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 1142
INTRODUCER:	Banking and Insurance Committee and Senator Hays
SUBJECT:	Treatments for Stable Patients
DATE:	February 4, 2016 REVISED:

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1142 amends the Insurance Code to allow an insured individual living with a complex or chronic medical condition or rare disease to continue to receive their brand drugs at a preferred cost for the calendar year. Currently, health insurers and pharmacy benefit managers often change their prescription drug formularies during the year as they respond to new drugs becoming available or changes in prices by drug manufacturers. As a result, certain prescription drugs may become more costly or unavailable to consumers during a plan year when they are unable to switch to a different health insurance plan.

The bill prohibits any pharmacy benefit manager (PBM) and any individual or group health insurance policy or HMO contract from limiting or excluding coverage for a drug for an insured with a complex or chronic medical condition or a rare disease if:

- The drug was previously approved for coverage by the insurer for a medical condition or disease; and
- The prescribing provider continues to prescribe the drug for the medical condition or disease; and the drug is appropriately prescribed and considered safe and effective for treating the insured's medical condition.

For any drug used to treat a complex or chronic medical condition or a rare disease that has been previously approved for coverage, the bill prohibits a health insurer, HMO or PBM from engaging any of the following activities, except during open enrollment periods:

- Placing limitations on the maximum coverage of prescription drug benefits;

- Increasing the out-of-pocket costs paid by the insured for the drug; and
- Moving the drug to a disadvantaged tier.

The Division of State Group Insurance indicates that the bill will have an indeterminate negative fiscal impact.

II. Present Situation:

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.[1] 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.[2] As part of the certification process used by the agency, an HMO must provide information to demonstrate that the HMO has the ability to provide quality of care consistent with the prevailing standards of care.[3] The OIR does not regulate or license pharmacy benefit managers.

Florida' State Group Insurance Program

Under the authority of s. 110.123, F.S., the Department of Management Services (DMS), through the Division of State Group Insurance, 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 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 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.

[1] Section 20.121(3)(a)1., F.S.
[2] Section 641.21(1), F.S.
[3] Section 641.495, F.S.

The program has no formulary management or other prescription drug management protocols, 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, without preference to health status, 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.

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.[4] The PPACA provides fundamental changes to the U.S. health care system by requiring 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 imposes many insurance requirements including required essential health benefits, rating and underwriting standards, review of rate increases, and internal and external appeals of adverse benefit determinations.[5] Section 1302 of the PPACA requires health plans that are required to provide coverage of essential health benefits (EHB), meet cost-sharing limits, and actuarial value requirements. The law directs that EHBs cover at least 10 specified categories, which includes prescription drugs.[6]

[4] 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. Pub. Law No. 111-148.
[5] Most of the insurance regulatory provisions in PPACA amend Title XXVII of the Public Health Service Act (PHSA), (42 U.S.C. 300gg *et seq*.).
[6] See https://www.cms.gov/cciio/resources/data-resources/ehb.html (last visited Feb. 4, 2016) for Florida's benchmark plan.

Prescription Drug Coverage

Currently, for purposes of a health plan complying with the essential health benefits, insurers and HMOs 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 essential health benefit (EHB) benchmark plan. For plan years beginning on or after January 1, 2017, plans must also use a Pharmacy and Therapeutics Committee (P&T) process that meets certain requirements. The P&T committee must 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.[7]

Formulary Drug List

The regulations require a health plan must publish an up-to-date and complete list of all covered drugs on its formulary drug list, including any tiered structure and any restrictions on the manner in which a drug can be obtained, in a manner that is easily accessible to plan enrollees, prospective enrollees, the state, the marketplace, HHS, and the public. Additionally, insurers and HMOs must also make this information available in a standard-readable format to provide the opportunity for third parties to create resources that aggregate information on different plans.

Drug Exceptions Process

Under current HHS regulations, 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 based on exigent circumstances. Under this expedited process, the issuer must make its coverage determination no later than 24 hours after it receives the request. This requirement, commonly referred to as the "exceptions process," applies to drugs that are not included on the plan's formulary drug list. For plan years beginning in 2016, these processes must also include certain processes and timeframes for the standard review process, and have an external review process if the internal review request is denied. The costs of the non-formulary drug provided through the exceptions process count towards the annual limitation on cost sharing and actuarial value of the plan.[8]

Proposed HHS Notice of Benefit and Payment Parameters for 2017

According to the OIR, the tentative CMS deadline for insurers and HMOs for the submission of 2017 rates and forms to CMS and the OIR is May 11, 2016.[9]

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[7] 45 CFR s. 156.122.

[8] 45 C.F.R. s. 156.122(c). The drug exception process is distinct from the coverage appeals process, which applies if an enrollee receives an adverse benefit determination for a drug that is included on the plan's formulary drug list. The coverage appeals process has separate requirements for its external review process and allows for a secondary level of internal review before the final internal review determination for group plans. [45 C.F.R. s. 147.136]

[9] Center for Consumer Information and Insurance Oversight (CCIIO), Centers for Medicare & Medicaid Services (CMS), *Draft 2017 Letter to Issuers in the Federally-facilitated Marketplaces* (December 23, 2015), p. 9, *available at* https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-2017-Letter-to-Issuers-12-23-2015_508.pdf (last visited Feb.4, 2016).

Prescription Drug Cost Containment

Private-sector entities that offer prescription drug insurance coverage, such as employers, labor unions, and managed care companies, often hire pharmacy benefit managers (PBMs) to manage these insurance benefits. The PBMs engage in many activities to manage their clients' prescription drug insurance coverage. The PBMs assemble networks of retail pharmacies so that a plan sponsor's members can fill prescriptions easily and in multiple locations by just paying a copayment amount. The PBMs consult with plan sponsors to decide which drugs a plan sponsor will provide insurance coverage to treat each medical condition. The PBM manages this list of preferred drug products (formulary) for each of its plan sponsor clients. Consumers with insurance coverage are provided incentives, such as low copayments, to use formulary drugs.

Due to increasing health care expenditures, economic and financial uncertainties, as well as the development of new, more expensive technologies, insurers continue to look for cost containment methods. Further, greater payer demand for expenditure reductions will increase the pressure for therapeutic substitution in responding patients. However, 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.[10]

Non-Medical Switching of Prescription Drugs

Non-medical switching 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. A generic drug are copies of brand-name drugs and are the same in dosage form, safety, strength, route of administration, performance characteristics, and intended use.[11] Generic drugs must pass the same safety standards as a brand-name drug.

The second method of substitution involved products that have been deemed to have therapeutic equivalence with an originally prescribed medicine or therapy. These drugs will have a different chemical composition and use a different active ingredient than the originally prescribed drug.[12]

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.[13]

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[10] http://www.medscape.com/viewarticle/768031_5 (last visited Jan. 29, 2016).
[11] Federal Food and Drug Administration, *Understanding Generic Drugs* (last updated February 5, 2016) *available at* http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/default.htm (last visited Feb. 4, 2016).
[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 visited Feb. 4, 2016).
[13] 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-

Patients with rheumatic or immune disease who were identified as having switched anti-TNF agents for cost-influenced reasons showed a 62 percent increased likelihood of the need for additional treatment related to side effects of their new drug compared to 20 percent for patients who remained on the previous treatment.[14] For patients that were switched, there was a difference in the mean number of visits of 13 compared to 5.8 visits in the group that remained on stable treatment for the first 90 days.[15]

In 2007, a small national survey of nursing home administrators was conducted about the Medicare Part D prescription drug benefit and policies related to the potential clinical and cost implications of managing a pharmacy benefit for the long-term care population. More than 76 percent of the respondents said it was common for a resident's new drug to be less effective after a switch for formulary reasons.[16] Additionally, in 37 percent of switching situations, the side effects from the new drug created the need for a completely new medication to treat the side effect.[17] Nonmedical switches also increased administrative time and raised the overall risk of more costly outcomes.[18]

III. Effect of Proposed Changes:

Sections 1 and 2 create s. 627.42392 and subsection (44) of s. 641.31, F.S., and **Section 3** amends s. 627.6699, F.S.

The bill defines the term, "complex or chronic medical condition," as a physical, behavioral or development condition that does not have a known cure or that can be severely debilitating or fatal if left untreated or undertreated. The term, "rare disease," is defined to have the same meaning as provided in 42 U.S.C. s. 287a-1, a disease or condition that affects less than 200,000 persons in the United States.

The bill prohibits any pharmacy benefit manager (PBM) and any individual or group health insurance policy or HMO contract providing major medical coverage from limiting or excluding coverage for a drug for an insured with a complex or chronic medical condition or a rare disease if:

- The drug was previously approved for coverage by the insurer for a medical condition or disease of the insured,

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s/abstracts-2015/item/p354-analysis-of-outcomes-after-non-medical-switching-of-anti-tumor-necrosis-factor-agents.html?category_id=430 (last visited Feb. 4, 2016).

[14] Gibofsky A, et al., *Non-medical switch of anti-TNF agents may result in increased side effects, lack of efficacy,*(Paper #SAT0139), Presented at: European League Against Rheumatism Annual European Congress of Rheumatology; June 10-13, 2015; Rome), http://www.healio.com/rheumatology/psoriatic-arthritis/news/online/%7B4d3c5bb3-c81b-4f16-bf9c-6614e281f1d6%7D/non-medical-switch-of-anti-tnf-agents-may-result-in-increased-side-effects-lack-of-efficacy (last visited Feb. 4, 2016).

[15] Id.

[16] Bryan R. Cote, M.A., et al, *Impact of Therapeutic Switching in Long Term Care,* American Journal of Managed Care, (November 15, 2008) http://www.ajmc.com/journals/issue/2008/2008-11-vol14-n11sp/nov08-3703psp23-sp28/ (last visited Feb. 4, 2016).

[17] Id.

[18] Id.

- The prescribing provider continues to prescribe the drug for the medical condition or disease, and
- The drug is appropriately prescribed and considered safe and effective for treatment of the insured's medical condition or rare disease.

In addition, for any drug prescribed to an insured with a complex or chronic medical condition or a rare disease, the bill prohibits a health insurer, HMO or PBM from engaging any of the following actions, except during open enrollment periods:

- Placing limitations on the maximum coverage of prescription drug benefits,
- Increasing the out-of-pocket costs paid by the insured for the drug, and
- Moving the drug to a disadvantaged tier.

These provisions would not apply to a grandfathered health plan or to excepted benefits.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

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:

CS/SB 1142 allows insured individuals living with complex, chronic medical condition or rare diseases to continue to receive their brand drugs at a preferred cost for the calendar year. According to advocates of the bill, the bill will allow an insured individual who has been previously approved for a specific medication that is effective for stabilizing the patient to continue using the medication as long as he or she remains covered by the health plan.

C. Government Sector Impact:

Division of State Group Insurance

The bill will have an indeterminate negative fiscal impact.[19] The DMS indicates that the bill would allow an insured individual living with a complex or chronic medical condition or rare disease to continue to receive all their brand drugs at a "preferred" cost share throughout a calendar year, even when the PBM negotiates better pricing and rebates for interchangeable clinically appropriate brand drugs.

VI. Technical Deficiencies:

The provisions of the bill amend the Insurance Code and apply to insurers, HMOs, and pharmacy benefit managers. However, pharmacy benefit managers are not regulated under the Insurance Code.

The definition of the term, "complex or chronic conditions" may be difficult to interpret and implement. It is unclear which specific conditions would meet the definition.

VII. Related Issues:

According to the Office of Insurance Regulation, this bill partially addresses a consumer issue where an individual selects a plan based on the plan providing certain prescription drug benefits and the plan then changes its prescription drug benefits during the plan year. Under these types of situations, a consumer may face unexpectedly higher costs with an inability to switch to a different health insurance plan until the next open enrollment period. While an individual with a complex or chronic medical condition or rare disease may be more likely than the average person to select a health insurance plan based on the particular drug benefits of the plan, this issue is not limited to those with a complex or chronic medical condition or rare disease. As a result, the bill may be considered discriminatory as it seeks only to protect those with a complex or chronic medical condition or rare disease rather than all medical conditions.[20]

Pursuant to federal regulations, a group health plan is not required to provide coverage for any particular benefits to any group of similarly situated individuals. However, benefits provided under a plan must be uniformly available to all similarly situated individuals. Likewise, any restriction on a benefit or benefits must apply uniformly to all similarly situated individuals and must not be directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries (determined based on all the relevant facts and circumstances).[21]

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[19] Department of Management Services, *2016 Agency Legislative Bill Analysis* (Jan. 4, 2016) (on file with Senate Committee on Banking and Insurance).

[20] Office of Insurance Regulation, *2016 Agency Legislative Bill Analysis* (Dec. 29, 2015) (on file with Senate Committee on Banking and Insurance).

[21] 45 C.F.R. s. 146.121. For example, a plan may limit or exclude benefits in relation to a specific disease or condition, limit or exclude benefits for certain types of treatments or drugs, or limit or exclude benefits based on a determination of whether the benefits are experimental or not medically necessary, but only if the benefit limitation or exclusion applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries.

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.)

CS by Banking and Insurance on February 1, 2016:
The CS provides technical, conforming changes and revises the effective date of the bill from January 1, 2017, to January 1, 2018.

B. Amendments:

None.