S. 4189, Improving Needed Safeguards for Users of Lifesaving Insulin Now Act (INSULIN) Act of 2026

Section 1. Short Title; Table of Contents.
This section provides that the Act may be cited as the "INSULIN Act of 2026." It also includes a table of contents for the four titles of the Act.

Section 2. Sense of Congress.
This section states that it is the sense of Congress that provisions of Act will be offset for any costs to the Federal Government resulting from enactment.

Title I. Commercial Market Patient Protections

Section 101. Requirements with Respect to Cost-Sharing for Certain Insulin Products.
This section limits patient out of pocket cost-sharing to $35 or 25 percent of negotiated price of insulin per month, whichever is less. The limit to patient out-of-pocket would be effective January 1, 2028, and apply to employer sponsored health insurance coverage as well as ERISA plans.

Section 102. Application to Retiree and Certain Small Group Plans
This section requires that plans offered under ERISA and Internal Revenue Code rules are also required to limit the out-of-pocket monthly cost to patients to $35.

Section 103. Administration.
This section allows the Secretary of Health and Human Services to initially implement the provisions of the Act by January 1, 2028, through guidance and program instruction.

Title II. Pharmacy Benefit Manager Transparency and Rebate Reform

Section 201. Full Rebate on Insulin Pass-Through to Plan.
This section requires a pharmacy benefits manager or other entity working on their behalf to remit 100 percent of rebates, fees, discounts and other remuneration related to insulin use to group health plans.

Title III. Biosimilar Biological Produce and Generic Drug Competition and Affordability

Section 301. Ensuring Timely Access to Generics.
This section expands the authority of the Food and Drug Administration (FDA) to deny citizen petitions submitted under section 505(q) of the Federal, Food, Drug, and Cosmetic Act by allowing the agency to deny a petition if it determines the petition was submitted with the primary purpose of delaying the approval of a follow-on generic or biosimilar application, or if the petition does not raise valid scientific or regulatory issues. The section provides a list of factors FDA may consider when determining whether a petition was submitted with the primary purpose of delaying the application. The section requires a petition to be submitted within 60 days after the petitioner knew, or reasonably should have known, the information that formed the basis of the petition. The section eliminates the 150-day deadline under current law for FDA to respond to 505(q) petitions, and requires that parties file a 505(q) petition before filing suit

against FDA to challenge the agency's approval of a new drug through the 505 (b)(2) pathway, a generic drug, or a biosimilar product.

Section 302. Expediting Competitive Biosimilar Competition.
This section would create a new competitive biosimilar designation at FDA. Applicants who qualify for this designation will be eligible for flexibilities from FDA that will enable expedited review of their application.

Section 303. Insulin Competition Report.
This section requires HHS, CMS and FDA to complete a study and report to Congress within two years the extent and causes of delays in getting insulin products to market and recommend possible policy changes.

Title IV. Programs for Providing Affordable Insulin to Uninsured Individuals

Section 401. Pilot Program for Providing Affordable Insulin to Uninsured Individuals.
This section creates a pilot program for 10 states with high rates of uninsured individuals who are insulin dependent to create programs that identify individuals and get them low cost (i.e., $35/month) insulin and provide them with education and access to sufficient insulin to keep them healthy.

Section 402. GAO Study on Uninsured Individuals who Use Insulin.
This section directs the Comptroller General to conduct a study, in consultation with patient, clinical and provider groups on the characteristics of uninsured individuals who use insulin.

Section 403. Insulin Resource Center and Hotline for Uninsured Individuals.
This section directs the Secretary of Health and Human Services to issue a grant award to an entity to establish and maintain a resource center with information about affordable insulin, facilitate enrollment in manufacturer assistance programs, make a website available to the public about access to insulin and establish a 24-hour hotline where patients could speak with experts about access to insulin.