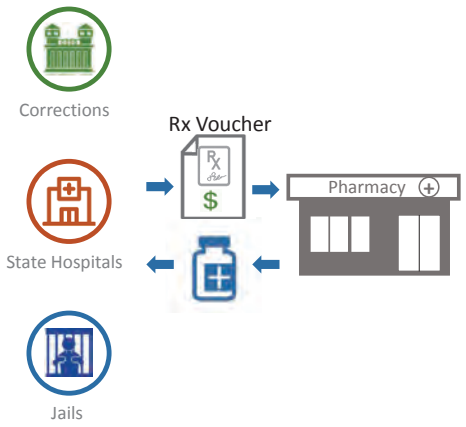
A state backed GPO program delivering best value pharmaceuticals and services to government and non-profit institutions.



- Services provided via a national organization
- Deliver aggressive class of trade pricing for public entities
- Regular market checks to ensure competitiveness
- No affiliation fee for government programs

Prescription Drug Voucher Program

An innovative prescription drug purchasing program for one-time only prescription drug fulfillment.



- Prescription drug service for individuals upon discharge or for emergent need use on site
- One time access to prescription at retail pharmacy
- Paid for by discharging institution
- Significant savings over pharmacy usual & customary price

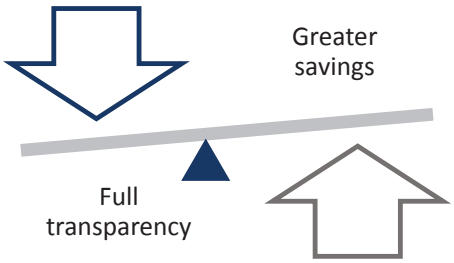
Medicaid Fee For Service Pharmacy Mgmt.

Developing a next generation CMS-certified pharmacy benefit administration (PBA) service.

Target availability: January 2023

Full Transparency

- Clarity in PBM contracting
- 100% pharmacy pass-through
- 100% rebate pass-through
- Fixed administrative fee per claim
- Annual market check
- History of performance above guaranteed rates
- Robust auditing



Experience – Public Sector Employee Programs

Demonstrated history of delivering value by eliminating PBM spread.

Contract Reprice Analyses (NW Consortium vs client's current contract)

	Pharmacy Claims	Allowed Amount ($s)	Consortium Amount ($s)	Savings ($s)[1]	Percent Savings
Public Employee Group	1,543,611	$236,884,685	$227,258,165	$9,626,520	4.1%
Managed Medicaid Plan	893,274	$64,566,367	$61,734,408	$2,831,959	4.4%
Small Commercial Group	6,785	$611,966	$572,320	$39,646	6.4%

[1] Savings reflect value of eliminating spread between Group's actual claims cost through their PBM and NW Consortium's contract financial guarantee amount plus administration fees (2017 – 2019 experience).

Experience – Public Sector Employee Programs

NW Consortium pass through contract delivers extended value to participating programs.

Consortium Over-Performance (NW Consortium actual performance vs contract guarantee)

	Pharmacy Claims	Guarantee Amount ($s)	Paid Amount ($s)	Savings ($s)[1]	Percent Savings
Public Employee Group #1	3,185,235	$420,004,915	$383,526,774	$36,478,141	8.7%
Public Employee Group #2	758,601	$88,896,244	$81,437,637	$7,458,607	8.4%
Managed Medicaid Program	454,443	$32,428,655	$31,770,704	$657,951	2.0%
Small Commercial Group	24,386	$4,090,499	$3,869,191	$221,308	5.4%

[1] Savings reflect difference between NW Consortium's contract financial guarantee amount and the actual group paid amount, plus program administration fees, based on actual experience (2019 experience).

Experience – Discount Card Program

State sponsored discount card delivers critical savings to state's most critical population.

Discount Card Performance (prescription drug cost and savings vs retail drug pricing)

	2019 Utilization	Total DCP Use[1]
Total prescriptions filled	295,958	6,739,180
Total prescription cost	$5,797,288	$163,162,308
Cost per Rx	$19.58	$24.21
Total prescription savings	$23,181,761	$252,468,291
Savings per prescription	$78.49	$37.46

[1] "Total" reflects all NW Consortium discount card member utilization from February 2007 through December 2019.

Future Direction

- Soliciting participation and growth from other states
- Evaluating alternatives to improve the pharmaceutical supply chain
  - Fulfillment
  - Wholesaler distribution
  - Manufacturer

Joining the Consortium

States may participate in the NW Consortium multiple ways:

	Participating State	Partner State
Statutory Authority	• No statute supporting participation in regional consortia as in Washington and Oregon	• State has statute supporting collaboration with regional consortia.
Intergovernmental Agreement	• Able to contract with the Consortium to deliver State agency or entity's needs	• Establish intergovernmental agreement with Oregon, and Washington.
Consortium-level participation	• No participation in Consortium Partners Advisory Committee	• Seat on Consortium Partners Advisory Committee • Election to Consortium Steering Committee possible

- Consortium Steering Committee is comprised of founding Consortium members from Oregon and Washington. New states could have a voting member elected to steering committee annually from Advisory Council.
- All Partner states will have Consortium Advisory Council representation.

Summary

- NW Consortium – a pharmacy services purchasing collaboration designed to work across states with public and private partners.
- Includes solutions for:
  - Public and private sector pharmacy benefit management
  - Medicaid (Managed Medicaid and FFS)
  - Group Purchasing / Own use
  - Individual prescription drug discount card
- Seeking participation from other states to join and grow value of programs available to public purchasers
- States and participating programs may use all or only certain programs available through the NW Consortium

Contact Information

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Consumer perspective on prescription drug prices: Recent trends and opportunities for change

Leigh Purvis, Director, Health Care Costs & Access
AARP Public Policy Institute

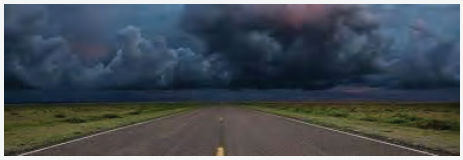
OVERVIEW

- **Why are prescription drugs getting so much attention?**
- **Why is this issue so important to AARP?**
- **What solutions are on the table?**
- **What's standing in our way?**
- **What's next?**

Jaw-dropping prices

3

Trouble ahead



- Specialty drug approvals have exceeded traditional drug approvals since 2010
  - Roughly half of drugs in the late stage of the FDA approval process are expensive specialty drugs
- Increased manufacturer focus on biologic drugs, orphan drugs, personalized medicine
  - Translation: products that can command high prices

4

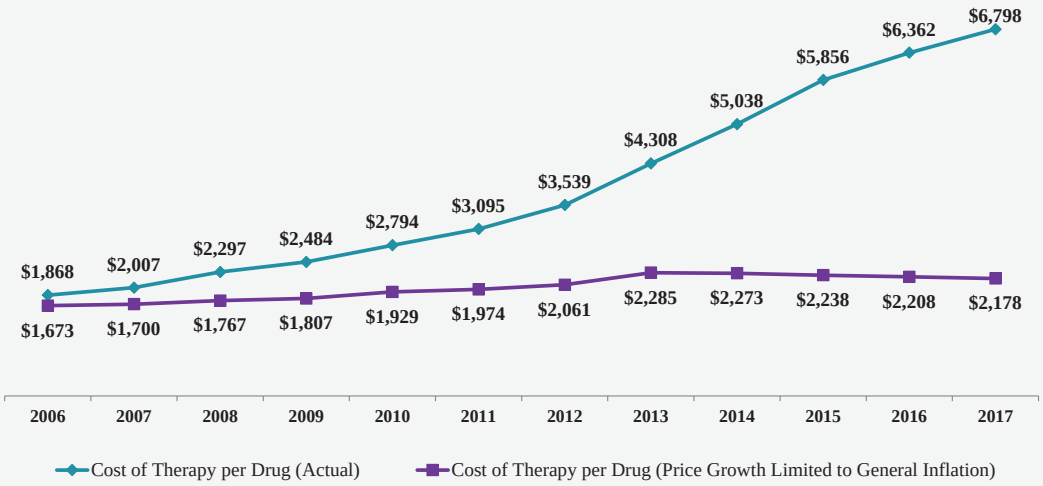
High launch prices are just the beginning…

- For over a decade, brand name drug price increases have exceeded inflation by 2-fold to more than 100-fold
- While individual drug prices and price increases can generate outrage, much less attention is paid to how they add up over time

5

If drug price changes had been limited to inflation between 2006 and 2017…

- The average annual cost for one brand name drug would have been more than $5,000 lower in 2017



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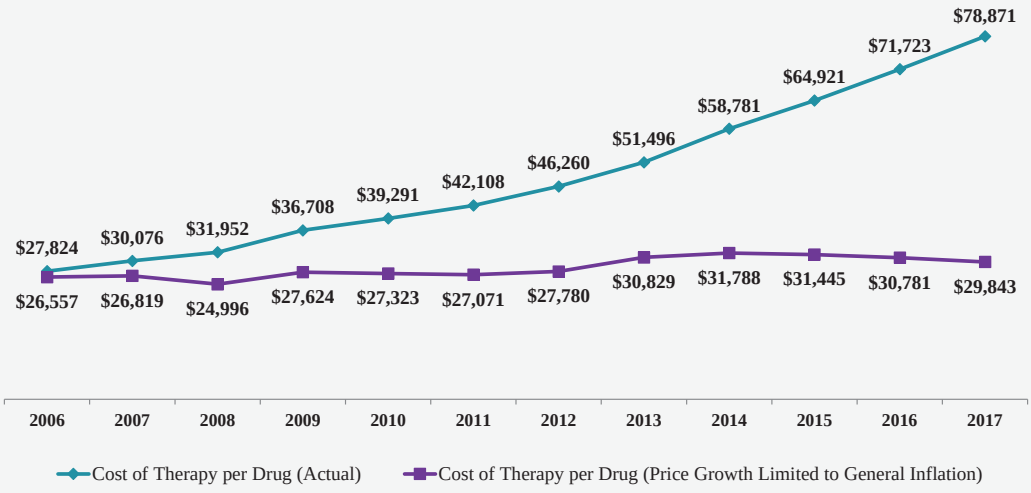
If drug price changes had been limited to inflation between 2006 and 2017…

- The average annual cost for one specialty drug would have been <u>almost $50,000 lower</u> in 2017



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OVERVIEW

- **Why are prescription drugs getting so much attention?**
- **<u>Why is this issue so important to AARP?</u>**
- **What solutions are on the table?**
- **What's standing in our way?**
- **What's next?**

8

Older adults are particularly vulnerable to high drug prices

- High Rx utilization
  - Average of 4.5 prescriptions/month
  - High prevalence of chronic illnesses
- Modest incomes
  - Median income is ~$26,000
  - 1/4 have incomes below ~$15,000
- Limited savings
  - 1/4 have less than ~$15,000 in savings

9

Taxpayer-funded programs are under increasing pressure

- Medicare Part B prescription drug spending more than doubled from $13 billion to $32 billion between 2005 and 2017
  - Beneficiaries are responsible for 20 percent of their costs
- Total Medicare Part D spending is approaching $150 billion
  - Increased use of coinsurance
  - Enrollees have out-of-pocket limit <u>but</u>...
- Medicaid program is also under considerable stress, which isn't helping state budgets

10

Private insurance is also affected

- An increasing number of employer-sponsored plans have a fourth or even higher tier of drug cost sharing
    - Average copayment for a fourth-tier drug is $123 and the average coinsurance is 29%
- High deductibles can create financial hardship
- Enrollees benefit from out-of-pocket maximums ($8,150/single, $16,300/family) but…

11

The problem is the

- High cost-sharing is obviously problematic but it is not the root of the problem
    - Efforts to limit cost-sharing without addressing drug prices is simply cost-shifting and will lead to higher premiums and costs down the road

- If the idea of asking someone to pay a relatively small percentage of the drug price is too much, *what are you saying about the overall price*?

12

Drug manufacturer programs are not a cure-all

- While helpful, patient assistance programs typically have strict eligibility criteria
- Each pharmaceutical company has its own qualifications, forms, processes for refills, and rules for re-qualifying
- Copay coupons seem helpful but ultimately lead to higher premiums
- Manufacturers tout increased spending on these programs but begs the question—*why not just drop the price*??

13

High drug prices affect everyone

14

OVERVIEW

- **Why are prescription drugs getting so much attention?**
- **Why is this issue so important to AARP?**
- **<u>What solutions are on the table?</u>**
- **What's standing in our way?**
- **What's next?**

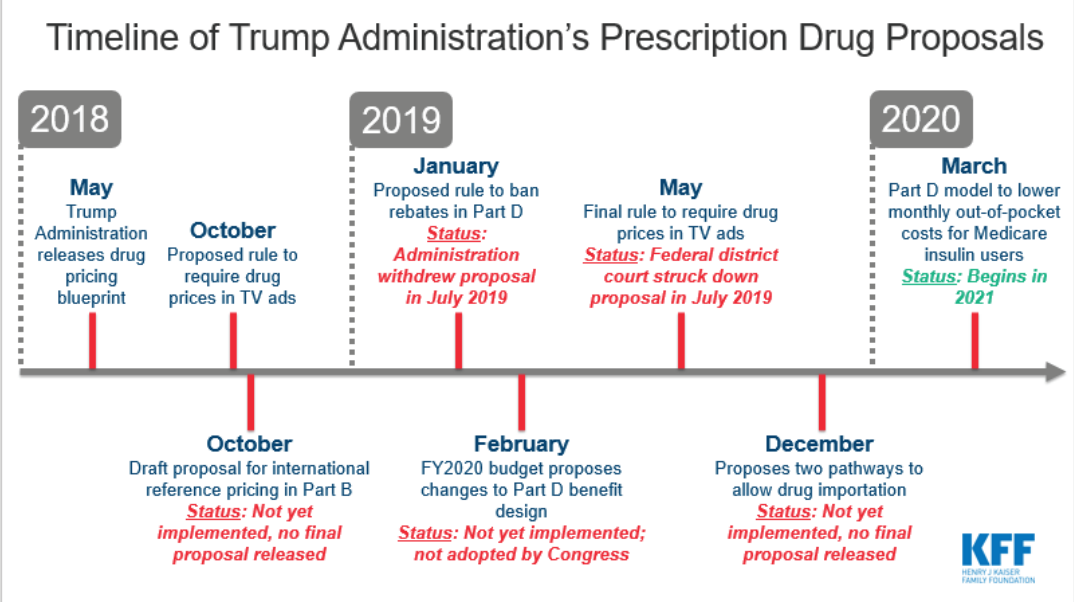
15

Consumers support a wide variety of solutions

- Multiple surveys show extremely strong, bipartisan support for reducing prescription drug prices

16

Administration has been very active…



17

"The rebate rule"


Meet the Rebate, the New Villain of High Drug Prices

A growing chorus, including the Trump administration, is calling for a rethinking of after-the-fact drug discounts that some say contribute to rising prices.

- Proposed effectively eliminating rebates under Medicare Part D but would have allowed discounts that flowed directly to patients at the pharmacy counter

    1. Estimated to increase federal spending by ~$200 billion
    2. Premiums would increase for all enrollees
    3. Unclear how many enrollees would see a meaningful reduction in out-of-pocket costs
        - 89% of Part D scripts do not have a rebate
        - 27% of brand name drugs have rebates >12% of gross drug cost
    4. *Drug prices would not change*

- Proposal was ultimately withdrawn but it's clear this is far from over

18

Strong signs of life in Congress pre-Covid

- LOTS of hearings
- LOTS of prescription drug-related legislation
  - REMS abuses
  - Pay-for-delay
  - Price transparency
  - Reduced market exclusivity for biologics
  - Patent reforms

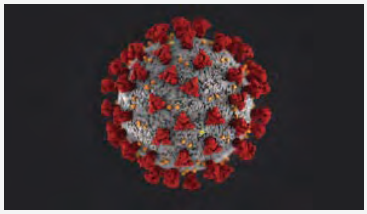
19

Still in play…

- The Lower Drug Costs Now Act (H.R. 3) would:
  - Allow Medicare to negotiate the price of prescription drugs
  - Modify the Part D structure and cap out-of-pocket costs at $2,000
  - Penalize drug companies that increase their prices faster than inflation
- The Prescription Drug Pricing Reduction Act (S. 2543; also known as Grassley-Wyden) would:
  - Modify the Part D structure and cap out-of-pocket at $3,100
  - Penalize drug companies that increase their prices faster than inflation

20

Also some Covid-related legislative action



- Strong interest in ensuring access and affordability for Covid-related treatments and vaccines
  - Advocates are highlighting taxpayer investments in products under development
  - Also trying to highlight misplaced incentives that led drug companies to focus on products that maximize profit over public health needs
- Legislation that focuses on access/affordability/transparency for Covid products could ultimately become a precedent for all drugs

21

States have been extremely busy

- In the absence of federal legislation, states will likely continue the trend of going it alone
  - Price gouging
  - Importation
  - Bulk purchasing
  - Affordability review boards/price transparency
  - **LOTS** of pharmacy benefit manager (PBM) bills

22

Price transparency/affordability review boards

- Originated from drug industry arguments that high prices and price increases were needed because (unverifiable reasons)
- Reality is we have no way of knowing how companies set launch prices or decide to make subsequent price increases
- Now seeing states take the natural next step by using what they learn to evaluate whether a drug price is justified and/or manage spending

23

Lots of interest in drug importation

- ~75% support the idea of allowing Americans to buy drugs imported from Canada
- Fits with larger narratives of “free-riding” and “fairness”
- Five states have passed legislation that would allow for drug importation; several more are actively pursuing the idea
- Administration has released proposed rule that creates a process for approving state-sponsored importation plans

24

Restricting mid-year formulary changes

- Midyear formulary changes can trap consumers in a plan that—while suitable at the beginning of the year—is no longer a good fit
- Some changes are positive (e.g., addition of new generics) but others can reduce access and affordability
- Efforts to restrict formulary changes must be balanced
    - While appearing consumer-friendly, freezing formularies indefinitely can actually lead to higher prescription drug prices and costs

25

Cost-sharing caps

- High level of interest, particularly for insulin
- Understandably popular with patients facing high prescription drug costs
- However, have to be mindful that remaining cost will come back in form of higher premiums and cost-sharing down the road
- Also preserve status quo for drug companies that could reduce incentives for them to change their behavior

26

Drug companies have ideas, too

- REBATES!! ❤️
- Value-based purchasing: idea of paying for drugs based on how well they work rather than what the market will bear
  - However, there is no universal definition of value and developing one will not be easy
  - Limited to only a few drugs at this point
- Expand use of biosimilars
- Blame everyone else (see: PBMs)

27

OVERVIEW

- **Why are prescription drugs getting so much attention?**
- **Why is this issue so important to AARP?**
- **What solutions are on the table?**
- **<u>What's standing in our way?</u>**
- **What's next?**

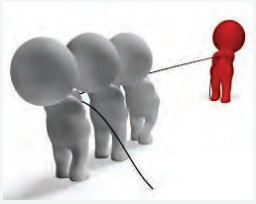
28

Current system is incredibly complicated

- Manufacturers hold a lot of power ("what the market will bear")
- Very fragmented system makes it extremely difficult to negotiate
  - "Squeezing the balloon"
- FDA's role is safety and efficacy—price is not a concern
  - Also does not compare drugs to existing therapies

29

Drug industry is an incredibly worthy adversary



- Drug lobby is well-funded and very effective
  - See: recent diversion of attention to pharmacy benefit managers… and insurers…and hospitals…and…
- Industry funding can make it difficult to figure out who's on "our side"
- Innovation/R&D and "it'd be a real shame…" messaging can be very effective with consumers and policy makers

30

OVERVIEW

- **Why are prescription drugs getting so much attention?**
- **Why is this issue so important to AARP?**
- **What solutions are on the table?**
- **What's standing in our way?**
- **What's next?**

31

What does the future hold?

- Really just a matter of waiting for the next source of outrage—and there will always be a next one
  - Hard to overstate how much is riding on drug company behavior over the next year or two
- High and growing drug prices will continue to draw attention as more people struggle to afford their medications

32

What's needed?

- Long-term, multi-pronged strategy
- Multi-stakeholder agreement on proposed solutions
  - Avoid "squeezing the balloon"
- Avoid creating "strange bedfellows"

33

What if nothing changes?

- The costs associated with prescription drugs are not sustainable for patients or payers
  - Reminder: this is an issue that consumers feel directly
- Efforts to reduce costs could save taxpayer-funded programs like Medicare and Medicaid billions of dollars
- Many patients will be unable to afford their prescription drugs if they do not receive some level of price relief

Innovation is meaningless if no one can afford to use it

34

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Blog: www.aarp.org/policyblog

35

INSULIN AFFORDABILITY IN WISCONSIN:

Consumer Experiences & Policy Recommendations

Governor‘s Task Force on Reducing Prescription Drug Prices

Gary Dougherty
Director, State Government Affairs
American Diabetes Association

July 22, 2020

INSULIN AFFORDABILITY

Insulin isn’t optional

INSULIN AFFORDABILITY

"I watched my parents struggle to afford the insulin my father needed to stay alive. The cost shouldn't impact someone's ability to maintain an acceptable quality of life"

J. H., Eau Claire

"I've lost my job twice in recent years. Both times I lost my health insurance. The first time, I had to go door to door with different doctors asking for insulin samples. (My husband and I) had to ask really difficult questions like 'Do we sell the house?' 'Do we skip meals to spend less on groceries?'"

D.W-R., Fitchburg

American Diabetes Association.

INSULIN AFFORDABILITY

"The cost of insulin is a real big part of my budget and is a hardship for me to afford on a limited income. This is legal robbery what the big pharmacy companies are doing to us."

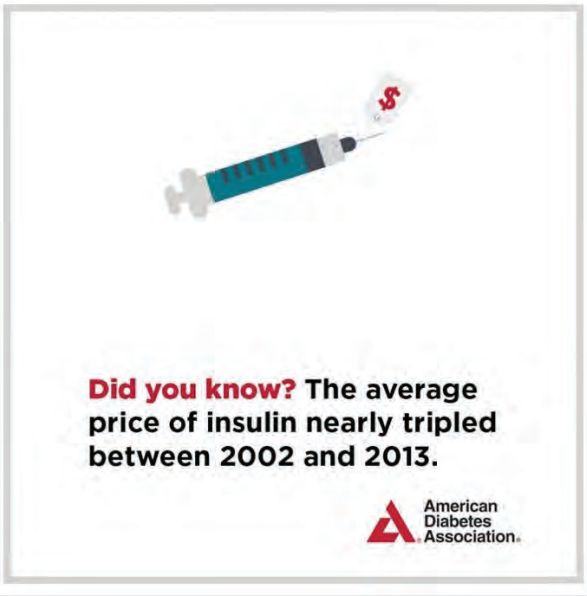
M.L., Milwaukee

"I just recently moved out on my own and often have had to choose between getting my insulin I need to survive and eating dinner. I shouldn't have to choose between staying alive and treating my incurable illness."

R.L., Oak Creek

American Diabetes Association.

INSULIN AFFORDABILITY



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INSULIN AFFORDABILITY

American Diabetes Association.

INSULIN AFFORDABILITY

- **439,000 adult Wisconsinites have diagnosed diabetes**

American Diabetes Association.

INSULIN AFFORDABILITY

- 439,000 adult Wisconsinites have diagnosed diabetes
- **135,000 more have diabetes, but don't know it**

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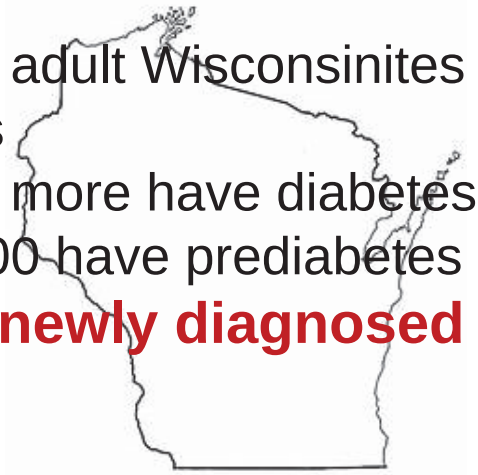
INSULIN AFFORDABILITY

- 439,000 adult Wisconsinites have diagnosed diabetes
- 135,000 more have diabetes, but don't know it
- **1,560,000 have prediabetes**

American Diabetes Association.

INSULIN AFFORDABILITY



- 439,000 adult Wisconsinites have diagnosed diabetes
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- **34,000 newly diagnosed each year**

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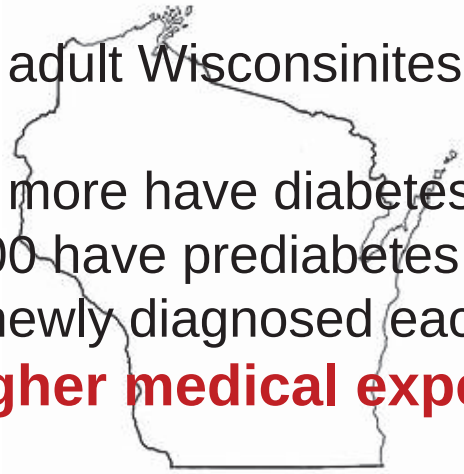
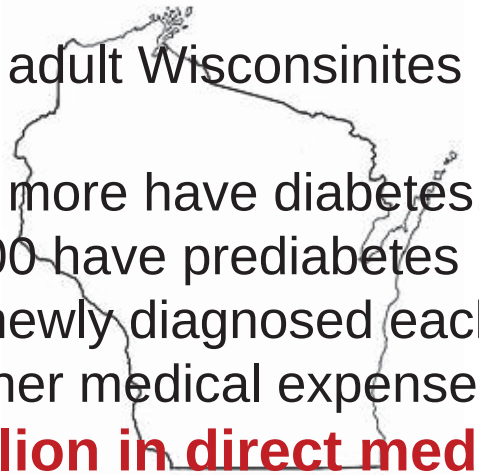
INSULIN AFFORDABILITY



- 439,000 adult Wisconsinites have diagnosed diabetes
- 135,000 more have diabetes, but don't know it
- 1,560,000 have prediabetes
- 34,000 newly diagnosed each year
- **2.3x higher medical expenses**

American Diabetes Association.

INSULIN AFFORDABILITY



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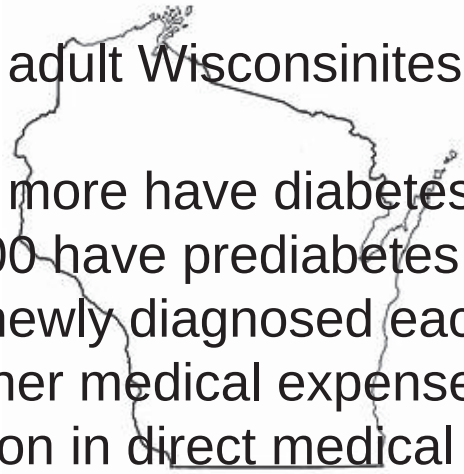
- **$4.1 billion in direct medical expenses**

American Diabetes Association.

INSULIN AFFORDABILITY



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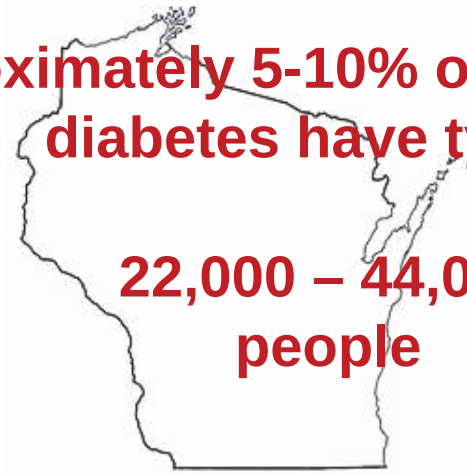
- 135,000 more have diabetes, but don't know it
- 1,560,000 have prediabetes
- 34,000 newly diagnosed each year
- 2.3x higher medical expenses
- $4.1 billion in direct medical expenses
- **$1.4 billion in indirect medical expenses**

American Diabetes Association.

INSULIN AFFORDABILITY



Approximately 5-10% of people with diabetes have type 1

22,000 – 44,000 people

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INSULIN AFFORDABILITY

#ConnectedForLife

Our Mission:

To prevent and cure diabetes and to improve the lives of all people affected by diabetes

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INSULIN AFFORDABILITY

ADA Board of Directors resolution *(11/2016)*

- **Substantially increase transparency in pricing**
- **Ensure no person with diabetes is denied affordable access to insulin.**
- **Congressional hearings to identify the reasons for the increases in insulin prices and to ensure that all people who use insulin have affordable access.**

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American Diabetes Association.

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STAND UP FOR
AFFORDABLE INSULIN

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Summary of Key Conclusions:

- The current pricing and rebate system encourages high list prices.
- There is a lack of transparency throughout the insulin supply chain.
- People with diabetes are financially harmed by high list prices and high out-of-pocket costs.
- Patient medical care can be adversely affected by formulary decisions.
- The regulatory framework for development and approval of biosimilar insulins is burdensome for manufacturers.

Insulin Access and Affordability Working Group: Conclusions and Recommendations

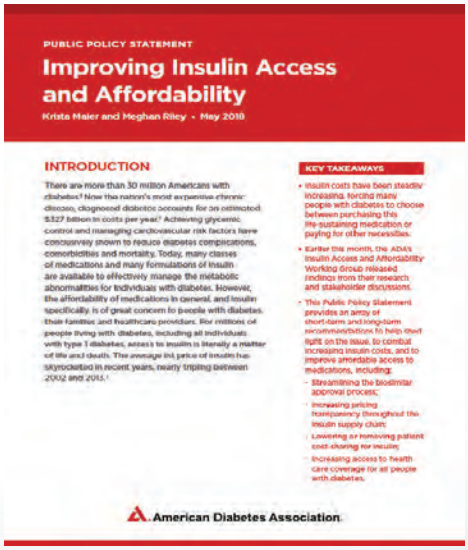
https://care.diabetesjournals.org/content/diacare/41/6/1299.full.pdf

American Diabetes Association.

INSULIN AFFORDABILITY

Summary of Key Recommendations:

- Increase pricing transparency throughout the insulin supply chain.
- Lower or remove patient cost-sharing for insulin.
- Streamline the biosimilar approval process.
- Increase access to health care coverage for all people with diabetes.



PUBLIC POLICY STATEMENT

Improving Insulin Access and Affordability

Krista Maier and Meghan Riley • May 2018

INTRODUCTION

KEY TAKEAWAYS

American Diabetes Association.

https://www.diabetes.org/sites/default/files/2019-10/insulin-affordability-one.pdf

American Diabetes Association.

INSULIN AFFORDABILITY

American Diabetes Association.

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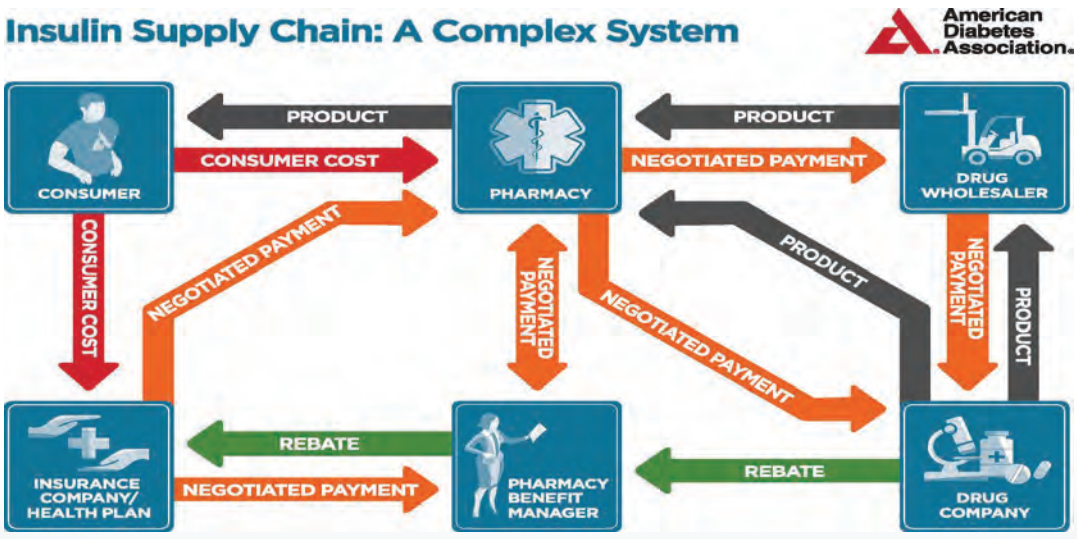

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How much does a vial of insulin cost?

American Diabetes Association.

INSULIN AFFORDABILITY

How much does a vial of insulin cost?

± $300

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How much does it cost to manufacture a vial of insulin?

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INSULIN AFFORDABILITY

How much does it cost to manufacture a vial of insulin?

$3.69 - $6.16

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Why is the cost of insulin so high?

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Why is the cost of insulin so high?

- Lack of transparency

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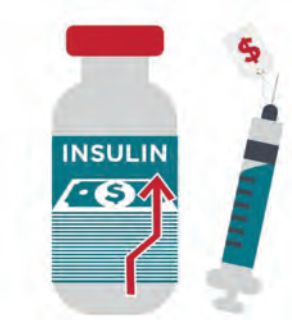
Why is the cost of insulin so high?



- Lack of transparency
- **Current pricing and rebate system**

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Why is the cost of insulin so high?

- Lack of transparency
- Current pricing and rebate system
- **No real competition**

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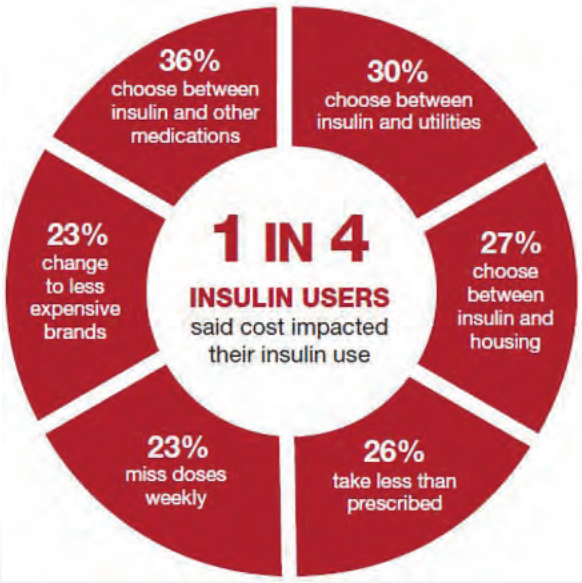

http://main.diabetes.org/dorg/PDFs/2018-insulin-affordability-survey.pdf

American Diabetes Association.

INSULIN AFFORDABILITY

www.insulinhelp.org

If you're struggling to pay for insulin, ADA can help. We've consolidated all the resources you need so that you can find help, fast.

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States are NOT waiting for the federal government to act

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Colorado Governor Jared Polis signing “first-in-the-nation” insulin co-pay cap bill into law.

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COLORADO - $100 cap
ILLINOIS - $100 cap
NEW MEXICO – $25 cap
MAINE – $35 cap
WEST VIRGINIA – $100 cap
UTAH – $30 cap
WASHINGTON – $100 cap
NEW YORK – $100 cap
VIRGINIA - $50 cap

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Wisconsin

SB 340
Sen. Dave Hansen

AB 411
Rep. Jimmy Anderson

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Common Questions

- **Why insulin and not other medications?**

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INSULIN AFFORDABILITY

Common Questions

- Why insulin and not other medications?
- **Won’t a cap result in higher premiums?**

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Legislative Recommendations:

- **Ensure access to adequate and affordable health insurance**
- **Require transparency throughout the insulin supply chain**
- **Lower or remove patient cost-sharing for insulin**
  - **Cap co-pays for insulin**
  - **Exempt insulin from the deductible**

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Legislative Recommendations:

- **Ensure value of co-pay assistance programs apply toward a patient's deductible**

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#EveryDayReality

- **More than 34 million Americans have diabetes**
- **Nearly 7 million of them rely on insulin**
- **Average price of insulin has nearly tripled between 2002-2013**
- **One in four are using less insulin than prescribed due to high costs**

American Diabetes Association.

American Diabetes Association®

Introduction to Vivent Health for the Governor's Task Force on Reducing Prescription Drug Prices

Bill Keeton, Vice President and Chief Advocacy Officer

Today's Discussion

- Status of HIV in Wisconsin
- What is Vivent Health?
- Who do we serve?
- What are our outcomes?
- How does the 340B program help us serve more patients, at a lower cost, with better outcomes?

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Status of HIV in Wisconsin

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HIV in Wisconsin

- Today, it is estimated there are about 9,000 people living with HIV in Wisconsin
- Annually, new HIV infections are down to about 225 from an historic high of 589 in the early 1990s
- HIV significantly impacts people and communities of color – people of color account for 16% of the state's population but account for 66% of new cases
- People with HIV live longer, healthier lives in Wisconsin than any where else in the nation according to data from the Agency for Healthcare Research and Quality (US Dept. of Health and Human Services)
- More than 50% of people with HIV in Wisconsin are effectively managing their HIV, meaning their health is optimized and they are physiologically unable to transmit HIV to someone else

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What is Vivent Health?

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Vivent Health Overview

Leading National HIV Organization

- Nation's premier HIV Medical Home – integrating medical, pharmacy, dental, and mental health care with comprehensive social services
- 15 locations throughout Wisconsin, Colorado, Missouri and Texas
- 425+ staff
- $150 million budget
- 10,000 patients and clients
- 350,000+ HIV prevention contacts

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VIVENT HEALTH HIV MEDICAL HOME

ACCESS to Comprehensive, Integrated Care

MEDICAL

BEHAVIORAL HEALTH

PHARMACY

DENTAL

LEGAL

CASE MANAGEMENT

HOUSING

FOOD

Who do we serve?

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Vivent Health Patients and Clients

- More than 90% of Vivent Health patients and clients are living in poverty, below 200% of FPL leading to food, shelter and economic vulnerability
- More than 85% of Vivent Health patients have co-occurring chronic disease or mental health diagnoses along with their HIV
- More than 55% of Vivent Health patients are over the age of 45

Vivent Health services are available to anyone living with HIV or at-risk for HIV regardless of their ability to pay for their services or their insurance status. We are proud to provide the same high level of care to our patients and clients regardless of their race, ethnicity, gender identity, sexual orientation, or poverty status.

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What are our outcomes?

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Quality Outcomes

Patients	National Standard	Vivent Health 2019
With a suppressed viral load	81%	95%
Prescribed ARV treatment	91%	98%
With diabetes that is well managed	35%	48%
With controlled hypertension	57%	57%
With a lipid disorder and well controlled cholesterol	NA	76%

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Quality of Life Outcomes

Independent study conducted by the UW Center for Health Systems Research and Analysis found that Vivent Health patients have:

- 52% lower hospitalization
- 48% lower unnecessary use of the emergency room
- 10% shorter hospital stays

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Finance Outcomes

Wisconsin taxpayers and health consumers **save approximately $12 million annually** in costs due to patients being cared for at the Vivent Health HIV Medical Home achieving high quality health outcomes

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How does the 340B program help us serve more patients, at a lower cost, with better outcomes?

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Quick 340B Overview

- The 340B program was established by Congress:
  - as a part of the Veterans Health Care Act of 1992;
  - as a way to provide relief to safety net providers for high drug prices;
  - in order to help such providers stretch scarce federal resources as far as possible, to reach more vulnerable patients, and deliver more comprehensive services; and
  - ***With no financial impact to tax payers.***

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Quick 340B Overview

The 340B Program:

- is administered by the Office of Pharmacy Affairs within the Health Resources and Services Administration of HHS
- has strict eligibility, reporting and compliance requirements that are in place to prevent fraud and abuse of the program and that come with significant penalties
- has received significant attention from Congress in recent years, but has not been changed due to overwhelming support and need

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Quick 340B Overview

As previously stated, the 340B program does not cost taxpayers anything. Instead, the program:

- generates **savings** that safety net providers are **required** to re-invest in critically needed programs and services for patients

340B savings are regulated:

- 340B safety net providers like Vivent Health must use the savings in limited ways aligned with their mission or grant funding

340B safety net providers are constantly engaged in self-audits and compliance work to ensure program integrity, often at significant cost

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How Does Vivent Health use 340B Savings

Ensuring Access to Health Care for All:

- Government programs often contain eligibility and program limitations that prevent Vivent Health from reaching everyone regardless of their ability to pay – **340B allows us to provide health care to everyone**
- Government grants are limited in scope and financial support, even when they work well. Vivent Health uses 340B savings to:
  - **keep our dental clinics in Madison and Green Bay open**;
  - **keep mental and behavioral health services operating in smaller communities** throughout Wisconsin;
  - **doubling the amount of food our pantries provide to clients;**

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How Does Vivent Health use 340B Savings

Ensuring Access to Medications:

- Even with patient assistance programs, specific medication access programs and other assistance, often times people living with HIV cannot afford their medications. **340B savings are used to ensure that ability to pay does not limit access to medicine**.

- ***Every Vivent Health patient who needs medications will receive them, every time they need them.***

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How Does Vivent Health use 340B Savings

Delivering the care people with HIV need:

- Grant funding and reimbursement revenue does not cover the costs of our comprehensive, integrated model of care. 340B savings allow us to
  - accommodate **high acuity patients who need enhanced levels of care**;
  - provide **dedicated adherence counseling**;
  - offer **clinical pharmacy services**; and
  - accommodate unforeseeable funding interruptions like **COVID-19 without interrupting patient care**

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Ryan White Clinics 340B for 340B Access

DISCRIMINATORY REIMBURSEMENT

A SERIOUS DANGER TO THE SAFETY NET & PUBLIC HEALTH

PREPARED FOR THE WISCONSIN GOVERNOR'S TASK FORCE ON REDUCING PRESCRIPTION DRUG PRICES

PEGGY TIGHE, J.D., PRINCIPAL POWERS LAW & RWC-340B

PEGGY TIGHE, J.D., PRINCIPAL, POWERS LAW & RWC-340B

- Nearly 30 years in government relations in Washington D.C.
- Practice focuses on patients, providers, and hospitals and health systems.
- Lead legislative strategist for Ryan White Clinics for 340B Access (RWC-340B).
  - National organization of HIV/AIDS medical providers receiving support under the Ryan White CARE Act.
  - The CARE Act provides funding for services primarily to poor and/or uninsured people with HIV/AIDS.
  - Ryan White providers are eligible to participate in the federal 340B Drug Discount Program, which enables them to expand and support care.
- Focus on legislative work and advocacy with Congress and State Legislatures
- Recently testified before Tennessee Senate on Discriminatory Reimbursement.

WHO ARE 340B SAFETY NET PROVIDERS?

- The 340B program is one of the most effective means of providing drug discounts to those most in need….at no cost to federal or state taxpayers.

- 340B safety net providers are defined in federal statute and include not-for-profit Ryan White Clinics, Community Health Centers, children's and cancer hospitals, hospitals that care for more Medicaid and Medicare patients (DSH) hospitals, State AIDS Drug Assistance programs, hemophilia treatment centers, and other safety net providers.

WHAT IS DISCRIMINATORY REIMBURSEMENT?

- Discriminatory reimbursement refers to the growing practice among pharmacy benefit managers (PBMs), other third party payers, and some manufacturers who…
  1. offer 340B safety net providers and their in-house or contract pharmacies lower reimbursement rates than those offered to non-340B entities;
  2. establish 340B-specific barriers to participating in payer's pharmacy network;
  3. exclude 340B safety net providers' pharmacies from pharmacy networks entirely;
  4. determine by drug which drugs it will offer as 340B; and/or
  5. create a "voluntary" reporting scheme that would undermine the safety net's ability to receive drugs at 340B prices.

FEDERAL GOVERNMENT ON DISCRIMINATORY REIMBURSEMENT

- Health Resources and Services Administration (HRSA), which administers the 340B program, has gone on record expressing its concern…
  - "if covered entities were not able to access resources freed up by the drug discounts when they…bill private health insurance, their programs would receive no assistance from the enactment of section 340B and there would be no incentive for them to become covered entities." HRSA (July 2005)
  - "By pursuing [a discriminatory reimbursement] policy, insurers may make it cost prohibitive for certain safety net providers to participate in the 340B program and reduce services to their patients." Letter from J. Somsak, Associate Administrator, Health Systems Bureau, HRSA (12/22/11)

RESPONSE FROM THE SAFETY NET

- Safety net providers participating in the 340B program are united in belief that discriminatory reimbursement undermines purpose of 340B program by
  - effectively transferring financial benefit of the program to non-340B PBM or payer;
  - reducing safety net providers' resources to care for needy patients; and
  - increasing costs to taxpayers

- For Ryan White Clinics (RWCs) – who are on the front lines of the pandemic and fighting to end the HIV/AIDS epidemic – Discriminatory Reimbursement is especially devastating.

EXAMPLES OF DISCRIMINATORY ACTIONS PBMS AND INSURERS

PBMS AND INSURERS

- PBM manuals, policy statements stating specifically that 340B entities will be treated differently than non-340B entities.
- Proposed contracts for pharmacy services noting that 340B entities will be paid a new contract term that is exactly less the 340B discount from the previous year or significantly reduced reimbursements.
- Contract terminations specific to 340B providers not noting any cause
- Exclusions from provider networks or forcing all 340B entities into 340B-only networks.

EXAMPLES OF DISCRIMINATORY ACTIONS: MANUFACTURERS MERCK

- July 6: Merck asked 340B providers to submit information for all its products purchased under 340B to a web-based platform, requires incredibly burdensome uploading of information on a weekly basis.
- Merck said that failure to submit data would require them to take steps that are "less collaborative, and substantially more burdensome."
  - Safety net providers expect "penalty" for not signing up to be..
    - Manufacturers will refuse to pay wholesalers the difference in the price wholesalers paid and the 340B price.
  - Impact: Removes wholesalers from 340B sales, they won't participate at a loss. Effectively removes benefit of the 340B program from the safety net.

EXAMPLES OF DISCRIMINATORY ACTIONS: MANUFACTURERS ELI LILLY

- Within 24 hours of Merck's announcement, Eli Lilly announced that it will no longer provide 340B-priced Cialis to contract pharmacies.
- Dangerous precedent for 340B program as any drug manufacturer could unilaterally decide to remove any 340B drug from contract pharmacies.
- Announcement posted on HRSA website.
- Challenge to HRSA regulatory authority. "There is no statutory obligation to provide 340B priced product to contract pharmacies," according to Lilly FAQs.
- Causes uproar among 340B Covered Entities, including serious discussions about lawsuits.

EXAMPLES OF DISCRIMINATORY ACTIONS: MANUFACTURERS ELI LILLY

> Effective, July 1, 2020, Lilly is limiting distribution of 340B ceiling price product of these Cialis formulations directly to covered entities and their child sites only. Contract pharmacies will not be eligible to receive these formulations of Cialis at the 340B ceiling price. Any contract pharmacy orders placed with a wholesaler as of June 30 will be honored. Covered entities that do not have an in-house pharmacy may contact 340B@lilly.com regarding the exception process to designate a contract pharmacy location.

STATE PROHIBITIONS ON DISCRIMINATORY REIMBURSEMENT

- Laws enacted in West Virginia, Minnesota, Montana, Oregon, Rhode Island, South Dakota, and Utah.
- Georgia Recently Passed Pro-340B Prohibition on Discriminatory Reimbursement, Legislation Awaiting Governor's Signature
- Stalled Legislation: Tennessee, Florida
  - Tennessee Advances Template Resolution for State Legislatures
- PBM Reform: Moving Vehicle for Discriminatory Reimbursement

STATE LAWS PROHIBITING DISCRIMINATORY REIMBURSEMENT

	West Virginia SB 489	Minnesota SF278	Montana SB 335	Oregon HB 2185	South Dakota HB 1137	Utah SB 138	Georgia HB 946
Enacted into law	Feb. 26, 2019	July 26, 2019	April 30, 2019	July 15, 2019	March 7, 2019	March 28, 2020	July 2, 2020
General 340B nondiscrimination provision	√	√	√	√	√	√	√
Protects all types of 340B safety net providers from discriminatory arrangements	√	√	√	√	√	√	√
Prohibits discriminatory arrangements by PBMs and third party payors	√	X (Exempts managed care contracts)	√	X (Prohibits only PBMs from such practices)	X (Prohibits only PBMs from such practices)	X	X (Prohibits only PBMs from such practices)
Specifically prohibits charge-backs or other adjustments based on 340B eligibility	√	X	X	X	X	√	√
Prohibits discrimination that interferes with the patient's choice to receive drugs from a 340B entity	√	X	X	X	X	√	X

340B STATE OPPORTUNITIES: GEORGIA PENDING LAW

(b) On and after July 1, 2021, a pharmacy benefits manager shall not:

(1) Discriminate in reimbursement, assess any fees or adjustments, or exclude a pharmacy from the pharmacy benefit manager's network on the basis that the pharmacy dispenses drugs subject to an agreement under 42 U.S.C. Section 256b; or

(2) Engage in any practice that:

(A) In any way bases pharmacy reimbursement for a drug on patient outcomes, scores, or metrics; provided, however, that nothing shall prohibit pharmacy reimbursement for pharmacy care, including dispensing fees from being based on patient outcomes, scores, or metrics so long as the patient outcomes, scores, or metrics are disclosed to and agreed to by the pharmacy in advance;

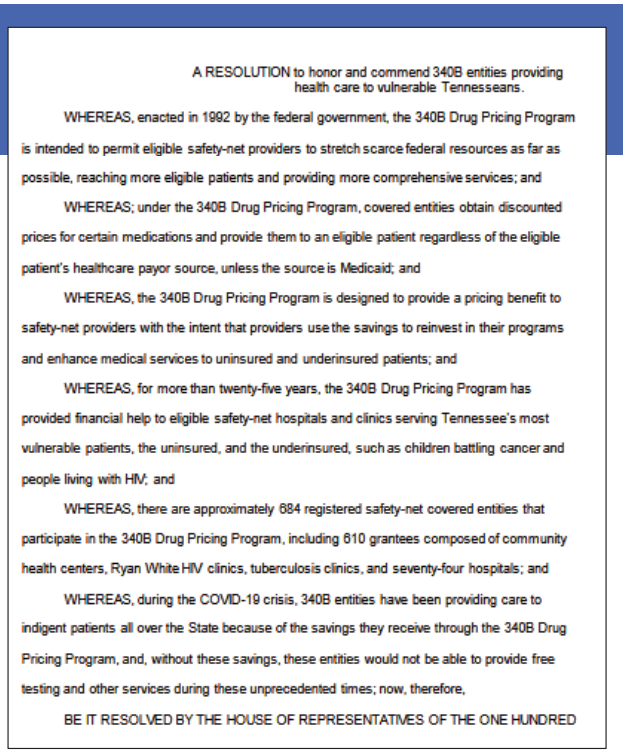
(B) Includes imposing a point-of-sale fee or retroactive fee; or

(C) Derives any revenue from a pharmacy or insured in connection with performing pharmacy benefits management services; provided, however, that this shall not be construed to prohibit pharmacy benefits managers from receiving deductibles or copayments.

(c) This Code section shall also apply to pharmacy benefits managers' reimbursements to dispensers."

TN STATE RESOLUTION ON 340B

- 340B is regulated at the federal level and has not been on the minds of state policy-makers until recently.
- Focus on educating Legislators on the federal 340B program, that is now in play in many state legislatures.
  - Advancing bills
  - Introducing resolutions
  - Testimony
  - Coalition-building



A RESOLUTION to honor and commend 340B entities providing health care to vulnerable Tennesseans.

WHEREAS, enacted in 1992 by the federal government, the 340B Drug Pricing Program is intended to permit eligible safety-net providers to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services; and

WHEREAS; under the 340B Drug Pricing Program, covered entities obtain discounted prices for certain medications and provide them to an eligible patient regardless of the eligible patient's healthcare payor source, unless the source is Medicaid; and

WHEREAS, the 340B Drug Pricing Program is designed to provide a pricing benefit to safety-net providers with the intent that providers use the savings to reinvest in their programs and enhance medical services to uninsured and underinsured patients; and

WHEREAS, for more than twenty-five years, the 340B Drug Pricing Program has provided financial help to eligible safety-net hospitals and clinics serving Tennessee's most vulnerable patients, the uninsured, and the underinsured, such as children battling cancer and people living with HIV; and

WHEREAS, there are approximately 684 registered safety-net covered entities that participate in the 340B Drug Pricing Program, including 610 grantees composed of community health centers, Ryan White HIV clinics, tuberculosis clinics, and seventy-four hospitals; and

WHEREAS, during the COVID-19 crisis, 340B entities have been providing care to indigent patients all over the State because of the savings they receive through the 340B Drug Pricing Program, and, without these savings, these entities would not be able to provide free testing and other services during these unprecedented times; now, therefore,

BE IT RESOLVED BY THE HOUSE OF REPRESENTATIVES OF THE ONE HUNDRED

http://www.capitol.tn.gov/Bills/111/Bill/HR0359.pdf

WHY PROHIBITIONS ON DISCRIMINATORY REIMBURSEMENT ARE NECESSARY

- Manufacturers are required by federal law to provide these discounts to the safety net, 42 U.S.C 256b.
- Manufacturers are finding ways to avoid this responsibility to provide discounts on drugs to safety net providers.
- Manufacturers were unsuccessful in trying to shrink the 340B program in Congress (2017-present), why should they be permitted to do it through those with whom they contract (PBMs and insurers), through state legislative action, or by their own actions?
- 340B discounts represent just over 2% of overall drug company revenues (American Hospital Association and 340BHealth).

WHY PROHIBITIONS ON DISCRIMINATORY REIMBURSEMENT ARE NECESSARY

- The 340B program is one of the most effective means of providing drug discounts to those most in need….at no cost to federal or state taxpayers.
- Threatening, or not protecting this program, represents the OPPOSITE of tackling rising drug prices.
- Now, more than ever, the safety net is doing what it is meant to do – protect public health.
- Ryan White Clinics will not only be able to help their vulnerable patients through the pandemic, but may also be irreparably harmed in their fight to end the HIV/AIDS epidemic if these practices are allowed to continue.

RWC340B Talking Points on Discriminatory Reimbursement

MAIN ASK: PLEASE PROTECT THE SAFETY NET FROM DISCRIMINATORY REIMBURSEMENT

We call on states to protect the safety net by prohibiting manufacturers or their agents from shrinking the discounts provided to the safety net through the 340B program.

Thank you for the Opportunity to Present.

Questions?

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STATE OF WISCONSIN
GOVERNOR'S TASK FORCE ON
REDUCING PRESCRIPTION DRUG PRICES

GOVERNOR'S TASK FORCE ON REDUCING PRESCRIPTION DRUG PRICES

August 25, 2020

10:00 a.m. – 2:00 p.m.

I. Welcome
- **Nathan Houdek, Deputy Commissioner, Office of the Commissioner of Insurance**

II. Consumer Experience

III. Policy Discussion
- **All Task Force Members**

IV. Closing Remarks and Next Steps
- **Nathan Houdek, Deputy Commissioner, Office of the Commissioner of Insurance**

V. Adjourn

Meeting Minutes
August 25, 2020
10 a.m. – 2 p.m.
Webinar via Zoom

Welcome
Nathan Houdek, OCI Deputy Commissioner and Task Force chair

- Key housekeeping items
  - A reminder that this is a public meeting.
  - Task Force members will have use of their microphones; the public does not.

Consumer Experience
Annette Huston, a registered nurse in Stevens Point, Wisconsin, was diagnosed in 1995 with multiple sclerosis (MS). It is a progressive disease that has no cure but can be slowed with medication.

- Ms. Huston stated that she has "great insurance" through her spouse. She pays about $500 out-of-pocket for medications that are specific to different symptoms. She takes two specific MS medications to slow the progress of the disease. These two prescriptions cost over $100,000 a year, of which she pays around $700 to $800 per year out-of-pocket with insurance.
- The MS medications that she takes to slow the progression of this disease are not on the Medicare formulary and in a couple of years she fears she will have to stop those medications because the costs are so burdensome as to make them inaccessible.

Policy Discussion: Overview
Deputy Commissioner Nathan Houdek – Chair

- Deputy Commissioner Houdek facilitated the discussion of the policy recommendations and options. A presentation is available on the Task Force website: https://rxdrugtaskforce.wi.gov/Documents/08252020RXTFMtg.pdf
- The provisions in AB114/SB100 will be included in the report. The structure of the Task Force Report to the Governor will be divided into three tiers.
- Tier 1 - Recommendations that have strong support from the majority of members.
- Tier 2 - Policy options that have been discussed but which have some concern or opposition from members.
- Tier 3 - Newer topics that have not had extensive discussions.
  - The final report will include additional explanations for each recommendation as well as rational and policies in other states. The report will not include specific legislative language or operationalizing of the recommendations. The report will include all comment letters in the final report which will be helpful for the governor and his staff.

Policy Discussion: Tier 1 – Majority Support

- AB114/SB100 – should move forward in the next legislative session and will be included as recommendations in the final report.

- Access the policy discussion power point document for a full list of Tier 1 recommendations: https://rxdrugtaskforce.wi.gov/Documents/08252020RXTFMtg.pdf
  Discussion:
  - A physician member of the task force stated that it would be ideal to know total costs to the system as well as patient out-of-pocket costs to make a more informed decision.
  - Another member stressed that it needs to be integrated into electronic health records for it to be used effectively.
- Establish a copay cap for insulin
  Discussion:
  - A member mentioned that the insulin should be limited to the preferred based on the formulary, not for all medications labeled insulin.
  - What is the copay cap? Will it be set at $100? Chairperson stated that the cap would be set by legislators to make a final decision.
  - Why choosing insulin when there might be other diseases/prescriptions that are more burdensome? The numbers of people using insulin and the fact that many insurers already have a cap make this option more viable.
  - Does this ultimately increase premium costs? In Colorado, after a year with an insulin copay cap, they didn't find an increase in premiums. The task force continues to balance reducing overall costs at a macro level with providing relief at a micro (individual) level, which are often in opposition to one another.
- Additional transparency and reporting requirements
  Discussion:
  - Because the system is currently opaque, additional information could lead to further cost-saving avenues in the future.
  - A member stressed that additional reporting requirement could put undue stress on parts of the pharmacy supply chain that are already understaffed.
  - What are the meaningful reporting items? A member raised the Wisconsin Hospital Association example which requires cost reporting on makes pricing information publicly available on the price-point and check-point websites.
- Additional oversight and regulation of PSAOs
- DATCP and DOJ – additional staff to focus on the pharmaceutical industry anti-trust cases
- Enhance support for free and charitable clinics (FCCs)
  - Additional state funding
  - Centralized repository to increase coordination and efficiency. Looking at a model in Iowa.
  - Allow for donated medications from other states to be received by Wisconsin FCC pharmacies
  - Allowing volunteering in free and charitable clinics to count toward continuing education credits for pharmacists
- Ensure that critical access hospitals and Ryan White Clinics participating in 340B drug discount programs can reinvest savings from drug purchases into patient care and support activities.

Discussion:
- There is considerable concern about how 340B programs impact discounts on commercial plans.
- What can we do to make sure that the entities are using this program as it was intended?
- The program has expanded in recent years and how can the program be limited and refocused so that it targets what it was intended to do? Many organizations that use 340B program attest to its rigid reporting and eligibility requirements. Others say that it is not being used as intended in many cases.

Policy Discussion: Tier 2 – Other Policy Options for Consideration

- Require that manufacturer prescription drug discount coupon payments be applied to deductibles and annual maximum out-of-pocket costs (when no generic is available).
  Discussion:
  - Concern from members that coupons ultimately drive up costs
- Create a prescription drug affordability/accountability review board to establish prescription drug spending targets for public sector entities
  Discussion:
  - Argue that this policy grows out of the need for transparency and ensuring that pricing decisions made by manufacturers are reasonable
  - Hope that the board will work toward lowest net cost
  - Drug affordability boards that simply cap drug costs could cause unintended consequences (i.e. if a state and manufacturer couldn't agree, would it preclude that medication being used in that state?)
- Allow importation of prescription medication from Canada or other approved countries
  Discussion:
  - Member would like to clarify that importation is not "up and running" in other states; do not have federal approval
- Focus administration of specialty drugs in lower-cost settings
  Discussion:
  - Part of total cost of care and being administered in a home setting can hopefully lower costs
  - Many task force members expressed wanting to ensure drugs are administered in safe settings
  - Further consideration between insurers and providers
- Additional reporting and oversight of the federal 340B drug discount program
- Develop best practice guidelines for PBM business practices
  - Create guidelines and resources related to rebate passthrough
- Enhance public awareness of pharmaceutical manufacturer patient assistance programs
  Discussion:
  - What can we do to make people aware of patient assistant programs: https://medicineassistancetool.org/ There is a website that PhRma has established.

From OCI perspective, promote private sector programs worth looking at and considering.

Policy Discussion: Tier 3 – Recent additions/other issues

- Licensure and regulation of pharmaceutical sales representatives
  Discussion:
  - Currently, this is under federal oversight – representatives cannot say anything that's not approved by FDA
  - Argue that this would place personal responsibility at the ground level similar to realtors, attorneys, etc.
  - Model law that has come out and will likely be a discussion in the future
- Additional disclosure for physicians and other health care providers that accept gifts or honoraria from pharmaceutical companies
  - Exists at the federal level.
- Additional regulatory oversight (licensure or regulation) of PBM brokers and consultants
- Require PBMs to act as a fiduciary on behalf of their plan sponsors
- Permanent expansion of pharmacist responsibilities for free & charitable clinics consistent with the expansion allowed during the COVID pandemic.
- Allow the state Department of Justice (DOJ) to have direct Civil Investigative Demand authority without seeking court authority each time – antitrust cases
- Create a dedicated health care fraud division within DOJ
  Discussion:
  - Having pharmaceutical experts at DOJ would be very helpful
- Additional restrictions on improper prescription drug marketing and advertising practice
- Create an insulin safety net program (similar to Minnesota)
- Create a value-based pilot project for diabetes medications

Closing Remarks

- Deputy Commissioner Houdek thanked the Task Force members for their time commitment and active engagement over the past few months.
- He also stated that this will be the last scheduled Task Force meeting for calendar year 2020, but the Task Force may convene again in 2021 to discuss issues raised during the biennial state budget process, the legislative session, or relating to a COVID-19 vaccine.

Adjourn

STATE OF WISCONSIN

GOVERNOR'S TASK FORCE ON REDUCING PRESCRIPTION DRUG PRICES

Policy Discussion: Overview

Overview

This document highlights recommendations and other policy options anticipated to be included in the September Task Force report to the Governor and serves as a framework for that report. Recommendations and other policy options for consideration will be divided into the AB 114/SB 100 provisions and three additional tiers, representing the varying levels of Task Force support expressed at meetings. The final report will include additional explanation for each recommendation, as well as the rationale for pursuing each. There will also be references to other state laws or descriptions of the possible direction(s) recommendations may take; offered as a means to help conceptualize the recommendations. The final report will not include proposed legislative language or specific detail related to operationalizing each recommendation. To ensure all viewpoints are reflected and appropriately acknowledged, comment letters from interested parties and the public will be included in the appendix of the report. Task Force members are also welcome to submit additional comments for inclusion with the report.

The charge of this Task Force, as outlined in Executive Order #39

- *The Task Force shall advise and assist the Governor in addressing excessive prescription drug prices and the financial burden that prescription drug prices place on Wisconsin residents. The Task Force shall do the following:*
  - *Gather and analyze data and information relating to the development, pricing, distribution, and purchasing of prescription drugs.*
  - *Review actions already taken by Wisconsin and other states to reduce prescription drug prices.*
  - *Identify opportunities to coordinate with other states and the federal government.*
  - *Recommend potential actions, which may include legislative, legal, regulatory, or community-based strategies, that can be taken to reduce prescription drug prices in Wisconsin.*
  - *The Task Force shall issue a report to the Governor on or before December 31 of each year summarizing the work completed by the Task Force and recommending potential action items to reduce the price of prescription drugs in Wisconsin.*

Policy Discussion: Policy Proposals with Majority Support

The following are policy proposals that will likely be included as recommendations in the report to the Governor based on discussions to-date and on majority support of Task Force members.

- **Major provisions included in 2019 AB 114/SB 100 (as amended)**
  - **Pharmacy Benefit Manager (PBM) rebate transparency**
  - **PBM licensure**
  - **Prohibition on gag clauses**
  - **Lowest cost at point-of-sale**
  - **Prohibition on retroactive claim reduction**
  - **PBM auditing requirements and restrictions**
- **Advocate for federal regulatory changes to address practices that delay the market entry of affordable generic equivalents and other market practices identified as drivers of prescription drug unaffordability**
- **Create a public sector prescription drug purchasing entity to coordinate and leverage the buying power of state agencies and other public sector purchasers (building off the work of the state Pharmacy Cost Study Committee)**
  - **This entity could explore other potential partnerships with a focus on helping Wisconsin residents access lower-cost prescription medications. One option would be to explore the creation of a prescription drug discount card program to offer access to discounted prescription medications for all eligible Wisconsin residents (similar to the Northwest Prescription Drug Consortium). Another option would be to consider a partnership with an organization like CivicaRx to directly purchase lower-cost medications.**
- **Explore and support efforts to improve physician access to real-time patient pharmacy benefit information to allow physicians to take out-of-pocket costs into consideration when prescribing medications**
- **Establish a co-pay cap for insulin**
- **Additional transparency and reporting requirements for prescription drug supply chain entities to better understand the drivers of high-cost prescription drugs and inform future policymaking**

Policy Discussion: Policy Proposals with Majority Support

- **Additional regulatory oversight (including potential licensure or registration) of Pharmacy Services Administrative Organizations (PSAOs)**
- **Enhance consumer protection oversight and hire more anti-trust attorneys to focus on improper pharmaceutical industry practices**
- **Enhance support for Wisconsin's free & charitable clinics & pharmacies (FCCPs)**
  - **Provide additional state funding for FCCPs (consider requiring a percentage of settlement funds from pharmaceutical industry lawsuits to be directed to FCCPs)**
  - **Create a centralized repository for donated medications and improve real-time inventory coordination across the statewide FCCP network**
  - **Allow interstate transfer ability so FCCPs can accept donated and approved medications from other states**
  - **Allow a percentage of continuing education requirements for pharmacists to be dedicated towards volunteerism to provide additional staff support for FCCPs**
- **Ensure that Federally Qualified Health Centers and Ryan White HIV/AIDS programs participating in the 340B drug discount program are able to reinvest savings from drug purchases into patient care and support activities**

Other Policy Options for Consideration

The following are policy proposals that have been raised and discussed, to some extent, throughout the work of the Task Force since the first meeting in November 2019. These proposals are not necessarily Task Force recommendations; however, these proposals may merit further discussion and consideration outside of the work of the Task Force. Also, of note, at least one Task Force member has expressed support for each of these proposals, while others have expressed concern or opposition. Including these proposals is also important for meeting the requirement to summarize the work of the Task Force, as directed by Executive Order #39.

- **Require that manufacturer prescription drug discount coupon payments be applied to deductibles and annual maximum out-of-pocket costs, if no generic exists or where a generic exists but the beneficiary obtained access to the prescribed drug after undergoing prior authorization, step therapy, or the insurer's exceptions and appeals process. Also require insurers to include a consumer disclosure with plan information making it clear the circumstances under which a manufacturer coupon applies to plan deductibles and the annual limitation on cost sharing.**
- **Create a prescription drug affordability/accountability review board to establish prescription drug spending targets for public sector entities**
- **Allow importation of prescription medication from Canada or other approved countries**
- **Focus administration of specialty drugs on lower-cost settings**
- **Additional reporting and oversight of the federal 340B drug discount program**
- **Develop best practice guidelines for PBM business practices**
- **Enhance public awareness of pharmaceutical manufacturer patient assistance programs**

Issues Raised but Not Thoroughly Discussed/Recent Additions

The following are policy proposals that were raised by Task Force members for potential consideration. However, the Task Force did not have time to discuss these items, so they are being included with acknowledgement that more analysis would be needed to determine if they merit favorable consideration.

- **Licensure and regulation of pharmaceutical sales representatives**
- **Additional disclosure for physicians and other health care providers that accept gifts or honoraria from pharmaceutical companies**
- **Additional regulatory oversight (licensure or regulation) of PBM brokers and consultants**
- **Require PBMs to act as a fiduciary on behalf of their plan sponsors**
- **Permanent expansion of pharmacist responsibilities for free & charitable clinics consistent with the expansion allowed during the COVID pandemic. Also consider telepharmacy and making it easier to allow remote dispensing sites for free & charitable clinics, in particular the frequency of onsite inspections and the required location of the pharmacist**
- **Allow the state Department of Justice (DOJ) to have direct Civil Investigative Demand authority without seeking court authority each time**
- **Create a dedicated health care fraud division within DOJ**
- **Additional restrictions on improper prescription drug marketing and advertising practices**
- **Create an insulin safety net program**
- **Create a value-based pilot project for diabetes medications**

Accompanying Publication

Report of the Governor's Task Force on Reducing Prescription Drug Prices

State of Wisconsin

Governor's Task Force on Reducing Prescription Drug Prices

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