

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 Appropriations

BILL: CS/CS/SB 800

INTRODUCER: Appropriations Committee; Banking and Insurance Committee; and Senators Broxson and Mayfield

SUBJECT: Medication Synchronization

DATE: April 22, 2017

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Johnson</u>	<u>Knudson</u>	<u>BI</u>	<u>Fav/CS</u>
2.	<u>Lloyd</u>	<u>Stovall</u>	<u>HP</u>	<u>Favorable</u>
3.	<u>Davis</u>	<u>Hansen</u>	<u>AP</u>	<u>Fav/CS</u>

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/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 covered 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 requires health insurers and health maintenance organizations (HMOs) that provide prescription drug coverage to offer insureds or members the option to align the refill dates of their prescription drugs through a network pharmacy at least once during the plan year. Controlled substances, prescription drugs dispensed in an unbreakable package, or a multidose unit of a prescription may not be partially filled for the purpose of aligning refill dates.

The bill requires health insurers and HMOs to pay a full dispensing fee to the network pharmacy unless otherwise agreed to by the plan and the network pharmacy. The health insurer or HMO must prorate cost-sharing obligations of the insured for each partial refill of a covered prescription drug dispensed to align refill dates. Notwithstanding these requirements for medication synchronization services, the bill deems certain existing medication synchronization programs, which provide for early refills, refill overrides, and access on the insurer or HMO's public website to information about the program as complying with the bill's requirements.

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

The effective date of the bill is January 1, 2018.

II. Present Situation:

Medication synchronization is a process where a pharmacist coordinates or synchronizes refills for a patient who is taking multiple covered prescriptions, allowing them to be filled on the same day each month. This model is sometimes also referred to as the “appointment based model” as the patient has made a set appointment each month to pick up all of their prescriptions. Pharmacy staff will usually call the patient ahead of their appointment day to confirm that there have been no changes to the medications and that each prescription should be refilled.¹ Partial fills for less than the standard refill amount are often required initially in order to align all patient medications to the same refill date.

Medication synchronization can be used as a tool to increase medication adherence. Poor adherence to medication refills is most often an issue among individuals who suffer from chronic diseases. A Robert Wood Johnson Foundation study found that over 50 percent of all Americans suffer from at least one chronic disease, including such chronic diseases as cancer, diabetes, heart disease, hypertension, stroke, mental disorders, or pulmonary conditions.² The National Community Pharmacists Association estimates the cost of medication non-adherence to be in excess of \$290 billion annually.³

Federal Health Care and Access to Prescription Drugs

Medicare Part D

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003⁴ 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 Medicaid Services currently requires health plans administering Medicare Part D plans to prorate copayments associated with refill synchronization.⁵ A Medicare enrollee may request less than a one-month’s supply and pay the required copayment or coinsurance based on the quantity actually received.⁶

¹ American Pharmacists Association, *Appointment Based Model*, <http://www.pharmacist.com/appointment-based-model> (last visited Mar. 29, 2017).

² National Community Pharmacists Association, *Pharmacists Advancing Medication Adherence - Moving Forward on A Solid Foundation: Year One Progress Report*, p.3, available at <http://www.ncpa.co/pdf/smm/PAMA2012annualreport.pdf> (July 2011 - June 2012) (last visited Mar. 29, 2017).

³ *Id.*

⁴ Pub. L. No. 108-173.

⁵ Medicare.gov, *Copayment/coinsurance in drug plans* <https://www.medicare.gov/part-d/costs/copayment-coinsurance/drug-plan-copayments.html> (last visited Mar. 29, 2017).

⁶ *Id.*

Patient Protection and Affordable Care Act

On March 23, 2010, the federal Patient Protection and Affordable Care Act (PPACA) was signed into law.⁷ 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,⁸ cost-sharing limits, rating and underwriting standards, and appeals of adverse benefit determinations.⁹

The PPACA requires issuers (insurers and HMOs) of qualified health plans (QHPs) to provide ten categories of essential health benefits (EHB), which includes prescription drugs.¹⁰ 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.¹¹ The deadline for insurers and HMOs to submit 2018 rates and forms to the Florida Office of Insurance Regulation (OIR) is May 3, 2017.

The QHPs must provide access to prescription drug benefits. An individual or small group health plan¹² 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 or her 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-order pharmacy may not be a viable option, such as when an individual does not have a stable

⁷ 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. L. No. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010.

⁸ 42 U.S.C. s.18022.

⁹ 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/2017/01/20/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 viewed Mar. 30, 2017).

¹⁰ See Center for Consumer Information & Insurance Oversight, *Information on Essential Health Benefits (EHB) Benchmark Plans* <https://www.cms.gov/ccio/resources/data-resources/ehb.html> (last visited Mar. 30, 2017) for Florida's benchmark plan.

¹¹ Center for Consumer Information & Insurance Oversight, *Qualified Health Plans*, <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/qhp.html> (last viewed Mar. 30, 2017).

¹² 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.

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

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.¹⁴ 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).

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 less than 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. Regarding 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 and found that approximately 23 states¹⁵ have considered medication synchronization legislation.¹⁶ Some states place restriction on the types of drugs that may be eligible for synchronization or limited synchronization to those with chronic conditions. For example, Ohio requires that the medication must meet the following criteria:

- 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;

¹³ Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, 80 FR 10820, 10821 (Feb. 27, 2015).

¹⁴ 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/remis/index.cfm> (last viewed Mar. 30, 2017).

¹⁵ See National Conference of State Legislators database available at <http://www.ncsl.org/research/health/prescription-drug-statenet-database.aspx> (last viewed Mar. 30, 2017).

¹⁶ See <http://www.ncpanet.org/newsroom/ncpa's-blog---the-dose/2015/06/18/states-take-the-lead-in-making-med-synchronization-easier> (last viewed Mar. 30, 2017).

- 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.¹⁷

Likewise, Kentucky law provides that a synchronized medication may not be a Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone.¹⁸ 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.¹⁹ 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.²⁰

Regulation of Insurance in Florida

The Florida Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, HMOs, and other risk-bearing entities.²¹ The Agency for Health Care Administration (agency) regulates the quality of care provided by HMOs under part III of ch. 641, F.S.²² Before receiving a certificate of authority from the OIR, an HMO must obtain a Health Care Provider Certificate from the agency.

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.²³ To administer the state group health insurance program, the DMS contracts with third party administrators for self-insured health plans, insured HMOs, and a pharmacy benefits manager (PBM), CaremarkPCS Health, L.L.C. (CVS/Caremark) for the state employees' self-insured prescription drug program.

III. Effect of Proposed Changes:

Sections 1 and 2 require health insurers and HMOs providing prescription drug coverage to offer medication synchronization services on all policies entered into or renewed on or after January 1, 2018. The medication synchronization services must allow insureds or members the option to align the refill dates of their prescription drugs through a network pharmacy at least once in a plan year.

¹⁷ See 2015 Ohio Act at

https://custom.statenet.com/public/resources.cgi?id=ID:bill:OH2015000H116&ciq=ncslde3&client_md=af8c8e805f456317976bcd68b3cfee7e&mode=current_text (last viewed Mar. 21, 2017).

¹⁸ See KRS 304.17A-165.

¹⁹ Chapter 689A.330 of NRS.

²⁰ See <http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=SP0284&item=3&snum=127> (last viewed Mar. 30, 2017).

²¹ Section 20.121(3)(a), F.S.

²² Section 641.21(1), F.S.

²³ 26 U.S.C. s. 125.

The bill limits the types of prescription drugs eligible for a partial refill under medication synchronization. It prohibits a partial fill to align refill dates for the following prescription drugs:

- Controlled substances;
- Prescription drugs dispensed in unbreakable packages; or
- Multi-dose units of prescription drugs.

Additionally, the bill requires health insurers and HMOs to pay a full dispensing fee to the network pharmacy unless otherwise agreed to by the plan and the network pharmacy. The health insurer or HMO must prorate cost-sharing obligations of the insured for each partial refill of a covered prescription drug dispensed to align refill dates.

Notwithstanding these requirements for medication synchronization services, the bill deems certain existing medication synchronization programs, which provide for early refills, refill overrides, and access on the insurer or HMO's public website to information about the program as complying with the bill's requirements.

The provisions of these sections apply to policies or contracts issued on or after January 1, 2018.

Section 3 provides this act takes effect January 1, 2018.

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:

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

Insurers and HMOs may incur additional costs associated with full dispensing fees associated with partial refills of covered drugs. Some insurers may also incur costs to revise their forms to comply with the bill.²⁵

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.²⁶

The DMS will need to make changes to the summary plan description currently used by the SGI Program's PBM to allow prescriptions to be filled at any point for medication synchronization.²⁷ The DMS will also need to develop and incorporate a proration schedule outlining and creating prorated copayment amounts for medication synchronization.²⁸

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 641.31 of the Florida Statutes.

This bill creates section 627.64196 of the Florida Statutes.

²⁴ Department of Management Services, *Senate Bill 800 Analysis* (Mar. 16, 2017) (on file with the Senate Committee on Health Policy).

²⁵ Office of Insurance Regulation, *Senate Bill 800 Analysis* (Feb. 13, 2017) (on file with the Senate Appropriations Subcommittee on General Government).

²⁶ Department of Management Services, *Senate Bill 800 Analysis* (Mar. 16, 2017) (on file with the Senate Appropriations Subcommittee on General Government).

²⁷ *Id.*

²⁸ *Id.*

IX. Additional Information:

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

CS/CS by Appropriations on April 20, 2017:

The committee substitute deems existing medication synchronization programs, which provide for early refills, refill overrides, and access on the insurer or HMO's public website to information about the program as complying with the bill's requirements.

CS by Banking and Insurance: on March 27, 2017:

The CS:

- Requires health insurers and HMOs that provide covered prescription drugs to offer insureds or members the option to use medication synchronization at least once in a plan year at a network pharmacy.
- Requires such health insurer and HMO to implement a process for dispensing drugs for the purpose of aligning the refill dates of such drugs.
- Requires health insurers and HMOs to pay a full dispensing fee to the network pharmacy for each partial refill of a covered drug dispensed to align refill dates, unless otherwise agreed to by the plan and the network pharmacy at the time of the insured or member requests medication synchronization.
- Excludes certain prescription drugs from being partially filled for the purpose of aligning refill drugs.
- Applies to policies or contracts renewed or entered into on or after January 1, 2018.

- B. **Amendments:**

None.