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:	CS/SB 860
INTRODUCER:	Banking and Insurance Committee and Senator Garcia
SUBJECT:	Pharmacy
DATE:	March 23, 2015
REVISED:	

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 860 creates provisions regulating activities and contracts of pharmacy benefit managers (PBMs). A PBM contracts with health plan sponsors, 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 purpose of the MAC 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.

The bill defines the terms, “contracted pharmacy,” “maximum allowable cost,” “pharmacy benefit manager,” and “plan sponsor.” The bill establishes criteria for a PBM to place a particular generic drug on a MAC list, which may result in some drugs being removed from the MAC list and being subject to higher reimbursement rates. The bill creates required disclosures and conditions for contracts between a PBM and a pharmacy, and between a PBM and a plan sponsor related to drug pricing. The bill also requires that each contract between a PBM and a contracted pharmacy must 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 would negatively affect the State Employees’ Health

Insurance Trust Fund by approximately $3 million for Fiscal Year 2015-16. 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 $271.1 billion, which was an increase of 2.5 percent from 2012. This increase in 2013 was attributable to price increases for brand name and specialty drugs, increased spending on new medicines, and increased utilization.

Regulation of Pharmacies and Pharmacy Benefit Management Companies

Pharmacies and pharmacists are regulated under the Florida Pharmacy Act (act) in chapter 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.[1] Each pharmacy is subject to inspection by the DOH and disciplined for violations of applicable laws relating to a pharmacy.[2]

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.[3]

Although PBMs are not subject to licensure in Florida, a PBM may obtain accreditation from various impartial, external organizations (accrediting bodies) that determines 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[4] accreditation in the following areas: pharmacy benefit management, drug therapy management, mail service pharmacy, specialty pharmacy, and call center.[5]

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

[1] Sections 465.005 and 465.022, F.S.
[2] Sections 465.015 and 465.016, F.S.
[3] Wojcik, J., States Try to Regulate Pharmacy Benefit Managers, businessinsurance.com, August 22, 2010.
[4] See URAC website at: https://www.urac.org/accreditation-and-measurement/accreditation-programs/ (last visited March 20, 2015).
[5] Department of Management Services correspondence, March 19, 2015 (one file with Banking and Insurance Committee).

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)[6] for brand-name drugs and at a MAC[7] 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.[8] 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 also 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 independent pharmacists according to recent news articles.[9] In 2005, about 50 percent of U.S. retail prescription drug sales were generics. In 2010, generics represented

[6] 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.
[7] MAC is a price set for generic drugs and is the maximum amount that the plan sponsor will pay for a specific drug.
[8] 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 March 18, 2015).
[9] Generic Pharmaceutical Association, Generic Drug Savings in the U.S., 2013 (on file with Banking and Insurance Committee).

about 71 percent of the market.[10] 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.[11]

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[12] 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 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 contractual provision to require CVS/caremark to provide, upon request, the most recent MAC list.[13]

III. Effect of Proposed Changes:

The bill creates a new section of law titled "Pharmacy benefit managers," under ch. 465, F.S., which is the Florida Pharmacy Act. The bill defines the following terms:

- "Contracted pharmacy" means a pharmacy or network of pharmacies that has executed a contract, which includes maximum allowable cost pricing requirements with a PBM and acts on behalf of a plan sponsor.

[10] US Pharm. 2013;38(6)(Generic Review suppl):6-10. Accessible at http://www.uspharmacist.com/content/s/253/c/41309/ (last visited March 18, 2015).
[11] Timothy W. Martin, *Drugstores Press for Pricing Data,* Wall Street Journal, March 27, 2013.
[12] 42 U.S.C. s. 1320b-23.
[13] Department of Management Services, 2015 Legislative Bill Analysis, dated March 6, 2015.

- "Maximum allowable cost" means the upper limit or maximum amount that a plan sponsor will pay for generic or brand-name drugs that have generic versions available, which are included on a pharmacy benefit manager-generated list of products.
- "Pharmacy benefit manager" means a person, business, or other entity that provides administrative services related to processing and paying prescription claims for pharmacy benefit and coverage programs. Such services may include contracting with a pharmacy or network of pharmacies; establishing payment levels for provider pharmacies; negotiating discounts and rebate arrangements with drug manufacturers; developing and managing prescription formularies, preferred drug lists, and prior authorization programs; ensuring audit compliance; and providing management reports.
- "Plan sponsor" means a health maintenance organization, an insurer, a Medicaid managed care plan as defined s. 409.962(9), F.S., a prepaid limited health service organization, or other entity contracting for PBM services.

The bill provides that a contract between a PBM and a pharmacy, which includes MAC pricing, must require the PBM to update MAC pricing information at least every 7-calendar days and establish a reasonable process for notice of updates.

In order to place a prescription drug on the MAC list, the PBM must ensure a drug has at least two or more nationally available, therapeutically equivalent, multiple-source generic drugs that:
- Have a significant cost difference;
- Are listed as therapeutically and pharmaceutically equivalent or "A" or "AB" rated in the U. S. Food and Drug Administration's most recent version of the Orange Book as of July 1, 2015;[14]
- Are available for purchase from national or regional wholesalers without limitations by all pharmacies in the state; and
- Are not obsolete or temporarily unavailable.

The bill requires a PBM to disclose in the contract between the PBM and the plan sponsor whether the PBM uses a MAC list for drugs dispensed at retail, but not for drugs dispensed by mail order.

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 14 days; 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 that may be purchased at a price at or below the MAC. If an appeal is upheld, the PBM must make an adjustment retroactive to the date the claim was adjudicated and make the adjustment effective for all similarly situated network pharmacies.

[14] The publication, ***Approved Drug Products with Therapeutic Equivalence Evaluations*** (the List, commonly known as the Orange Book), identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act).

The bill has an effective date of 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), Fla. Const., 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 plan sponsor or 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.[15] 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."[16]

[15] U.S. Const. art. I, ch. 10; art. I, s. 10, Fla. Const.
[16] *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).

If a law does impair contracts, the courts will assess whether the law is deemed reasonable and necessary to serve an important public purpose.[17] 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.[18]

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/SB 860 may result in a reduction in the number of drugs subject to the MAC list pricing of a PBM. As a result, a pharmacist may receive a higher reimbursement for dispensed drugs that are removed from the maximum allowable cost (MAC) list and are subject to a reimbursement at a higher brand-like rate.

Due to changes in the criteria for drugs to be eligible for the MAC list, the bill may increase prices for some generic drugs removed from the MAC list and subject them to higher brand-like pricing. 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 and now subject to brand pricing.

C. Government Sector Impact:

State Group Insurance

According to the Division of State Group Insurance (DSGI) of the Department of Management Services, the implementation of this bill is estimated to result in a negative $3 million fiscal impact to the State Employees' Health Insurance Trust Fund. [19] 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

[17] *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).
[18] *Pomponio v. Cladridge of Pompanio Condo., Inc.*, 378 So.2d 774 (Fla. 1980).
[19] Department of Management Services, 2015 Legislative Bill Analysis, March 6, 2015 (on file with Banking and Insurance Committee).

contracts could increase prescription drug costs for the program. Because of these combined factors, the CVS/caremark anticipates that SB 860 would have an annual negative fiscal impact of $3 million to the State Employees' Health Insurance Trust Fund. The trust fund is funded by contributions paid by state employees and state agency and university employers. The negative fiscal impact of this bill to the trust fund could result in a larger increase in employer and/or employee contributions for health insurance than otherwise might be required.

Additionally, the DSGI notes the bill:

- Requires that, for a drug to be placed on a MAC list the drugs must have a "significant cost difference." A fiscal impact cannot be determined without a definition of this phrase.
- Requires that the drugs are "available for purchase from national or regional wholesalers without limitations by all pharmacies in the state." This language appears overly broad, and some pharmacies in the state may be limited in scope and practice such that a particular drug would not be available to "all pharmacies." Further, it is unclear how a PBM could make such a determination regarding every pharmacy in the state. The DSGI suggests language that would specify the types of pharmacies at which the drug is available for purchase.
- May result in the member (state employee or retiree) paying the brand copayment to correspond to the higher brand pricing that the DSGI would pay.

Medicaid

According to the Agency for Health Care Administration (agency), CS/HB 555, which is similar to CS/SB 860, appears to be tasking the plans to have a State Maximum Allowed Cost (SMAC) similar to the agency's SMAC. The bill does not impact the relationship between the agency and managed care plans participating in the Statewide Medicaid Managed Care program, but rather adds requirements for transparency on pricing for PBMs that are contracting with managed care plans and requirements regarding the relationship between PBM and their contracted pharmacies. As currently written, there is no direct impact on Medicaid.[20]

Division of Risk Management/Department of Financial Services

According to the Division of Risk Management (DRM) of the Department of Financial Services (DFS), the fiscal impact on prescription drug costs for injured state workers is indeterminate at this time.[21] The DRM spends approximately $13 million per year for pharmacy benefits, which is a much lower amount than the costs for the Division of State Group Insurance program. The fiscal impact on prescription drug costs for injured state workers is uncertain. The Division of Risk Management is contracted through January 1, 2017, with a pharmacy benefit manager to manage prescription costs for injured state workers. Due to prohibitions in the state constitution on impairment of contracts, it is

[20] Agency for Health Care Administration correspondence, March 19, 2015 (on file with Banking and Insurance Committee).
[21] Department of Financial Services, 2015 Legislative Bill Analysis, March 19, 2015 (on file with Banking and Insurance Committee).

unlikely any effects of this legislation would occur until expiration of the current contract.

The fiscal impact of SB 860 on prescription costs for injured state workers is probably less of an impact than on group health insurance since s. 440.13(12)(c), F.S., prescribes a reimbursement amount at the average wholesale price plus $4.18 for a dispensing fee unless a lower rate has been negotiated for workers' compensation prescriptions. The current provisions of s. 440.13(12)(c) F.S., operate as a maximum rate with flexibility to negotiate lower rates. Since this section is not addressed by the bill, it is likely that compensation medication would continue to be reimbursed at the statutory amount. Although unlikely, if this legislation is interpreted to disallow reimbursement pursuant to s. 440.13(12)(c) F.S., there is the possibility of undetermined cost increases in compensation claims. Removal of the statutory maximum rate has the potential to increase the negotiated rates depending on the bargaining position of the parties. Although the bill may limit a PBM's ability to negotiate rates below the statutory rate for workers' compensation medications, the MAC likely would apply to many fewer workers' compensation prescriptions than those prescriptions paid under group health insurance.

VI. Technical Deficiencies:

Some of the terms and conditions provided in the bill may be difficult to interpret, implement, or enforce by the stakeholders. For example, the bill provides that in order to place a drug on the MAC list, the drug must have at least two therapeutically equivalent, multiple-source generic drugs, which have a "significant cost difference" and are available for purchase "without limitations" by all pharmacies in the state from national or regional wholesalers. It is unclear how "significant" and "without limitation" would be determined.

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.

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 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.
- Provides technical clarifying changes.

B. Amendments:

None.

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