

# United States Senate

WASHINGTON, DC 20510

April 11, 2022

Dear Colleague:

As co-chairs of the Senate Diabetes Caucus, we write to you today to solicit your input on our bipartisan proposal to address the skyrocketing costs of insulin.

More than 37 million Americans live with diabetes, including an estimated one in every three seniors. The disease is one of the leading causes of death in the United States, claiming over 100,000 lives in 2021, and is also the most expensive chronic condition in the nation, costing a total of \$327 billion per year. Medical costs for Americans with diabetes are more than double those incurred by individuals without diabetes, and one out of every three Medicare dollars go to treating people with diabetes.

Individuals with diabetes who use insulin, particularly those with Type 1, need this medication every day in order to live; it is a matter of life or death. Insulin is a 101-year-old product that revolutionized diabetes treatment, transforming it from a debilitating, fatal disease to a manageable chronic condition. The team of scientists that discovered insulin sold the patent to the University of Toronto for a dollar each; a move intended to ensure those in need would always have affordable access.<sup>1</sup>

Today, insulin is one of the most expensive categories of drugs purchased by private and government health care payers. The rising cost of insulin presents a barrier to care for a growing number of Americans with diabetes. Out-of-pocket costs increase with list prices, and for people without insurance, the costs are untenable. Between 2012 and 2016, the average list price of insulin nearly doubled.<sup>2</sup> According to the Health Care Cost Institute, the price of an average 40-day supply of insulin rose from \$344 in 2012 to \$666 in 2016.

We continuously hear from patients and health care workers that, at these costs, insulin products are out of reach for far too many. If left unabated, list prices and rebates will continue to rise and the market will remain opaque. With this in mind, we have drafted the attached proposal that directly addresses the root problems in the insulin market, while simultaneously extending vital

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<sup>1</sup> Hegele, Robert A., "Insulin Affordability," *The Lancet*, May 2017. Available at: [https://www.thelancet.com/journals/landia/article/PIIS2213-8587\(17\)30115-8/fulltext](https://www.thelancet.com/journals/landia/article/PIIS2213-8587(17)30115-8/fulltext)

<sup>2</sup> Biniek, Jean Fuglesten and Johnson, William, "Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices," Health Care Cost Institute, January 2019. Available at: <https://www.healthcostinstitute.org/research/publications/entry/spending-on-individuals-with-type-1-diabetes-and-the-role-of-rapidly-increasing-insulin-prices>

beneficiary protections that will foster competition and broader access to desperately needed insulin products.

Today, we ask for your input on our proposal on how Congress can address these issues. Please share your feedback to [insulin@shaheen.senate.gov](mailto:insulin@shaheen.senate.gov). Thank you for your time and work in support of our efforts.

Sincerely,



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Jeanne Shaheen  
United States Senator



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Susan M. Collins  
United States Senator

## **Patient Protections with Respect to the Cost of Insulin Covered Under Private Health Insurance**

- **Encourage insulin manufacturers to reduce their list prices** by (1) **ensuring that insurance plans and pharmacy benefit managers cannot collect rebates** – which drive up drug costs at the point of sale – on insulins that roll prices back to 2006 or equivalent levels, (2) **making such insulins eligible for cost-sharing protections**, including waiver of any applicable deductible and limiting copays or coinsurance to no more than \$35 per month; and (3) **supporting patient access to such insulins** by ensuring coverage and that prior authorization or other medical management requirements cannot be imposed to limit beneficiary use.
  - Insulin manufacturers that opt to reduce prices in this manner would certify to the HHS Secretary that their current list price is no greater than the list price for the same insulin in 2006. The Secretary will maintain a public list of qualifying products, and insulins could remain on the list in subsequent years if they certify that they have not raised their price by more than rate of inflation since the initial certification.
  - Insulins introduced after 2006 without an applicable 2006 list price could still obtain these incentives by certifying to the Secretary that their list price is no greater than the weighted average 2006 list price of insulins in its category (short-acting, rapid-acting, or long-acting). The Secretary, could identify other appropriate categories as warranted to account for future innovation.
  - Any manufacturers that knowingly submit false or incomplete data in certifying their eligibility for these incentives could be subject to civil monetary penalties not to exceed double the amount of rebates they paid for insulin under the Medicaid Drug Rebate Program in the previous calendar year. Any funds collected would be directed to the Medicare Hospital Insurance Trust Fund.
- **Limit out-of-pocket costs for patients with diabetes** by ensuring that group and individual market health plans must **waive any deductible and limit cost-sharing to no more than \$35 per month**, for at least one insulin of each type and dosage form.

## **Patient Protections with Respect to the Cost of Insulin Covered Under Medicare**

- **Encourage insulin manufacturers to reduce their list prices** by (1) **ensuring that insurance plans and pharmacy benefit managers cannot collect rebates** – which drive up drug costs – on insulins that roll prices back to 2006 or equivalent levels, (2) **making such insulins eligible for cost-sharing protections**, including waiver of any applicable deductible and limiting beneficiary cost-sharing to no more than \$35 per month; and (3) **supporting patient access to such insulins** by ensuring coverage and that prior authorization or other medical management requirements cannot be imposed to limit beneficiary use.
  - Insulin manufacturers that opt to reduce prices in this manner would certify to the HHS Secretary that their current list price is no greater than the list price for the same insulin in

2006. The Secretary will maintain a public list of qualifying products, and insulins could remain on the list in subsequent years if they certify that they have not raised their price by more than rate of inflation since the initial certification.
- Insulins introduced after 2006 without an applicable 2006 list price could still obtain these incentives by certifying to the Secretary that their list price is no greater than the weighted average 2006 list price of insulins in its category (short-acting, rapid-acting, or long-acting). The Secretary, in consultation with FDA, could identify other appropriate categories as warranted to account for future innovation.
  - Any manufacturers that knowingly submit false or incomplete data in certifying their eligibility for these incentives could be subject to civil monetary penalties not to exceed double the amount of rebates they paid for insulin under the Medicaid Drug Rebate Program in the previous calendar year. Any funds collected would be directed to the Medicare Hospital Insurance Trust Fund.
- **Limit out-of-pocket costs for patients with diabetes** by ensuring that Medicare Part D and Medicare Advantage Prescription Drug plans must **waive any deductible and limit cost-sharing to no more than \$35 per month**, for at least one insulin of each type and dosage form.