NCSL

# Prescription Drug Learning Group

Portland, Oregon

June 21, 2023

# Welcome

# Slides

https://www.ncsl.org/events/details/prescription-drug-peer-learning-group

# Meeting Objectives

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NATIONAL CONFERENCE OF STATE LEGISLATURES

- Build knowledge about prescription drug policy
- Exchange ideas and solutions related to prescription drug policy
- Meet and learn from legislators from other states
- Connect with policy experts
- Identify practical information and resources to use in your state
- Have fun! ☺

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# Agenda

- Welcome and Introductions
- Overview of State Policy Trends
- Insulin Affordability: What's Next?
- Pharmacy Benefit Managers: Caught in the Middle

**Lunch**

- Price and Cost Transparency
- Prescription Drug Affordability Boards
- Containing Prescription Drug Costs in Medicaid

# The National Conference of State Legislatures

- Bipartisan membership organization
  - All 50 states and the territories
    - 7,386 state legislators
    - All state legislative staff (30,000+)
- Goals:
  - To improve the quality & effectiveness of state legislatures
  - To promote policy innovation and communication among state legislatures
  - To ensure states a strong, cohesive voice in the federal system
- Research, education, technical assistance
- Voice of the states in the federal system

# NCSL Leadership and Officers

**Tim Storey**

NCSL Chief Executive Officer

**Wisconsin Speaker Robin Vos**

NCSL President

**Ann Sappenfield**

NCSL Staff Chair

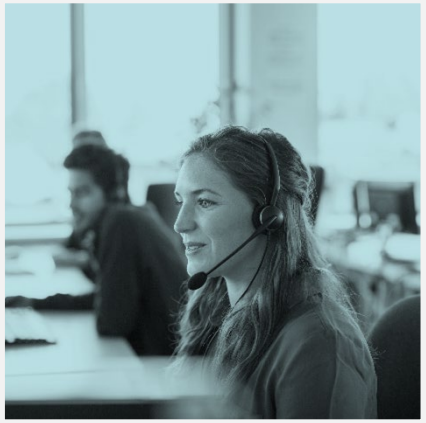
# How NCSL Strengthens Legislatures

## Policy Research

NCSL provides trusted, nonpartisan policy research and analysis

## Connections

NCSL links legislators and staff with each other and with experts



## Training

NCSL delivers training tailored specifically for legislators and staff

## State Voice in D.C.

NCSL represents and advocates on behalf of states on Capitol Hill

## Meetings

NCSL meetings facilitate information exchange and policy discussions

# Publications, Legislative Tracking Databases & Resources

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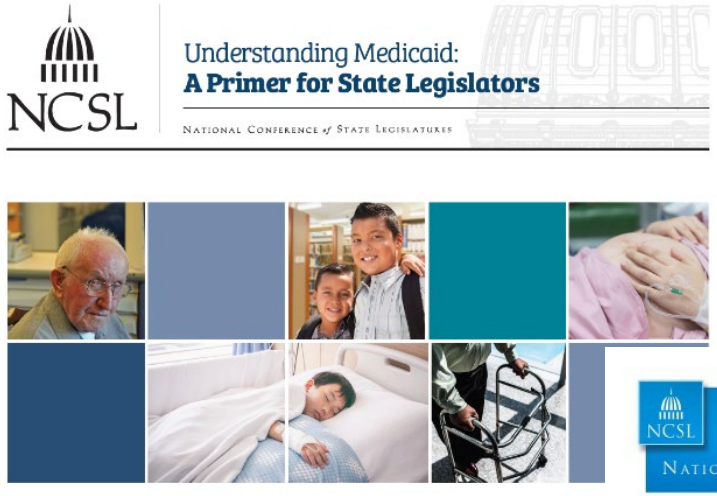
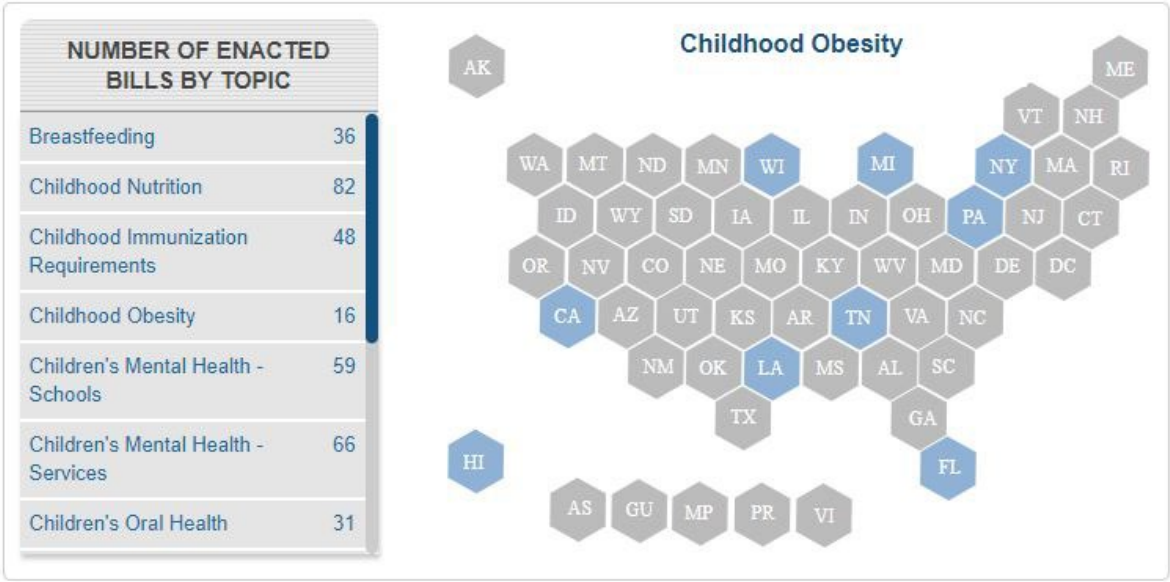
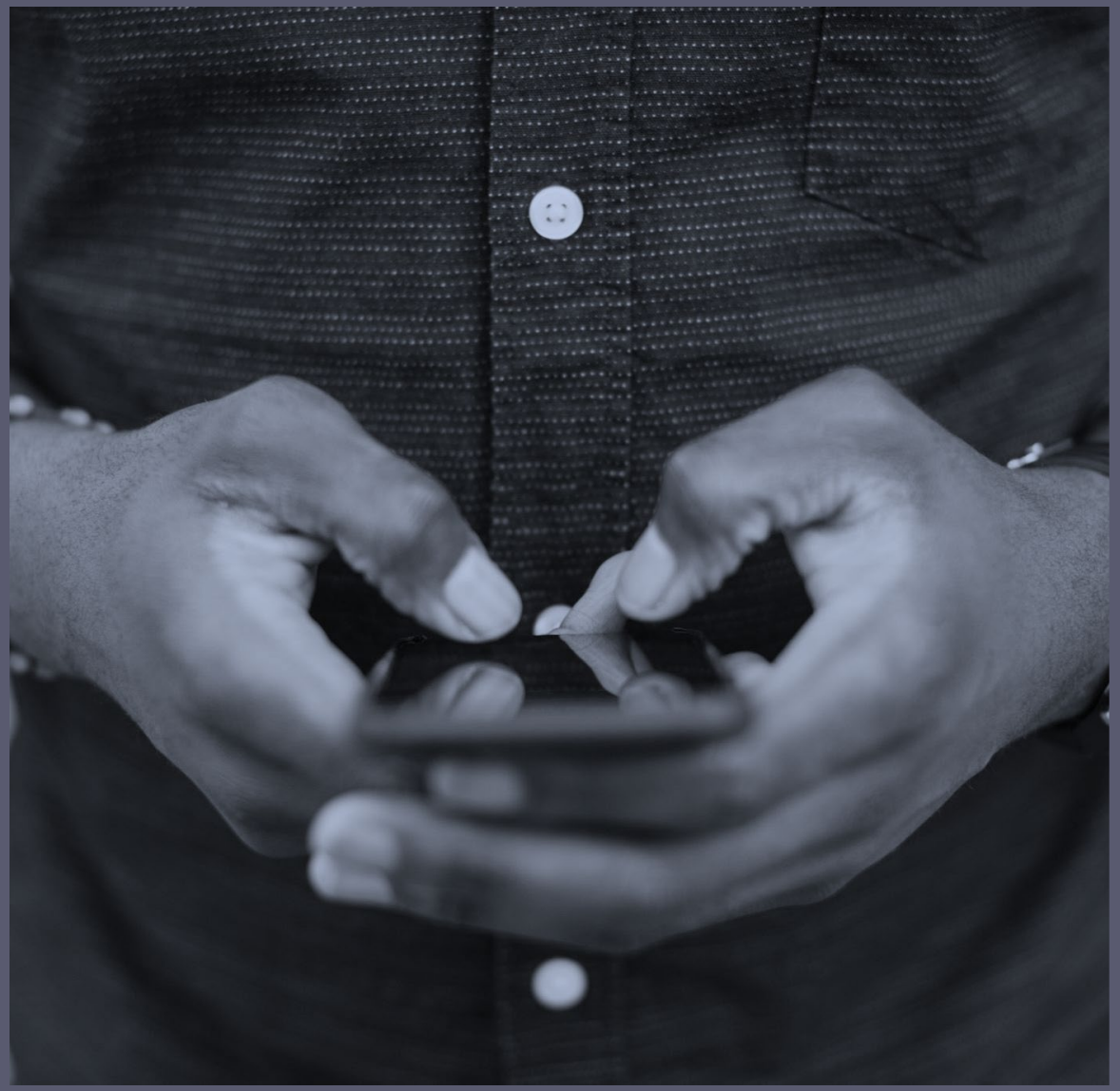




# Stay Connected

- Learn about NCSL training
- Subscribe to policy newsletters
- Read State Legislatures magazine
- Bookmark the NCSL Blog
- Listen to “Our American States” podcast
- Watch recorded policy webinars and training sessions
- Attend a meeting or training
- Follow @NCSLorg on social media



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# Opportunities to Dive Deep into Policy

# 2023 Indy Legislative Summit

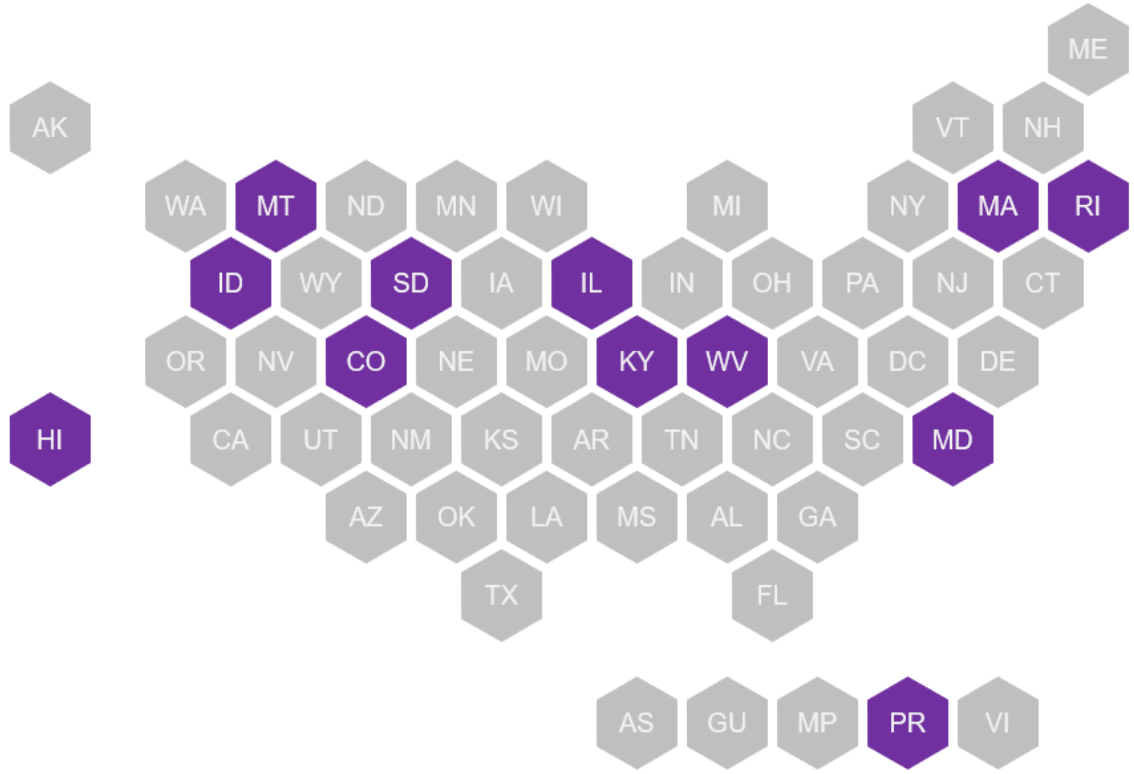
NCSL LEGISLATIVE SUMMIT INDY2023

Aug. 14-16, 2023

# Introduce Yourself!

- Name
- State
- What is one thing you hope to learn about?
- Fun Fact

*Please keep your responses less than 30 seconds*

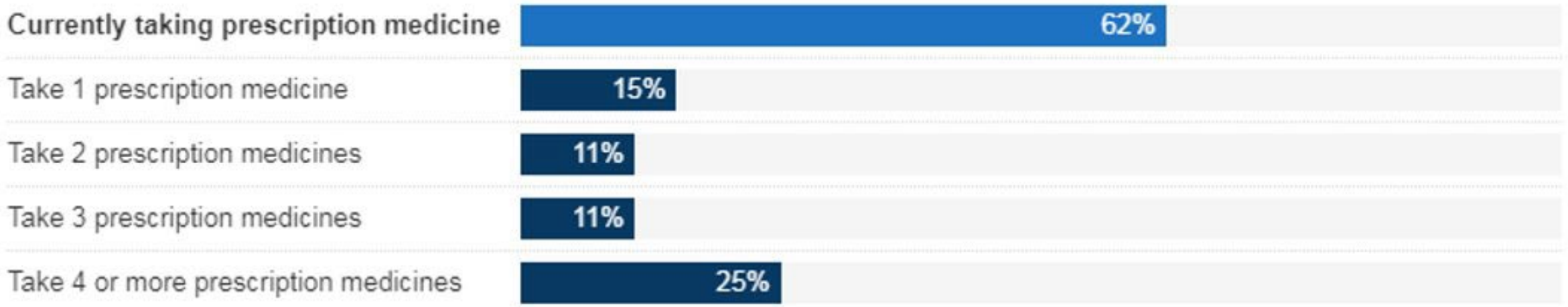


# Overview of State Prescription Drug Policy Efforts

Figure 1

# Six In Ten Adults Report Currently Taking At Least One Prescription Medicine; One Quarter Say They Take Four Or More

Percent who say they take the following number of prescription drugs:



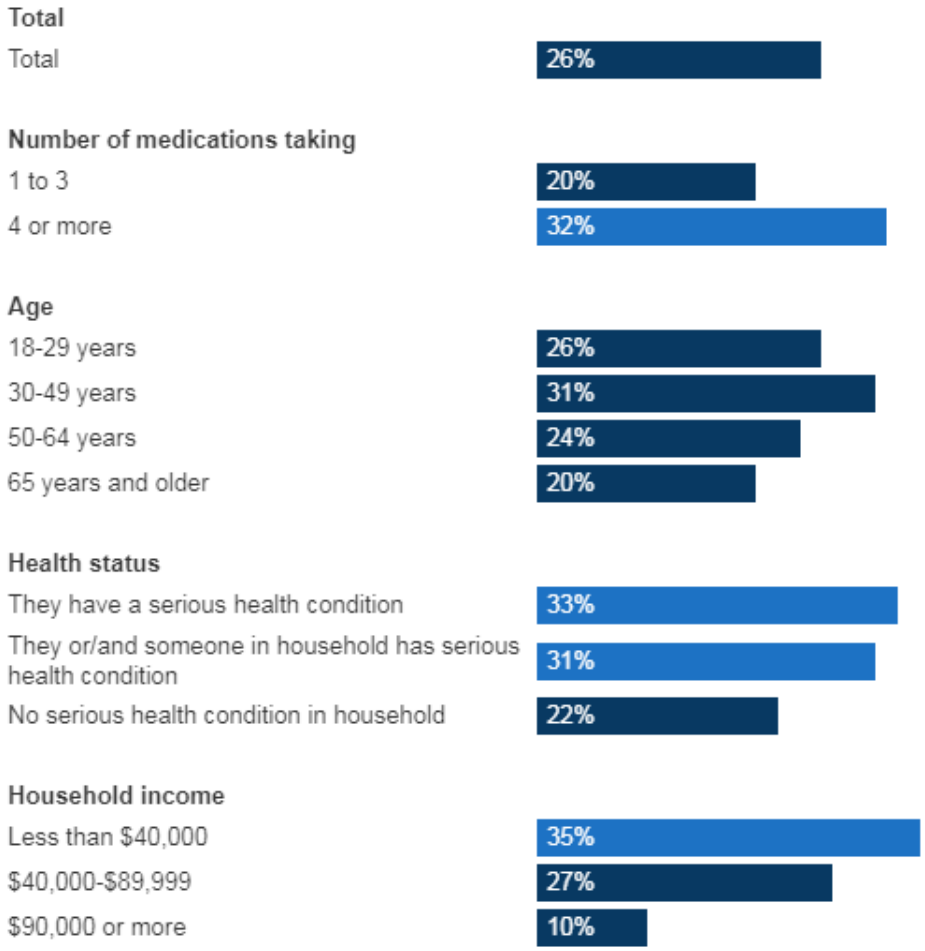

NOTE: See topline for full question wording.
SOURCE: KFF Health Tracking Poll (Sept. 23- Oct. 4, 2021) • PNG

KFF

Figure 3

## Who Has Difficulty Affording Their Prescription Drugs?

Percent who say it is difficult to afford the cost of their prescription medicine:




NOTE: See topline for full question wording.
SOURCE: KFF Health Tracking Poll (Sept. 23- Oct. 4, 2021) • PNG

KFF

# Patient costs and adherence

Overall personal health care spending on prescription drugs averages 12-15%

The U.S. spends $1300 per person per year

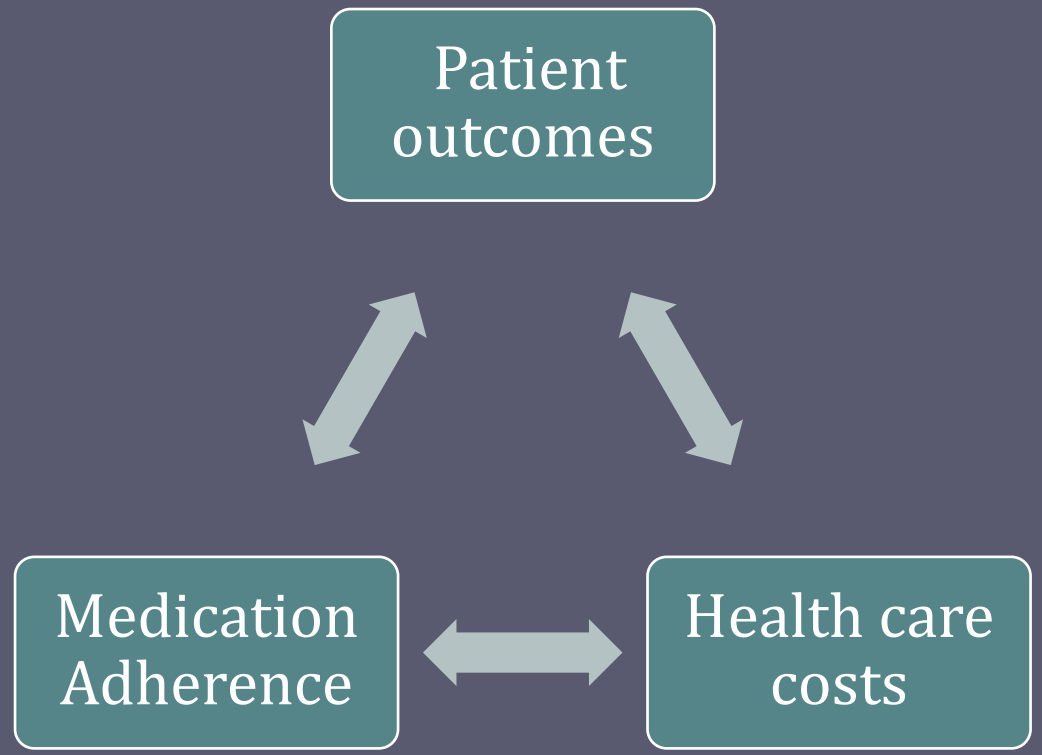
Cost may be a barrier to adherence which may lead to poor health outcomes which can impact costs—so says:

National Institutes of Health

Centers for Disease Control and Prevention

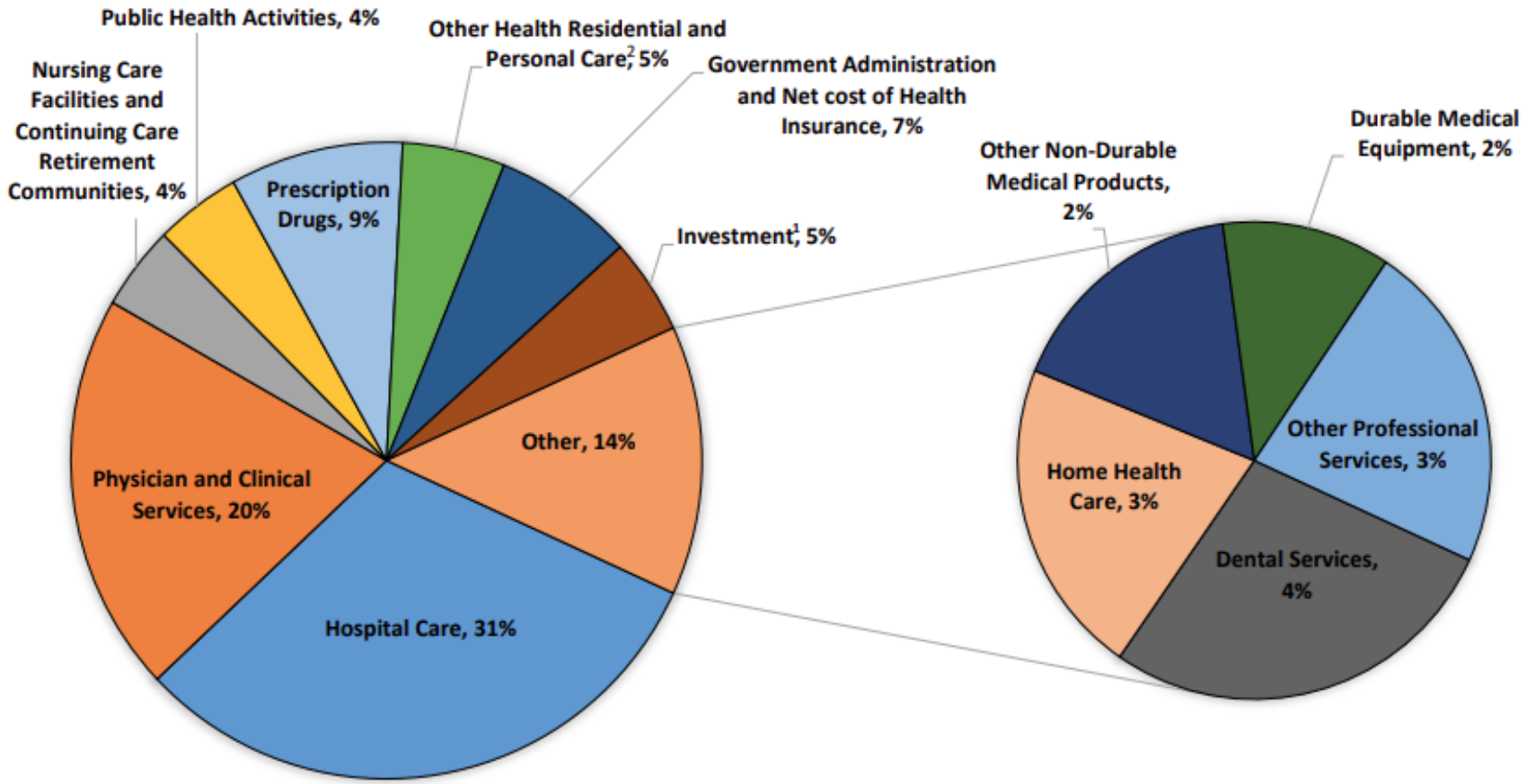
IQVIA

And many more....




- https://www.kff.org/medicare/issue-brief/how-does-prescription-drug-spending-and-use-compare-across-large-employer-plans-medicare-part-d-and-medicaid/
- https://www.gao.gov/prescription-drug-spending
- https://data.oecd.org/healthres/nurses.htm#indicator-chart

# THE NATION'S HEALTH DOLLAR ($4.3 TRILLION), CALENDAR YEAR 2021: WHERE IT WENT




[1] Includes Noncommercial Research and Structures and Equipment.

[2] Includes expenditures for residential care facilities, ambulance providers, medical care delivered in non-traditional settings (such as community centers, senior citizens centers, schools, and military field stations), and expenditures for Home and Community Waiver programs under Medicaid.

Note: Sum of pieces may not equal 100% due to rounding.

SOURCE: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group.

# States As...

## Purchasers

- Medicaid
  - 5-10% of state Medicaid dollars spent on prescription drugs
  - All 50 states participate in the Medicaid Drug Rebate Program (MDRP) for federal rebates
  - Generally, 23.1% for brand-name; 13% for generic
  - Must cover all drugs from participating manufacturers
- Departments of Corrections

## Regulators

- Fully Insured plans
- Marketplace plans
- Small employer plans
- State employee health plans
- State Retirees

- *https://www.macpac.gov/publication/trends-in-medicaid-drug-spending-and-rebates/*
- *https://phrma.org/policy-issues/medicaid*

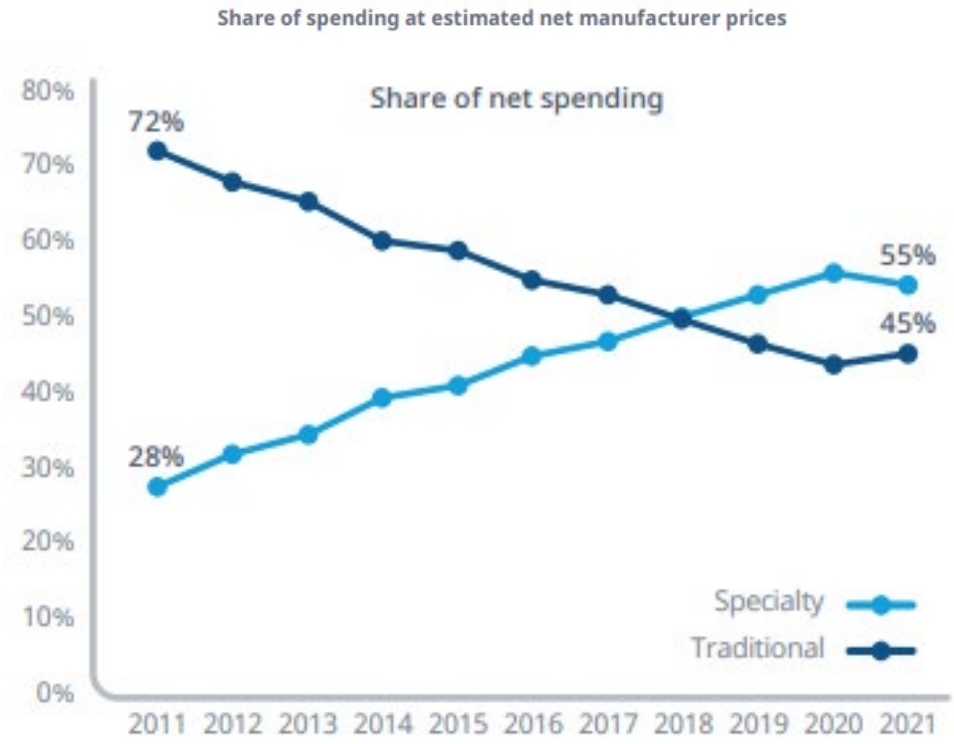
# Products

US Food and Drug Administration (FDA) approved products

- 20,000+ prescription drug products approved for marketing (dosages; delivery method)
- 400 FDA-approved biologics products
  - Includes insulin, vaccines
  - 40 FDA-approved biosimilars—generic versions of biologics
    - 27 have been launched in the U.S.
- Generics = 90% of filled prescriptions, brand = 10%

- https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2022
- https://www.centerforbiosimilars.com/biosimilar-approvals

# Specialty drugs




Source: IQVIA Institute, Mar 2022.

3% of prescriptions, but 55 % spending goes to brand-name specialty medicines

- Treatments for complex or chronic conditions, rare diseases
- Require special administration, handling and storage
- High monthly cost = $1000/30-day supply

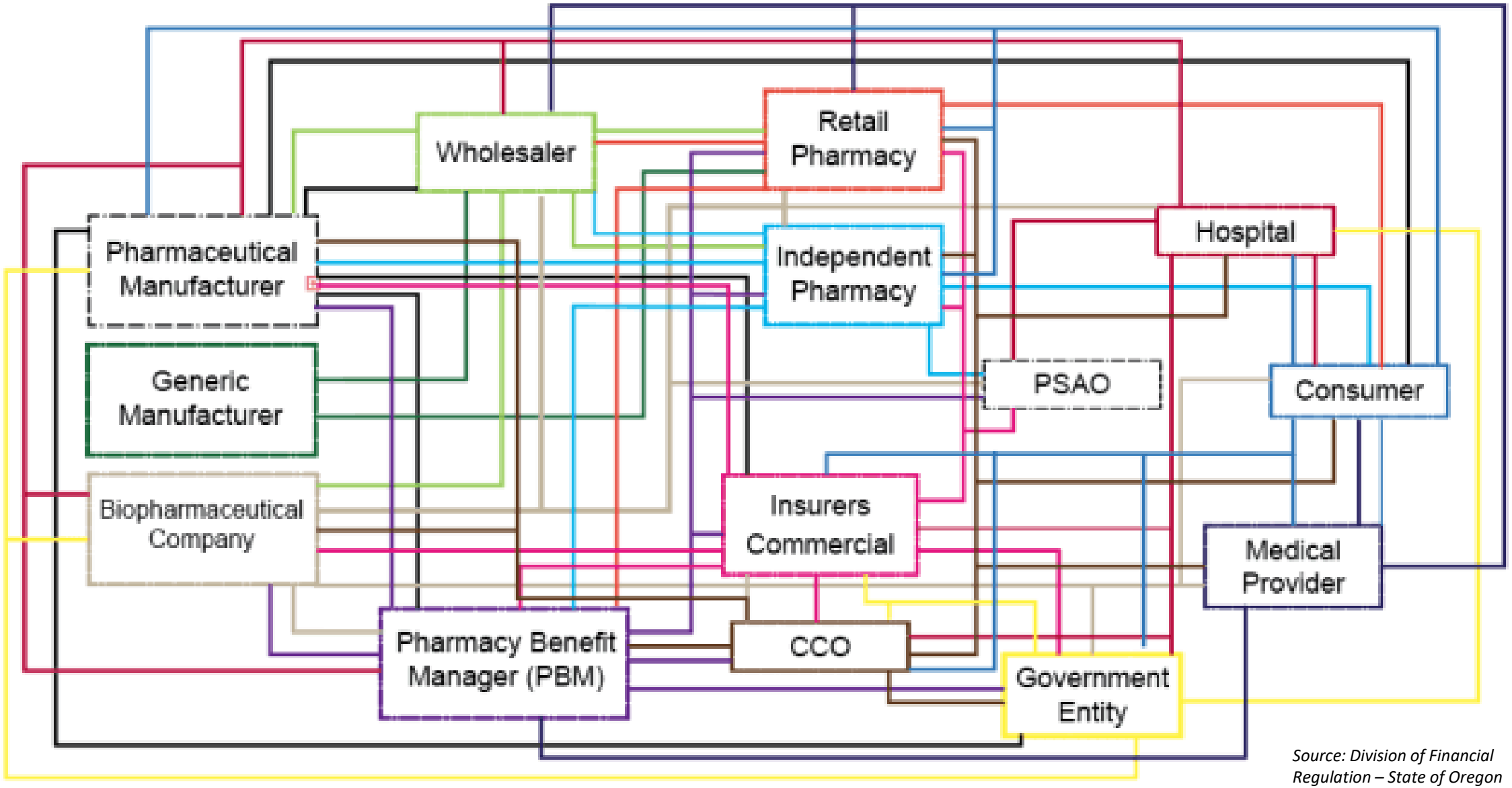
And don't forget about cell and gene therapies—one tops $3.5 million dollars

- https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-use-of-medicines-in-the-us-2022/iqvia-institute-the-use-of-medicines-in-the-us-2022.pdf

# Prescription Drugs Can....

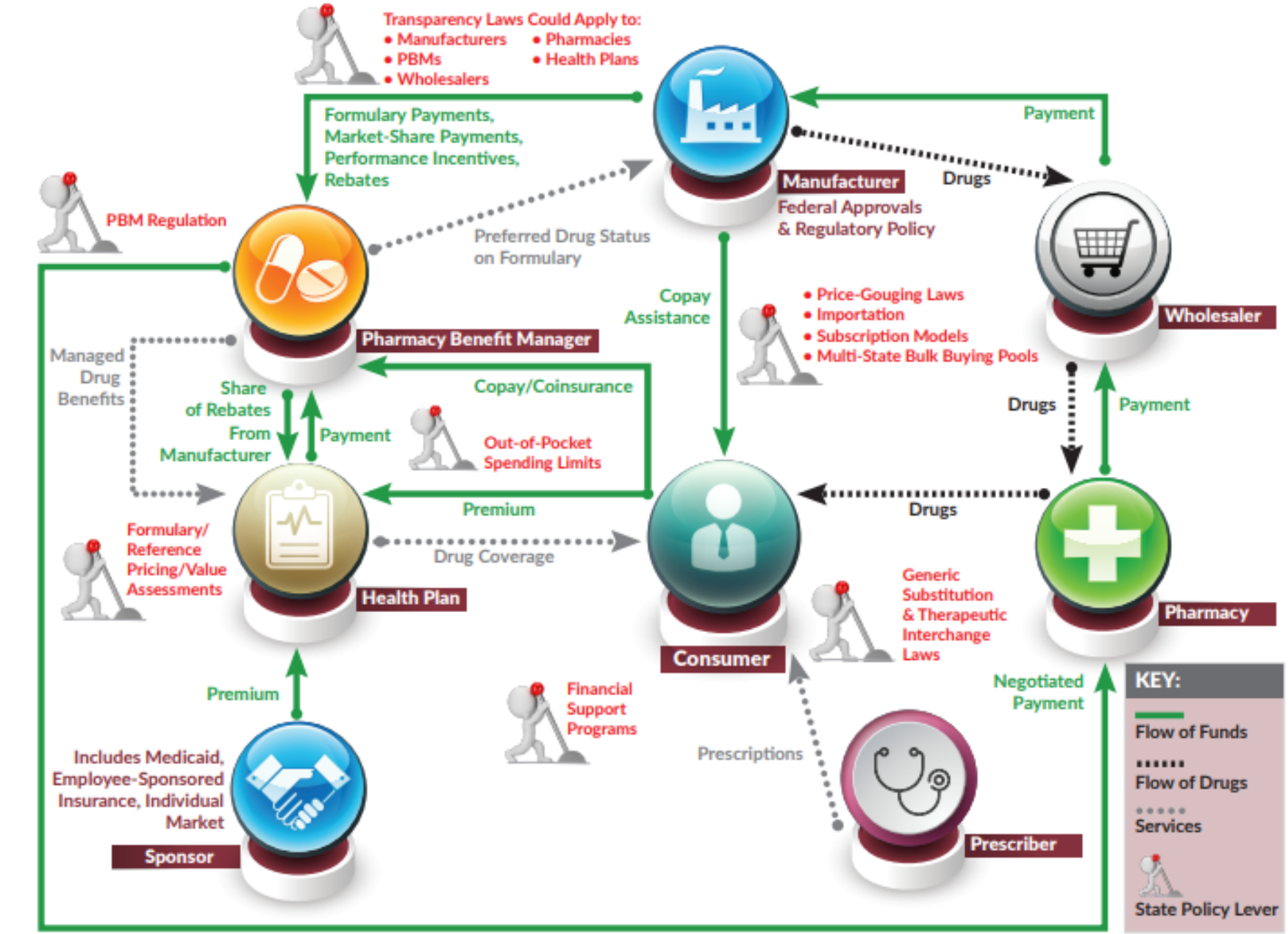
- Decrease indirect costs such as missed days of work, reduction in patient or caregiver productivity
- Be cheaper alternatives to hospitalizations, surgery, nursing facilities and emergency room visits
- Defend against or cure disease, improve quality of life, or prevent death

## Figure 1: Pharmaceutical Supply Chain: All Direct Transactional Relationships.




*Source: Division of Financial Regulation – State of Oregon*

*Figure 1.* **State Policy Levers in the Retail Prescription Drug Supply Chain**



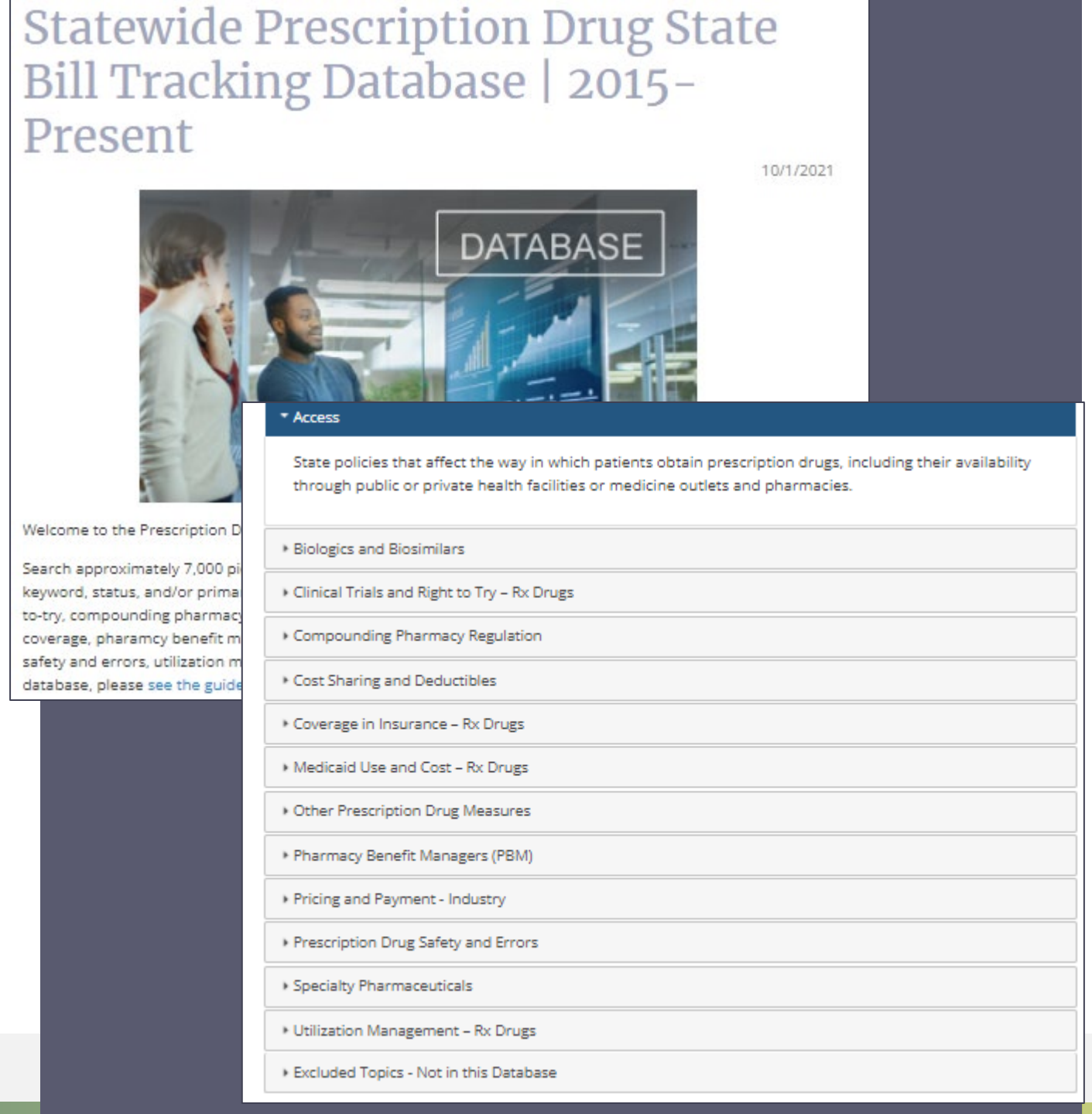

Note: Model represents non-specialty prescription drugs covered by health insurance.

*Source: Adapted by the Kansas Health Institute from "Follow the Money: The Flow of Funds in the Pharmaceutical Distribution System," Health Affairs Blog, June 13, 2017.*

# NCSL Prescription Drug Policy Database

- Spans seven years and tracks legislation in all 50 states, D.C. and the territories
- Search over **7,000 pieces of introduced and enacted** legislation in 13 categories
- Almost **800 bills** tracked across all 50 states and PR for 2023!
  - Over 100 enacted in 32 states.

https://www.ncsl.org/research/health/prescription-drug-statenet-database.aspx



# NCSL Resources

## NCSL's Prescription Drug Policy Resource Center

has information on....

- State Drug Wholesale Importation Programs
- 340B Drug Pricing Program and the States
- Copayment Adjustment Programs
- Bulk Purchasing
- Prescription Drugs and the Approval Process

**And so much more!!!!**

# Insulin Affordability: What's Next?

# TRIVIA

## How Many People Live With Diabetes in the U.S.?

A. 28.7 million
B. 1.9 million
C. 96 million
D. 37.3 million

# TRIVIA

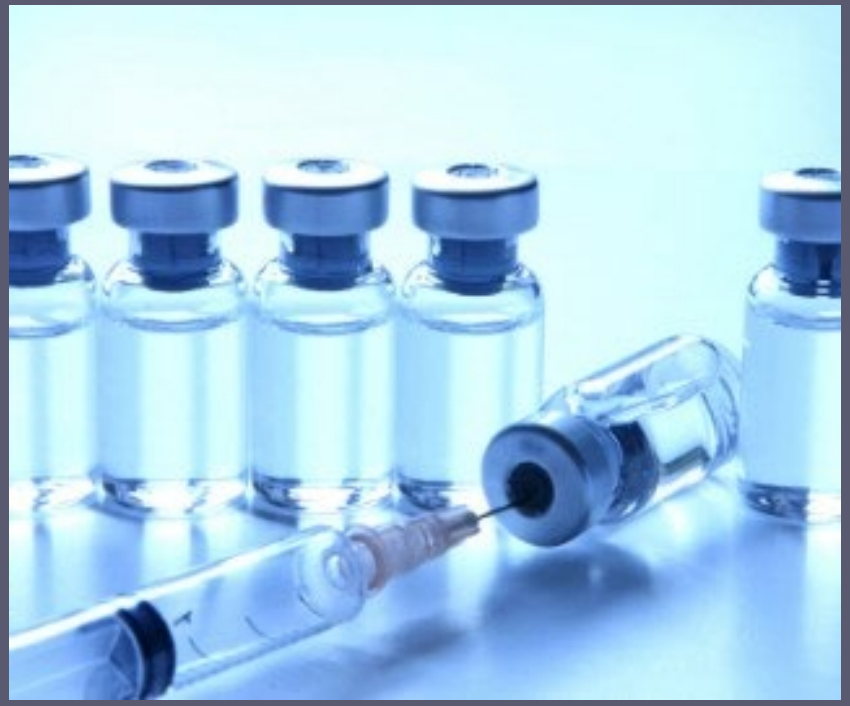
## How Many People Live With Diabetes in the U.S.?

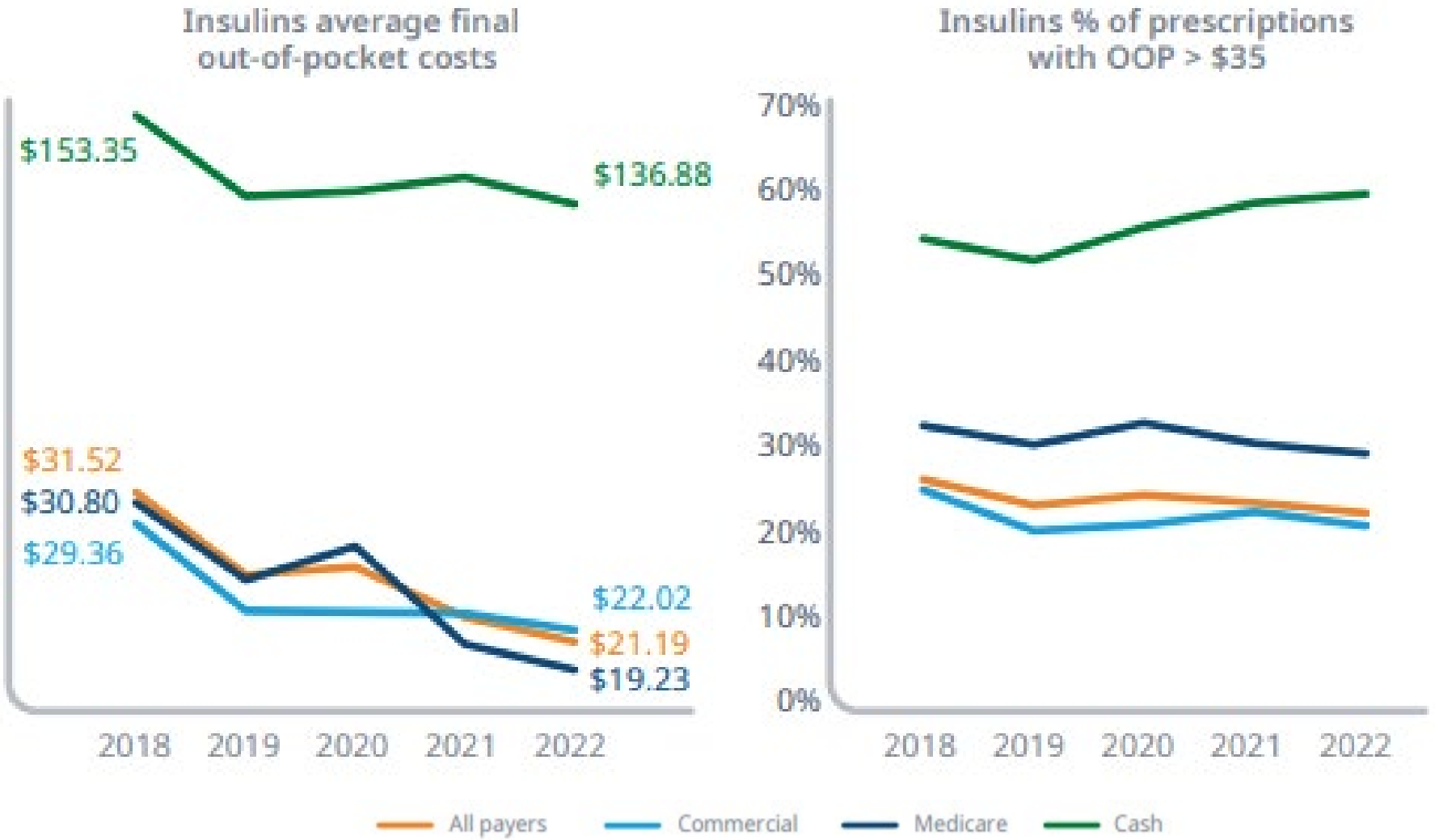
A. 28.7 million
B. 1.9 million
C. 96 million
D. 37.3 million

28.7 million people have a diagnosis of diabetes in the U.S.

They may need:

- Insulin
  - 31% use insulin
  - Type 1 requires insulin therapy
  - Type 2 may or may not need insulin
- Supplies:
  - Continuous glucose monitors (CGMs)
  - Insulin pumps
  - Lancets
  - Test strips
- Self-management education and support



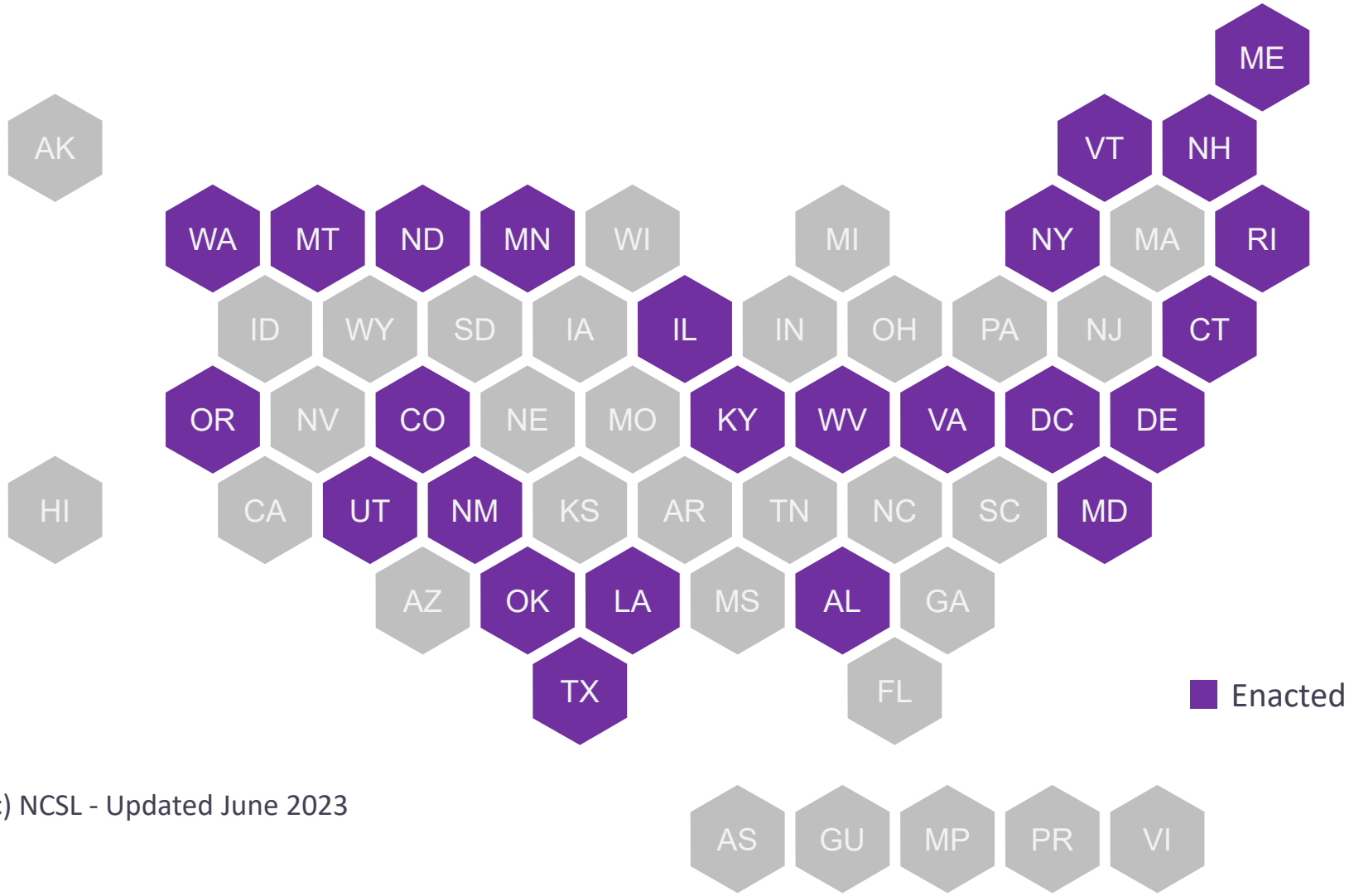



Source: IQVIA LAAD Sample Claims Data, Dec 2022.

- Testing supplies account for 27% of overall pharmacy costs for people living with diabetes.

- 56% of people with type 1 use supplies that add to their cost burden.

# State Legislation Capping Insulin Copayments

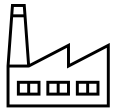



(c) NCSL - Updated June 2023

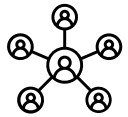
# Beyond insulin copay limitations

Copay limits on diabetic supplies = Connecticut, Delaware, West Virginia and D.C.

Emergency assistance programs = Colorado and Minnesota



Partnerships to manufacture insulin = California



Network adequacy standards for suppliers of durable medical equipment = New Mexico

Insulin manufacturers must verify whether the unavailability of a generic is due to pay for delay contracts = Texas

# Federal Policy

## Biosimilars

- Biosimilars are "generics" formulations of biologics
- Two biosimilar insulins approved - one is interchangeable, one is not

## Inflation Reduction Act (IRA)

- Starting Jan. 1, caps monthly out of pocket costs for insulin at $35 for Part D
- Monthly cap for Part B starts July 1
- Does not apply to private market/employer-sponsored plans or uninsured

# Think, Pair, Share

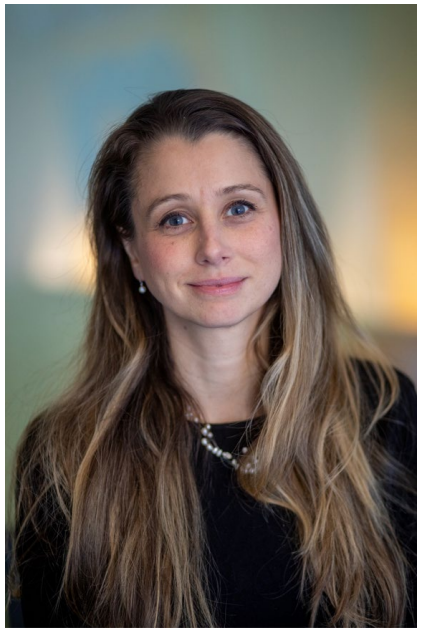
Turn to your partner and discuss:

- How is your state addressing insulin affordability?
- Do you have additional ideas to address this issue in your state?
- If you were going to dive deeper into this issue, what questions do you have?
- Do you need to involve others or gather information/data?

# Speakers

## Sharon Lamberton, PhRMA

## Dr. Mariana Socal, Johns-Hopkins



# Insulin Affordability: What's Next

*Sharon Lamberton, MS, RN*

*NCSL Prescription Drug Peer Learning Group, Portland, OR*

*June 21, 2023*

# Medical Innovation Has Transformed the Lives of Patients with Diabetes

A century ago, patients were treated with insulins from pigs and cattle.

Today, patients have access to insulins that operate at the molecular level which more closely resemble insulin released naturally in the body.

## More recent advances have driven much of this transformation.

- Maintenance of stable and consistent blood sugar levels is better than ever before, helping to avoid serious complications and reduce weight gain.
- Longer-acting insulins provide coverage for over 24 hours and enable greater flexibility in dosing and reduced risk of dangerous blood sugar drops.
- Rapid-acting insulins—including an inhaled form—enable dosing directly before or even after meals, rather than in anticipation of meals.
- Insulin pens offer greater convenience, including some that reduce injections for high doses or ease of use in children.

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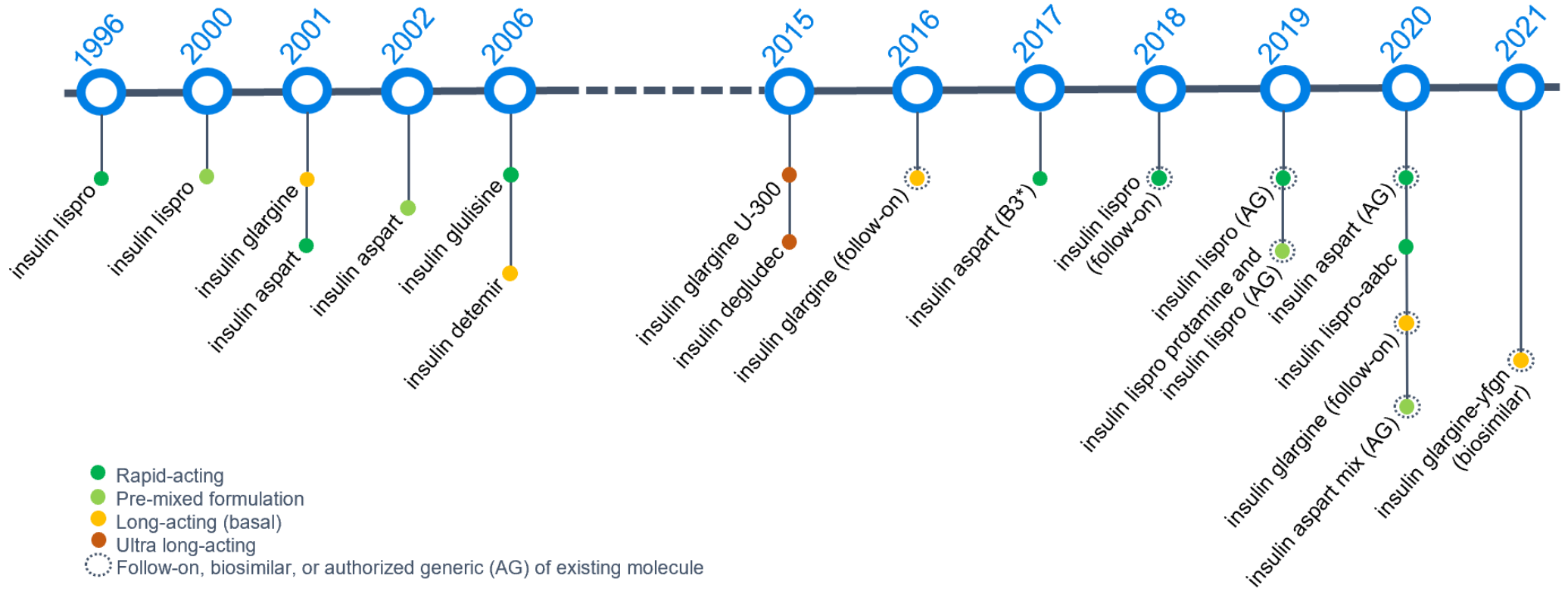
NOTE: Modern insulin treatment protocol often requires long-acting insulin to provide a base level of coverage all day along with meal-time administration of insulin to modulate spikes in blood glucose.

# Market Launches of Insulin Analogs, 1996-2021

**A wide range of brand insulins and lower-list priced insulins have become available to patients in recent decades.**

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**Following the transition date, authorized generics are regarded as unbranded biologics.

SOURCE: Milliman, Analysis of Insulin Competition and Costs in the United States, December 2021.

# Current System Can Lead Middlemen to Favor Medicines with High List Prices and Large Rebates

While follow-on, authorized generic and biosimilar insulins drive competition across the market, misaligned incentives mean PBMs may block patient access to these lower list-priced products in favor of products with large rebates.

- Follow-on insulins launched in 2016 and 2018 have been found to capture just 2-17% of the market share in Medicare by 2019.
- In 2022, two of the three largest PBMs excluded insulin authorized generics from national commercial formularies
- None of the nation's 3 largest PBMs included the low-list priced interchangeable biosimilar insulin on 2022 and 2023 national commercial formularies.

* Following the transition date, authorized generics are regarded as unbranded biologics.

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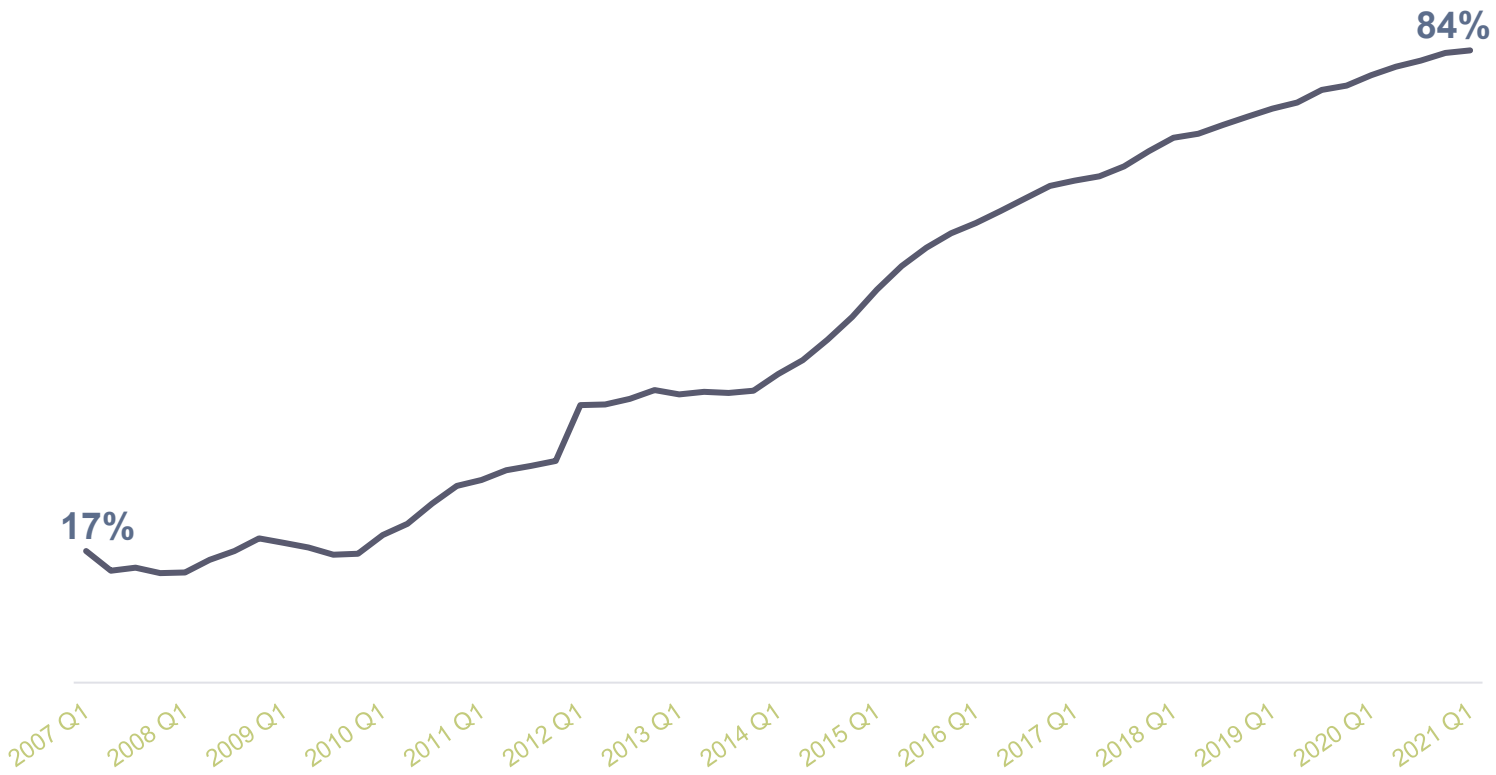
SOURCES: MedPAC Report to Congress, March 2022; Fein, A. "A World Without Rebates: Predictions for How the Channel Will Evolve and Why Drug Prices Will Go Down," March 20, 2019; Xcenda. "Skyrocketing growth in PBM formulary exclusions continues to raise concerns about patient access." May 24, 2022; Drug Channels, Five Takeaways from the Big Three PBMs' 2022 Formulary Exclusions January 2022. Drug Channels. The Big Three PBMs' 2023 Formulary Exclusions: Observations on Insulin, Humira, and

# Discounts, Rebates and Other Payments Have Increased Dramatically in Recent Years, Lowering the Cost of The Most Commonly Used Insulins by 84% in 2021

- Average Gross-to-Net Difference for Insulin Analogs, 2007-2021

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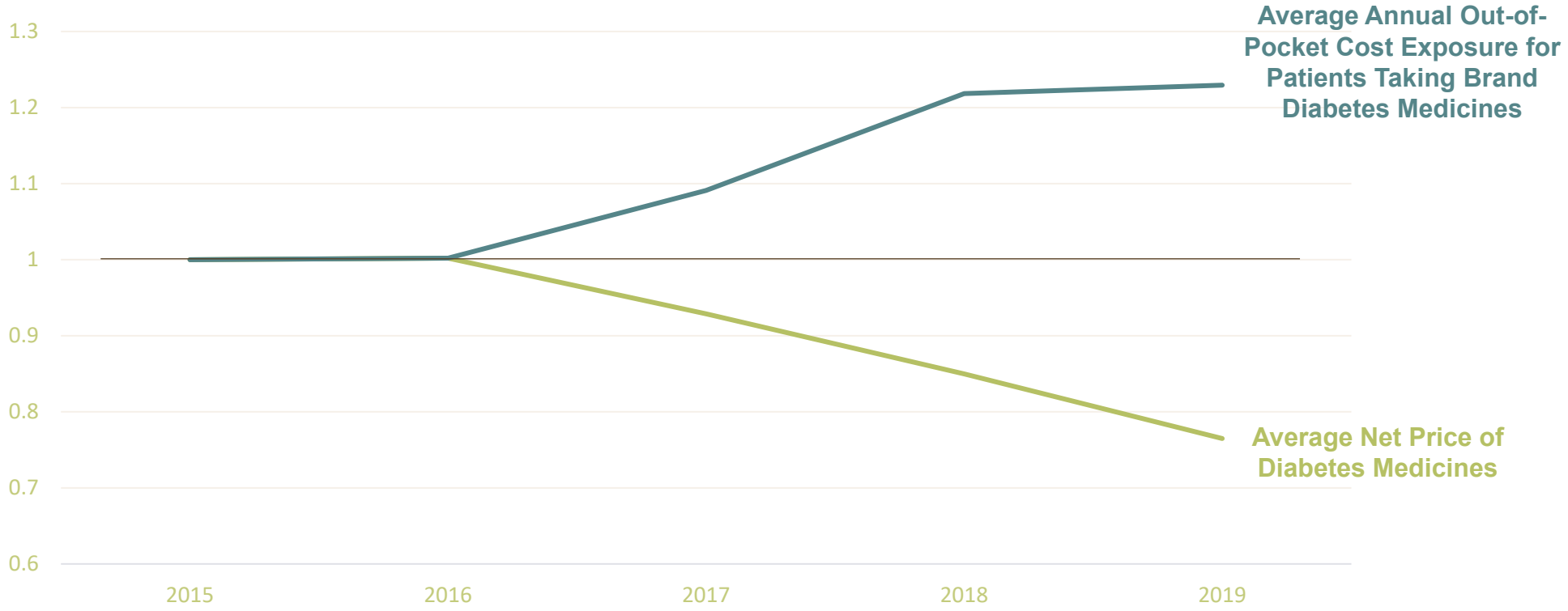
SOURCE: Milliman, Analysis of Insulin Competition and Costs in the United States, December 2021.

# As Net Prices for Diabetes Medicines Fall, Insurers and their PBMs Use Deductibles and Coinsurance to Shift More of The Costs for Medicines onto Patients




NOTES: Out-of-pocket exposure measures the amount health plans required patients to pay; manufacturer cost sharing assistance could help patients pay this required amount. Diabetes net price data includes both brand and generic medicines.

SOURCES: IQVIA U.S. Market Access Strategy and Consulting, July 2020.; IQVIA, "Diabetes Costs and Affordability in the United States." June 2020.

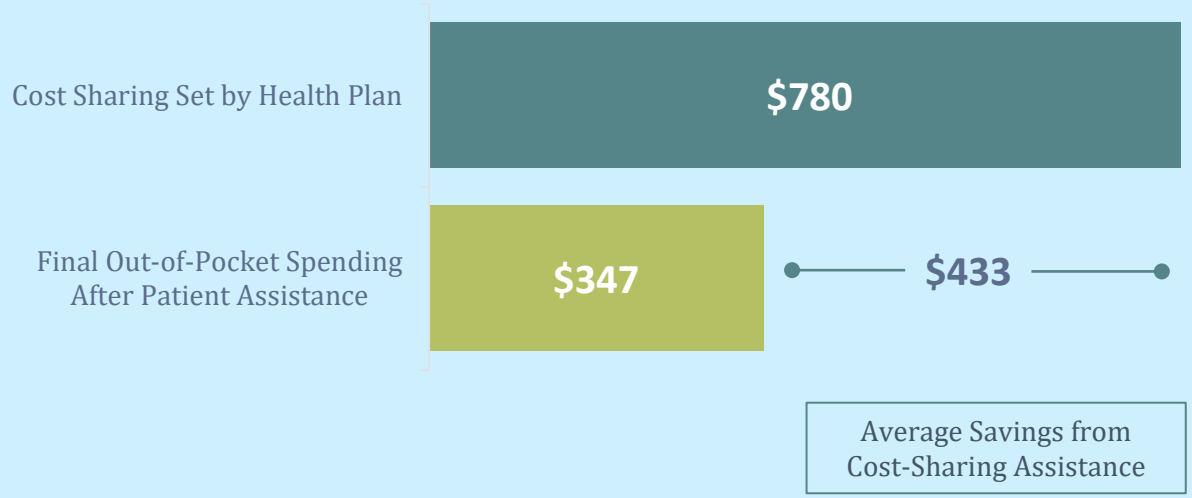
# Patient Spending On Brand Diabetes Medicines Would Have Been Twice As High Without Cost-Sharing Assistance

Patients just beginning treatment with brand medicines are nearly

**3x**

more likely to abandon their treatment at the pharmacy if they don't use cost-sharing assistance.

○ **Average Cost Sharing Requirement and Final Annual Out-of-Pocket Spending for Patients Taking Brand Diabetes Medicines Who Used Cost-Sharing Assistance, 2019**




NOTES: Includes out-of-pocket spending for condition-specific brand medicines only. Out-of-pocket cost sharing requirement measures the amount health plans required patients to pay. Difference between cost sharing requirement and final out-of-pocket spending represents the savings from use of cost sharing assistance.

SOURCES: IQVIA, Patient Affordability, Part 2, 2018; PhRMA. Commercially Insured Patients with Chronic Conditions Face High Cost Sharing for Brand Medicines. January 2021. Available at: https://phrma.org/cost-and-value/commercially-insured-patients-with-chronic-conditions-face-high-cost-sharing-for-brand-medicines

# Policy Solutions to Address Insulin Affordability Challenges

- **In the absence of broader systemic reforms to the rebate system misaligned incentives will continue to drive affordability challenges.**

## Require Rebate Pass-Through

Insurers and PBMs should pass through negotiated rebates and discounts and provide first dollar coverage of insulin, to help lower out-of-pocket costs for insulin and allow patients to spread costs throughout the year.

## Address Incentives that Harm Patients, Benefit Middlemen

PBMs should be:

- Prohibited from receiving compensation tied to a medicine's price. Instead, PBMs should receive a fixed fee for their services.
- Required to disclose aggregate rebates and other fees insurers and middlemen get so stakeholders can fully benefit from negotiated savings.
- Required to act in the best interest of patients and health insurance clients, forcing them to put patients' wellbeing over their own financial interests.

## Address Affordability in the Commercial Market

Patients managing chronic diseases should not be subject to a deductible, rather they should have at least some of their medicines covered by their insurance from day one.

Provide flat copays for insulin to patients in the commercial market and count cost-sharing assistance toward deductibles and out-of-pocket maximums

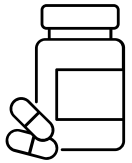
# PhRMA Created the Medicine Assistance Tool (MAT) To Help Patients Navigate Medicine Affordability

A search engine to connect patients with

**900+**

assistance programs offered by biopharmaceutical companies, including some free or nearly free options

Resources to help patients navigate their insurance coverage



Links to biopharmaceutical company websites where information about the cost of a prescription medicine is available

**Learn more at www.MAT.org**

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# Insulin Affordability: What's Next?

Mariana Socal, MD PhD
Associate Scientist
Johns Hopkins University
msocal1@jhu.edu

# About me

- Overview of research portfolio:
  - Drug formularies, utilization, and spending
  - Role of pharmacies and PBMs
  - Competition, biosimilars including insulin
  - Pharmaceutical supply chain, drug shortages

- Practice activities:
  - Technical assistance (Federal government, Congress, States)
  - Public testimony (Congress, States, federal agencies)
  - Information sessions (self-insured employers, media)

msocal1@jhu.edu

# Main origins of insulin affordability problems

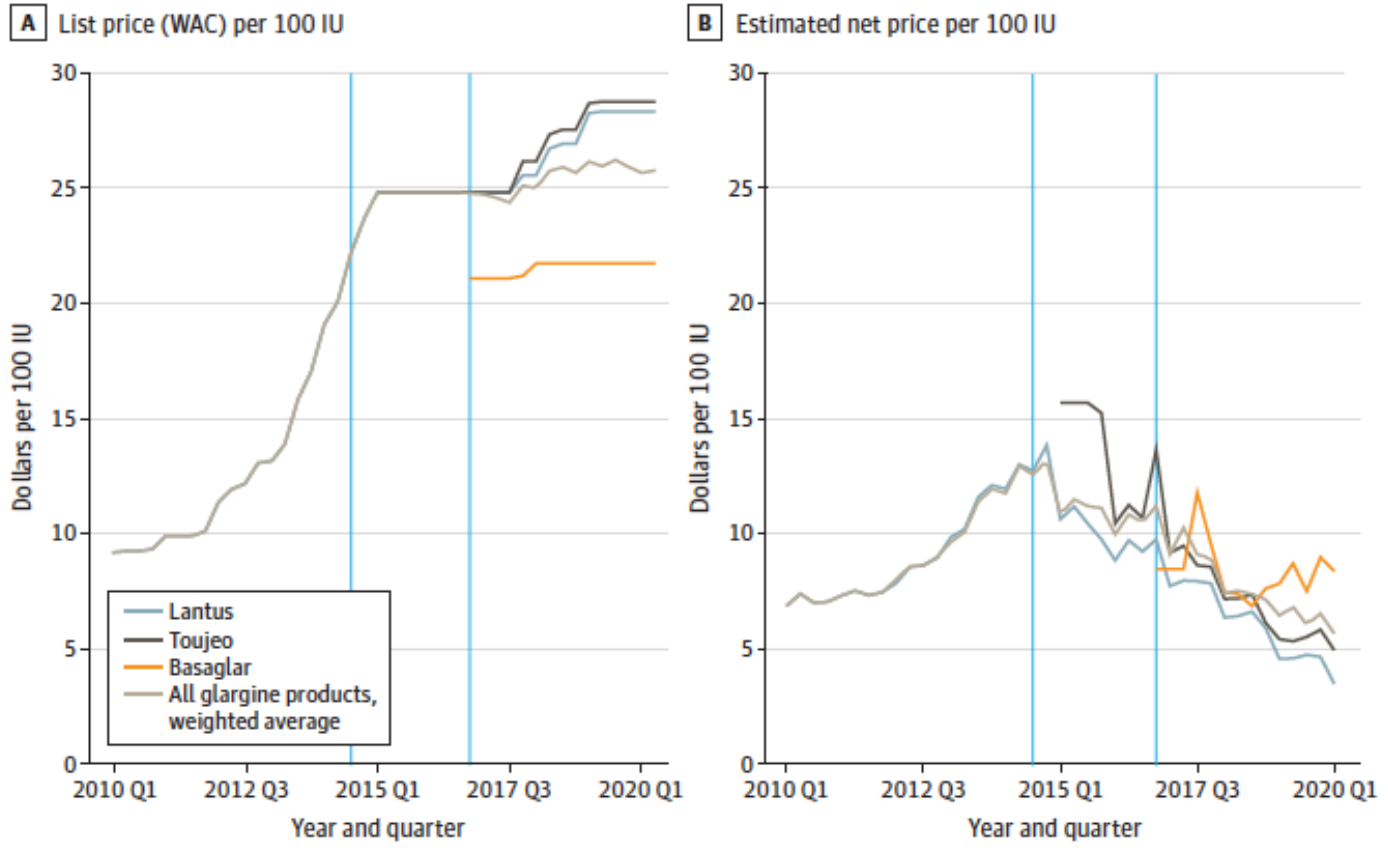
- About 1/4 of patients use less than prescribed due to **high out-of-pocket (OOP) costs**
  - Affordability has been mainly a problem of users, not of insurers

- Large difference between list and net prices of insulin
  - High list prices are a problem for uninsured/underinsured patients who pay full price
  - Fully-insured patients are also a problem because insurers may **cost-shift** to patients
    - Example: coinsurance (requiring the patient to pay a percentage of the drug's cost)

- How is patient pay calculated?
    - Over the manufacturer price or the price negotiated by the insurer?

# How the high prices of insulin can pose challenges for patients

**Figure 1. List Price and Estimated Net Price of Insulin Glargine Products**




The first blue vertical line represents the tentative US Food and Drug Administration approval of the insulin glargine injection biosimilar, Basaglar, in August 2014. The second blue vertical line represents Basaglar's US market entry on December 15, 2016. WAC indicates wholesale acquisition cost.

Patient payment is calculated over the higher list price, NOT the lower price negotiated by insurers

For glargine insulin the difference is 5-fold

# Solutions implemented thus far: a patchwork of approaches

- 1) Out-of-pocket caps: stop insurers from cost-shifting
  - States were the first to implement out-of-pocket caps
  - Inflation Reduction Act (IRA) 2022 implemented OOP cap for Medicare
  - Gaps: uninsured, commercial patients according to state

- 2) Biosimilars: introduce lower, transparently-priced options to the market
  - Unbranded insulin (Semglee), CivicaRx, California Cal-Rx Initiative

- 3) Lower list prices: Manufacturers' response to changing incentives
  - Addresses Medicaid rebate cap removal (January 2024)
  - Manufacturers will still make a profit on their products even after the price change

Thank you !

msocal1@jhu.edu

# Q & A

# Discussion

# Break

# Pharmacy Benefit Managers: Caught in the Middle

# State Pharmacy Benefit Manager Reforms

# Utilization Management Processes

NCSL
NATIONAL CONFERENCE OF STATE LEGISLATURES

## Step Therapy

- Patients may be required to try a lower cost drug that is therapeutically equivalent before "stepping up" to a more expensive drug.

## Non-Medical Switching

- Patients may be switched to a different prescription drug products for non-medical reasons, like when there is a change in a PBMs formulary.

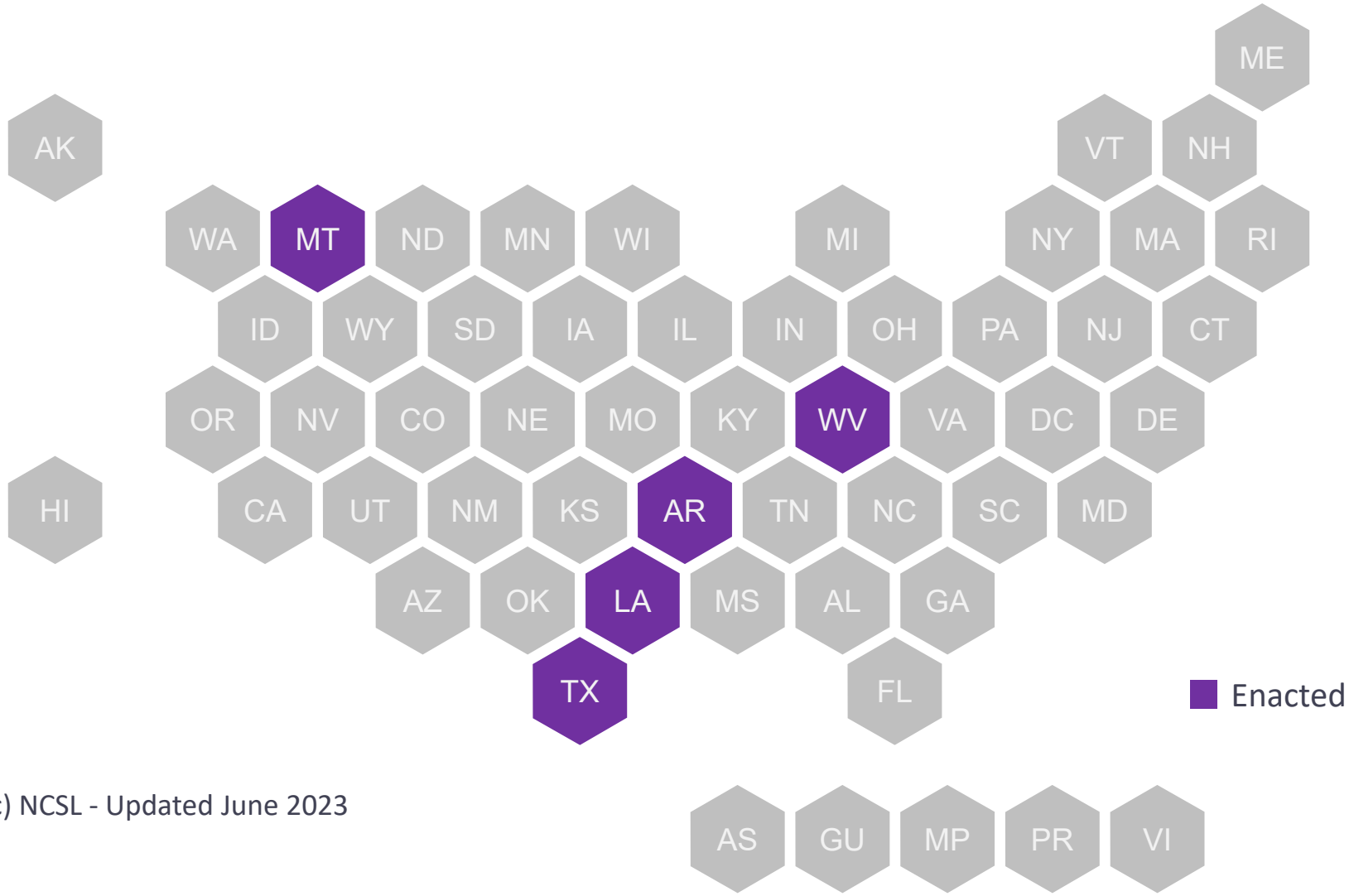
## Prior Authorization

- When a health care provider must obtain health plan or PBM approval before a drug can be prescribed and subsequently covered.

## Copay Accumulators

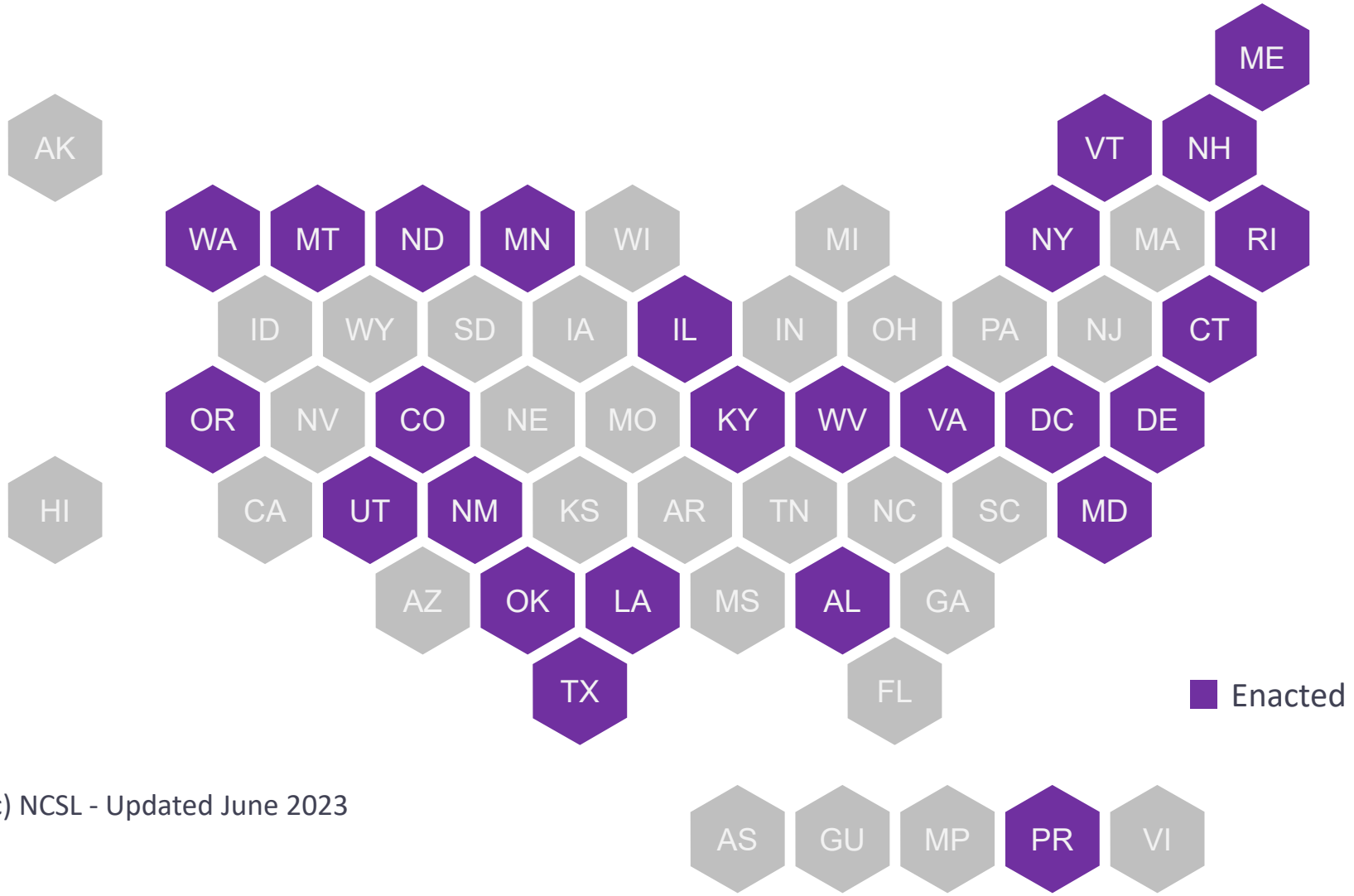
- Restricts the use of manufacturer copay coupons from being applied to a patient's out of pocket maximum, like deductibles.

# Prior Authorization Exemptions




(c) NCSL - Updated June 2023

# State Legislation Capping Copayments

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# Rebate Pass Through

## State Legislative Examples

### Arkansas
### House Bill 1481

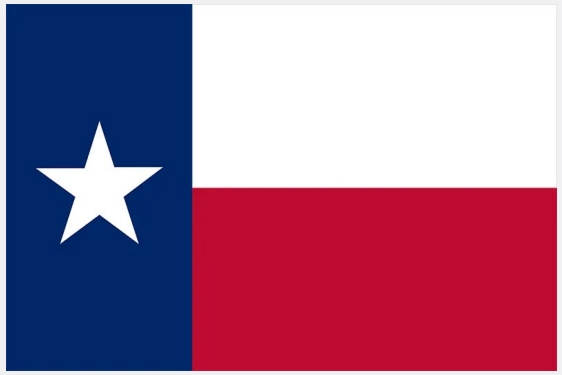
Health plan enrollees


### Indiana
### Senate Bill 8

Plan sponsors/enrollees


### Texas
### House Bill 4990

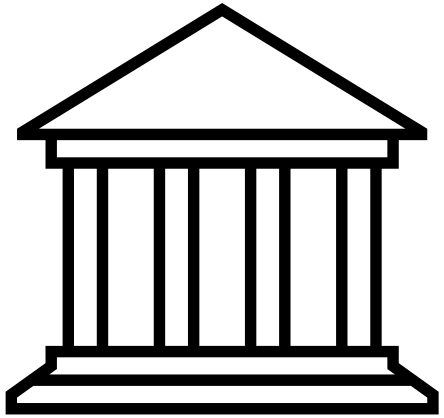
State employees, teachers and retirees, corrections



# Federal Action

Over the past year....

- Investigation on PBM market impact by the Federal Trade Commission.
- Congress has proposed several PBM reform measures including:
  - Ban spread pricing.
  - Prohibit pharmacy clawbacks.
  - Require PBMs to annually report to FTC and/or plan sponsors.
  - Pass through rebates to plan sponsors.
  - Authorize state attorneys general to enforce provisions.



# State Profile Review and Discussion

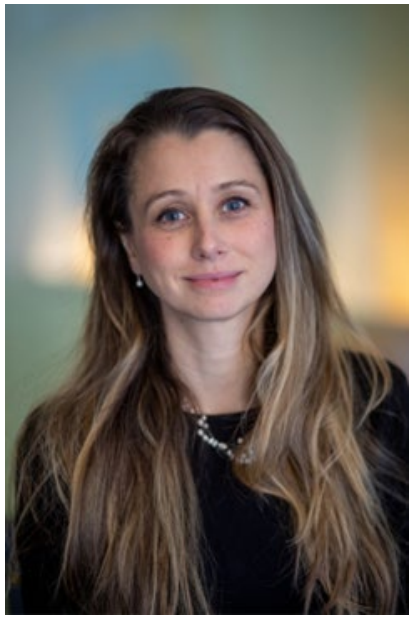
Take 5 minutes to review your state profile and jot down your thoughts to the following questions:

- Is there something that surprises you?
- Is there a policy option missing from your chart that interests you?
- What were some bills related to PBMs that your legislature considered during the 2023 session, if any?

# Speakers

## Jane Horvath, Horvath Health Policy

## Dr. Mariana Socal, Johns-Hopkins



# Pharmacy Benefit Managers
# What They Do/How They Do It
# Why States are Concerned

NCSL Rx Workshop

June 21, 2023

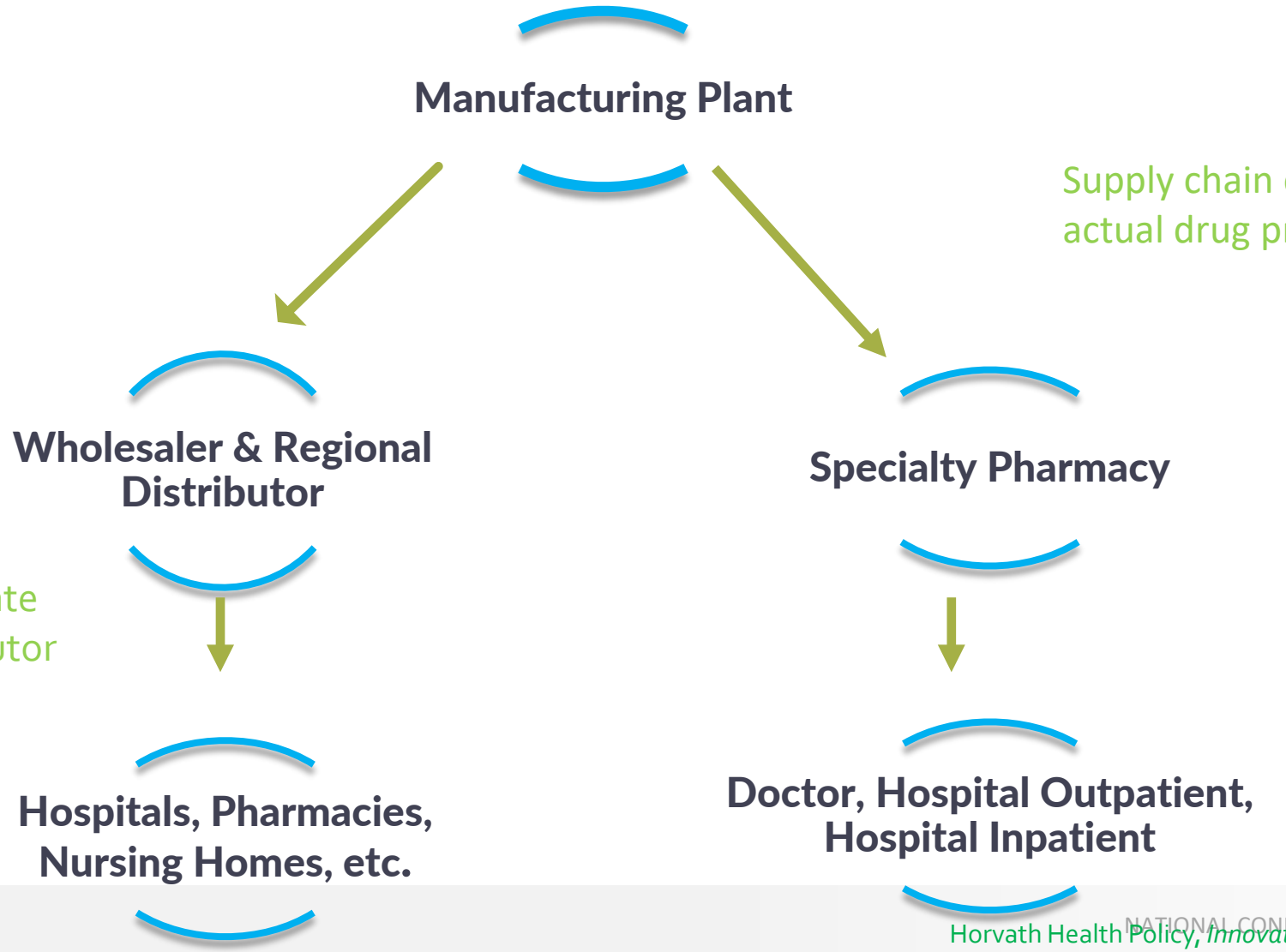
Jane Horvath

Horvath Health Policy

# BACKGROUND

## Pharmaceutical Market Players

# Basics of Rx Product Supply Chain – no PBMs



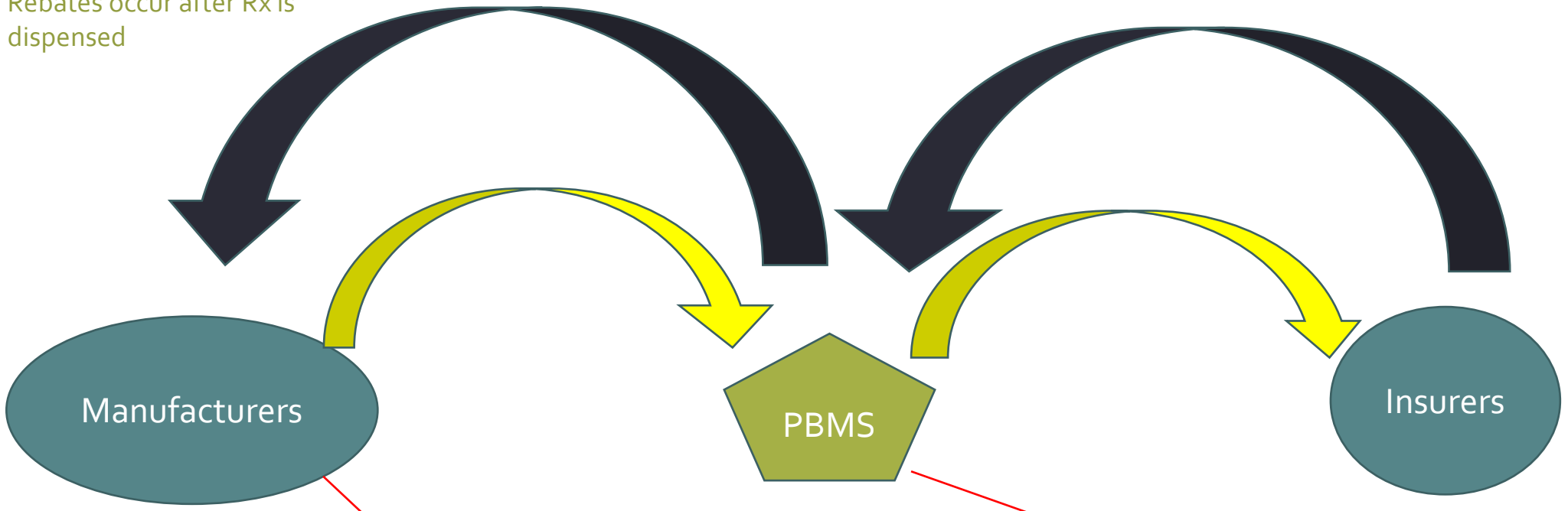

Supply chain entities buy/own/sell actual drug products.

Repackagers operate in between distributor and end purchaser

# Basics of the Rx 'financing chain'

PBMs & insurers do not buy, sell, or own drugs. They pay for drugs used by enrollees

Rebates occur after Rx is dispensed




One-off: Mfrs may negotiate on-invoice discounts with large medical facilities. Wholesaler sells Rx at the negotiated discount. Wholesaler then 'made whole' by mfr. Mfr does not sell directly

Hospitals

PBM reimburses product cost & professional fee

Outpatient Pharmacies

# Who Does What? PBMs (or Insurers without PBM)

- Create pharmacy networks
  - Negotiate pharmacy professional (aka dispensing) fees
  - Set drug reimbursement amounts
  - Pay pharmacy claims, bill insurers for amounts paid to pharmacies
  - Operate mail order pharmacy (PBM only, not insurers)
- Operate formulary
  - Small plans often use PBM national formularies, large plans may design their own
  - Negotiate manufacturer rebates based on formulary placement
  - Decides on pharmacy utilization management strategies
- Reimburse pharmacies and providers for drugs dispensed or administered to enrollees
- Collect manufacturer price concessions based on paid Rx claims
- Health plans are state-licensed; not all states license PBMs

Horvath Health Policy, *Innovations in Healthcare Financing Policy*

# Market Evolution & Issues of Concern

PBM Business Practices

# Evolution of PBM Role in Brief (1)

- Retail pharmacy benefit administration was straightforward and low overhead until about 35 years ago.
  - Drugs priced to maximize sales
  - Drugs priced to compete in the market for sales (on-invoice price, not rebates)
  - Whether managed care or fee for service, PBMs paid pharmacy claims without need for strong cost management.
- Wonderful scientific advancement led to more Rx treatments for more illnesses.
  - Lots more people taking lots more drugs, leads to lots more costs
  - Rx management starts to get complicated
- Manufacturers in 1990s started to focus on product *price* rather than *sales volume* to meet revenue targets.
  - Start of the movement to value based pricing
  - Even the originator of the industry value-based pricing strategy says it's gone too far. (STAT First Opinion Kember 5/13/2022)
  - PBM role expanded – pharmacy networks, mail order, Rx deductibles, dictate (rather than negotiate) pharmacy reimbursements

# Evolution of PBM Role in Brief (2)

- Increasing complexity and cost of Rx benefit led to greater role for PBM
  - Active formulary management (what is covered and how it is covered)
  - Active pharmacy network management (provider network creation)
  - Active pharmacy reimbursement management (not paying just what is billed)
  - Active negotiation with manufacturers for rebates on costly drugs
    - More rebates means a better formulary position for manufacturers' drug(s)
- Growth in pharmacy complexity led to growth in size of PBM industry
- Growth of PBM industry led to industry mergers/consolidation
- PBM industry consolidation led to vertical corporate integration (mergers)
  - with mail order pharmacy, then retail pharmacy, then insurers, then medical practices, group purchasing organizations
  - Hypothesis: This is why the industry became so powerful and misaligned with customers and providers


Source: Drug Channels 12/2022 https://www.drugchannels.net/

# PBM Business Practice Concerns

- Improper Patient Pay and Access Policies
  - Patient copay exceeds what PBM will reimburse the pharmacy
  - Gag on pharmacist patient counseling on costs and alternatives
    - Outlawed in all states with new federal law
  - Financial penalties/higher cost share for patient failure to use mail order or corporate pharmacy chain.
- Independent pharmacies can be impacted by PBM competition
  - Discriminatory pharmacy reimbursement policies
  - Discriminatory pharmacy audit and claims payment reviews
  - Arbitrary claw back of money PBM already paid to pharmacy
  - Prohibit community pharmacy from home delivery (boosts PBM mail order operations)
  - *All these provisions may be fine for market battles between corporations, but these same provisions drive independent pharmacies out of business.*

# PBM Business Practice Concerns

- Lack of transparency to employer and other health plans
  - Spread Pricing: charging health plan clients more for enrollee drug spend than the PBM actually spent (Centene – 10 state AG settlements)
  - Contracts and operational complexity prevent smaller insurers from innovating
- Contract provisions that can increase Rx spend
  - Opt to cover higher priced drugs with higher rebates over generics or lower cost Rx alternates
    - Increases rebates while increasing total spend
  - Opt to cover lower cost drugs with lower or no rebates
    - Low-cost versions of insulins and other drugs only available to people without insurance – because PBMs will not cover for insureds
- Vertical integration of insurer, PBM and pharmacy (retail and specialty) does not ensure alignment around patient care
  - CVS/CVSCaremark/Aetna consolidation. Medicare Part D, Whistleblower lawsuit
- And now…..
  - PBMs/Conglomerates creating Group Purchasing Organizations…negotiate and collect rebates…even less transparency

# State Government Responses

PBM Business Practice Concerns

# Brief History of PBM Regulation

- Concerns of independent pharmacists morphed into a more general review of PBM business practices. Trends in state regulation
  - 2012-2013 – laws to regulate PBM pharmacy audits, PBM reimbursement/payment to pharmacies
  - 2015-2017– limit patient out of pocket costs relative to cost of the drug, ban gag clauses, reviews of state employee and Medicaid PBM contracts
  - 2017 – 7 states enact laws. Broader PBM business practice concerns, including transparency (NV, OR)
  - 2018 – 14 states enact 25 laws
  - 2019 – 20 states enact 24 laws
  - 2020 – 20 new laws and feds enact transparency law that includes PBM transparency. 1st report due in 2023
  - 2021 – 15 states enact 21 new laws new focus on discrimination of 340B entities
  - 2022 – 11 states enact 18 new laws
- States have returned to their statutes multiple times to address PBM business practice concerns
- Rutledge v PCMA decision December 2020, Supreme Court.
  - States can regulate all health plans in a state with regard to healthcare rate setting. PBM contractors for employer plans not exempt from state regulation.

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# West Virginia PBM Law – Example of State Laws

- 2017 – Pharmacy Audit Integrity Act – addresses unfair audit practices SB522. Requires PBM registration
- 2019 – Fairness in Cost-Sharing Act – requires counting of patient Rx cost sharing that is paid for by a third party on behalf of patient HB2770
- 2019 -- Pharmacy Audit Integrity Act – adds more limits on PBM practices and consumer protections SB489
- 2020-- Pharmacy Audit Integrity Act – replaces registration requirement with licensure requirement HB4058
- 2021 -- Pharmacy Audit Integrity Act – add'l consumer protections and PBM rebate reporting HB2263
- 2022-- Pharmacy Audit Integrity Act – add'l consumer protections and market behavior rules HB4112

# PBM Rules Across the States

- Halt unbalanced patient cost and access policies
  - Patient cost share cannot exceed PBM pharmacy reimbursement
  - No gag clause
  - No $ penalties when patient does not use mail order
  - No reimbursement or access discrimination of 340B pharmacies
  - Allow patient choice of pharmacy without penalties
  - Patient cost-share based on PBM's net cost (after rebates)
- Halt policies that disadvantage independent pharmacies
  - No reimbursement policies that disadvantage independents
  - No unfair audit practices
  - Allow independents to provide home delivery
  - Minimum pharmacy dispensing fees of $10.49
  - No performance metrics for dispensed drugs (ie generic dispensing rate)
  - Allow performance metrics for pharmacy care
  - Pharmacy reimbursement cannot be less than NADAC (federal drug cost survey file) or wholesale acquisition cost
  - No pharmacy network participation requirements more stringent than State laws

# PBM Rules Across States

- Improve market transparency
  - Require PBM licensure
  - Ban spread pricing
  - Report to Division of Insurance (DOI) rebates collected, retained by PBM, passed through to the health plan and/or passed through to patient
  - Report to DOI rebates by therapeutic class
  - Report to DOI pharmacy reimbursement formula
  - Report to DOI pharmacy network adequacy
  - Report on annual wholesale acquisition cost (WAC) of 25 highest spend drugs
  - Report rebates received in aggregate and therapeutic class

# Feds Get Started Regulating PBMs

- 2019 Congress bans any contract that prohibits pharmacy from advising patients on Rx costs and purchase options
  - Follows laws of many states
- 2021 Require all health plans and their PBMs
  - to report to Dept of Labor and Health and Human Services data:
    - 50 Rx  for highest cost, for most prescribed, for largest spending increase
    - Follows laws of many states
    - Detailed data on patient costs, rebates, fees, etc for each drug
    - Report to public in 2023
- 2022 Federal Trade Commission (FTC)
  - decides to investigate PBM industry -- ongoing
- 2023
  - 7 Senate PBM bills, 3 out of Committee
  - 5 House PBM bills,  2 out of Committee
  - Bills follow various laws of many states

# Innovations/Alternatives

- Oregon/Washington Array Rx
  - Non-profit, open to other states, private plans
    - Many services
    - NV uses the discount card
- Employer Coalition
  - Created new PBM for purposes of working the Mark Cuban's Low Cost Drugs
- Manufacturers
  - Launching Rx at 2 price points
    - 1 for PBMs that want large rebates and high price
    - 1 for PBM, payers that want lower list price
  - Announcing significant price cuts for on-patent products and setting up their own distribution system to control price all the way to the consumer(Lilly)
  - Low Cost Drugs and CIVICA Rx setting up their own distribution systems to improve consumer access and ensure that the price stays low through the supply chain

# Thank You!

Jane Horvath

Horvath Health Policy, *Innovations in Healthcare Financing Policy*

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*Funding Sources: contractor to Arnold Ventures, The Impact Project, State of Oregon, AARP, and other state-facing consulting groups*

JOHNS HOPKINS
BLOOMBERG SCHOOL
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# Pharmacy Benefit Managers: Role, Impact, and Reform

Mariana Socal, MD PhD
Associate Scientist
Johns Hopkins University
msocal1@jhu.edu

# PBM Roles (*insurers, employers, Medicare PDPs, Medicaid MCOs)

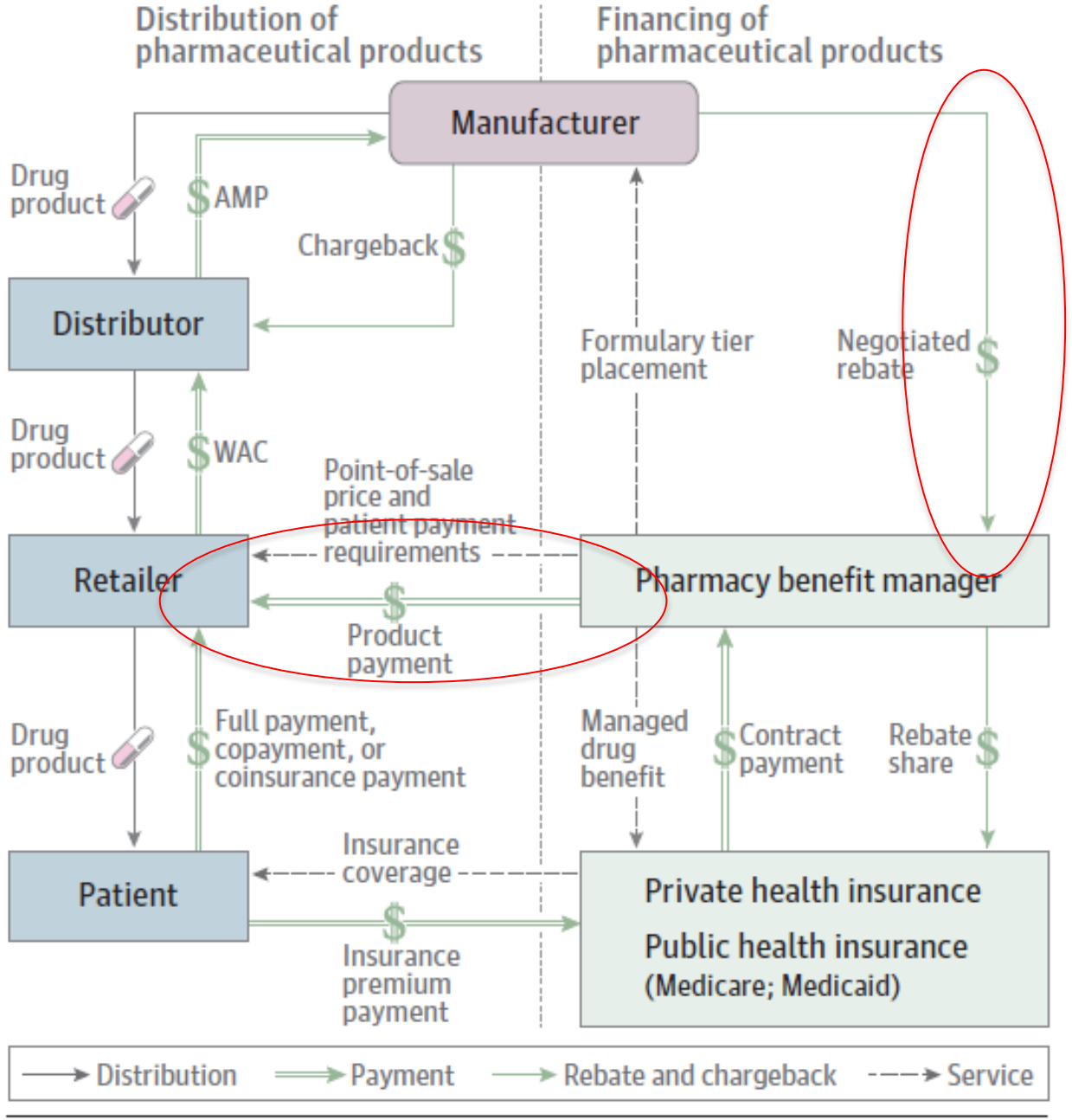
- 1) **Help insurers* determine formulary of which drugs will be covered and for which price**
  - But PBMs do not pay for drugs (have no “skin in the game”).
  - Rather, PBMs can make a profit if more expensive products are covered
    - For branded drugs: PBM negotiates between insurers and drug manufacturers
    - PBM negotiates a rebate, can keep a portion of the rebate
  - For generic drugs: PBM negotiates between insurers and pharmacies
    - PBM can create a “spread” (“spread pricing”) and keep it

- 2) **Help insurers determine how much a patient will be required to pay for a drug**
  - PBM has incentive to cost-shift to patients; helps keep premiums low

- 3) **Create pharmacy networks & “negotiate” prices with pharmacies**
  - PBM sets a confidential and proprietary list for pharmacy reimbursement (MAC list)
  - PBM has incentive to favor pharmacies with which they are integrated

# PBM drug price negotiations

Figure. Flow of Pharmaceutical Funds, Products, and Services




Generic drugs- spread pricing

Branded drugs- rebates

AMP = average manufacturer price
WAC = wholesale acquisition cost

Dabora, Turaga & Schulman, JAMA July 4, 2017 Volume 318, Number 1

# PBM Impacts

- **Higher patient and payor spending -> lower access**
  - Waste-free formularies: 9% - 15% savings in post-rebate PMPM spending
  - High-cost branded drugs, me-too products, high-cost generics create profit to PBM
- **Cost-shifting to patients through high deductibles and coinsurance requirements**
  - Insulin example
- **Low transparency**
  - Prices are unknown, sometimes even for the plan sponsor
- **Potentially anticompetitive practices against unaffiliated pharmacies**
  - Prevents patients and insurers from accessing marketplace options
  - Pharmacy closures

# Reform efforts

- Our research: in 2021, 41 states had implemented regulations on PBM pricing and reimbursement practices
  - Challenge: too many “problem” practices – but similar incentives
  - Challenge: plan sponsors are “hooked” on rebate checks, resistant to change
  - Possible solution: require state intervention; ideally, change the incentives

- Federal legislation (example 2023: Pharmacy Benefit Manager Reform Act (Senate)
    - Bans spread pricing and requires that rebates be passed through to plan sponsors
    - Requires annual reports to the FTC: $ plan paid for drugs, $ paid to pharmacy
    - Prohibits clawbacks of Medicare DIR fees

  - GAPS: “pass-through” bills do not require rebates to be passed to patients; bills do not include delinking PBM compensation from list prices of drugs; what constitutes a rebate can be redefined

Thank you !

msocal1@jhu.edu

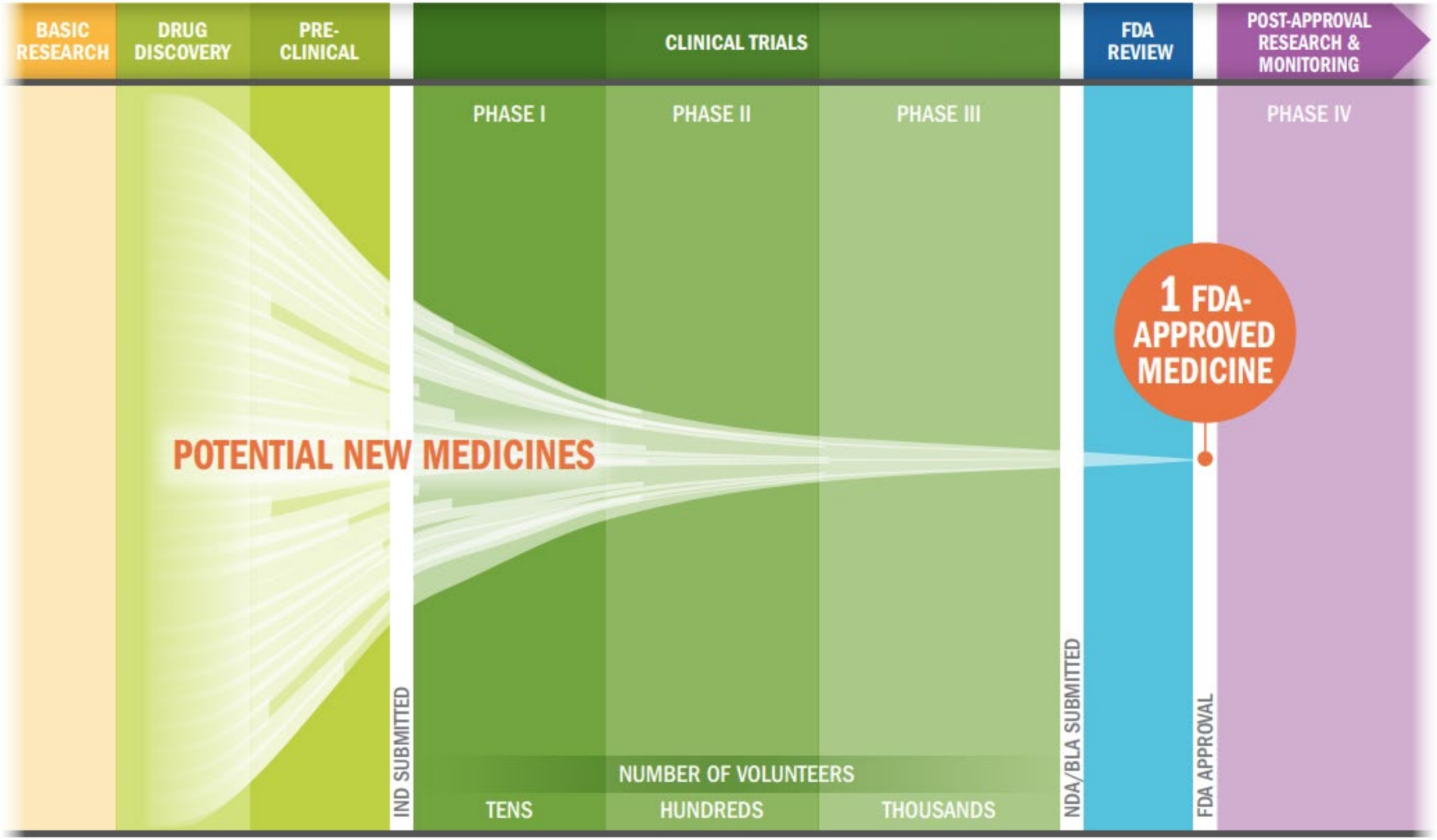
# Q & A

# Discussion

# Lunch

# Price and Cost Transparency

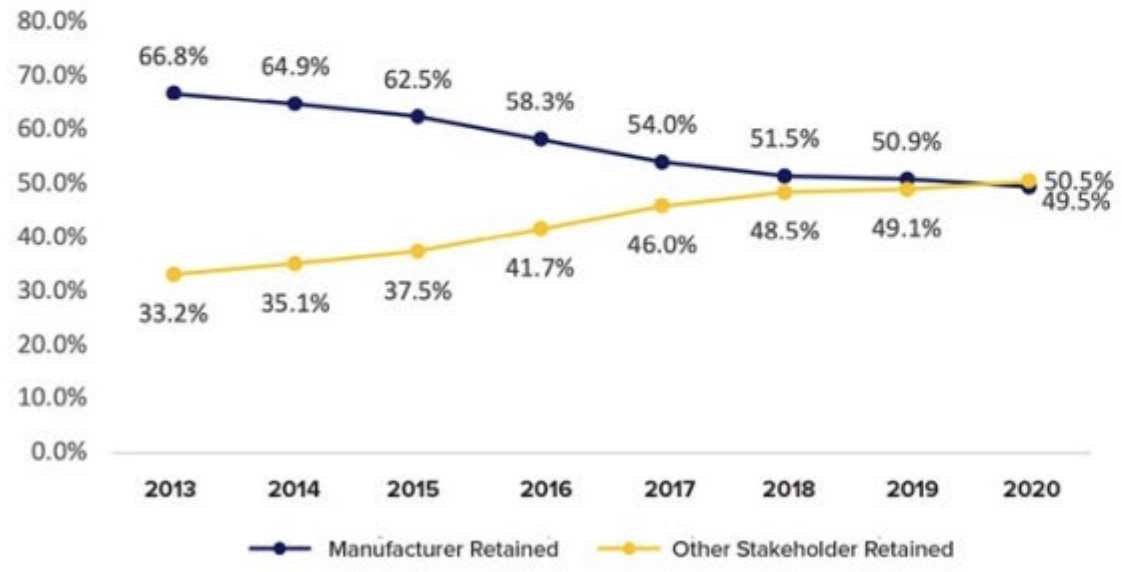
# THE BIOPHARMACEUTICAL RESEARCH AND DEVELOPMENT PROCESS



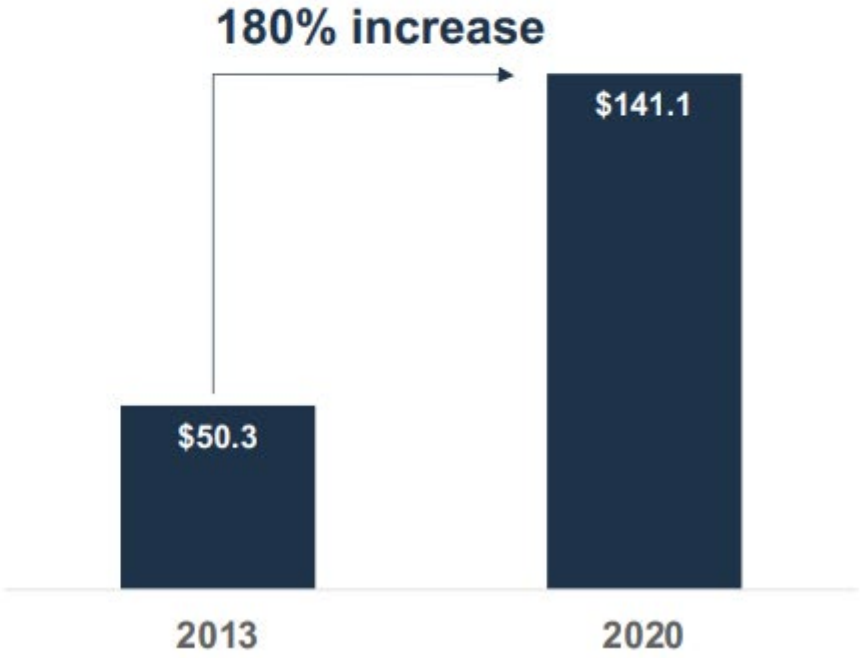

Key: IND: Investigational New Drug Application, NDA: New Drug Application, BLA: Biologics License Application

# Revenue Distribution

## Total Brand Medicine Spending ($B) 2013-2020



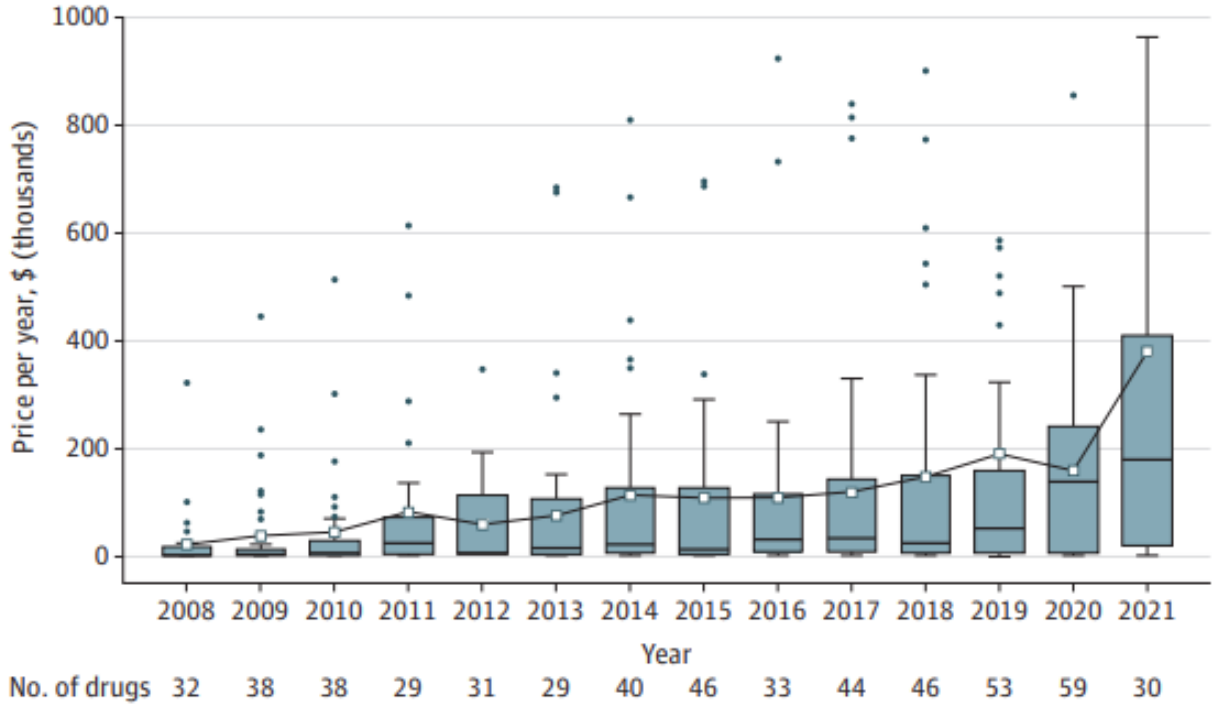

## Total Brand Medicine Spending Received by Payers ($B)




*Pharmaceutical Research and Manufacturers of America: Cost in Context*

# Launch prices

**Figure. Prices for Newly Marketed Drugs, 2008-2021**




*Rome and Kesselheim, Trends in Prescription Drug Launch Prices, 2008-2021*

# Transparency: State Examples

| Price Increases | Launch Prices | PBMs | Health Plans | PSAOs | Wholesalers |
|---|---|---|---|---|---|
| California | California | Arkansas | California | Washington | Maine |
| Connecticut | Connecticut | Connecticut | Connecticut | | Virginia |
| Maine | Maine | Iowa | Maine | | |
| Minnesota | Minnesota | Louisiana | North Dakota | | |
| Nevada | New Hampshire | Maine | Oregon | | |
| North Dakota | North Dakota | Michigan | Texas | | |
| Oregon | Oregon | Minnesota | Utah | | |
| Texas | Vermont | Nevada | Vermont | | |
| Utah | Virginia | New Hampshire | Washington | | |
| Vermont | Washington | New York | West Virginia | | |
| Virginia | | North Dakota | | | |
| Washington | | Texas | | | |
| West Virginia | | Utah | | | |
| | | Virginia | | | |
| | | Washington | | | |

# The Ball is in Your Court

- The person with the ball has 45 seconds to talk about price and cost transparency efforts in their state.
- Throw it to someone who hasn't shared!

# Speakers

**Jane Horvath, Horvath Health Policy**

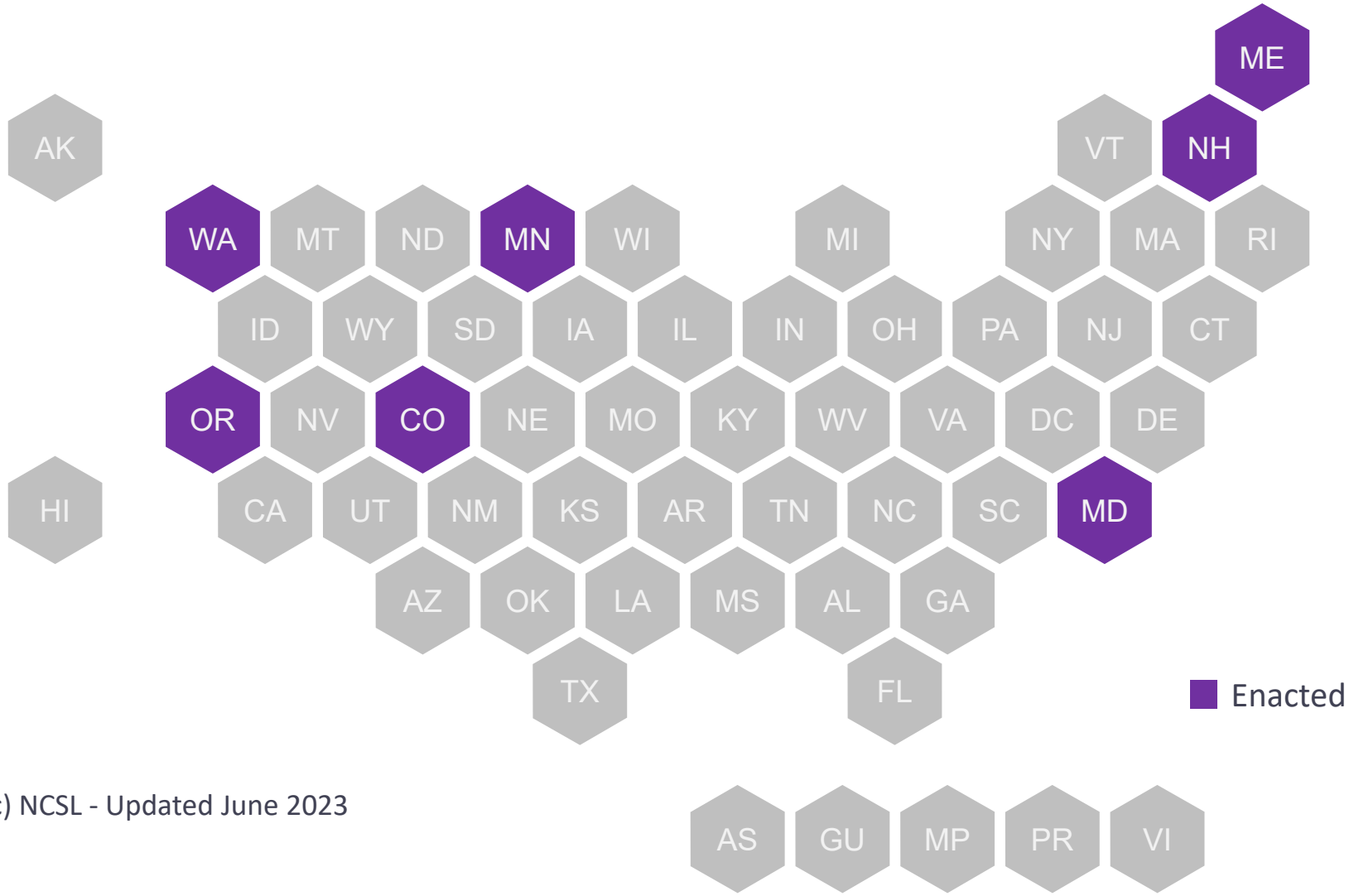
**Dr. Hussain Lalani, Harvard (PORTAL)**

# Q & A

# Discussion

# Prescription Drug Affordability Boards

# State Prescription Drug Affordability Boards (PDAB)

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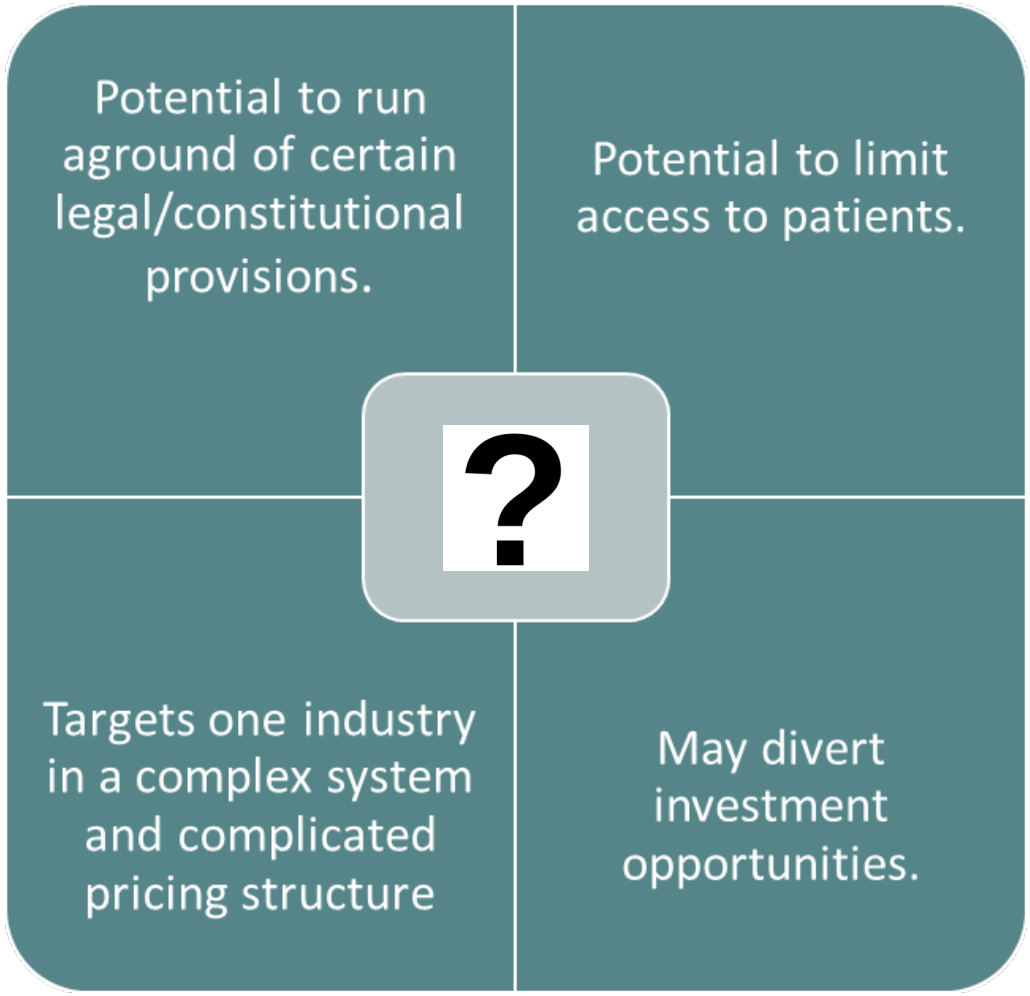
# States With Upper Payment Limits

# Stakeholder questions



# Small Group Discussion

- Identify a spokesperson.
- Each person takes a turn to pull a prompt from the cup.
- Groups have 10 minutes for discussion.
- Spokesperson will share out.

# Speakers

**Jane Horvath, Horvath Health Policy**

**Dr. Hussain Lalani, Harvard (PORTAL)**

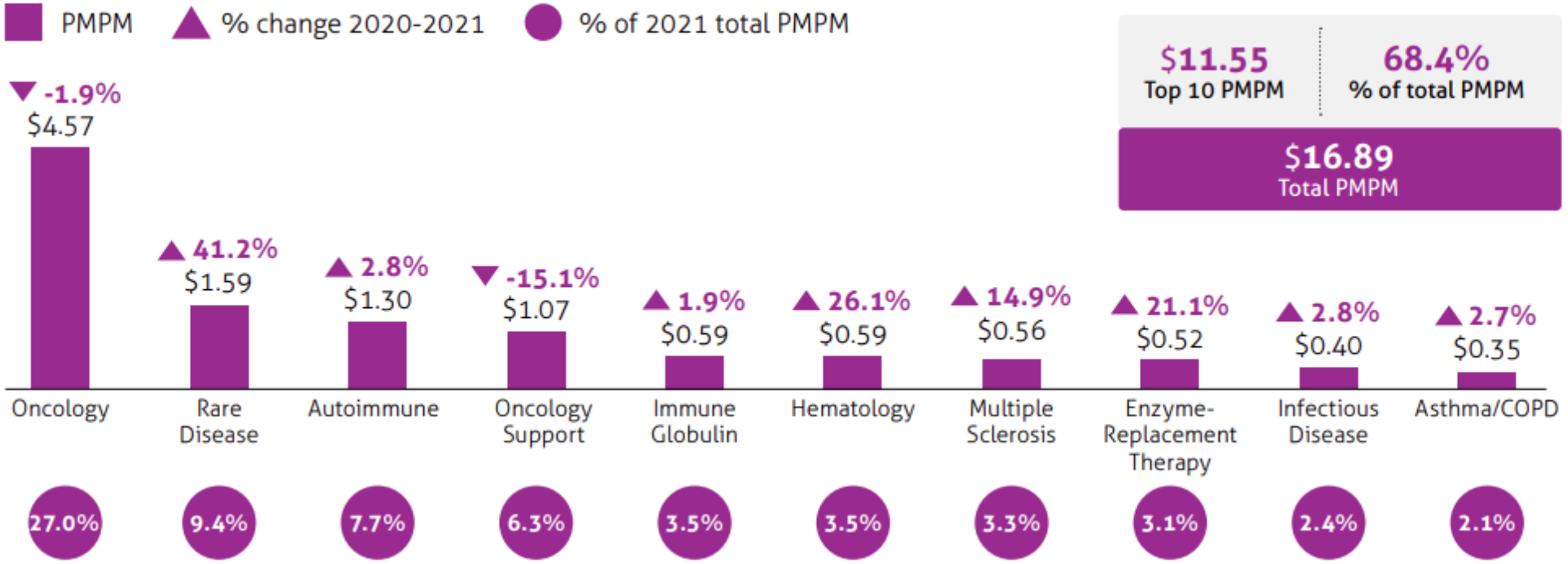
# Q & A

# Discussion

# Break

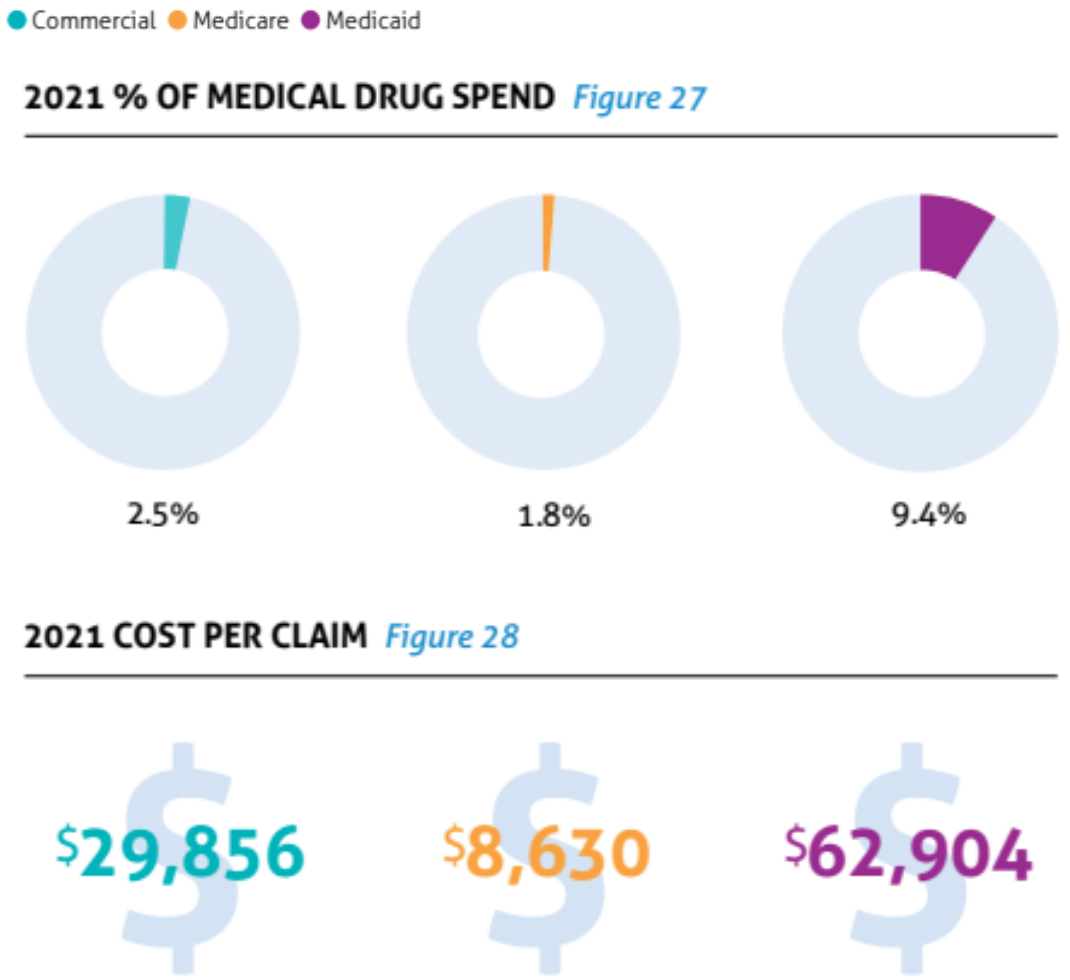
# Payment Models in Medicaid

## 2020-2021 TOP 10 DRUG THERAPY CATEGORIES BY PMPM SPEND *Figure 23*



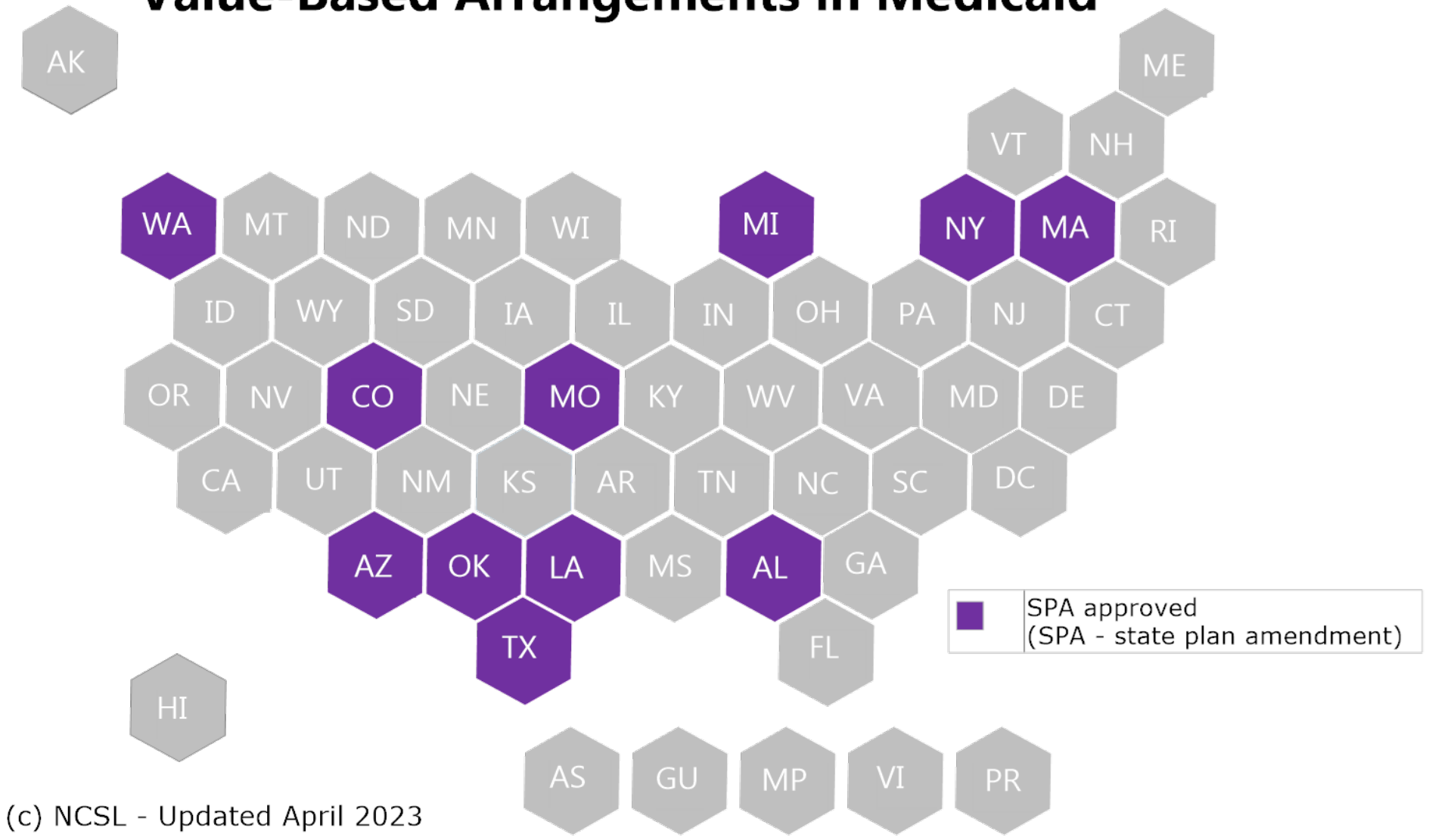

*2022 Magellan Rx Medical Pharmacy Trend Report*

# Medicaid Drug Spending on Rare Disease




*2022 Magellan Rx Medical Pharmacy Trend Report*

# Value-Based Arrangements in Medicaid

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# NCSL MATCH GAME!

# Rules of the Game

- Break into four groups.
- For 10 minutes, teams will work together to match the term with the correct definition.
- Teams will identify a spokesperson.
- Teams will buzz in to answer the question.
- If the answer is incorrect, the remaining teams will have a chance to ring in.
- The team with the most correct answers, wins.

# Match One

Payers are reimbursed for the drug and other medical costs if the product does not work as intended.

# Match One

Payers are reimbursed for the drug and other medical costs if the product does not work as intended.

WARRANTY MODEL

# Match Two

Tools that health plans and PBMs use to ensure patient safety and the use of cost-effective medicines.

# Match Two

Tools that health plans and PBMs use to ensure patient safety and the use of cost-effective medicines.

UTILIZATION MANAGEMENT

# Match Three

An unlimited quantity of the drug is provided for an agreed-upon amount.

# Match Three

An unlimited quantity of the drug is provided for an agreed-upon amount.

SUBSCRIPTION MODEL

# Match Four

Allows a payer to spread the cost of a drug over a defined period to offset single, upfront costs.

# Match Four

Allows a payer to spread the cost of a drug over a defined period to offset single, upfront costs

PAY-OVER-TIME MODEL

# Match Five

Mitigates risk associated with higher-than-expected utilization. The reinsurer absorbs the risk of claims over a certain amount.

# Match Five

Mitigates risk associated with higher-than-expected utilization. The reinsurer absorbs the risk of claims over a certain amount.

REINSURANCE OR STOP-LOSS

# Match Six

Arrangements that consolidate the purchasing power of states.

# Match Six

Arrangements that consolidate the purchasing power of states.

BULK PURCHASING ARRANGEMENTS

# Match Seven

When a PBM keeps a portion of the amount, or spread, between what the health plan pays the PBM and the amount that the PBM reimburses the pharmacy for a beneficiary’s prescription.

# Match Seven

When a PBM keeps a portion of the amount, or spread, between what the health plan pays the PBM and the amount that the PBM reimburses the pharmacy for a beneficiary's prescription.

SPREAD PRICING

# Match Eight

Requires pharmacy service providers to utilize one formulary.

# Match Eight

Requires pharmacy service providers to utilize one formulary.

UNIFORM DRUG LIST

# Match Nine

States can choose to include, or exclude, the pharmacy benefit or certain classes of drugs from their Medicaid Managed Care (MCO) contracts.

# Match Nine

States can choose to include, or exclude, the pharmacy benefit or certain classes of drugs from their Medicaid Managed Care (MCO) contracts.

CARVE-IN OR CARVE-OUT

# Match Ten

A mechanism that re-allocates funding between Managed Care Organizations (MCOs) should any individual MCO incur a disproportionate amount of costs due to high-priced drugs.

# Match Ten

A mechanism that re-allocates funding between Managed Care Organizations (MCOs) should any individual MCO incur a disproportionate amount of costs due to high-priced drugs.

HIGH RISK POOL

# Match Eleven

Allows payers to reimburse drugs in installments over the course of several months or years.

# Match Eleven

Allows payers to reimburse drugs in installments over the course of several months or years.

ANNUITY MODEL

# AND THE WINNER IS.....

THANK YOU FOR PLAYING!!

# Speaker

## Anne Winter, FTI Consulting

National Conference of State Legislators

# Containing Prescription Drug Costs in Medicaid

FTI CONSULTING™

June 21, 2023

# Net Medicaid Drug Spending

- **Manufacturers must sign a rebate agreement with CMS to ensure Medicaid coverage of their outpatient prescription drugs**
- 600 companies, including all large ones, have agreements
- States can negotiate supplemental rebates with companies in which they get a higher rebate than the federally negotiated amount
- Rebates offset a substantial portion of Medicaid drug spending:

| **Annual FFS Medicaid Prescription Drug Spending and Rebates, FFY 2021** | (In Billions) |
|---|---|
| Prescribed Drugs | 25 |
| Drug Rebate Offset – National | (16) |
| Drug Rebate Offset – State Sidebar Agreement | (2) |

- Drugs for which supplemental rebates are not available may be put in non-preferred PDL categories
- Specialty drug rebates are at or near the federal minimum in most cases
- States actively manage specialty drug utilization, especially for high-cost, low-rebate drugs
- Table does not include $20B in pharmacy related rebates that states receive from MCO lives – Kaiser study has overall 55% rebate discount in 2021.



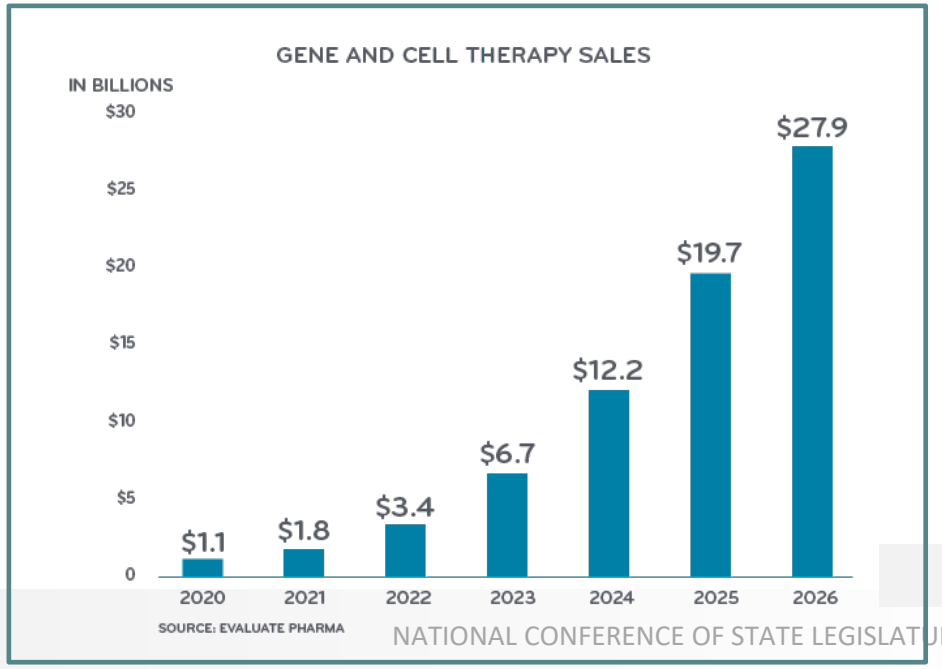
Sources: Centers for Medicare and Medicaid Services, "Medicaid Financial Management Report; FY2021" (CMS 64 Reports).

# The Cell and Gene Therapy Pipeline is Here

Health payers are in the direct path of a robust pipeline of more than 30 gene and cell therapies (CGTs) by 2026 that along with extraordinary clinical benefits they may have high price tags.

Value-based pricing arrangements can align incentives among stakeholders but will they may not be enough. The government and private sectors are working to develop other payment models that will reimburse high-cost specialty drugs based on the benefit they provide for the patient and healthcare system and to mitigate financial risk.

Alternative financing mechanisms are emerging to supplement value-based pricing to mitigate the financial impact on patients and payers.



# Alternative Financial Strategies

***Challenge: Pipeline of 30 gene and cell therapies has payers exploring alternative financing strategies***
***Potential Solution: Reinsurance/Stop Loss of Gene Therapies is emerging as front running strategy with or without value-based arrangements***

## Centers for Medicare and Medicaid Services

- **Cell and Gene Therapy Access model** (Executive Order) a CMMI pilot to determine whether CMS-negotiated outcome-based improve beneficiary access and outcomes and reduce health care costs?
- **Lift 100% AMP ceiling** for rebates (IRA).
- **Medicaid Drug Price Verification Survey** (proposed rule)
- **PBM reporting** (proposed rule)

## PBM Strategies

- **Reinsurance programs** for gene and cell therapies
- **PMPM** for gene therapy network participation. First day coverage and no cost to members
- **Stop loss** – similar to reinsurance

## PhRMA Strategies

- Novartis with Swiss Reinsurance Group (Swiss Re) to **provide reinsurance** to China for Novartis' cancer drugs.
- **Roche partnering with Swiss Re on reinsurance** for a Chinese health plan
  - Roche provides data on types of cancer and treatability
  - Swiss Re calculates risk and cost and calculates then provides reinsurance
  - Roche's chief executive told Bloomberg that 6M people are enrolled

## Think Tanks (Tufts University NEWDIGS)

- **Precision financing solutions** for therapies with large, upfront, acute costs with accruing benefits
- The Financing and Reimbursement of Cures in the US (FoCUS) collaborative consists of 100 orgs and 400 individuals across supply chain.
- Multiple strategies were whittled down to four and "scored" based upon

# Q & A

# Discussion

# Final Thoughts

# Reach out with questions!!!

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# Thank you!

Please don’t forget to complete your evaluation!