

LEGISLATIVE GUIDE FOR INSULIN FOR ALL

How States Can Make Medicines Affordable



Art by Mike Lawson



INTRODUCTION

Since 1996, pharmaceutical corporations have increased the price of a vial of insulin from \$21 to more than \$275. Confronted with industry price-gouging, nearly a quarter of patients who rely on insulin to survive have reported rationing it. At least twelve people have died from insulin rationing, with many more deaths likely unreported.

It does not have to be this way. As the federal government contemplates reform, states can also implement major policies to improve insulin access. States have historically been at the forefront of protecting consumers. State attorneys general led the battle against the tobacco industry. State transparency laws related to drug company payments to doctors inspired the federal Sunshine Act.

This document aims to provide an accessible overview of state policies that could increase insulin access and affordability. It analyzes both the short-term steps intended to promote immediate access, and more transformative solutions intended to realize insulin for all. This document draws from the path-breaking work done by activists and researchers across the country.

At least 12 people have died since 2017 from rationing their insulin



25% of insulin users report rationing due to high prices

PRINCIPLE 1: WE NEED BOLD, STRUCTURAL SOLUTIONS

The insulin crisis is real. Everyone should be able to afford the medicine they need, irrespective of who they are, what they look like, or what insurance coverage they have. Yet 58 million Americans reported struggling to pay for their prescription medicine in the past year. Making medicines affordable requires addressing the monopoly pricing power of pharmaceutical companies. Voters are demanding bold changes. 84 percent support breaking patent monopolies to reduce prices. The majority of Americans support the idea of the government manufacturing insulin.

PRINCIPLE 2: STATES CAN HELP LEAD THE WAY

Despite the wave of legislative activity in the past few years, states have yet to fully embrace their authority in reining in prescription drug prices. While state action is a complement—not a substitute—for federal action, state officials have considerable opportunity to reform drug pricing. Advocates can push both state and federal officials to be ambitious.

PRINCIPLE 3: PEOPLE POWER CAN WIN

The insulin crisis has led to unprecedented interest and activity around prescription drug pricing. Since 2018, advocates have started 35 new #insulin4all Chapters across the country. Some have successfully helped pass legislation.

People have real power. We can use this power to advocate for what people need and deserve, not what is convenient. Complex compromises can seem “realistic” but the political effort and resources required to introduce, implement and defend a small fix can suffocate larger reforms. Compromises can also allow some political officials to claim victory and move on, leaving the fundamental problems of inequitable access unaddressed.

For decades, an unspoken truth in Washington and state capitals across the country was that the pharmaceutical industry was untouchable. This time around, things are different. Advocates can seize this opportunity to make insulin for all a reality.

EMERGENCY INSULIN REFILL

SHORT-TERM STEPS

Emergency prescription refill laws allow a pharmacist to dispense an emergency supply of insulin to a patient without a prescription.

Emergency insulin access can help people who are not able to see their doctor. The law was first passed in Ohio and is commonly referred to as Kevin's Law. It is named after Kevin Houdeshell, who passed away in 2014 from rationing his insulin after he was unable reach his doctor to refill his expired prescriptions.

Incorporating additional features can strengthen emergency insulin refill provisions.

This legislation can be strengthened by increasing the quantity that is dispensed (e.g., a 30-day supply). It can also be strengthened by ensuring that emergency refills are available more than once a year, and including chronic maintenance drugs for other conditions, such as asthma inhalers.

Emergency insulin access provisions do not address affordability. Price remains a barrier. The provisions do not address the pharmaceutical industry's ability to set high prices.

EXAMPLES

Ohio House Bill 188

The first bill that incorporated emergency prescription refills. The bill could be strengthened in several ways, including by allowing a pharmacist to dispense an emergency prescription refill to a patient more than once per year.



Oregon Senate Bill 9

The bill allows patients to access emergency refill insulin and supplies up to three times in a year, and requires some insurance plans to reimburse refills.

Questions to Consider

How can this policy be designed to benefit more people?

In some states, emergency refill legislation has been expanded to include other medications, including inhalers, blood pressure medications, mental health medications, and HIV maintenance medications. Adding these medications can make the bill more inclusive.

How can it be combined with more transformative policies to target the price of insulin?

To begin to address wider affordability concerns, a proposal in New York packaged emergency refill legislation with an insurance copay cap and an insulin assistance demonstration program.

Emergency insulin access programs could also include demands for drug affordability boards which would regulate prices. Advocates could also push for insulin competitive licensing to introduce low-cost generic competition, or for the government to produce its own affordable insulin.

How can advocates claim victory and celebrate more modest, yet life-saving, proposals in a way that does not diminish the prospect for transformative reform?

Advocates should always provide context, and keep the relationships built with legislators. They can talk about problems the bill seeks to fix, while acknowledging all the issues it does not address. Advocates can also talk about how this bill is a step towards the larger, structural changes needed. They can list out the ultimate goal: affordable insulin for all.

"Many people with type 1 diabetes have suffered, walking away from their pharmacy with no insulin because the law prohibits emergency refills. In January of 2014, doing so claimed our son Kevin's life. Through our advocacy efforts, we have been able to pass Kevin's Law in several states, and hope to pass it in every one across the USA."

-**Dan Houdeshell**,
father of Kevin Houdeshell

INSURANCE COPAY CAP

SHORT-TERM STEPS

States can lower costs for some patients by limiting the monthly insurance co-payment for insulin or imposing similar out-of-pocket limits.

Copay caps and out-of-pocket limits can only help make insulin affordable for some people with insurance. Because of federal law, state copayment caps and out-of-pocket limits are limited to a small subset of insurance plans. This excludes plans subject to federal regulation, such as Medicare plans and most private employer-sponsored plans. These plans cover hundreds of millions of Americans.

In addition, because they are tied to insurance status, copay caps and out-of-pocket limits do not benefit people without insurance. According to the CDC, 30 million people are uninsured nationally.

Copay caps and out-of-pocket limits do not lower the price of insulin. Copay caps and similar out-of-pocket limits only lower the out-of-pocket cost of insulin. The distinction between price and cost is significant. Copay caps push the high costs of insulin onto insurance companies, state governments, and other consumers, which over time could lead to higher premiums.

EXAMPLES

Colorado House Bill 19-1216

The bill caps out-of-pocket costs for some people with state-regulated insurance plans to \$100 for a 30-day supply of insulin.

The bill can provide meaningful relief to some with private insurance. But the bill was inaccurately portrayed as the solution to a much larger crisis.

This framing generated national headlines and allowed some political officials to claim victory, even as the source of the problem remained unaddressed.



Connecticut House Bill 5175

The bill caps out-of-pocket costs for some people with state-regulated insurance plans to \$50 for a 30-day supply of insulin. It also includes limits on supplies.

Copay caps and out-of-pocket limits do not tackle the source of high prices. High insulin costs are rooted in the unjustifiably high prices set by Eli Lilly, Novo Nordisk and Sanofi. Copay caps still leave these corporations untouched, despite their responsibility for the insulin crisis in this country. In some cases, copay caps are actually supported by the pharmaceutical industry because they allow corporations to continue price-gouging.

Questions to Consider

Who benefits from this policy? Who is burdened by this policy? Who is left out?

Legislation that limits out-of-pocket payments, like copayments and coinsurance, is often backed by the pharmaceutical industry. The legislation does not reduce the price of insulin, but instead shifts the costs onto health insurers. In the long run, requiring insurance companies to take on the unchecked cost of insulin could lead to higher insurance premiums for everyone. Additionally, out-of-pocket limits do not help many people with insurance, and the uninsured. This is particularly concerning because the uninsured are the most vulnerable individuals in the type 1 diabetes community and are at higher risk for rationing.

How can this policy be designed to benefit more people?

Similar to emergency insulin legislation, packaging copay cap proposals with insulin assistance programs could help more people. In general, limiting out-of-pocket costs for consumers should be accompanied with requiring manufacturers to set an affordable price. For example, copay caps could be supplemented with establishment of drug affordability boards or requirements for other price regulations. Competitive licensing to introduce low-cost insulin is another option to push for, along with pushing for the government to produce affordable insulin.

How can advocates claim victory and celebrate steps forward while not diminishing the prospect for transformative reform?

Context and nuance are key. Advocates can be motivated by achieving the passage of new legislation, while also continuing to raise all the issues the policy does not address. Advocates can also talk about how this bill is a step towards the larger, structural changes needed. They should keep their language and focus on the ultimate goal: affordable insulin for all.

INSULIN ASSISTANCE PROGRAM

SHORT-TERM STEPS

An insulin assistance program allows some individuals to receive insulin at participating pharmacies with a nominal co-payment.

Assistance programs can help some people access insulin. Advocates in Minnesota overcame significant opposition to help pass this proposal. It is named after Alec Smith, a 26-year old who passed away after rationing his insulin due to its price. The Minnesota law benefits individuals who are not enrolled in prescription drug plans that limit insulin cost-sharing to \$75 or less per month.

Depending on their structure, assistance programs can start to hold pharmaceutical companies accountable. The Minnesota law requires pharmaceutical corporations to provide insulin for an urgent-need safety net program. It also creates a continuing safety net that requires the corporations to develop a patient assistance program for low-income individuals. While this policy does not lower the price of insulin, it helps ensure that pharmaceutical corporations start to bear at least some responsibility for their price-gouging.

EXAMPLES

Minnesota House File 3100

Thanks to the tireless work of #insulin4all advocates, this bill, named the Alec Smith Emergency Insulin Act in honor of the 26-year-old Minnesotan who passed away from insulin rationing in 2017, became law in April 2020.



"No one should have to choose between paying their bills, buying groceries, or paying for their insulin. No one should have to ration their insulin because they can't afford the skyrocketing prices. This bill will prevent more needless deaths."

-**Nicole Smith-Holt**, mother of Alec Raeshawn Smith and T1International Charity Ambassador

Questions to Consider

How can this policy be designed to benefit more people and how can it be combined with stronger policies to target the price of insulin?

The insulin assistance program starts to hold corporations responsible by requiring them to pay for the costs of insulin for some patients. A more comprehensive approach would target the list price of insulin to make sure everyone could benefit. For example, the proposal could be supplemented with demands for lower list prices through drug affordability boards or other price regulations. Another option is to push for competitive licensing and public insulin production.

How can advocates claim victory for modest proposals in a way that does not diminish the prospect for transformative reform?

Advocates should frame this policy as a step towards the larger, structural changes that are needed. Celebrating progress while acknowledging that insulin for all is not yet achieved is key. Advocates can use the victory to share nuances and build momentum so that the next steps are easier to achieve.

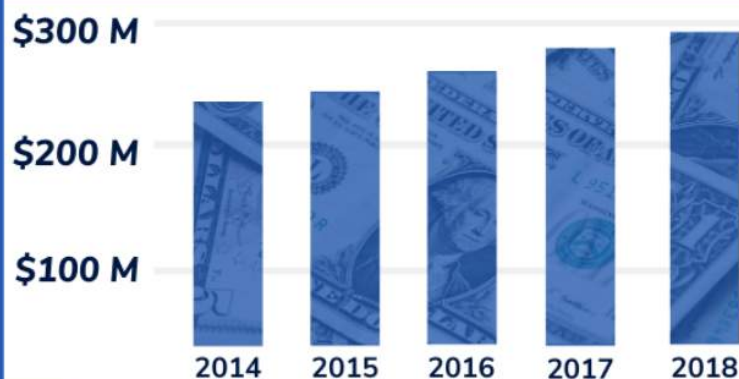


BIG PHARMA

IS FUNNELING

MILLIONS INTO POLITICAL CONTRIBUTIONS

AND LOBBYING



TRANSPARENCY

SHORT-TERM STEPS

States can better understand the costs associated with insulin by requiring transparency.

Transparency is most helpful when states request detailed information about research and development costs, marketing expenses, pricing strategies and profits. To date, no such state bill has been fully enacted due to concerns about trade secrets laws. However, legal scholars have suggested that these concerns are overstated, arguing that “given their significant budgetary and public health interest, states are well-positioned to require public disclosure of substantial information.” The more detailed and disaggregated the information, the more useful it can be.

By itself, transparency along the supply chain can sometimes be used to distract from the greed of the pharmaceutical industry and delay meaningful action. We already know the essential facts of the insulin crisis. Manufacturers have increased the price of insulin from \$21 to \$275. People are struggling to afford the medicine they need to survive. Many different actors are involved in the supply chain, but the pharmaceutical companies profit the most. Even after rebates, the price of insulin is close to \$150. That is three times the price in other countries, and four times its inflation-adjusted original price.

EXAMPLES

U.S. Congress Transparent Drug Pricing Act of 2017.

The Act requires detailed reporting of research and development costs, marketing expenses, profits, federal benefits, and prices in other countries. It also imposes substantial penalties if pharmaceutical companies fail to comply. While it is a federal proposal, it can serve as a model for states.



Nevada Senate Bill 539.

Nevada was the first state to enact laws requiring transparency about insulin prices, rebates, total administrative expenditures and profits. After legal threats from the pharmaceutical industry, the law was modified to keep more information secret.

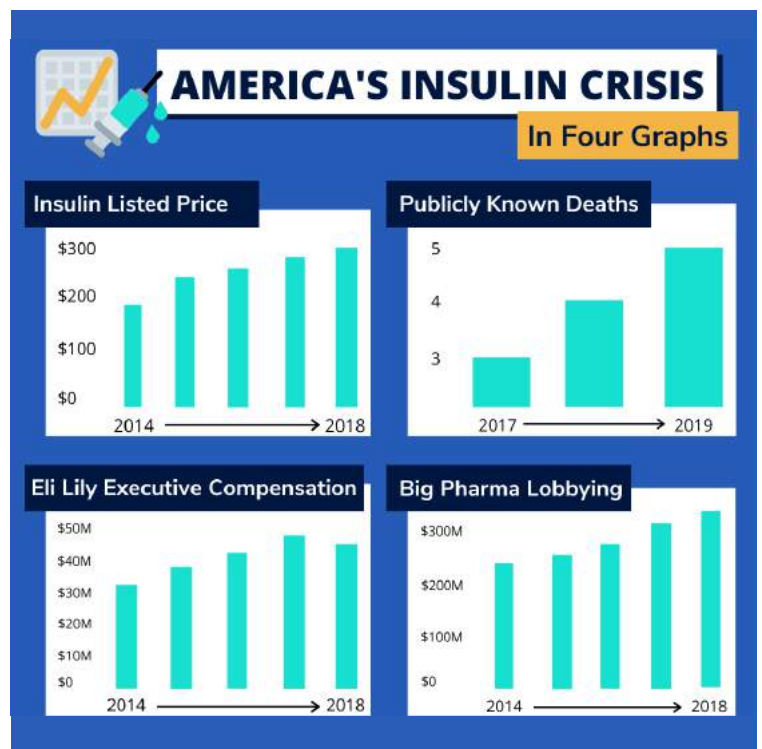
Questions to Consider

How can advocates persuade legislators to make the most transparent and detailed legislation possible?

Advocates can explain that states have already passed transparency legislation. The legislation has consistently shown the burden posed by high-priced drugs. What we need now is a more detailed set of analyses that look at the relationship between research and development costs, marketing expenses, pricing strategies and profits. Advocates can rely on legal experts to fight back against industry claims of “trade secrecy” to make sure that states are fully embracing their power to make vital information public.

How can transparency legislation be used to make insulin affordable? How can this policy be combined with more transformative policies to target the price of insulin?

Transparency by itself does not reduce the price of insulin, but it gives us a better picture of what is happening behind the scenes. To address prices, as with other short-term bills, it can be supplemented with demands for drug affordability boards to regulate prices, for insulin competitive licensing to introduce low-cost generic competition, or for the government to produce affordable insulin.



LIMITING PRICE SPIKES

SHORT-TERM STEPS

States can limit future price spikes on insulin.

Fining companies for raising drug prices beyond inflation could help prevent further price-gouging.

Manufacturers have increased the price of insulin over 1200% since the 1990s, and the list price only keeps increasing. Drug-makers typically increase the price of medicines twice per year.

Limiting annual price increases would not lower existing prices. The price of insulin is already outrageous and unjustifiable. Limiting price hikes could thus provide limited relief.

Questions to Consider

How can this policy be combined with more transformative policies to target the high price of insulin?

Limiting price spikes does not reduce the existing price of insulin. To address existing prices, the proposal can be supplemented with demands for drug affordability boards or other price regulations, for insulin competitive licensing to introduce low-cost generic competition, or for the government to produce affordable insulin.

EXAMPLES

U.S. Congress Stop Price Gouging Act

The bill would penalize drug companies that unjustifiably increase prices by imposing financial penalties proportionate to the price spike. Revenues collected through the bill would fund research and development at the National Institutes of Health. While it is a federal proposal, it can serve as a model for states. States, for example, could redirect any revenues to insulin access programs.



Pew Charitable Trusts Model Legislation

The model legislation is a helpful starting point. The bill would impose a tax on drug price increases to discourage companies from increasing prices.

DRUG AFFORDABILITY BOARDS

TRANSFORMATIVE POLICIES

Much like how they set rates for electricity and water, states can regulate medicine prices to make insulin more affordable.

Drug affordability boards would transform the role of states in regulating drug prices. Developing an independent body to evaluate and set limits on the prices of medicines would be a groundbreaking victory for patients.

Drug affordability boards could substantially reduce the price of medicines. The government imposes almost no constraints on what a manufacturer can charge for a medicine in the U.S. The rationale for affordability boards is clear: insulin is like water. Its price should be regulated in the same way. There is no reason why insulin should cost three times as much in the U.S. as it does in other countries.

The primary barrier to enacting affordability boards is political pressure. States have considerable authority and experience in regulating the price of insurance, and utilities, like water and electricity. The primary reason they have failed to regulate the price of pharmaceuticals is industry pressure. But things are changing. Legislators in many different states have introduced affordability board legislation.

EXAMPLES

Maryland House Bill 768

A strong coalition helped Maryland pass initial legislation implementing a Prescription Drug Affordability Board. Due to industry pressure, the board currently does not have the authority to set pricing limits, but it may be able to set limits in the future for drugs purchased by state, county, or local governments with the approval of the Legislative Policy Committee of the Maryland General Assembly.

National Academy for State Health Policy Model Legislation

The model legislation is a helpful starting point. It could be strengthened by explicitly including insulin, and all drugs that create significant affordability challenges.

Questions to Consider

Does the proposed affordability board have the authority to set prices? Who is able to purchase medicines set at the prices by affordability board? Does the proposal cover insulin?

All these questions are key pieces to address to ensure the strongest affordability board possible.

"It's time to put an end to pharmaceutical price-gouging. Patients with diabetes deserve affordable insulin and supplies because access to healthcare is a human right."

-**Elizabeth Pfister**, Executive Director of TInternational

How can advocates build the political power necessary to push for affordability boards?

Advocates can explain how affordability boards address a key part of the monopoly pricing problem and could bring relief to many different people across the state. Advocates can point to the significant public support for such an option.

Advocates can also connect with other groups who may be pushing for systemic drug pricing reform in their states and interested national groups. Advocates can draw from the experiences of other states and connect in-state legislators to like-minded legislators across the country.



COMPETITIVE LICENSING REQUESTS

TRANSFORMATIVE POLICIES

States can ask the federal government to break monopolies and authorize low-cost generic competition through competitive licensing.

Breaking monopolies could help increase real competition and lower prices. According to the Food and Drug Administration, generic competition can lead to price reductions of more than 95% when there are six or more generic competitors. Analogue insulins do not have any generic competition. Instead, the big three brand-name insulin companies dominate the market.

In addition to gaming the regulatory system, one reason these companies have monopolies (and sometimes oligopolies) is because of patents. Patents block generic competition from entering the market. Patents are central to the industry business model. Simply talking about competitively licensing patents to increase generic competition can be enough to bring companies to the negotiating table to lower prices.

Without any legislative action, states can start exploring how to break patent monopolies. The state government could request the federal government to use its authority to use patents and permit generic competition. Under the Eleventh Amendment, the state could also explore legal claims about how its sovereignty could protect it from patent infringement claims.

EXAMPLE

Louisiana 1498 Request

In 2017, Louisiana Secretary of Health and Human Services Rebekah Gee began exploring asking the federal government to license patents to increase generic competition for a \$1000 per pill hepatitis C cure. She convened a group of high-profile academics, who helped build the case for action. She also asked for public comments on the proposal. Facing public pressure, the manufacturer, Gilead Sciences, was eager to negotiate. Gee leveraged the threat of licensing to negotiate a new discount payment model to lower hepatitis C treatment costs. Under the “Netflix” model, Louisiana will have unlimited access to the treatment for a fixed annual sum. The New York Times Editorial Board later endorsed the use of competitive licensing.

Questions to Consider

How can advocates build the political power necessary to push for competitive licensing?

Drawing on the example of the Louisiana model, advocates can explain how licensing patents to introduce generic competition can provide leverage for states to dramatically reduce prices.

More people in Louisiana have received hepatitis C treatment in the first seventy-five days of the new program than the entire fiscal year of 2019. Advocates can also point to the significant public support for breaking monopolies.

Connecting with policy and academic experts can be especially useful here. Linking up with other advocates and groups pushing for systemic drug pricing reform in their states is also helpful. There are several groups pushing to break monopolies at the federal level, including Public Citizen.



PUBLIC INSULIN

TRANSFORMATIVE POLICIES

States can produce their own affordable insulin.

Public insulin could lower prices and increase access.

Researchers estimate that the cost of producing analog insulin is merely \$6. A not-for-profit, government insulin manufacturer could produce insulin at an affordable price and ensure a reliable supply. While the path to producing and selling insulin could take years, developing the idea could shift the current drug pricing paradigm.

U.S. states have a long history of producing pharmaceuticals.

Up until the 1990s, Massachusetts and Michigan both produced vaccines for their residents. The majority of voters still support the government manufacturing insulin.

Developing public insulin would require addressing regulatory and patent barriers.

The Food and Drug Administration (FDA) approves all new drugs and biologics on the market. To finance the regulatory studies required by the FDA, states could collectively pool resources. To address patent issues, states could consider asking the federal government to use its patent licensing authority and/or explore how their state sovereignty may make them immune from patent infringement claims. Alternatively, states could focus on developing insulins that are no longer protected by patents (e.g., insulin lispro, or Humalog).

EXAMPLE

U.S. Congress Affordable Drug Manufacturing Act

The legislation was introduced in Congress in 2018. It would create a federal manufacturer to produce generic medicines, including types of insulin no longer protected by patents. While it is a federal proposal, it can serve as a model for states.



"Essential medicines like insulin could and should be developed and sold by public institutions in the public interest. These organizations could be designed to ensure that public health needs are their top priority rather than profits for shareholders."

-**Fran Quigley**, Clinical Professor of Law, Health and Human Rights Clinic, Indiana University Robert H. McKinney School of Law

Questions to Consider

How can advocates build the political power necessary to push for public insulin?

Drawing on the historical examples of state production, advocates can explain how a state manufacturer can help increase competition and provide lower prices. Advocates can point to the significant public support for government manufacturing.

Again, advocates can connect with other groups who may be pushing for systemic drug pricing reform in their states and interested national groups. Advocates can also try to bring together interested state legislators to start helping pool resources and coordinating efforts.

"Nobody should ever have to think twice about how they pay for their medicines. A better world is possible."

-Zain Rizvi, Law and Policy Researcher with Public Citizen



ELI LILLY

INCREASED THEIR EXECUTIVE COMPENSATION BY

\$10 M

SINCE 2014

BY GOUGING DRUG PRICES

