

BOARD INSULIN UPDATE

EXECUTIVE SUMMARY

- Lawmakers are tackling unfinished business on insulin affordability early in the 118th Congress
- Two bipartisan Senate proposals (Shaheen-Collins and Warnock-Kennedy) are leading contenders to waive deductibles and cap copays for insulin for the commercially insured
- Senate leadership has expressed interest in including insulin provisions in a larger prescription drug pricing package but have not yet voiced a preference between the two approaches

The second wave of legislative efforts to tackle insulin costs comes despite recent commitments from Eli Lilly and Company, Novo Nordisk and Sanofi to reduce the list price of certain insulin products by January 1, 2024 — a decision policy experts say is a response to political headwinds, generic competition and bigger Medicaid rebates set to kick in in 2024.

Patient needs remain unmet: The Inflation Reduction Act of 2022 (IRA) included provisions to eliminate deductibles and cap monthly insulin cost sharing at \$35 for **Medicare beneficiaries**, but the commercial insurance piece failed to get the support of 60 senators to overcome a filibuster, leaving the needs of uninsured and commercially underinsured people with diabetes unaddressed. At the time, seven Senate Republicans voted to keep the private insurance cap in the bill: Josh Hawley (MO), Susan Collins (ME), Cindy Hyde-Smith (MS), John Kennedy (LA), Bill Cassidy (LA), Lisa Murkowski (AK) and Dan Sullivan (AK). Today there are multiple pieces of legislation on insulin pricing currently in the Senate. Currently, two are receiving bipartisan attention and support.

The <u>Affordable Insulin Now Act of 2023</u> by Sens. Raphael Warnock (D-GA) and John Kennedy (R-LA) focuses on reducing patient OOP cost sharing to increase access

Extends the IRA's Medicare provisions to more people with diabetes – waiving deductibles and capping copays to the lesser of \$35 or 25 percent of net cost for a 30-day supply of one of each insulin type and form. Specifically, S. 954:

- Requires private group or individual plans to cover one of each insulin dosage form (vial, pen) and insulin type (rapid-acting, short-acting, intermediate-acting, and long-acting) with no deductible and copays not to exceed \$35 per month.
- Requires the HHS Secretary to establish a program to reimburse qualifying entities which likely refers to federally qualified health centers (FQHCs) eligible for 340B insulin pricing for covering any costs that exceed \$35 for a 30-day supply of insulin to uninsured patients.

Co-chairs of the Senate Diabetes Caucus, Sens. Shaheen (D-NH) and Collins (R-ME) have introduced the <u>Improving Needed Safeguards for Users of Lifesaving Insulin Now (INSULIN) Act of 2023</u> which takes a comprehensive strategy to address the costs of insulin by removing barriers to access, capping out-of-pocket costs, fostering competition and extending patient protections.

Limits monthly cost-sharing for at least one insulin type and dosage form to \$35 or 25 percent of the net cost, whichever is lower.



Requires pharmacy benefit managers (PBMs) to pass through 100 percent of insulin rebates and discounts from manufacturers to insurance plans (the likely rationale is to eliminate current incentives for PBMs to favor high list price-high rebate products by requiring them to relinquish any rebates and discounts; however, since most large PBMs and insurers are vertically integrated it is unclear how impactful the requirement would be without broader structural reforms to the system).

Promotes competition from generic and biosimilar drugs by easing the approval process and formulary access for biosimilar drugs in Medicare Part D.

Largely limits insurers from imposing prior authorization and medical management on insulin products and seeks to speed up new competition to further reduce costs.

• The expanded scope of the Shaheen/Collins bill reflects a shift from strict OOP costs to cover a broader set of access issues to include generic competition, PBMs and prior authorization practices.

Both pairs of Senators are jockeying to have their own bill prioritized by Senate Majority Leader Chuck Schumer (D-NY) and HELP Committee Chair Bernie Sanders (I-VT) as the Senate HELP Committee focuses its attention on drug pricing and lowering costs.

Neither Chair Sanders nor Senate Majority Leader Schumer have demonstrated a preference between the two bills and have avoided a firm stance while assembling other pieces of a large drug-pricing measure that could get a vote as soon as this month.

Specifically, Sen. Schumer is not tipping his hand on a sensitive issue that will alienate some of his members no matter what he does given his close relationships with both Shaheen and Warnock and has committed to getting a \$35 insulin bill passed, and the details are still being worked out.

Chair Sanders predicted a future effort to bring the various insulin bills together, a path to which Warnock appears agreeable. However, Sens. Shaheen and Collins said their legislation is so sweeping compared with the Warnock-Kennedy bill that the two approaches would be nearly impossible to reconcile.

Additional Insulin Legislation:

<u>Sen. Hawley</u> introduced a bill earlier this year capping monthly cost sharing for insulin at \$25 per month for people with diabetes enrolled in private health plans and Medicare.

In March, <u>Sen. Sanders</u> introduced legislation that would prohibit manufacturers from selling any insulin for more than \$20 per 1000 units (vials, pens, cartridges or other delivery forms) in the U.S.