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/SB 1494
INTRODUCER:	Health Policy Committee, Senator Montford and others
SUBJECT:	Prescription Drug Pricing Transparency
DATE:	February 6, 2018
REVISED:	

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

Please see Section IX. for Additional Information:
COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

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 prescription drug coverage. The bill also creates a requirement for pharmacy benefit managers (PBMs) to biennially register with the Office of Insurance Regulation (OIR), provide information on certain key personnel, report within 60 days changes in key personnel and other information, and pay registration and renewal fees that cover administrative costs of the OIR or $500, whichever is less.

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.

The PBM's contracts with insurers and HMOs must require the PBM to update 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 a small, negative fiscal impact on the Office of Insurance Regulation.

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

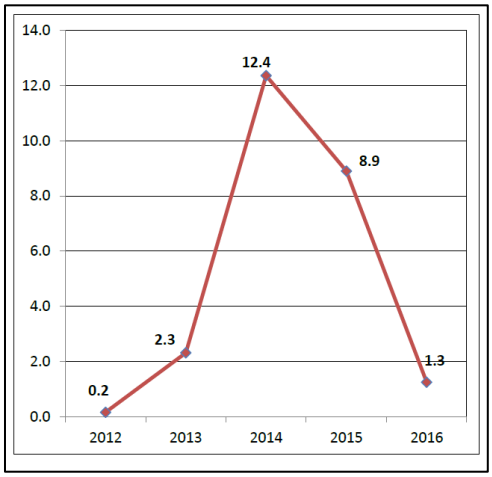
II. Present Situation:

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 large growth rates of these time periods are largely attributed 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 slowing in 2016 is linked to the approval of fewer new drugs, slower growth in brand name drugs, and a decline 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

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

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[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 (December 6, 2017), p. 152, *available at* https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2017.1299 (last visited Feb. 1, 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 visited Feb. 1, 2018).
[6] *Id.*
[7] *Supra* note 5, at 155.

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
- Disease management programs.

[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)* (last modified Jan. 8, 2018) *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html (last visited Feb. 1, 2018).
[11] *Supra* note 6, at 5.
[12] A list of drugs that a health plan uses to make reimbursement decisions.

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 drugmakers and drugstores.[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 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

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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.*
[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).

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 specify how much the health sponsors 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]

A PBM administers the prescription drug part of a health plan on behalf of the plan sponsor, self-insured employers, insurers, and health maintenance organizations. Some states require PBMs to

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[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. 2, 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 visited Feb. 1, 2018).
[29] Sections 465.005 and 465.022, F.S.
[30] Sections 465.015 and 465.016, F.S.

either register with state insurance regulators or be licensed as third-party administrators.[31] States enacting regulations of PBMs are as follows. [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.

At each contract execution or renewal between a PBM and a pharmacy, current law requires the contract to include requirements that the MAC pricing will be updated at least every seven calendar days and that a process will be maintained 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]

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 pharmacy benefit manager contracts. The provisions are moved to newly created sections specific to different types of products under the insurance code which fall under the jurisdiction of the OIR.

Section 3 creates s. 624.490, F.S., to implement a PBM registration and bi-annual renewal process within the OIR.

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[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. 1, 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. 1, 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. 1, 2018).
[33] Section 465.1862(2), F.S.

The bill also defines a 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, the PBM is required to submit:

- A registration fee;
- A copy of the PBM's corporate charter, articles of incorporation, or other charter document;
- A completed registration form showing the identity, address, and taxpayer identification number, as applicable, of:
  - The registrant;
  - The chief executive officer;
  - The chief financial officer; and
  - Each person or entity responsible for the day-to-day operations and affairs of the registrant, or the similarly situated individuals for each of those positions.

Upon receipt of a completed registration form and the registration fee, the OIR is to issue a registration certification to the PBM. The registration certificate is valid for two years from the date issued. The certificate is nontransferable.

The bill directs the OIR to set the registration and renewal fees in an amount sufficient to cover the costs of administering the registration process or $500, whichever is less.

The PBM must report any changes to the OIR in the controlling interests of the PBM within 60 days of the change.

The OIR is directed to adopt rules to administer the registration process.

Sections 4, 5 and 6 create ss. 627.64741, 627.6572, and 641.314, F.S., to require a contract between a PBM and a health insurer that issues individual policies, large group health insurance policies, or HMO and a PBM to include certain specific terms:

- The PBM must 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.
- The PBM must 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.
- The PBM is prohibited from limiting 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.

The PBM is prohibited from requiring a consumer to pay for a prescription in an amount which exceeds the lesser of the applicable cost sharing amount or the retail price in the absence of prescription drug coverage.

The changes in this act 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:

None.

B. Private Sector Impact:

Each pharmacy benefit manager seeking to do business in the state will be required to complete a new registration process with the OIR and pay a registration fee, the amount of which is to be determined by the OIR. The PBM will incur administrative costs and time to complete the registration process and to maintain updated information with the OIR.

CS/SB 1494 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. The ability of the pharmacist to notify the patient of the availability of alternative drugs may, according to some insurers, increase the costs of health care.

C. Government Sector Impact:

The OIR will be required to implement and manage a registration process for PBMs under the bill. The initial and biennial registration certificate fees would be determined by the OIR and could not exceed the costs of administering the process or $500, whichever is less.

The OIR's fiscal impact statement includes a request for an additional Analyst to work the PBM registrations/renewal and updates to registrations received throughout the year. Costs to upgrade technology for the new PBM registration process are also shown in the chart below.

Office of Insurance Regulation – Fiscal Impact Statement[34]		
Item	**Description**	**Total**
Salary and Benefits		$74,141
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 two years from the date of issuance.	
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**

VI. Technical Deficiencies:

The bill requires the PBM to submit articles of incorporation or other charter documents to register with the OIR. However, the bill also specifies that the OIR shall issue a registration certificate upon receipt of a completed registration form and registration fee and does not require submission of the articles of incorporation before the certificate is issued. The current order of approval could result in the OIR issuing a PBM certificate to a PBM that is not in compliance with the Florida Statutes.[35]

VII. Related Issues:

The OIR noted 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.[36] This may result in the approval of an individual with a criminal background, for example. Additionally, the bill requires the collection of taxpayer identification numbers, but does not authorize the OIR to conduct background screenings. The OIR requests that this information be removed from the registration form unless the office can use the data to conduct screenings.

With an effective date of July 1, 2018, the bill may have an impact on the insurance and HMO rates already set and filed for 2018, according to the OIR.[37] It was suggested by the OIR that it may be more appropriate to modify the effective date to January 1, 2019, to coincide with the effective date of the insurer and HMO rate cycles.[38]

Finally, the OIR requested the 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.

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

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 Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

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.

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 pharmacy's or PBM's ability 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.