

Insulin Affordability Presentation to:
North Carolina Diabetes Advisory Council
November 8, 2019

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Covering the states of: AL, AR, FL, GA, LA, MS, MO, NC, SC, TX

2019 Legislative & Regulatory Priorities



2019 State and Federal Legislative & Regulatory Priorities

In all areas, there is an ongoing commitment to achieving health equity.

Diabetes Research and Programs

- Increase overall funding dedicated to diabetes research, programs, and clinical translation of research, including, but not limited to:
 - The National Institute of Diabetes and Digestive and Kidney Diseases at the National Institutes of Health.
 The Division of Diabetes Translation at the Centers for Disease Control and Prevention.
- The Special Diabetes Program for type 1 research and programs in American Indian/Alaska Native
- The National Diabetes Prevention Program to support community-based programs to prevent type 2 diabetes including in disparately impacted communities.
- Diabetes research and prevention programs in states
- Innovative funding for diabetes research and programs.
- Protect and expand research opportunities.

Access to Adequate and Affordable Health Care

- Ensure public and private health insurance coverage options, including, but not limited to, those under the
 Affordable Care Act, Medicare, Medicaid, Children's Health Insurance Program, and state-mandated benefits
 provide adequate and affordable access to the medications, tools, education, and health care necessary to meet
 the ADA's Standards of Medical Care in Diabetes.
- Oppose weakening of existing protections for people with diabetes and prediabetes in federal and state law.
 Make insulin affordable and accessible for all who need it and require transparency throughout the insulin

Prevention

supply chain.

- Assess the burden of diabetes and prediabetes to develop, implement, and promote diabetes prevention policies and programs.
- Reduce obesity, improve nutrition, address food insecurity, and increase physical activity in communities.

Discrimination

- Ensure students with diabetes are medically safe and have access to the same educational opportunities as nears without diabetes.
- Ensure laws and policies for private and commercial driver's licenses result in fair treatment of people with diabetes.
- Ensure fair treatment of employees with diabetes.
- Ensure fair treatment of people with diabetes accessing places of public accommodation and public services.

Health Equity

- Promote health equity among at risk populations affected by diabetes and prediabetes.
- Address diabetes-related social determinants of health

Advancing Treatments and Technology

 Provide scientific expertise to regulators on issues related to diabetes and the need for improved means to treat, monitor, and prevent diabetes.

1-800-DIABETES

www.diabetes.org/advocacy

- Funding for Diabetes Research and Programs
- Access to Adequate and Affordable Health Care
- Prevention
- Fight Discrimination
- Health Equity
- Advancing Treatments and Technology





Stand Up for Affordable Insulin



ADA is committed to making insulin affordable and accessible for all who need it and require transparency throughout the insulin supply chain.



Insulin Affordability Microsite: makeinsulinaffordable.org

- Petition
- Personal stories
- Resolution





Working Group White Paper

Summary of Key Conclusions:

- The current pricing and rebate system encourages high list prices.
- There is a lack of transparency throughout the insulin supply chain.
- People with diabetes are financially harmed by high list prices and high out-of-pocket costs.
- Patient medical care can be adversely affected by formulary decisions.
- The regulatory framework for development and approval of biosimilar insulins is burdensome for manufacturers









Insulin Access and Affordability Working Group: Conclusions and Recommendations

https://doi.org/10.2337/dci18-0019

There are more than 30 million Americans with diabetes, a disease that costs the U.S. more than \$327 billion per year (1,2). Achieving glycemic control and controlling cardiovascular risk factors have been conclusively shown to reduce diabetes compli cations, comorbidities, and mortality. To achieve these desired outcomes, the medical community now has available many classes of medications and many formulations of insulin to effectively manage the metabolic abnormalities for people with diabetes However, the affordability of medications in general, and for insulin specifically, is currently of great concern to people with diabetes, their families, health care providers insurers, and employers. For millions of people living with diabetes, including all individuals with type 1 diabetes, access to insulin is literally a matter of life and death. The average list price of insulin has skyrocketed in recent years, nearly tripling between 2002 and 2013 (3). The reasons for this increase are not entirely clear but are due in part to the complexity of drug pricing in general and of insulin pricing in particular.

As the price of insulin continues to rise, individuals with diabetes are often forced to choose between purchasing their medications or paying for other necessities, exposing them to serious short- and long-term health consequences (4–9). To find solutions to the issue of insulin affordability, there must be a better understanding of the transactions throughout the insulin supply chain, the impact each stakeholder has on what people with diabetes pay for insulin, and the relative efficacy of therapeutic options. Thus, as the nation's leading voluntary health organization whose mission is "to prevent and cure diabetes and to improve the lives of all people affected by diabetes," the American Diabetes Association (ADA) is committed to finding ways to provide relief for individuals and families who lack affordable access to insulin.

In the spring of 2017, the ADA Board of Directors convened an Insulin Access and Affordability Working Group (Working Group) to ascertain the full scope of the insulin TN affordability problem, to advise the ADA on the execution of strategies, and to provide "University of Maryland School of Medicine high-level direction to the ADA related to this issue. The composition of the Working Boltimore, MD Group is provided in Supplementary Table 1. The Working Group identified increased transparency throughout the insulin supply chain and a number of other interventions Corresponding author: William T. Cefalu, wcefalu@ as important steps toward developing viable, long-term solutions to improve insulin

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Public Policy Statement

Summary of Key Recommendations:

- Increase pricing transparency throughout the insulin supply chain.
- Lower or remove patient cost-sharing for insulin.
- Streamline the biosimilar approval process.
- Increase access to health care coverage for all people with diabetes.

PUBLIC POLICY STATEMENT

Improving Insulin Access and Affordability

Krista Maier and Meghan Riley • May 2018

INTRODUCTION

There are more than 30 million Americans with diabetes.1 Now the nation's most expensive chronic disease, diagnosed diabetes accounts for an estimated \$327 billion in costs per year.2 Achieving glycemic control and managing cardiovascular risk factors have conclusively shown to reduce diabetes complications, comorbidities and mortality. Today, many classes of medications and many formulations of insulin are available to effectively manage the metabolic abnormalities for individuals with diabetes. However, the affordability of medications in general, and insulin specifically, is of great concern to people with diabetes, their families and healthcare providers. For millions of people living with diabetes, including all individuals with type 1 diabetes, access to insulin is literally a matter of life and death. The average list price of insulin has skyrocketed in recent years, nearly tripling between 2002 and 2013.3

KEY TAKEAWAYS

- Insulin costs have been steadily Increasing, forcing many people with diabetes to choose between purchasing this life-sustaining medication or paying for other necessities.
- Earlier this month, the ADA's Insulin Access and Affordability Working Group released findings from their research and stakeholder discussions.
- This Public Policy Statement provides an array of short-term and long-term recommendations to help shed light on the Issue, to combat Increasing Insulin costs, and to Improve affordable access to medications, including:
- Streamlining the biosimilar approval process;
- Increasing pricing transparency throughout the Insulin supply chain;
- Lowering or removing patient cost-sharing for insulin;
- Increasing access to health care coverage for all people with diabetes.



American Diabetes Association.



Engaged in 172 bills related to health care access



54 Medicaid bills

- Expanding and defending eligibility
- Prohibiting work and community engagement requirements
- Closing coverage gaps



51 bills increasing access to medications

- Insulin copay cap bills
- Transparency in the drug pricing chain
- Step therapy and prior authorization protocols
- Prohibiting mid-year formulary changes
- Cost-sharing requirements
- Non-medical switching
- Prohibiting pharmacy gag clauses



50 bills improving or preserving health insurance coverage

- Prohibiting/regulating short-term limited duration plans or other lesser quality plans
- Prohibiting interstate sale of insurance
- Improving the stability of marketplaces





- Over 7 million Americans depend on exogenous insulin to live.
- The price of insulin tripled between 2002 and 2013 and the price of insulin continues to rise
- 1 in 4 people with diabetes have reported rationing their insulin due to cost.
- The ADA believes that no one in need of insulin should ever go without and strongly supports legislation to help increase insulin affordability



Proce Poloseo

American Diabetes Association® Applauds Colorado Governor and State Legislature for Passing HB 1216: Reduce Insulin Prices Bill

May 22, 2019 Arlington, Virginia

On May 22, 2019, Colorado Governor Jared Polis signed the first bill in the nation that will cap insulin co-pays at \$100 per month, regardless of the number of vials needed. House Bill 1216: Reduce Insulin Prices, also enlists the Colorado Attorney General to investigate the rising price of insulin in Colorado and make recommendations to the General Assembly for further action. The American Diabetes Association (ADA) applauds Governor Polis and bill sponsors, Representative Dylan Roberts and Senators Kerry Donovan and Kevin Priola, for their leadership on this important legislation to reduce the burden of insulin costs for people living with diabetes.

"This American Diabetes Association-supported legislation is monumental for people living with diabetes," said LaShawn McIver, MD, Senior Vice President of Government Affairs & Advocacy. "There are more than 30 million Americans living with diabetes, and approximately 7.4 million of them must take insulin every day to live. With the prices of insulin nearly tripling between 2002 and 2013, people with diabetes often face financial hardships affording their insulin. Many are faced with tough decisions to either cut back or skip doses, or forgo other necessities to pay for insulin. Thank you to Governor Polis, Representative Roberts, and Senators Donovan and Priola for this legislation and their continued efforts to protect the more than 400,000 Coloradans living with diabetes."

In order to make insulin more affordable for people who need it, the ADA supports legislation to increase insulin pricing transparency throughout the supply chain (Colorado HB18-1009).

- Insulin transparency bills require costs and profits reporting from each of the stakeholders in the insulin supply chain: drug manufacturers, PBMs, health insurers, and pharmacies.
- These reports would then be made public.

The ADA was monumental in the passage of the nation's first co pay cap on insulin in Colorado.

- Colorado HB19-1216, caps the monthly co pay for insulin to \$100, regardless of the number of vials or type of insulin needed.
- Enlists the Attorney General of CO to investigate the rising costs of insulin in the state and to make the report public. Over 20 other states are anticipating the introduction of similar legislation in 2020.

We support Medicaid expansion to help make insulin more affordable:

Idaho and Nebraska passed expansion on the 2018 ballot

We support public options in health insurance (Medicaid buy-in):

- Washington state (SB-5526) and Colorado HB19-1004.
- Connecticut is also considering a public option bill.





State Government Affairs Engagement Opportunities



- Local committees and activities
- Become a point of contact for state and federal legislation
- Promote ADA advocacy through social media and your networks







Questions?

Please email Veronica De La Garza at vdelagarza@diabetes.org or call at (800) 676-4065 ext. 6017

