



STATE OF WISCONSIN

**GOVERNOR'S TASK FORCE ON
REDUCING PRESCRIPTION DRUG PRICES**

Wifi Network: matcguest

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

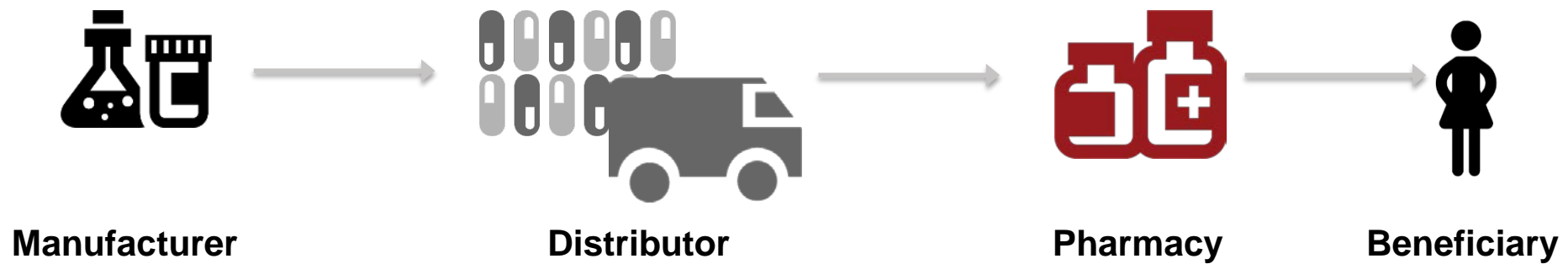
PBM Economics and New Models

1. PBM economics

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

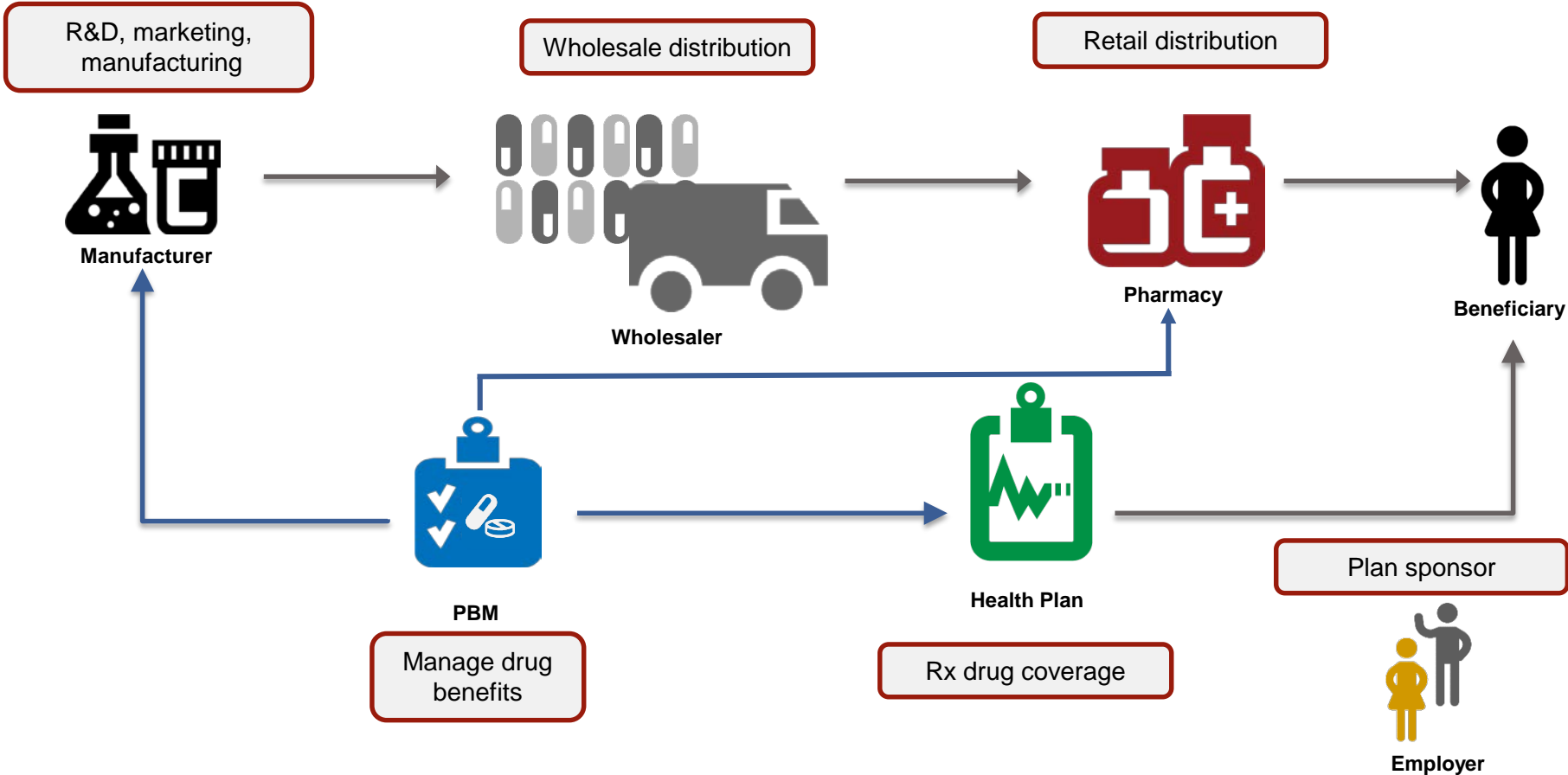
2. Subscription models for prescription drugs

Flow of prescription drugs

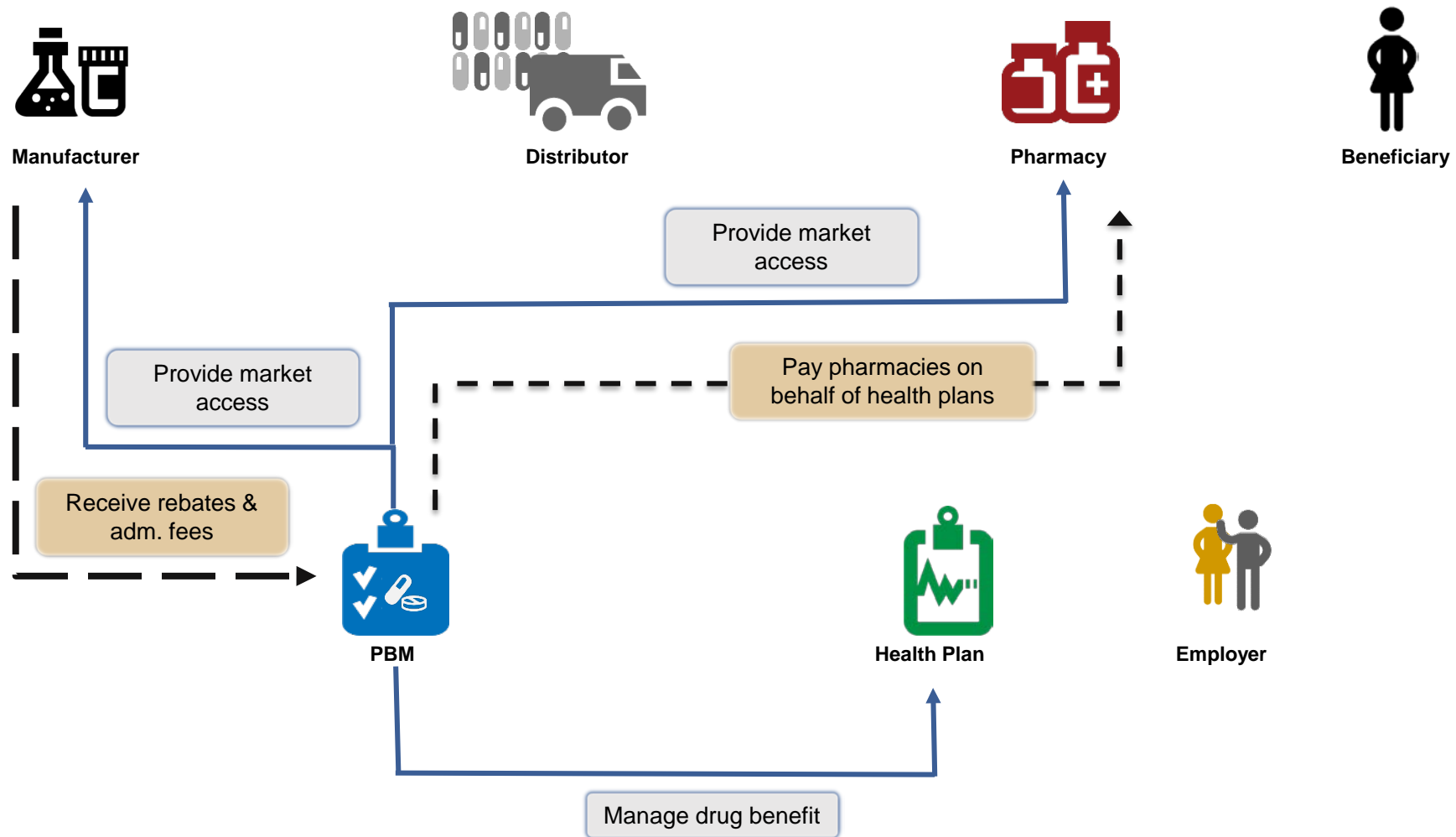


PBMs are true middle men, they play no role in the physical distribution of prescription drugs to consumers

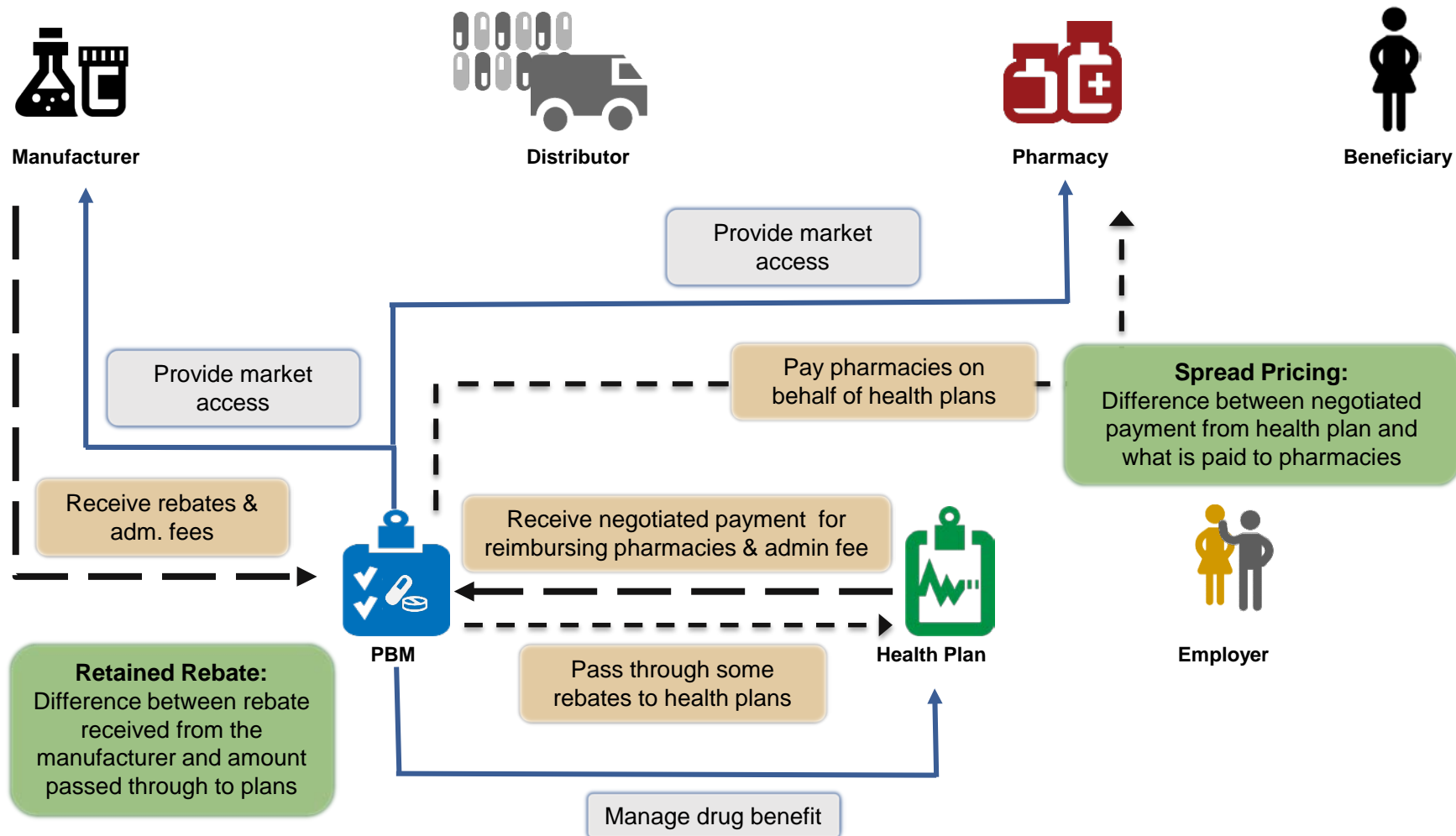
Flow of services



PBM relationship with other supply chain participants



How do PBMs make money?



PBM Economics

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

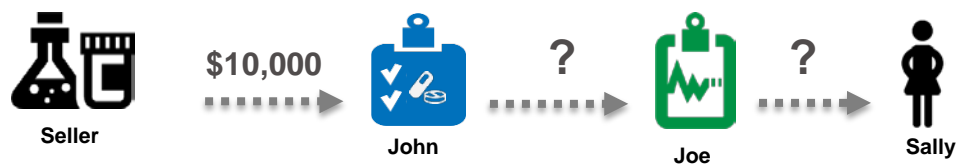
Buying a house:

- 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?



Lack of transparency means consumers might not benefit from higher rebates

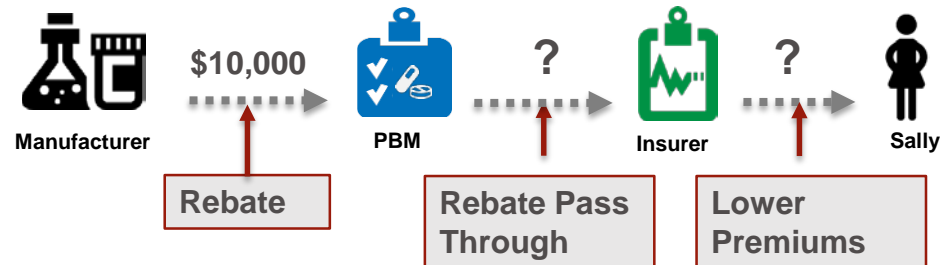
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Rebates misalign incentives: Not choosing cheaper drugs

	 PBM keeps	 Cost to health plans	 Cost to consumers?
 Drug A Retail Price: \$200 • rebate of \$50	\$5 <input checked="" type="checkbox"/>	\$155	
 Drug B Retail Price: \$100 • rebate of \$30	\$3	\$73 <input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Uninsured might pay list price <input checked="" type="checkbox"/> Insured consumers below deductible might pay list price <input checked="" type="checkbox"/> Insured may pay higher premiums

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

Lack of competition in the supply chain

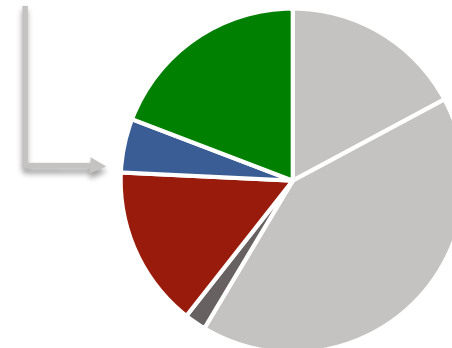
- Highly concentrated supply chain with few key players controlling large market shares

 **CVS**Health

 **EXPRESS SCRIPTS**

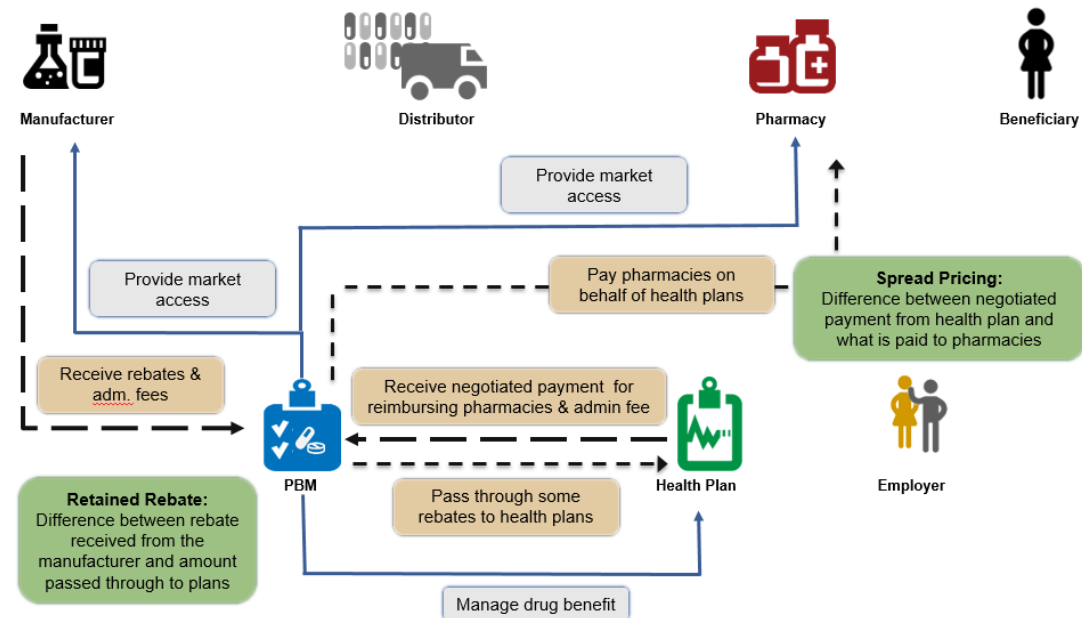
 **OPTUMRx**

- 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.



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”



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



PBM Economics

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

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

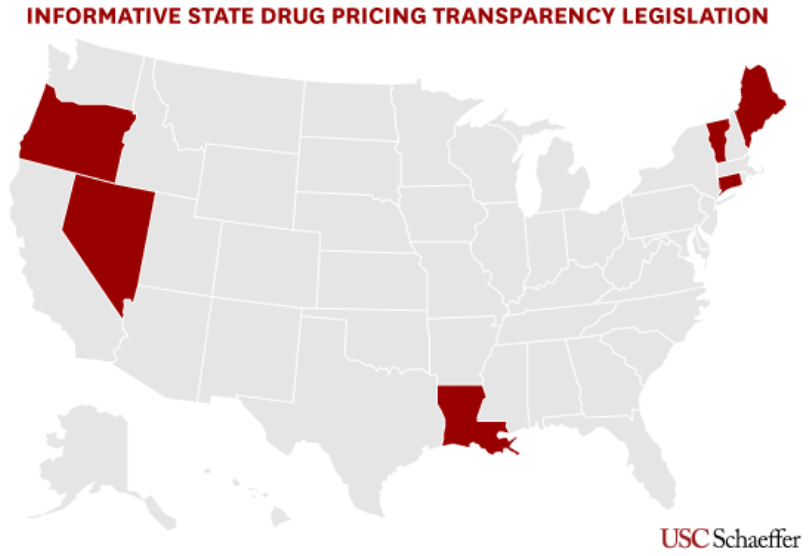
Evaluation of recent state policies show limited improvement in transparency

166 drug pricing bills identified between 2015 and 2018

↳ **35** bills passed in 22 states included a transparency component

↳ **7** bills were “**informative**”

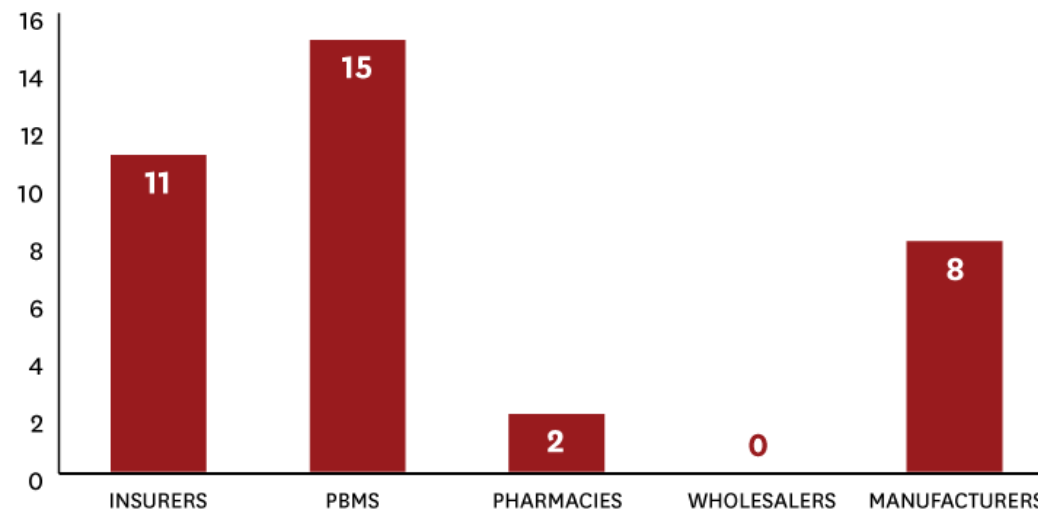
Informative: reveals previously unavailable information in the form of profits or real transaction prices for supply chain participants



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



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 PBMs with incentives of payers and consumers

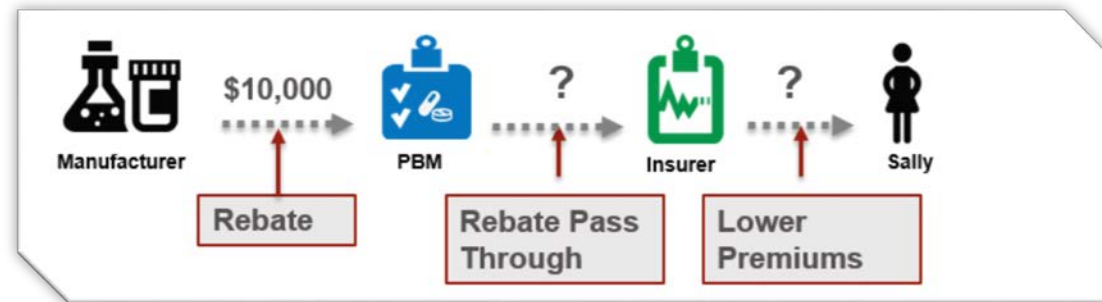
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Recommendation three: Mandate pass-through of rebate to consumers

- 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

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

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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2. Subscription models for prescription drugs

My journey into subscription models started in 2015

It was motivated by three facts:

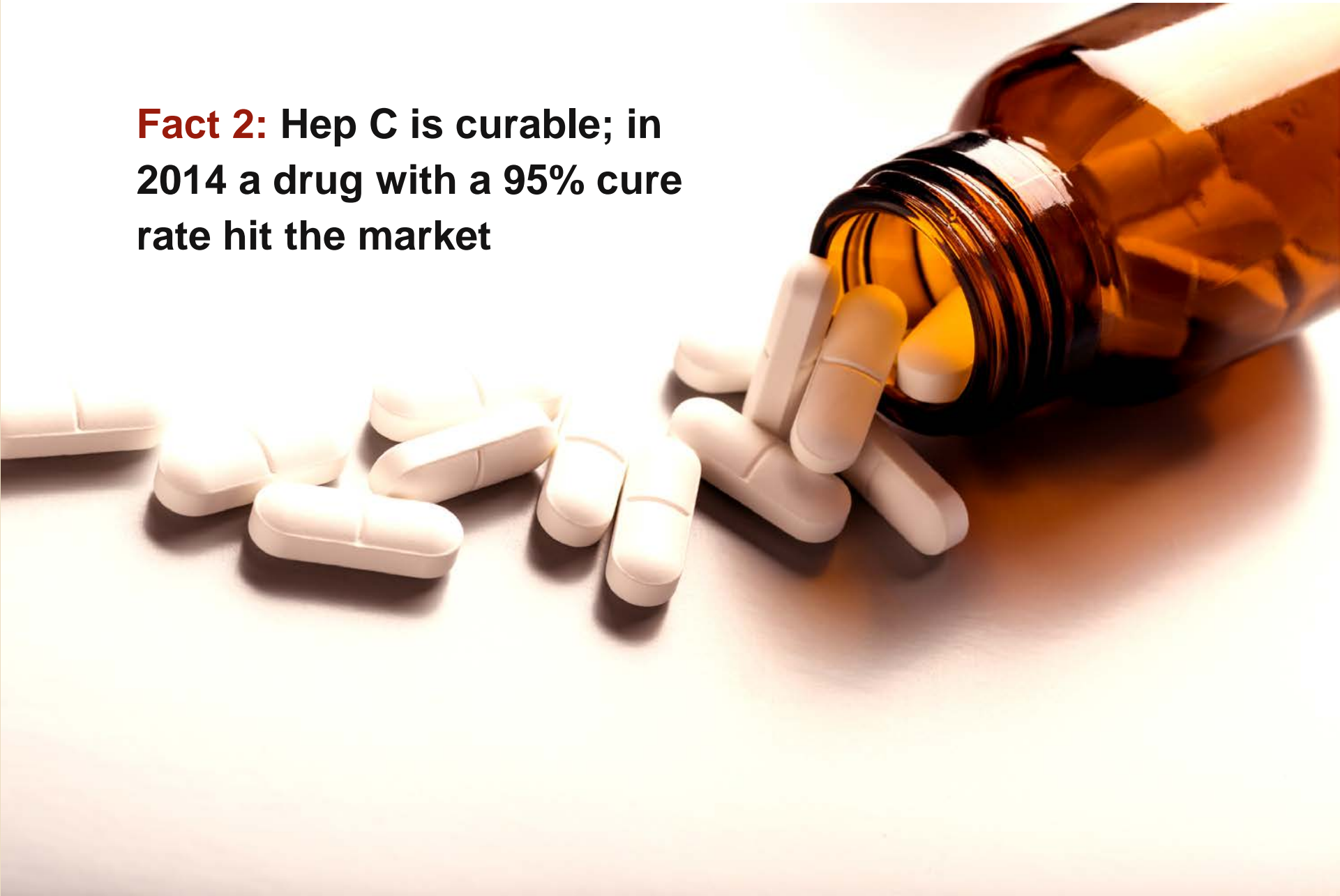
Fact 1: According to the CDC 20,000 people die from hepatitis C in the US each year

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

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



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



Less than 3 in 100

Medicaid beneficiaries have received the cure.



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

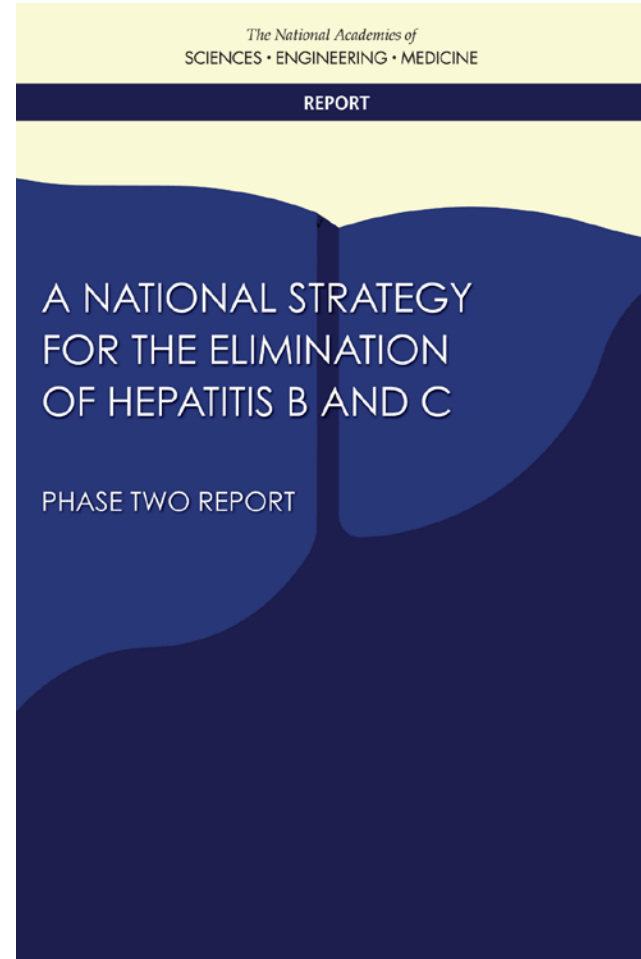


Less than 1 in 100

Prison inmates have received the cure.



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

Louisiana is the first state to implement the subscription model



Annals of Internal Medicine®

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IDEAS AND OPINIONS | 17 JULY 2018

A Novel Strategy for Increasing Access to Treatment for Hepatitis C Virus Infection for Medicaid Beneficiaries

Neeraj Sood, PhD; Diane Ung, JD; Anil Shankar, JD; Brian L. Strom, MD, MPH

REPORT

Policy brief: A novel strategy for increasing access to Hep C treatment for Medicaid beneficiaries

Neeraj Sood, Diane Ung, Anil Shankar, and Brian L. Strom · Tuesday, May 15, 2018

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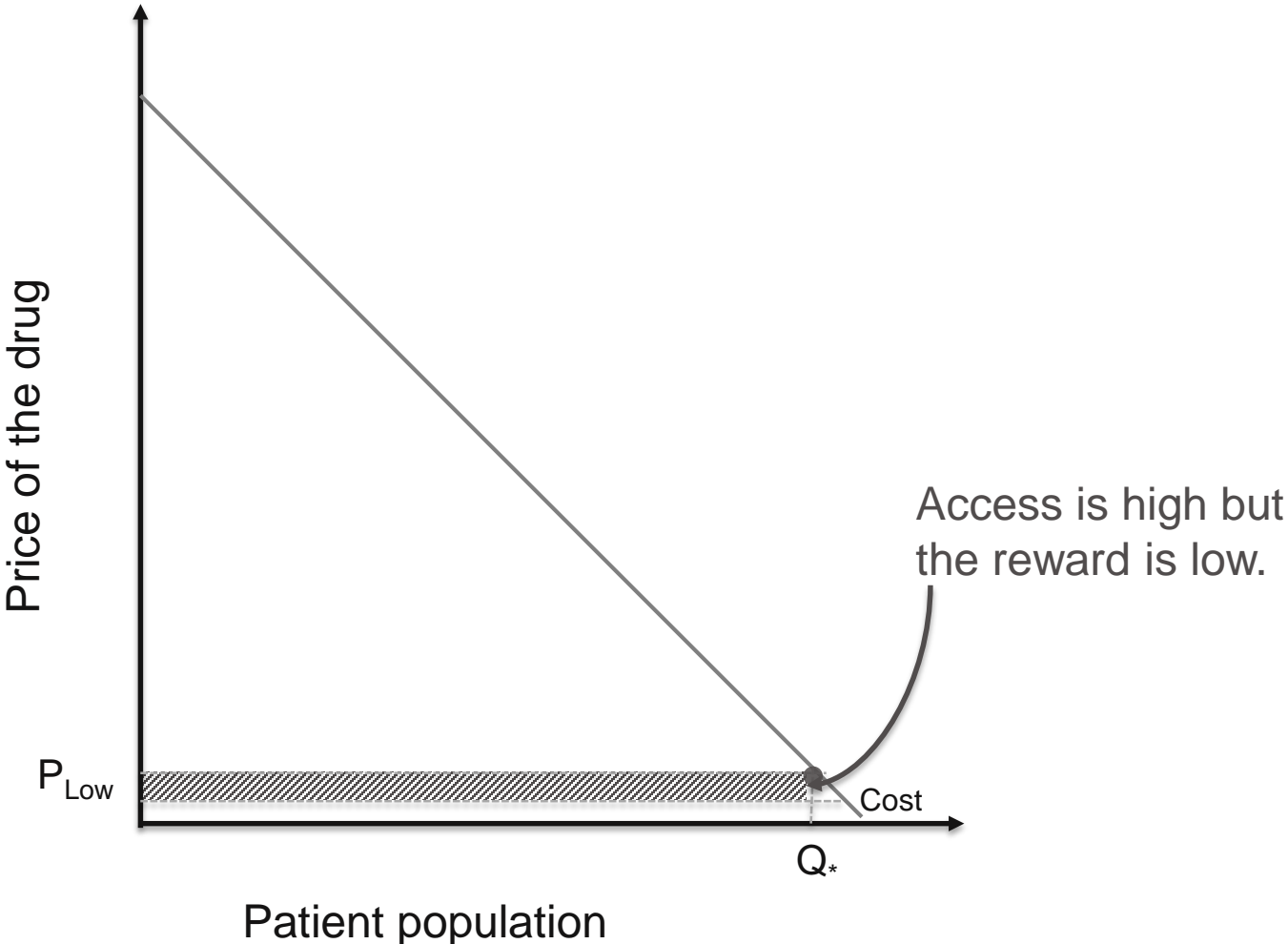
DOWNLOAD ↓

📄 Hep C Policy Proposal

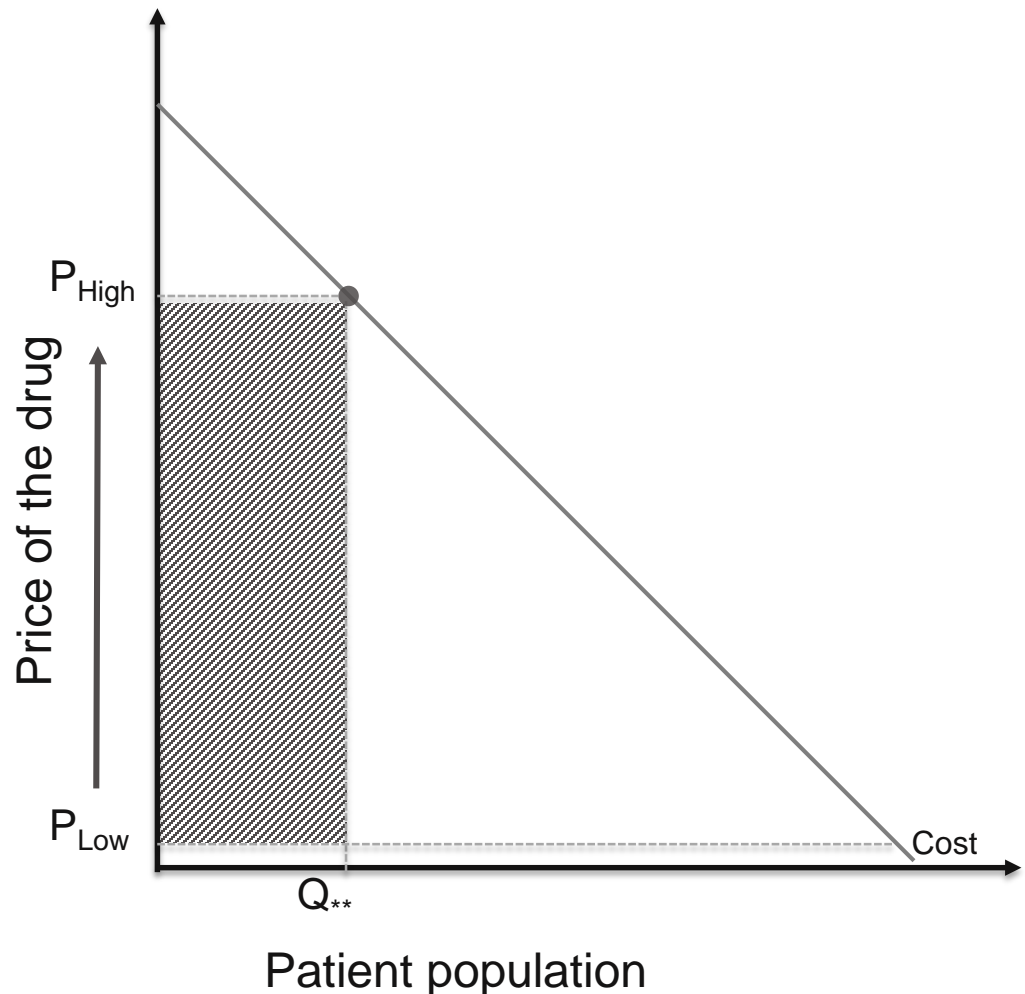
Editor's Note: This analysis is part of the USC-Brookings Schaeffer Initiative for Health Policy, which is a partnership between the Center for Health Policy at Brookings and the University of Southern California Schaeffer Center for Health Policy & Economics. The Initiative aims to inform the national health care debate with rigorous, evidence-based analysis leading to practical recommendations using the collaborative strengths of USC and Brookings.

Four other states have also received CMS approval

Low prices promote access but do not reward innovation

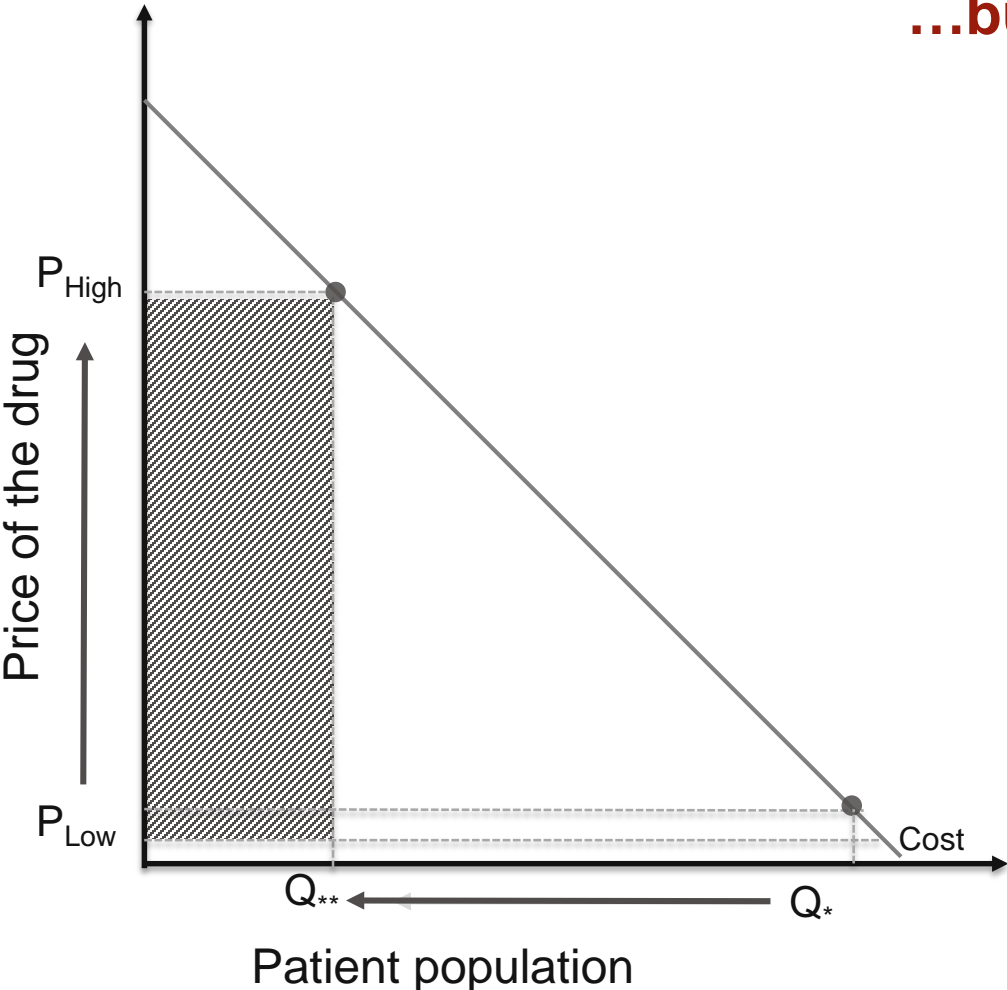


Firms set high prices to make money



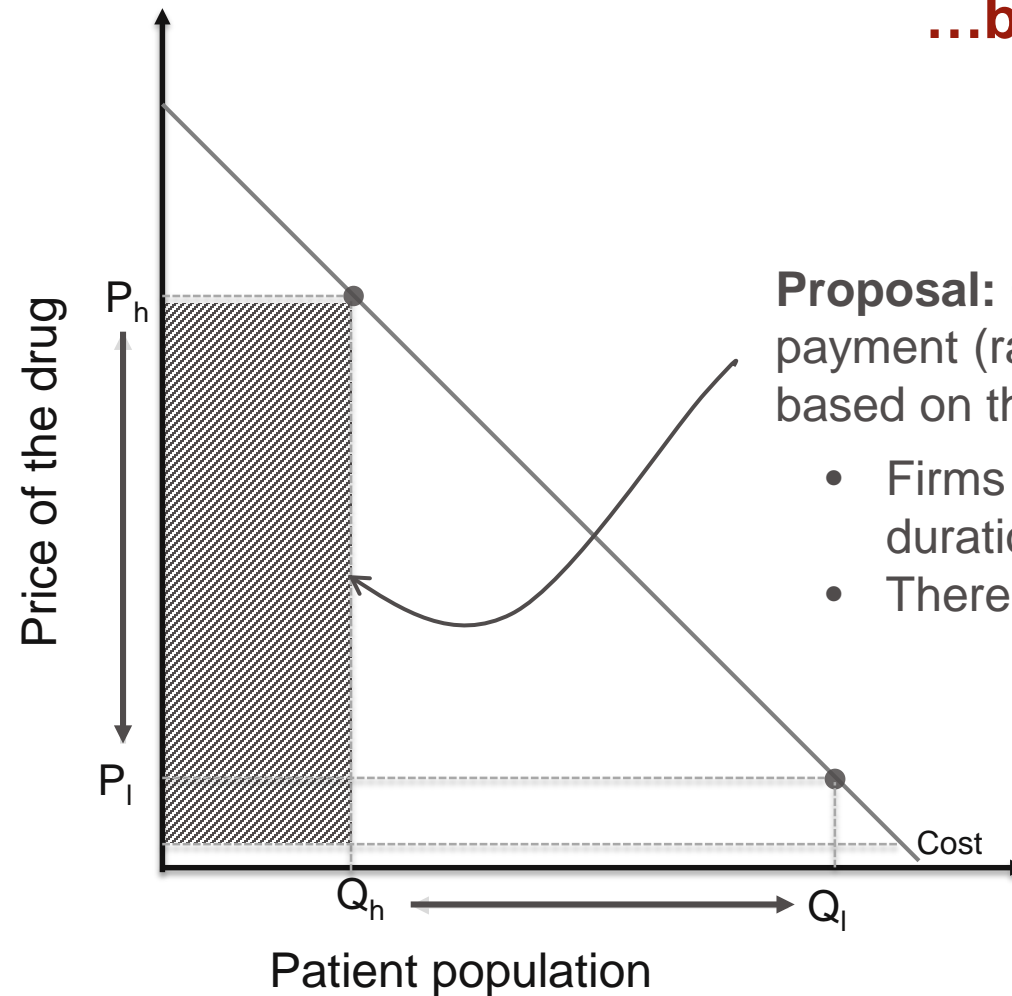
Firms set high prices to make money

...but it limits access



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

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**

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

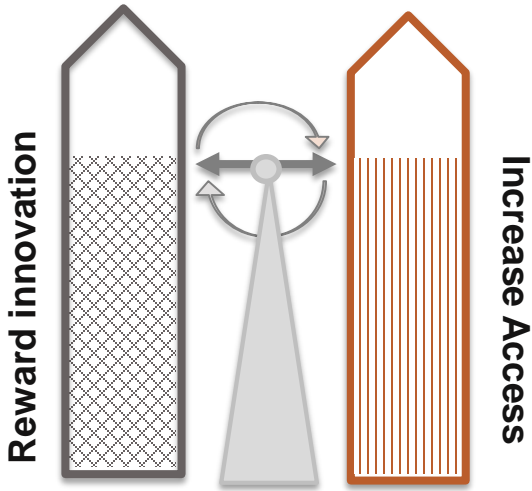
\$200 Million for one year



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



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



Significantly more patients receive treatment

Incentive to innovate is maintained

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

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

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**

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**

USC Price

Sol Price School of Public Policy

USC Schaeffer

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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

IngenioRx Overview



Rob Gallé

Chief Operating Officer, IngenioRx





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 NCQA¹

≈1 in 8

Americans are
Anthem members²

30 years

experience driving
pharmacy strategy

≈68,000

network
pharmacies³

>175MM

pharmacy claims
annually³

>6,000

wholly dedicated
Rx associates

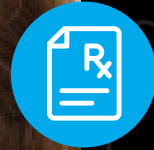


Eliminating trade offs, maximizing value

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

A whole-health approach with guaranteed impact

What that means

Singular focus on total cost of care

Maximizing value across stakeholders

Deep partnership with providers

What we do

Plan-specific, total cost guarantees

Wholly independent formulary process

Consistent approach to cost management

Optimizing site-of-care decisions

Value-based arrangements with providers







Holding manufacturers accountable for outcomes

Consistent clinical criteria across medical and pharmacy

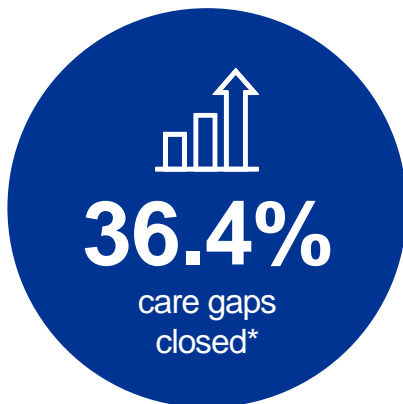
Pushing actionable insights to the exam room

Thinking nationally, acting locally

Value of our programs

Disease/condition	Impact
 Asthma	<ul style="list-style-type: none"> • 14% fewer admissions • 8% lower medical costs • \$588 PMPY savings
 Kidney Disease	<ul style="list-style-type: none"> • 13% fewer admissions • 3% lower medical costs • \$444 PMPY savings
 Coronary Artery Disease	<ul style="list-style-type: none"> • 13% fewer admissions • 9% lower medical costs • \$1,068 PMPY savings
 Diabetes	<ul style="list-style-type: none"> • 7% fewer admissions • 7% lower medical costs • \$600 PMPY savings
 Heart Failure	<ul style="list-style-type: none"> • 24% fewer admissions • 19% lower medical costs • \$3,552 PMPY savings
 Hypertension	<ul style="list-style-type: none"> • 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.



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.

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



IngenioRxSM



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

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

Navitus Overview

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



- Serves 600+ clients including employers, health plans, government, unions, etc.



- Owned by SSM Health in St. Louis, MO



- URAC accredited PBM and specialty pharmacy



- 6 million members and growing



- 4.5 out of 5 Stars EGWP Rating by CMS, the highest among PBM-sponsored EGWP Plans*



- Nationwide presence with corporate campuses in Madison and Appleton, WI; Austin, TX; and Phoenix, AZ

*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.

What does a PBM do?

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



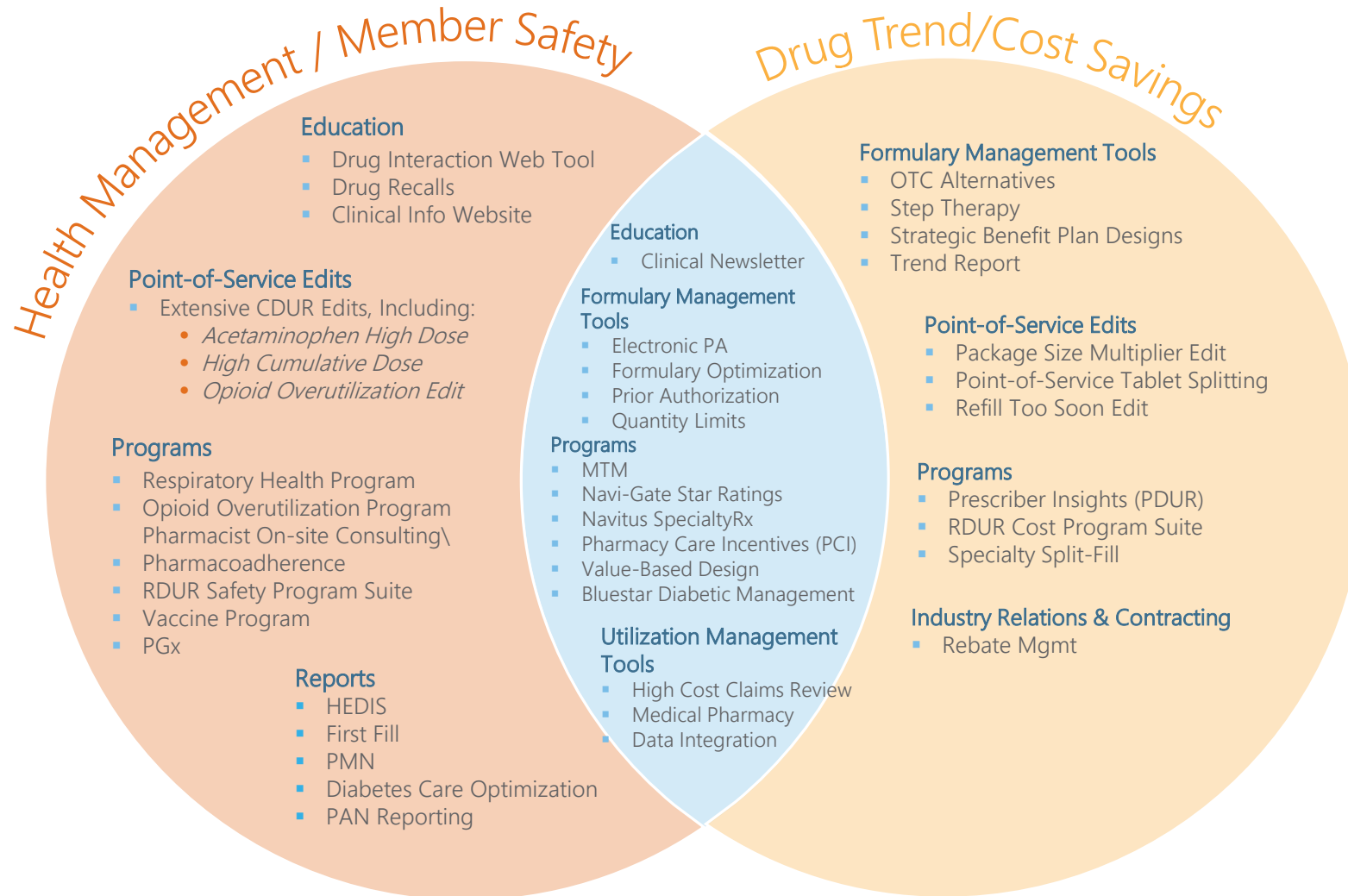
Operations

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

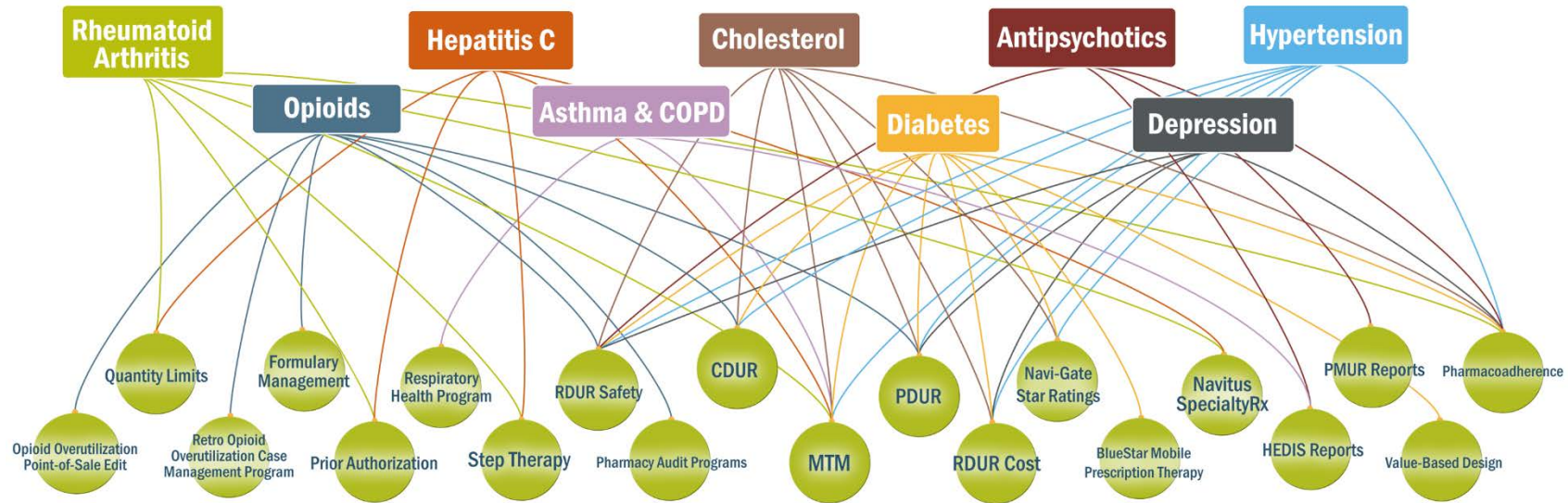
Technology

- 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

Population Health Overview



Population Health



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

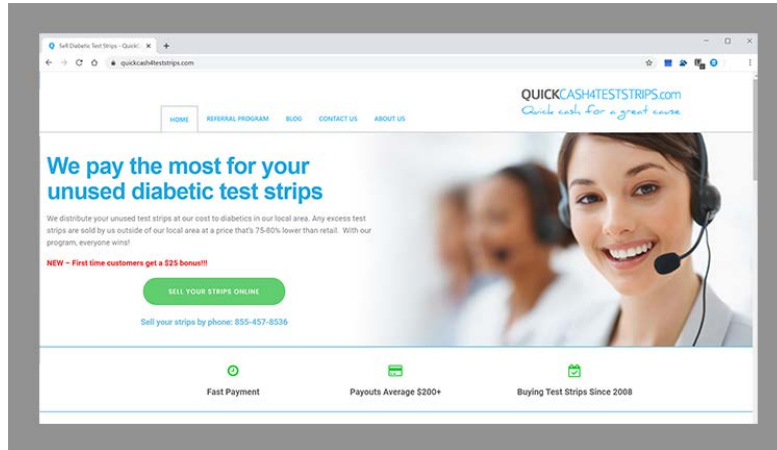
 - Diabetic Supplies / Gray Market

- **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

Selling of Diabetic Supplies

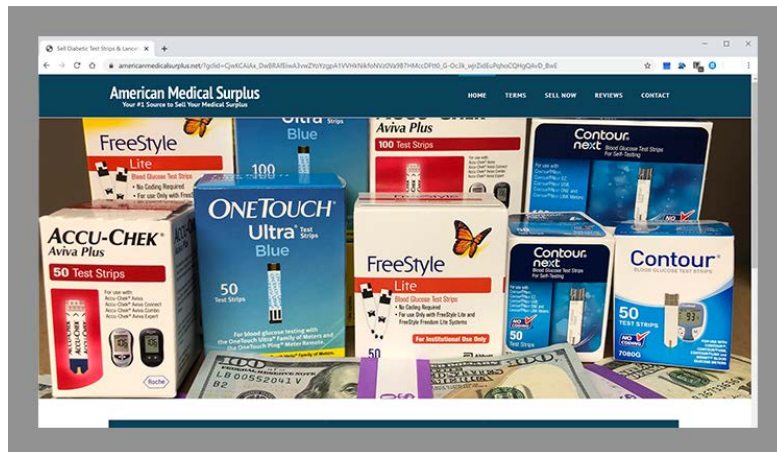
“how to sell my diabetic supplies”



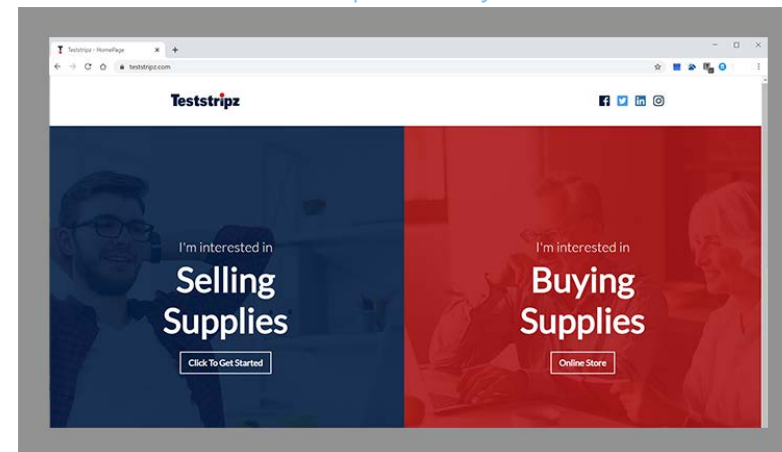
QuickCash4TestStrips.com



TestStrips4Money.com



AmericanMedicalSurplus.com




TestStripz.com

Preprint Form Example

CATEGORY	DRUG	DIRECTIONS	QTY/OR	REFILL
PAIN	<input type="checkbox"/> DICLOFENAC 3% GEL	APPLY 1 TO 2 GRAMS TO THE AFFECTED AREA(S) 3 TO 4 TIMES DAILY AS LONG AS DIRECTED BY PHYSICIAN.	200 GRAMS	
	<input type="checkbox"/> LIDO/TETRACAINE 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	
	<input type="checkbox"/> 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	
	<input type="checkbox"/> 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	<input type="checkbox"/> 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	
	<input type="checkbox"/> 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 ANTI-FUNGAL	<input type="checkbox"/> ECANOZOLE 1% CREAM	APPLY 1 TO 2 GRAMS TO AFFECTED AREA(S) 1 TO 2 TIMES DAILY AS DIRECTED BY PHYSICIAN. USE AS LONG AS DIRECTED BY PHYSICIAN.	120 GRAMS	[Handwritten signature]
	<input type="checkbox"/> 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 ANTI-BIOTIC ANTI-FUNGAL	<input type="checkbox"/> VANCOMYCIN 280mg CAPSULE	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	[Handwritten signature]
	<input type="checkbox"/> ECANOZOLE 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	<input type="checkbox"/> NAPROXEN SOB CR 375mg TABLETS	TAKE 1 TABLET BY MOUTH TWICE DAILY AS NEEDED FOR PAIN.	180 TABLETS	
	<input type="checkbox"/> FINOPROFEN 400mg CAPSULES	TAKE 1 CAPSULE BY MOUTH THREE TIMES A DAY AS NEEDED FOR PAIN.	90 CAPSULES	
PPI	<input type="checkbox"/> OMEP SOB-BICARB 40/1100mg TABLETS	TAKE 1 CAPSULE BY MOUTH EVERY MORNING WITHOUT FOOD.	30 CAPSULES	
WELLNESS	<input type="checkbox"/> MEBOLIC TABLETS	TAKE 1 TO 2 TABLETS BY MOUTH DAILY. (125mg VITAMIN C, 500IU VITAMIN D3, 25mg THIAMINE, 12.5mg VITAMIN B6, 1mg FOLIC ACID, 1mg VITAMIN B12, 5mg NADH, 50mg COENZYME Q-10).	60 TABLETS	
ORAL STEROID	<input type="checkbox"/> PREDNISOLONE 20mg/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	<input type="checkbox"/> CHLORZOXAZONE 250mg TABLETS	TAKE 1 TABLET BY MOUTH 3 TIMES DAILY AS NEEDED FOR MUSCLE SPASMS OR PAIN.	90 TABLETS	
ANTI INFECTIVE	<input type="checkbox"/> 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	<input type="checkbox"/> DIFLORASONE 0.05% OINTMENT	APPLY 1 TO 2 GRAMS TO AFFECTED AREA(S) UP TO 1 TO 4 TIMES DAILY AS NEEDED. USE 2 WEEKS ON, 1 WEEK OFF AS LONG AS DIRECTED BY PHYSICIAN.	120 GRAMS	
MIGRAINE	<input type="checkbox"/> VANATOI LIQUID SOL'N	TAKE 1 TO 2 TABLETSPOONS BY MOUTH EVERY 4 HOURS AS NEEDED FOR MIGRAINE (MAXIMUM 4 TABLETSPOONS PER DAY). (50mg/15ml BUTALBUTAL, 32.5mg/15ml ACETAMINOPHEN, 40mg/15ml CAFFEINE)	1410 MILLILITER	
PATCH	<input type="checkbox"/> 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	<input type="checkbox"/> CALCIPOTRIENE 0.005% CREAM	APPLY 1 TO 2 GRAMS TO AFFECTED AREA(S) TWICE DAILY. USE AS LONG AS DIRECTED BY PHYSICIAN.	120 GRAMS	

Preprinted Forms

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



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.

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This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

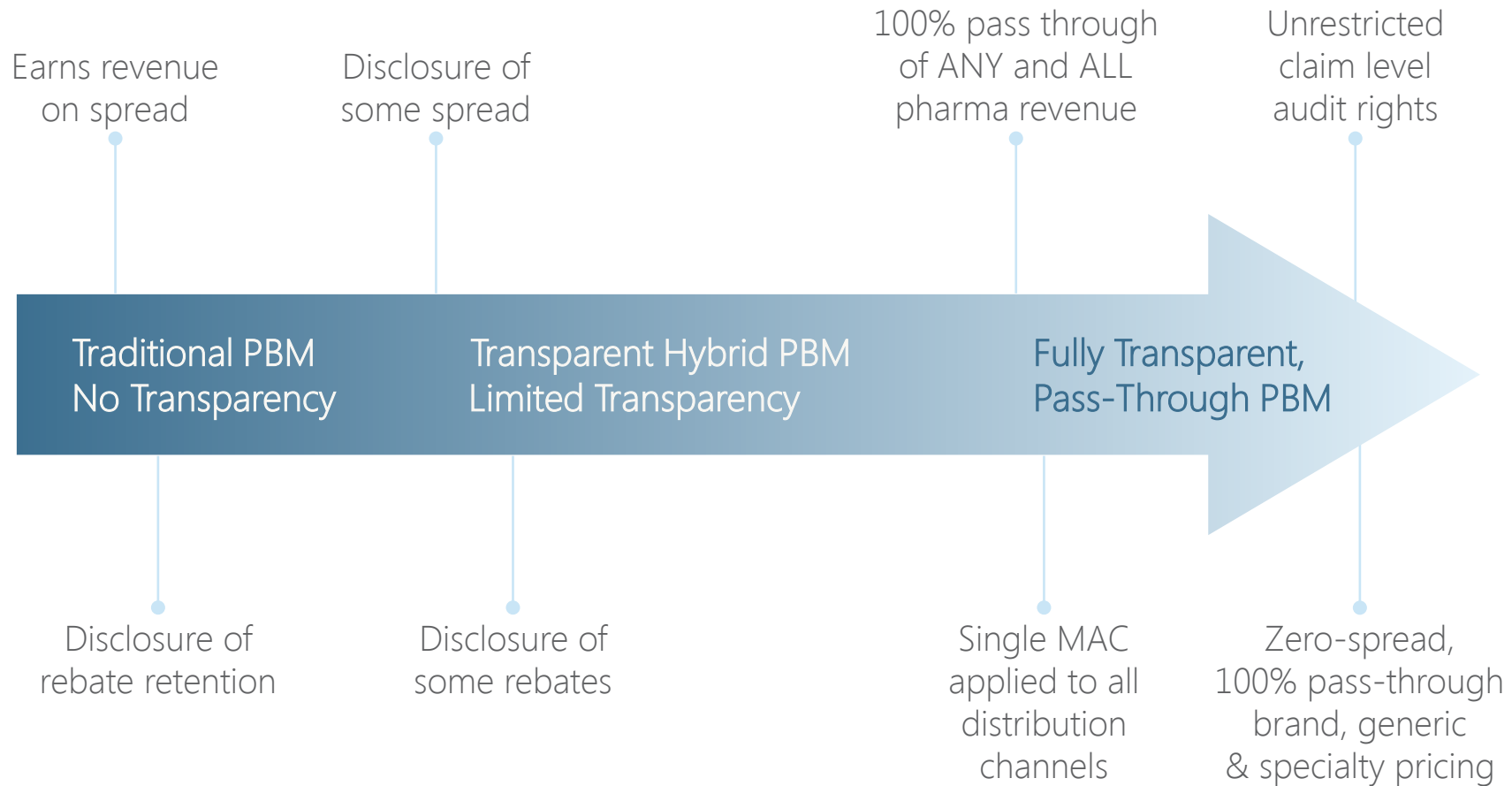
1

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



PBM Business Models

Degrees of PBM Transparency



PBM Pricing Models

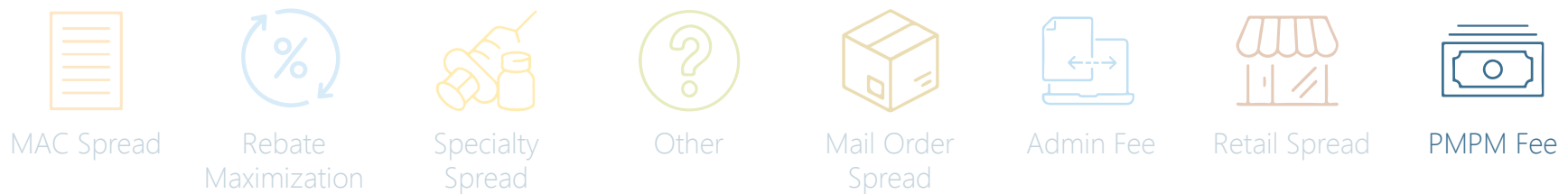
Traditional



Transparent Hybrid

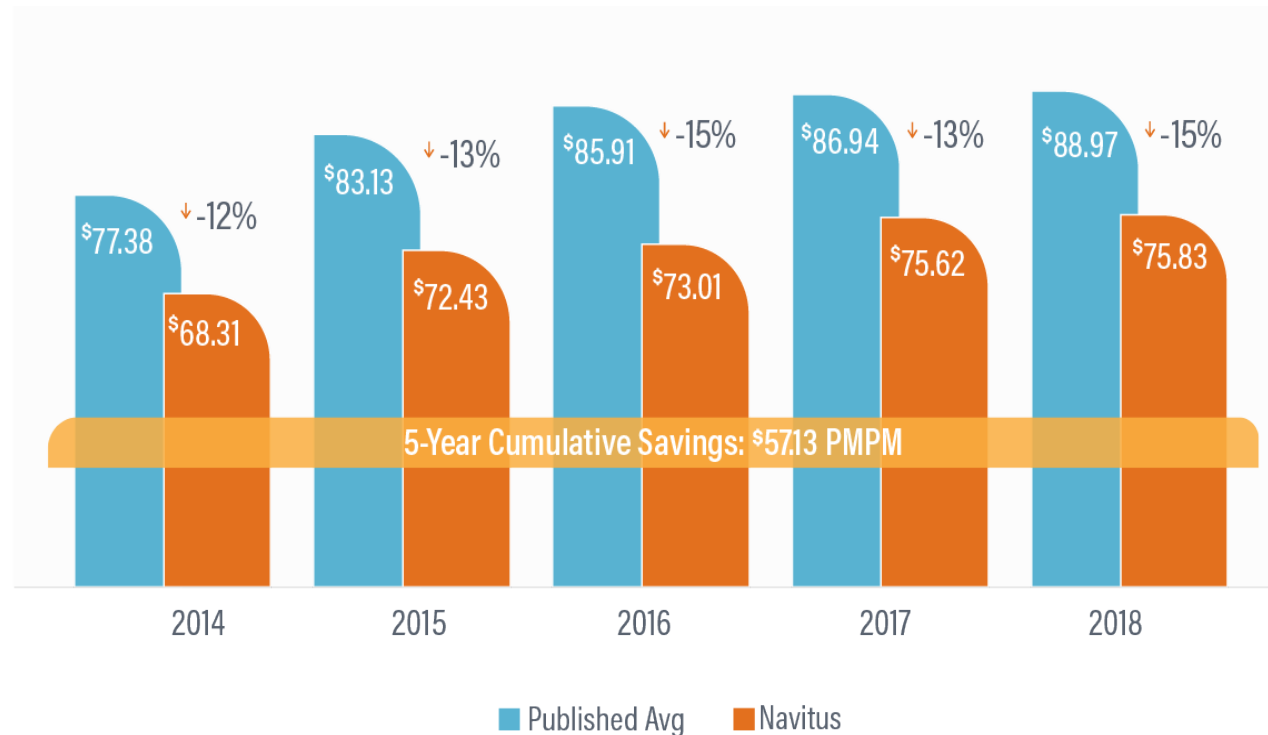


Pass-Through



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.

PBM Legislative Activity

TYPES OF LEGISLATION REGULATING PBMs

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

<p>1</p> <h2>Drug Price & PBM Transparency</h2>  <p>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.</p> <p>STATES: AR, IA, IL, LA, TX, MA, ME, MN, MT, NC, NE, NH, NJ, NM, NY, PA, RI, SC, TX, UT, WA, WI, WY</p>	<p>2</p> <h2>Licensure/Registration</h2>  <p>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.</p> <p>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</p>	<p>3</p> <h2>Step Therapy</h2>  <p>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</p> <p>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</p>
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Note: bolded states indicate adopted legislation

TYPES OF LEGISLATION REGULATING PBMs

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4

Gag Clauses & Claw Back Prohibitions




Prohibits use of gag clauses in contracts between PBMs and pharmacies. Gag clauses prevent pharmacists from telling patients about cheaper prescription alternatives. Clawbacks prohibited so patient copays cannot exceed total cost of the drug to the PBM or insurer.

STATES:
AL, IN, **DE**, HI, IL, IN, LA, **MA**, MD, ME, **MN**, MT, NC, ND, **NE**, **NJ**, NM, NV, **NY**, OH, OK, OR, PA, SC, SD, TN, TX, WA, WY

5

Pharmacy Networks



Bills providing requirements related to adequate pharmacy network, pharmacy choice, pharmacy audits, and MAC appeals. Some also prohibit mail order pharmacies from being considered part of the network.

STATES:
Network Adequacy/Pharmacy Choice: OK, CO, DE, IA, KY, MD, ME, **MN**, MT, NJ, NY, OK, OR, TX, VA, WA, WI, WV
Audits: **FL**, LA, NJ, MN, NM, OH, OK, PA, RI, **SC**, **TN**, **TX**, **VA**, WI, **WV**
Appeals: **AZ**, FL, HI, IN, LA, MA, **MD**, MN, NM, NY, OR, SC

6

Copay Accumulator Bans



Requires plans to consider all payments made by a beneficiary, or on behalf of a beneficiary, when calculating the beneficiary's overall contribution to any cost-sharing obligations. Arizona provides only for coupon payments to apply to deductible if no generic exists.

STATES:
AZ, IL, KY, ID, KY, NH, OR RI, **VA**, **WV**

Note: bolded states indicate adopted legislation

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

Thank You.



CIVICATM

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™

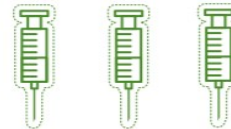
REDUCING DRUG SHORTAGES THROUGH COLLABORATION

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



Health Systems continue to join Civica, including:





- 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



CIVICA™



Quality



Supply



Sustainability



STATE OF WISCONSIN

**GOVERNOR'S TASK FORCE ON
REDUCING PRESCRIPTION DRUG PRICES**

Contact information:

Email: OCIRXDrugTaskForce@wisconsin.gov

Website: RxDrugTaskForce.WI.gov