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/CS/SB 1494
INTRODUCER:	Banking and Insurance Committee; Health Policy Committee; and Senator Montford and others
SUBJECT:	Prescription Drug Pricing Transparency
DATE:	February 20, 2018 REVISED:

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 1494 requires a pharmacist or his or her authorized employee to inform customers of potential lower cost generically equivalent alternatives for their prescriptions and whether a prescription's cost sharing amount exceeds the retail price in the absence of insurance coverage. The bill also requires pharmacy benefit managers (PBMs) to register with the Office of Insurance Regulation (OIR) and pay a biennial registration fee not to exceed $500. A PBM is a person or entity doing business in this state, which contracts to administer or manage prescription drug benefits on behalf of a health insurer or a health maintenance organization (HMO) to residents of this state.

Further, the bill requires that contracts of PBMs with insurers or HMOs must require the PBM to update the maximum allowable cost (MAC) information every seven calendar days and include specific terms to prohibit PBMs from limiting a pharmacist's ability to disclose to customers when cost sharing may exceed the retail price of a drug or the availability of a more affordable alternative drug. The bill also prohibits any contract between a PBM and a health insurer or HMO from requiring a customer to pay an amount that exceeds the applicable cost-sharing amount or the retail price of the drug in the absence of prescription drug coverage.

The bill has an estimated fiscal impact of $79,141 on the Office of Insurance Regulation for the funding of one FTE and technology upgrades.

The effective date of the act is July 1, 2018.

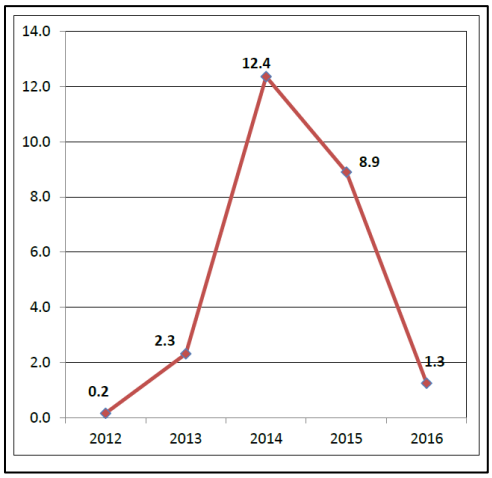
II. Present Situation:

Prescription Drugs Costs

In 2016, total health care expenditures in the United States reached $3.3 trillion, a 4.3 percent increase over the 2015 level.[1] Of that amount, prescription drug coverage accounted for $328.6 billion, up from $324.5 billion which was only a year to year growth rate of 1.3 percent.[2] In the prior year, 2014 to 2015, the annual growth trend in prescription drugs had been 8.9 percent and then 12.4 percent in the annual period of 2013 to 2014.[3] The significant growth rates of these periods are attributed largely to new medicines for hepatitis C and higher use rates for brand-names medications due to losses in certain patent protections.[4]

The graph below from the Centers for Medicare and Medicaid Services, Office of the Actuary, shows the Annual Growth in Retail Prescription Drug Spending from 2012 through 2016 highlighting the moderate increase in spending from 2015 to 2016 of 1.3.[5] The 2016 decline in spending is linked to the approval of fewer new drugs, slower growth in brand name drugs, and a drop in spending in hepatitis C drugs.[6]

Graph 1 - Annual Growth in Retail Prescription Drug Spending - 2012 - 2016



SOURCE: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics

[1] Micah Hartman, Anne B. Martin, Nathan Espinosa, et al, *National Health Care Spending in 2016: Spending and Enrollment Growth Slow After Initial Coverage Expansions*, Health Affairs – January 2018 (Dec. 6, 2017), p. 152, available at https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2017.1299 (last viewed Feb. 15, 2018).
[2] *Id at 153.*
[3] *Id.*
[4] *Id at 155.*
[5] Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group, *Annual Growth in Retail Prescription Drug Spending, 2012-2016*, Slide 12, available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/NHE-Presentation-Slides.pdf (last viewed Feb. 9, 2018).
[6] *Id.*

As shown in Table 1, the largest payer for prescription drugs is private health insurance coverage at 43 percent.[7]

Utilization data shows an increase in 2016 in the number of prescriptions dispensed, especially for drugs that treat high blood pressure, high cholesterol, and mental health.[8] An increase in the use of specialty drugs may have also played a part in the increased costs. Expenditures on specialty drugs are rising more rapidly than on other drugs; however, there is no clear definition of what is a "specialty drug."

Table 1: Retail Prescription Growth Rates, 2015-2016[9,10]

Payer	Percentage of Market	Percent Growth	
		2015	2016
Overall – All Payers	100%	8.9%	1.3%
Private Health Insurance	43%	10.4	0.8
Medicare	29%	9.3	2.8
Medicaid	10%	13.4	5.5
Out-of-pocket spending	14%	1.6	(1.0)

A different review of national prescription drug data from 2010 to 2014 attributes the rise in prescription drug spending to multiple factors from 2010 to 2014: population growth (10 percent), an increase in the number of prescriptions dispensed per person (30 percent), economy-wide inflation (30 percent), and the remaining 30 percent to changes in the composition of drugs prescribed toward higher priced products or price increases for drugs which drove average price increases in excess of general inflation.[11]

Pharmacy Benefits Managers (PBMs)

Health insurers, HMOs, and other purchasers of health benefits coverage increasingly utilize PBMs to provide a range of services related to the acquisition and management of prescription drugs. The PBMs negotiate with retail pharmacies to obtain various discounts on prescription drug prices. PBMs also provide the following services to its customers:

- Pharmacy claims processing;
- Mail-order pharmacy services;
- Rebate negotiations with drug manufacturers;
- Development of pharmacy networks;
- Formulary management;[12]
- Prospective and retrospective drug utilization reviews;
- Offer incentives to plan participations to use generic drug substitutions; and

[7] *Supra* note 5, at 155.
[8] *Supra* note 1, at 156.
[9] *Id.*
[10] Centers for Medicare and Medicaid Services, National Health Expenditure Data – Historical, *2016 - Table 16 – Retail Prescription Expenditures (Average Annual Percent Change from Previous Year Shown)* (Jan. 8, 2018) available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html (last viewed Feb. 15, 2018).
[11] *Supra* note 6, at 5.
[12] A list of drugs that a health plan uses to make reimbursement decisions.

- Disease management programs.

The decision of plan sponsors to use PBMs to control pharmacy benefit costs, however, can shift business away from retail pharmacies. A PBM can often use aggregate volume to offer its clients savings with discounts from pharmaceutical manufacturers and pharmacies.[13] An estimated 266 million Americans have their pharmacy benefits managed by a PBM.[14] An industry advocacy group estimates that PBMs have saved an average of $941 per person per year compared to unmanaged expenditures,[15] including a total of $43.4 billion across all payors in Florida.[16]

Approximately 60 PBMs are operational nationally, and the three largest – Express Scripts, CVS/Caremark, and OptumRx – report filling or managing a combined 5.1 billion prescriptions annually.[17,18, 19] PBMs use different tools and methods to reduce costs and find savings for payors through reductions in the unit costs of drugs, the mix of drugs that are prescribed, and in the modification of patient behavior through either reduction of inappropriate use of certain prescriptions or improvements in patient adherence to drug regimens.[20]

Examples of unit cost reductions may be in discounts to pharmacy network participants, use of manufacturer rebates, or the increased use of mail order pharmacies. PBMs may also encourage a greater use of generic drugs over certain brand name drugs, require step therapy, or implement tiered copayment levels for different types of prescriptions to achieve desired savings. Reducing or eliminating certain types of patient behaviors through quantity limits, prior authorization requirements, or other patient management programs are also tools that may be used.[21] Each PBM may generate savings from these actions which may also translate into savings for the patient and the payor.

Most patients assume that their share of cost of that prescription will be less than the actual retail cost of the prescription (or the non-insured cash price) of the drug. However, this may not always be the case. In cases where the retail price of the drug is less than a patient's applicable cost share, a patient could pay the regular cost sharing, regardless of the retail price; pay the lower retail price; or, some other amount based on the contract terms between the PBM and the pharmacy. If a pharmacist is obligated to charge this higher price, the PBM may collect as

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[13] Bill Alpert, *Pharmacy Benefit Managers Under Pressure,* Barrons (July 23, 2016) *available at* https://www.barrons.com/articles/pharmacy-benefit-managers-under-fire-1469247082 (last visited Feb. 1, 2018).
[14] Visante, Prepared for the Pharmaceutical Care Management Association, *The Return on Investment on PBM Services* (November 2016), Slide 2, *available at* https://www.pcmanet.org/wp-content/uploads/2016/11/ROI-on-PBM-Services-FINAL.pdf (last visited Feb. 1, 2018).
[15] *Id.*
[16] Pharmaceutical Care Management Association, *How Much PBMs are Saving: State by State* http://drugbenefitsolutions.com/prescription-costs/ (last visited Feb. 1, 2018).
[17] Express Scripts, *Corporate Overview* https://lab.express-scripts.com/about/ (last visited Feb. 1, 2018).
[18] CVS Health, *Investor Fact Sheet* (November 2017) *available at* http://investors.cvshealth.com/~/media/Files/C/CVS-IR-v3/documents/cvs-factsheet-111017.pdf (last visited Feb. 1, 2018).
[19] OptumRx, *About Optum* https://www.optum.com/about.html (last visited Feb. 1, 2018).
[20] *Supra* note 15, at 4.
[21] *Id.*

revenue the difference between a patient's cost share and the lower retail price.[22] One recent *New York Times* article cited a statistic that for up to 10 percent of drug transactions, the patient could have gotten a better price without an insurance card for a prescription than with his or her coverage.[23]

Maximum Allowable Cost Pricing List

Contracts between a PBM and health plan sponsors, insurers, or HMOs specify how much such entities will pay the PBMs for brand name and generic drugs. These prices are typically set as a discount off the average wholesale price[24] for brand-name drugs and at a maximum allowable cost (MAC)[25] for generic drugs, plus a dispensing fee. The MAC represents the upper limit price that a payor, such as a state or a plan sponsor has through its PBM, will pay or reimburse for generic and brand drugs that have generic versions available.[26] A national survey represents that 92 percent of large employers have such a list in place through their PBM.[27]

A MAC pricing list creates a standard reimbursement amount for identical products, and is a common cost management tool developed from a proprietary survey of wholesale prices in the marketplace, taking into account market share, inventory, reasonable profits margins, and other factors. The purpose of the MAC pricing list is to ensure that the pharmacy is motivated to seek and purchase generic drugs at the lowest price in the marketplace. The federal Medicare Part D program and 44 state Medicaid programs use some type of MAC price lists to reduce costs.[28]

Regulation of Pharmacies and Pharmacy Benefit Management Companies

In Florida, PBMs are not regulated or licensed. However, the Board of Pharmacy under ch. 465, F.S., regulates pharmacies, adopts rules to implement the provisions of the Pharmacy Act, and takes other actions according to duties conferred upon it.[29] Each pharmacy is subject to inspection by the Department of Health (DOH) and may be disciplined for violations of applicable laws and rules relating to a pharmacy.[30]

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[22] National Community Pharmacists Association. *Statement for the Record: National Community Pharmacists Association*, U.S. House Committee on Oversight and Government Reform, (Feb. 4, 2016), *available at* http://www.ncpa.co/pdf/ncpa-ogr-statement.pdf (last visited Feb. 1, 2018).
[23] Charles Orsnstein, *When Buying Prescription Drugs, Some Pay More With Insurance Than Without It,* The New York Times, (December 9, 2017), *available at* https://www.nytimes.com/2017/12/09/health/drug-prices-generics-insurance.html (last visited Feb. 1, 2018).
[24] Average wholesale price is the retail list price (sticker price) or the average price that manufacturers recommend wholesalers sell to physicians, pharmacies, and others, such as hospitals.
[25] Maximum allowable cost is a price set for generic drugs and is the maximum amount that the plan sponsor will pay for a specific drug.
[26] Brent J. Eberle, RPh, Alan Van Amber, *Your PBM's MAC List Impacts Your Bottom Line,* Managed Healthcare Executive, (December 1, 2008), available at http://managedhealthcareexecutive.modernmedicine.com/managed-healthcare-executive/content/your-pbms-mac-list-impacts-your-bottom-line (last visited Feb. 15, 2018).
[27] *Id.*
[28] Medicaid.gov, *Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State (Quarter Ending September 2017),* available at https://www.medicaid.gov/medicaid/prescription-drugs/state-prescription-drug-resources/drug-reimbursement-information/index.html (last viewed Feb. 15, 2018).
[29] Sections 465.005 and 465.022, F.S.
[30] Sections 465.015 and 465.016, F.S.

A PBM administers the prescription drug part of a health plan on behalf of plan sponsors, insurers, and HMOs. Some states require PBMs to either register with state insurance regulators or be licensed as third-party administrators.[31] Types of state regulation of PBMs include: [32]

Licensure/Registration of PBMs		Patient Protections and Pricing Transparency	Both Licensure and Patient Protections
Iowa (2007) Kansas (2006) Kentucky (2016) Maryland (2003) New Mexico (2016)	North Dakota (2005) Rhode Island (2004) South Dakota (2004) Wyoming (2016)	Georgia (2017) Louisiana (2016) North Carolina (2017) Tennessee (2009) Texas (2017)	Arkansas (2015) Connecticut (2007, 2017) Washington (2014)

A PBM may obtain accreditation from various accrediting bodies that determine if certain national standards are 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 accrediting body to ensure that it is conducting business in a manner that meets predetermined criteria and is consistent with national standards. Current law provides that a contract between a PBM and a pharmacy must include requirements that the PBM:

- Update the MAC pricing at least every seven calendar days; and
- Maintain a process to eliminate drugs in a timely manner from the MAC lists or drug price lists, and to remain consistent with changes in pricing data that is used in formulating the MAC prices and product availability.[33]

However, no state agency is responsible for enforcing these provisions.

III. Effect of Proposed Changes:

Section 1 amends s. 465.0244, F.S., to require a pharmacist or his or her authorized employee to notify customers:

- If a less expensive, generically equivalent drug product is available for his or her prescription; and
- If the customer's cost sharing obligation for his or her prescription exceeds the retail price of the customer's prescription in the absence of prescription drug coverage.

Section 2 repeals s. 465.1862, F.S., relating to contracts between pharmacy benefit manager and pharmacies.

Section 3 creates s. 624.490, F.S., to require the OIR to implement a PBM registration and biennial registration renewal process beginning January 1, 2019. The bill also defines a

[31] Joanne Wojcik, *States Try to Regulate Pharmacy Benefit Managers*, Business Insurance (August 22, 2010), available at http://www.businessinsurance.com/article/20100822/ISSUE07/308229997 (last visited Feb. 15, 2018).
[32] *See also* Pharmacists United for Truth and Transparency, *State Regulations in Pharmacy Benefit Management*, available at https://www.marleydrug.com/wp-content/uploads/2016/05/PUTT_State-Regulations_061713a.pdf (last viewed Feb. 15, 2018), and National Association of Community Pharmacists, *State Laws Reforming the Practices of Pharmacy Benefit Managers (PBMs)*, available at http://www.ncpanet.org/pdf/leg/nov12/pbm_enacted_legislation.pdf (last viewed Feb. 15, 2018).
[33] Section 465.1862(2), F.S.

pharmacy benefit manager to mean a person or entity who is doing business in this state, which contracts to administer prescription drug benefits on behalf of a health insurer or a health maintenance organization to residents of this state.

To register, a PBM is required to submit a completed registration on a form, which contains the name and address of the registrant and the directors and officers of the registrant. Upon receipt of a completed registration form, the registration fee, and required documents, the OIR must issue a registration certification to the PBM. The registration certificate is valid for 2 years. The certificate is nontransferable.

The PBM must report to the OIR any changes in the information required for registration within 60 days of the change. The Financial Services Commission must adopt by rule an initial registration fee not to exceed $500 and a registration renewal fee not to exceed $500. The commission must adopt rules to implement the registration process.

Sections 4, 5 and 6 create ss. 627.64741, 627.6572, and 641.314, F.S., respectively, to require a contract between a PBM and a health insurer, or a PBM and a HMO, mandate that the PBM:

- Update its MAC information at least every seven calendar days. The term "MAC" is defined as the per unit amount that a PBM reimburses a pharmacist for a prescription drug, excluding dispensing fees.
- Maintain a process that will, in a timely manner, eliminate drugs from the MAC lists or modify drug prices to remain consistent with changes in pricing data used in formulating MAC and product availability.
- May not limit a pharmacist's ability to disclose to the consumer whether the consumer's cost sharing obligation exceeds the retail price for a covered prescription drug and disclosure of the availability of a more affordable alternative drug.

These provisions would apply to individual and group policies and contracts of insurers and HMOs, respectively. Further, these sections prohibit a PBM from requiring a consumer to pay for a prescription in an amount that exceeds the lesser of the applicable cost sharing amount or the retail price in the absence of prescription drug coverage. The changes in these sections are effective for contracts entered into or renewed on or after July 1, 2018.

Section 6 provides an effective date for the act of July 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:

The bill creates a registration program within the Office of Insurance Regulation for pharmacy benefit managers. The Financial Services Commission must adopt by rule an initial registration fee that may not exceed $500 and a renewal fee that may not exceed $500.

B. Private Sector Impact:

Each pharmacy benefit manager seeking to do business in the state will be required to complete the new registration process with the OIR and will be required to pay a biennial registration fee and renewal fee. The PBM will incur administrative costs to complete the registration process and to maintain updated information with the OIR.

The bill prohibits a PBM from limiting a pharmacist from notifying a patient if the patient's cost sharing obligation exceeds the retail price for a covered drug and of the availability of a more affordable alternative drug. This could reduce the out-of-pocket costs of some consumers. However, some insurers suggest that this practice may increase the costs of health care.

C. Government Sector Impact:

The bill requires the OIR to implement and maintain a registration process for PBMs. The initial registration fee and the biennial registration certificate fees are capped at $500 each, and the Financial Services Commission must adopt by rule such fees.

The OIR's fiscal impact statement includes a request for one additional FTE to administer the PBM registrations, renewals, and updates to registrations. Costs to upgrade technology for the new PBM registration process are also shown in the chart below.

Office of Insurance Regulation – Fiscal Analysis[34]		
Item	**Description**	**Total**
Reinsurance/Financial Specialist (1 FTE)	Work initial registration filings from PBMs and continued administration of registrants due to changes in controlling interests and monitoring/documenting renewals of registrations expiring at the end of 2 years from the date of issuance.	$74,141
Contracted Services Technology System Upgrade (one time)	Update technology systems and operations to create registration process for PBMs.	$5,000
FIRST YEAR ANNUAL TOTAL:		**$79,141**

[34] Office of Insurance Regulation, *Senate Bill 1494 Analysis* (January 15, 2018), p. 4 (on file with the Senate Committee on Health Policy and Senate Committee on Banking and Insurance).

VI. Technical Deficiencies:

None.

VII. Related Issues:

PBM Registration Process. The OIR notes that the bill does not include any guidelines by which the OIR could evaluate, approve, or disapprove the registration application or renewal of a PBM other than the completeness of a form.[35] This may result in the approval of an individual with a criminal background, for example.

OIR Oversight and Enforcement Authority. The OIR requests the statutory authority to conduct market examinations on the registered PBMs and to require the PBMs to pay for the costs of those exams under s. 624.3161, F.S., as is done for all other market conduct examinations. The bill does not provide the OIR with statutory authority to determine or enforce a PBM's compliance with the provisions of this bill.

VIII. Statutes Affected:

This bill substantially amends section 465.0244 of the Florida Statutes.

This bill creates the following sections of the Florida Statutes: 624.490, 627.64741, 627.6572, and 641.314.

This bill repeals section 465.1862 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.)

CS/CS by Banking and Insurance on February 20, 2018:
The CS/CS revises the Office of Insurance Regulation (OIR) registration process for pharmacy benefit managers (PBMs) in the following manner:

- Requires PBMs to register with the OIR beginning January 1, 2019.
- Caps the initial registration fee at $500 and renewal fee at $500.
- Clarifies that the PBM must submit all required registration information prior to the issuance of the registration certificate by the OIR.
- Provides technical conforming changes.

CS by Health Policy on February 6, 2018:
The CS adds the ability for a pharmacist's authorized employee, in addition to the requirement for a pharmacist, to inform a customer of the availability of less expensive, generically equivalent drug product for his or her prescription and as to whether a customer's cost-sharing obligation exceeds the retail price of the prescription drug in the absence of prescription drug coverage.

[35] *Id.*

The CS repeals s. 465.1862, F.S., relating to pharmacy benefits manager contracts; however, these provisions are moved to the insurance code under the jurisdiction of the OIR.

Additionally, the CS modifies the PBM registration process by:

- Eliminating requirements for an individual's social security number;
- Removing the requirement that PBM's submit the names of those individuals or entities with 10 percent or greater controlling ownership interest with the registration or biennial renewal;
- Deleting the definition of controlling interest;
- Extending the notice period for information changes to 60 days from 30 days; and
- Capping the maximum fees that may be charged by the OIR for administering the process at $500.

The CS deletes the requirement that the contracts between PBMs and insurers and HMOs include a prohibition against limiting the ability of the pharmacy or PBM to substitute a less expensive, generically equivalent drug product for a brand name drug.

For contracts between health insurers and HMOs and the PBMs, the CS amends the comparison points relating to the consumer's out of pocket cost for prescription drugs from three to two, so the consumer pays the lesser of the applicable cost-sharing amount or the retail price of the drug in the absence of prescription drug coverage. The third reference point, the allowable claim amount for the prescription drug, is deleted.
The CS also creates s. 627.6572, F.S, making the provisions relating to PBM contract reporting on MAC cost information and contract provision requirements applicable to group health insurance policies.

B. Amendments:

None.