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 Health Policy

BILL:	CS/SB 1180
INTRODUCER:	Banking and Insurance Committee and Senators Mayfield and Harrell
SUBJECT:	Consumer Protection from Nonmedical Changes to Prescription Drug Formularies
DATE:	April 5, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	**Fav/CS**
2.	Lloyd	Brown	HP	**Pre-meeting**
3.			RC	

Please see Section IX. for Additional Information:

PLEASE MAKE SELECTION

I. Summary:

CS/SB 1180 amends the Insurance Code to provide additional consumer protections by prohibiting health insurance policies and health maintenance organization contracts, which provide major medical coverage, from removing a covered prescription drug from its formulary while an insured is taking a medically-necessary prescription drug prescribed by a treating physician, except during the renewal period. The bill also generally prohibits an insurer or health maintenance organization (HMO) from reclassifying a drug to a more restrictive tier, increasing the cost sharing of an insured, or reclassifying a drug to higher cost-sharing tier during the policy year. Under current law, only HMOs offering group contracts are prohibited from increasing the copayment for any benefit or removing, amending, or limiting any of the contract benefits except at renewal time, with some exceptions.

According to the Division of State Group Insurance (DSGI) of the Department of Management Services, their pharmacy benefit managers (PBMs) anticipate that implementation of the bill would result in an increase cost of approximately $1.7 million due to the absence of quarterly drug list tier changes; $1.5 million due to lost rebates (1 percent of current rebates), $75,000 from maintaining lower cost-sharing tiers (not moving drug to a non-preferred tier when a generic becomes available), and approximately $100,000 in administrative charges associated with a custom formulary.

The bill does not have a fiscal impact on the Florida Medicaid program since the bill specifically excludes the Medicaid managed care plans from these provisions.

II. Present Situation:

Access to affordable health care can be a significant issue for anyone with an illness, but it is particularly critical for individuals who have conditions with the potential to cause death, disability, or serious discomfort unless treated with the most appropriate medical care in a timely manner. In recent years, many innovative treatments for diseases that affect large populations, such as cancer, hepatitis C, diabetes, and multiple sclerosis have been approved. Some of the benefits of these innovative drugs include fewer side effects, convenience (oral solids instead of injectables), and greater efficacy.[1] However, the financial burden resulting from out-of-pocket drug costs can lead patients with chronic illnesses to forgo prescribed drugs, ultimately affecting their health.

Prescription Drug Cost Containment

Health care spending in the United States is expected to grow an average of 5.5 percent annually from 2018-2027, reaching nearly $6.0 trillion by 2027.[2] Prescription drug spending is projected to have grown 3.3 percent in 2018. This acceleration is due to faster anticipated utilization growth, partially driven by an increase in the introduction of new drugs. Prescription drug spending growth is expected to increase to 4.6 percent in 2019, because of 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, 2020-2027, prescription drug spending is projected 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 consistently treat their disease states.[3]

A majority of adults aged 18-64, nearly 60 percent, reported being prescribed a medication in the past 12 months in one study sponsored by the federal Centers for Disease Control and Prevention.[4] Approximately 70 percent of all prescriptions carry out-of-pocket costs, such as requirements for co-insurance, co-payments, or deductible, with generics having an average cost of $6 per prescription and brand names an average cost of $30 per prescription.[5]

Many adults who are prescribed drugs with higher out-of-pocket costs will forego their prescriptions or will take other measures, including considering other non-medication therapies, to avoid the out-of-pocket costs. Researchers found that while the number of adults who asked their health care provider for an alternative medical treatment option with a lower out-of-pocket cost had dropped from the prior study, the percentage was still 19.8 percent.[6] Other strategies that adults used included not taking the medication as prescribed, which could mean skipping

---

[1] *See* HEALTH AFFAIRS 35, No. 9 (2016): 1595-1603.
[2] Office of the Actuary, Centers for Medicare & Medicaid Services (CMS), National Health Expenditure Projections 2018-2027, *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ForecastSummary.pdf (last viewed April 3, 2019).
[3] *Id.*
[4] Robin A. Cohen, et al, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, *Strategies Used by Adults Aged 18-64 to Reduce Their Prescription Drug Costs, 2017*, *NCHS Data Brief* (March 2019), p. 1, https://www.cdc.gov/nchs/data/databriefs/db333-h.pdf (last visited March 21, 2019).
[5] Robin A. Cohen, *supra* note 4.
[6] Robin A. Cohen, s*upra* note 4

doses, taking less than the prescribed dose, delaying a refill; or using alternative therapies instead of the prescribed medication.[7]

For patients that switched drugs for non-medical reasons, one report found that these patients had higher increases in their non-drug spending compared to patients who had no changes in their medications.[8] If a patient had multiple switches, the increases could be even higher, depending on the disease condition. For example, a patient with Crohn's disease who experienced no switches had an average monthly increase in non-drug spending of $2,072; if switched to a lower cost prescription, then he or she may have experienced an average increase of $4,499. If there were multiple drug switches, then the average per member per month increase was $4,890 in non-drug spending.[9] While the cost of the prescriptions drug may have decreased for the insurer, the costs for the other non-drugs expenses have increased related to that health care condition. Almost 40 percent of patients who experienced a change in medications for non-medical reasons indicated that the change was so frustrating that it led them to stop taking their medications altogether.[10]

Due to increasing health care expenditures, public and private employers and insurers continue to look for cost containment methods, including the reduction of prescription drug costs. Many employer-sponsored health plans and insurers contract with pharmacy benefit managers (PBMs). The PBMs negotiate drug prices with pharmacies and drug manufacturers on behalf of health plans and, in addition to other administrative, clinical, and cost-containment services, process drug claims for the health plans. A PBM generally manages a preferred drug list or formulary for each of its plan sponsors. Insurers and self-insured employers provide insureds with financial incentives, such as lower copayments, to use preferred drugs.

Non-Medical Switching or Substitution of Prescription Drugs

Non-medical switching or substitution of prescription drugs occurs when there may be multiple options available within a treatment class and a less expensive or patient-preferred medicine is substituted, often for cost containment reasons. There are typically three types of non-medical types of switching that occur with prescription drugs. First, non-medical switching may be as simple as the substitution of a brand name drug for its generic equivalent. Generic drugs are chemically very similar to the brand-name drugs using the same active ingredient, and are the same in dosage form, safety, strength, route of administration, performance characteristics, and intended use.[11] A generic drug must pass the same safety standards as a brand-name drug.

---

[7] Robin A. Cohen, *supra* note 4, at 2 - 4.
[8] Institute for Patient Access, *Cost Motivated Treatment Changes & Non-Medical Switching – A Commercial Health Plans Analysis* (August 2017), *available at* https://instituteforpatientaccess.org/wp-content/uploads/2018/05/IfPA_Non-Medical-Switching-Commercial-Claims-Analysis_Aug-2017.pdf (last viewed on April 2, 2019).
[9] Institute for Patient Access, *supra* note 8.
[10] Institute for Patient Access, *supra* note 8.
[11] U.S. Food and Drug Administration, *Understanding Generic Drugs* (page last updated 06/05/2018) *available at* http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/default.htm (last visited Mar. 13, 2019).

The second method of switching or substitution involves dispensing drugs that are therapeutically equivalent to, but chemically different from, the originally prescribed drug.[12] A therapeutically equivalent drug is expected to produce a similar patient outcome as the reference drug or treatment.[13]

Biosimilar drugs are a third category of drugs which are produced through biotechnology. A biosimilar is highly similar to[14] and has no clinically meaningful differences[15] from an existing Food and Drug Administration-approved reference product.[16] Some research indicates that the biologic therapy medications of some patients are being switched for nonclinical reasons, despite the lack of data to support this practice and an abundance of data demonstrating clinically meaningful differences among biologics.[17] For example, one study reviewing the reason for adjusting anti-tumor necrosis (TNF) agents involving patients primarily with rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, or ulcerative colitis found that non-medical switching of anti-TNF agents was associated with an increase in side effects and lack of efficacy that also led to an increase in health care utilization.[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 coverage available to all individuals and employers, without exclusions for preexisting conditions, and mandates that issuers (insurers and HMOs) provide 10 essential health benefits;[20] which includes prescription drugs.

Current Prescription Drug Coverage Requirements

To comply with the essential health benefit requirement for prescription drugs, issuers must include in their formulary or preferred drug lists the greater of one drug for each U.S.

---

[12] Rachel Chu, et al, *Patient Safety and Comfort - The Challenges of Switching Medicines* (2010) *available at* http://www.patients-rights.org/uploadimages/Patient_Safety_and_Comfort_The_Challenges_of_Switching.pdf (last viewed Mar. 13, 2019).

[13] Rachel Chu, et al, *supra* note 12, at 9.

[14] "Highly similar to" means the characteristics of the product, such as purity, chemical identity, and bioactivity of both the reference product and the proposed biosimilar product have been compared and have only minor differences in the clinically inactive components. These differences are carefully evaluated by the FDA to ensure the biosimilar meets the FDA's high approval standards and are acceptable.

[15] "No Clinically meaningful differences" means that the proposed biosimilar product has demonstrated through human exposure and response studies its safety and effectiveness, an assessment of clinical immunogenicity, and if needed, additional clinical studies.

[16] U.S. Food and Drug Administration, *Biosimilar and Interchangeable Products* (page last updated 10/23/2017) *available at* https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm#biological (last viewed April 2, 2019).

[17] *See* Alan Reynolds, et al, *When is switching warranted among biologic therapies in rheumatoid arthritis?* Medscape.com. http://www.medscape.com/viewarticle/768031_5 (last viewed Mar. 13, 2019).

[18] D.T. Rubin, et al, *Analysis of outcomes after non-medical switching of anti-tumor necrosis factor agents,* European Crohn's and Colitis Organisation (2015) *available at* https://www.ecco-ibd.eu/index.php/publications/congress-abstracts/abstracts-2015/item/p354-analysis-of-outcomes-after-non-medical-switching-of-anti-tumor-necrosis-factor-agents.html?category_id=430 (last viewed Mar. 13, 2019).

[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 March 30, 2010.

[20] 42 U.S.C. s. 18022.

Pharmacopeia (USP) category and class; or the same number of drugs in each USP category and class as the state's EHB benchmark plan. Issuers must have a Pharmacy and Therapeutics Committee to design formularies using scientific evidence that will include consideration of safety and efficacy, cover a range of drugs in a broad distribution of therapeutic categories and classes, and provide access to drugs that are included in broadly accepted treatment guidelines. Plans providing EHBs must have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not included on the plan's formulary drug list. Such procedures must include a process to request an expedited review.[21]

Proposed Changes to Prescription Drug Coverage for the 2020 Plan Year

The proposed federal rules[22] for the 2020 plan year would allow individual, small group, and large group market health insurance issuers to adopt mid-year formulary changes to optimize the use of new generic drugs as they become available, consistent with the approach to Medicare Part D.[23] At that time, the issuer also would be permitted to remove the equivalent brand drug from the formulary or move the equivalent brand drug to a different cost-sharing tier on the formulary. Issuers would also be required to provide enrollees the option to request coverage for a brand drug that was removed from the formulary through the applicable coverage appeal process or the drug exception request process.

The proposed rule also revises the requirements for how such issuers treat cost-sharing for brand drugs when a generic equivalent is available. The proposed rule would exempt certain cost-sharing from the maximum out-of-pocket limit if an insured selects a brand drug when a medically appropriate generic drug is available. Insurers would be required to provide notice to the patient and the treating provider of the patient. Insurers would be required to provide enrollees the option to request coverage for a brand drug that was removed from the formulary through the applicable coverage appeal process or the drug exception request process.

Regulation of Insurers and Health Maintenance Organizations in Florida

The Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, HMOs, and other risk-bearing entities.[24] The Agency for Health Care Administration (AHCA) regulates the quality of care provided by HMOs under part III of ch. 641, F.S. Before receiving a certificate of authority from the OIR, an HMO must receive a Health Care Provider Certificate from the AHCA.[25]

Currently, an HMO may increase the copayment for any benefit, or delete, amend, or limit any of the benefits under a group contract only upon written notice to the contract holder at least

[21] 45 C.F.R. s. 156.122.
[22] U.S. Department of Health and Human Services, *Proposed HHS Notice of Benefit and Payment Parameters for 2020 Fact Sheet*, available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/Proposed-2020-HHS-Fact-Sheet.PDF (last viewed Mar. 9, 2019).
[23] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L. 108-173) established a voluntary, outpatient prescription drug benefit under Medicare Part D, effective January 1, 2006. Medicare Part D provides coverage through private prescription drug plans (PDPs) that offer only drug coverage, or through Medicare Advantage (MA) prescription drug plans (MA-PDs) that offer coverage as part of broader, managed care plans.
[24] Section 20.121(3), F.S.
[25] Section 641.21(1), F.S.

45 days in advance of the time of coverage renewal. The HMO may amend the contract with the contract holder, with such amendment to be effective immediately at the time of coverage renewal. The written notice to the contract holder must specifically identify any deletions, amendments, or limitations to any of the benefits provided in the group contract during the current contract period, which will be included in the group contract upon renewal. This provision does not apply to any increases in benefits. The notice requirements do not apply if benefits are amended, deleted, or limited, pursuant to a request of the contract holder.[26]

Florida's State Group Insurance Program

Under the authority of s. 110.123, F.S., the DMS, through the DSGI, administers the state group health insurance program under a cafeteria plan consistent with section 125, Internal Revenue Code. To administer the state group health insurance program, the DMS contracts with third party administrators for self-insured health plans, insured HMOs, and a pharmacy benefit manager (PBM) for the state employees' self-insured prescription drug program pursuant to s. 110.12315, F.S.

The state employees' self-insured prescription drug program has three cost-share categories for members: generic drugs, preferred brand name drugs (those brand name drugs on the preferred drug list), and non-preferred brand name drugs (those brand name drugs not on the preferred drug list).[27] Generic drugs are the least expensive and have the lowest member cost share, preferred brand name drugs have the middle cost share, and non-preferred brand name drugs are the most expensive and have the highest member cost share.

State Group Health Insurance Prescription Drug Co-Payments[28]		
Drug Tier	**Retail Up to 30 Day Supply**	**Retail and Mail Up to 90 Days Specialty Medications**
Generic	$7	$14
Preferred Brand	$30	$60
Non-Preferred Brand	$50	$100

Contractually, the PBM for the state employees' self-insured prescription drug program updates the preferred drug list quarterly as brand drugs enter the market and as the PBM negotiates pricing, including rebates with manufacturers.[29]

Regulation in Other States of Changes to Prescription Drug Formularies

Staff conducted a limited survey of some states that had enacted legislation addressing formulary benefit changes or cost-sharing limits:

[26] Section 641.31(36), F.S.
[27] Department of Management Services, *State Employees' Prescription Drug Plan,* available at https://www.mybenefits.myflorida.com/content/download/142818/952917/2019_Benefits_at_a_Glance_PPO_Standard_FINAL_073118.pdf (last viewed Mar. 13, 2019).
[28] Department of Management Services, *supra* note 27.
[29] CVS caremark, *2019 Plan Year-State Employees' Prescription Drug Plan,* available at https://www.mybenefits.myflorida.com/content/download/142756/952578/OE_for_2019_Brochure_two_-_page_FINAL_rev_081518.pdf (last viewed Mar. 13, 2019).

- Louisiana: Formulary change must occur at the time of coverage renewal and prior notice must be given to each affected covered employer and enrollee, or individual.[30]
- California: Prohibits changes in cost sharing designs during the plan or policy year, except when such change is required by state or federal law.[31]
- Nevada: Prohibits a health insurer that offers individual coverage from removing prescription drugs from a formulary or moving a drug to a higher cost-sharing tier during the plan year with some exceptions.[32]
- New Mexico: Limits when health insurance policies may change prescription drug coverage, with exceptions, and requires prior notification of all affected enrollees.[33]
- Virginia: Requires insurers to establish a process for insureds to obtain continued access to drugs that they have been receiving for at least 6 months prior to a formulary change at a cost-sharing level that is no higher than the level imposed on formulary drugs.[34]
- Texas: Prohibits insurers and HMOs from making mid-year formulary benefit and cost-sharing changes since 2012.[35]
- Illinois: Protects patients who have previously had coverage approved for a drug to continue at the same benefit level for the duration of a plan year.[36]

Several other states have legislation pending that would freeze formularies during the plan year except to allow for drug products to be added. In some circumstances, the formulary is frozen with respect only to certain chronic conditions.

III. Effect of Proposed Changes:

Section 1 creates s. 627.42393, F.S., and **Sections 2 and 3** amend s. 627.6699, F.S., and s. 641.31, F.S., respectively.

The bill amends the Insurance Code to provide additional consumer protections by prohibiting a health insurer or HMO from removing a medically necessary covered drug from its formulary during the policy year except during coverage renewal with some limited exceptions. These provisions would apply to individual and group policies or contracts providing medical, major medical, or similar comprehensive coverage. An insurer or HMO may remove a prescription drug from its list of covered drugs during the policy year if:

- The U.S. Food and Drug Administration has issued a statement about the drug which calls into question the clinical safety of the drug; or
- The manufacturer of the drug has notified the U.S. Food and Drug Administration of a manufacturing discontinuance or potential discontinuance of the drug as required by s. 506C of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s. 356c.

The bill also prohibits an insurer or HMO from reclassifying a medically necessary drug to a more restrictive drug tier; increasing the amount that an insured must pay out-of-pocket for a

[30] La Admin. Code title 37, pt. XIII, ss. 14111, 14115, and 14117.
[31] CAL. INS. Code, §10199.449; Effective Jan. 1, 2017; Approved by the Governor August 25, 2016.
[32] Nevada Division of Insurance, *Adopted Regulation R074*-14 (uncodified).
[33] N.M. Stat. ss. 59A-22-49.4, 59A-23-7.13, 59A-46-50.4, and 59A-47-45.4.
[34] *See* Va. Code Ann. s. 38.2-3407.9.01.
[35] Tex. Ins. Code ss. 1369.0541 and 1501.108.
[36] Correspondence on file with Senate Banking and Insurance Committee.

copayment, coinsurance, or deductible for prescription drugs; or reclassifying a drug to a higher cost-sharing tier during the policy year.

The bill also:
- Does not prohibit the addition of prescription drugs to the list of drugs covered under the policy during the policy year.
- Does not amend s. 465.025, F.S., which provides conditions under which a pharmacist may substitute a generically equivalent drug product for a brand name drug product.
- Does not amend s. 465.0252, F.S., which provides conditions under which a pharmacist may dispense a substitute biological product for the prescribed biological product.

The provisions of the bill do not apply to grandfathered health plans, as defined in s. 627.402, F.S., or to limited benefits set forth in s. 627.6513(1)-(14), F.S.

Section 4 provides that the bill fulfills an important state interest.

Section 5 provides the bill is effective January 1, 2020.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The county/municipality mandates provision of article VII, section 18 of the Florida Constitution may apply if the bill requires local governments to spend funds. If those provisions do apply, in order for the law to be binding upon the cities and counties, the Legislature must find that the law fulfills an important state interest, and one of the following relevant exceptions must apply:
- The expenditure is required to comply with a law that applies to all persons similarly situated; or
- The law must be approved by two-thirds of the membership of each house of the Legislature.

Since this bill requires all public sector health plans to limit drug changes in the formulary and insureds' cost sharing, it appears the bill applies to all persons similarly situated (state, counties, and municipalities).

The bill includes a finding that the act 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.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

By limiting changes to the prescription drug formulary, CS/SB 1180 would provide continuity of care for insureds receiving brand drugs for the entire plan year.

The prohibition on mid-policy year changes to drug formularies may increase the claim costs for health insurers and HMOs providing prescription drug benefits. Any increased costs would likely be passed along to insureds. The provisions of the bill would not apply to ERISA (the federal Employee Retirement Income Security Act of 1974)[37] self-insured plans, which represent approximately 50 percent of the insureds in Florida. ERISA preempts the regulation of such plans by the states.

C. Government Sector Impact:

Division of State Group Insurance Program

The PBM for the Division of State Group Insurance (program) projects moderate-to-high fiscal impact to the program due to the bill's restrictions on moving a preferred brand name drug to non-preferred when a generic product becomes available, which would result in less utilization of lower-cost generic alternatives and less rebate pass-through.

The program's PBM anticipates additional operational burdens to hold the program's preferred drug lists constant throughout the year instead of current quarterly updates. The bill's requirement to keep the drug list constant would require a custom drug list. Based on calendar year 2018 utilization, the program's PBM estimates a $1.7 million negative impact from not making quarterly drug list tier changes: $1.5 million from lost rebates (1 percent of current rebates), $75,000 from maintaining lower cost share (not moving drug to non-preferred when a generic becomes available), and approximately $100,000 in administrative charges associated with a custom formulary.[38]

[37] 29 U.S.C. s. 1001 et seq. (1974).
[38] Department of Management Services, *Senate Bill 1180 Analysis* (Mar. 6, 2019) (on file with the Senate Committee on Banking and Insurance).

Likewise, the implementation of this bill may result in an indeterminate negative fiscal impact on local governments.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 627.42393 and 641.31.

This bill creates section 627.6699 of the Florida Statutes.

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 March 18, 2019:
The CS prohibits health insurance policies and health maintenance organization contracts, if such policies and contracts pertain to major medical coverage, from removing or reclassifying to a more restrictive drug tier, a covered prescription drug from its formulary while an insured is taking a medically-necessary prescription drug prescribed by a treating physician, except during the renewal period.

B. Amendments:

None.