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 Health Policy

BILL:	CS/CS/SB 860
INTRODUCER:	Health Policy Committee, Banking and Insurance Committee and Senator Garcia
SUBJECT:	Pharmacy
DATE:	April 2, 2015 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	**Fav/CS**
2.	Lloyd	Stovall	HP	**Fav/CS**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 860 creates s. 465.1862, F.S., within the Florida Pharmacy Act, to regulate activities and contracts of pharmacy benefit managers (PBMs). A PBM contracts with health insurance plans, such as a health maintenance organization or insurer, to manage the cost and quality of the plans' drug benefits and may provide a variety of related services. The maximum-allowable cost (MAC) is the payment for the unit ingredient costs for off-patent prescription drugs (generics). The PBM, an insurer, or a health maintenance organization may develop a MAC list based on a proprietary survey of wholesale prices and other factors.

The bill defines the terms, "maximum allowable cost," "pharmacy benefit manager," and "health insurance plan." For a PBM to place a particular generic drug on a MAC list, the drug must be generally available for purchase by pharmacies in this state from a national or regional wholesaler and not be obsolete. The bill requires disclosures and conditions for contracts between a PBM and a pharmacy related to drug pricing. The bill also requires that each contract between a PBM and a contracted pharmacy include a process for appeal, investigation, and resolution of disputes regarding MAC pricing.

According to the Division of State Group Insurance of the Department of Management Services, the implementation of this bill, as originally filed, would negatively affect the State Employees' Health Insurance Trust Fund by approximately $3 million for Fiscal Year 2015-2016. An updated fiscal impact is not available for the CS/CS/SB 860. According to the Agency for Health Care Administration, the CS has no direct impact on Medicaid. The impact on local governments

is indeterminate. The impact on insurers and private sector employers that use PBMs for providing drug benefits is indeterminate.

II. Present Situation:

Advances in pharmaceuticals have transformed health care over the last several decades. In 2013, retail prescription drug spending totaled $272.2 which was an increase of 3.3 percent from 2012.[1] This increase in 2013 was attributable to price increases for brand name and specialty drugs, increased spending on new medicines, and increased utilization. The projected growth for prescription drug spending in 2014 was 6.8 percent and 6.4 percent for 2015.[2]

Regulation of Pharmacies and Pharmacy Benefit Management Companies

Pharmacies and pharmacists are regulated under the Florida Pharmacy Act (act) in ch. 465, F.S. The Board of Pharmacy (board), created under the Department of Health (DOH), adopts rules to implement provisions of the act and takes other actions according to duties conferred on it by the act.[3] Each pharmacy is subject to inspection by the DOH and disciplined for violations of applicable laws relating to a pharmacy.[4]

Pharmacy benefit managers (PBMs) administer the prescription drug part of health plans on behalf of plan sponsors, such as self-insured employers, insurers, and health maintenance organizations (HMOs). Currently, PBMs are not subject to regulation in Florida. Some states, such as Connecticut, Georgia, Kansas, Louisiana, Maryland and South Dakota, require PBMs to either register with state insurance regulators or be licensed as third-party administrators.[5]

Although PBMs are not subject to licensure in Florida, a PBM may obtain accreditation from various impartial, external organizations (accrediting bodies) that determine if certain national standards are being met. Accreditation is an evaluative, rigorous, transparent, and comprehensive process in which a health care organization undergoes an examination of its systems, processes, and performance by an impartial external organization (accrediting body) to ensure that it is conducting business in a manner that meets predetermined criteria and is consistent with national standards. CVS/caremark, the PBM for the State Group Insurance program holds URAC[6] accreditation in the following areas: pharmacy benefit management, drug therapy management, mail service pharmacy, specialty pharmacy, and call center.[7]

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[1] Centers for Medicare and Medicaid Services, *National Health Expenditure Projections 2013-2023,* http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2013.pdf (last visited: Mar. 27, 2015).
[2] Id.
[3] Sections 465.005 and 465.022, F.S.
[4] Sections 465.015 and 465.016, F.S.
[5] Joanne Wojcik, *States Try to Regulate Pharmacy Benefit Managers*, Business Insurance, August 22, 2010, *available at* http://www.businessinsurance.com/article/20100822/ISSUE07/308229997
[6] See URAC website at: https://www.urac.org/accreditation-and-measurement/accreditation-programs/ (last visited Mar. 27, 2015).
[7] Department of Management Services correspondence, March 19, 2015 (on file with the Senate Banking and Insurance Committee).

Pharmacy Benefit Managers and Pharmacies

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.

MAC Pricing List

Contracts between a PBM and health plan sponsors specify how much the health plan sponsors will pay PBMs for brand name and generic drugs. These prices are typically set as a discount off the average wholesale price (AWP)[8] for brand-name drugs and at a MAC[9] for generic drugs (and sometimes brand drugs that have generic versions), plus a dispensing fee. The MAC represents the upper limit price that a plan will pay or reimburse for generic drugs and sometimes brand drugs that have generic versions available (multisource brands). A MAC pricing list creates a standard reimbursement amount for identical products. A MAC pricing list is a common cost management tool that is developed from a proprietary survey of wholesale prices existing in the marketplace, taking into account market share, inventory, reasonable profits margins, and other factors.

The federal Medicare Part D program and 45 state Medicaid programs use some type of MAC price lists to reduce costs.[10] The MAC price lists are used by many private employer prescription drug plans for retail generic prescriptions.

The purpose of the MAC pricing list is to ensure that the pharmacy or their buying groups are motivated to seek and purchase generic drugs at the lowest price in the marketplace. If a pharmacy procures a higher-priced product, the pharmacy may not make as much profit or in some instances may lose money on that specific purchase. If a pharmacy purchases generic drugs at a more favorable price, they will be more likely to make a profit.

In addition to negotiating rebates with drug manufacturers, PBMs negotiate with retail pharmacies to obtain various discounts on prescription drug prices. Additionally, PBMs try to assure adequate access for patients enrolled in the various health plans to obtain their prescription drugs. A PBM may also be responsible for the development and management of a drug formulary, which is a list of drugs that a health plan uses to make reimbursement decisions.

Many PBMs offer incentives to their enrollees to select generic instead of brand-name drugs since the generics are less costly than their brand-name counterparts. The use of generic drugs has saved consumers an estimated $1.2 trillion over a decade, but it has adversely affected

[8] AWP is the retail list price (sticker price) or the average price that manufacturers recommend wholesalers sell to physicians, pharmacies and others, such as hospitals.
[9] MAC is a price set for generic drugs and is the maximum amount that the plan sponsor will pay for a specific drug.
[10] Medicaid Drug Pricing in State Maximum Allowable Cost Programs, Office of Inspector General, OEI-03-11-00640, August 2013 *available at* https://oig.hhs.gov/oei/reports/oei-03-11-00640.asp (last visited Mar. 27, 2015).

independent pharmacists according to recent news articles.[11] In 2005, about 50 percent of U.S. retail prescription drug sales were generics. In 2010, generics represented about 71 percent of the market.[12] The increasing use of generics is pushing the dollar volume of prescription-drug sales down. In response, drugstores have advocated legislation requiring the PBMs to share pricing information that would help drugstores negotiate bigger reimbursements and avoid dispensing drugs that are not financially feasible.[13]

In November, U.S. Senator Bernie Sanders (I-Vt.) led a Senate hearing about recent pricing spikes in some generic drugs. The hearing followed a joint investigation Senator Sanders led with U.S. Representative Elijah Cummings (D-Md.).[14] One of the comments made during the hearing quoted that a small percentage of certain generic drugs increased more than 1,000 percent in the past year.[15] Included in the hearing materials was data showing that one half of generic medicines went up between last summer and this summer with some common medicines rising by over 500 percent.[16] In such an environment, a static MAC list could result in inadequate reimbursement to the pharmacy despite best efforts to purchase from the lowest cost source.

Federal Pharmacy Benefits Managers Transparency Requirements

On March 23, 2010, President Obama signed into law Public Law No. 111-148, the Patient Protection and Affordable Care Act (PPACA), and on March 30, 2010, President Obama signed into law Public Law No. 111-152, the Health Care and Education Affordability Reconciliation Act of 2010, amending PPACA. The law[17] requires Medicare Part D plans and qualified health plan issuers who have their own PBM or contract with a PBM to report to the U.S. Department of Health and Human Services (HHS) aggregate information about rebates, discounts, or price concessions that are passed through to the plan sponsor or retained by the PBM. In addition, the plans must report the difference between the amount the plan pays the PBM and the amount that the PBM pays its suppliers (spread pricing). The reported information is confidential, subject to certain limited exceptions.

State Group Health Insurance Program and the PBM Contract

Under the authority of s. 110.123, F.S., the Department of Management Services (DMS), through the Division of State Group Insurance (DSGI), administers the state group insurance program

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[11] Generic Pharmaceutical Association, Generic Drug Savings in the U.S., 2013 (on file with the Senate Banking and Insurance Committee).
[12] US Pharm. 2013;38(6)(Generic Review suppl):6-10. Accessible at http://www.uspharmacist.com/content/s/253/c/41309/ (last visited March 27, 2015).
[13] Timothy W. Martin, *Drugstores Press for Pricing Data,* Wall Street Journal, March 27, 2013.
[14] Senator Sanders and Representative Cummings have also filed legislation that would require drugmakers to extend rebates to Medicaid when drugmakers raise prices greater than inflation. This is the current federal law for brand-name drugs. *see http://www.sanders.senate.gov/newsroom/press-releases/drugmakers-mum-on-huge-price-hikes*
[15] Ed Silverman, *Should Generic Drug Makers Pay Medicaid Rebates Tied to Inflation?* Wall Street Journal Pharmalot (Nov. 24, 2014) http://blogs.wsj.com/pharmalot/2014/11/24/should-generic-drug-makers-pay-medicaid-rebates-tied-to-inflation/ (last visited: Mar. 27, 2015).
[16] U.S. Senate Subcommittee on Primary Health and Aging, Senate Committee on Health, Education, Labor and Pensions, *Ranking Member Cummings and Chairman Sanders Investigate Staggering Price Increases for Generic Drugs* (Oct. 2, 2014) http://www.sanders.senate.gov/download/face-sheet-on-generic-drug-price-increases?inline=file (last visited: Mar. 27, 2015).
[17] 42 U.S.C. s. 1320b-23.

providing employee benefits such as health, life, dental, and vision insurance products under a cafeteria plan consistent with Section 125, Internal Revenue Code.

As part of the state group health insurance program, the DMS contracts with a pharmacy benefits manager (PBM), CaremarkPCS Health, L.L.C. (CVS/caremark), to administer the state employees' prescription drug program. The DMS and the State of Florida are not a party to the private business contracts between the PBM and its retail pharmacies. According to DMS, the MAC is the payment for the unit ingredient costs for off-patent drugs (generics) developed by a PBM or an insurance plan. The DMS has a contractual provision to require CVS/caremark to provide, upon request, the most recent MAC list.[18]

III. Effect of Proposed Changes:

The bill creates s. 465.1862, F.S., titled "Pharmacy benefit managers," under ch. 465, F.S., the Florida Pharmacy Act.

The bill defines the following terms under this new section:

- "Maximum allowable cost" means the upper limit or maximum amount that a health insurance plan will pay for generic or brand-name prescription drugs that have available generic versions available, which are included on a list of products generated by a pharmacy benefit manager.
- "Pharmacy benefit manager" means a person entity doing business in this state which contracts to administer or manage prescription drug benefits on behalf of a health insurance plan that provides prescription drug benefits to residents of this state.
- "Health insurance plan" means the same as "health insurance" under s. 627.6482(6), F.S. Section 627.6482(6), F.S., defines health insurance as any hospital and medical expense incurred policy, minimum premium plan, stop-loss coverage, health maintenance organization contract, prepaid health clinic contract, multiple-employer welfare arrangement contract, or fraternal benefit society health benefits contract, whether sold as an individual or group policy or contract. The term does not include any policy covering medical coverage or personal injury protection coverage in a motor vehicle policy, coverage issued as a supplement to liability insurance, or workers' compensation.

The bill provides that in each contract between a PBM and a pharmacy, the contract must:

- Require the PBM to update MAC pricing information at least every seven business days;
- Establish a reasonable process for notice within one business day after the pricing information is updated through either electronic, print or telephonic format; and
- Maintain a procedure to eliminate products in a timely manner from the MAC pricing information to remain consistent with marketplace changes.

Before placing a prescription drug on the MAC list, the PBM must ensure a drug is:

- Generally available for purchase from a national or regional wholesaler by pharmacies in this state; and
- Not obsolete.

[18] Department of Management Services, *2015 Legislative Bill Analysis - SB-860(March 6, 2015)* (on file with the Senate Banking and Insurance Committee).

The bill requires that contracts between PBMs and pharmacies contain a process for appealing, investigating, and resolving disputes regarding MAC pricing. The process must limit the right to appeal to 30-calendar days following the initial claim; require the resolution of the dispute within seven business days after an appeal is received by the PBM; and require the PBM to provide contact information of the person who is responsible for processing the appeal.

If an appeal is denied, the PBM must provide the reason and identify the national drug code of an alternative prescription drug that may be purchased at a price at or below the MAC, as determined by the PBM. If an appeal is upheld, the PBM must make an adjustment to the MAC pricing within one business day after the date the appeal is upheld and make the adjustment effective for all similarly situated network pharmacies.

The bill is effective date on July 1, 2015.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. Other Constitutional Issues:

Under article VII, section 18(a) of the Florida Constitution, a mandate includes a general bill requiring counties or municipalities to spend funds. Counties and municipalities are not bound by a general law to spend funds or take an action unless the Legislature has determined that such a law fulfills an important state interest and one of the specific exceptions specified in the state constitution applies. The implementation of this bill may require counties and municipalities to spend funds or take actions regarding health insurance programs for their employees because of a decreased number of prescription drugs being capable of being placed on a maximum allowable cost (MAC) pricing list. One of those mandate exceptions is that the law applies to all persons similarly situated, including the state and local governments. This bill may apply to all similarly situated persons, including the state and local governments. Therefore, a finding by the Legislature that the bill fulfills an important state interest would remove the bill from the purview of the constitutional provision.

The new contracting requirements could be an impairment of contracts if any contracts between a PBM and a pharmacy are multi-year contracts. The United States Constitution and the Florida Constitution prohibit the state from passing any law impairing the

obligation of contracts.[19] The courts will subject state actions that impact state-held contracts to an elevated form of scrutiny when the Legislature passes laws that impact such contracts. *Cf. Chiles v. United Faculty of Fla.*, 615 So.2d 671 (Fla. 1993). "[T]he first inquiry must be whether the state law has, in fact, operated as a substantial impairment of a contractual relationship. The severity of the impairment measures the height of the hurdle the state legislation must clear."[20]

If a law does impair contracts, the courts will assess whether the law is deemed reasonable and necessary to serve an important public purpose.[21] The court will also consider three factors when balancing the impairment of contracts with the important public purpose:

- Whether the law was enacted to deal with a broad economic or social problem;
- Whether the law operates in an area that was already subject to state regulation at the time the contract was entered into; and,
- Whether the effect on the contractual relationship is temporary; not severe, permanent, immediate, and retroactive.[22]

A law that is deemed to be an impairment of contract will be deemed to be invalid as it applies to any contracts entered into prior to the effective date of the Act.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/CS/SB 860 may result in a reduction in the number of drugs subject to the MAC list pricing of a PBM if the drugs are not generally available. As a result:

- A pharmacist may receive a higher reimbursement for dispensed drugs that are removed from the maximum allowable cost (MAC) list.
- Employers and insurers may incur indeterminate additional costs for drugs that are removed from the MAC list. These costs could be shifted to policyholders as an increase in copayments for drugs removed from the MAC list.

C. Government Sector Impact:

According to the Division of State Group Insurance (DSGI) of the Department of Management Services, the implementation of the original bill was estimated to result in a

[19] U.S. Const. art. I, ch. 10; art. I, s. 10, Fla. Const.
[20] *Pomponio v. Claridge of Pompano Condominium, Inc.,* 378 So.2d 774 (Fla. 1980). *See also General Motors Corp. v. Romein,* 503 U.S. 181 (1992).
[21] *Park Benzinger & Co. v. Southern Wine & Spirits, Inc.,* 391 So.2d 681 (Fla. 1980); *Yellow Cab C., v. Dade County,* 412 So. 2d 395 (Fla. 3rd DCA 1982). *See also Exxon Corp. v. Eagerton,* 462 U.S. 176 (1983).
[22] *Pomponio v. Cladridge of Pompanio Condo., Inc.,* 378 So.2d 774 (Fla. 1980).

negative $3 million fiscal impact to the State Employees' Health Insurance Trust Fund.[23] Any costs incurred by a PBM to administer the provisions of this bill may be passed to the DMS as increased administrative fees. Limiting the generic drugs that can be subject to MAC pricing and affecting the aggressiveness of MAC pricing within pharmacy contracts could increase prescription drug costs for the program. An updated fiscal impact on the CS/CS/SB 860 was not available at the time of publication of this analysis.

Medicaid

There is no direct impact on Medicaid.[24]

Division of Risk Management/Department of Financial Services

According to the Division of Risk Management (DRM) of the Department of Financial Services (DFS), the CS/CS/SB 860 results in no fiscal impact on prescription drug costs for injured state workers.[25]

VI. Technical Deficiencies:

The bill creates a new section in ch. 465, F.S., relating to pharmacies. It is unclear whether the Board of Pharmacy or the Department of Health would have the authority to enforce the provisions of the bill. Currently, the Board of Pharmacy and the Department of Health have no regulatory authority over PBMs.

To avoid any issue as to the application of the mandate provision of the state constitution, consideration should be given to adding a statement to the bill that it fulfills an important state interest.

The definition of "health insurance plan" cross references s. 627.6482(6), F.S. This section of law is scheduled for repeal effective October 1, 2015.[26] Once repealed, this definition will not have a reference point.

Section 465.1862(3), F.S., refers to placing a prescription drug on a list of products. For clarity, it should identify the list of products subject to the maximum allowable cost pricing. Also in this subsection, the bill refers to a prescription drug as not obsolete. It is not apparent what obsolete means in this context. Does it mean discontinued, withdrawn from the market, or some other meaning?

Section 465.1862(4)(a)1 refers to the appeal process and the right to limit an appeal to "after the initial claim." This phrase needs a more defined reference point, such as after claim submission or after claim adjudication.

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[23] Department of Management Services, *Senate Bill 860 Analysis* (March 6, 2015) (on file with the Senate Committee on Banking and Insurance).
[24] Agency for Health Care Administration correspondence, (March 19, 2015) (on file with the Senate Committee on Banking and Insurance).
[25] Email from Patty Cromartie, Department of Financial Services, relaying information from Molly Merry of the Division of Risk Management (April 1, 2015) (on file with the Senate Committee on Health Policy),
[26] *see* Ch. 2013-101, s. 20, Laws of Florida

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 465.1862 of the Florida Statutes.

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 Health Policy on March 31, 2015
The committee substitute:

- Removes the definition for "contracted pharmacy" and "plan sponsor;"
- Adds definition for "health insurance plan" through a cross reference to s. 627.6482(6), F.S.;
- Modifies the time standard for updating MAC cost pricing information from at least every 7 calendar days to every 7 business days and permits review of such information by contracted pharmacies via electronic, print or telephonic formats within one business day after an update at no cost to the contracted pharmacy;
- Requires the PBM to maintain a procedure to eliminate products subject to MAC pricing in a timely manner in order to remain consistent with marketplace changes;
- Revises requirements for MAC pricing to require that in order to place a prescription drug on a list, the PBM must ensure it is generally available from a national or regional wholesaler and not obsolete;
- Removes MAC price listing requirements related to significant cost differences and the need for at least two therapeutically or pharmaceutically equivalents;
- Deletes disclosure requirements for differences in MAC pricing in retail versus mail order;
- Modifies the investigation and resolution process to require investigation and resolution within seven business days after an appeal is received by the PBM rather than within 14 days;
- Revises pricing after appeal denial to add "as determined by the PBM"; and
- Modifies the appeal provision to require the PBM to make an adjustment to the MAC pricing within one business day after the date the appeal is upheld rather than retroactive to the date the claim was adjudicated.

CS by Banking and Insurance on March 23, 2015:
The CS provides the following changes:

- Eliminates the requirement for a pharmacy benefit manager (PBM) to maintain a procedure to eliminate products from the maximum allowable cost (MAC) list or to modify the MAC pricing within 3 days after a change if such products no longer meet the requirements of this section.
- Deletes the requirement that a PBM promptly change the MAC pricing list to reflect any change in the marketplace that affects the cost of a drug.

- Requires a drug have at least two, instead of three, nationally available, therapeutically equivalent, multiple-source generic drugs that meet other specified criteria before it can be placed on the MAC list.
- Removes the requirement that a PBM disclose to a plan sponsor the methodology used to establish a MAC pricing.
- Revises mandatory provisions required for contracts between a pharmacy and a PBM regarding the appeal, investigation, and resolution of MAC pricing disputes.

B. Amendments:

None.