

## MEMORANDUM

**Date:** May 31, 2019  
**To:** The Honorable Sara Cambensy, State Representative  
**Attn:** Mary Wardell  
**From:** Amanda Gallaher, Research Analyst  
**Re:** **Diabetes and Insulin (Request #19-01097)**

In response to your request, the Research Services Division is providing information related to diabetes and insulin. Specifically, you asked how many individuals in Michigan have type 1 and type 2 diabetes; how many individuals have died from diabetes-related complications each year over the last 15 years; how many deaths were related to inadequate insulin treatment; how the price of insulin has changed over the last two decades; how many people ration their insulin in the state or, if not available, nationwide; what are known or given reasons for the rise in the cost of insulin; what current state and federal laws impact how pharmaceutical companies set insulin prices or how insurers share the price with consumers. I reviewed the scientific literature, news articles, resources and data from policy research organizations and government agencies, and our office archive to respond to your questions.

### 1. How many individuals in Michigan have type 1 and type 2 diabetes?

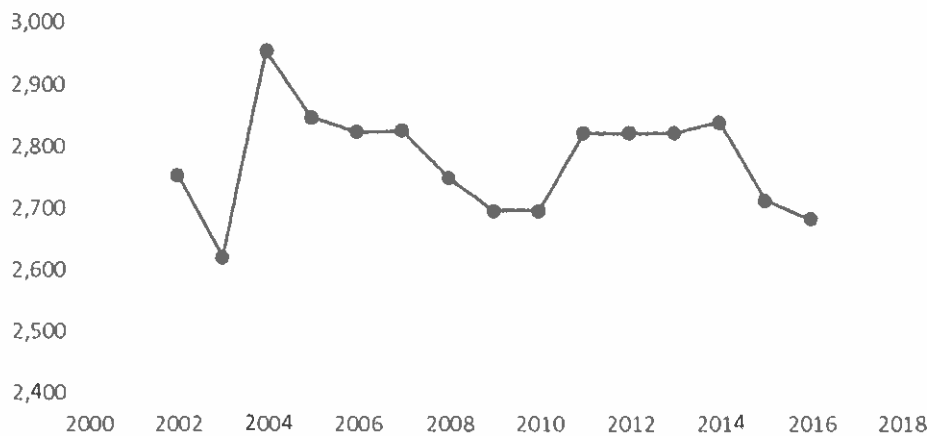
According to the Centers for Disease Control and Prevention (CDC), approximately 864,882 Michigan adults or about 11.2% of the adult population in 2016 had a diabetes diagnosis. State and federal disease surveillance datasets do not differentiate between type 1 and type 2 diabetes, but in 2016, the CDC estimated that nationwide 5.8% of diagnosed cases were type 1 and 90.9% were type 2, with 3.3% of cases being other types.

### 2. How many individuals in Michigan have died from diabetes-related complications each year over the last 15 years?

Year	Number of Deaths from Diabetes in Michigan 2002-2017
2002	2,753
2003	2,620
2004	2,954
2005	2,846
2006	2,823
2007	2,825
2008	2,749
2009	2,695

2010	2,695
2011	2,821
2012	2,821
2013	2,821
2014	2,838
2015	2,711
2016	2,681
2017	2,795

Number of Deaths from Diabetes  
in Michigan 2002-2017



Source: Michigan Resident Death Files, Division for Vital Records & Health Statistics, Michigan Department of Health & Human Services.

**3. How many deaths were related to inadequate insulin treatment?**

I have not been able to identify any statistics on deaths directly related to inadequate insulin treatment. A lack of access to insulin for those who rely on it can lead to diabetic ketoacidosis (DKA) and coma or even death, but DKA has multiple causes (e.g. undiagnosed diabetes or infection) so statistics regarding DKA-related mortality rates do not necessarily indicate that there was inadequate insulin treatment related to a lack of access to insulin. Similarly, patients with diabetes who have poor glycemic (blood sugar) control may have a higher risk of death, but I have not found any studies that make the direct connection between poor glycemic control, a lack of access to insulin, and mortality. See question #5 below for a summary of a study that looked at the relationship between cost-related underuse of insulin and glycemic control.

**4. How has the price of insulin changed over the last two decades?**

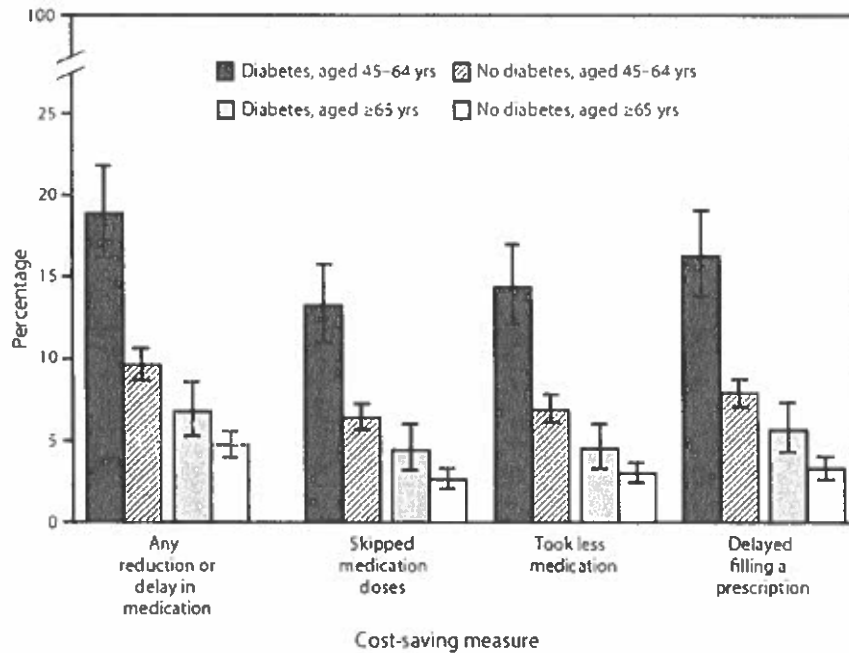
A [2016 study](#) in the Journal of the American Medical Association found that the average price of insulin nearly tripled from 2002 to 2013, increasing from \$4.34 per milliliter to \$12.92. A [2019 brief](#) from the Health Care Cost Institute (funded in part by four health insurance companies) estimates that the median price of insulin products nearly doubled (92% increase) from 2012 to 2016 at the point-of-sale to patients. Note that this does not include rebates or coupons that patients receive, which can significantly impact the cost. More recently, the U.S. Senate Finance Committee [requested information](#) about drug price increases

from three insulin companies. Eli Lilly’s Humalog increased from \$35 in 2001 to \$234 in 2015 (585% increase), Novo Nordisk’s Novolog increased from \$289 in 2013 to \$540 in 2019 (87% increase), and Sanofi’s Lantus increased from \$244 in 2013 to \$431 in 2019 (77% increase).

**5. How many people ration their insulin in the state or, if not available, nationwide?**

According to a 2019 study, about a quarter of patients surveyed use less insulin than prescribed due to the cost. Individuals who rationed insulin were more likely than those who did not to have poor glycemic control (43% versus 28%). The survey was completed at a single urban diabetes center in New Haven County, Connecticut, so the authors are cautious about the generalizability of these findings to other populations. The study found that individuals who reported cost-related underuse of insulin were more likely to have poor glycemic control, but given that it was a cross-sectional study, it is not possible to prove whether cost-related underuse led or poor glycemic control or whether other factors were contributing. Cross-sectional studies are observational studies that take place at one point in time. I was not able to find any other studies in Michigan or elsewhere that studied rates of insulin rationing.

While not specific to insulin, a 2015 survey by the CDC provides insights into medication rationing by patients with diabetes. The CDC found that individuals 45-64 years with diabetes were more likely than those without diabetes to skip medication doses (13.2% versus 6.4%), reduce the amount taken (14.4 versus 6.9%), or delay filling a prescription (16.3% versus 4.7%) to save money than individuals without diabetes in the last 12 months. See the chart below. The survey did not provide information about whether the medication was insulin.



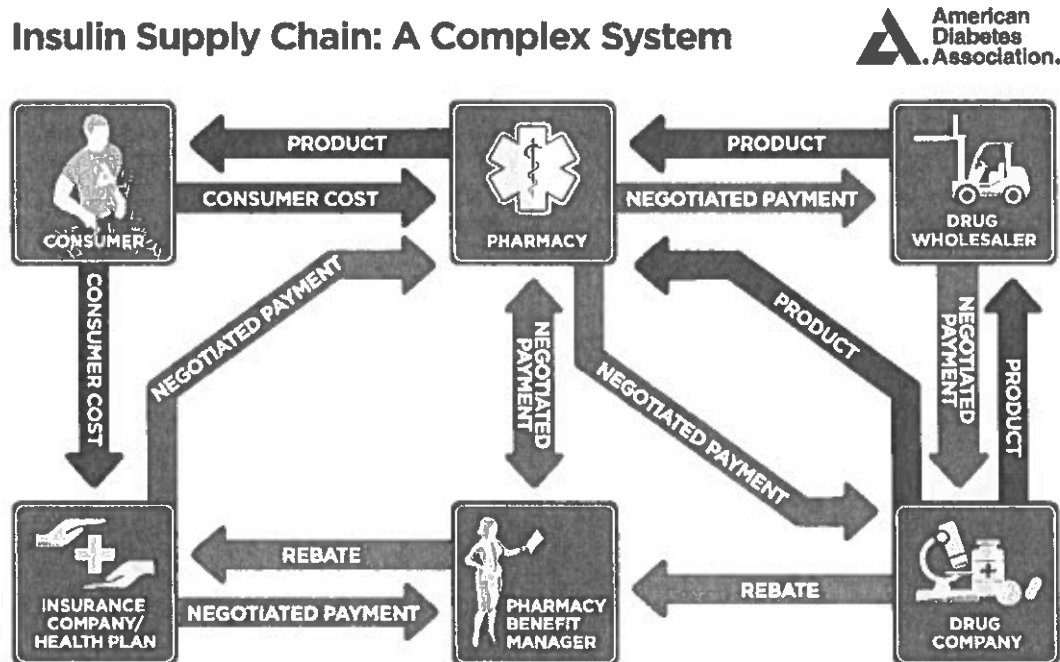
Source: QuickStats: Percentage of Adults Aged ≥45 Years Who Reduced or Delayed Medication to Save Money in the Past 12 Months Among Those Who Were Prescribed Medication, by Diagnosed Diabetes Status and Age — National Health Interview Survey, 2015. MMWR Morb Mortal Wkly Rep 2017;66:679. DOI: <http://dx.doi.org/10.15585/mmwr.mm6625a5>

## 6. What are known or given reasons for the rise in the cost of insulin?

In 2017, the American Diabetes Association convened an Insulin Access and Affordability Working Group to address the cost of insulin. The [resulting report](#) cited the factors described below as contributors to the rise in insulin's cost. I recommend reviewing the report for more detail.

### *Complex supply chain*

As summarized in the image below, the insulin supply chain is a complex system where there are many different buyers and sellers. Negotiations in many of the steps in this chain can have an impact on insulin price.



### *List price*

The list prices of insulin set by the drug manufacturer are often cited as contributing to rising costs for patients. The report suggests that the prices of one manufacturer influence those of other manufacturers.

### *Shift towards more expensive insulins*

Over the last decade, there has been a shift from the use of less expensive human insulins (i.e., insulins that are identical to insulin found in the human body) to more expensive human insulin analogs. These analogs function similarly to human insulins, but some argue that they may improve diabetes management.

### *Gap between list price and net price*

The report notes that the gap between the list and net prices of insulin have been growing. Net price is the list price minus fees paid to wholesalers, discounts paid to pharmacies, and rebates paid to pharmacy benefit managers or health plans. The authors raise the question of who is actually benefiting from this increasing gap.

### *Rebates and discounts*

The gap between list price and net price may be a result of an increasing role of negotiated rebates and discounts between various stakeholders. The report highlights the leverage of pharmacy benefit managers in their rebate and discount negotiations with both manufacturers and pharmacies.

### *Lack of transparency*

The report highlights the lack of transparency in stakeholder negotiations, which can make it challenging to know what components(s) of the supply chain may be contributing most to higher insulin costs.

### *Formularies*

The availability of various types of insulins on drug formularies can impact which insulins are accessible to patients. Formularies are the list of drugs that health plans will cover. While clinical considerations are most important for determining drug placement on formularies, incentives may play a role.

### *Insurance coverage*

Patient insurance coverage and the degree of cost-sharing are also important contributors for patient out-of-pocket costs.

### *State and Federal Laws*

Laws also play an important role in drug costs. See question #7.

## **7. What current state and federal laws impact how pharmaceutical companies set insulin prices or how insurers share the price with consumers?**

There are numerous state and federal laws that directly or indirectly impact insulin pricing and cost-sharing between insurers and consumers. I have provided some examples, but they are not all-inclusive because this issue is complex. Insulin prices can be impacted by many different factors.

### *Michigan Laws*

Specific to insulin, Michigan's Insurance Code (PA 218 of 1956) requires insurers that provide outpatient pharmaceutical coverage to include insulin coverage for the treatment of diabetes if medically necessary and prescribed by a physician [[MCL 500.3406p\(4\)\(a\)](#)]. Health care corporations must also provide insulin coverage for medically necessary diabetes treatment prescribed by a physician [[MCL 550.1416b\(3\)\(e\)](#)]. Additionally, the "sale of insulin for human use" is excluded from being taxed under the General Sales Tax Act (PA 167 of 1988) and the Use Tax Act (PA 94 of 1937) ([MCL 205.54d](#) and [MCL 205.94a](#)).

In addition to laws that address insulin directly, there have been many other efforts to reduce drug costs, especially through Medicaid, including the Michigan Preferred Drug List, the Multi-State Pooling Agreement, the Pharmaceutical Best Practices Initiative, and Medicaid outcomes-based drug contracts. Please let me know if you would like information about any of these initiatives. In 2018, Michigan enacted legislation allowing pharmacists to provide generic drugs that are "interchangeable biological drug products" in place of high-cost, brand name drugs (Public Act 41 of 2018). Changes to a prescription must be communicated with the prescriber. More recent legislation clarified that pharmacists must pass along cost savings if the individual buying the drug is not submitting a health insurance claim to a third-party payment source (Public Act 246 of 2018). Pharmacists are prohibited from charging more than the

retail price for the lower cost drug product. I was not able to find information about the impact of these initiatives or laws on insulin specifically.

### *Federal Laws*

For reference, insulins are either considered “biologics” (complex molecules produced by living things) or biosimilars (molecules that are nearly identical to biologics). Patent laws are particularly important in the discussion of insulin prices and manufacturers because they determine how long manufacturers can sell a product prior to the approval of generic drugs, which are often less expensive. Insulin has not historically been regulated as most biologics are under the Public Health Service Act. Instead, they have been regulated under the Federal Food, Drug, and Cosmetic Act, which has made it challenging to introduce generic insulins to the market.

In 2010, Congress passed the Biologics Price Competition and Innovation Act to give the Food and Drug Administration (FDA) the authority to create a new pathway to approve biosimilar and interchangeable products, which opens biologics to more competition. Under new rules to be introduced in 2020, insulins will be regulated as biologics and biosimilars. Insulins will no longer be eligible for the 12-year exclusivity period, where they are protected from competition. According to the FDA Commissioner, Scott Gottlieb, the rules will increase competition leading to reduced prices and more access. Critics argue that these policies do not do enough to decrease insulin prices for patients who are currently struggling to pay for them.

In addition to the laws mentioned above, there are numerous laws that broadly impact drug pricing, cost-sharing with insurers, and consumer costs. I have not assessed their impact on insulin specifically.

- *Medicaid Rebates* – The Medicaid rebate program requires drug manufacturers who want to provide drugs through Medicaid and other federal programs to enter into a national agreement that allows states to get the “best price” offered to purchasers.
- *Affordable Care Act* - The Patient Protection and Affordable Care Act (ACA) prohibits insurers from imposing lifetime insurance caps, which can be important for coverage of expensive drugs. The ACA has helped reduce the Medicare Part D coverage gap and increased the minimum Medicaid drug rebate rate from 15.1% to 23.1%. Prescription coverage is required to be an essential health benefit that must be covered under most private health insurance plans.
- *Gag Clauses* - In 2018, Congress passed legislation prohibiting states from enacting gag clauses that prevent pharmacists from being able to tell customers about less expensive ways to pay for prescription drugs for Medicare, employer-sponsored, and health care exchange plans (S.2554 and S.2554 of 2018).
- *Current efforts* - The President’s 2018 [Blueprint to Lower Drug Costs and Reduce Out-of-Pocket Costs](#) discusses federal strategies to improve competition, allow for better negotiation, provide incentives for lower list prices, and lower out-of-pocket costs.

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If you would like clarification or have any further questions regarding this issue or another issue, please contact the Research Services Division at 3-5200.

## Insulin Industry Spokesperson Says Prices Are 'Flat To Declining'

Contrary to the claims of Democratic lawmakers who say the price of insulin has spiked in recent years, a spokesperson for the Pharmaceutical Research and Manufacturers of America (PhRMA) responded today that "discounts and rebates . . . have kept net prices flat to declining in recent years."

Tiffany **HAYERLY**, director of Public Affairs for the Washington D.C.-based PhRMA, said the insulin market is extremely competitive and health plans and pharmacy benefit managers negotiate for those discounts.

"As a result of market negotiations, industry analysts report that negotiated discounts, rebates and other price concessions can lower the list price of insulin by 70 percent or more. However, these savings are often not shared with patients whose out-of-pocket costs continue to grow. The biopharmaceutical industry is committed to ensuring patients can afford the medicines they need, and ensuring negotiated rebates and discounts are resulting in lower costs for patients at the pharmacy counter is a key step," Haverly stated in an emailed response to *MIRS'* follow up questions.

Friday, Rep. John **CHIRKUN** (D-Roseville) has said the price of insulin has gone up about six times in the last five or six years, explaining why he and Rep. Sara **CAMBENSY** (D-Marquette) introduced two bills last week addressing insulin prices (See "[What About A 100-A--Month Cap On insulin Co-Pays.](#)" 6/14/19).

Cambensy's 🐾 [HB 4701](#) would cap co-pays for insulin at \$100 per month. Chirkun's 🐾 [HB 4702](#) calls on the Michigan Attorney General to investigate price setting for insulin and to report back to the Legislature.

Also on Friday, U.S. Rep. Haley **STEVENS** (D-Birmingham) issued a report that contends the price of insulin has increased tenfold in the past two decades. The report also noted Lantus Solostar brand insulin costs \$268 here in the U.S., but only \$33 in Australia and \$51 in the United Kingdom. Novolog costs \$583 here in the U.S. but only \$28 in Australia and \$42 in the UK, [according to the report](#).

"International price comparisons often take the artificially low price set by foreign governments and compares it with high list prices that don't represent what Americans actually pay for their medicines," Haverly stated. "These comparisons don't take into account the access restrictions patients face in other countries because of these often socialized medicine policies, or the savings negotiated by insurers and pharmacy benefit managers. Due to negotiations in the U.S. market-based system, the net prices for the most commonly used classes of insulin have fallen in recent years. In fact, long-acting insulins are less expensive today than in 2010."

She contended the U.S. health system encourages investment in innovation, and the

biopharmaceutical industry leads the world in investment in research and development. Further, it supports nearly 5 million jobs here.

"Conversations about access and affordability are critically important, and we want to ensure patients can afford their medicines, but comparing the U.S. health system to those of countries with socialized medicine is a fallacy, and as seen in those countries, when governments set prices, patients lose access," she said.

Haverly said the biopharmaceutical industry is committed to working with legislators to help lower patients' out-of-pocket costs.

"Medical innovation continues to transform the lives of diabetes patients. For example, patients now have access to longer- and rapid-acting insulins, as well as products like insulin pens that offer patients more convenience and ease in managing their disease," she said.

[A report on advances in insulin treatment and a timeline of its development](#) is available on the PhRMA website.