

# How NCSL Strengthens Legislatures



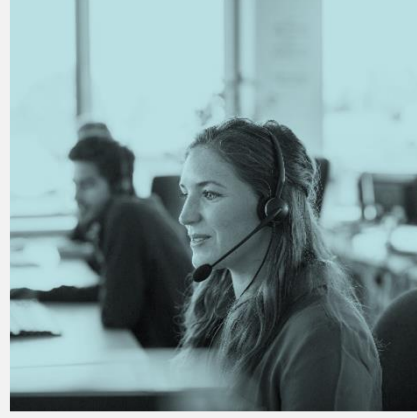
## Policy Research

NCSL provides trusted, nonpartisan policy research and analysis



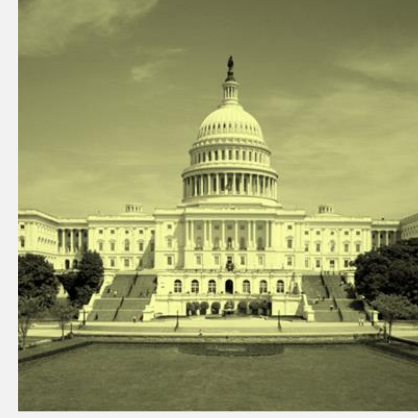
## Connections

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

# 2023 Indy Legislative Summit

The logo features a stylized dome icon to the left of the text. The text is arranged in three lines: 'NCSL' in large black letters, 'LEGISLATIVE' in smaller black letters, and 'SUMMIT' in very large, bold teal letters. Below 'SUMMIT' is 'INDY 2023' in orange letters. To the right of the text is a decorative graphic of teal and white squares arranged in a grid-like pattern.

 **NCSL** LEGISLATIVE  
**SUMMIT**  
INDY 2023

Aug. 14-16, 2023

# Speakers



**Sharon Lamberton**

Deputy Vice President,  
State Policy and External  
Outreach

Pharmaceutical Research  
and Manufacturers  
Association of America  
(PhRMA)



**Allan Coukell**

Senior Vice President for  
Public Policy

CivicaRx



**Representative Liz  
Thomson**

New Mexico



# Agenda

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Overview of State  
and Federal Policy

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Initiatives from

- Industry
  - CivicaRx
- 



State Respondent

- New Mexico
- 



Discussion &  
Questions

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Walk Away with  
a Takeaway

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# TRIVIA

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

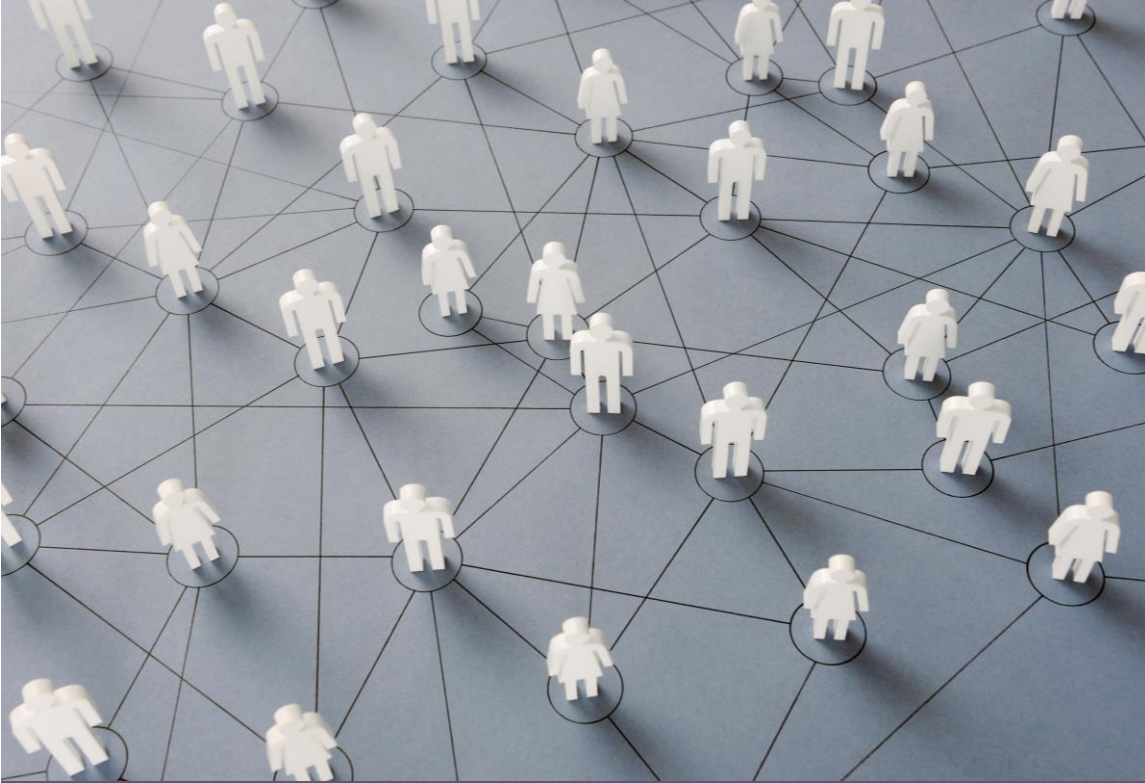
- A. 28.7 million
- B. 1.9 million
- C. 96 million
- D. 37.3 million

*Please enter your answer into the chat*

# 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**



# Overview of State and Federal Policy

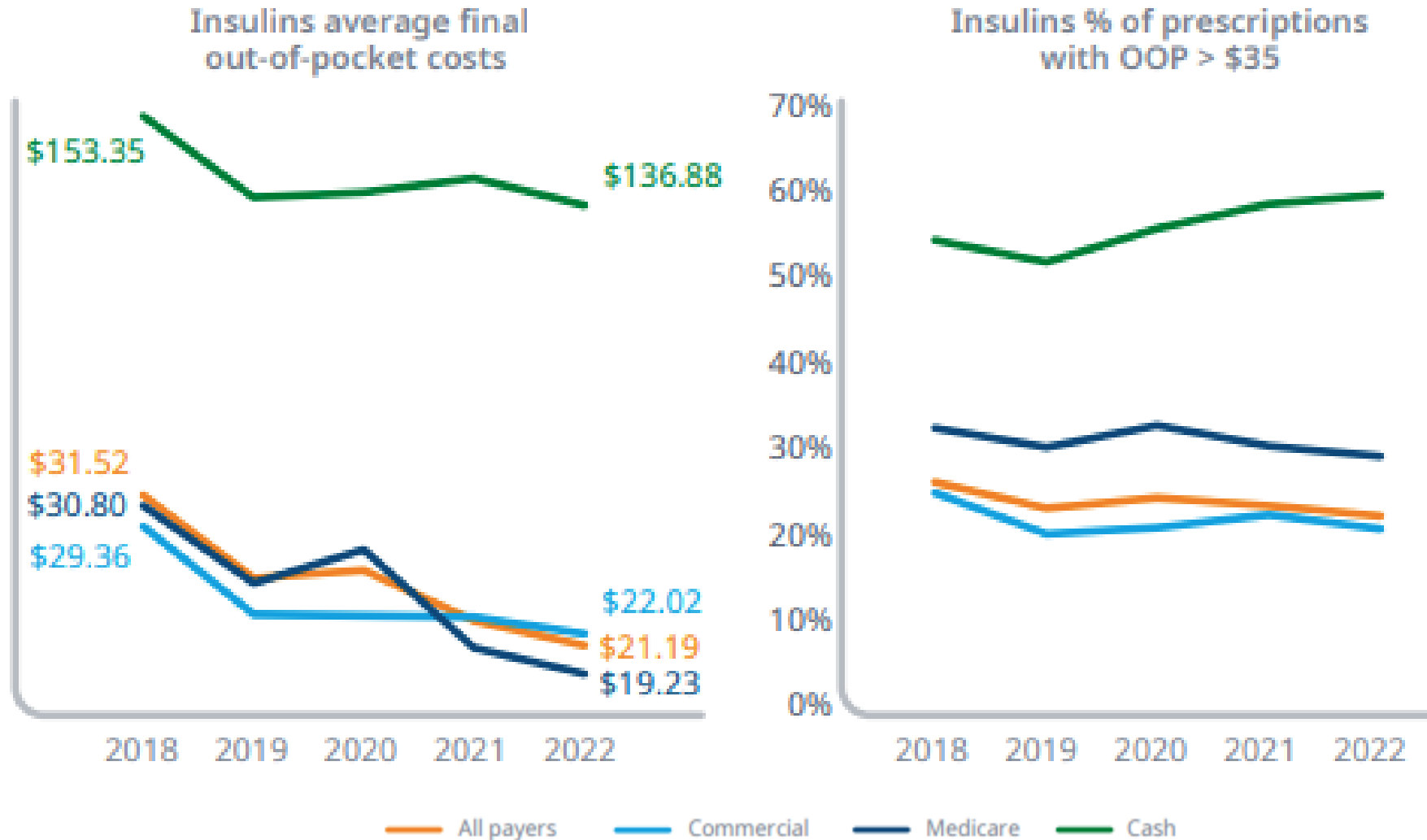
28.7 million people have a diagnosis of diabetes in the U.S.

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



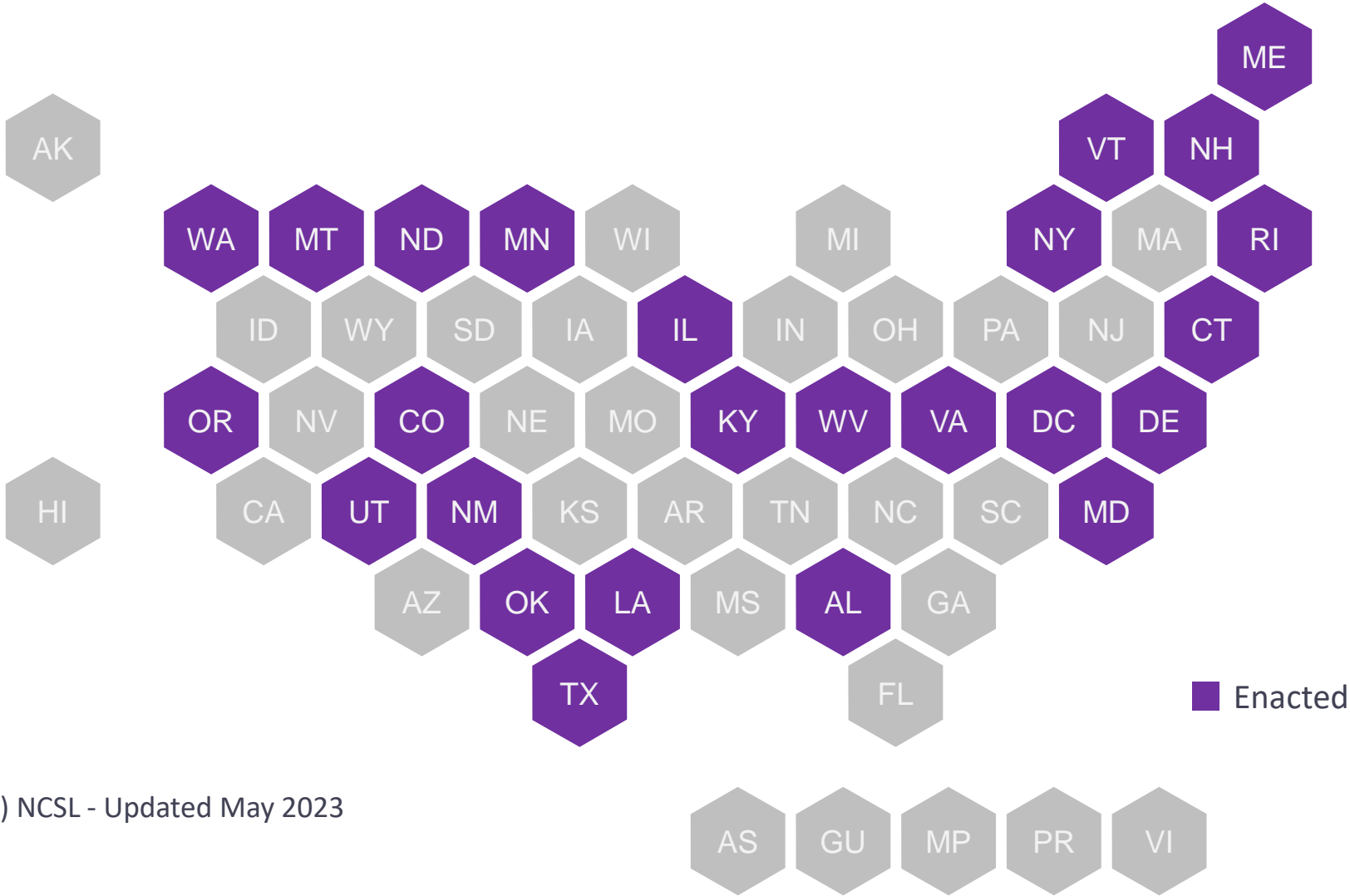




- Testing supplies account for 27% of overall pharmacy costs for people living with diabetes.
- 56% of people with type 1 use supplies that add to their cost burden.



# State Legislation Capping Copayments



(c) NCSL - Updated May 2023

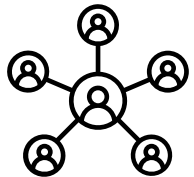
# Beyond copay limitations



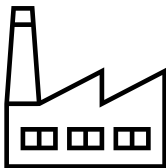
Copay limits on diabetic supplies = Connecticut, Delaware, West Virginia and D.C.



Emergency assistance programs = Colorado and Minnesota



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



Partnerships to manufacture insulin = California

## **Biosimilars**

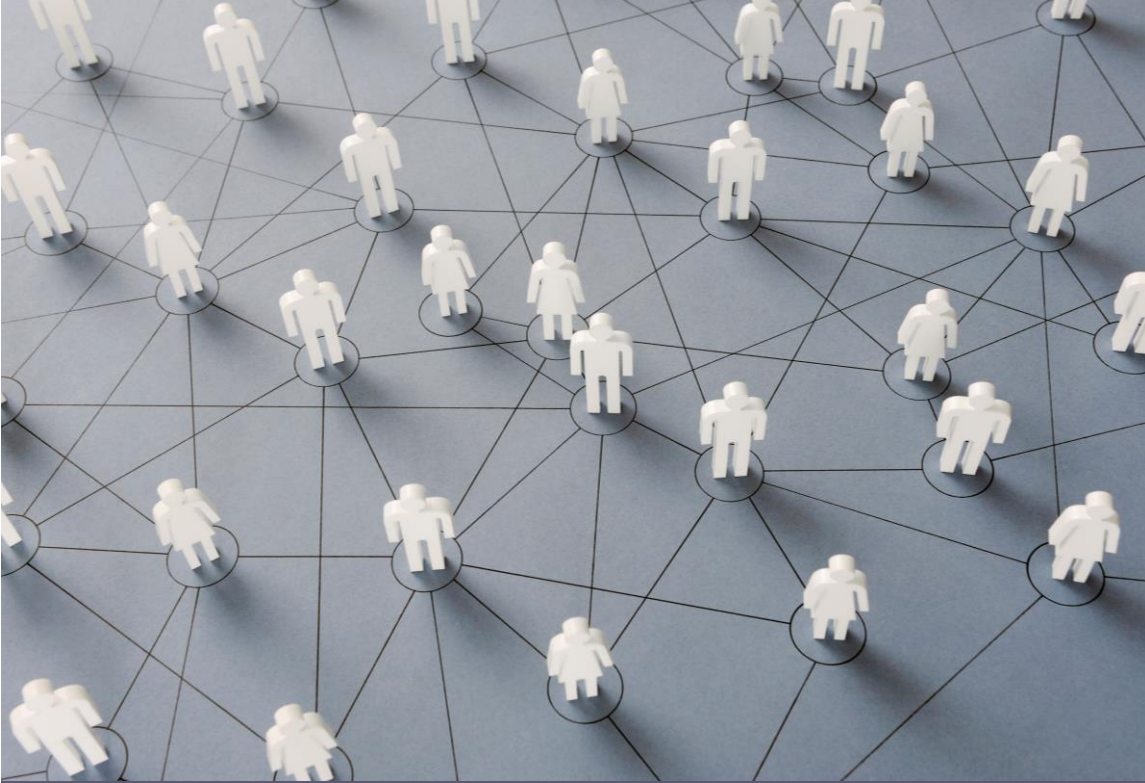
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- Biosimilars are "generics" formulations of biologics
- Two biosimilar insulins approved - one is interchangeable, one is not

## **Inflation Reduction Act (IRA)**

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- 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



# Industry Initiatives

# Prescription Medicines: Insulin Costs in Context

*Sharon Lamberton, MS, RN*  
*NCSL Forum on Insulin*  
*May 19, 2023*

# Several States Capped Copays for Insulin

## 22 states + DC

- \$100 – CO, IL, AL, WV, NY, VT
- \$75 – LA, OR
- \$50 - VA
- \$40 – RI
- \$35 - WA, MN, ME, DE
- \$30 – UT, OK, KY, MD, NH
- \$25 – NM, TX, CT



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# 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.

# Better Diabetes Management Saves Money and Improves Health Outcomes

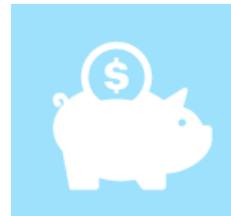
**22**  
**million**

Americans live with **uncontrolled** diabetes.

## Improving Medication Adherence Among Patients with Diabetes Could:



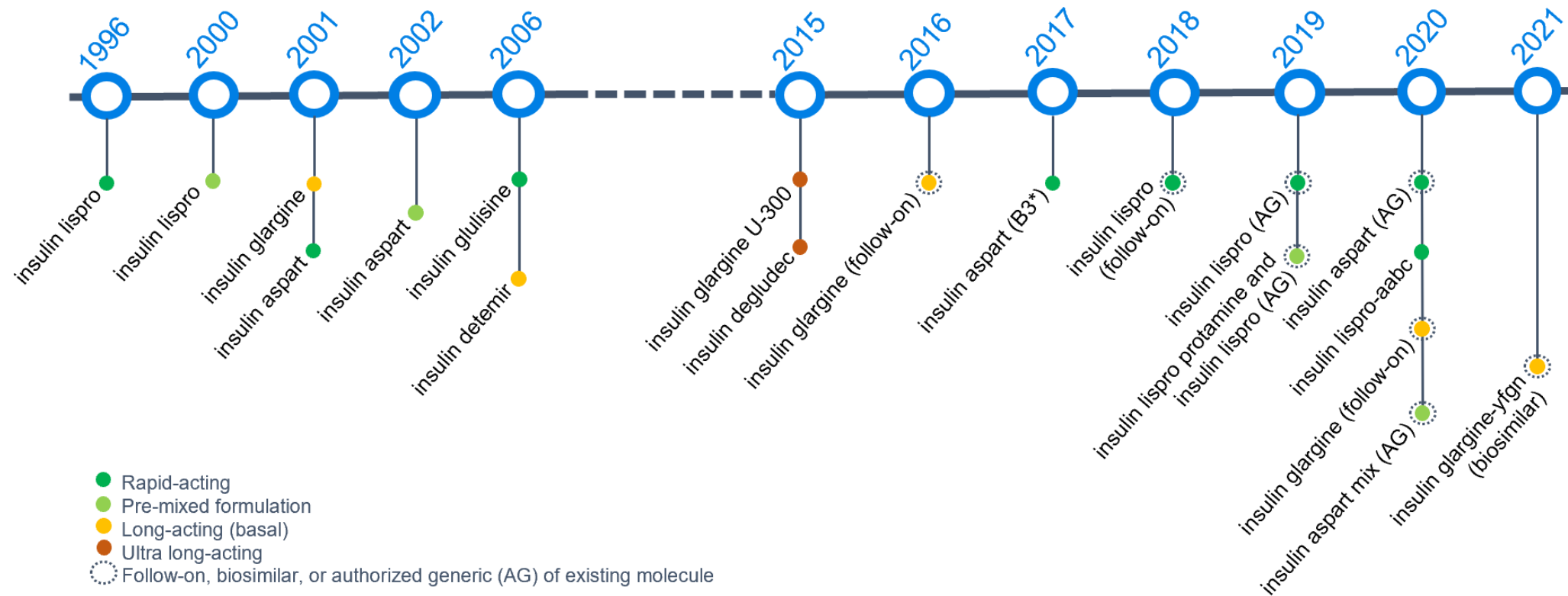
Result in 1 million fewer ER visits and hospitalizations annually



Save \$8.3 billion for the U.S. health care system each year

# 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.



# 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.

# Negotiating Power Is Increasingly Concentrated Among Fewer Pharmacy Benefit Managers (PBMs)

## Insurers & PBMs determine:

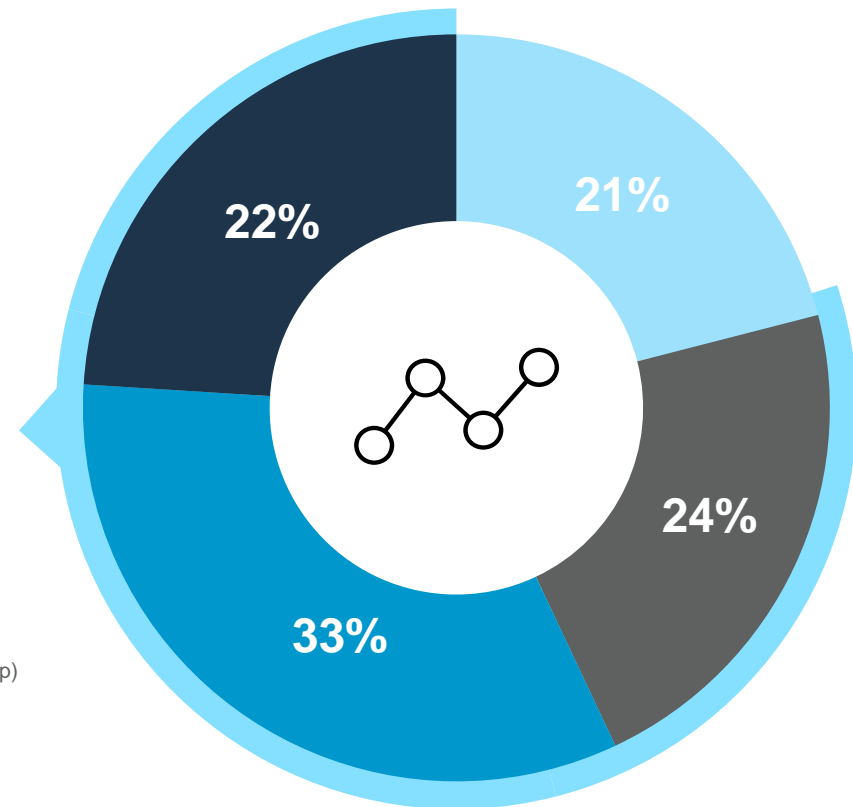
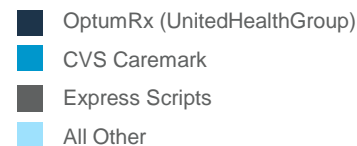
**IF MEDICINE IS COVERED**  
on the formulary

**PATIENT OUT-OF-POCKET COST**  
based on tier placement

**ACCESS BARRIERS**  
like prior authorization or fail first

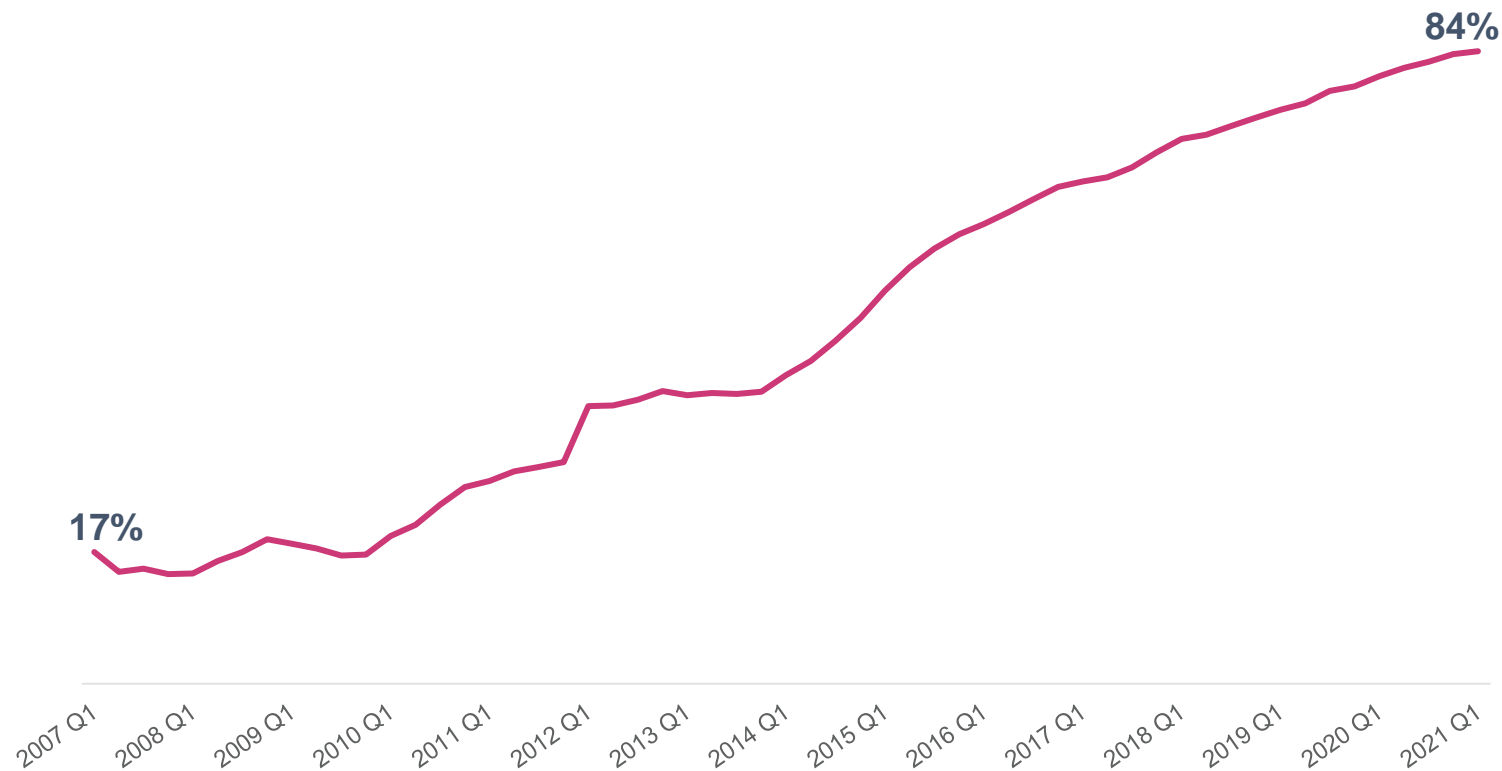
**PROVIDER INCENTIVES**  
through preferred treatment guidelines and pathways

Top 3 PBMs' Market Share:  
**79%**



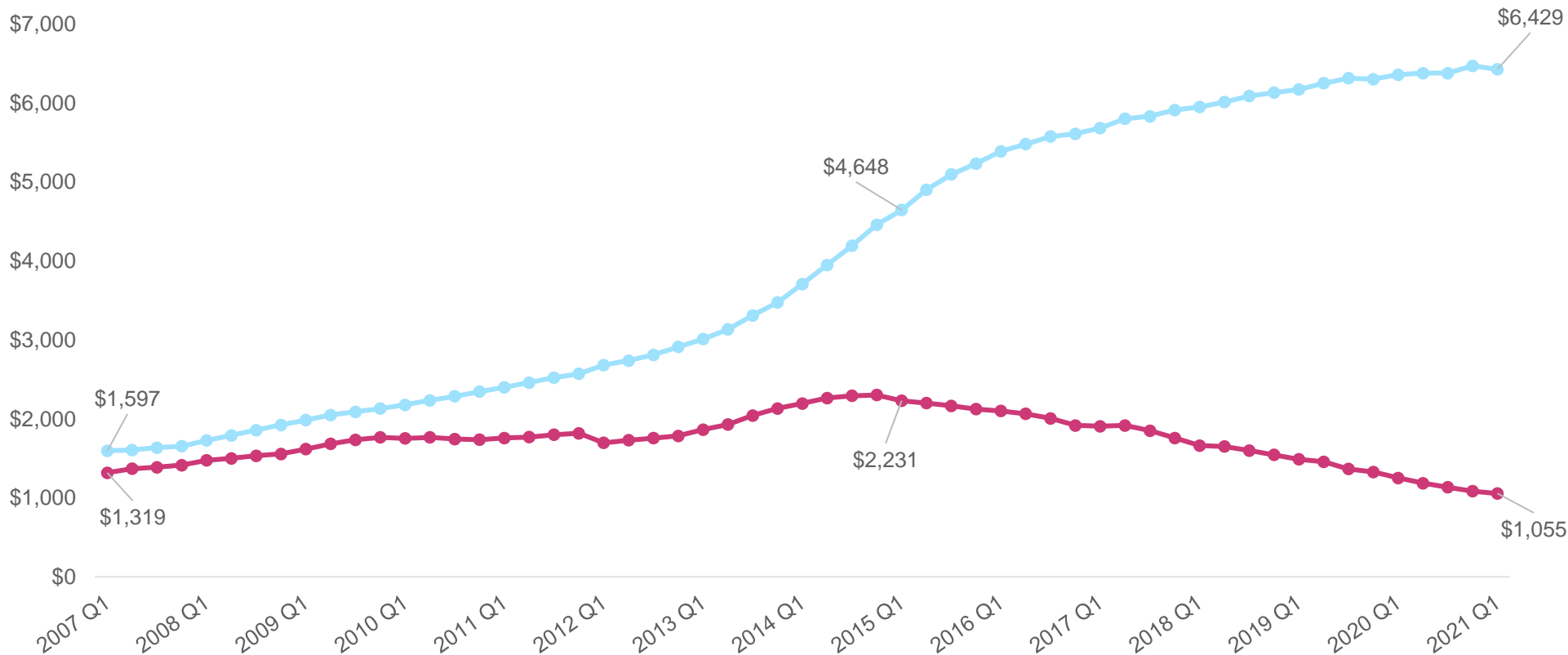
# Discounts, Rebates and Other Payments Have Increased Dramatically in Recent Years, Lowering the Cost of The Most Commonly Used Insulins by 84% in 2021

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



# The Average Net Costs of the Most Commonly Used Insulins are 20% less than in 2007

Insulin Analogs: Average Gross Cost And Net Manufacturer Revenue Per Patient, Per Year, By Quarter 2007-2021



Others in the supply chain, such as PBMs, have received a growing share of total spending on insulins.

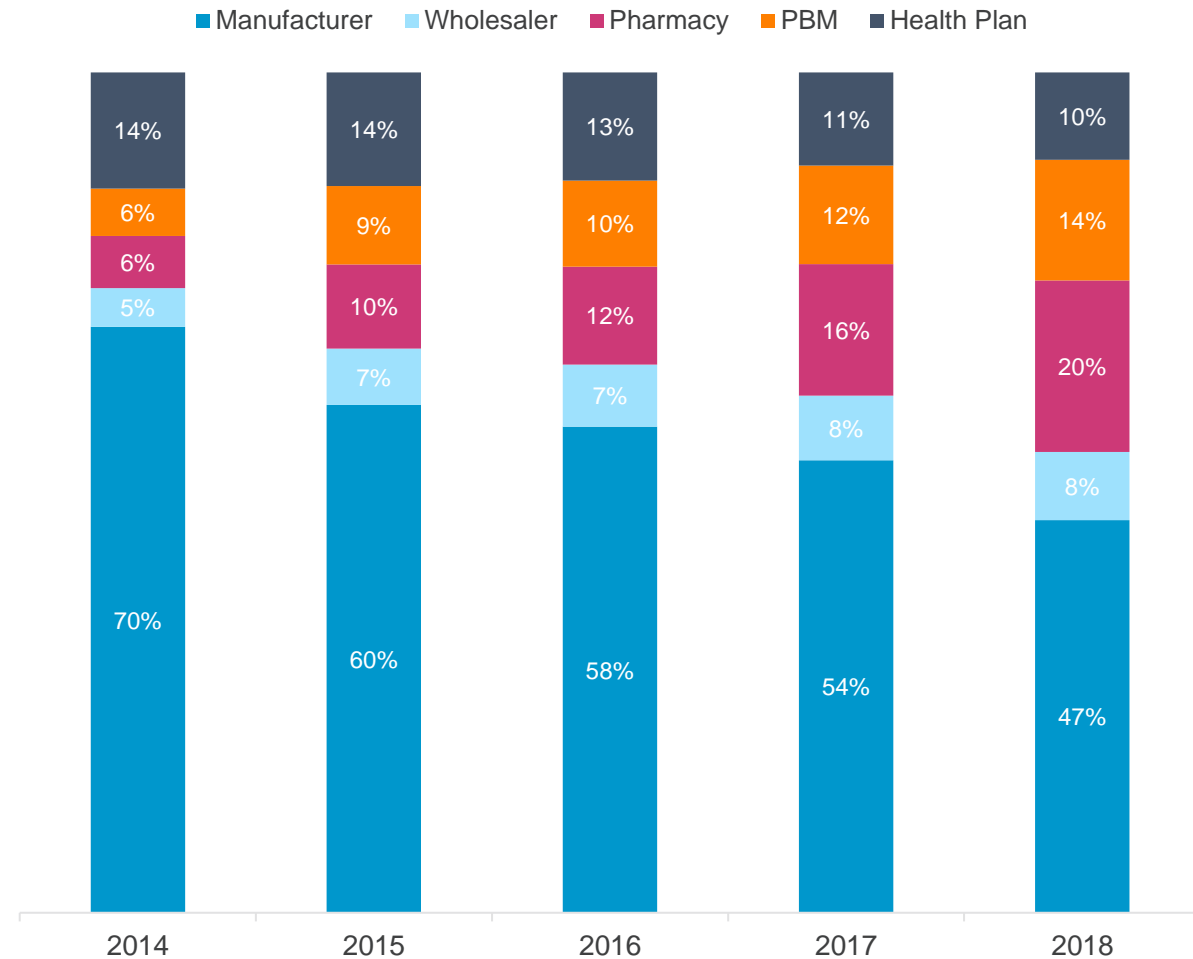
**Between 2014 and 2018, the share of total spending on insulins retained by PBMs increased 155%.**

*“PBMs have an incentive for manufacturers to keep list prices high, since the rebates, discounts, and fees PBMs negotiate are based on a percentage of a drug’s list price—and PBMs retain at least a portion of what they negotiate.”*

--Senate Finance Committee



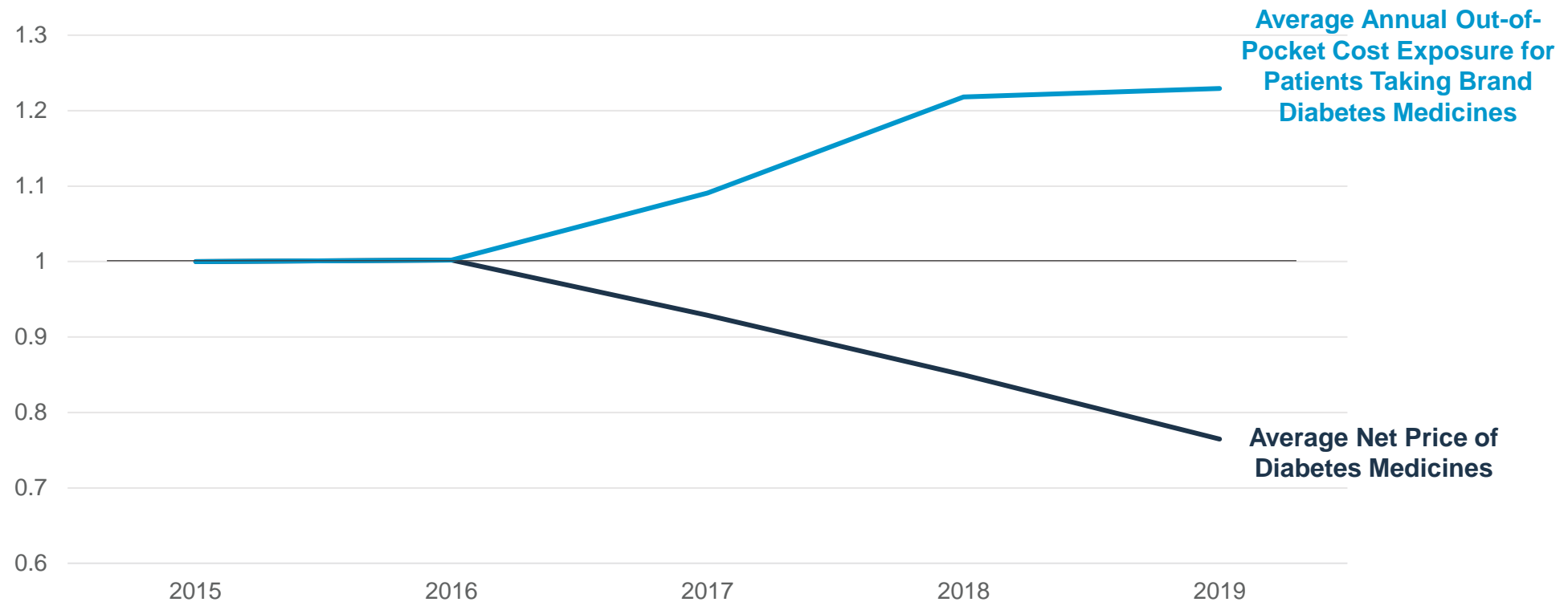
### Share of Net Expenditures on Insulin Captured by Manufacturers, Wholesalers, PBMs, Pharmacies, and Health Plans



SOURCE: Van Nuys K, Ribero R, Ryan M, Sood N. Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans From 2014 to 2018. JAMA Health Forum. 2021;2(11):e213409; Senate Finance Committee. “Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug,” 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.

# Patients with Coinsurance and Deductibles Pay More on Average for Diabetes Medicines

Patients who filled prescriptions for brand diabetes medicines while in the deductible spent

**3.6x more**

out of pocket than patients with only fixed copays.

Patients with coinsurance cost sharing who filled prescriptions for brand diabetes medicines spent

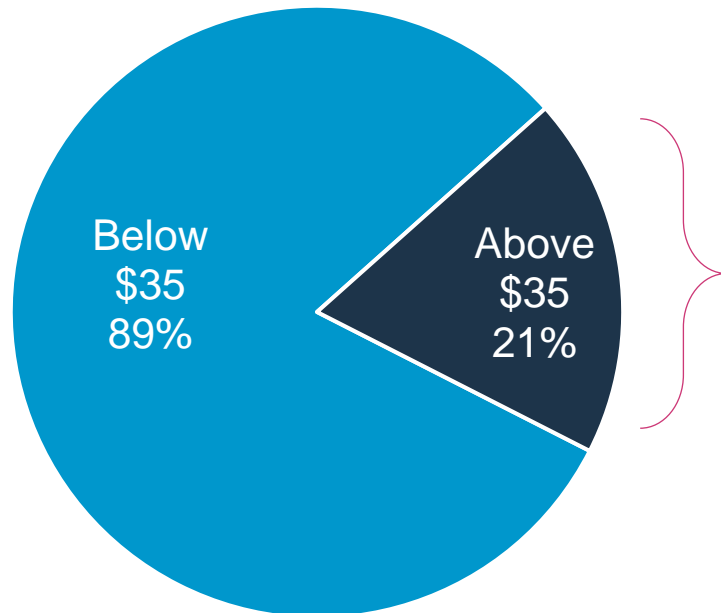
**4x more**

out of pocket than patients with fixed copays.



# A Small Share of Insulin Scripts Account for the Majority of Total Spending – The Opposite of How Insurance Should Work

## Insulin Prescriptions with Out-of-Pocket Costs Above \$35, Commercial Market, 2022



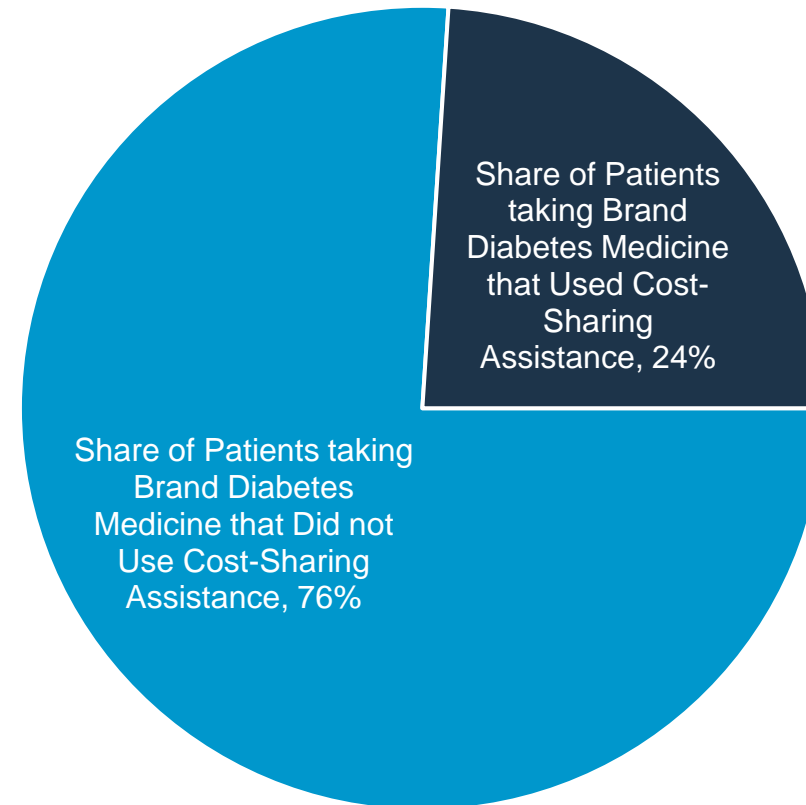
**While just 21% of insulin prescriptions cost patients more than \$35 out of pocket, these prescriptions account for 77% of total patient spending on insulin.**

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## Insulin Manufacturers Have Long Provided Patient Assistance And Cost-Sharing Assistance Programs for Patients with Diabetes

In 2023, companies used these existing programs to limit patient out-of-pocket costs of commonly used insulins to \$35 or less per month for those in the commercial market and to help the uninsured.

### Nearly 1 in 4 Patients Taking Brand Diabetes Medicines Use One or More form of Cost-Sharing Assistance in 2021



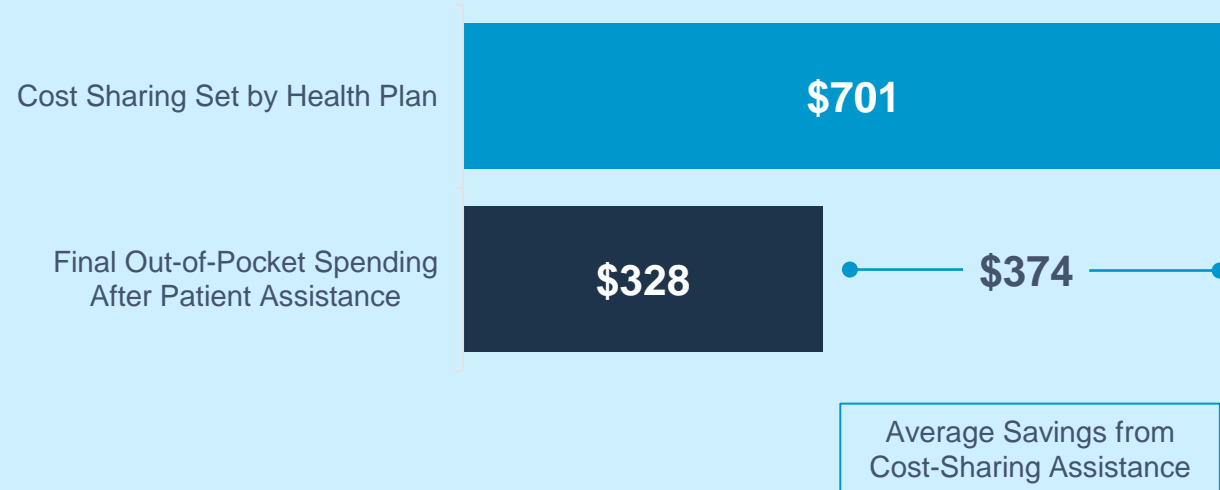
# Patient Spending On Brand Diabetes Medicines Would Have Been Twice As High Without Cost-Sharing Assistance

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, 2021



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.

# 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

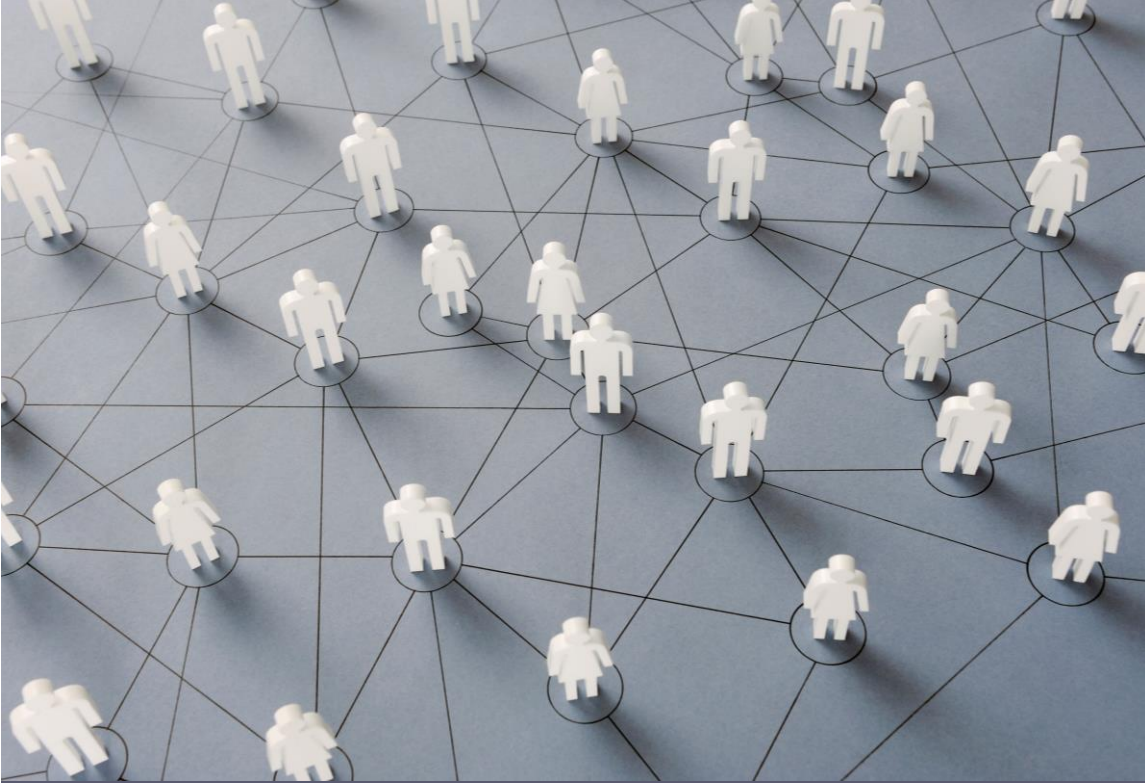
Patients managing chronic diseases should not be subject to a deductible, rather they should have at least some of their medicines covered by their insurance from day one.

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

# PhRMA Resources

- [Meet MAT, the Medicine Assistance Tool](#)
- [Ten Key Facts About Insulin and Patient Affordability](#)
- [Insulin: Key Facts on Access & Affordability](#)





# CivicaRx and State Partnerships



# Civica Affordable Insulin Update



Allan Coukell, BSc(Pharmacy)  
SVP Public Policy & President, Civica Foundation  
NCSL Webinar  
19 May 2023

NATIONAL CONFERENCE OF STATE LEGISLATURES

# Civica: a nonstock, nonprofit generic drug company

Mission: make quality generic  
medications **available** and  
**affordable** to everyone.

# Drug shortages

Dozens or hundreds of **essential drugs** not available at any given time.

Shortages **harm patients**.

**Over 90%** of surveyed hospitals reported having to identify alternative therapies to manage spending.

Drug shortages add **hundreds of millions** in extra health care costs.



## *Faced With a Drug Shortfall, Doctors Scramble to Treat Children With Cancer*

A critical chemotherapy medication is in short supply, and physicians say there is no appropriate substitute.

Give this article 59



# Civica today

**120M** VIALS FOR **50M** PATIENTS

**55+**  
Health  
Systems  
Members

**>1,500**  
hospitals

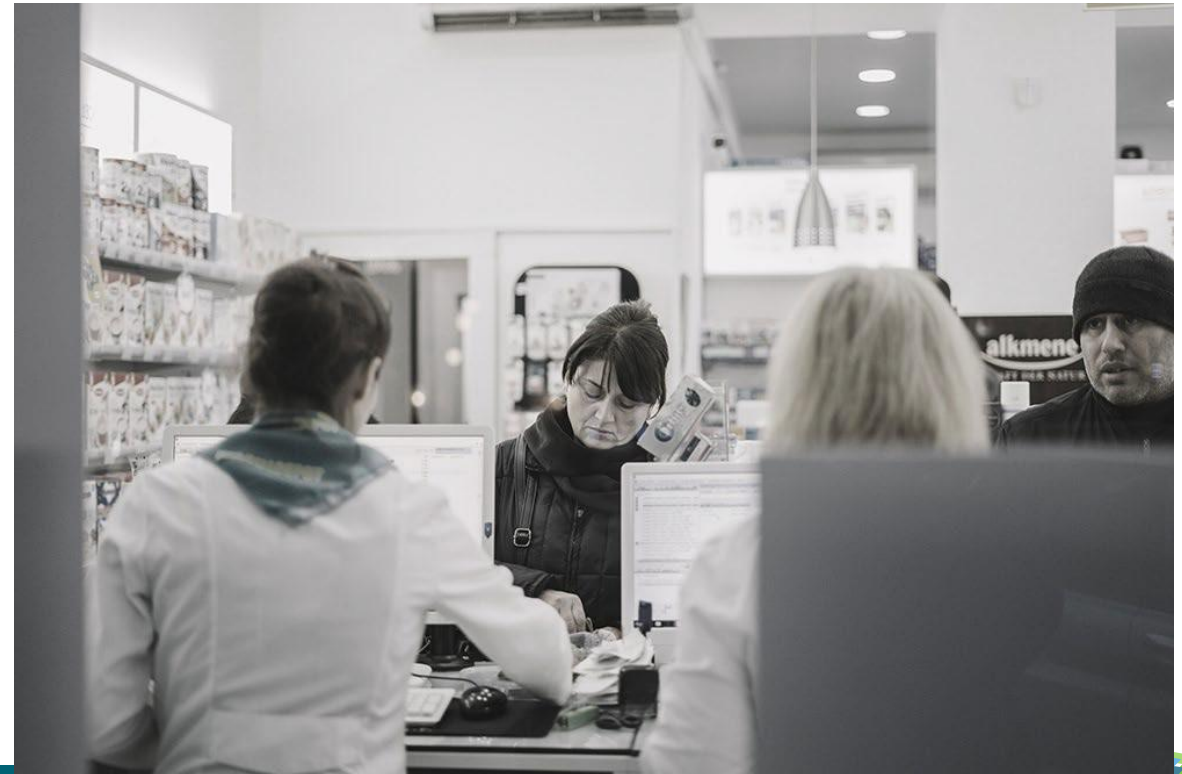
**1/3**  
of U.S.  
licensed  
beds

**80+** MEDICINES

# Expanding the mission: Lowering Costs for High-priced Generics at the Pharmacy Counter



**With BCBS companies and Anthem, we've created a new entity that is open to other health plans, employers, retailers and other health care innovators who will pass along savings to consumers.**

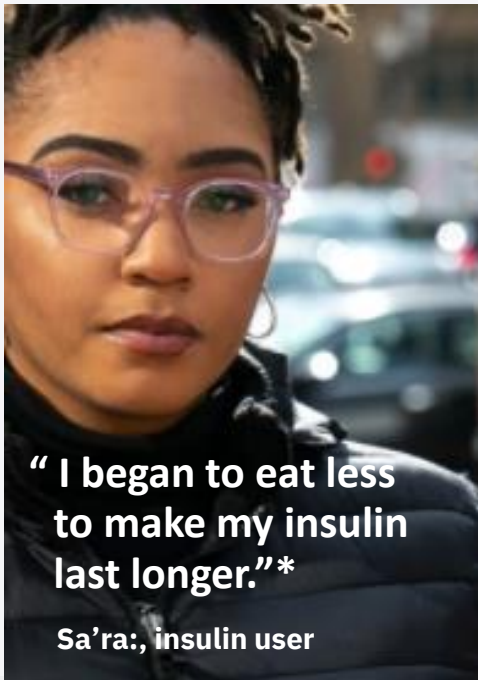


# Civica Petersburg, the future home of affordable insulin

**CIVICA**<sup>®</sup>

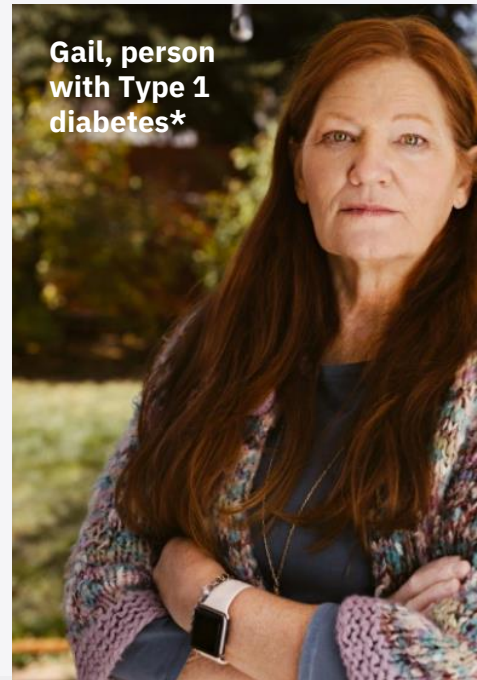


**Millions of Americans** require insulin to manage their diabetes, and some are forced to make painful tradeoffs because of pervasively high costs.



25%

of patients in one study skipped or took smaller doses than prescribed due to high insulin cost



“ We’re told if you don’t take care of yourself, you’re going to lose your eyesight or **lose a kidney...in reality, the biggest fear we have is not being able to afford insulin**, which is the only thing that keeps us alive.”\*

\**Fortune* Dec. 6, 2021

# Affordable insulin

- Civica will develop, manufacture and distribute insulins at significantly lower prices than insulins currently on the market.
- Civica will produce three interchangeable insulins:
  - **glargine** (Lantus)
  - **lispro** (Humalog)
  - **aspart** (Novalog)
- Each will be available in vials & prefilled pens
- One-price model – no hidden rebates or price concessions
- 





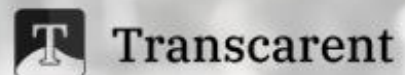
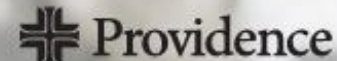
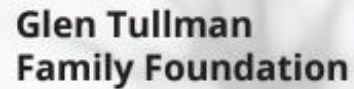
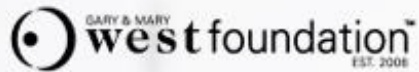
# Pricing

- Civica's goal is to provide insulin at the **lowest sustainable cost** in the U.S that allows us to cover the cost of development, production and distribution.
- Civica will set a **maximum recommended price** *to the consumer* of no more than \$30 per vial and no more than \$55 for a box of five prefilled pens, a significant discount to prices today.



# Civica Foundation

Support from Leading Advocates  
to Reduce Cost of Insulin



# Civica and California

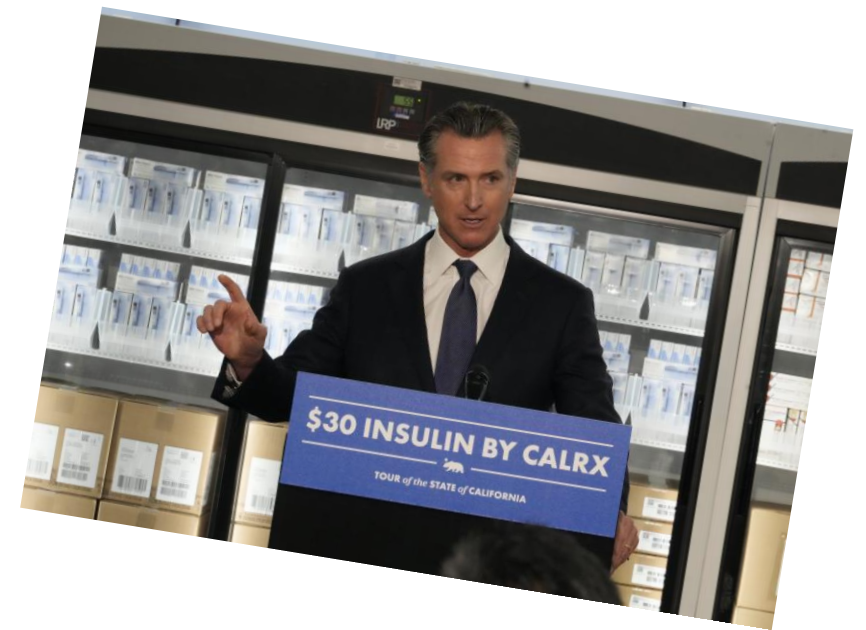
**California Picks  
Generic Drug  
Company Civica to  
Produce Low-Cost  
Insulin**

-Kaiser Health News

**CIVICA<sup>®</sup>**

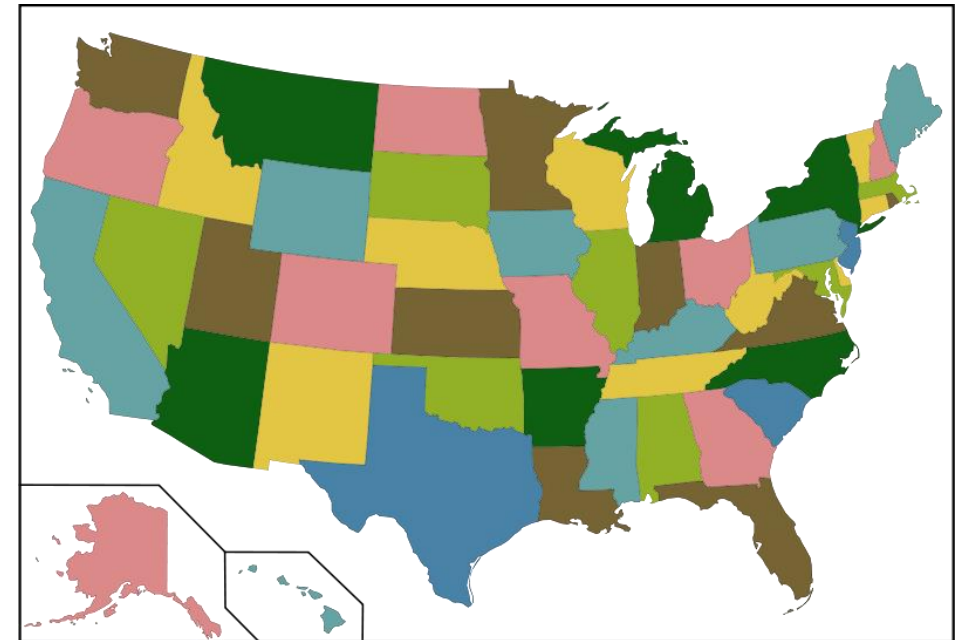
# California has contributed \$50 million towards the Civica Affordable Insulin Initiative

- California has selected Civica as its insulin manufacturing partner.
- Californians will have access to Civica's low-cost insulins via a program called the **CalRx Biosimilar Insulin Initiative**.
- Same pricing as Civica insulin.
- Consideration of future manufacturing site.



# Opportunities for states to partner

- Supporting R&D
- Ensure coverage of lowest list-price insulin
- Direct contracting
- Coverage by state employee plans
- Partner for safety net
- State manufacturing??



Thank  
you!

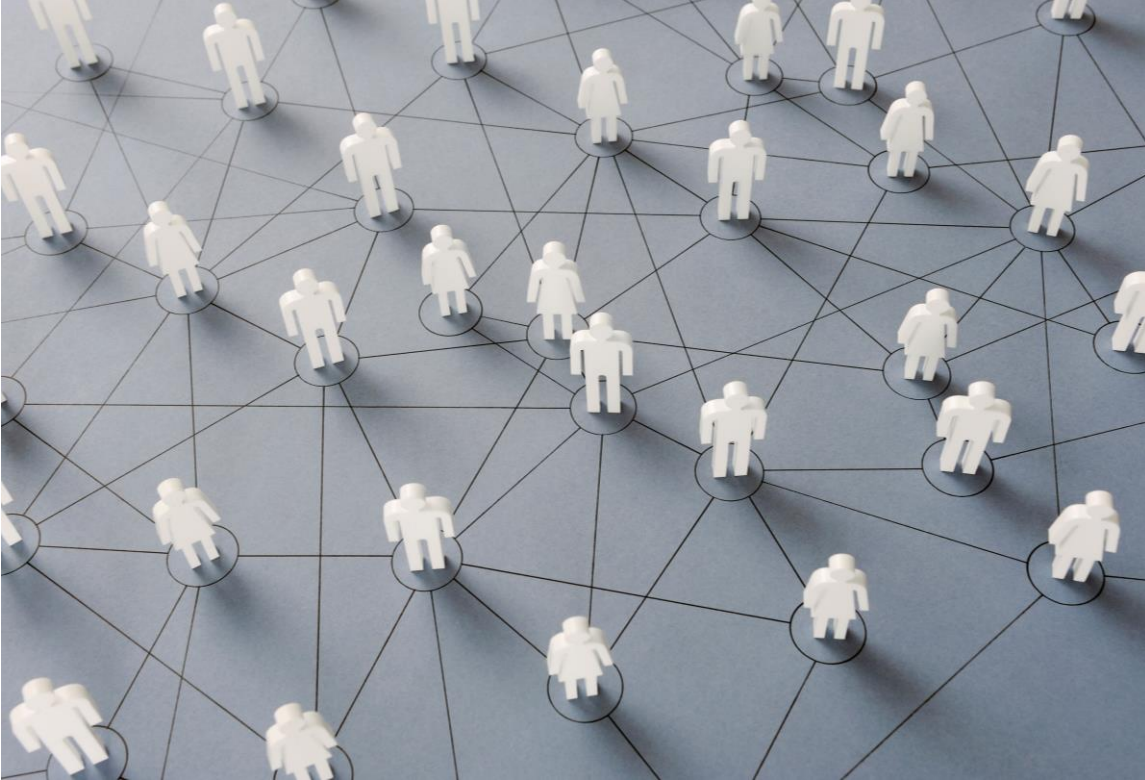
CIVICA<sup>®</sup>



## Legislation in New Mexico

### NM H 53

Relating to health insurance; updating coverage for individuals with diabetes; requiring consistent and timely delivery of medically necessary diabetic resources.



# Discussion and Questions





Walk Away with a Takeaway!

-Enter one thing you've learned into the chat

# NCSL Resources

Slides and a recording of this webinar will be available on the webpage.

- [Prescription Drug Policy Resource Center](#)
- [Diabetes State Mandates and Insulin Copayment Caps](#)
- [Prescription Drug State Bill Tracking Database | 2015-Present](#)
- [Improving Access and Affordability of Insulin and Diabetic Supplies](#)



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**Reach out anytime!**

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Thank you!