Insight

INSULIN Act: Beyond the $35 Price-cap Headline

JACK LEIMANN | NOVEMBER 10, 2026

Executive Summary

- The big headline of the bipartisan Improving Needed Safeguards for Users of Lifesaving Insulin Now (INSULIN) Act is a $35 per month cap on out-of-pocket insulin prices for those on private insurance plans and not covered by similar efforts – including the Inflation Reduction Act and nearly 30 independent state laws.
- But the legislation also includes far less covered, but arguably more impactful, provisions such as a pilot program to support increasing states' access to insulin, increasing generic and biosimilar competition by reforming the citizen petitions process for new generic drug products, and expediting a review pathway for biosimilars.
- Though the bill is touted as a pricing and affordability measure, incorporating population studies and patient outreach provisions, such as the pilot program and generic and biosimilar competition sections, may offer longer-term solutions to insulin market issues.

Introduction

The Senate Health, Education, Labor, and Pensions (HELP) Committee passed the Improving Needed Safeguards for Users of Lifesaving Insulin Now (INSULIN) Act in August, a bipartisan bill that would cap the out-of-pocket cost of insulin at $35 a month for private and employer-sponsored insurance plans. The INSULIN Act also includes consumer-focused sections on promoting generic and biosimilar competition in the overall prescription drug market, the initiation of a pilot program for insulin access for the uninsured administered by states, a commissioned Government Accountability Office (GAO) study to better understand the insulin-using population, and the establishment of an insulin resource center and

hotline.

The most discussed section of the INSULIN Act is its proposed imposition of a price cap on monthly cost-sharing for beneficiaries in commercial insurance plans, modeled after separate insulin price caps at the federal and state levels, along with insulin manufacturers' self-imposed cap. Though price caps are an ineffective long-term solution, other provisions in the bill have the potential to be impactful and provide a foundation for considering future long-term solutions in the insulin market. In particular, its proposed pilot program address uninsured insulin-users, aiming to provide relief to the population with no prior access to the price caps. The generic and biosimilar competition sections may have significant impact increasing competition throughout drug markets outside of insulin specific reform.

This insight reviews how policies proposed in the INSULIN Act could affect the diabetic patient population and commercial insulin market. Based on this review, the INSULIN Act would operate more as a consumer protection bill by having the government standardize the prices rather than an affordability bill reducing the costs of insulin. This is furthered by its incorporation of population studies and patient outreach provisions. Though the proposed price cap would likely have the largest direct patient impact in the short-term, the generic and biosimilar competition sections and pilot program are more likely to offer longer-term solutions to insulin access and affordability problems.

INSULIN Act Overview

The Centers for Disease Control and Prevention estimates that 40.1 million – or 12 percent of the population – have diabetes, with 115.2 million adults estimated to be prediabetic. Insulin is a key therapeutic for the management of diabetes, which is either a lack of natural insulin in the body, known as Type 1, or resistance to insulin, known as Type 2. Both Type 1 and Type 2 patients may require an insulin prescription to maintain blood sugar levels.

Insulin policy debates recur regularly, with many documented access and affordability issues for patients. The INSULIN Act is intended to increase both competition in the insulin market and access to insulin regardless of insurance status. The bill's proposed biosimilar and generic competition sections and insulin pilot program have the potential to ensure more informed policymaking regarding insulin access and affordability. Long-term solutions require developing a clearer understanding of the insulin-using patient population, and documenting access issues to their prescription.

Price Cap

The INSULIN Act addresses commercial market patient pricing, setting a monthly insulin price cap for consumers in commercial health plans. The cap is equal to the lesser of $35 or

25 percent of a negotiated price for a 30-day supply of insulin for private insurance members.

The bill's price cap mirrors other ineffective efforts to address insulin costs for insured individuals. The Inflation Reduction Act caps the price of insulin at $35 a month for Medicare Parts B and D, allowing Medicare enrollees to purchase price-capped insulin since 2023. Outside of the Medicare program, 29 states and Washington D.C. have implemented their own insulin price caps ranging from $25–$100 per month. Many of these states have a cap of $35 or lower, though seven of the 29 states currently have a price set higher than $35 a month. Price-capped insulin is also available through the three main U.S. insulin producers Eli Lilly, Sanofi, and Novo Nordisk which have a self-imposed price cap on their insulin products.

Capping the price of insulin may make it more affordable for consumers in the short-term, but price caps also have future unintended consequences that are difficult to anticipate. A more durable policy would reduce the costs of production to naturally and competitively lower prices. Implementation would not occur until 2028. Moreover, the price cap would only apply to group and individual health plans; the uninsured population may not be impacted by this provision.

Generic and Biosimilar Competition

The bill also seeks to address generic and biosimilar competition in the overall prescription drug market, pointing to certain attempts to delay introduction of new generic and biosimilar drug products. Generic drugs are Food and Drug Administration (FDA) approved substitutes for a small-molecule, brand-name drug and are often sold at a lower price. Generics contain the same active ingredient as the brand-name drug and typically proceed through a shorter approval process, allowing manufacturers to bring them to market at lower cost. This bill designates citizen petition submissions to the FDA as the primary avenue for seeking civil action against a generic or biosimilar product application. Additionally, this bill allows the Secretary of the Department of Health and Human Services (HHS) to reject citizens' petitions submitted with the primary purpose of delaying approval of a generic or biosimilar application, based on testimony before the HELP Committee.

Biosimilars serve the same role for biologic drugs, requiring FDA approval to have no clinically meaningful difference from its reference biologic product. Biologics such as insulin are derived from living cells, tissues, or other biological materials, and are substantially more complex to manufacture than small-molecule medicines. The Biologics Price Competition and Innovation Act, passed in 2009, created an abbreviated FDA-approval pathway for biosimilars. Competition unfortunately remains limited in the insulin market

with only six FDA-approved insulin biosimilars, despite evidence showing that competitive generic and biosimilar entry reduces drug prices. The INSULIN Act seeks to increase competition by allowing the HHS secretary to designate biosimilar product applications for an undefined expedited review process, based on a new definition of inadequate biosimilar competition for a biological product. One important outstanding regulatory issue, however, is interchangeability – the ability of a pharmacist, subject to state law, to substitute a biosimilar for its reference biologic without first consulting the prescribing clinician. Because this is covered under a separate statutory framework, additional legislative action would be needed to remedy this issue.

Pilot Program

The bill would establish a pilot program for 10 states to aid uninsured insulin users by providing insulin at a price compliant with the monthly $35 insulin price cap. The 10 participating states would receive grant funding based in part on their rates of diagnosed diabetes patients and uninsured individuals. Funding would support activities including assisting in the purchase or dispensing of insulin for the uninsured and increasing enrollment in programs where drug manufacturers aid low-income individuals.

This program would begin in fiscal year 2027 and would likely be the bill's most impactful provision to provide timely aid for patients in need, given the long-horizon targets of other sections of the legislation. While seemingly straightforward, the application process for the states to receive funding will ultimately inform the impacted population.

GAO Study

The bill would commission a GAO study on the characteristics and demographics of uninsured insulin-users, establishing a foundational understanding for potential future policies to build on. This study would include surveying available data on any states or regions with a higher prevalence of uninsured individuals using insulin, potential reasons for an individual's uninsured status, along with their demographics and income level. The bill would require GAO to stipulate the characteristics of uninsured individuals using insulin within two years following enactment.

The insulin-dependent population represents an important cohort of health care users. The GAO study would provide more research on the uninsured portion of this population, which – because of its unique characteristics – may be underrepresented in current federal data. Incorporating new data on the uninsured insulin-using population could be vital for the success of future policies to address insulin affordability. For example, the study results may show that the uninsured insulin-using population is smaller than anticipated and does not

require sweeping policy solutions. Conversely, it could demonstrate a large-than-acknowledged population in need of dire access and affordability support.

Insulin Resource Center and Hotline

This section would authorize grants to organizations to aid uninsured individuals seeking insulin by creating a website with access information and establishing a 24-hour patient hotline with experts available. The section authorizes $2 million annually between fiscal years 2027–2032 to establish the center. While not a direct source for insulin prescriptions or resources itself, access to information and connections to facilitate prescriptions is potentially beneficial. In addition to the specific insulin-related information that a patient might seek, it may also improve broader health literacy of the uninsured population by educating them on their available options for care.

Looking Forward

The Senate version of the INSULIN Act received bipartisan support, reported out of the HELP Committee on a 17–5 vote, after reincorporating the pilot program and resource center through a 12–10 amendment vote with bipartisan support. A vote on the Senate floor has not yet been scheduled. While it could be considered as a standalone bill, reports suggest provisions addressing issues such as drug pricing and health care affordability may be attached to one of several must-pass legislative vehicles at the end of the year.

A similar version of the INSULIN Act was introduced in the House of Representatives with bipartisan support and sent to the Committees on Energy and Commerce, Education and Workforce, and Ways and Means. The House version shares most of the same content as its Senate counterpart, including the same price cap, GAO provisions, and expedited biosimilar pathway, but it does not include the pilot program or generics section reforming the citizen petition process. The path for the INSULIN Act to make it to the House floor is currently unclear.

Conclusion

Overall, the Senate version of the INSULIN Act may be beneficial for patients with an insulin prescription but is more aligned with consumer protection efforts and access rather than direct affordability measures. This bill would likely not directly result in lower insulin costs, despite the price cap, though it could lead to a better understanding of the insulin-using population**.** The proposed price cap would presumably have the largest direct patient impact; however, it is likely limited to short-term effects. The GAO study and resource center are expected to have a more indirect effect, potentially benefitting future rather than current policymaking. The generic and biosimilar competition sections and pilot program

serve as broader, consumer-focused sections, which may influence the wider drug market and long-term affordability and access policy.