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Policy Research
NCSL provides trusted, nonpartisan policy research and analysis

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NCSL links legislators and staff with each other and with experts

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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

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

Overview of State and Federal Policy

Initiatives from
• Industry
• CivicaRx

State Respondent
• New Mexico

Discussion & Questions

Walk Away with a Takeaway
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
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 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
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
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
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.

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.
Better Diabetes Management Saves Money and Improves Health Outcomes

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

22 million Americans live with uncontrolled diabetes.

SOURCES: American Diabetes Association.; Jha, et al. “Greater Adherence to Diabetes Drugs is Linked to Less Hospital Use and Could Save Nearly $5 Billion Annually.” Health Affairs
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.

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

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 nation 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 (PBM)

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

Source: Drug Channels Institute, March 2023.

Top 3 PBMs’ Market Share:

- OptumRx (UnitedHealthGroup) 22%
- CVS Caremark 21%
- Express Scripts 24%
- All Other 33%

Source: www.phrma.org/cost
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

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

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

Average Annual Out-of-Pocket Cost Exposure for Patients Taking Brand Diabetes Medicines

Average Net Price of Diabetes Medicines

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.


www.phrma.org/insulin
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.

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

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.

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

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost Sharing Set by Health Plan</td>
<td>$701</td>
</tr>
<tr>
<td>Final Out-of-Pocket Spending After Patient Assistance</td>
<td>$328</td>
</tr>
<tr>
<td>Average Savings from Cost-Sharing Assistance</td>
<td>$374</td>
</tr>
</tbody>
</table>

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. February 2023. Available at: https://phrma.org/-/media/Project/PhRMA/PhRMA-Refresh/Report-PDFs/G-IQVIA-Condition-Specific-Report_Feb-2023.pdf

www.phrma.org/insulin
## 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.

<table>
<thead>
<tr>
<th>Require Rebate Pass-Through</th>
<th>Address Incentives that Harm Patients, Benefit Middlemen</th>
<th>Address Affordability in the Commercial Market</th>
</tr>
</thead>
</table>
| 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. | 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. | 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: 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.
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
Millions of Americans require insulin to manage their diabetes, and some are forced to make painful tradeoffs because of pervasively high costs.

“I began to eat less to make my insulin last longer.”*

Sa’ra:, insulin user

“...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

25% of patients in one study skipped or took smaller doses than prescribed due to high insulin cost

Gail, person with Type 1 diabetes*
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
California Picks Generic Drug Company Civica to Produce Low-Cost Insulin

-Kaiser Health News
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!
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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Colleen Becker
Project Manager
NCSL Health Program

Reach out anytime!

Email  Phone
Colleen.Becker@ncsl.org  720-713-0298
Thank you!