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 924
INTRODUCER:	Senator Baxley
SUBJECT:	Health Benefit Coverage for Prescription Eye Drop Refills
DATE:	January 22, 2018
REVISED:	

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

I. Summary:

SB 924 requires a health insurance policy or health maintenance organization (HMO) contract, which provides coverage for prescription eye drops for the treatment of chronic eye disease or condition, to provide for an early refill of the eye drops at 80 percent of the predicted days of use. An insurer or HMO must provide coverage for an early refill if the refill is dispensed on or before the last day of the prescribed dosage period (but not earlier than the 24th day for a 30-day supply, 48th day for a 60-day supply, and 72nd day for a 90-day supply), and the original prescription allows for additional quantities. Prescription eye drops covered under this bill are subject to the same deductibles, copayments, coinsurance, or cost-sharing provisions established for all other prescription drug benefits under the policy or contract.

According to the Department of Management Services, the bill would have no fiscal impact on the self-insured State Employees' Prescription Drug Plan.

II. Present Situation:

Prescription eye drops are used to treat acute and chronic conditions. Patients with ocular hypertension, glaucoma, uveitis, or chronic dry eye disease may require multiple refills to treat these chronic diseases and conditions.[1]

Accidental overuse or wastage (too many drops at once or drops outside of the eye) can exhaust the eye drops in a bottle before the projected period of use, which may lead to medication compliance issues. Besides overuse and wastage, systematic adherence to a treatment regimen may contribute to early bottle exhaustion. A 2014 study evaluated the prevalence of self-reported

[1] Allaboutvision, *Eye Problems and Diseases* available at http://www.allaboutvision.com/conditions/ (last viewed Jan. 22, 2018).

early glaucoma eye drop bottle exhaustion and associated risk factors.[2] Self-reported early glaucoma bottle exhaustion regularly affected 5 percent of patients in the population and 25 percent reported early exhaustion at least once; the main risk factor was poor vision in at least one eye. The study noted that at least nine states had enacted legislation relating to early refills since 2013.[3]

Federal Health Insurance Provisions

Federal Patient Protection and Affordable Care Act

The federal Patient Protection and Affordable Care Act (PPACA) was signed into law on March 23, 2010.[4] The PPACA provides fundamental changes to the 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.[5] 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 PPACA directs coverage of at least 10 specified categories of essential health benefits, including prescription drugs.[6]

Medicare Prescription Drug Coverage of Early Refills

Medicare Part D is a Medicare prescription drug plan. These plans add drug coverage to original Medicare, some Medicare Cost Plans, some Medicare private fee-for-service plans, and Medicare Medical Savings Account plans.[7] The Centers for Medicare and Medicaid Services (CMS) recognizes that early refill edits are an important utilization management tool used to promote compliance and prevent waste. However, CMS notes that it is important that Part D[8] sponsors implement such edits in a manner that does not unreasonably put beneficiaries at risk of interruptions in drug therapy that potentially has serious consequences. The CMS recommends that Part D sponsors permit refills at 70 percent of the predicted days of use. By way of an example, for a prescribed medication with an expected duration of 30 days of use, the refills would be allowed at day 21.[9]

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[2] Moore DB, Walton C, Moeller KL, Slabaugh MA, Mudumbai RC, Chen PP. Prevalence of self-reported early glaucoma eye drop bottle exhaustion and associated risk factors: a patient survey. *BMC Ophthalmology*. 2014;14:79. doi:10.1186/1471-2415-14-79, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4072615/#B9 (last viewed Jan. 19, 2018).

[3] A limited survey by Banking and Insurance Committee staff indicated at least two additional states (Illinois and Oklahoma) had enacted legislation since the study's date of publication (on file with Banking and Insurance Committee).

[4] 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.

[5] 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*.).

[6] See https://www.cms.gov/cciio/resources/data-resources/ehb.html (last viewed Jan.10, 2018) for Florida's benchmark plan.

[7] Medicare, *How to get drug coverage*, available at https://www.medicare.gov/sign-up-change-plans/get-drug-coverage/get-drug-coverage.html#1372 (last viewed Jan. 20, 2018).

[8] Medicare, Part D (Drug Coverage) available at https://www.medicare.gov/part-d/ (last viewed Jan. 20, 2018)

[9] Department of Health and Human Services, CMS, *Early Refill Edits on Topical Ophthalmic Products*, (June 2, 2010) available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoEarlyRefillOpth_060210.pdf (last viewed Jan. 17, 2018).

Office of Insurance Regulation

The Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, HMOs, and other risk-bearing entities.[10] The Agency for Health Care Administration 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.[11]

State Group Health Insurance Program

The Department of Management Services (DMS), through the Division of State Group Insurance, administers the state group health insurance program under a cafeteria plan consistent with s. 125, Internal Revenue Code.[12] To administer the state group health insurance program, 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 pursuant to s. 110.12315, F.S. The program typically makes benefits changes on a plan year basis, which is January 1 through December 31.

The state employees' self-insured prescription drug program has three cost-share categories for members: generic drugs, preferred brand name drugs (those brand name drugs on the preferred drug list), and non-preferred brand name drugs (those brand name drugs not on the preferred drug list). The PBM for the state employees' self-insured prescription drug program updates the preferred drug list quarterly, as generic and brand name drugs enter the market, and as the PBM negotiates pricing, including rebates with manufacturers.

Generic drugs are the least expensive and have the lowest member cost share, preferred brand name drugs have the middle cost share, and non-preferred brand name drugs are the most expensive and have the highest member cost share. Generally, prescriptions written for a brand name drug, preferred or non-preferred, are substituted with a generic drug when available. If the prescribing provider states on the prescription that the brand name drug is "medically necessary" over the generic equivalent, the member will pay only the brand name (preferred or non-preferred) cost share. If the member requests the brand name drug over the generic equivalent, then the member will pay the brand name (preferred or non-preferred) cost share plus the difference between the cost of the generic drug and the brand name drug.

The program covers all federal legend drugs (open formulary) for covered medical conditions, and employs very limited utilization review and clinical review for traditional or specialty prescription drugs. Specialty drugs are high-cost prescription medications used to treat complex, chronic conditions such as cancer, rheumatoid arthritis, and multiple sclerosis. Specialty drugs often require special handling (e.g., refrigeration during shipping) and administration (such as injection or infusion).

[10] Section 20.121(3), F.S.
[11] Section 641.21(1), F.S.
[12] Section 110.123, F.S.

The federal out-of-pocket limit applies to members of the state group self-insured health plans and insured HMOs, all of which include prescription drug coverage. Copayments (and coinsurance for high deductible plans) for each drug tier are the same for all plans, 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

California Study on the Coverage of Early Refills of Prescription Eye Drops

In 2016, similar legislation[13] was introduced in California. The California Health Benefits Review Program (CHRP) evaluated the legislation.[14] In CHRP's report, the total increase in expenditures statewide for premiums of employers, employees, and individuals was estimated to be $483,000 for a 12-month period. Additionally, the increase in enrollees' out-of-pocket expenses for covered benefits was estimated to be $112,000 for the same period.

According to CHRP, the bill was most likely to improve adherence among typically adherent patients. However, there was insufficient evidence to suggest that the limited number of additional days (often as few as 1-3 days) of adherence made possible by the bill would measurably impact the effectiveness of treatment. For this reason, the study did not project a measurable impact on the population's health outcomes within the first year of the bill's passage into law. However, the study noted the average age of Californians has been increasing, and is expected to continue to do so. Resulting increases in age-related chronic eye conditions may lead to greater use of eye drops and eye ointments and so to greater use of the earlier refills that the bill would require. The report noted that the mandate would alter the terms but not require new benefit coverage and so would not exceed federal essential health benefits. The CHBRP expects that, on average, the post mandate possibility of earlier refill coverage would result in one additional refill per year among enrollees with a chronic condition and changed benefit coverage.[15]

III. Effect of Proposed Changes:

Sections 1, 2, and 3 require that individual and group health insurance policies and HMO contracts, which provide coverage for prescription eye drops to treat a chronic eye disease or condition, must provide coverage for prescription eye drop refills if the following criteria are met:

[13] Assembly Bill (AB) 1831 (introduced February 2016) would prohibit denial of refill coverage for covered topical ophthalmic products (TOPs) at and after 70 percent of predicted use. The TOPs include eye drops and eye ointments. The terms of coverage for 85 percent of enrollees would change, where coverage had been available for refills at and after 75 percent to 85 percent of projected use, refills would be covered at 70 percent of projected use.

[14] The California Health Benefits Review Program (CHBRP) was established in 2002 to provide the California Legislature with independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit mandates and repeals, per its authorizing statute.

[15] CHRP Study available at Analysis of California Assembly Bill (AB) 1831 Topical Ophthalmic Refills (Apr. 2016) http://chbrp.ucop.edu/index.php?action=read&bill_id=199&doc_type=3 (last viewed Jan. 21, 2018).

- The refill is dispensed on or before the last day of the prescribed dosage period (but not earlier than the 24th day for a 30-day supply, 48th day for a 60-day supply, and 72nd day for a 90-day supply) and the original prescription allows for additional quantities.
- The bill provides the prescription eye drop refills are subject to the same member cost share as all other prescription drug benefits under the policy or contract.

Section 4 provides for a July 1, 2018, effective date.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

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:

To the extent a commercial insurer or HMO is not currently providing access to such early refills, this bill would provide insureds with access to such additional coverage.

The provisions of the bill will not apply to employers that offer self-insured plans.[16] In Florida, an estimated 63 percent of private sector enrollees are enrolled in self-insured plans. Further, the bill would not apply to Medicaid plans since the bill does not amend ch. 409, F.S.

C. Government Sector Impact:

According to DMS, the bill would provide for an 80 percent refill threshold, which is more restrictive than the current 75 percent threshold allowed under the self-insured State

[16] 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.

Employees' Prescription Drug Plan. The PBM for DMS estimates that the bill would not have a fiscal impact on the self-insured State Employees' Prescription Drug Plan.[17]

VI. Technical Deficiencies:

None.

VII. Related Issues:

The effective date of the bill is July 1, 2018. Health plans have already filed and received approval of their forms and rates for 2018.[18] Further, many policies and contracts provide coverage on a calendar year basis. An effective date of January 1, 2019, for the bill would allow plans to incorporate the additional coverage requirements into their policies and contracts.

If the bill mandates additional coverage beyond what is currently required in the Florida Insurance Code, the bill may be subject to the requirements or s. 624.215, F.S. This provision creates a framework for the Legislature to conduct a systematic review of the impact of creating new mandates. The law requires that the proponent of proposed legislation mandating health benefit coverage submit a report to the Agency for Health Care Administration and the legislative committee having jurisdiction. The report must assess, among other things, the utilization rate of the treatment or service, the extent and impact of current coverage, the level of demand for the treatment or service and for insurance in general, the level of interest of collective bargaining agents in negotiating for such coverage, the cost of such coverage and the impact of such coverage on the overall cost of health care.

If this bill is deemed to provide a state-mandated benefit that exceeds the essential health benefits of Florida's benchmark plan, the federal Patient Protection Affordable Care Act (PPACA) requires states to defray such costs of state-mandated benefits.[19] The CHRP study of pending legislation in California noted that the mandate would alter the terms but not require new benefit coverage and so the mandate would not exceed the essential health benefits provided by California's benchmark plan.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 627.662 and 641.31.

This bill creates section 627.6411 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.

[17] Department of Management Services, *Analysis of SB 924 (Nov. 21, 2017) (on file with Banking and Insurance Committee).*
[18] Office of Insurance Regulation, *Analysis of SB 924* (on file with Senate Banking and Insurance Committee).
[19] 42 U.S. Code § 18031(d)(3)(B) and 45 CFR §155.170.

B. Amendments:

None.