HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 95 Consumer Protection from Nonmedical Changes to Prescription Drug Formularies
SPONSOR(S): Health Innovation Subcommittee, Massullo, MD and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 182

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	13 Y, 0 N, As CS	Tuszynski	Poche
2) Insurance & Banking Subcommittee			
3) Appropriations Committee			
4) Health & Human Services Committee			

SUMMARY ANALYSIS

Spending on prescription drugs has risen sharply in the United States over the past few years. From 2013 to 2015, out-of-pocket costs for prescription drugs increased 20 percent. Additionally, prescription drug prices surged an average of almost 10 percent from June 2015 to May 2016.

In an attempt to contain prescription drug costs, insurers and pharmacy benefits managers (PBMs) manage lists of preferred drug products, known as formularies, in their plans. These formularies are typically three "tiered" formularies, meaning that the health plan enrollee or member would pay the lowest copayment for the first tier of prescription drugs, which are usually generics, a somewhat higher copayment for the second tier of prescription drugs, which are usually preferred brand name drugs without a generic equivalent, and the highest copayment for the third tier of drugs, usually non-preferred brand drugs or brand drugs with a generic equivalent. Insurers and PBMs employ a variety of formulary management techniques to contain prescription drug costs.

For most medicines, there exists several similar or alternative products; these can be either 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. The stated goal of non-medical switching is to achieve an improved or neutral outcome with the new drug while reducing overall treatment costs. However, some studies show that non-medical switching can cause increased side-effects and lower efficacy for prescribed conditions, leading to increased health care utilization and an overall increase in health care costs.

CS/HB 95 prohibits an individual or small group health insurer or a health maintenance organization (HMO) from removing a prescription drug from the formulary during the policy year. The bill provides two exceptions to this restriction: a prescription drug may be removed from the formulary during the policy year if the Food and Drug Administration (FDA) issues a statement questioning the safety of the drug or the manufacturer of a drug notifies the FDA that it is no longer manufacturing the drug or potentially plans on not manufacturing the drug. The bill permits changes to the formulary at the time coverage is renewed with the insurer or HMO.

The bill prohibits during a policy year an individual or small group health insurer or HMO from reclassifying a prescription 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 a prescription drug, or reclassifying a drug to a higher cost-sharing tier. The bill permits prescription drugs to be added to the list of covered prescription drugs during the policy year.

The provisions of the bill do not apply to the State Group Insurance Program, grandfathered health plans as defined under s. 627.402, F.S., or to limited benefit insurance products listed in s. 627.6513, F.S. Finally, the bill does not inhibit a pharmacist from substituting a generically equivalent drug for a brand name drug or dispensing a substitute biological product for the prescribed biological product.

The bill does not appear to have a fiscal impact on state or local government.

The bill provides an effective date of January 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

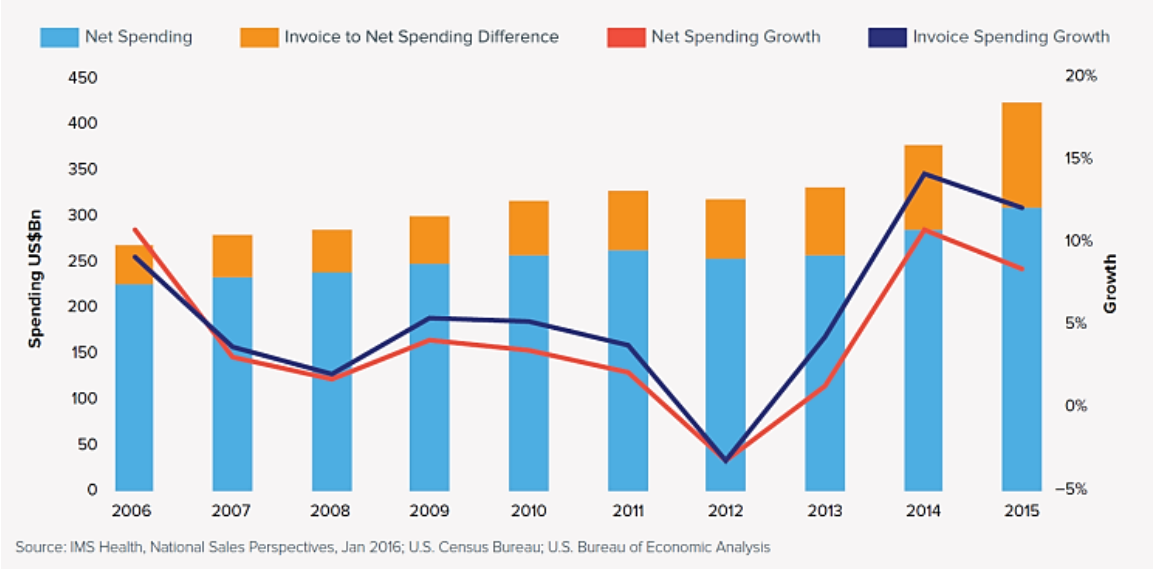
A. EFFECT OF PROPOSED CHANGES:

Present Situation

Prescription Drug Cost and Pricing

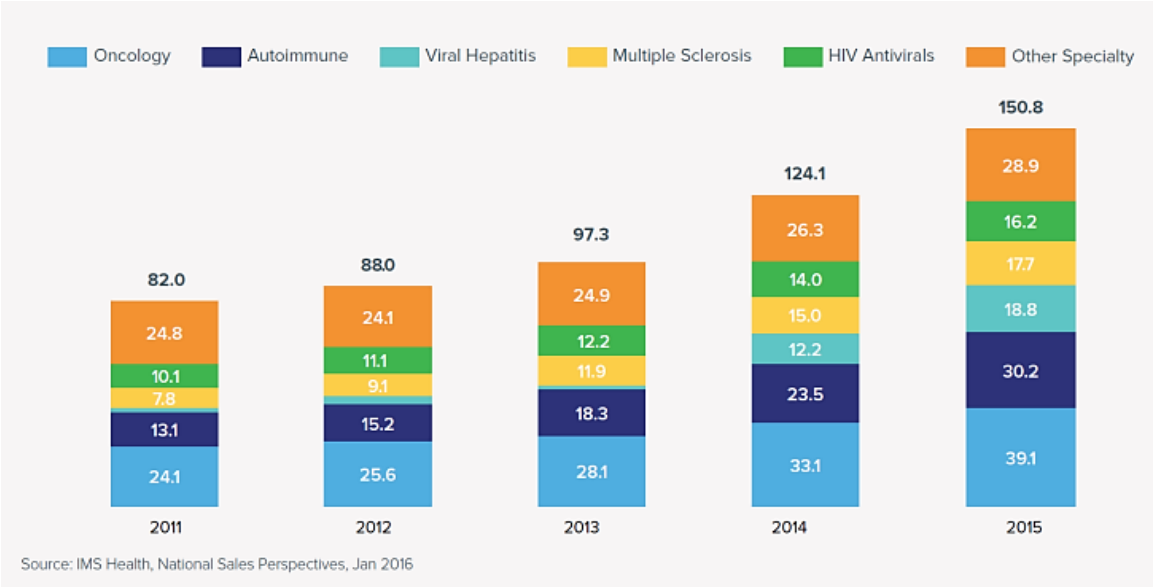
Spending on prescription drugs has risen sharply in the United States over the past few years.[1] From 2013 to 2015, out-of-pocket costs for prescription drugs surged 20 percent,[2] rising to an average cost of $44 per brand name prescription drug.[3] Additionally, prices increased an average of almost 10 percent from June 2015 to May 2016.[4] Specialty prescription drug prices are projected to increase 18.7 percent in 2017, accounting for 35 percent of the prescription drug spending trend even though they account for less than one percent of prescriptions.[5] Recent increases are not only an increase in spending in terms of dollars, but also as a percentage of total healthcare spending.[6]

Total Spending on Prescription Drugs[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 February 18, 2017).
[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 February 18, 2017).
[3] Beth Braverman, *Prescription Drug Prices Headed for Double-Digit Increases in 2017*, THE FISCAL TIMES, Oct. 24, 2016, http://www.thefiscaltimes.com/2016/10/24/Prescription-Drug-Prices-Headed-Double-Digit-Increases-2017 (last visited February 18, 2017).
[4] Brad Tuttle, *Prescription Drug Prices in America Are Rising Like No Other Industry*, TIME, Jul. 14, 2016, http://time.com/money/4406167/prescription-drug-prices-increase-why/ (last visited February 18, 2017)
[5] Supra, FN 3. Specialty drugs are high-cost prescription medications used to treat complex, chronic conditions and often require special handling and administration.
[6] 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 February 18, 2017).
[7] *Medicines Use and Spending in the U.S. – A Review of 2015 and Outlook to 2020,* QUINTILESIMS, APR. 2016, http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2015-and-outlook-to-2020 (last visited February 18, 2017).

Spending on Specialty Prescription Drugs[8]



Pharmaceutical companies take into account a number of factors, including the market for the particular drug, the cost of comparative treatments, research and development costs, the price of manufacturing and ingredients, and profit maximization when deciding what price to set for their drugs.[9] The costs associated with developing a new prescription drug can be very high. A recent analysis by the Tufts Center for the Study of Drug Development of the average cost to develop and gain marketing approval for a new drug estimated the cost at $2.558 billion, and noted that when post-approval research and development activities were included, the cost rose to $2.870 billion.[10] The following factors increased clinical costs for prescription drug development:

- Increased clinical trial complexity;
- Larger clinical trial sizes;
- Higher input costs from the medical sector;
- Changes in protocol design to include efforts to gather health technology assessment information; and
- Testing on comparator drugs to accommodate payer demands for comparative effectiveness data.[11]

Per capita prescription drug spending in the United States exceeds that in all other countries, largely driven by brand-name drug prices that have been increasing in recent years at rates far beyond the consumer price index.[12]

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, and greater efficacy.[13] However, the financial

[8] Id.
[9] *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System*, Special Committee On Aging, United States Senate (Dec. 2016), *available at,* https://www.collins.senate.gov/sites/default/files/DP%20Report.pdf (last visited February 18, 2017).
[10] Joseph A. DiMasi, Henry G. Grabowski, and Ronald W. Hansen, *Innovation in the pharmaceutical industry: New estimates of R&D costs*, Journal of Health Economics, Volume 47, pp. 20-33 (May 2016).
[11] Id.
[12] Aaron S. Kesselheim, Jerry Avorn, and Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform,* JAMA. 2016;316(8):858-871. doi:10.1001/jama.2016.11237.
[13] *See* HEALTH AFFAIRS 35, No. 9 (2016): 1595-1603, http://content.healthaffairs.org/content/35/9/1595.full.

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

Formularies

Employers, labor unions, and managed care companies that offer insurance coverage for prescription drugs often hire pharmacy benefit managers (PBMs) to manage the benefits.[14] A PBM uses many techniques to manage prescription drug insurance coverage, which are included in the contract between the PBM and the employer, union, or managed care company. For example, a PBM assembles networks of retail pharmacies so that plan members can fill prescriptions easily and in multiple locations. A PBM will also consult with a plan sponsor to decide which drugs to include in the coverage benefit to treat each medical condition.[15]

A PBM also manages a list of preferred drug products, known as a formulary, to contain the cost of prescription drugs. A formulary is typically divided into three "tiers", meaning that a member would pay the least amount of copayment for the first tier of drugs, which are usually generics, a somewhat higher copayment for the second tier of drugs, usually preferred brand drugs without a generic equivalent, and the highest copayment for the third tier of drugs, usually non-preferred brand drugs or those brand drugs with a generic equivalent.[16]

Non-Medical Switching of Prescription Drugs

For most medicines, there exists several similar or alternative products which can be either a generic or a therapeutically equivalent drug.[17] 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.[18] Non-medical switching is designed to achieve an improved or neutral outcome by using the new drug, while reducing overall treatment costs.[19]

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.[20] Non-medical switching may also involve products that have been deemed to have therapeutic equivalence with an originally prescribed medicine or therapy.[21] These drugs will have a different chemical composition and use a different active ingredient than the originally prescribed drug.[22]

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

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[14] Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies*, August 2005, pg. 1, available at https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitrpt_0.pdf (last accessed February 18, 2017).
[15] Id.
[16] Id. at pg. 11.
[17] 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 February 18, 2017).
[18] 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 accessed February 18, 2017).
[19] Id.
[20] 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 February 18, 2017).
[21] Id.
[22] Supra, FN 17 at pg. 9.

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.[23]

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.[24] 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.[25]

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.[26] 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.[27] Non-medical switches also increased administrative time and raised the overall risk of more costly outcomes.[28]

Drug Patents and Exclusivity

The Constitution of the United States provides for the protection of intellectual property:

> "Congress shall have power . . . to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."[29]

The United States Patent and Trademark Office (PTO) grants patents to inventors excluding any other from making, selling, or using an invention throughout the United States for a set time period.[30] Generally, the PTO grants patents for a term of 20 years from the date of the patent application.[31] The Food and Drug Administration (FDA) recognizes certain patents that are eligible for protection during the new drug application and approval process: [32]

- Active ingredient;
- Formulation/composition;
- Particular approved indication or method; and
- Certain other patents, such as polymorphs and metabolites of drug substances. [33]

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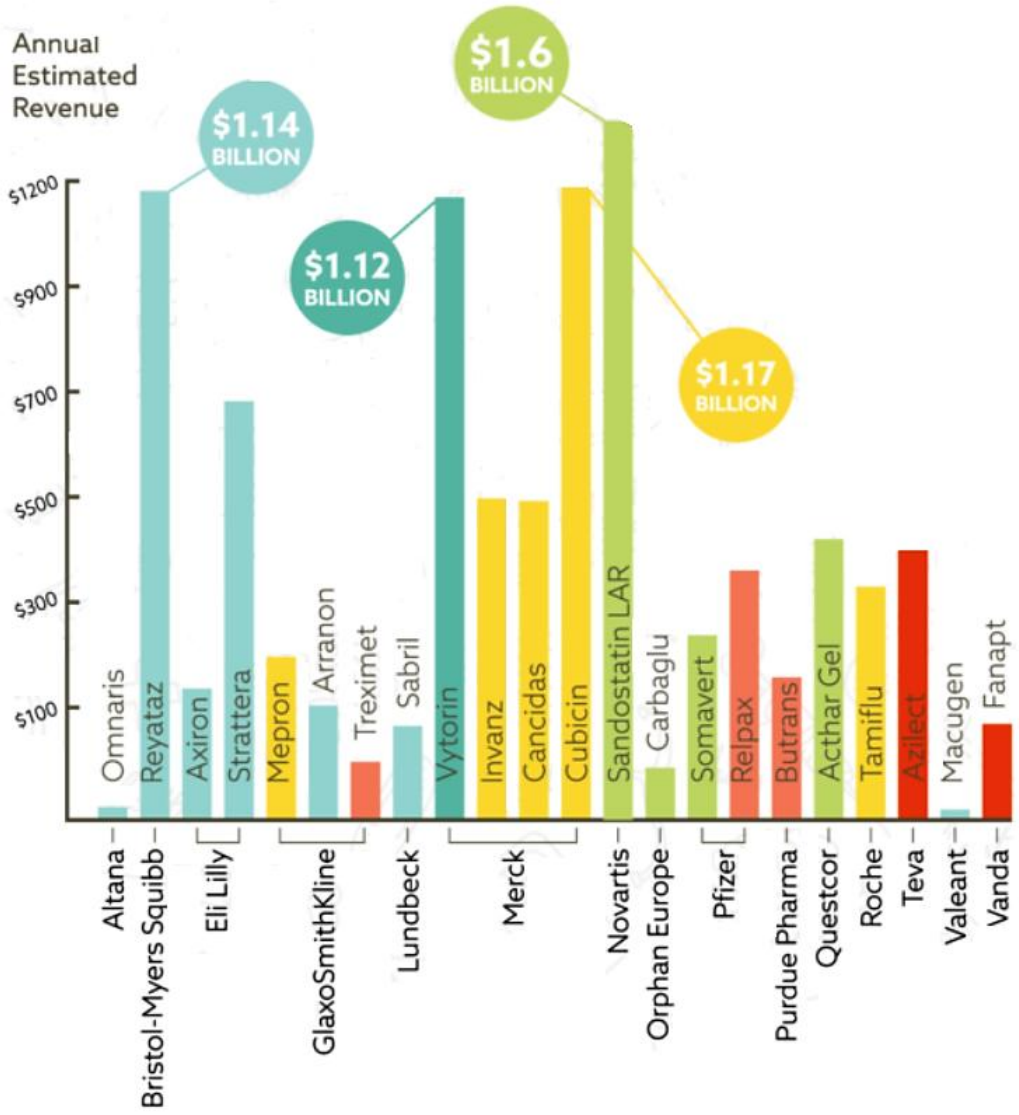
[23] D.T. Rubin, et al, *Analysis of outcomes after non-medical switching of anti-tumor necrosis factor agents,* European Crohn's and Colitis Organisation (2015) *available at* https://www.ecco-ibd.eu/index.php/publications/congress-abstract-s/abstracts-2015/item/p354-analysis-of-outcomes-after-non-medical-switching-of-anti-tumor-necrosis-factor-agents.html?category_id=430 (last visited February 18, 2017).
[24] 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 accessed February 18, 2017).
[25] Id.
[26] 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 February 18, 2017).
[27] Id.
[28] Id.
[29] U.S. CONST. art. I, s. 8.
[30] 35 U.S.C. s. 154(a)(1).
[31] 35 U.S.C. s. 154(a)(2).
[32] United States Patent and Trademark Office, *General information concerning patents*, available at https://www.uspto.gov/patents-getting-started/general-information-concerning-patents (last accessed February 23, 2017).
[33] Polymorphism refers to the occurrence of different crystalline forms of the same drug substance and metabolites are compounds created by the human body during the metabolism of a drug substance.

In addition to patent protections granted by the PTO, the FDA has the ability to grant "exclusivity" to drugs by implementing delays and prohibitions on the approval of competitor drugs.[34] The purpose of exclusivity is to promote a balance between new drug innovation and generic drug competition.[35] Exclusivity can be granted for terms as short as 180 days (patent challenges) to as long as 7 years (orphan drugs[36]).[37] Patents attach regardless of approval status, whereas exclusivity only attaches upon approval of a drug.[38] Drugs may have both patent and exclusivity protections.[39]

Drugs Losing Patent Protection in 2017

Once a drug loses patent protection, a manufacturer may produce a generic equivalent version of the drug. According to some estimates, sales of generic equivalent drugs can account for a 90% reduction in sales of a formerly patented drug.[40] On average, generic equivalents cost 80-85% less than a patented drug.[41] Determining what drugs may come off patent in a given year is not a straightforward task. Drug companies have developed strategies to extend patents by securing second generation patents on drug products like polymorphs, new formulations, and new uses.[42] Even with this uncertainty, industry watchers expect 22 major drugs to lose patent protection in 2017, four of which have annual revenue of over $1 billion dollars each:[43]

[34] United States Food and Drug Administration, Drugs, *Frequently asked Questions on Patents and Exclusivity*, available at https://www.fda.gov/drugs/developmentapprovalprocess/ucm079031.htm#What_is_the_difference_between_patents_a (last accessed February 24, 2017).
[35] Id.
[36] 21 C.F.R. Part 316; Orphan drugs treat diseases and conditions that are so rare and so few individuals are affected that a pharmaceutical company may reasonably expect relatively small sales in comparison to the cost of developing the drug and consequently incur a financial loss. The extended exclusivity encourages pharmaceutical companies to develop drugs for such diseases and conditions by providing a timeframe within which research and development costs can be recouped and a profit can be realized.
[37] 21 C.F.R. Ss. 314.105 – 314.108.
[38] Supra, FN 34.
[39] Supra, FN 34.
[40] Dickson, *The Major Pharmaceuticals Losing Patent Protection in 2017*, January 5th, 2017, available at http://blog.dicksondata.com/2017/01/drugs-losing-patent-protection-in-2017/ (last accessed February 25, 2017).
[41] Id.
[42] Gupta, H., et. al., *Patent Protection Strategies*, J Pharm Bioallied Sci. 2010 Jan-Mar; 2(1): 2–7, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3146086/ (last accessed February 27, 2017).
[43] Id. In order of annual estimated revenue, Sandostatin LAR is an extended release treatment for carcinoid syndrome in patients with certain tumors. Cubicin is an antibacterial medication that treats skin and bloodstream infections. Reyataz treats HIV-1 infection. Vytorin decreases bad cholesterol and increases good cholesterol in the blood.



Source: Dickson; *The Major Pharmaceuticals Losing Patent Protection in 2017*, January 5th, 2017

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.[44] 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 and mandates required essential health benefits,[45] cost-sharing limits, rating and underwriting standards, and appeals of adverse benefit determinations.[46] PPACA also requires issuers (insurers and HMOs) of qualified health plans (QHPs) to provide essential health benefits (EHB), which includes prescription drugs.[47]

[44] 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.
[45] 42 U.S.C. s.18022.
[46] Id.
[47] See Centers for Medicare & Medicaid Services, The Center for Consumer Information & Insurance Oversight, *Information on Essential Health Benefits Benchmark Plans*, https://www.cms.gov/cciio/resources/data-resources/ehb.html (last visited February 18, 2017).

Prescription Drug Coverage

For purposes of meeting EHBs for prescription drugs, issuers must include in the formulary 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 design a formulary using scientific evidence, including the consideration of safety and efficacy, coverage for a range of drugs in a broad distribution of therapeutic categories and classes, and providing 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. Such procedures must include a process to request an expedited review.[48]

Changes in Medicare Part D Formularies

Medicare Part D[49] plans may alter their formularies from year to year and, in limited circumstances, make changes within a plan year.[50] 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.[51] The following formulary changes are allowed: [52]

- 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.[53]

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.[54] 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' 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, health maintenance organizations (HMO), and other risk-bearing entities.[55] 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 AHCA.[56]

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[48] 45 C.F.R. s. 156.122.
[49] 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.
[50] 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 February 18, 2017).
[51] Id.
[52] Id. at pg. 37.
[53] Id.
[54] Id.
[55] S. 20.121(3), F.S.
[56] S. 641.21(1), F.S.

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.[57]

State Group Insurance Program

The Department of Management Services (DMS), through the Division of State Group Insurance (DSGI), administers the state group health insurance program (Program) under a cafeteria plan consistent with section 125 of the Internal Revenue Code.[58] To administer the Program, 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 (prescription drug program).[59]

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.[60] 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.[61]

The prescription drug program covers all federal legend drugs[62] for covered medical conditions, and employs very limited utilization review and clinical review for traditional or specialty prescription drugs.[63] Copayments and coinsurance for high deductible plans for each drug tier are the same for all members, as follows:[64]

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

The Program typically makes benefits changes on a plan year basis, which is January 1 through December 31.[65] The following chart illustrates the estimated impact of preferred drug list tier changes implemented by the Program's PBM for calendar years 2015 and 2016:[66]

[57] S. 641.31(36), F.S.
[58] S. 110.123, F.S.
[59] SS. 110.123(3) and 110.12315, F.S.
[60] S. 110.12315(a), F.S.
[61] Department of Management Services, *2017 Agency Analysis of House Bill 182,* pg. 2, (February 6, 2017) .
[62] "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."
[63] Supra, FN 46.
[64] Id.
[65] Id.
[66] The Program PBM is CVS/Caremark, which became the PBM on January 1, 2015, so the estimated quarterly impacts for the 2015 calendar year do not include the first quarter of that year. Information received from an email from Program staff dated February 17, 2017 (on file with Health Innovation Subcommittee staff).

CALENDAR YEAR 2015 [6]					
Impact Type	Unique Drugs Impacted	Total Rxs Impacted	$ Added Cost to Plan	$ Cost Savings to Plan	# Members Impacted
Positive (Tier 3 to Tier 2)	43	5,779	($114,694)	$0	1,669
Negative (Tier 2 to Tier 3)	80	4,001	$0	$70,454	1,416
Total	**123**	**9,780**	**($114,694)**	**$70,454**	**3,081**

CALENDAR YEAR 2016 [7]					
Impact Type	Unique Drugs Impacted	Total Rxs Impacted	$ Added Cost to Plan	$ Cost Savings to Plan	# Members Impacted
Positive (Tier 3 to Tier 2)	42	9,918	($189,900)	$0	1,628
Negative (Tier 2 to Tier 3)	71	23,367	$0	$445,100	4,101
Total	**113**	**33,285**	**($189,900)**	**$445,100**	**5,772**

Effect of the Bill

CS/HB 95 prohibits an individual or small group health insurer or a HMO from removing a prescription drug from the formulary during the policy year. The bill provides two exceptions to this restriction: a prescription drug may be removed from the formulary during the policy year if the FDA issues a statement questioning the safety of the drug or the manufacturer of a drug notifies the FDA that it is no longer manufacturing the drug or potentially plans on not manufacturing the drug. Changes to the formulary are permitted at the time coverage is renewed with the insurer or HMO.

The bill will prevent insurers and HMOs, and their PBMs, from utilizing certain formulary management techniques during the plan year. The prohibition may increase prescription drug plan costs for insureds and members of insurers and HMOs that implement those management techniques. However, insureds and members will benefit from unchanged prescription drug coverage during the entire plan year.

The bill prohibits during a policy year an individual or small group health insurer or HMO from reclassifying a prescription 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 a prescription drug, or reclassifying a drug to a higher cost-sharing tier. For example, during a policy year, insurers, HMOs, and their PBMs will not be able to encourage the use of newly allowed generic equivalent drugs by moving a drug that loses patent protection to a more restrictive tier. However, insureds and members can plan for consistent prescription drug costs during the policy year. The bill permits prescription drugs to be added to the list of prescription drugs covered during the policy year, which may provide insureds and members with access to additional prescription drugs during the policy year.

The provisions of the bill do not apply to the State Group Insurance Program, grandfathered health plans, as defined under s. 627.402, F.S., or to limited benefit insurance products listed in s. 627.6513, F.S., such as limited scope dental or vision benefits, hospital indemnity or other fixed indemnity insurance, or automobile medical payment insurance. The bill does not inhibit a pharmacist from substituting a generically equivalent drug for a brand name drug or dispensing a substitute biological product for the prescribed biological product.

The bill states that the Legislature finds the act to fulfill an important state interest.

The bill provides for an effective date of January 1, 2018.

B. SECTION DIRECTORY:

Section 1: Amends s. 110.123, F.S., relating to state group insurance program.
Section 2: Creates s. 627.42393, F.S., relating to insurance policies; limiting changes to prescription drug formularies.
Section 3: Amends s. 627.6699, F.S., relating to the Employee Health Care Access Act.
Section 4: Amends s. 641.31, F.S., relating to health maintenance contracts.
Section 5: Provides an effective date of January 1, 2018.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill has no fiscal impact on the Florida Medicaid program as it does not amend Chapter 409, F.S., nor does it require any change to current Medicaid policies or procedures.[67]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

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

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

By limiting changes to the prescription drug formulary, the bill would allow insureds to maintain their prescribed brand drugs at a preferred cost for the policy year. The prohibition on changes to drug formularies in the middle of a plan year could increase prescription drug costs for health insurers and HMOs, and lead to higher costs for insureds and members.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to require counties or municipalities to spend funds or take action requiring the expenditures of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of state tax shared with counties or municipalities.

2. Other:

The bill would not apply to self-insured plans that are covered under the Employee Retirement Income Security Act of 1974 (ERISA). ERISA preempts the regulation of such plans by the state.

B. RULE-MAKING AUTHORITY:

Not applicable.

[67] Email correspondence with staff from the Agency for Health Care Administration dated February 20, 2017 (on file with Health Innovation Subcommittee staff).

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 22, 2017, the Health Innovation Subcommittee adopted a strike-all amendment to HB 95. The strike-all amendment:

- Exempted the State Group Insurance Program from the bill provisions;
- Allowed a health insurer or HMO to make changes to the prescription drug formulary at the time of coverage renewal, rather than only during open enrollment;
- Removed the requirement that small group carriers maintain continuity of care under new s. 627.42393;
- Prohibited small group carriers from making prescription drug formulary changes as limited under new s. 627.42392; and
- Stated that the Legislature finds the act to fulfill an important state interest.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.