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 Governmental Oversight and Accountability

BILL:	SB 780
INTRODUCER:	Senator Garcia
SUBJECT:	Provision of Pharmaceutical Services
DATE:	February 8, 2016
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	**Favorable**
2.	Peacock	McVaney	GO	**Pre-meeting**
3.			AP	

I. Summary:

SB 780 prohibits an insurer or health maintenance organization (HMO) from requiring an insured living with a chronic illness to obtain pharmaceutical services, including prescription drugs, from a mail-order pharmacy. The bill defines the term, "chronic illness," to mean human immunodeficiency virus infection (HIV), epilepsy, hypertension, or diabetes. The bill allows an insured with a chronic illness to use any willing retail pharmacy that accepts the terms and reimbursements as those given to a mail-order pharmacy. The bill requires insurers and HMOs to provide insureds with a chronic illness an explanation of the payment or reimbursement method and charges applicable to a mail order pharmacy and a comparison of such method and charges applicable to other providers of pharmaceutical services.

The bill requires mail order pharmacy contracts with HMOs or with insurers offering group or blanket plans to include a contract provision requiring the mail-order pharmacy to disclose to an insured living with a chronic illness the availability of pharmaceutical services from retail pharmacies and that the exclusive use of a mail order pharmacy is not required. 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.

The bill is effective July 1, 2016.

According to the Division of State Group Insurance, the bill will have an indeterminate negative fiscal impact. The magnitude of the impact will be based on the change in behavior of the insureds, the number of drugs removed from the Specialty Drug List, and the negative impact to the pricing terms of the pharmacy benefit manager (PBM) contract.

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 patient 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, rating and underwriting standards, review of rate increases, and internal and external appeals of adverse benefit determinations.[4] Section 1302 of the 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, 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 regulations require a health plan to publish an up-to-date and complete list of all covered drugs on its formulary drug list, including any tiered structure and any restrictions on the manner

[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 visited Jan.14, 2016) for Florida's benchmark plan.
[6] 45 CFR s. 156.122.

in which a drug can be obtained, in a manner that is easily accessible to plan enrollees, prospective enrollees, the state, the marketplace, HHS, and the public. Additionally, insurers and HMOs must also make this information available in a standard-readable format to provide the opportunity for third parties to create resources that aggregate information on different plans.

Access at Retail Pharmacies

For plans years beginning on or after January 1, 2017, an individual or small group health plan7 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.

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 under 45 CFR 156.135.

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 will be able to go to any pharmacy to access his prescription drug benefit and those plans will be in compliance with this standard.

The issuers 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. The 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.[8]

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.[9] 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

[7] The Patient Protection and Affordable Care Act (Pub. L. 111–148). This regulation would not apply to large group plans, self-insured plans, transitional plans, or grandfathered plans.

[8] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, 80 Fed. Reg. 10820, 10821.

[9] FDA requires a Risk Evaluation and Mitigation Strategies (REMS) for certain 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 visited Jan. 28, 2016).

access on the formulary drug list that plans must make publicly available under 45 CFR s. 156.122(d).[10]

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.[11] 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.[12]

Florida's State Group Health 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.[13] 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.[14]

Currently, the state employees' self-insured prescription drug program allows members receiving prescription drugs for chronic conditions specified in this bill, to use any retail pharmacy that accepts the same contractual terms, conditions, and reimbursement as the mail order pharmacy for up to a 90-day supply of all non-specialty maintenance medications. These retail pharmacies may be participating in either the PBM's retail pharmacy network or the State of Florida specific "maintenance 90 at retail" pharmacy network. Copayments and conditions for a 90-day supply at retail are the same as for mail order.

The DMS contract with the PBM requires specialty drugs to be dispensed by its specialty pharmacy, which is considered mail order. This exclusive arrangement means the state benefits from aggressive discounts off the average wholesale price, as well as a quarterly minimum rebate guarantee per specialty prescription payment, with an annual "true-up" of 100 percent of all rebates. An independent P&T committee determines which prescription drugs are specialty medications based on a variety of factors, including compliance, clinical indications, special handling (e.g., temperature requirements), and cost.

III. Effect of Proposed Changes:

Sections 1 creates s. 627.6442, F.S., and **Section 2** amends s. 641.31, F.S. These sections prohibit health insurers and HMOs, respectively, from requiring an insured living with a chronic illness to obtain pharmaceutical services including drugs exclusively from a mail order

[10] Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, 80 Fed. Reg. 10820, 10821.
[11] Section 20.121(3)(a), F.S.
[12] Section 641.21(1), F.S.
[13] 26 U.S.C. s. 125.
[14] Section 110.12315, F.S.

pharmacy. The bill defines the term, "chronic illness," to mean as human immunodeficiency virus infection (HIV), epilepsy, hypertension or diabetes.

The bill allows insured individuals living with a chronic illness to obtain pharmaceutical services, including prescription drugs, related and unrelated to their chronic illness, through any willing retail pharmacy that agrees to the same terms and conditions applicable to a mail order pharmacy and accepts payment or reimbursement from the health insurer. This reimbursement or payment may not exceed the amount paid to a network mail order pharmacy for the same services.

Further, insurers and HMOs are required to provide insureds living with a chronic illness with an explanation of the payment or reimbursement method and charges applicable to network mail order pharmacy and a comparison of such method and charges with other providers of pharmaceutical services.

Mail order pharmacies contracting with HMOs or insurers (offering group or blanket plans) are required to include a contract provision requiring the mail-order pharmacy to disclose in its initial written correspondence with an insured living with a chronic illness that they may obtain pharmaceutical services from other providers, and that the exclusive use of a mail order pharmacy is not required.

Upon written request, the health insurer or HMO is required to provide information pertaining to the terms and conditions applicable to mail order pharmacies and to pharmacies desiring to provide services to insureds living with a chronic illness in their service area. If the pharmacy agrees to the same terms and conditions, the insurer is required to pay the pharmacy the same amount a mail order pharmacy is paid for the same pharmaceutical services.

Section 3 provides that the bill takes effect July 1, 2016.

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 counties' or municipalities' ability 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:

Retail pharmacies may experience greater pharmaceutical sales volume to the extent patients shift their prescription drug purchases from mail order pharmacies to retail pharmacies. Mail order pharmacies will experience a similar reduction in sales volume.

The provisions of the bill will not apply to employers that offer self-insured plans.[15] In Florida, an estimated 63 percent of private sector enrollees are enrolled in self-insured plans.

It is not clear how the "any willing pharmacy" provision would affect the operations or contracts of health insurers or HMOs with defined networks.

C. Government Sector Impact:

The Division of State Group Insurance

If it is determined that SB 780 applies to the state group health insurance plans (mostly self-insured plans with two fully insured HMOs for the 2016 plan year), then the state employees' self-insured prescription drug program currently complies with the bill except for drugs on the specialty drug list. The Department of Management Services (DMS) could renegotiate its contract and pricing terms with the PBM regarding the method by which specialty drugs are dispensed. Removing the exclusivity provision of the contract most likely will negatively affect pricing terms (discount off average wholesale price and the quarterly minimum rebate guarantee per specialty prescription payment).[16] The DMS notes that the bill takes effect July 1, 2016; however, the state group health insurance program typically makes benefits changes on a plan year basis, which is January 1 through December 31.

Office of Insurance Regulation

Indeterminate. The OIR has not provided a fiscal impact of the bill on the OIR.[17]

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[15] 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.

[16] Department of Management Services, *2016 Agency Legislative Bill Analysis* (December 11, 2015) (on file with Senate Committee on Banking and Insurance).

[17] Office of Insurance Regulation, *2016 Agency Legislative Bill Analysis* (December 15, 2015) (on file with Senate Committee on Banking and Insurance).

VI. Technical Deficiencies:

Generally, part VI of ch. 627, F.S., applies to individual health insurance coverage only. Section 627.601, F.S., provides "nothing in this part applies to or affects: (2) Any group or blanket policy, except as provided in ss. 627.648-627.6499." The newly created subsection 627.6442(3), F.S., of part VI specifically includes "group or blanket accident and sickness policy, plan, or other contract" and appears to conflict with s. 627.601(2), F.S. The bill does not amend part VII of ch. 627, F.S., relating to group policies.

In order to avoid a conflict with federal regulations that become effective January 1, 2017, consideration should be given to adding an exemption for prescription drugs where the FDA has restricted distribution of drugs to certain facilities or practitioners or when appropriate dispensing of drugs requires special handling, coordination, or patient education not available in a retail pharmacy.

VII. Related Issues:

Limiting the effects of this bill to insureds with an 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.[18] For example, a person suffering from asthma and living with a chronic illness as defined by the bill will be permitted to obtain all of his prescriptions, related and unrelated to his chronic illness, from a retail pharmacy that agrees to the same terms and conditions applicable to a mail order pharmacy and accepts payment or reimbursement from the health insurer. Another person suffering from asthma but not living with a chronic illness as defined by the bill could be required to use a mail order pharmacy to purchase his asthma medication.

Insurers and HMOs are required to provide insureds living with a chronic illness an explanation of the payment or reimbursement method and charges applicable to a mail order pharmacy and a comparison of such method and charges to other providers of pharmaceutical services. It is unclear, especially for newly covered individuals, how the insurer or the HMO will know which insureds or subscribers are living with a chronic illness.

The bill has potential privacy concerns as pharmacies will be notified that a person has one of the four chronic illnesses and is thus eligible to purchase medications at the retail pharmacy. The insured may not want the information relating to the chronic illness disclosed, particularly if the prescription he is purchasing from the retail pharmacy is not intended to address the chronic illness.

The bill provides that if a pharmacy agrees to the same terms, conditions, and payment as the mail-order pharmacy, the insurer or HMO is required to pay any willing retail pharmacy the same amount that is paid to a network mail order pharmacy for the same pharmaceutical

[18] 45 C.F.R. s. 146.121.

services. It is unclear whether the non-network retail pharmacy will be subject to credentialing by the insurer or HMO.

VIII. Statutes Affected:

This bill substantially amends section 641.31 of the Florida Statutes.

This bill creates section 627.6442 of the Florida Statutes.

IX. Additional Information:

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

None.

B. Amendments:

None.

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