

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: CS/SB 116

INTRODUCER: Banking and Insurance Committee; Senator Cruz and others

SUBJECT: Prescription Insulin Drugs

DATE: January 15, 2020

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	Fav/CS
2.	_____	_____	AEG	_____
3.	_____	_____	AP	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 116 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 of 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 have 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, which includes copayment, coinsurance, and deductible requirements. Due to significant increases in the cost of insulin, many patients with diabetes are going without insulin or rationing their doses, which may place

¹ See Centers for Disease Control and Prevention, *Diabetes Glossary*, <https://www.cdc.gov/diabetes/library/glossary.html#> and <https://www.cdc.gov/diabetes/pdfs/library/socialmedia/diabetes-infographic.pdf> (last viewed Dec. 2, 2019).

² *Id.*

³ *Diabetes Care* 2018;41:1299.

⁴ *JAMA Intern Med.* 1019 Jan; 179(1): 112-114.

an individual at risk for serious health complications. Diabetes is the seventh leading cause of death in the United States.⁵

The Department of Management Services estimates that implementation of the bill will result in a fiscal impact in the range of \$14,000 to \$17,500 per year on the State Group Insurance program.

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

⁵ Centers for Disease Control and Prevention, *What is diabetes?* <https://www.cdc.gov/media/presskits/aahd/diabetes.pdf> (last viewed Dec. 2, 2019).

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 Dec. 2, 2019).

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 Projected National Health Expenditures 2018-2027¹²

In 2019, private health insurance spending is expected to increase by 3.3 percent. This trend is the net effect of faster spending growth in many services such as physician and clinical services and prescription drugs. In 2019, prescription drug spending growth is projected to increase by 4.6 percent, due to faster utilization growth from both existing and new drugs, as well as a modest increase in drug price growth. For the remainder of the projection, 2020-27, prescription drug spending is expected to grow by 6.1 percent per year on average, influenced by higher use anticipated from new drugs and efforts by employers and insurers that encourage patients with chronic conditions to treat their disease.

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 2013.¹³ 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. During that time, insulin use rose only modestly. While the composition of insulins used 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. 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.¹⁴

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.¹⁵

¹² See National Health Expenditure Projections 2018-2027, Forecast Summary, The Office of the Actuary in the Centers for Medicare & Medicaid Services, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ForecastSummary.pdf> (last viewed Nov. 20, 2019).

¹³ See *supra* note 3, at 1299.

¹⁴ Health Care Cost Institute, *Price of Insulin Prescription Doubled Between 2012 and 2016*. (2017), <https://healthcostinstitute.org/research/publications/entry/spending-on-individuals-with-type-1-diabetes-and-the-role-of-rapidly-increasing-insulin-prices> (last viewed Dec. 2, 2019). 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. Rebates and coupons result in lower net spending (for both payers and patients).

¹⁵ See *supra* note 3, at 1300.

Federal Patient Protection and Affordable Care Act

The federal Patient Protection and Affordable Care Act (PPACA)¹⁶ requires health insurers and HMOs to make specified coverage available to all individuals, without exclusions for preexisting conditions, and mandates coverage of ten essential health benefits,¹⁷ including prescription drugs, for qualified health plans.

The PPACA prescribes maximum out-of-pocket limits for cost sharing by insureds or subscribers who purchase qualified health plans.¹⁸ 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.¹⁹

Status of Insulin Copayment Cap Legislation in Other States

On May 22, 2019, the governor of Colorado signed legislation that requires an insurer or HMO, which provides coverage for prescription insulin drugs, to cap the maximum amount that an insured or subscriber is required to pay at \$100 per 30-day supply of insulin.²⁰ This cap applies regardless of the amount or type of insulin needed to fill the prescription. However, this law would not preclude an insurer or HMO from capping the cost sharing at less than \$100 per 30-day supply.

In November 2019, similar legislation passed both houses of the Illinois Legislature.²¹ The act requires an insurer or HMO, which 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

¹⁶ 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.

¹⁷ 42 U.S.C. s. 18022.

¹⁸ For the 2020 plan year, the out-of-pocket limit for a Marketplace plan or qualified health plan is \$8,200 for an individual plan and \$16,400 for a family plan. See Health.gov, Glossary, <https://www.healthcare.gov/glossary/out-of-pocket-maximum-limit/> (last viewed Dec. 1, 2019).

¹⁹ For 2020, 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 \$6,900 for an individual or \$13,800 for a family. See Health.gov, *High Deductible Plan*, <https://www.healthcare.gov/high-deductible-health-plan/> (last viewed Dec. 1, 2019).

²⁰ House Bill 19-1216, Session Law Ch. 248, https://leg.colorado.gov/sites/default/files/2019a_1216_signed.pdf (last viewed Dec. 2, 2019).

²¹ SB 667, 101st General Assembly of Illinois.

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.²²

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.²³

State Group Health Insurance Program

The Department of Management Services (DMS) 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.²⁴ To administer the state group health insurance program, the DMS contracts with third party administrators for self-insured health plans, fully insured HMOs, and a pharmacy benefits manager (PBM) for the state employees' Self-Insured Prescription Drug Program (Prescription Drug Program).²⁵

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. Specialty drugs, as defined by the PBM, are dispensed by the PBM's specialty pharmacies pursuant to the state contract and plan benefit documents. The 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.²⁶ Copayments (and coinsurance for high deductible plans) for each drug tier are the same for all members.

III. Effect of Proposed Changes:

Sections 1 and 2 create s. 627.64085, F.S., and s. 627.65746, F.S., respectively, to require an individual or group health insurance policy, which 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 bill authorizes the Financial Services Commission to adopt rules to implement provisions of the bill. The sections also define the term, "prescription insulin drug."

²² 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 viewed Dec. 2, 2019).

²³ Section 20.121(3), F.S. The Office of Insurance Regulation is a unit 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.

²⁴ Section 110.123, F.S.

²⁵ Section 110.12315, F.S.

²⁶ Effective January 1, 2020, the program will implement a standard control formulary, which will include a list of drugs that are subject to review for medical necessity prior to coverage. [Ch. 2019-100, s. 3, Laws of Fla.]

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

Section 4 amends s. 641.31, F.S., to require an HMO contract, which 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 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, 2021.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The implementation of a capped 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.

The impact of the bill on insurers and HMOs is indeterminate. 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.²⁷

A 2017 study by Milliman evaluated potential approaches to reduce patient cost sharing on insulins through insurance benefit design changes.²⁸ The study analyzed the impact of exempting insulin from the deductible 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 70-95 cents per member per year. The report stated that this cost could be shared among plan members in the form of higher premium (or contribution) levels. The report noted that the cost could be absorbed by the plan sponsor, in the form of a higher medical loss ratio. These estimates do not include assumptions about changes in medical cost because of lowering insulin out-of-pocket costs.

The provisions of the bill would not apply to coverage offered by self-insured employer plans, which are regulated by federal law.²⁹

C. Government Sector Impact:

The Division of State Group Insurance of the Department of Management Services (DMS) 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. Based on current insulin claims volume and low enrollment in the HDHP, the third-party administrator for the prescription drug program projects a fiscal impact in the range of \$14,000 to \$17,500 per year.³⁰ This analysis is based on the assumption that each insulin dependent participant will fill only one prescription for insulin in a 30-day period. However, the DMS notes that it is not unusual for sugar levels to vary on a daily basis, which could result in the need for more insulin in a 30-day period. Additional prescription fills within a 30-day period would alter the analyses for both the standard and HDHP HMO and PPO plans.³¹

²⁷ 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).

²⁸ Milliman, *Mitigating out-of-pocket costs for prescription drugs: Supplement brief on exempting insulin from the deductible* (May 30, 2017). On file with Banking and Insurance Committee.

²⁹ Self-insured plans are regulated pursuant to the federal Employee Retirement Income Security Act of 1974 (ERISA).

³⁰ Department of Management Services, SB 116 Legislative Analysis (Sep. 10, 2019).

³¹ *Id.*

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

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

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

IX. Additional Information:**A. Committee Substitute – Statement of Changes:**

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

CS by Banking and Insurance on January 15, 2020:

The CS applies the provisions of the bill to small group policies.

B. Amendments:

None.