HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1363 Consumer Protection from Nonmedical Changes to Prescription Drug Formularies
SPONSOR(S): Health Market Reform Subcommittee, Williamson
TIED BILLS: **IDEN./SIM. BILLS:** SB 1180

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Market Reform Subcommittee	13 Y, 1 N, As CS	Grabowski	Crosier
2) Insurance & Banking Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Spending on prescription drugs has risen sharply in the United States over the past decade. Insurers and health maintenance organizations (HMOs) use many cost containment strategies to manage drug spending and utilization. For example, plans may limit the quantity of a drug that they will cover over a certain period of time, require enrollees to obtain prior authorization from the plan before obtaining certain prescriptions, procedures or treatments, or require enrollees to first try a preferred drug before obtaining a more expensive drug.

For most branded drugs, there exists several similar or alternative products which can be either a generic or a therapeutically equivalent drug. Therapeutic interchange, or non-medical switching, is the practice of switching or dispensing drugs that are chemically distinct but therapeutically similar in terms of their efficacy, safety, and tolerability profiles. Non-medical switching is designed to achieve an improved or neutral outcome by using the new drug, while reducing overall treatment costs. However, non-medical switching of drugs can occasionally lead to adverse outcomes.

HB 1363 amends the Insurance Code by prohibiting a health insurer or HMO from removing a covered drug from its formulary during the policy year, with limited exceptions. Only in cases where the safety of a drug has been called into question by the U.S. Food and Drug Administration or where a drug may be discontinued in the near future will an insurer or HMO be permitted to remove coverage during the plan year.

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 prohibitions outlined in the bill apply only if an insurer or HMO secures an acquisition price for a drug that will be in effect for the entire plan year.

The bill does not prohibit the addition of prescription drugs to an insurer's formulary during the plan year, and it does not alter the ability of a pharmacist to dispense certain substitute drugs as provided in the Pharmacy Code.

The bill does not apply to health plans holding grandfathered status under the PPACA, nor does it apply to Medicaid managed care plans.

The bill would have an indeterminate negative fiscal impact to the State, by virtue of its applicability to the Division of State Group Insurance.

The bill provides an effective date of January 1, 2020.

FULL ANALYSIS

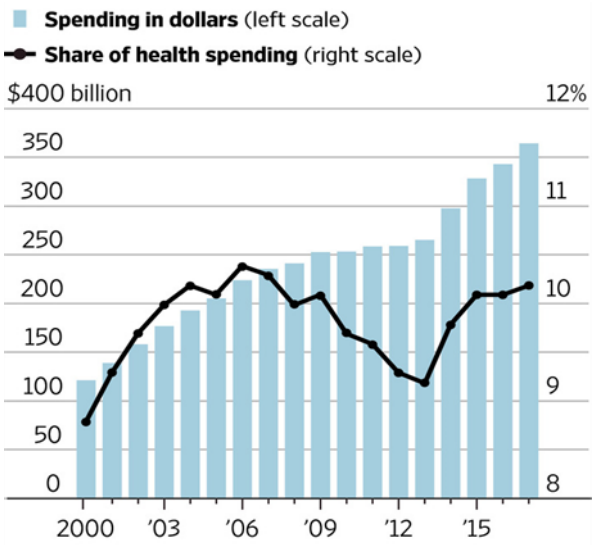
I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

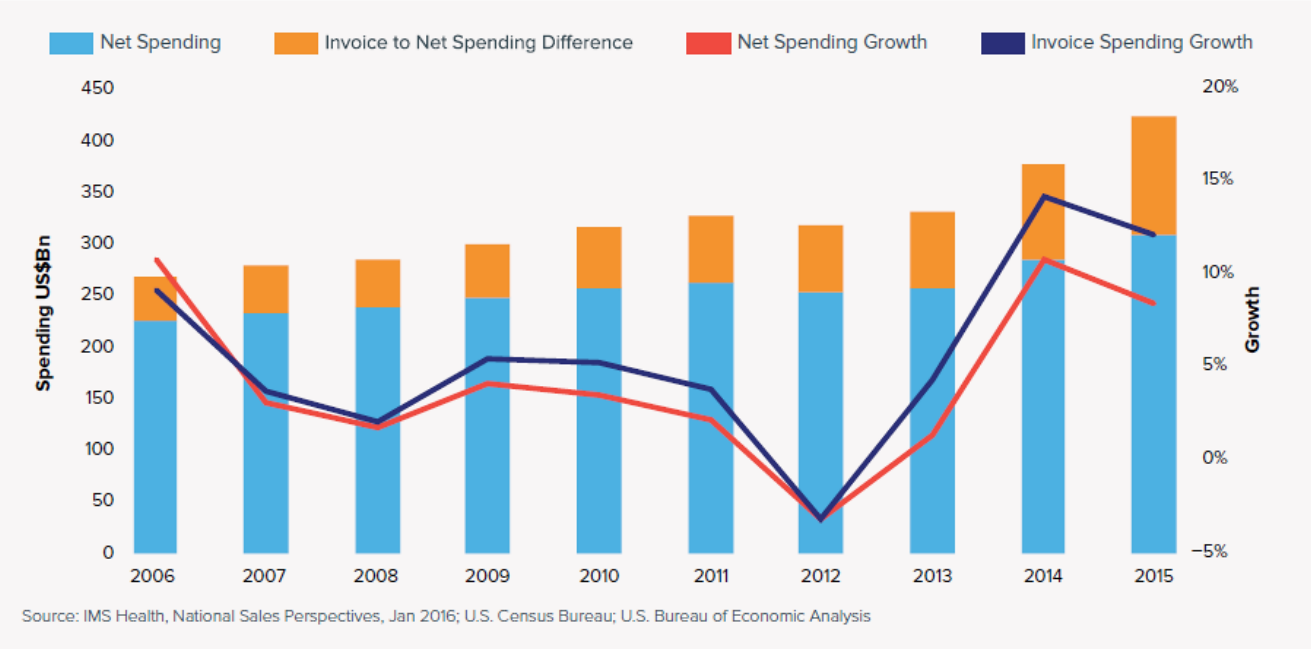
Spending on prescription drugs has risen sharply in the United States over the past few years.[1] From 2013 to 2015, out-of-pocket costs for prescription drugs rose 20 percent,[2] to an average cost of $44 per brand name prescription drug.[3] Additionally, prescription drug prices increased an average of almost 10 percent from June 2015 to May 2016.[4] Specialty prescription drug prices are projected to increase 14.3 percent in 2019, accounting for 35 percent of the prescription drug spending trend even though they represent a small minority of prescriptions.[5] Recent increases in prescription drug prices are not only an increase in spending in terms of dollars, but also as a percentage of total healthcare spending.[6]

Prescription Drug Spending as a Share of Health Spending 2000-2017[7]

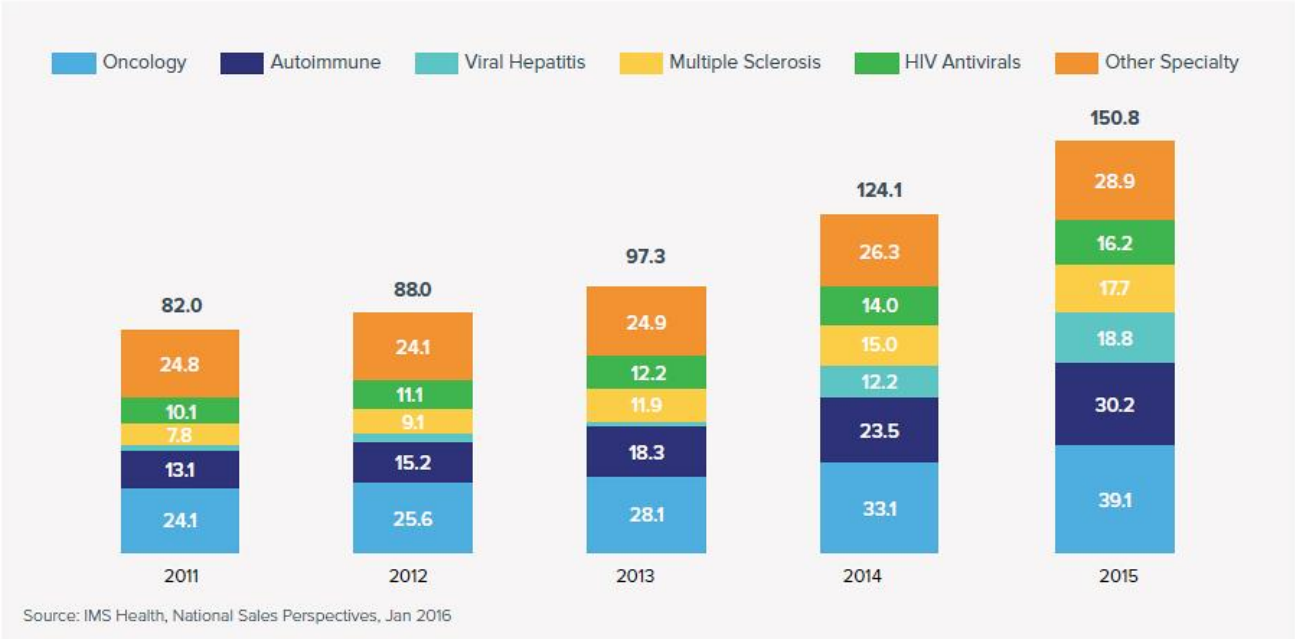


[1] Ameet Sarpatwari, Jerry Avorn, and Aaron S. Kesselheim, *State Initiatives to Control Medication Costs — Can Transparency Legislation Help?*, N. ENGL. J. MED. 2016; 374:2301-2304 Jun. 16, 2016, http://www.nejm.org/doi/full/10.1056/NEJMp1605100#t=article (last visited March 13, 2019).
[2] Troy Parks, *Drug pricing needs transparency, physicians say*, AMA WIRE, Jan. 26, 2017, https://wire.ama-assn.org/ama-news/drug-pricing-needs-transparency-physicians-say (last visited March 13, 2019).
[3] 2017 Segal Health Plan Cost Trend Survey, available at https://www.segalco.com/media/2716/me-trend-survey-2017.pdf (last visited March 13, 2019)
[4] TRUVERIS, *Americans faced double digit increases in prescription drug prices in 2014, according to Truveris National Drug Index*, https://truveris.com/press-releases/ndi-americans-faced-double-digit-increases-in-prescription-drug-prices-in-2014/ (last visited March 13, 2019)
[5] 2019 Segal Health Plan Cost Trend Survey, available at https://www.segalco.com/annual-health-plan-cost-trend-survey/2019/#PublicSector. (last visited March 13, 2019). Specialty drugs are high-cost prescription medications used to treat complex, chronic conditions and often require special handling and administration.
[6] CENTERS FOR MEDICARE AND MEDICAID SERVICES, *National Health Expenditures by Type of Service and Source of Funds: Calendar Years 1960 to 2015*, .zip file available at, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html (Last visited March 13, 2019).
[7] Jonathan D. Rockoff, *How Do We Deal With Rising Drug Costs?,* THE WALL STREET JOURNAL, Apr. 10, 2016, https://www.wsj.com/articles/how-do-we-deal-with-rising-drug-costs-1460340357 (last visited March 13, 2019).

Total U.S. Spending on Prescription Drugs, 2015[8]



Total U.S. Spending on Specialty Prescription Drugs, 2015[9]



[8] *Medicines Use and Spending in the U.S. – A Review of 2015 and Outlook to 2020,* QUINTILESIMS, APR. 2016, https://morningconsult.com/wp-content/uploads/2016/04/IMS-Institute-US-Drug-Spending-2015.pdf (last visited March 13, 2019).
[9] Id.

Health Insurance

Health insurance is the insurance of human beings against bodily injury or disablement by accident or sickness, including the expenses associated with such injury, disablement, or sickness.[10] Individuals purchase health insurance coverage with the purpose of managing anticipated expenses related to health or protecting themselves from unexpected medical bills or large health care costs. Managed care is the most common delivery system for medical care today by health insurers.[11] Managed care systems combine the delivery and financing of health care services by limiting the choice of doctors and hospitals.[12] In return for this limited choice, however, medical care is less costly due to the managed care network's ability to control health care services. Some common forms of managed care are preferred provider organizations[13] (PPO) and health maintenance organizations[14] (HMO).

Cost Containment in Health Insurance

Insurers use many cost containment strategies to manage medical and drug spending and utilization. For example, plans may place utilization management requirements on certain procedures and therapies and on the use of certain drugs on their formulary. These requirements can include limiting the quantity of drug that they will cover over a certain period of time, requiring enrollees to obtain prior authorization from their plan before filling a prescription (prior authorization), or requiring enrollees to first try a preferred drug to treat a medical condition before obtaining an alternate drug for that condition (step therapy).

Pharmacy Benefit Managers

Advances in pharmaceuticals have transformed health care over the last several decades. Many health care problems are prevented, cured, or managed effectively using prescription drugs. As a result, national expenditures for prescription drugs have grown from $121 billion in 2000 to $324.5 billion in 2016.[15] Health plan sponsors, which include commercial insurers, private employers, and government plans, such as Medicaid and Medicare, spent $277 billion on prescription drugs in 2015, while consumers paid $45.5 billion out-of-pocket for prescription drugs that year.[16]

Health plan sponsors contract with pharmacy benefit managers (PBMs) to provide specified services, which may include developing and managing pharmacy networks, developing drug formularies, providing mail order and specialty pharmacy services, rebate negotiation, therapeutic substitution, disease management, utilization review, support services for physicians and beneficiaries, and processing claims.[17] Payments for the services are established in contracts between health plan sponsors and PBMs.[18] For example, contracts will specify how much health plan sponsors will pay PBMs for brand name and generic drugs. These prices are typically set as a discount off the average

[10] S. 624.603, F.S.
[11] Florida Department of Financial Services, *Health Insurance and Health Maintenance Organizations, A Guide for Consumers,* available at http://www.myfloridacfo.com/Division/Consumers/understandingCoverage/Guides/documents/HealthGuide.pdf (last visited March 13, 2019).
[12] Id.
[13] S. 627.6471, F.S.
[14] Part I of chapter 641, F.S.
[15] Centers for Medicare and Medicaid Services, *National Health Expenditure Data, Historical,* available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html (last visited March 13, 2019).
[16] Id.
[17] Office of Program Policy Analysis & Government Accountability, *Legislature Could Consider Options to Address Pharmacy Benefit Manager Business Practices*, Report No. 07-08 (Feb. 2007), available at http://www.oppaga.state.fl.us/MonitorDocs/Reports/pdf/0708rpt.pdf (last visited March 13, 2019).
[18] Id.

wholesale price[19] for brand-name drugs and maximum allowable cost price for generic drugs, plus a dispensing fee.[20]

Prior Authorization

Under prior authorization, a health care provider is required to seek approval from an insurer before a patient may receive specified medical services or prescription drugs under the plan. For example, most insurers or PBMs will have a preferred drug list (PDL), which is an established list of one or more prescription drugs within a therapeutic class deemed clinically equivalent and cost effective. Prior authorization would limit an insured's ability to obtain another drug within the therapeutic class that is not part of the PDL without the insurer or PBM authorizing that drug.

Step Therapy Protocols

In some cases, plans require an insured to try one drug first to treat his or her medical condition before they will cover another drug for that condition. For example, if Drug A and Drug B both treat a medical condition, a plan may require doctors to prescribe the most cost effective drug, Drug A, first. If Drug A does not work for a beneficiary, then the plan will cover Drug B. This form of cost containment is commonly called step therapy. Step therapy is also known as fail-first as the insurer restricts coverage of expensive therapies unless patients have already failed treatment with a lower-cost alternative.

Researchers report that there is mixed evidence on the impact of step therapy policies.[21] A review of the literature found that there is little good empirical evidence for or against cost savings and utilization reduction.[22] Some studies suggest that step therapy policies have been effective at reducing drug costs without increasing the use of other medical services,[23] while other studies have found that step therapy can increase total utilization costs over time because of increased inpatient admissions and emergency department visits.[24]

Non-Medical Switching or Substitution of Prescription Drugs

For most medicines, there exists several similar or alternative products which can be either a generic or a therapeutically equivalent drug.[25] Therapeutic interchange, or non-medical switching, is the practice of switching or dispensing drugs that are chemically distinct but therapeutically similar in terms of their efficacy, safety, and tolerability profiles.[26] Non-medical switching is designed to achieve an improved or neutral outcome by using the new drug, while reducing overall treatment costs.[27]

Non-medical switching may include substituting a brand-name drug for its generic equivalent. Generic drugs are copies of brand-name drugs with the same dosage form, safety, strength, route of administration, performance characteristics, and intended use.[28] Non-medical switching may also

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[19] Average wholesale price is the retail list price (sticker price) or the average price that manufacturers recommend wholesalers sell to physicians, pharmacies and others, such as hospitals.
[20] Supra, FN 15.
[21] Rahul K. Nayak and Steven D. Pearson, *The Ethics Of 'Fail First': Guidelines and Practical Scenarios for Step Therapy Coverage Policies*, Health Affairs 33, No.10 (2014):1779-1785.
[22] Motheral, B.R., *Pharmaceutical Step Therapy Interventions: A Critical Review of the Literature*, Journal of Managed Care Pharmacy 17, no. 2 (2011) 143-55, available at http://www.jmcp.org/doi/pdf/10.18553/jmcp.2011.17.2.143 (last visited March 13, 2019).
[23] Supra, FN 21 at pg. 1780.
[24] Id.
[25] Rachel Chu, et al, *Patient Safety and Comfort - The Challenges of Switching Medicines* (2010), pg 8, *available at* http://www.patients-rights.org/uploadimages/Patient_Safety_and_Comfort_The_Challenges_of_Switching.pdf (last visited March 22, 2019).
[26] Flood, J., Mihalik, C., Fleming, R., Strober, B., Zucker, D. & Burgoyne, D., The Use of Therapeutic Interchange for Biologic Therapies, Managed Care Magazine, January 2007, p. 51. http://www.managedcaremag.com/archives/0701/0701.peer_switch.html (last visited March 22, 2019).
[27] Id.
[28] Federal Food and Drug Administration, *Understanding Generic Drugs* (last updated January 13, 2017) *available at* http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/default.htm (last visited March 22, 2019).

involve products that have been deemed to have therapeutic equivalence with an originally prescribed medicine or therapy.[29] These drugs will have a different chemical composition and use a different active ingredient than the originally prescribed drug.[30]

One study reviewed reasons for adjusting anti-tumor necrosis (TNF) agents involving patients with rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, or ulcerative colitis. The study found that non-medical switching of anti-TNF agents was associated with an increase in side effects and lack of efficacy that led to an increase in health care utilization.[31]

Patients with rheumatic or immune disease who were identified as having switched anti-TNF agents for cost-based reasons showed a 62 percent greater likelihood for additional treatment related to side effects from the new drug compared to 20 percent for patients who remained on the previous treatment.[32] For patients that were switched within the first 90 days of treatment, the study found an increase, from 5.8 to 13, in the mean number of health care provider visits required for those patients.[33]

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 non-medical switch for formulary reasons.[34] 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.[35] Non-medical switches also increased administrative time and raised the overall risk of more costly outcomes.[36]

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.[37] 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[38] and other provisions.

The PPACA requires insurers and HMOs that offer qualified health plans (QHPs) to provide ten categories of essential health benefits (EHB), which includes prescription drugs.[39] In Florida, the federal Health Insurance Marketplace must certify such plans of an insurer or HMO as meeting the EHB and

[29] Id.
[30] Supra, FN 25 at pg. 9.
[31] 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 visited March 22, 2019).
[32] 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 March 22, 2019).
[33] Id.
[34] 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 March 22, 2019).
[35] Id.
[36] Id.
[37] The Patient Protection and Affordable Care Act (Pub. L. No. 111-148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. No. 111-152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010.
[38] 42 U.S.C. s. 18022
[39] See Center for Consumer Information & Insurance Oversight, *Insurance on Essential Health Benefits (EHB) Benchmark Plans* https://www.cms.gov/cciio/resources/data-resources/ehb.html (last visited March 13, 2019).

other requirements.[40] The federal deadline for insurers and HMOs to submit 2018 annual rates and forms to the Florida Office of Insurance Regulation was May 3, 2017.[41] Recently, the U.S. Department of Health and Human Services (HHS) proposed federal regulations that included provisions to provide states with additional flexibility in the definition of EHBs for 2019 and 2020 and increase affordability of health insurance for the individual and small group markets.[42]

Prescription Drug Coverage

For purposes of complying with the federal EHB for prescription drugs, plans 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. Plans must have a Pharmacy and Therapeutics Committee design formularies using scientific evident 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. The PPACA also requires plans to implement an internal appeals and independent external review process if an insured is denied coverage of a drug on the formulary.[43]

Plans are required to publish a current and complete list of all covered drugs on its formulary drug list, including any tiered structure and any restrictions on the way a drug can be obtained, in a manner that is easily accessible to insureds, prospective insureds, the state, and the public.[44] Restrictions include prior authorization, step therapy, quantify limits and access restrictions.[45]

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.[46] The Agency for Health Care Administration (agency) regulates the quality of care 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.[47] 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.[48]

All persons who transact insurance in the state must comply with the Code.[49] OIR has the power to collect, propose, publish, and disseminate any information relating to the subject matter of the Code,[50] and may investigate any matter relating to insurance.[51]

Florida State Employee 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 (DSGI), administers the state group insurance program by providing employee benefits such as health, life, dental, and vision insurance products under a cafeteria plan consistent with s. 125, Internal Revenue Code. To administer the state group health insurance

[40] Center for Consumer Information & Insurance Oversight, *Qualified Health Plans,* https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/qhp.html (last visited March 13, 2019).
[41] Office of Insurance Regulation, *Guidance to Insurers,* available at http://www.floir.com/sitedocuments/PPACANoticetoIndustry201802032017.pdf (last visited March 13, 2019).
[42] *See* Proposed Rule, 82 FR 51052 (Nov. 2, 2017) available at https://www.federalregister.gov/documents/2017/11/02/2017-23599/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2019 (last visited March 13, 2019).
[43] 45 C.F.R. s. 147.136
[44] 45 C.F.R. s. 156.122(d)
[45] According to CMS, this formulary drug list website link should be the same direct formulary drug list link for obtaining information on prescription drug coverage in the Summary of Benefits Coverage, in accordance with 45 CFR s. 147.00(a)(2).
[46] S. 20.121(3)(a), F.S.
[47] S. 641.21(1), F.S.
[48] S. 641.495, F.S.
[49] S. 624.11, F.S.
[50] S. 624.307(4), F.S.
[51] S. 624.307(3), F.S.

program, DMS contracts with third part administrators, HMOs, and a PBM for the state employees' prescription drug program pursuant to s. 110.12315, F.S.

The prescription drug program has three cost-share categories for members: generic drugs, preferred brand name drugs, which are those brand name drugs on the preferred drug list, and non-preferred brand name drugs, which are those brand name drugs not on the preferred drug list.[52] The PBM for the 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.[53]

The prescription drug program covers all federal legend drugs[54] for covered medical conditions, and employs very limited utilization review and clinical review for traditional or specialty prescription drugs.[55] Copayments and coinsurance for high deductible plans for each drug tier are the same for all members, as follows:[56]

State Group Health Prescription Drug Co-payments		
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

Effect of Proposed Changes

HB 1363 amends the Insurance Code by prohibiting a health insurer or HMO from removing a covered drug from its formulary during the policy year, with limited exceptions. These provisions 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 only 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 prohibitions outlined in the bill apply only if an insurer or HMO secures an acquisition price for a drug that will be in effect for the entire plan year.

The bill does not prohibit the addition of prescription drugs to an insurer's formulary during the plan year, and it does not alter the ability of a pharmacist to dispense certain substitute drugs as provided in ss. 465.025 and 465.0252, F.S.

[52] S. 110.12315(a), F.S.
[53] Department of Management Services, *2019 Agency Analysis of Senate Bill 1180,* pg. 2, (March 6, 2019).
[54] "Legend drug" means a drug that is approved by the FDA and is available by prescription only. These drugs historically contained an inscription, or legend, denoting them as prescribed. Today, they typically state "Rx Only."
[55] Supra, FN 53.
[56] Id.

The bill does not apply to health plans holding grandfathered status under the PPACA, nor does it apply to Medicaid managed care plans.

The bill provides an effective date of January 1, 2020.

B. SECTION DIRECTORY:

Section 1: Creates s. 627.42393, F.S., relating to insurance policies; limiting changes to prescription drug formularies.
Section 2: Amends s. 627.6699, F.S., relating to the Employee Health Care Access Act.
Section 3: Amends s. 641.31, F.S., relating to health maintenance contracts.
Section 4: Indicates that the Legislature finds the act fulfills an important state interest.
Section 5: Provides an effective date of January 1, 2020.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill would have an indeterminate negative fiscal impact on the DSGI. The significance of the impact would be contingent on whether the contracted PBM is able to negotiate stable drug prices for a given plan year, which would then activate the prohibitions on mid-year formulary changes. Requiring the DSGI to maintain brand name drugs on the preferred list when other less expensive drugs are available could increase the aggregate drug costs incurred by the program.[57]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   Local governments could see an increase in the cost of prescription drug coverage for their employees.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

By limiting changes to the prescription drug formulary, the bill may allow insureds to maintain their prescribed brand drugs at a preferred cost for the policy year.

D. FISCAL COMMENTS:

None.

[57] Supra, FN 53 at pg. 3.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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. The bill requires health insurers and HMOs to limit changes to drug formularies and cost-sharing during a plan year, provided that those entities secure stable drug acquisition prices, which could lead to spending by local governments; however, an exemption may apply because the bill applies to all persons similarly situated.

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.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Current law provides OIR with sufficient rule-making authority to execute the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 26, 2019, the Health Market Reform Subcommittee adopted an amendment to the bill. The amendment specifies that the prohibition on mid-year changes to drug formularies and patient cost-sharing applies only if an insurer or HMO secures an acquisition price for a prescription drug that will be in effect for the entire plan year.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute as passed by the Health Market Reform Subcommittee.