

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Banking and Insurance

BILL: SB 786

INTRODUCER: Senators Cruz and Berman

SUBJECT: Prescription Insulin Drugs

DATE: March 23, 2021

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	Pre-meeting
2.			AHS	
3.			AP	

I. Summary:

SB 786 requires individual and group health insurance policies and health maintenance organization (HMO) contracts that provide coverage for prescription insulin drugs for the treatment of diabetes to cap the cost-sharing obligation of an insured or subscriber for a 30-day supply of such drugs at an amount not to exceed \$100.

Diabetes is a chronic disease caused by the body's inability to create enough insulin or properly use the insulin it produces to break down glucose (blood sugar) to use as energy for the body.¹ When the body cannot respond to insulin or does not make enough insulin, insulin is taken by injection or other means.²

Recent studies have found that the average list price of insulin nearly tripled between 2002 and 2013³ and that cost-sharing or out-of-pocket costs per prescription doubled over the past 10 years.⁴ The out-of-pocket costs of prescription insulin drugs for insureds or subscribers can vary due to different benefit designs and cost sharing requirements, including copayment, coinsurance, and deductible requirements. Due to significant increases in the cost of insulin, many patients with diabetes go without insulin or ration their doses, which may place an individual at risk for serious health complications. Diabetes is the seventh leading cause of death in the United States.⁵

¹ See Centers for Disease Control and Prevention, *Diabetes Glossary*, <https://www.cdc.gov/diabetes/pdfs/library/socialmedia/diabetes-infographic.pdf> (last viewed Mar. 16, 2021).

² *Id.*

³ *Diabetes Care* 2018;41:1299.

⁴ *JAMA Intern Med.* 2019 Jan; 179(1): 112-114.

⁵ Centers for Disease Control and Prevention, *What is diabetes?* <https://www.cdc.gov/media/presskits/aahd/diabetes.pdf> (last viewed Mar. 16, 2021).

The Department of Management Services estimates that implementation of the bill will result in a negative fiscal impact of approximately \$21,000 annually on the State Group Insurance program.

The bill may have an indeterminate negative fiscal impact on local governments if health premiums increase as a result of the bill.

II. Present Situation:

Diabetes is a condition resulting from the body's inability to use blood glucose for energy.⁶ In Florida, approximately 13.1 percent of the adult population, or 2.4 million people, have diabetes.⁷ Every year, an estimated 105,000 people in Florida are diagnosed with diabetes.⁸

Type 1 and Type 2 diabetes are the two main types of diabetes.⁹ Type 1 diabetes occurs when an individual does not produce enough insulin to enable blood sugar to enter cells for energy. Type 1 diabetes develops most often in young people, but can appear in adults. About 5 percent of the people who have diabetes have Type 1. Type 2 diabetes is characterized by high blood glucose levels caused by either a lack of insulin or the body's inability to use insulin efficiently. Type 2 diabetes develops most often in middle-aged and older adults, but can appear in children, teens, and young people. About 90 percent of people with diabetes have Type 2.

Access to adequate and affordable health care can be a significant issue for anyone with an illness, but it is particularly critical for individuals who have diabetes or other chronic conditions with the potential to cause death, disability, or serious side effects, unless treated with the most appropriate medical care in a timely manner. In recent years, the federal government has approved many innovative treatments for chronic conditions that affect large populations. Some of the benefits of these innovative drugs include fewer side effects, convenience, and greater efficacy.¹⁰ However, the financial burden resulting from out-of-pocket drug costs can lead patients with chronic illnesses to forgo or ration prescribed drugs, ultimately affecting their health. People who have diabetes are at higher risk of serious health complications, such as death, blindness, kidney failure, heart disease, stroke, or loss of toes, feet, or legs.¹¹

⁶ Centers for Disease Control and Prevention, *Diabetes Glossary*, <https://www.cdc.gov/diabetes/library/glossary.html#> (last viewed Dec. 2, 2019).

⁷ American Diabetes Association, *The Burden of Diabetes in Florida*, <http://main.diabetes.org/dorg/PDFs/Advocacy/burden-of-diabetes/all-states.pdf> (last viewed Mar. 17, 2021).

⁸ *Id.*

⁹ *See About Diabetes, Types of Diabetes*, Centers for Disease Control, <https://www.cdc.gov/diabetes/basics/index.html>. (last viewed Dec. 2, 2019). In addition, to Type 1 and Type 2 Diabetes, gestational diabetes may develop in pregnant women who have never had diabetes. Gestational diabetes usually goes away after childbirth, but increases the mother's risk for Type 2 diabetes later in life.

¹⁰ *See* HEALTH AFFAIRS 35, No. 9 (2016):1595-1603.

¹¹ *See supra* note 3 at 1299 and 1306. An example was provided of an individual with Type 1 diabetes who required four vials of insulin at a monthly out-of-pocket cost of \$1,948 until the family meets the health plan's deductible. The individual began skipping insulin doses due to the high monthly cost, and suffered health complications.

Trends in National Health Care Expenditures

In 2019, total US health care spending increased 4.6 percent from the prior year to reach \$2.8 trillion or \$11,482 per person.¹² Over the past 20 years, US drug spending has increased by 330 percent compared with a 208 percent increase in total US health expenditures.¹³

Cost of Insulin

Recent reports note the significant increase in the cost of insulin. One study found that the average list price of insulin has nearly tripled between 2002 and 2013.¹⁴ Another study, which looked at Type 1 diabetes, noted a rapid increase in total health care spending, driven primarily by gross spending on insulin that doubled over the period.¹⁵ During that time, insulin use only rose modestly. While the composition of insulin use shifted, the price of all types of insulin and insulin products increased, with point-of-sale prices roughly doubling on average between 2012 and 2016.¹⁶ The study concluded that increases in insulin spending were driven primarily by increases in insulin prices, and to a lesser extent, a shift towards use of more expensive products.¹⁷

According to a recent workgroup of the American Diabetes Association, reasons for this price increase “...are not entirely clear but are due to the complexity of drug pricing and of insulin pricing in particular.” The workgroup noted that many stakeholders (drug manufacturers, drug wholesalers, pharmacy services administrative organizations, pharmacy benefit managers, health plans, employers, and consumers) are involved in multiple payment and distribution transactions within the supply chain for insulin. Currently, Eli Lilly, Novo Nordisk, and Sanofi are the three insulin drug manufacturers serving the United States.¹⁸

Federal Patient Protection and Affordable Care Act

The Federal Patient Protection and Affordable Care Act (PPACA)¹⁹ requires health insurers and HMOs to make specified coverage available to all individuals, without exclusions for preexisting

¹² Centers for Medicare and Medicaid Services, *National Health Expenditure 2019 Highlights*, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical> (last visited Mar. 16, 2021).

¹³ Kirzinger, A., et. al., for the Kaiser Family Foundation. *US Public’s Perspective on Prescription Drug Costs*. *JAMA*. 2019;322(15):1440. doi:10.1001/jama.2019.15547, <https://jamanetwork.com/journals/jama/fullarticle/2752910> (last visited Mar. 16, 2021).

¹⁴ See *supra* note 3, at 1299.

¹⁵ Health Care Cost Institute, *Insulin Prices Were the Primary Drive of Rapid Increases in Spending on Type 1 Diabetes* (2019), <https://healthcostinstitute.org/research/publications/entry/spending-on-individuals-with-type-1-diabetes-and-the-role-of-rapidly-increasing-insulin-prices> (last viewed Mar. 16, 2021). The report did not have information on manufacturer rebates or coupons for insulin, because this information is proprietary and not publicly available. The report measured gross spending using the point-of-sale prices that are reported on a claim for a prescription drug. The report notes that rebates and coupons result in lower net spending (for both payers and patients).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ See *supra* note 3, at 1300.

¹⁹ The Patient Protection and Affordable Care Act (Pub. Law No. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. Law No. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on Mar. 30, 2010.

conditions, and mandates coverage of ten essential health benefits,²⁰ including prescription drugs, for qualified health plans offered to individuals and small groups.

The PPACA prescribes maximum out-of-pocket limits for cost sharing by insureds or subscribers who purchase qualified health plans.²¹ The minimum annual deductible is the amount that an individual must pay for medical expenses before the plan will pay any medical costs. The maximum out of pocket cost is the total amount (deductibles, copayments, and coinsurance) an individual must pay for covered services during a plan year. A high-deductible health plan (HDHP) has a higher annual deductible than typical health plans offered by insurers or HMOs, and a maximum limit on the sum of the annual deductible and out-of-pocket medical expenses that an insured or subscriber must pay for covered expenses.²²

Insulin Copayment Cap Laws in Other States

On May 22, 2019, the governor of Colorado signed legislation that requires an insurer or HMO that provides coverage for prescription insulin drugs to cap the maximum amount that an insured or subscriber must pay at \$100 per 30-day supply of insulin.²³ This cap applies regardless of the amount or type of insulin needed to fill the prescription.

In 2020, Illinois enacted similar legislation.²⁴ The act requires an insurer or HMO that provides coverage for prescription insulin drugs to limit the total amount an insured is required to pay for a covered prescription insulin drug to \$100 per 30-day supply of insulin regardless of the type and amount of insulin needed by the insured. The act also provides an annual cost adjustment increase to this cap based on the percentage change from the preceding year in the medical care component of the Consumer Price Index of the Bureau of Labor Statistics of the United States Department of Labor.²⁵

The Florida Office of Insurance Regulation

The Office of Insurance Regulation (OIR) licenses and regulates the activities of life, health, property, and casualty insurers, health maintenance organizations (HMOs), and other risk-bearing entities.²⁶

²⁰ 42 U.S.C. s. 18022.

²¹ For the 2021 plan year, the out-of-pocket limit for a Marketplace plan or qualified health plan is \$8,550 for an individual plan and \$17,100 for a family plan. See Health.gov, Glossary, <https://www.healthcare.gov/glossary/out-of-pocket-maximum-limit/> (last visited Mar. 16, 2021).

²² For 2021, a high deductible health plan (HDHP) is defined as any plan with a deductible of at least \$1,400 for an individual or \$2,800 for a family. An HDHP's total yearly out-of-pocket expenses (including deductibles, copayments, and coinsurance) may not exceed \$7,000 for an individual or \$14,000 for a family. See Health.gov, *High Deductible Plan*, <https://www.healthcare.gov/high-deductible-health-plan/> (last visited Mar. 16, 2021).

²³ House Bill 19-1216, Session Law Ch. 248, https://leg.colorado.gov/sites/default/files/2019a_1216_signed.pdf (last visited Mar. 16, 2021).

²⁴ Public Act 101-0625.

²⁵ The medical care index is one of eight major groups in the Consumer Price Index (CPI). See Bureau of Labor Statistics of the U.S. Department of Labor *Measuring Price Change in the CPI: Medical Care*, <https://www.bls.gov/cpi/factsheets/medical-care.htm> (last visited Mar. 16, 2021).

²⁶ Section 20.121(3), F.S. The Office of Insurance Regulation is an office within the Financial Services Commission (FSC). The FSC is composed of the Governor, the Attorney General, the Chief Financial Officer, and the Commissioner of Agriculture. The FSC members serve as the agency head for purposes of rulemaking under ss. 120.536-120.565, F.S.

State Group Health Insurance Program

The Department of Management Services (Department), Division of State Group Insurance (DSGI) administers the state group health insurance program under a cafeteria plan consistent with s. 125 of the Internal Revenue Code.²⁷ As part of the State Group Insurance Program, the Department contracts third party administrators for self-insured health plan, fully insured HMOs, and a pharmacy benefits manager (PBM), CaremarkPCS Health, L.L.C. (CVS Caremark), for the state employees’ Self-insured Prescription Drug Plan.²⁸

The Employee Prescription Drug Program covers all federal legend drugs (open formulary) for covered medical conditions and employs very limited utilization review and clinical review for traditional or specialty prescription drugs.²⁹ Specialty drugs, as defined by the PBM, are dispensed by the PBM’s specialty pharmacies, pursuant to the state contract and plan benefit documents.³⁰

The Prescription Drug Program provides the following four dispensing options: participating 30-day retail pharmacies, participating 90-day retail pharmacies, the PBM’s mail-order pharmacies, and the PBM’s specialty pharmacies.³¹ Copayments (and coinsurance for high deductible plans) for each drug tier are the same for all members, as described below. Member out-of-pocket cost share would be higher than those listed below, if a generic drug is available, and the member, not the prescriber, requests the brand name drug.³²

Standard Plans

Drug Tier	Retail – Up to 30-Day Supply	Retail and Mail – Up to 90-Day Supply and Specialty Medications
Generic	\$7	\$14
Preferred Brand	\$30	\$60
Non-Preferred Brand	\$50	\$100

High Deductible Health Plans

Drug Tier	Retail – Up to 30-Day Supply	Retail and Mail – Up to 90-Day Supply and Specialty Medications
Generic	30%	30%
Preferred Brand	30%	30%
Non-Preferred Brand	50%	50%

The State Group Insurance Program typically makes benefits changes on a plan year basis, which is January 1 through December 31. Benefit changes are subject to approval by the Legislature.³³

²⁷ Section 110.123, F.S.

²⁸ Section 110.123(5), F.S.

²⁹ Department of Management Services, SB 786 Legislative Analysis (Feb. 18, 2021).

³⁰ Section 110.12315(2), F.S.

³¹ Section 110.12315(8), F.S. Department of Management Services, Division of State Group Insurance, *2021 Benefits State Employees’ Prescription Drug Plan*, https://www.mybenefits.myflorida.com/content/download/150426/1002145/2021_CVS_Caremark_Brochure.pdf (last visited Mar. 10, 2021).

³² Section 110.12315(2) and (8), F.S.

³³ Section 110.123(3), F.S.

III. Effect of Proposed Changes:

Sections 1 and 2 create ss. 627.64085, F.S., and s. 627.65746, F.S., respectively, to require an individual or group health insurance policy that provides coverage for prescription insulin drugs to cap the total amount of cost sharing that an insured is required to pay for such drugs at an amount not to exceed \$100 per 30-day supply, regardless of the amount or type of insulin needed to fill the prescription. The sections define the term, “prescription insulin drug.”

The bill authorizes the Financial Services Commission to adopt rules to implement provisions of the bill. The sections also define the term, “prescription insulin drug.”

Section 3 amends s. 627.6699, F.S., to require that the provisions of Section 2, relating to group policies, apply to small group policies.

Section 4 amends s. 641.31, F.S., to require an HMO contract that provides coverage for prescription insulin drugs, to cap the total amount of cost sharing that a subscriber is required to pay for covered insulin drugs at an amount not to exceed \$100 per 30-day supply, regardless of the amount or type of insulin needed to fill the prescription. The sections define the term, “prescription insulin drug.”

The bill authorizes the Financial Services Commission to adopt rules to implement provisions of the bill. The section also defines the term, “prescription insulin drug.”

Section 5 provides the bill takes effect January 1, 2022.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

Article VII, section 18(a) of the Florida Constitution provides, in pertinent part, that “no county or municipality shall be bound by any general law requiring such county or municipality to spend funds or take action requiring the expenditure of funds unless the Legislature has determined that such law fulfills an important state interest, and the law requiring such expenditure is approved by two-thirds of the membership of each house of the Legislature.”

The bill requires group employer plans that provide coverage for prescription insulin drugs for the treatment of diabetes, to cap the cost sharing of a 30-day supply of such drugs at an amount not to exceed \$100. The fiscal impact of this mandate is indeterminate.

The bill does not provide that it fulfills an important state interest.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

F. Tax/Fee Issues:

None.

G. Private Sector Impact:

The implementation of a cap on cost sharing for prescription insulin drugs will reduce the financial burden for some insureds and subscribers that have higher cost-sharing requirements for insulin drugs. Access to more affordable insulin drugs may prevent or mitigate future illnesses and complications associated with diabetes.

Access to more affordable insulin may result in greater adherence and better outcomes for patients, thereby reducing overall medical and drug expenses associated with diabetes. In 2019, Cigna and Express Scripts introduced their Patient Assurance Program, which caps out-of-pocket costs of insulin at \$25 for a 30-day supply for eligible individuals enrolled in participating non-government funded pharmacy plans managed by Express Scripts, including Cigna and other plans.³⁴

The impact of the bill on insurers and HMOs is indeterminate.

A cost-sharing cap may have the effect of increasing the prescribing of brand name products, higher-cost products, and higher-cost delivery methods over generics, lower-cost products, and lower-cost delivery methods. However, pharmacy benefit managers may change formularies to substitute lower cost insulins for higher cost insulins or imposing additional step therapy requirements on higher cost insulins may offset this.³⁵

A 2017 study by Milliman evaluated potential approaches to reduce patient cost sharing on insulins through insurance benefit design changes.³⁶ The study analyzed the impact of

³⁴ Cigna and Express Scripts. *News Release*, <https://www.cigna.com/newsroom/news-releases/2019/cigna-and-express-scripts-introduce-patient-assurance-program-to-cap-out-of-pocket-costs-at-25-per-30-day-insulin-prescription> (last viewed Dec. 4, 2019).

³⁵ Office of Insurance Regulation, *2021 Legislative Session, SB 786*, (Feb. 19, 2021).

³⁶ Milliman, *Mitigating out-of-pocket costs for prescription drugs: Supplement brief on exempting insulin from the deductible* (May 30, 2019), <https://milliman-cdn.azureedge.net/-/media/milliman/importedfiles/ektron/mitigating-costs-insulin-users.ashx> (last visited Mar. 17, 2021).

exempting insulin from cost sharing for patients in high deductible health plans only. According to the report, providing out-of-pocket cost relief to members who use insulin increases the total cost to the high deductible health plan. The analysis found that the increase in cost would be approximately \$5.12 per member per year.

H. Government Sector Impact:

Impact on Local Governments

The bill's coverage requirements may increase costs incurred by local governments by an indeterminate amount.

Division of State Group Insurance of the Department of Management Services.³⁷

The Department of Management Services (Department) notes that implementation of the bill may affect members enrolled in the health maintenance organization and preferred provider organization high-deductible health plans (HDHP) covered by the prescription drug program. In a HDHP, a member's out-of-pocket cost is 30 percent for generic drugs, 30 percent for preferred brand drugs, and 50 percent for non-preferred brand drugs. The third-party administrator for the prescription drug program projects a negative fiscal impact of \$21,000 for the plan year, as described in the following analysis, below, provided by the Department.

The language currently included as "insulin drug at an amount not to exceed \$100 per 30-day supply" is impactful due to a 30-day supply being a very subjective metric. Insulin utilization will fluctuate widely from person to person and will even vary month to month for the same individual depending on how well controlled the individual's diabetes is.

Because of this variance, looking at a 30-day supply claim can be impactful, and the Department estimated below the cost assumptions of how this might affect the Division of State Group Insurance program. Whether as a result of the deductible or the 30 percent coinsurance, there are several insulin claims within January-December 2020 that are above \$100 per 30 days. Any costs over the member maximum would move to the plan cost; therefore, the total cost to the DSGI plan would be approximately \$21,000.

- PPO Standard and PPO HDHP impact = \$15,000.
- HMO Standard and HMO HDHP impact = \$6,000.

V. Technical Deficiencies:

None.

VI. Related Issues:

Lines 41-43, 61-63, and 88-91 provide that the sections do not preclude an insurer or HMO from reducing an insured's cost-sharing obligation by an amount greater than the amount specified in

³⁷ *Supra* Note 29.

the bill. The OIR suggests clarifying these sections by specifying that the sections do not prohibit the insurer from capping the cost sharing obligation at a lower dollar amount, rather than referring to a reduction in the insured's or subscriber's cost sharing obligation.³⁸

The bill authorizes the Financial Services Commission to adopt rules. The Office of Insurance indicates that rules would not be necessary to implement the bill.³⁹

VII. Statutes Affected:

This bill substantially amends sections 627.6699 and 641.31 of the Florida Statutes.

This bill creates sections 627.64085 and 627.65746 of the Florida Statutes.

VIII. Additional Information:

A. Committee Substitute – Statement of Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

³⁸ *Supra* note 33.

³⁹ *Id.*