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 800
INTRODUCER:	Senators Broxson and Mayfield
SUBJECT:	Medication Synchronization
DATE:	March 24, 2017
REVISED:	

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

I. Summary:

SB 800 establishes coverage and payment requirements relating to medication synchronization. Medication synchronization is a process where a pharmacist coordinates or synchronizes refills for a patient who is taking multiple prescriptions, allowing them to be filled on the same day each month. Partial fills for less than the standard refill amount are often required in order to align all patient medications to the same refill date. Medication synchronization can be used as a tool to increase medication adherence. The bill prohibits health insurance policies and health maintenance organization (HMO) contracts from denying coverage for a partial supply of medication dispensed by a network pharmacy if certain conditions are met. The bill requires such policies and contracts to authorize and apply a prorated daily cost-sharing rate for prescriptions under certain circumstances, and prohibits such policies and contracts from paying prorated dispensing fees for a partial fill or refill.

The fiscal impact of the bill on the Division of State Group Insurance is indeterminate.

II. Present Situation:

Federal Health Care and Access to Prescription Drugs

Medicare Part D

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003[1] 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. The Centers for Medicare and

[1] P.L. 108-173.

Medicaid Services currently requires health plans administering Medicare Part D plans to prorate copayments associated with refill synchronization.[2]

Patient Protection and Affordable Care Act

On March 23, 2010, the federal Patient Protection and Affordable Care Act (PPACA) was signed into law.[3] The 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. The PPACA also mandates required essential health benefits,[4] cost-sharing limits, rating and underwriting standards, and appeals of adverse benefit determinations.[5]

The PPACA requires issuers (insurers and HMOs) of qualified health plans (QHPs) to provide 10 categories of essential health benefits (EHB), which includes prescription drugs.[6] To be certified as a QHP, the insurer must also submit an application, follow established limits on cost sharing, and be certified by the federal Health Insurance Marketplace.[7] The deadline for insurers and HMOs to submit 2018 rates and forms to the OIR is May 3, 2017.

The QHPs must provide access to prescription drug benefits. An individual or small group health plan[8] providing QHPs must allow enrollees to obtain prescription drug benefits at in-network retail pharmacies, unless a drug is subject to restricted distribution by the U.S. Food and Drug Administration; or a 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 a network, retail pharmacy, for plans that do not have a network, the enrollee may go to any pharmacy to access his prescription drug benefit. In those situations, those plans would be deemed 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 a network retail pharmacy. The federal Department of Health and Human Services (HHS) notes that there are instances in which obtaining a drug through a mail-

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[2] See https://www.medicare.gov/part-d/costs/copayment-coinsurance/drug-plan-copayments.html (last visited Mar. 21, 2017).
[3] 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.
[4] 42 U.S.C. s.18022.
[5] President Trump, Executive Order 13765, *Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal*, https://www.whitehouse.gov/the-press-office/2017/01/2/executive-order-minimizing-economic-burden-patient-protection-and (Jan. 20, 2017). President Trump issued an executive order indicating that it is the intent of his administration to seek the prompt repeal of PPACA. (last visited Mar. 19, 2017).
[6] See Center for Consumer Information & Insurance Oversight, *Information on Essential Health Benefits (EHB) Benchmark Plans* https://www.cms.gov/cciio/resources/data-resources/ehb.html (last visited Feb. 13, 2017) for Florida's benchmark plan.
[7] Center for Consumer Information & Insurance Oversight, *Qualified Health Plans*, https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/qhp.html (last visited Feb. 13, 2017).
[8] 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.

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.[9]

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.[10] 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).[11]

Medication Synchronization

Medication synchronization is a tool that can improve adherence when patients are on a regular medication regimen. Medication synchronization can also reduce the administrative burden on patients who take multiple medications by reducing the number of refill dates. A retail or mail order pharmacy would coordinate all of a patient's prescription medications so that the drugs have the same refill date each month. The pharmacist initially performs a comprehensive review of the patient's medication regimen to determine the appropriateness of each therapy.

A partial fill can be required to align the patient's medications to a single refill date. Currently, some plans may not provide coverage for a refill for less than a 30-day supply. Patients may be required to pay a full month's copayment or coinsurance for a month's supply of medications. In some cases, pharmacies trying to submit a claim for adjusted quantities, will receive a "refill too soon" rejection, and the plan will deny coverage altogether, resulting in the patient paying out of pocket to cover the cost for the amount of medication needed to align their refills. Contingent on the plan, some plans will allow a limited number of overrides per year for special circumstances, such as a vacation supply, replacement of lost medication, or medication synchronization. In regards to dispensing fees, some plans will prorate the dispensing fee payment to the pharmacy that reflects a partial refill of a prescription.

Staff conducted a limited survey of states [12] that found that approximately 20 states have enacted medication synchronization legislation.[13] Some states place restriction on the types of drugs that may be eligible for synchronization. For example, Ohio requires that the medication must be the following criteria:

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

[10] 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 FDA's list of currently approved REMS is available at: http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm (last visited Mar. 20, 2017).

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

[12] See National Conference of State Legislators database available at http://www.ncsl.org/research/health/prescription-drug-statenet-database.aspx (last visited Mar. 21, 2017).

[13] See http://www.ncpanet.org/newsroom/ncpa's-blog---the-dose/2015/06/18/states-take-the-lead-in-making-med-synchronization-easier (last visited Mar. 21, 2017).

- Cannot have quantity limits, dose optimization criteria, or other requirements that would be violated if synchronized;
- Not have special handling or sourcing needs, as determined by the policy, contract, or agreement, that require a single, designated pharmacy to fill or refill the prescription;
- Be formulated so that the quantity or amount dispensed can be effectively divided in order to achieve synchronization;
- Not be a schedule II controlled substance, opiate, or benzodiazepine.[14]

Likewise, Kentucky law provides that a synchronized medication may not be a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone.[15] Nevada law states that the synchronization provisions do not apply to unit-of-use packaging for which synchronization is not practicable or to a controlled substance.[16] In Maine, prescriptions for solid oral doses of antibiotics and solid oral doses that are dispensed in their original container as indicated in the federal Food and Drug Administration prescribing information or are customarily dispensed in their original packaging to assist a patient with compliance are excluded from the medication synchronization requirements.[17]

Regulation of Insurance 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 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.[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), CaremarkPCS Health, L.L.C. (CVS/Caremark) for the state employees' self-insured prescription drug program.[21]

[14] See 2015 Ohio Act at https://custom.statenet.com/public/resources.cgi?id=ID:bill:OH2015000H116&ciq=ncsldc3&client_md=af8c8e805f456317976bcd68b3cfee7e&mode=current_text (last visited Mar. 21, 2017).
[15] See KRS 304.17A-165.
[16] Chapter 689A.330 of NRS.
[17] See http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=SP0284&item=3&snum=127 (last visited Mar. 21, 2017).
[18] Section 20.121(3)(a), F.S.
[19] Section 641.21(1), F.S.
[20] 26 U.S.C. s. 125.
[21] Section 110.12315, F.S.

III. Effect of Proposed Changes:

Sections 1 and 2 prohibit a health insurance policy or HMO contract providing prescription drug coverage in Florida from denying coverage for a partial supply of medication dispensed by a network pharmacy. Further, the policy or contract must authorize and apply prorated daily cost-sharing rates to prescriptions that are dispensed by a network pharmacy for the partial supply if:

- The prescribing practitioner or pharmacist determines the fill or refill is in the best interest of the insured; and
- The insured requests or agrees to a partial supply for the purpose of synchronizing his or her medication.

Further, an insurance policy or contract:

- Must allow, for purposes of medication synchronization, a network pharmacy to override any denial code indicating that a prescription drug is being refilled too soon.
- May not use payment structures that provide prorated dispensing fees. Dispensing fees for partially filled or refilled prescriptions must be paid in full for each prescription dispensed, regardless of any prorated copayment for the insured or member or fee paid for alignment services.

Section 3 provides that this act takes effect July 1, 2017.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. Constitutional Issues:

The bill revises provisions affecting persons who have or may have a contract with an insurer or HMO. In *Pomponio v. Claridge of Pompano Condominium, Inc.*,[22] the Florida Supreme court stated that some degree of flexibility has developed over the last century in interpreting the contract clause in order to ameliorate the harshness of the original rigid application used by the United States Supreme Court. The Florida Supreme Court invalidated a statute, as an unconstitutional impairment of contract, which required the deposit of rent into a court registry during litigation involving obligations under a contract lease. The court set forth several factors to be considered in balancing whether a state law has in fact operated as a substantial impairment of a contractual relationship,

[22] *Pompano v. Claridge of Pompanio Condominium, Inc.*, 378 So.2d 774 (Fla. 1979).

stating "[t]he severity of the impairment measures the height of the hurdle the state legislation must clear."

The court stated that if there is minimal alteration of contractual obligations, the inquiry may end at its first stage. Severe impairment pushes the inquiry into a careful examination of the nature and purpose of the state legislation. The factors to be considered are whether:

- The law was enacted to deal with a broad, generalized economic or social problem;
- The law operates in an area that was already subject to state regulation at the time the contract was entered into; and
- The effect on the contractual relationships is temporary, or whether it is severe, permanent, immediate, and retroactive.

In *United States Fidelity & Guaranty Co. v. Department of Insurance,*[23] the Florida Supreme Court followed *Pomponio* and said that the method requires a balancing of a person's interest to not have his or her contracts impaired, with the state's interest in exercising its legitimate police power. The court adopted the method used by the U.S. Supreme Court, in which the threshold inquiry is "whether the state law has, in fact, operated as a substantial impairment of a contractual relationship." The severity of the impairment increases the level of scrutiny.

Relevant to the extent of the impairment is whether the industry the complaining party had entered had been regulated in the past because if the party was already subject to regulation when the contract was entered, then it is understood that it would be subject to further legislation upon the same topic. If the state regulation constitutes a substantial impairment, the state must have a significant and legitimate public purpose and any adjustment of the rights and responsibilities of the contracting parties must be appropriate to the public purpose justifying the legislation.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Implementation of medication synchronization may improve medication adherence for patients, particularly patients with chronic conditions who are on multiple-medication regimens.

According to DMS, for a preferred provider organization enrollee filling maintenance medications at a retail pharmacy, any partial fill would count as one of their three 30-day fills at retail before being required to use 90-day retail or 90-day mail order.[24]

[23] *United States Fidelity & Guaranty Co. v. Department of Insurance,* 453 So.2d 1355 (Fla. 1984).
[24] Department of Management Services, *2017 Agency Legislative Bill Analysis of SB 800* (Mar. 16, 2017) (on file with Banking and Insurance Committee).

Insurers and HMOs may incur additional costs associated with the mandatory full dispensing fees associated with partial refills.

C. Government Sector Impact:

Local governments may experience an indeterminate increase in pharmacy dispensing fees if they are required to pay full dispensing fees for partial refills.

DMS/Division of State Group Insurance

Currently, the program does not allow for the synchronization of medication, if that synchronization requires an early refill. The fiscal impact on the program is unknown.[25]

VI. Technical Deficiencies:

According to DMS, amendments to s. 110.12315, F.S., would be necessary to incorporate provisions regarding prorated member cost sharing.

The term, "alignment service fee," is undefined. It is unclear whether it is separate or included in the dispensing fee. (See lines 45 and 68.)

VII. Related Issues:

The bill provides an effective date of July 1, 2017, which may not provide adequate time for insurers and HMOs to modify their computer systems to implement the provisions of the bill. Many plans, such as the exchange plans and Division of State Group Insurance, operate on a calendar year basis. According to the OIR, the deadline for insurers and HMOs to submit their 2018 rates and forms for products on or off the exchange is May 3, 2017.[26] An effective date of applying the provisions to contracts or policies entered on or after January 1, 2018, would allow additional time to implement the provisions.

VIII. Statutes Affected:

This bill substantially amends section 641.31 of the Florida Statutes.

This bill creates section 627.64196 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.

[25] Id.
[26] Office of Insurance Regulation, *Guidance to Insurers*, available at http://www.floir.com/sitedocuments/PPACANoticetoIndustry201802032017.pdf (last viewed Mar. 19, 2017).

B. Amendments:

None.