

HB19-1216: REDUCE INSULIN PRICES

Concerning measures to reduce a patient's costs of prescription insulin drugs.

Details

Bill Sponsors:	House – <i>Roberts (D)</i> , <i>McCluskie (D)</i> Senate – <i>Donovan (D)</i> and <i>Priola (R)</i>
Committee:	House Health & Insurance
Bill History:	2/28/2019- Introduced 3/20/2019- House Health & Insurance Refer Amended to House Appropriations
Next Action:	Hearing in House Appropriations
Fiscal Note:	<u>3/18/2019 Version</u>

Bill Summary

The bill establishes an out-of-pocket maximum for cost sharing at \$100 per 30-day supply of insulin. The Department of Law is tasked with investigating the price of insulin that is made available to Colorado consumers in order to ensure adequate consumer protections in the pricing of insulin and whether further protections are needed. A report is to be published with the findings.

Issue Summary

Insulin & Diabetes

In a typical pancreas, beta cells make the hormone insulin. At each meal, the cells release insulin to assist the body use or store the glucose it gets from food.¹ In individuals that have type 1 diabetes, the pancreas no longer makes insulin; the beta cells have been destroyed so the person needs insulin shots to use the glucose from food. Those with type 2 diabetes still make insulin, but their bodies do not respond well to it. Some with type 2 diabetes need to use pills or insulin shots to assist their body in utilizing the glucose properly. In 2015, 30.3 million Americans (9.4 percent of the population) had diabetes, of those 1.25 million had type 1 diabetes.² Only 23.1 of those projected to have diabetes had been diagnosed and 1.5 million are diagnosed with diabetes each year.

There are a variety of types of insulin that differ in their strength, how quickly they work, when they peak, and how long they last. In order to be effective, insulin must be injected under the skin to reach the bloodstream.¹ Although individuals with type 1 diabetes must use insulin to manage their diabetes, those with type 2 diabetes can utilize medication other than insulin. There are a variety of drugs that can be used to treat diabetes, including medications like metformin, sulfonylureas, and meglitinides.³

Diabetes Medications in the U.S.

About 7.4 million people with diabetes use insulin in the U.S.⁴ Presently, there are three insulin manufacturers in the U.S., Eli Lilly, Novo Nordisk, and Sanofi. There are no true generics of insulin sold in the

¹ American Diabetes Association (July 2015). *Insulin Basics*. Retrieved from <http://www.diabetes.org/living-with-diabetes/treatment-and-care/medication/insulin/insulin-basics.html>

² American Diabetes Association (2018). *Statistics about Diabetes*. Retrieved from <http://www.diabetes.org/diabetes-basics/statistics/>

³ Mayo Clinic (2019). *Type 2 Diabetes*. Retrieved from <https://www.mayoclinic.org/diseases-conditions/type-2-diabetes/diagnosis-treatment/drc-20351199>

⁴ Cefalu, W.T., et al. (June 2018). Insulin Access and Affordability Working Group: Conclusions and Recommendations. *Diabetes Care* 41(6). 1299-1311. Retrieved from <http://care.diabetesjournals.org/content/41/6/1299>

nation. The average wholesale acquisition cost (WAC), a list price, for insulin increased by 15-17 percent per year from 2012 to 2016.⁴ From 2012-2016 the average annual out-of-pocket spending per person with type 1 diabetes for insulin rose from \$2,864 to \$5,705.⁵ During this period average daily insulin utilization in this population only rose 3 percent. Antidiabetics were the second most costly drug group in Medicaid in 2017.⁶ Approximately 45 percent of people in the U.S. with diabetes report sometimes forgoing care due to cost.⁷

Diabetes in Colorado

The American Diabetes Association approximates that more than 416,000 people in Colorado have diabetes but estimate 118,000 have not been diagnosed.⁸ In 2012, the total cost of care per patient with diabetes was over \$13,000 in Colorado.⁹ Diabetes is the 8th leading cause of death in the state.

Case Study: Nevada

The Nevada state legislature passed a bill in 2017, Senate Bill 539, which required the state Department of Health and Human Services to compile a list of drugs that are essential to treat diabetes and the manufacturers that produce those drugs. Reports are required to be submitted to the Department on these essential diabetes drugs manufacturers and pharmacy benefit managers (PBMs). A March 2019 report pursuant to the information required in the state law had a variety of findings for calendar year 2017.¹⁰ The average reported profit reported for these drugs was more than \$47 million but the median profit was below \$300,000. Furthermore, 28 percent of reports of drugs either incurred a loss or earned no profit. The most frequent reported justifications for price increases of essential diabetes drugs were research and development, changes in marketplace dynamics, rebates, production costs, and inflation. Reports indicate that 60 percent of manufacturers provided \$0 of patient financial assistance; however, for those that reported assistance, the average total amount was reported to be more than \$10 million. The total PBM negotiated rebates was reported to be almost \$1.7 billion. A rebate is the return of a portion of the purchase price; prescription drug rebates are generally paid by a manufacturer to a PBM, who then shares a portion with the insurer.

This Legislation

The legislative declaration asserts that almost 20,000 Coloradans are diagnosed with diabetes each year. It continues by stating that as of January 1, 2018, nearly 300,000 Colorado adults had been diagnosed and 100,000 were undiagnosed but living with the disease. Every person in the state with type 1 diabetes and many of those with type 2 rely on insulin to survive. Approximately four billion dollars are the annual medical cost related to diabetes in Colorado. Of that, about 18 percent (\$700 million) is for prescription drugs to treat the disease. The declaration continues to affirm that insulin prices rose by 45 percent from 2014 to 2017, and rose by 545 percent (adjusted for inflation) in the past 14 years. A quarter of type 1 diabetics reported insulin underuse due to the cost of the drug. Due to these data points, the bill declares that it is

⁵ Biniak, J.F. & Johnson, W. (Jan. 21, 2019). *Spending on Individuals with Type1 Diabetes and the Role of Rapidly Increasing Insulin Prices*. Retrieved from <https://www.healthcostinstitute.org/research/publications/entry/spending-on-individuals-with-type-1-diabetes-and-the-role-of-rapidly-increasing-insulin-prices>

⁶ Young, K. (Feb. 15, 2019). *Utilization and Spending Trends in Medicaid Outpatient Prescription Drugs*. Kaiser Family Foundation. Retrieved from https://www.kff.org/medicaid/issue-brief/utilization-and-spending-trends-in-medicaid-outpatient-prescription-drugs/?utm_source=hs_email&utm_medium=email&utm_content=2&hsenc=p2ANqtz-yCJbDbYOq4G3HZRkC-FbXECRUx2pAJwdFd258IPxq1vV5N3o9tQt71A_o6Mvx7PVJBL2TgcNhlucMiDssSMLtGA1Fgw&hsmi=2

⁷ Balick, R. (Aug. 2018). Soaring insulin prices have patients terrified and pharmacists scrambling. *Pharmacy Today* 24(8). 43-44. Retrieved from [https://www.pharmacytoday.org/article/S1042-0991\(18\)31099-5/fulltext](https://www.pharmacytoday.org/article/S1042-0991(18)31099-5/fulltext)

⁸ American Diabetes Association (2016). *The Burden of Diabetes in Colorado*. Retrieved from <http://main.diabetes.org/dorg/PDFs/Advocacy/burden-of-diabetes/colorado.pdf>

⁹ CO Department of Public Health and Environment (Nov. 2015). *Diabetes' Impact in Colorado*. Retrieved from https://www.colorado.gov/pacific/sites/default/files/DC_Factsheet_Facts_For_Action_Diabetes_In_Colorado_November_2015.pdf

¹⁰ Nevada Department of Health and Human Services (March 8, 2019). *Supplemental Report: 2017 Essential Diabetes Drugs*. Retrieved from <http://dhhs.nv.gov/uploadedFiles/dhhsnv.gov/content/HCPWD/Supplemental%20Drug%20Transparency%20Report%203.7.19.pdf>

important to enact policies to reduce the costs for Coloradans with diabetes to obtain life-saving and life-sustaining insulin.

The bill defines “cost sharing” as a copayment or coinsurance amount imposed on a covered person for a covered prescription drug, in accordance with their health plan.

If a carrier imposes a cost sharing amount for insulin, it is to cap the total cost sharing for insulin, including cost sharing once the deductible is met, at an amount to not exceed \$100 per 30-day supply of insulin, regardless of the amount or type of insulin needed to fill the prescription. This does not prevent a carrier from reducing the cost sharing requirements further than this requirement. The bill allows for the Commissioner of Insurance to use their enforcement powers to ensure compliance.

The Department of Law, headed by the Attorney General, is to investigate the price of insulin that is made available to Colorado consumers in order to ensure adequate consumer protections in the pricing of insulin and whether further protections are needed. During the investigation, the Department is to gather, compile, and analyze information about the organization, practices, pricing information, data, reports, and other necessary information. Any publicly available information related to drug pricing should also be considered. If it is necessary to fulfill the investigation requirements, the Attorney General can issue a civil investigative demand that requires a state department, carrier, pharmacy benefit manager, or manufacturer of insulin drugs made available in Colorado to provide material, answers, data, or other relevant information. A business or person is not compelled to provide proprietary information or trade secrets, as previously defined in state law.¹¹ By November 1, 2020 the Department is to issue a report that details its findings. The report should be submitted to the Governor, Commissioner of Insurance, as well as the House and Senate Judiciary Committees. The report must include:

- A summary of insulin pricing practices and variables that contribute to pricing of health plans
- Policy recommendations to control and prevent overpricing of insulin in Colorado
- Any recommendations for improvements to the “Colorado Consumer Protection Act” to prevent deceptive sales acts related to insulin
- Any other information that the Department finds necessary

The bill takes effect August 2, 2019, unless a referendum petition is filed against the bill or section of the bill. The bill applies to health plans issued or renewed on or after January 1, 2020, unless a referendum petition is filed.

Reasons to Support

The bill takes into consideration of consumers’ immediate needs while investigating the long-term effect and possible solutions regarding insulin pricing. This may allow diabetes patients to spread out their required costs longer before reaching their deductible instead of having to spend a lot of money at the beginning of each year on their required drug. Some assert that the out-of-pocket maximum may encourage adherence to the medication, which could avert costs associated with unmanaged diabetes that could increase the costs for health plans.

Supporters

- American Diabetes Association
- Colorado Center on Law and Policy
- Colorado Consumer Health Initiative
- Colorado Cross-Disability Coalition

¹¹ C.R.S. 7-74-102(4). "Trade secret" means the whole or any portion or phase of any scientific or technical information, design, process, procedure, formula, improvement, confidential business or financial information, listing of names, addresses, or telephone numbers, or other information relating to any business or profession which is secret and of value. To be a "trade secret" the owner thereof must have taken measures to prevent the secret from becoming available to persons other than those selected by the owner to have access thereto for limited purposes.

- Colorado Insulin for All
- Colorado Pharmacist Society
- Colorado Division of Insurance
- International Diabetes Federation

Reasons to Oppose

Some may assert that out-of-pocket maximum for insulin would increase plan costs, as the plan would need to cover any difference between the current consumer payment and what the health plan must pay. There is concern that there is a broad scope of duties delegated to the Department of Law, which could infringe of proprietary information of entities.

Opponents

- Colorado Bioscience Association
- CVS Health
- Pharmaceutical Research and Manufacturers of America (PhRMA)
- United Health Care

Other Considerations

It is notable that the report and investigation in regards to insulin pricing is to be conducted by the Department of Law rather than the Division of Insurance (DOI) or Department of Health Care Policy and Financing (HCPF). Some assert that the DOI or HCPF would be more appropriate, but others rebut that the Department of Law is appropriate as it is tasked with consumer protection and suited to understand the legal complexities that may be involved.

It is also important to note that the out-of-pocket maximum only applies to plans that are under the regulatory purview of the DOI, including the individual, small group, and portions of the large group market. The Employee Retirement Income Security Act of 1974 (ERISA) is a federal law that does not allow state regulators and lawmakers to regulate self-insured plans, where employers become the insurer. In 2017, approximately 44 percent of private employers in Colorado self-insured at least one plan.¹²

About this Analysis

This analysis was prepared by Health District of Northern Larimer County staff to assist the Health District Board of Directors in determining whether to take an official stand on various health-related issues. The Health District is a special district of the northern two-thirds of Larimer County, Colorado, supported by local property tax dollars and governed by a publicly elected five-member board. The Health District provides medical, mental health, dental, preventive and health planning services to the communities it serves. This analysis is accurate to staff knowledge as of date printed. For more information about this summary or the Health District, please contact Alyson Williams, Policy Coordinator, at (970) 224-5209, or e-mail at awilliams@healthdistrict.org.

¹² Division of Insurance (Dec. 10, 2018). *Health Insurance Cost Report for Calendar Year 2017*. Retrieved from https://drive.google.com/drive/folders/0B_UoCf17OVmWfmdCd1g5bXJC22Z2XZwDiWk1wbktpWUQwUTgwT2Jit3pMeWl1UU1zMEZOTG8