INSULIN Act Summary

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. The rising cost of insulin presents a barrier to care for a growing number of Americans living with diabetes. Out-of-pocket costs increase with list prices, and for people without insurance, the costs are untenable. According to the Kaiser Family Foundation, Part D enrollees spent nearly \$1 billion out-of-pocket on insulin in 2019, four times the amount spent in 2007. According to the Health Care Cost Institute, nearly 9 percent of patients with private insurance paid an average of \$403 per month for their insulin in 2019.

With this in mind, Sen. Shaheen and Sen. Collins have drafted the *Improving Needed Safeguards for Users of Lifesaving Insulin Now (INSULIN) Act*, which directly addresses the root problems in the insulin market, while simultaneously extending vital beneficiary protections that will foster competition and broader access to desperately needed insulin products.

The *INSULIN Act* would:

- 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 limit list price to the 2021 net prices for Medicare Part D 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.
 - O Insulin manufacturers that opt to reduce prices in this manner would certify to the Secretary of the Department of Health and Human Services (HHS) that their current list price is no greater than the Medicare Part D net price for the same insulin in 2021. 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 the rate of inflation since the initial certification.
 - Insulins introduced after 2021 without an applicable net price could still obtain these incentives by certifying to the Secretary that their list price is no greater than the weighted average 2021 net price of insulins in its category.
 - o If a manufacturer increases the list price over the certified price, the manufacturer will pay the difference between the certified price and the actual price, multiplied by the number of units sold. All funds collected would be directed to the Medicare Hospital Insurance Trust Fund.
- <u>Limit out-of-pocket costs for patients with diabetes</u> 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.

¹ https://www.kff.org/medicare/issue-brief/insulin-out-of-pocket-costs-in-medicare-part-d/

² https://healthcostinstitute.org/hcci-research/capping-out-of-pocket-spending-on-insulin-would-lower-costs-for-a-substantial-proportion-of-commercially-insured-individuals-1