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 182
INTRODUCER:	Senator Mayfield
SUBJECT:	Consumer Protection from Nonmedical Changes to Prescription Drug Formularies
DATE:	February 6, 2017
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	**Pre-meeting**
2.			HP	
3.			RC	
4.				
5.				
6.				

I. Summary:

SB 182 amends the Insurance Code to provide additional consumer protections by prohibiting a health insurer or a health maintenance organization (HMO) from removing a covered prescription drug from its formulary except during open enrollment with some limited exceptions. The bill also prohibits an insurer or HMO from reclassifying a drug to a more restrictive tier, increasing the out-of-pocket costs (e.g., copayment, coinsurance, or deductible) 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 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 the insureds access to these drugs during a plan year. The insured is unable to switch to a different health insurance plan until the next open enrollment.

The Division of State Group Insurance (DSGI) of the Department of Management Services indicates that the bill will have an indeterminate, negative fiscal impact. The pharmacy benefit manager of the DSGI estimates the annual loss of rebates from drug manufacturers to the state is $9.2 million and the annual additional costs of drugs to the DSGI is $50,000.

The bill has no fiscal impact on the Florida Medicaid program, as it does not amend ch. 409, F.S., which governs the Florida Medicaid program, nor does it require Medicaid to amend existing policies or procedures.

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 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 from out-of-pocket drug costs can lead patients with chronic illnesses to forgo prescribed drugs, ultimately affecting their health.

Prescription Drug Cost Containment

In 2014, spending on retail prescription drugs in the United States was approximately $298 billion.[2] In 2015, total retail prescription drug spending increased by 9 percent, reaching $325 billion. The significant growth in 2015 was attributed to certain cost drivers, such as, spending on new drugs, price growth for existing brand-name drugs, increased spending on generics, and a decrease in the number of expensive drugs whose patents have expired.[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 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 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

[1] *See* HEALTH AFFAIRS 35, No. 9 (2016): 1595-1603.
[2] *See* HEALTH AFFAIRS 36, No. 1 (2017):166-176.
[3] *Id.*
[4] Federal Food and Drug Administration, *Understanding Generic Drugs available at* http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/default.htm (last visited Feb. 2, 2017).

dispensing drugs that are therapeutically equivalent to but chemically different from the originally prescribed drug.[5]

Research notes 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

Health Insurance Reforms

The federal Patient Protection and Affordable Care Act (PPACA) was signed into law on March 23, 2010.[8] The PPACA requires health insurers to make coverage available to all individuals and employers, without exclusions for preexisting conditions and without basing premiums on any health-related factors. The PPACA also mandates required essential health benefits,[9] cost-sharing limits, rating and underwriting standards, and appeals of adverse benefit determinations. The PPACA requires issuers (insurers and HMOs) of qualified health plans (QHPs) to provide 10 categories of essential health benefits (EHB), which includes prescription drugs.[10] The federal deadline for insurers and HMOs to submit 2018 rates and forms to the Centers for Medicare and Medicare and the Office of Insurance Regulation is May 13, 2017.[11] [12]

Prescription Drug Coverage

For purposes of complying with PPACA's EHBs 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

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[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 Feb. 2, 2017).

[6] *See* http://www.medscape.com/viewarticle/768031_5 (last viewed Feb. 2, 2017).

[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 Feb. 4, 2017).

[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.

[10] See https://www.cms.gov/cciio/resources/data-resources/ehb.html (last visited Feb. 2, 2017) for Florida's benchmark plan.

[11] Center for Consumer Information and Insurance Oversight (CCIIO), Centers for Medicare & Medicaid Services (CMS), *2018 Letter to Issuers in the Federally-facilitated Marketplaces* (Dec. 16, 2016), p. 7, *available at* https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2018-Letter-to-Issuers-in-the-Federally-facilitated-Marketplaces.pdf. (last viewed Feb.2, 2017).

[12] President Trump, Executive Order 13765, *Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal* (Jan. 20, 2017). President Trump issued an executive order indicating that it is the intent of his administration to seek the prompt repeal of PPACA.

benchmark plan. Issuers must have a Pharmacy and Therapeutics Committee 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.[13]

An issuer does not provide EHBs if its benefit design discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.[14] Issuers of QHPs may not employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in QHPs.[15]

Changes in Medicare Part D Formularies

Medicare Part D[16] plans may alter their formularies from year to year, and in limited circumstances, to make changes to their formularies within a plan year.[17] Plans may not change therapeutic categories and classes of drugs within a plan year, except to account for new therapeutic uses or to add newly approved Part D drugs. If Part D plans remove drugs from their formularies during a plan year (or change cost-sharing or access requirements), they must provide timely notice to the Centers for Medicare and Medicaid Services (CMS), affected enrollees, physicians, pharmacies, and pharmacists.

Formulary changes are allowed in limited circumstances. Plans may immediately remove drugs from their formularies that are deemed unsafe by the FDA or are pulled from the market by their manufacturers. Plans may make formulary maintenance changes after March 1, such as replacing a brand-name drug with a new generic drug or modifying formularies because of new information on safety or effectiveness. These changes require CMS approval and 60 days' notice to appropriate parties.

The CMS will generally give positive consideration to formulary maintenance changes such as expanding formularies by adding drugs, moving a drug to a lower tier (thereby reducing copayments or coinsurance), or eliminating utilization management requirements. Plans may only remove drugs from a formulary, move covered drugs to a less-preferred tier status, or add utilization management requirements in accordance with approved procedures and after 60 days'

[13] 45 C.F.R. s. 156.122.
[14] 45 C.F.R. s. 156.125.
[15] 45 C.F.R. s. 156.225.
[16] 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.
[17] Centers for Medicare and Medicaid, *Medicare Prescription Drug Benefit Manual*, Chapter 6, (Jan. 15, 2016) available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. (last viewed Feb. 2, 2017).

notice to appropriate parties. Plans may make such changes only if enrollees currently taking the affected drugs are exempt from the formulary change for the remainder of the plan year.

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.[18] The Agency for Health Care Administration (agency) 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 agency.[19]

Currently, under the Insurance Code, 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 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.[20]

Florida' State Group Insurance Program

Under the authority of s. 110.123, F.S., the Department of Management Services (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). 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.

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. Generally, prescriptions written for a brand name drug, preferred or non-preferred, will be substituted with a generic drug when available. If the prescribing provider states on the prescription that the brand name drug is "medically necessary" over the generic equivalent, the member will pay only the brand name (preferred or non-preferred) cost share. If the member requests the brand name drug over the generic

[18] Section 20.121(3), F.S.
[19] Section 641.21(1), F.S.
[20] Section 641.31(36), F.S.

equivalent then the member will pay the brand name, (preferred or non-preferred) cost share plus the difference between the cost of the generic drug and the brand name drug.

The 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. Specialty drugs are high-cost prescription medications used to treat complex, chronic conditions such as cancer, rheumatoid arthritis and multiple sclerosis. Specialty drugs often require special handling (e.g., refrigeration during shipping) and administration (such as injection or infusion).

The federal out-of-pocket limit applies to members of the state group self-insured health plans and insured HMOs, all of which include prescription drug coverage. Copayments (and coinsurance for high deductible plans) for each drug tier are the same for all members, as follows:

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

The program typically makes benefits changes on a plan year basis, which is January 1 through December 31.[21]

Health Insurance Mandate Report

Section 624.215, F.S., requires that a report assessing the social and financial impact of any proposal for legislation that mandates health benefit coverage or mandates offering requirements must be submitted to Agency for Health Care Administration and the legislative committee having jurisdictions.

According to a report provided by advocates of the bill, the bill will not increase coverage of drug benefits or the total cost of health care. [22] 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. According to the report, there is no indication that the bill will have an impact on the cost of coverage. Advocates cite studies that document that some nonclinical drug substitutions may increase overall health care costs and result in adverse outcomes.

[21]Department of Management Services, *2017 Agency Legislative Bill Analysis of SB 182* (Jan. 19, 2017) (on file with Senate Committee on Banking and Insurance Committee).
[22] *Non-Medical Switching, Health Insurance Mandate Report* (Jan. 2017) (on file with Senate Committee on Banking and Insurance Committee).

Regulation of Prescription Drug Formularies Changes in Other States

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 is required to each affected covered employer and enrollee, or individual.[23] California prohibits changes in cost sharing designs during the plan or policy year, except when such change is required by state or federal law.[24] 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.[25] New Mexico generally limits when health insurance policies may change prescription drug coverage, with exceptions, and requires prior notification of all affected enrollees.[26] Virginia requires insurers to establish a process for insureds to obtain continued access to drugs that they have been receiving for at least six months prior to a formulary change at a cost-sharing level that is no higher than the level imposed on formulary drugs.[27] Texas prohibits insurers and HMOs from making mid-year formulary benefit and cost-sharing changes.[28]

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.

SB 182 amends the Insurance Code to provide additional consumer protections by prohibiting a health insurer or health maintenance organization (HMO) from removing a covered drug from its formulary during the policy year except during open enrollment with some limited exceptions. These provisions would apply to individual and group policies and contracts. An insurer or health maintenance organization (HMO) may remove a prescription drug from its list of covered drugs during the policy year if:

- The United States 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 United States Food and Drug Administration of a manufacturing discontinuance or potential discontinuance of the drug as required by s. 506C 32 of the of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s. 356c.

SB 182 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.

SB 182 also:

- Does not prohibit the addition of prescription drugs to the list of drugs covered under the policy during the policy year.

[23] La. Admin. Code title 37, pt. XIII, ss. 14111, 14115, and 14117.
[24] Chapter 192, Statutes of 2016. Approved by the Governor August 25, 2016.
[25] Nevada Division of Insurance, *Adopted Regulation R074*-14 (uncodified).
[26] N.M. Stat. ss. 59A-22-49.4, 59A-23-7.13, 59A-46-50.4, and 59A-47-45.4.
[27] *See* Va. Code Ann. s. 38.2-3407.9.01.
[28] Tex. Ins. Code ss. 1369.0541 and 1501.108.

- Does not alter or 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 alter or 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 benefits set forth in s. 627.6513(1)-(14), F.S.

Section 4 provides the bill is effective January 1, 2018.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The county/municipality mandates provision of Art. 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 does not provide a finding that the bill fulfills an important state interest.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

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 allow insureds to receive their brand drugs at a preferred cost for the policy year. Currently, the Insurance Code only prohibits HMO group contracts from increasing a member's copayment for any benefit or reducing a benefit during a plan year with some exceptions.

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)[29] self-insured plans, which represent approximately 50 percent of the insureds in Florida. ERISA preempts the regulation of such plans by state regulation.

C. Government Sector Impact:

Division of State Group Insurance

The bill provides limitations on changes in formularies by allowing insureds to continue to obtain specified brand drugs at a "preferred" cost share throughout a calendar year; as a result, SB 182 prohibits the State Employees' Prescription Drug Plan from obtaining lower costs, even when the PBM negotiates better pricing and rebates for equally clinically effective brand and generic drugs. The PBM states for the three quarterly formulary updates in 2016, approximately 1,100 of 139,000 drug plan users were impacted.

The DSGI indicates that the bill will have indeterminate and substantial negative fiscal impact.[30] The severity of the impact would be contingent on the number of brand drugs that are required to remain on the preferred drug list when other, less expensive, interchangeable and clinically appropriate brand and generic drugs are available. The DSGI notes, that not only would the cost of the medication be higher for the prescription drug program, but also the rebates from manufacturers to the program would be reduced significantly. The PBM provided the following estimates regarding the recurring impact on the DSGI:

- An additional cost of drugs to the State of Florida of $50,000.
- Loss of manufacturers' rebates to the State of Florida of $9.2 million.

Florida Medicaid Program

According to the Agency for Healthcare Administration, the bill has no fiscal impact on the Florida Medicaid program since it does not amend ch. 409, F.S., governing Florida Medicaid, nor does it require Medicaid to amend existing policies or procedures.[31]

[29] 29 U.S.C. 1001 et seq. (1974).
[30] Department of Management Services, *2017 Agency Legislative Bill Analysis of SB 182* (Jan. 19, 2017) (on file with Senate Committee on Banking and Insurance Committee).
[31] Email from Tony Guzzo, Agency for Healthcare Administration (Feb. 1, 2017) (on file with Senate Committee on Banking and Insurance).

VI. Technical Deficiencies:

Lines 113-114 reference the terms, “continuity of care” and “medically stable patients,” which are not defined in the bill.

For group HMO contracts, the requirements of Section 3 of the bill, which creates subsection (46) of s. 641.31, F.S., may duplicate or create ambiguity with some of the provisions of existing s. 641.31(36), F.S. For example, s. 641.31(36), F.S. allows an HMO to 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. SB182 allows changes in the formulary and out-of-pocket costs to occur during open enrollment. The PPACA open enrollment occurs November 1, 2017 through January 31, 2017. However, the PPACA plan year is typically January 1 through December 31.

VII. Related Issues:

None.

VIII. Statutes Affected:

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

This bill creates section 627.42392 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.