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 492
INTRODUCER:	Senator Garcia
SUBJECT:	Provision of Pharmaceutical Services
DATE:	January 12, 2018
REVISED:	

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

I. Summary:

SB 492 prohibits an insurer or health maintenance organization (HMOs) issuing individual or group health policies or contracts from requiring an insured or subscriber to obtain a prescription drug for the treatment of a chronic illness exclusively from a mail-order pharmacy unless the drug is considered an excluded drug. The bill defines the term "chronic illness" to mean human immunodeficiency virus infection (HIV), epilepsy, hypertension, or diabetes. The bill defines the term "excluded drug" to mean a drug subject to restricted distribution by the U.S. Food and Drug Administration or a drug that requires special handling, provider coordination, or patient education and cannot be provided by a retail pharmacy. The bill allows an insured to obtain prescription drugs, other than an excluded drug, for the treatment of a chronic illness through any retail pharmacy that accepts the same terms and reimbursements as those given to a mail-order pharmacy by an insurer or health maintenance organization.

The bill requires insurers and HMOs that issue major medical policies or contracts and provide coverage through a mail order pharmacy to disclose in the outline of coverage that an insured or subscriber may obtain prescription drugs for treatment of a chronic illness from a retail pharmacy and that the exclusive use of a mail order pharmacy is not required, unless the drug is an excluded drug. Currently, state law does not prohibit an insurer or HMO from requiring an insured to obtain prescription drugs from a mail-order pharmacy or from charging a higher copayment for the use of a retail pharmacy.

It is anticipated that the bill will have a minimal impact on the State Group Insurance program.

II. Present Situation:

Access to Prescription Drugs

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 co-payment 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.

Mail-Order Pharmacies

The PBMs may use mail-order pharmacies to manage prescription drug costs. Many plan sponsors encourage patients with chronic conditions who require repeated refills to seek the discounts that 90-day prescriptions and high-volume mail-order pharmacies can offer. Many PBMs own their own mail-order pharmacies. Insurers and PBMs use a variety of incentives to encourage the use of mail order pharmacies; especially for beneficiaries taking maintenance medications. Plans may offer lower copayments for mail order drugs, charge deductibles for retail purchases, or impose limitations on the number of prescriptions at a retail pharmacy. Some health plans have "mandatory mail order" programs that reimburse beneficiaries for maintenance medications only if the beneficiaries fill those prescriptions by mail. Some insurers are ambivalent about the savings offered by mail order or point to equivalent or better savings that can be achieved from filling 90-day supplies in network retail pharmacies. These payers contend that enrollees benefit from face-to-face contact with a pharmacist.[1]

While PBMs provide pharmacy claims processing and mail-order pharmacy services to their customers, many provide additional services, including rebate negotiations with drug manufacturers, development of pharmacy networks, formulary management, prospective and retrospective drug utilization reviews, generic drug substitutions, and disease management programs. The decision of plan sponsors to use PBMs to control pharmacy benefit costs, however, can shift business away from retail pharmacies.

Concerns about Mail-Order Pharmacy

According to advocates of this bill, there is much documented reporting of inconsistencies across the healthcare system in the execution of the mail-order pharmacy model, as summarized below.

- Unlike specialty or many local pharmacies, mail-order pharmacies are often not consistent in proactively reaching out to the patients to provide refill reminders. The healthcare community has observed better health outcomes for chronically ill patients when pharmacies maintain close contact with their patients.

[1] Maryland Health Care Commission and Maryland Insurance Administration, Maintenance Drug Prescriptions-Mail Order Purchases Study (Dec. 23, 2005) (on file with Senate Committee on Banking and Insurance).

- Delivery methods are also inconsistent. Patients report privacy concerns (i.e., medication being delivered to family members, roommates, or neighbors who do not have knowledge of the patient's health status). Couriers sometimes leave medication requiring refrigeration outside, potentially rendering the medication ineffective. Leaving the medication package at the door also exposes it to possible theft.
- Although patients may save money through mail order, filling medication through mail order for a 90-day period can be cost prohibitive to the patient from a cash flow perspective. A copayment for a 30-day supply of medication is often more affordable for a patient than a copayment for a 90-day supply when required at the point of sale.[2]

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.[3] 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 and rating and underwriting standards.[4] PPACA requires health plans that are required to provide coverage of essential health benefits (EHB), to meet cost-sharing limits and actuarial value requirements. The law directs that EHBs cover at least 10 specified categories of coverage, including prescription drugs.[5]

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 (P&T) committee 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.[6]

Formulary Drug List. The federal regulations require health plans 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 manner in which a drug can be obtained, in a manner that is easily accessible to plan enrollees, prospective enrollees, the state and federal government, and the

[2] AIDS Healthcare Foundation email (Jan. 28, 2016) (on file with Committee on Banking and Insurance).
[3] The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. P.L. 111-148.
[4] 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*.).
[5] See https://www.cms.gov/cciio/resources/data-resources/ehb.html (last viewed Jan.10, 2018) for Florida's benchmark plan.
[6] 45 CFR s. 156.122.

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.[7]

Access at Retail Pharmacies

For plans years beginning on or after January 1, 2017, an individual or small group health plan[8] providing essential health benefits must implement the following access procedures:

A health plan must allow enrollees to obtain prescription drug benefits at in-network retail pharmacies, unless:

- The drug is subject to restricted distribution by the U.S. Food and Drug Administration; or
- The drug requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy.[9]

A health plan may charge enrollees a different cost-sharing amount for obtaining a covered drug at a retail pharmacy, but all cost sharing will count towards the plan's annual limitation on cost sharing.[10]

The health plans retain the flexibility to charge a lower cost-sharing amount when obtaining the drug at an in-network retail pharmacy. While this provision requires coverage of a drug at an in-network retail pharmacy, for plans that do not have a network, the enrollee may go to any pharmacy to access his prescription drug benefit and those plans will be in compliance with this standard.

The plans need only provide enrollees with the option to access drugs that are not exempted under 45 CFR s. 156.122(e) at an in-network retail pharmacy. According to the HHS final rules, certain drugs have a Risk Evaluation and Mitigation Strategy (REMS) that includes Elements to Assure Safe Use that may require that pharmacies, practitioners, or health care settings that dispense the drug be specially certified and that may limit access to the drugs to certain health care settings.[11] If the health plan finds it necessary to restrict access to a drug for either of the reasons listed above, it must indicate this restricted access on the formulary drug list that plans must make publicly available under 45 CFR s. 156.122(d).[12]

The federal Department of Health and Human Services (HHS) notes that there are instances in which obtaining a drug through a mail-order pharmacy may not be a viable option, such as when an individual does not have a stable living environment and does not have a permanent address, or when a retail pharmacy option better ensures that consumers can access their EHB prescription drug benefit on short notice.[13]

---

[7] *See* 45 C.F.R. 156.122(d).
[8] These provisions of PPACA do not apply to large group plans, self-insured plans, transitional plans, or grandfathered plans.
[9] *See* 45 C.F.R. s. 156.122(e)(2).
[10] *See* 45 CFR s. 156.130.
[11] FDA requires a Risk Evaluation and Mitigation Strategies (REMS) for specified drugs to ensure that the benefits of a drug or biological product outweigh its risks. The following is FDA's list of currently approved REMS: http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm (last viewed Jan. 10, 2018).
[12] PPACA; HHS Notice of Benefit and Payment Parameters for 2016, 80 Fed. Reg. 10820, 10821.
[13] *Id.*

Regulation of Health 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.[14] 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 obtain a Health Care Provider Certificate from the agency.[15]

Florida's 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.[16] To administer the state group health insurance program, the DMS contracts with third party administrators for self-insured health plans, insured health maintenance organizations (HMOs), and a pharmacy benefits manager (PBM), for the state employees' self-insured prescription drug program.[17]

The state employees' self-insured prescription drug program has four dispensing avenues: participating 30-day retail pharmacies, participating 90-day retail pharmacies, the PBM's mail order pharmacies, and the PBM's specialty pharmacies. Contractually, and as stated in the benefit documents, specialty drugs, as defined by the PBM, must be dispensed by the PBM's specialty pharmacies. Specialty drugs are often high-cost prescription medications or medications for conditions. These drugs generally require additional monitoring for compliance and adherence. The drugs are used to treat complex and/or chronic conditions such as cancer, rheumatoid arthritis, human immunodeficiency virus, and multiple sclerosis. Specialty drugs often require special handling (e.g., refrigeration during shipping) and administration (e.g., injection or infusion).

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

III. Effect of Proposed Changes:

Sections 1, 2 and 3 prohibit insurers and health maintenance organizations offering major medical individual or group health policies or contracts, respectively from requiring an insured

[14] Section 20.121(3)(a), F.S.
[15] Section 641.21(1), F.S.
[16] 26 U.S.C. s. 125.
[17] Section 110.12315, F.S.

or subscriber to obtain a prescription drug for the treatment of a chronic illness exclusively from a mail order pharmacy, unless the drug is an excluded drug. "Chronic illness" is defined as human immunodeficiency virus infection (HIV), epilepsy, hypertension or diabetes. "Excluded drug" is defined to mean a drug subject to restricted distribution by the U.S. Food and Drug Administration or a drug that requires special handling, provider coordination, or patient education and cannot be provided by a retail pharmacy.

The bill allows an insured or subscriber to obtain prescription drugs for the treatment of a chronic illness, through a retail pharmacy that agrees to the same terms and conditions, including credentialing, applicable to a mail order pharmacy and accepts payment or reimbursement from the health insurer or HMO. This requirement applies unless the drug is an excluded drug. This reimbursement or payment may not exceed the amount paid to a network mail order pharmacy for the same prescription drugs for the treatment of a chronic illness.

Further, insurers and HMOs that issue a major medical policies or contracts that provide coverage for prescription drugs through a mail order pharmacy are required to disclose in the outline of coverage that an insured may obtain prescription drugs for the treatment of a chronic illness from a retail pharmacy, and that the exclusive use of a mail order pharmacy is not required unless the drug is an excluded drug.

The requirements in sections 1 and 2 (relating to individual and group health insurance policies) do not apply to grandfathered plans as defined in s. 627.402, F.S., or to benefits set forth in s. 627.6561(5)(b), (c), (d), and (e), F.S.

The requirements in section 3 (relating to health maintenance organizations) do not apply to grandfathered health plans as defined in s. 641.313(1)(c), F.S., or to benefits set forth in s. 641.31071(b), (c), (d), and (e), F.S.

Section 4 provides the bill will take effect January 1, 2019.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The mandate restrictions do not apply because the bill does not require counties and municipalities to spend funds, reduce the ability of counties or municipalities to raise revenue, or reduce the percentage of a state tax shares with counties and municipalities.

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:

The bill may provide greater choice for consumers in filling prescriptions at local retail pharmacies rather than through mail order. Further, advocates of the bill note that the healthcare community has observed better health outcomes for chronically ill patients when pharmacies maintain close contact with their patients.

Retail pharmacies may experience an indeterminate increase in pharmaceutical sales volume to the extent patients shift their prescription drug purchases from mail order pharmacies to retail pharmacies. Mail order pharmacies may experience a similar reduction in sales volume. The impact of the bill on health insurers or HMOs with defined networks is indeterminate.

The provisions of the bill will not apply to employers that offer self-insured plans.[18] In Florida, an estimated 63 percent of private sector enrollees are enrolled in self-insured plans.

C. Government Sector Impact:

The Division of State Group Insurance

Under the current PBM that administers the state employees' self-insured prescription drug program, CVS/caremark; all drugs to treat HIV infection are classified as specialty drugs due to the sensitive nature of the diagnosis, privacy concerns, and history of noncompliance of these drugs. The bill would not apply to drugs that are injectable or require special handling. As a result, those types of drugs used to treat HIV infection or any of the other specific chronic conditions would continue to be dispensed by the PBM's specialty pharmacy. CVS /caremark, the PBM for the state employees' self-insured prescription drug program, expects minimal impact from the bill.[19]

Office of Insurance Regulation

None.[20]

---

[18] The federal Employee Retirement Income Security Act of 1975 (ERISA) allows employers to self-insure in order to offer uniform health benefits across states. A plan that is self-insured is subject to ERISA's requirements. Such employers are not required to cover health care services for state-mandated benefits.

[19] Department of Management Services, *2018 Legislative Analysis* SB 492 (Jan. 5, 2018) (on file with Senate Committee on Banking and Insurance).

[20] Office of Insurance Regulation, *2018 Legislative Analysis of SB 492* (Oct. 20, 2017) (on file with Senate Committee on Banking and Insurance).

VI. Technical Deficiencies:

Limiting the coverage or effects of this bill to insureds and subscribers who have one of the four "chronic conditions" delineated (immunodeficiency virus infection, epilepsy, hypertension or diabetes) may be considered discriminatory. Under the 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.[21]

The bill does not amend s. 627.6699, F.S., relating to small group policies. Therefore, the restrictions on the copayments that may be imposed when an insured elects to use a pharmacy that is not a mail order pharmacy may not apply to these policies.

VII. Related Issues:

The bill has potential privacy concerns as pharmacies would have to be notified that a person has one of the four specified chronic conditions in order to receive the benefits under the bill. The insured may not understand that these protections apply only to medications treating the chronic illness and may not want to have this medical information disclosed or may want to receive other prescription drugs from the retail pharmacy.[22]

VIII. Statutes Affected:

This bill substantially amends section 641.31 of the Florida Statutes.

This bill creates the following sections of the Florida Statutes: 627.6442 and 627.6572.

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.

[21] 45 C.F.R. s. 146.121.
[22] Office of Insurance Regulation, *2018 Legislative Analysis of SB 492* (Oct. 20, 2017) (on file with Senate Banking and Insurance Committee).