

Insulin Deserts

The Urgency of Lowering the Cost of Insulin for *Everyone*







This report was prepared by staff in the Offices of Senator Reverend Warnock and Senator Kennedy November 2023

Table of Contents

| Executive Summary | 4 |
|--|----|
| Insulin Deserts: The Urgency of Lowering the Cost of Insulin for <i>Everyone</i> | 4 |
| Inventing Insulin | 5 |
| Momentum | 5 |
| Insulin Deserts: Everyone Deserves Access | 7 |
| Consequences of Insulin Injustice | 11 |
| Bipartisan Affordable Insulin Now Act of 2023: The Solution to Insulin Deserts | 13 |
| \$35 Cap for Patients with Private Insurance | 13 |
| \$35 Program for Uninsured Patients | 13 |
| Offset | 13 |
| Why Congress Must Act | 14 |
| Endnotes | 17 |

Insulin Deserts: The Urgency of Lowering the Cost of Insulin for *Everyone*

Executive Summary

Despite progress over the last few years to lower out-of-pocket costs of insulin, unaffordable insulin remains pervasive across the country. In fact, while state initiatives and manufacturer price cuts have improved access for many, this progress has also widened the disparities in access to affordable insulin, particularly in areas the offices of Senator Reverend Warnock and Senator Kennedy have identified as "Insulin Deserts."

This report confirms the need for legislation to make insulin affordable for *both* privately insured and uninsured Americans. This conclusion is based on the following data:

- 1. There are <u>813</u> counties that are Insulin Deserts counties in the top half of the country by both uninsured rates and diabetes prevalence.
- 2. Insulin Deserts are more concentrated in the American South, and particularly the Southeastern region of the country.
- 3. Uninsured Americans in Insulin Deserts are poorer, less likely to have high-speed internet access, and less likely to be college graduates than uninsured Americans in non-Deserts, exacerbating the difficulties of navigating the complex web of patient assistance programs.

Congress must pass the only bipartisan proposal that tackles the cost of insulin for <u>all</u> Americans: the bipartisan *Affordable Insulin Now Act of 2023*.



"I'm a doctor and I have multiple patients who don't always take their full dose of insulin so they can save money. This has caused organ damage, emergency department visits and hospitalizations."

– Harry from Macon, GA

Inventing Insulin

In the early 1920s, researchers discovered that injecting insulin into a diabetic 14-year-old would lower blood glucose levels and save the child's life. Knowing the life-saving capabilities of this newly discovered drug, the researchers sold the patent to the University of Toronto for one dollar.

In the century since its discovery, insulin now comes in many dosage forms and types, but the cost to produce insulin remains low. A 2018 study found that the most commonly used insulin only costs \$2 to \$4 per vial to produce.³

Despite this, Americans with private insurance or Medicare pay an average of \$63 per fill of insulin while uninsured Americans pay on average \$123 per fill.⁴ Why are Americans facing high costs at the pharmacy counter?

Momentum

According to the American Diabetes Association, more than 37 million Americans, or 11.3 percent of the population, live with diabetes.⁵ Recent data indicates that over 7 million Americans with diabetes use insulin in a given year.⁶ Studies indicate that these numbers may rise in the coming decades.⁷

Insulin is seven to ten times more expensive in the United States than in other countries.⁸ Between 2014 and 2019, the list prices of certain types of insulin in the United States increased upwards of 50 percent, totaling more than \$500 per unit of insulin.⁹

In recent months, both Congress and private manufacturers have taken steps to reverse this alarming trend. In 2022, Congress capped the monthly copay of insulin for seniors and people with disabilities on Medicare at \$35. This policy went into effect on January 1, 2023, and is estimated to benefit 1.5 million seniors and people with disabilities who use insulin. However, a provision to extend the \$35 copay cap to those with private insurance failed in the Senate by just three votes. 11

In March 2023, the three insulin manufacturers announced voluntary steps to lower the price of their insulins: Eli Lilly announced that all out-of-pocket costs for their insulin products would be automatically capped at \$35 and its generic product would be priced at \$25 per vial. In 2023, Novo Nordisk and Sanofi also announced steps to cut prices of their popular insulin products.

Insulin manufacturers Eli Lilly, Novo Nordisk, and Sanofi together control roughly 90 percent of the insulin market in the United States. ¹² In March 2023, these three insulin manufacturers announced voluntary steps to lower the price of their insulin products. ¹³ Eli Lilly announced that all out-of-pocket costs for their insulin products would be automatically capped at \$35 per month and its generic product would be priced at \$25 per vial. ¹⁴ Novo Nordisk and Sanofi also announced steps to cut prices of their popular insulin products. ¹⁵

While these announcements are important steps that can save lives, they are also completely voluntary actions taken by drug companies likely in response to immense public pressure. Nothing in federal law prevents these companies from raising their prices if the public stops paying attention.

Half of all states—the laboratories of democracy—have taken their own steps to cap the cost of insulin for their residents, under both Democratic and Republican political control. As shown below, twenty-six states have implemented insulin copay caps, ranging from Alabama to Minnesota, and from Nebraska to Texas.¹⁶

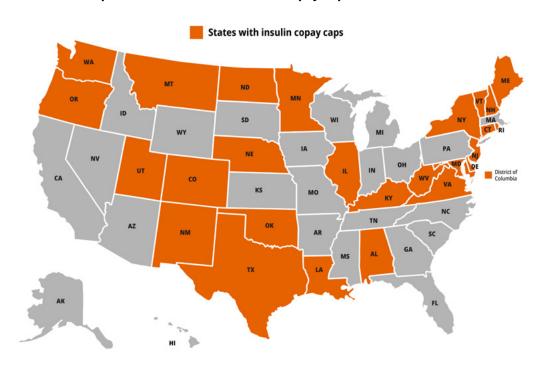


Figure 1. States That Have Implemented State-Level Insulin Copay Caps

While these developments are promising, as many as 2.75 million Americans have no federal protections against unaffordable insulin.¹⁷

Insulin Deserts: Everyone Deserves Access



"[The cost of m]edicine is so high that sometimes I have to choose between paying for medication and food. It's terrible that in this country, the richest nation on earth, Americans have to make these choices. It's just not right! Capping insulin at \$35 dollars a month would help me pay for insulin, my other medications, and give me more money to pay my bills, cover the cost of car, dental, and health insurance and put more food in my refrigerator. "

- Cathy from Hiram, GA

In 2011, the Centers for Disease Control and Prevention (CDC) identified areas of the U.S. comprised of 644 counties across 15 states with high prevalence of diabetes. Most of these counties are in the Southeast and Appalachian regions of the country. People living in these counties also have less access to health care compared to other regions of the United States. However, no analysis to date has directly examined counties that both have high rates of diabetes and high rates of uninsured patients.

To improve our understanding and demonstrate the need for a universal federal insulin copay cap, the Offices of Senator Reverend Warnock and Senator Kennedy conducted original analysis using data from the CDC, U.S. Census Bureau, and U.S. Department of Health and Human Services to identify the communities harmed most by the lack of an insulin cap. This analysis provides the most granular picture to date of who would benefit most from a federal insulin copay cap and where they live.

To do so, the Offices conducted an original county-level analysis that combined data examining uninsured rates²¹ and diabetes prevalence.²² The analysis isolates the counties that are in the top half of counties for *both* the percentage of individuals who are uninsured as well as diabetes prevalence. **We call these counties "Insulin Deserts."**

There are 813 Insulin Deserts across the country, and they are geographically concentrated in the American South and Southeast. Over 75 million non-elderly people live in Insulin Deserts, including over 12 million who are uninsured.

In Insulin Deserts, the average prevalence rate of diabetes is 10.2% compared to 8.4% in non-Deserts.²³ Among non-elderly individuals, 16.1% of those in Insulin Deserts are uninsured, compared to 8.3% in non-Deserts.

Figure 2. Rate of Diabetes and Uninsured Non-Elderly Adults in Insulin Deserts

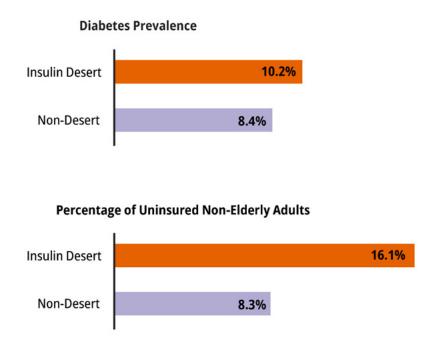


Figure 3. Insulin Deserts

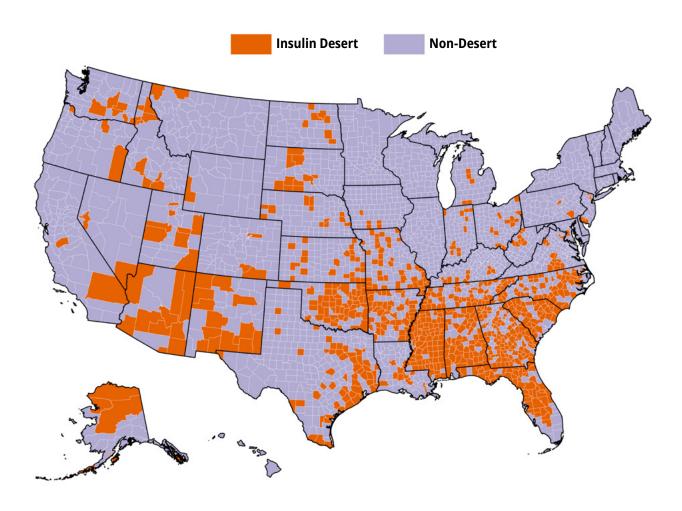
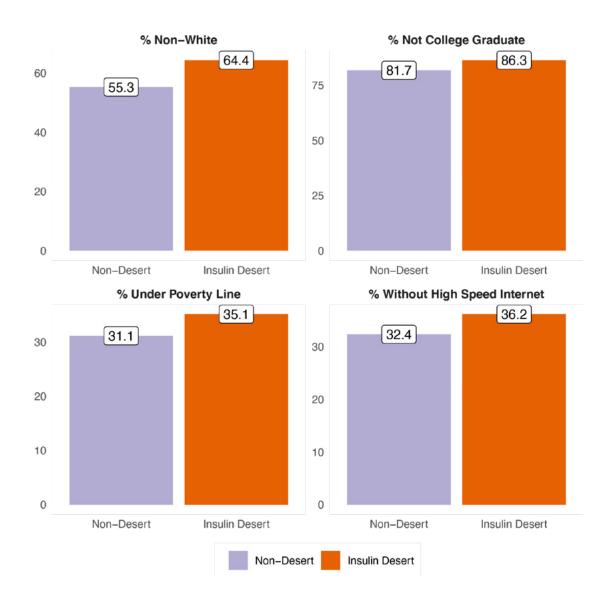


Table 1: Top 10 States for Insulin Deserts

| State | % of Uninsured Population Living in Insulin Deserts | Number of Insulin Deserts |
|----------------|--|---------------------------|
| Mississippi | 95.2% | 75 |
| Oklahoma | 88.6% | 50 |
| Alabama | 82.5% | 53 |
| Nevada | 81.9% | 3 |
| Arizona | 81.8% | 10 |
| Texas | 74.5% | 55 |
| Arkansas | 73.7% | 43 |
| Georgia | 71.4% | 105 |
| Tennessee | 69.2% | 53 |
| South Carolina | 69.1% | 36 |

Within the uninsured population, those who live in Insulin Deserts can face additional obstacles to obtaining essential health care, including insulin. According to U.S. Census data, the uninsured population who live in Insulin Deserts are poorer, less likely to be college graduates, more likely to be a person of color, and less likely to have high-speed Internet access than the uninsured population in non-Deserts.²⁴

Figure 4: Uninsured Populations In and Outside of Insulin Deserts



Consequences of Insulin Injustice



I have been a Type 1 diabetic since 1985, and I spend \$150 a month on my insulin. I am on other diabetic medications as well, but the cost of insulin is not something that I can easily afford.

Jessica from Statesboro, GA

Every year, 246,000 uninsured Americans use insulin.²⁵ When including Americans who experience a lapse in insurance coverage, that number rises to 542,000.²⁶

These Americans face significantly higher costs—more than double—to obtain insulin compared to insulin users with insurance.²⁷ In 2019, patients without insurance spent an average of \$996 annually on insulin.²⁸ And more than 71 percent of insulin prescriptions for uninsured individuals cost more than \$100 out-of-pocket every time that they refill their supply.²⁹

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What happens when families can't afford these costs? According to a study published in the *Annals of Internal Medicine*, many uninsured Americans with diabetes ration their insulin.³⁰ Insulin rationing due to cost is more common in lower-income and marginalized populations.³¹ Rationing insulin can also lead to chronic kidney disease, heart disease, diabetic retinopathy, stroke, and end stage renal disease.³²

To help with affordability, some patients use forms of insulin that are cheaper but may be less effective or convenient. The Commonwealth Fund, an independent health care research foundation, discovered that uninsured Americans are more likely than others to use older forms of insulin.³³ Some insulin users may prefer to use pens instead of vials because of ease of use and lessened pain during injection.³⁴ However, pens for rapid-acting insulin can be 40 percent more expensive than the vial form.³⁵

While some manufacturers offer voluntary programs to assist with the price of insulin, these programs do not reach all eligible Americans, and there is no permanent policy that will guarantee all low-income Americans access to this drug that they need to live.

More than 71 percent of insulin prescriptions for uninsured individuals cost more than \$100 out-of-pocket every time that they refill their supply.

Given the high costs of insulin, even those who can theoretically afford the out-of-pocket costs may be forced to make hard choices about whether to pay the rent, buy groceries, or purchase their insulin.³⁶

Lack of adequate access to insulin has wide-ranging effects both for individuals and our society. Diabetics who ration their insulin can end up in the emergency room for amputations and with other severe, or even fatal, complications.³⁷ Every year, federal and state government spending totals \$11.3 billion on hospitalizations related to complications from diabetes.³⁸ The average cost for inpatient hospital stays from diabetes complications ranges from \$8,426 to \$23,359.³⁹



I am a physician and work for a public hospital in Atlanta that serves the uninsured and underserved population. Uncontrolled diabetes results in severe complications, heart attacks, strokes, loss of vision, chronic kidney disease leading to dialysis, amputations. All these complications lead to early disability.

- Wilhelmina from Atlanta, GA

In 2022, the total cost of diabetes in the United States was \$412.9 billion.⁴⁰ This includes \$106.3 billion in the indirect costs of diabetes, such as missing days of work due to illness or complications.⁴¹ A key culprit in direct costs is spending on insulin, which has almost tripled over the last ten years from \$8 billion to **\$22.3 billion per year**.⁴²

Ensuring that all Americans who need insulin can afford it not only improves the lives of patients but also reduces the costs to our economy.

Bipartisan Affordable Insulin Now Act of 2023: The Solution to Insulin Deserts

In March 2023, Senator Reverend Warnock and Senator Kennedy introduced the first bipartisan insulin bill of the 118th Congress: the *Affordable Insulin Now Act of 2023*. This legislation is the only bill introduced in Congress that would address insulin deserts and give everyone access to affordable insulin.

\$35 Cap for Patients with Private Insurance

The bill caps cost-sharing for insulin products at \$35 per month under private insurance plans. This will help the nearly 2.5 million Americans who have private insurance and use insulin. More than 1 in 3 Americans with private insurance who need insulin pay more than \$35 per month, and nearly 1 in 5 pay more than \$70 per month.⁴³

According to the nonpartisan Congressional Budget Office (CBO), this important reform will cost less than \$1 per month in additional insurance premiums.

\$35 Program for Uninsured Patients

The bill creates a new program, administered by the U.S. Department of Health and Human Services, for uninsured Americans to access insulin for no more than \$35 per month and would reimburse insulin providers for costs above \$35. This program takes the onus off vulnerable, uninsured Americans who are often the ones least shielded from extremely high costs. This policy would potentially benefit up to 542,000 Americans per year.

Offset

The bill reaffirms Senator Reverend Warnock and Senator Kennedy's commitment to fiscal responsibility by requiring the two programs to be fully paid for. The CBO estimates the private insurance cap to cost \$629 million over ten years. The U.S. Department of Health and Human Services' Office of Planning and Evaluation has conducted a preliminary analysis of the \$35 program for the uninsured that estimates the program would cost no more than \$670 million over ten years.

When the cost of diabetes to Americans is over \$410 billion per year, this legislation will save money and save lives.

Why Congress Must Act

1. With the recent momentum, why do we need the bipartisan *Affordable Insulin Now Act of 2023*? Don't uninsured people already have access to affordable insulin?

Insulin access is better today for many than it was just a few years ago. However, many Americans still face barriers that prevent them from obtaining affordable insulin.

Manufacturer-sponsored cost-sharing programs can be hard to navigate, with unclear eligibility requirements, challenges with renewal, and limits to specific types of insulin.⁴⁴ These programs have no obligation to accept patients who apply and are not required to comply with federal health privacy protection laws.⁴⁵

Moreover, to access manufacturer-sponsored cost-sharing programs, most patients need internet access to apply. According to the Federal Communications Commission (FCC), more than 8.5 million U.S. homes and businesses are in areas that lack access to high-speed broadband. In fact, an FCC study found that diabetes prevalence is 41 percent higher in the counties with the worst access to connectivity. This is confirmed by our original analysis, which shows that 36% of uninsured individuals living in Insulin Deserts lack high-speed internet access.

Most importantly, while the recent actions of insulin manufacturers to lower prices or offer other cost-sharing programs are laudable, nothing prevents these entities from raising prices after public interest and outrage have faded.

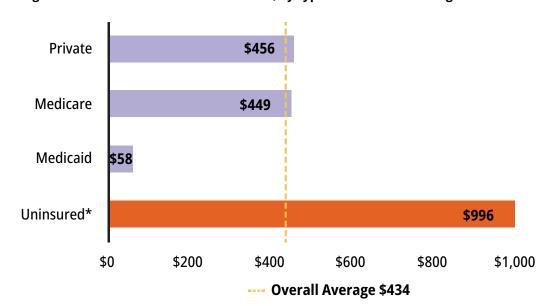


Figure 5. Average Annual Out-of-Pocket Costs of Insulin, by Type of Insurance Coverage⁴⁸

Similarly, state-level cost caps are promising but do not apply to all plans. For example, state legislation may not apply to some federally-regulated plans under the Employee Retirement Income Security Act (ERISA).⁴⁹ Furthermore, most state-level caps do not include insulin costs for those who are uninsured.⁵⁰

Exclusions may even apply to independent charity assistance programs. According to one study, 97 percent of such programs exclude the uninsured.⁵¹ These programs may also cover more expensive brands of drugs, increasing costs overall.⁵²

In short, while many of these programs are promising, they are voluntary and not required by law, and there are still gaps for the most vulnerable Americans, who face barriers to accessing existing programs.⁵³

2. Isn't it enough to crack down on pharmacy benefit managers (PBMs)?

PBMs and other intermediaries are an important part of the drug pricing puzzle, but addressing PBMs alone is not enough.

Because PBMs extract a rebate based on the price of the drug, they can be incentivized to choose drugs with higher prices for a spot on an insurance plan's list of covered drugs.⁵⁴ However, other actors also contribute to rising costs. For example, despite Eli Lilly dropping the price of its generic insulin to \$25, a 2023 report from the Offices of Senators Warren, Blumenthal, and Warnock found that in 43 percent of pharmacies surveyed across the country, the \$25 generic version was not available to patients.⁵⁵

This means that PBMs are only part of the problem. While Congress continues to examine comprehensive drug pricing policies, uninsured insulin users need a program they can rely on to access this life-saving drug.

3. How much would the bipartisan Affordable Insulin Now Act of 2023 cost?

The nonpartisan CBO found that the private insurance copay cap would cost about \$629 million over 10 years. The U.S. Department of Health and Human Services estimates that the program to cap the costs of insulin for uninsured Americans would cost no more than \$670 million over 10 years. These costs pale in comparison to the \$412.9 billion in annual expenses for diabetes in the United States, ⁵⁶ including treating the complications of inadequate insulin access.

Continuing to let uninsured people fall through the cracks of a fractured system and exacerbate their unmanaged diabetes symptoms is ultimately more expensive to the health care system

and to American taxpayers. Rationing insulin can result in high blood sugar, which can lead to severe complications like heart disease, chronic kidney disease, nerve damage, vision problems, amputations, and even death.⁵⁷

In 2020, the health care system spent \$11.3 billion on preventable hospitalizations from complications like amputations and diabetic ketoacidosis, with Black patients representing over 21 percent of those hospitalized for complications.⁵⁸ The average cost for inpatient stays from diabetes complications ranges from \$8,426 to \$23,359.⁵⁹

4. Would the bipartisan *Affordable Insulin Now Act of 2023* discourage people from enrolling in health insurance?

As of January 1, 2023, all Medicare enrollees have a \$35 monthly copay cap on their insulin products.⁶⁰ And the first section of the *Affordable Insulin Now Act of 2023* caps the copay of insulin under private insurance plans at \$35. Generally, Medicaid recipients have access to very low-cost or free insulin.⁶¹ In an environment where everyone has access to insulin at no more than \$35 out-of-pocket, there is little incentive for someone not to enroll in health insurance and use this program instead.

Access to affordable insulin ensures that individuals stay healthy and avoid complications that can leave them in the hospital. Stable access to insulin can better equip people who are uninsured and rely on insulin to enter or re-enter the workforce, where they can enroll in private insurance. However, in ten states, there are Americans who do not have any access to affordable health care due to those states not fully expanding Medicaid.⁶²

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For 28 counties, the data on uninsured population by county compiled by the U.S. Department of Health and Human Services, *supra* note 21, omits an estimate of the percentage of the uninsured who are college graduates. This indicates that there were fewer than three underlying observations and that such data has been censored. *See* Office of the Assistant Secretary for Planning and Evaluation, "Methodological Description," *U.S. Department of Health and Human Services* (Mar. 21, 2021), https://aspe.hhs.gov/sites/default/files/documents/fe1 a63dba4082ac65b4e8c5991dda799/2019-methodological-description.pdf. For this analysis, we assume none of the uninsured population in these counties is a college graduate. Omitting these counties, 27 of which are outside of Insulin Deserts, from the analysis entirely does not significantly alter the results to the tenth decimal place: under this alternate specification,

86.3% of the uninsured in Insulin Deserts are not college graduates versus 81.7% of those in non-Deserts.

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