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 1180
INTRODUCER:	Senator Mayfield
SUBJECT:	Consumer Protection from Nonmedical Changes to Prescription Drug Formularies
DATE:	March 15, 2019
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	**Pre-meeting**
2.			HP	
3.			RC	

I. Summary:

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 the prescription drug except during the renewal period. The bill also generally prohibits an insurer or 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.

Often, insureds with chronic, disabling conditions select a health insurance policy or contract based on the availability of certain drugs on the formulary at a preferred cost. Typically, health insurers and pharmacy benefit managers (PBMs) may change their prescription drug formularies during the year in response to the availability of new drugs or changes in prices by drug manufacturers. As a result, certain prescription drugs may become more costly or unavailable, thereby restricting an insured's access to these drugs during a plan year. However, the insured is unable to enroll in a different health insurance plan until the next open enrollment

According to the Division of State Group Insurance (DSGI) of the Department of Management Services, their pharmacy benefit managers anticipates that implementation of the bill would result in an increase costs 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 share (not moving drug to non-preferred 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 it does amend any of the provisions relating to the program.

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 new drug introductions. 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, 2020-27, 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.[3]

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. The PBM generally manages the list of preferred drug products (formulary) for each of its plan sponsors. Insurers and self-insured employers provide insureds with financial incentives, such as lower copayments, to use formulary 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. Non-medical switching may be as simple as the

[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.go v/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ForecastSummary.pdf (last viewed March 2, 2019).
[3] *Id.*

substitution of a brand name drug for its generic equivalent. Generic drugs are copies of brand-name drugs and are the same in dosage form, safety, strength, route of administration, performance characteristics, and intended use.[4] A generic drug must pass the same safety standards as a brand-name drug. The second method of switching or substitution involves dispensing drugs that are therapeutically equivalent to but chemically different from the originally prescribed drug.[5]

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.[6] 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.[7]

Federal Patient Protection and Affordable Care Act

The federal Patient Protection and Affordable Care Act (PPACA)[8] 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;[9] 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 drug list the greater of one drug for each U.S. 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

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[4] Federal Food and Drug Administration, *Understanding Generic Drugs available at* http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/default.htm (last visited Mar. 13, 2019).

[5] 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).

[6] *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).

[7] 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-abstract-s/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).

[8] 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.

[9] 42 U.S.C. s. 18022.

appropriate drugs not included on the plan's formulary drug list. Such procedures must include a process to request an expedited review.[10]

Proposed Changes to Prescription Drug Coverage for the 2020 Plan Year

The proposed federal rules[11] 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.[12] 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.[13] 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.[14]

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 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

[10] 45 C.F.R. s. 156.122.
[11] 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).
[12] 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.
[13] Section 20.121(3), F.S.
[14] Section 641.21(1), F.S.

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.[15]

Florida's State Group Insurance Program

Under the authority of s. 110.123, F.S., the DMS, through the DGSI, 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).[16] 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. 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.[17]

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. In Louisiana, the 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.[18] California prohibits changes in cost sharing designs during the plan or policy year, except when such change is required by state or federal law.[19] Nevada generally 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.[20] New Mexico generally limits when health insurance policies may change prescription drug coverage, with exceptions, and requires prior notification of all affected enrollees.[21] 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.[22] Since 2012,

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[15] Section 641.31(36), F.S.
[16] 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).
[17] 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).
[18] La Admin. Code title 37, pt. XIII, ss. 14111, 14115, and 14117.
[19] CAL. INS. Code, §10199.449; Effective Jan. 1, 2017; Approved by the Governor August 25, 2016.
[20] Nevada Division of Insurance, *Adopted Regulation R074*-14 (uncodified).
[21] N.M. Stat. ss. 59A-22-49.4, 59A-23-7.13, 59A-46-50.4, and 59A-47-45.4.
[22] *See* Va. Code Ann. s. 38.2-3407.9.01.

Texas has prohibited insurers and HMOs from making mid-year formulary benefit and cost-sharing changes.[23] Advocates or the bill note that the following states have implemented a similar protection to SB 1180, too. These include:

- Louisiana: Health plans can only modify a policy's drug coverage at renewal, and with approval by the insurance commissioner. Prohibited modifications during the plan year include: removing a drug, adding prior authorization requirements, imposing a quantity limit, imposing a new step-therapy restriction, moving the drug to a higher tier, unless a generic is available.
- Illinois: The law generally 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.[24]

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 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 drug to a more restrictive drug tier; increasing the amount that an insured must pay out-of-pocket for a 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.

[23] Tex. Ins. Code ss. 1369.0541 and 1501.108.
[24] Correspondence on file with Senate Banking and Insurance Committee.

Section 4 provides that the act 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, the bill 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 (Employee Retirement Income Security Act of 1974)[25] self-insured plans, which represent approximately 50 percent of the insureds in Florida. ERISA preempts the regulation of such plans by the states.

According to advocates[26] of the bill, the bill will not increase coverage of drug benefits or the total cost of health care. The bill should reduce costs because non-medical switches generally increase healthcare resource utilizations. A study of patients with complex chronic conditions in Medicare Part B found that payments for patients who were switched from their therapy for non-medical reasons increased by $8,711.52.[27] The bill creates transparency for consumers to know that the coverage benefit they sign up for is the coverage benefit they will receive for the plan year. The bill addresses the practice of some insurers and HMOs marketing certain pharmacy benefits to consumers at open enrollment, only to change the benefits during the plan year when insureds are generally unable to change plans. Further, advocates report that physicians, pharmacists, and other healthcare administrators have reported that nonmedical switching increases administrative time, increases side effects or new unforeseen effects, and increases downstream costs to plans.

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 its inability to move a preferred brand name drug to non-preferred when a generic product becomes available; less member movement to lower cost generic alternatives and less rebate pass through.

The program's PBM anticipates additional operational burden to hold the program's preferred drug lists constant throughout the year instead of current quarterly updates and keeping the drug list constant would require a custom drug list. Based on calendar year 2018 utilization, the program's PBM projected approximately $1.7M impact from not making quarterly drug list tier changes: $1.5M from lost rebates (1 percent of current rebates), $75K from maintaining lower cost share (not moving drug to non-preferred

[25] 29 U.S.C. 1001 et seq. (1974).
[26] .Correspondence on file with the Senate Committee on Banking and Insurance.
[27] *Cost-Motivated Treatment Changes: Implications for Non-Medical Switching*, Institute for Patient Access (Oct. 2016), http://allianceforpatientaccess.org/wp-content/uploads/2016/10/IfPA_Cost-Motivated-Treatment-Changes_October-2016.pdf

when a generic becomes available), and approximately $100K in administrative charges associated with a custom formulary.[28]

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: 627.6699 and 641.31.

This bill creates section 627.42393 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.)

None.

B. Amendments:

None.

[28] Department of Management Services, *Senate Bill 1180 Analysis* (Mar. 6, 2019) (on file with the Senate Committee on Banking and Insurance).