

Insulin Access & Affordability



Diabetes in America

Diabetes impacts [more than 34 million people](#) in the US. This chronic disease is a result of how the body processes [glucose](#). When it goes untreated or is not treated properly it can lead to many other co-morbid diseases and illnesses.

Treatment depends on what type of diabetes you have. The most common form is type 2, where the body doesn't use [insulin](#) properly. Type 1 diabetes, which accounts for 5% - 10% of all cases, is the result of the body not producing any insulin. In the early 1920's, the first pure form of insulin was manufactured as a treatment for patients with diabetes. This scientific breakthrough transformed diabetes from a fatal condition to a manageable disease. Today, between 10% - 20% of people with type 2 diabetes need insulin to control their blood sugar. However, all people with type 1 diabetes require insulin every day to survive – it is a matter of life or death.

Clinical Impact on People with Diabetes

[When insulin therapy is disrupted](#), blood sugar builds up in the bloodstream increasing the risk for many acute and long-term health issues, including [diabetic ketoacidosis](#), which can lead to diabetic coma or even death. Over time, unmanaged diabetes can cause nerve damage, kidney disease, high blood pressure, stroke, skin, and eye complications.

Those who need insulin every day and are confronted with barriers to access (such as lack of affordability) may develop what is referred to as [“insulin insecurity”](#) – the disruption or the threat of disruption in getting access. This can greatly impact the health and well-being for those with type 1 diabetes, causing significant anxiety and distress. In some cases, it means resorting to non-traditional, risky and even desperate measures to access insulin. Research has found that the practice of [insulin rationing](#) (taking smaller doses or skipping a dose altogether) is more common than the health care system wants to admit.

The Problem

Cost. Access. These are the biggest barriers for those in need of insulin. Out-of-pocket costs and outcomes for people with diabetes who rely on insulin vary depending on the type of health insurance they have as well as the type of insulin prescribed. In some cases, a physician might prescribe insulin that is most cost-effective for the patient but not necessarily the best choice for their medical needs or what is available on their formulary. It is well known that patients are more likely to be compliant on a prescription regimen if it is affordable.

Millions of people with diabetes who need this life-saving medication face affordability barriers in the form of rising insulin prices and out-of-pocket costs. For those with insurance, especially in high deductible health plans (HDHP), out-of-pocket costs can come in the form of upfront deductibles, copays, and/or coinsurance. For the uninsured, footing the bill for the entire cost of the drug is often required and out of reach.

Timeline of Insulin Innovations

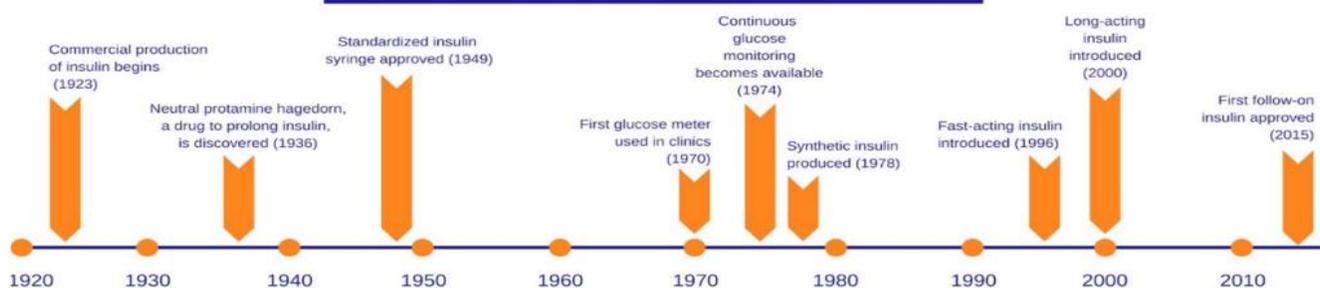


Figure 1: From Congressional Diabetes Caucus Insulin Inquiry 2018

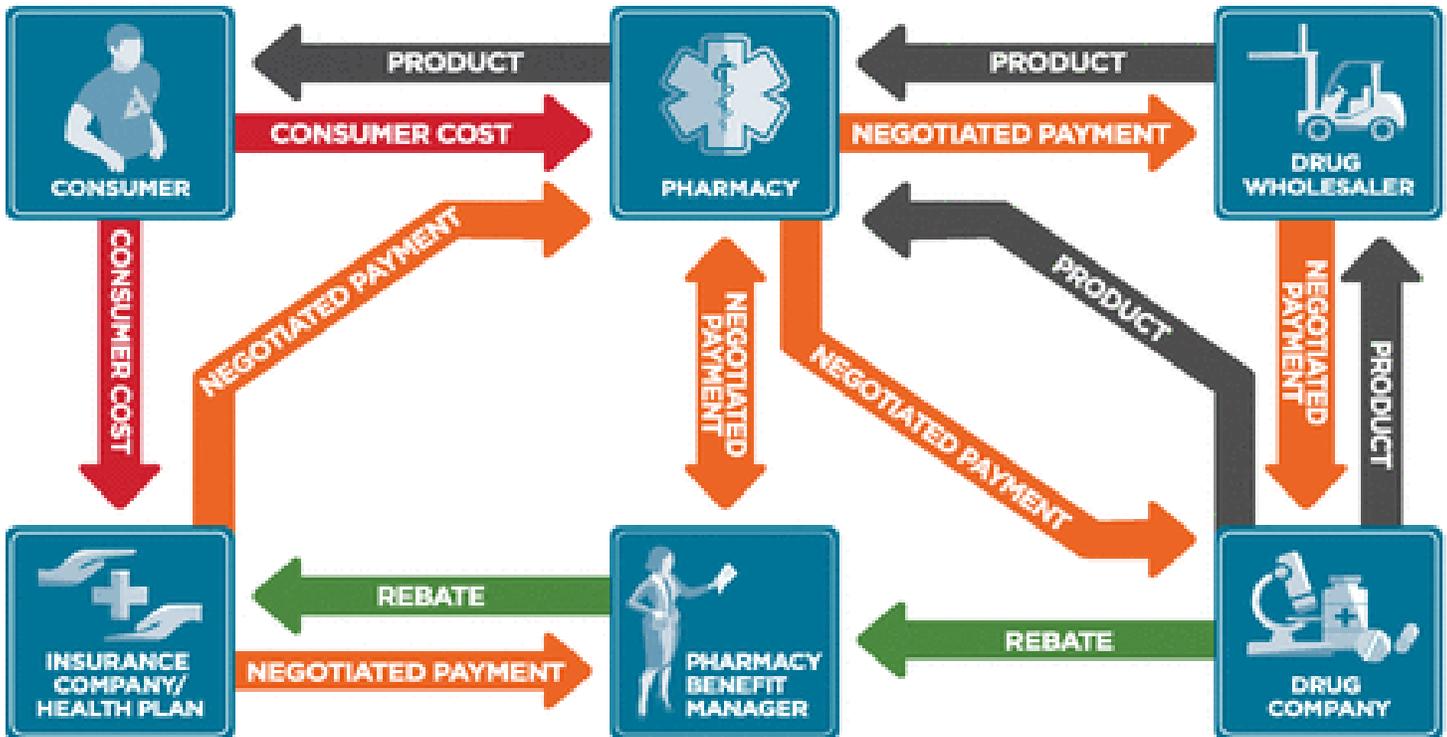


Figure 2: From Diabetes Care 2018 Jun; 41(6): 1299-1311. <https://care.diabetesjournals.org/content/41/6/1299>

Insulin Pricing: The Issues

The average list price of insulin has skyrocketed in recent years, nearly tripling between 2002 and 2013 and doubling between 2012 and 2016, making this essential medicine unaffordable for many.

The three multinational drug companies that make insulin for people with diabetes in the US say the price increases are justified – their profits have not increased with inflation, and the cost of research and negotiation with health insurers and pharmacists are high. However, insulin pricing is complex and there is little transparency throughout the supply chain as to the flow of dollars.

As noted in Figure 2, numerous stakeholders are involved, including drug manufacturers and wholesalers, health plans, PBMs, pharmacies and employers. **Negotiations and the many transactions between these stakeholders involving prices, fees and rebates ultimately determines the price paid by the person with diabetes at the point of sale.** These factors continue to drive up cost all along the payment system.

Insulin Pricing and the American Diabetes Association (ADA):

In 2017, the American Diabetes Association Board of Directors brought together a [working group](#) to better understand the full scope of the insulin affordability problem and find ways to provide relief for those who lack affordable access. The group identified the following significant issues contributing to this problem:

- Current pricing and drug rebate systems that encourages high list prices
- Lack of transparency throughout the insulin supply chain; it is unclear exactly how the money flows and how much each stakeholder profits
- PBMs which have substantial market power contribute to increased prices
- Impact of people with diabetes who are financially harmed by high list prices and out-of-pocket costs
- Patient's medical care can be adversely affected by formulary decisions
- Burdensome regulatory framework for development and approval of biosimilar insulins for manufacturers
- Prescribing patterns favoring newer, more expensive insulins

[Click here to review](#) the conclusions and recommendations from the working group.

Employer Call to Action

Self-insured employers have options on how they treat coverage for insulin. In July 2019, the federal government updated guidelines for HDHPs to include the addition of insulin and other glucose-lowering agents to their preventive drug list which allows coverage before reaching the deductible.

State legislation does not impact self-insured employers, as the employer may choose to match insulin copay limits or not. Even the various government entities within a state may opt for different coverage levels based on their contract with local health plans.

The employer may choose to adopt diabetes management programs from their PBM or other vendors to manage insulin costs and support the patient. In this case, the costs are born by the employer with the promise of better health for those affected by diabetes and lower overall health care spend.

New Centers for Medicare and Medicaid Services (CMS) guidance caps insulin copays at \$35 for a range of access following the May 2020 Executive Order.

Self-insured employers can follow this action and limit copays. They may also consider:

- Plan design strategies
 - Formulary: Ensure all insulins are in the formulary – review formulary for insulin placement
 - Cost sharing: Place insulins in the lowest pricing tier possible (reducing co-pay/co-insurance)
 - Allow use of copay cards
- Value-based design strategies for out-of-pocket costs
 - Add a care model that allows engaged members to receive insulin at reduced cost or for free
 - Reward members for achieving lowered HbA1c by lowering/removing cost share
- Contract reviews with PBM and medical carriers
- Holding vendor partners accountable
 - Performance guarantees with PBMs/carriers
 - Risk-based contracting with PBMs/carriers
 - Annual contract reviews

Employers should consider the broader impact to medical costs, employee retention and productivity related to insulin access and high costs. Employer communications regarding diabetes and insulin coverage and support are also key. Communication strategies will be covered at the end of this paper.

State Legislative Update

The employer call to action follows on and is linked to what is happening at the State and Federal level. In total, lawmakers in 36 states are trying to tackle the issue of unaffordable insulin prices. [The American Diabetes Association](#) is urging governors in every state to set up a zero-dollar copay for insulin during the pandemic and advance legislation that would cap copays for insulin once the pandemic is over. To date, 10 states have enacted insulin pricing laws since 2019 (CO, IL, ME, NH, NM, NY, UT, VA, WA, WV).

Unfortunately, [the drug industry often pushes back on legislation](#) that involves pricing and copay caps for the uninsured. Instead their focus is to push the cost to insurers, controlling insulin costs through copays. When carriers lower or cap insulin copays, they pay more of the cost. This does not deal with the root cause of the problem, which is the high cost of insulin and affordability for all people with diabetes who depend on it, including those without insurance.

Most of the proposals currently under consideration will likely result in cost shifting versus cost reduction. This strategy means the drug makers do not have to take responsibility for lowering the cost.

[State and federal policymakers and private entities](#) continue to work on a variety of policy changes to address the rising cost of insulin. Some of these include:

- Insurance coverage of insulin as preventive medicine
- Out-of-pocket caps
- Rebate pass-through at point of sale
- Price transparency
- Bulk purchasing
- Free emergency supplies
- State assistance programs

Congressional Diabetes Caucus: Policy Recommendations

The Congressional Diabetes Taskforce conducted a bipartisan inquiry to investigate the issue of rising insulin prices. [In their final report](#), they called on Congress to pursue policy change and legislative actions to:

- Increase transparency in pricing
- Curb the inflationary effects of rebates
- Mitigate the impacts of formulary changes
- Promote increased market competition (among insulin makers)
- Encourage the use of value-based contracts

They also state that Congress should consider working on targeted patent reforms to prevent anti-competitive practices and [streamline the drug approval process at the Food and Drug Administration for biosimilar insulins](#). The FDA has approved three biosimilar insulins since 2015.

More biosimilars are anticipated now that insulin is a biologic (Insulin: A Drug or a Biologic section).

Insulin: A Drug or a Biologic?

Another issue impacting affordability is a lack of competition in the insulin market, due in large part to how insulin has been categorized historically.

[Technically, insulin meets the definition of a biologic](#). Historically insulin has been on the market longer than the FDA rules for biologics. Thus, it has always been regulated as a drug. Even when the new FDA regulatory path for biosimilars was created in 2010, classifying insulin as such was not possible.

[On March 23, 2020](#), insulin was officially moved to a new legal and regulatory framework: The Biologics Price Competition and Innovation Act (BPCIA). This means that all insulins on the market have been officially labeled as biologics. As a result, these drugs can serve as a reference product for biosimilar or interchangeable drugs approved through the FDA's abbreviated licensure pathway. This new pathway has the potential to increase patient access, add more choices and reduce costs. The prior approved biosimilar insulins will be listed on the biosimilar list.

MBGH Diabetes Toolkit

MBGH created the [Employer Toolkit: Diabetes in the Workplace](#) to help employers gain access to knowledge, best practices and high-quality resources to more effectively manage diabetes with their workforce and plan members. Vetted by human resources/health benefits professionals, these resources are available at no cost and designed to help employers:

- Understand the economic impact of diabetes in the workplace
- Determine what data is available and how to obtain it from health plans
- Gain management support for a diabetes program initiative
- Create an action plan to address program, educational and messaging gaps for diabetes management in the work environment
- Gather [Employer Case Studies](#) with value-based benefit designs

Toolkit sections include:

- [Building a Business Case](#)
- [Program Strategies](#)
- [Benefit Plan Design Approaches](#)
- [Communications & Engagement Strategies](#)
- [Evaluation & Measurement](#)
- [Tools & Resources](#)

Videos include:

- [Employer Perspective on Toolkit](#)
- [Employer Diabetes & Business Case](#)
- [Employee Pre-diabetes & Diabetes](#)
- [Employee Pre-diabetes & Diabetes Spanish](#)
- [Diabetes Prevention Program \(DPP\)](#)

[Why Employers Shouldn't Ignore Diabetes](#), is a report that provides actionable steps employers of any size can take to more effectively manage diabetes and pre-diabetes with their covered populations.

Employer Communications

Once you have assessed your strategy for how you will address insulin access and cost, it's time to focus on how to communicate with your target audiences and put a plan in action.

Overall, keep these tips in mind:

- Sequence your communications like you are telling a story and reinforce the key messages on a regular basis
- Align communications with vendor partners to ease employee confusion about what is available and how to access the information, while using any tools and resources they may have to enhance existing themes
- Make messaging personal, relevant, timely and demonstrate value when possible
- Customize tactics/communications to fit your different audiences (healthy employees, those at risk for developing diabetes and those already diagnosed)
- Speak the same language (especially when dealing with different generations)
- Build trust – a new program or resource needs to come across as “we are here to help you” versus the company just wants to save money

6 Ways to Engage Employees

[ROC Group](#) has developed TAANSA®, a helpful model for employee engagement and influence rooted in the neuroscience of communication. Applied to diabetes engagement, ROC offers these six tips:



- **TRUST**
A Trusted Messenger. Who is first reaching out to employees or family members? The message needs to come from a trusted source. How close do employees feel to that source?
- **ATTENTION**
Meaningful Attention. Are you appealing to emotion rather than reason? Though we often write business communications by making a rational case, emotion is one of the key ways to get and keep attention.
- **AFFINITY**
A Credible Message. How well do the motives in the message match those of the reader? Have you made sure he or she is the main character in the message, not the company or vendor?
- **NEED**
So What? Why would the employee or family member need this program? Are you tapping pain or pleasure, fear or hope? Will participating make the person feel accepted or rejected?
- **SOLUTION**
Now What? After you've structured your messaging properly, you can explain the program.
- **ACTION**
Prompt Action. What do you want the person to do: Sign up? Take the call? Participate continuously? The type of engagement you want will determine how best to prompt action.

For more information please go to the [MBGH Diabetes Management in the Workplace toolkit](#).

The Power of MBGH!

[Midwest Business Group on Health \(MBGH\)](#) is one of the nation's largest non-profit coalitions of leading employers. Members are represented by human resources/health benefits professionals – collectively we serve as catalysts for change in addressing the US's health care challenges.



130+ Members

Self-insured
employers of all sizes



\$12+ Billion

Employer members' annual
health care benefits spend



4 Million

Total lives
represented



More Info

- [Insulin Access and Affordability Working Group: Conclusions and Recommendations](#) (*Diabetes Care, June 2018*)
- [Insulin: A lifesaving drug too often out of reach](#) (*Congressional Diabetes Caucus, April 2019*)
- [Understanding the Insulin Market](#) (*American Action Forum, March 2020*)
- [Federal and State Actions to Address Insulin Costs](#) (*American Action Forum, April 2020*)
- [States are trying to cap the price of insulin. Pharmaceutical companies are pushing back.](#) (*NBC News, August 15, 2020*)
- [Insulin is Now a Biologic – What Does That Mean?](#) (*American Diabetes Association, March 23, 2020*)
- [Old Dog, New Tricks?](#) How the BPCIA Could Increase Generic Competition for Insulins (*Biosimilar Development, June 23, 2020*)
- [Insulin Cost and Pricing Trends](#) (*American Action Forum, April 2, 2020*)
- [The High Cost of Insulin in the United States: An Urgent Care to Action.](#) (*Mayo Clinic Proceedings, January 1, 2020*)
- [Insulin in America: A Right of a Privilege?](#) (*DiabetesSpectrum, August 29, 2016*)
- [8 Reasons Why Insulin is so Outrageously Expensive](#) (*T1International, January 20, 2019*)
- [Federal and State Actions to Address Insulin Costs](#) (*American Action Forum, April 29, 2020*)
- [MBGH Diabetes Management in the Workplace Toolkit.](#)