

More than [7 million Americans](#) with diabetes rely on insulin on a daily basis to help manage their condition and 14 million seniors in Medicare live with diabetes. But, the rising price of insulin and other diabetes drugs is a problem that plagues our healthcare system – and hurts millions of patients. Surging insulin prices have gotten so out of hand that [one in four people with diabetes](#) report that they are skipping doses. With the population of diabetics rising, the disease burden from diabetes will only multiply for patients and payors.

Here are some key facts about the high and rising price of insulin and why competition in the marketplace is needed:

INSULIN PRICES CONTINUE TO SKYROCKET

- Manufacturers [doubled the price](#) of insulin over just four years, from an average price of \$344 in 2012 to \$666 in 2016.
- Medicare Part D spending on insulin [increased 840 percent](#) between 2007 and 2017, outpacing the growth in the number of beneficiaries using insulin.
- Care for people with diabetes accounts for one out of every five dollars spent on health care in the U.S.

NO COMPETITION IN INSULIN MARKET KEEPS PRICES HIGH

Insulin is over 100 years old and until recently there have been no therapeutic alternatives for most major long-acting insulins. Three pharmaceutical manufacturers control 99 percent of the market, limiting competition and enabling them to raise prices as high as they want.

From 2012 – 2016, Sanofi [hiked prices](#) 18 percent each year for its insulin drug, Lantus Solostar. The result has been unsustainable prices for patients and costs for payors including the Medicare and Medicaid programs. In fact, during this time period, total spending on Lantus by Medicare and Medicaid increased 132 percent.

How is this possible? Sanofi [used](#) the patent system in the U.S. to maintain monopoly protection and monopoly pricing for Lantus. In total, Sanofi filed 74 patent applications generating the potential to delay competition for 37 years.

HOW PBMs HELP PATIENTS MANAGE THEIR DIABETES

PBMs are working to improve care and lower costs for patients with chronic conditions like diabetes by:

- **Lowering out-of-pocket costs:** PBMs offer plan options that include a fixed out-of-pocket cost or \$0 co-pays for insulin, or that cover diabetes medications even before the deductible is met as part of a preventive drug list. PBMs also offer point-of-sale rebates to ensure patients see discounts when they pick up their insulin at the pharmacy counter.
- **Encouraging lower-cost alternatives:** After the FDA approved the follow-on biologic Basaglar and PBMs began adopting the product as the preferred drug on formularies, [one PBM](#) achieved a 9 percent drop in out-of-pocket costs for patients for a 30-day supply of Basaglar compared to Sanofi's Lantus.
- **Holistic care management:** PBMs have developed disease-specific programs to help patients manage their chronic conditions, like diabetes. These programs offer services like integrated digital tools to ensure the patient, their doctors and pharmacists all have easy access to the information they need to increase adherence and provide the best care, wellness programs, additional screenings and in-person counseling opportunities, among others.

POLICY SOLUTIONS

PBMs have been able to negotiate with competing brand manufacturers to obtain significant discounts off list prices, but the solution that will benefit everyone who uses insulin is true generic and biosimilar competition which will drive down list prices. Specifically, Congress could take the following actions to help ease the cost burden for diabetes patients taking insulin:

- Foster the widespread adoption of zero-dollar co-pays on preventive medications like insulin;
- Pass the bipartisan CREATES Act to end the manipulation by drug manufacturers of the Risk Evaluation and Management Strategies (REMS) program to block timely entry of generic competition;
- Prohibit "pay-for-delay" settlements between manufacturers that delay the market entry of lower-cost alternatives;
- Restrict "ever-greening" of patents in which drug manufacturers make minor changes to their product, or to the delivery technology for their product, to extend the patent exclusivity period;
- Reduce the exclusivity period for brand and specialty drugs;
- Support efforts to promote greater uptake of biosimilars, especially given FDA's recent guidance to treat insulin as a biosimilar beginning in 2020.