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.)

	Prep	ared By: Th	e Professional S	taff of the Committe	e on Health Polic	су	
BILL:	SB 492						
INTRODUCER:	Senator Garcia						
SUBJECT:	Provision of Pharmaceutical Services						
DATE:	January 25	5, 2018	REVISED:				
ANALYST		STAFF DIRECTOR		REFERENCE		ACTION	
. Johnson		Knudson		BI	Favorable		
. Lloyd		Stovall		HP	Pre-meeting		
				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.

The bill has an effective date of January 1, 2019.

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 the 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
- Mail orders can also lead to communication errors or safety problems. Daily medications may not always arrive on time which can be dangerous for individuals that rely on lifesaving drugs.³
- Auto-renewal of obsolete prescriptions. Mail order pharmacies might auto-renew • prescriptions that a patient may no longer be taking or where the dosage has been modified. This leads to a waste of medications or a patient mistakenly taking old doses of medications.⁴ Noting the complaints received by the federal Centers for Medicare and Medicaid Services (CMS), the CMS strongly encouraged beginning in 2014 that Part D plans⁵ obtain patient consent prior to filling an automatic refill, to combat fraud and abuse.⁶

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, 2010.⁷ 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.⁸ PPACA requires health plans that are mandated 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.9

² AIDS Healthcare Foundation email (Jan. 28, 2016) (on file with the Senate Committee on Banking and Insurance).

³ Ginger Skinner, Using a Mail Order Pharmacy Doesn't Always Save You Money, Consumer Reports, (March 14, 2016) https://www.consumerreports.org/pharmacies/mail-order-pharmacy-doesnt-always-save-money/, (last visited Jan. 25, 2018). ⁴ Id.

⁵ Part D Medicare plans are prescription drug coverage plans.

⁶ Centers for Medicare and Medicaid Services, Note to Medicare Advantage Organizations, Prescription Drug Sponsors, and Other Interested Parties (February 15, 2013), pg. 133, https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2014.pdf

⁷ 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.

⁸ 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.).

⁹ See https://www.cms.gov/cciio/resources/data-resources/ehb.html (last viewed Jan. 10, 2018) 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 (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.¹⁰

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 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.¹¹

Access at Retail Pharmacies

For plans years beginning on or after January 1, 2017, an individual or small group health plan¹² 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.¹³

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.¹⁴

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.

¹⁰ 45 CFR s. 156.122.

¹¹ See 45 C.F.R. 156.122(d).

¹² These provisions of PPACA do not apply to large group plans, self-insured plans, transitional plans, or grandfathered plans.

¹³ See 45 C.F.R. s. 156.122(e)(2).

¹⁴ See 45 CFR s. 156.130.

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.¹⁵ 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).¹⁶

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.¹⁷

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.¹⁸ The Agency for Health Care Administration (agency) regulates the quality of care provided by HMOs under part III of ch. 641, F.S. Before receiving a certificate of authority from the OIR, an HMO must obtain a Health Care Provider Certificate from the agency.¹⁹

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.²⁰ 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.²¹

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 complex conditions. These drugs generally require additional monitoring for compliance and adherence. The drugs are used to treat complex and/or chronic conditions such

¹⁷ Id.

²⁰ 26 U.S.C. s. 125.

¹⁵ 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: <u>http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm</u> (last viewed Jan. 10, 2018).

¹⁶ PPACA; HHS Notice of Benefit and Payment Parameters for 2016, 80 Fed. Reg. 10820, 10821.

¹⁸ Section 20.121(3)(a), F.S.

¹⁹ Section 641.21(1), F.S.

²¹ Section 110.12315, F.S.

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	\$50	\$100		
Brand				

Florida Medicaid

The Florida Medicaid program is a partnership between the federal and state governments. Each state operates its own Medicaid program under a state plan approved by the CMS. The state plan outlines Medicaid eligibility standards, benefits, policies, and reimbursement methodologies.

Florida Medicaid is administered by the Agency for Health Care Administration (AHCA) and financed with state and federal funds. The program provides comprehensive health care benefits to approximately 4 million Floridians. The estimated expenditures for the state's 2017-2018 fiscal year are over \$26 billion.²²

Eligibility for Medicaid is based on a number of factors, including age, household size, or individual income, and assets. State eligibility payment guidelines are provided in s. 409.903, F.S., (Mandatory Payments for Eligible Persons) and s. 409.904, F.S., (Optional Payments for Eligible Persons). Minimum coverage thresholds are established in federal law for certain population groups such as children.

Current law permits the AHCA to limit the size of the Medicaid pharmacy networks based on need, competitive bidding, price negotiations, credentialing, or similar criteria.²³ The AHCA has also been directed in statute to expand the home delivery of pharmacy products to those recipients who elect to receive pharmacy products, with a focus on those recipients with chronic diseases for which pharmacy expenditures represent a significant portion of the Medicaid budget or population.²⁴

The *Medicaid Prescribed Drug Services Coverage Policy* sets two requirements for coverage and does not mention chronic diseases, but is based on meeting two conditions:²⁵

²² Florida Office of Economic and Demographic Research, *Social Services Estimating Conference Medicaid Caseloads and Expenditures and Expenditures Executive Summary (July 17, August 3, and August 9, 2017),* <u>http://edr.state.fl.us/Content/conferences/medicaid/execsummary.pdf</u>, (Last visited Jan. 25, 2018).

²³ Section 409.912(5)(a)4, F.S.
²⁴ Section 409.912(4)(a)8, F.S.

²⁵ Agency for Health Care Administration, Prescribed Drugs Services Coverage Policy (December 2017),

- The provider agrees to replace any lost shipments at no cost to the Medicaid member or to the state.
- The mail order service charges no additional costs to the Medicaid recipient or to Florida Medicaid.

Statewide Medicaid Managed Care Program

Part IV of ch. 409, F.S., was created in 2011 by ch. 2011-134, L.O.F., and governs the Statewide Medicaid Managed Care Program. (SMMC). The SMMC, authorized under federal Medicaid waivers, is designed for the AHCA to issue invitations to negotiate²⁶ and competitively procure contracts with managed care plans in 11 regions of the state to provide comprehensive Medicaid coverage for most of the state's enrollees in the Medicaid program. SMMS has two components: managed medical assistance (MMA) and long-term care managed care (LTCMC).

The LTCMC component began enrolling Medicaid recipients in August 2013 and completed its statewide rollout in March 2014. The MMA component began enrolling Medicaid recipients in May 2014 and finished its rollout in August 2014. As of January 1, 2018, over 3.8 million Medicaid eligibles were enrolled in an MMA plan and an additional 748,368 were receiving fee-for service benefits.²⁷

Under MMA, prescription drugs are a covered benefit.²⁸ Plans must meet network adequacy requirements which includes both time and distance standards for urban and rural counties and a ratio standard of one pharmacy for each 2,500 enrollees.²⁹ The MMA plans are prohibited from exclusively using mail-order pharmacies to meet their pharmacy network access needs.³⁰ The AHCA reiterates this prohibition in its contracts with the MMA plans, noting that mail order may be an option for recipients.³¹

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 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

²⁶ An "invitation to negotiate" is a written or electronically posted solicitation for vendors to submit competitive, sealed replies for the purpose of selecting one or more vendors with which to commence negotiations for the procurement of commodities or contractual services. *See* s. 287.012, F.S.

²⁷ Agency for Health Care Administration, Statewide Medicaid Enrollment Report (January 2018),

²⁸ Section 409.973(x), F.S.

²⁹ Agency for Health Care Administration, *Presentation to Senate Health Policy Committee – Florida Medicaid: Statewide Medicaid Managed Care Pharmacy Networks (February 16, 2016)*, slide 8,

https://ahca.myflorida.com/medicaid/recent presentations/SMMC Pharmacy Network Senate Health Policy 2016-02-16.pdf, (last visited Jan. 25, 2018).

³⁰ Section 409.967(2)(c)1, F.S.

³¹ Agency for Health Care Administration, SMMC Plans - Model Contract, *Attachment II (Core Contract Provisions), Exhibit II-A – Effective Date: June 1, 2017, Managed Medical Assistance (MMA) Program, pg. 61, http://www.ahca.myflorida.com/medicaid/statewide_mc/pdf/Contracts/2017-06-01/EXHIBIT_II-A Managed Medical Assistance (MMA) Program 2017-06-01.pdf, (last visited Jan. 25, 2018).*

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 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.³² 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, expects the implementation of the bill would have a minimal negative fiscal impact on the state employees' self-insured prescription drug program.³³

Office of Insurance Regulation

None.34

³² 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.

³³ Department of Management Services, 2018 Legislative Analysis SB 492 (Jan. 5, 2018) (on file with Senate Committee on Banking and Insurance).

³⁴ Office of Insurance Regulation, 2018 Legislative Analysis of SB 492 (Oct. 20, 2017) (on file with Senate Committee on Banking and Insurance).

Agency for Health Care Administration

The state Medicaid program manages its own pharmacy benefit program and network standards. The bill does not appear to exempt the Medicaid program from its provisions.

Currently, the Medicaid program allows its plans to use mail-order pharmacies so long as they are not the only option available to the recipient and if the pharmacies meet two conditions relating to absorbing the costs of lost shipments and incurring no additional costs to either the recipient or the Medicaid program. The provisions of the bill may be in conflict with how the current Medicaid mail-in program operates since Medicaid does not include any such exclusions.

If applied to the Medicaid program, the bill could impact how Medicaid is able to operate its mail order and home delivery services under the fee-for-service and MMA programs.

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.³⁵

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.³⁶

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.

³⁵ 45 C.F.R. s. 146.121.

³⁶ Office of Insurance Regulation, 2018 Legislative Analysis of SB 492 (Oct. 20, 2017) (on file with the Senate Banking and Insurance Committee).

IX. **Additional Information:**

Committee Substitute – Statement of Changes: (Summarizing differences between the Committee Substitute and the prior version of the bill.) Α.

None.

Β. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.