HOUSE OF REPRESENTATIVES
FINAL BILL ANALYSIS

BILL #:	CS/CS/HB 351	**FINAL HOUSE FLOOR ACTION:**	
SUBJECT/SHORT TITLE	Prescription Drug Pricing Transparency	115 **Y's**	0 **N's**
SPONSOR(S):	Health & Human Services Committee; Health Innovation Subcommittee; Santiago and others	**GOVERNOR'S ACTION:**	Approved
COMPANION BILLS:	CS/CS/CS/SB 1494		

SUMMARY ANALYSIS

CS/CS/HB 351 passed the House on March 1, 2018, and subsequently passed the Senate on March 8, 2018.

The bill requires pharmacy benefit managers (PBMs) that conduct business in Florida to register with the Office of Insurance Regulation (OIR) by submitting an application, certain identifying organizational information, and an annual registration fee. An expanded definition of the term "pharmacy benefit manager" is included in the bill.

The bill requires that a contract between a PBM and a health plan include prohibitions on certain practices that limit patient access to pricing information. The bill specifies that a contract must require the PBM to update maximum allowable cost pricing information at least once every seven days. This requirement was previously in the Pharmacy Practice Act; the bill moves this language to the Insurance Code, which gives OIR enforcement authority. The bill also requires a contract to limit patient cost sharing for a drug to the lesser of the applicable cost sharing amount or the retail price of that drug.

The bill creates an affirmative duty for a pharmacist to communicate to a patient the availability of a lower cost, generically equivalent drug if one exists and whether the patient's cost sharing obligation exceeds the retail price of a drug in the absence of prescription drug coverage.

The bill applies to contracts entered into or renewed on or after July 1, 2018.

The bill has an insignificant negative fiscal impact on state government and an indeterminate negative fiscal impact on local governments.

The bill was approved by the Governor on March 23, 2018, ch. 2018-91, L.O.F., and will become effective on July 1, 2018.

I. SUBSTANTIVE INFORMATION

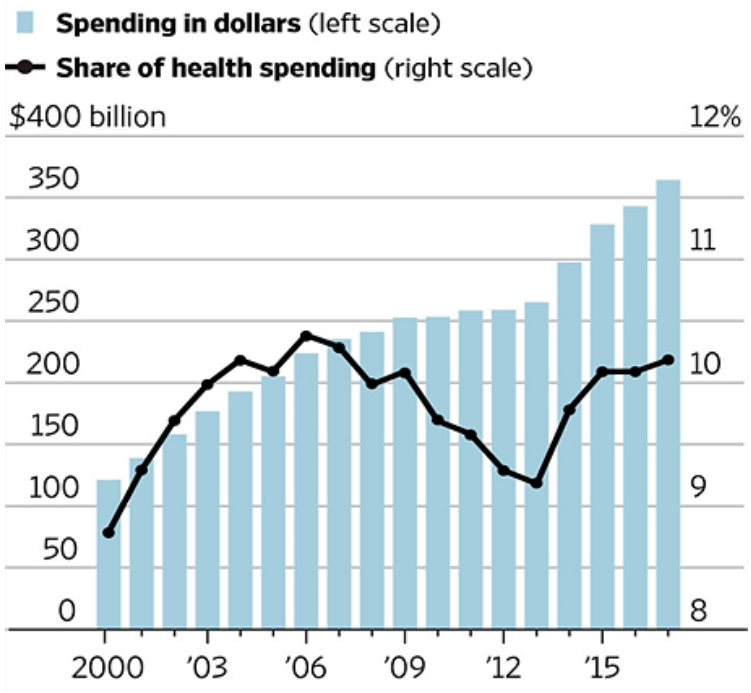
A. EFFECT OF CHANGES:

Background

Prescription Drug Cost and Pricing

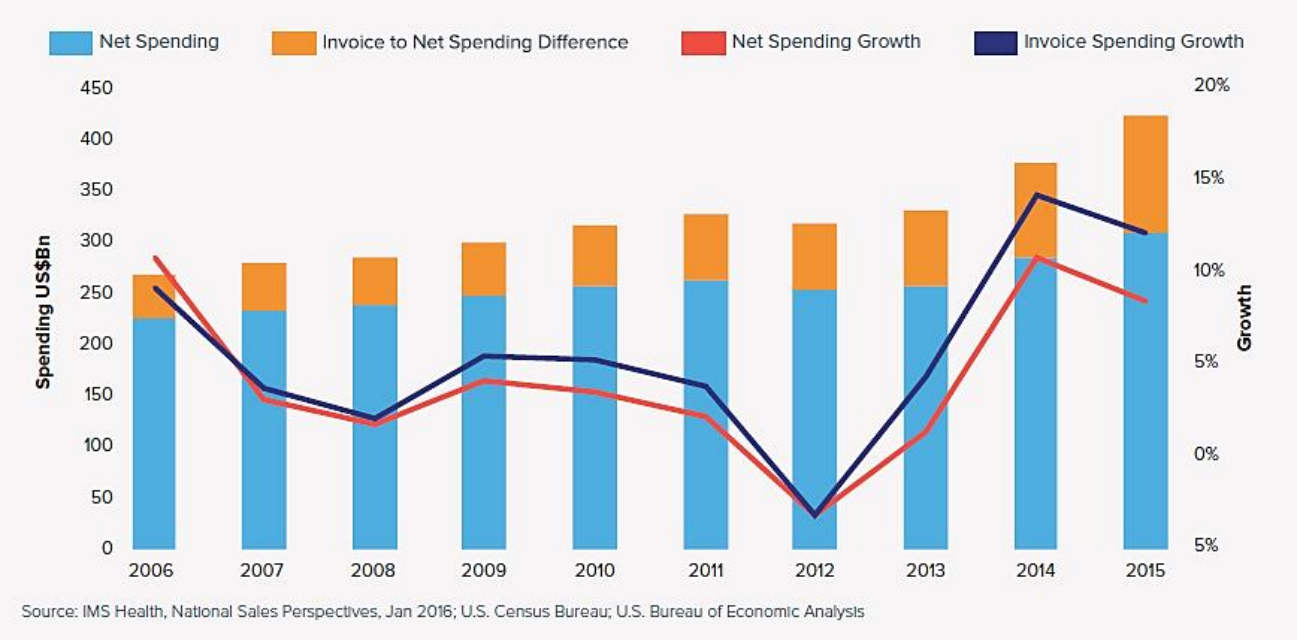
Spending on prescription drugs has risen sharply in the United States over the past few years.[1] From 2013 to 2015, out-of-pocket costs for prescription drugs rose 20 percent,[2] to an average cost of $44 per brand name prescription drug.[3] Additionally, prescription drug prices increased an average of almost 10 percent from June 2015 to May 2016.[4] Specialty prescription drug prices are projected to increase 18.7 percent in 2017, accounting for 35 percent of the prescription drug spending trend even though they account for less than one percent of prescriptions.[5] Recent increases in prescription drug prices are not only an increase in spending in terms of dollars, but also as a percentage of total healthcare spending.[6]

Prescription Drug Spending as a Share of Health Spending 2000-2017[7]

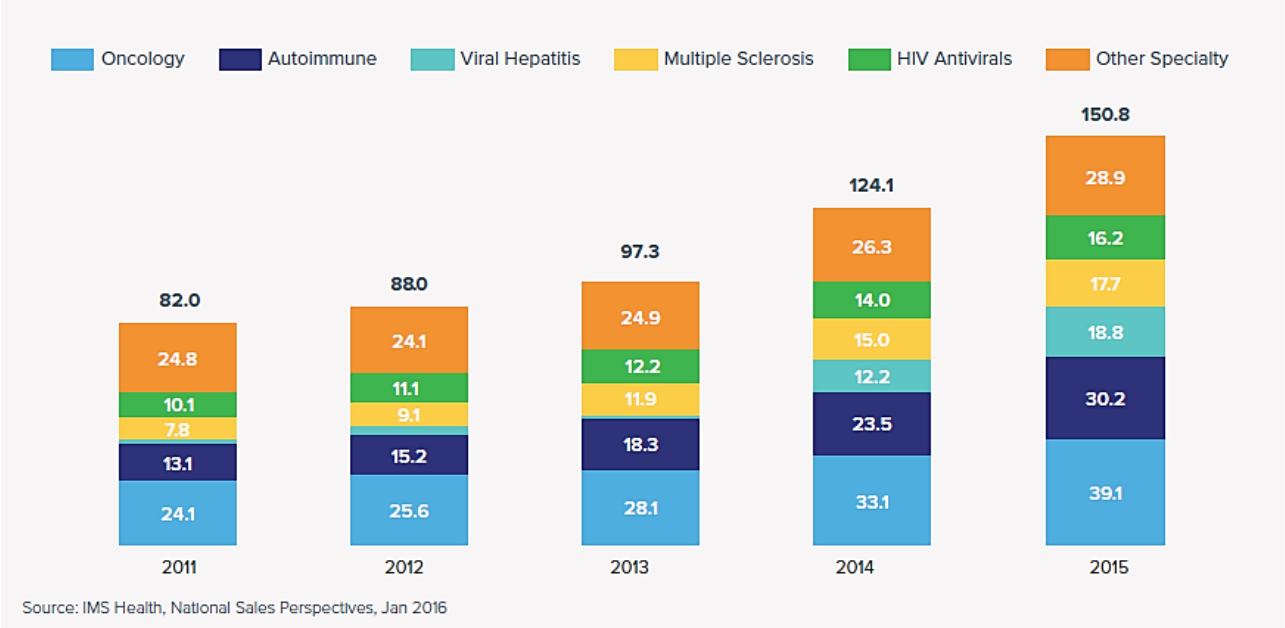


[1] Ameet Sarpatwari, Jerry Avorn, and Aaron S. Kesselheim, *State Initiatives to Control Medication Costs — Can Transparency Legislation Help?*, N. ENGL. J. MED. 2016; 374:2301-2304 Jun. 16, 2016, http://www.nejm.org/doi/full/10.1056/NEJMp1605100#t=article (last visited March 13, 2017).
[2] Troy Parks, *Drug pricing needs transparency, physicians say*, AMA WIRE, Jan. 26, 2017, https://wire.ama-assn.org/ama-news/drug-pricing-needs-transparency-physicians-say (last visited March 10, 2017).
[3] 2017 Segal Health Plan Cost Trend Survey, *available at*, https://www.segalco.com/media/2716/me-trend-survey-2017.pdf (last visited March 13, 2017)
[4] TRUVERIS, *Americans faced double digit increases in prescription drug prices in 2014, according to Truveris National Drug Index*, https://truveris.com/press-releases/ndi-americans-faced-double-digit-increases-in-prescription-drug-prices-in-2014/ (last visited March 13, 2017)
[5] *Supra*, note 3. Specialty drugs are high-cost prescription medications used to treat complex, chronic conditions and often require special handling and administration.
[6] CENTERS FOR MEDICARE AND MEDICAID SERVICES, *National Health Expenditures by Type of Service and Source of Funds: Calendar Years 1960 to 2015*, .zip file available at, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html (Last visited March 13, 2017).
[7] Jonathan D. Rockoff, *How Do We Deal With Rising Drug Costs?,* THE WALL STREET JOURNAL, Apr. 10, 2016, https://www.wsj.com/articles/how-do-we-deal-with-rising-drug-costs-1460340357 (last visited March 13, 2017).

Total U.S. Spending on Prescription Drugs, 2015[8]



Total U.S. Spending on Specialty Prescription Drugs, 2015[9]



Pharmacy Benefit Managers

Health insurers and HMOs increasingly utilize pharmacy benefit managers (PBMs) to provide a range of specified services related to the acquisition and distribution of prescription drugs.[10] PBMs enter into contracts with both health plans and pharmacies. PBMs negotiate with drug manufacturers, on behalf of health plans, in an effort to purchase drugs at reduced prices or with the promise of additional rebates. This negotiation process often involves the development of drug formularies, which are tiered

[8] *Medicines Use and Spending in the U.S. – A Review of 2015 and Outlook to 2020,* QUINTILESIMS, APR. 2016, HTTPS://MORNINGCONSULT.COM/WP-CONTENT/UPLOADS/2016/04/IMS-INSTITUTE-US-DRUG-SPENDING-2015.PDF (last visited March 13, 2018).
[9] Id.
[10] The term "pharmacy benefit manager" is defined in S. 465.1862(b), F.S.

drug lists that incentivize the use of some drugs over others.[11] PBMs simultaneously negotiate with pharmacies to establish reimbursements for dispensing prescription drugs to patients.

PBMs have become major participants in the pharmaceutical supply chain. These entities first emerged as claims processors in the late-1960s and early 1970s, but began to assume much more complex responsibilities in the 1990s in concert with advancements in information technology.[12] By 2016, PBMs were responsible for managing the pharmacy benefits of about 266 million Americans.[13] Around 60 PBMs are currently operational in the United States, and the three largest – Express Scripts, CVS Caremark, and OptumRx – have a combined market share of more than 60%.[14] PBMs assert that their services result in significant savings for both insurers and patients.[15] Broadly, PBMs generate revenue from the following sources:

- Fees from their clients (insurers, self-insured employers, union health plans, and government) for the administration of claims and drug dispensing;
- A share of the savings from rebates negotiated from drug companies – in most cases, the rebates are shared between the PBM and the health insurer or plan sponsor; and
- A combination of revenues and savings from maintaining pharmacy networks, including per prescription fees[16] from network pharmacies and volume-based contracting.

Each PBM generates revenues from all or some combination of these sources. In theory, the negotiating leverage of PBMs should translate into savings for patients, employers and insurers in the form of reduced drug costs. In addition, health insurers benefit from sharing in the increased manufacturer rebates that PBMs are often able to realize,[17] which may also reduce costs for consumers and employers.

Drug Price Transparency

An insured patient generally fills prescriptions with a reasonable expectation of the costs that he or she will incur upon doing so. Depending on the nature of an insured's prescription drug benefit, the patient can expect to incur a copayment, coinsurance, and/or deductible when filling a prescription.[18] Although patients often assume that their cost-sharing responsibility will be less than the retail cost (or non-insured "cash" price) of a drug, this is not always the case.[19] In cases where the retail price of a drug is less than a patient's applicable cost-share, numerous outcomes are possible. In some cases, a pharmacist may simply charge the patient the lower retail price. In other cases, however, the pharmacist may be obligated by contract with a PBM or health plan to charge the patient the full,

---

[11] Academy of Managed Care Pharmacy (AMCP). *Formulary Management*. Available at http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=9298 (last accessed December 20, 2017). See also, Pharmaceutical Care Management Association (PCMA). *Pharmacy Contracting & Reimbursement*. Available at https://www.pcmanet.org/policy-issues/pharmacy-contracting-reimbursement/ (last accessed December 20, 2017).

[12] "The ABCs of PBMs: Issue Brief." National Health Policy Forum. October 27, 1999. Available at http://ww.nhpf.org/library/issue-briefs/IB749_ABCsofPBMs_10-27-99.pdf (last accessed December 20, 2017).

[13] Pharmaceutical Care Management Association (PCMA). "That's What PBMs Do." Available at http://thatswhatpbmsdo.com/ (last accessed December 20, 2017).

[14] Fein, Adam J. *2017 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*. Drug Channels Institute. February 2017. Available at http://drugchannelsinstitute.com/products/industry_report/pharmacy/ (last accessed December 20, 2017).

[15] Visante. *The Return on Investment (ROI) on PBM Services*. November 2016. Available at https://www.pcmanet.org/wp-content/uploads/2016/11/ROI-on-PBM-Services-FINAL.pdf (last accessed December 20, 2017).

[16] "Health Policy Brief: Pharmacy Benefits Managers," *Health Affairs*, September 14, 2017. Pharmacies are generally expected to submit a fee for each prescription to PBMs in order to participate in the PBM's network. DOI: 10.1377/hpb2017.13 (last accessed December 20, 2017).

[17] Id.

[18] Kaiser Family Foundation/Health Research & Education Trust. *2017 Employer Health Benefits Survey*. Section 9: Prescription Drug Benefits. Available at https://www.kff.org/health-costs/report/2017-employer-health-benefits-survey/ (last accessed December 20, 2017).

[19] Hiltzik, Michael. "The 'Clawback': Another hidden scam driving up your prescription prices." *Los Angeles Times*. August 9, 2017. Available at http://www.latimes.com/business/hiltzik/la-fi-hiltzik-clawback-drugs-20170809-story.html (last accessed December 20, 2017).

applicable cost-share. If a pharmacist is obligated to charge this higher price, the PBM may then collect as revenue the difference between a patient's cost-share and the lower retail price.[20]

While it is health insurers – and not PBMs – that are responsible for setting applicable cost-sharing amounts for patients, PBM practices have become the target of litigation in numerous jurisdictions around the United States.[21] These lawsuits, filed in California, Illinois, and Rhode Island, among other states, allege that practices employed by various PBMs violate federal racketeering and state consumer protection laws.[22]

Pharmacies and pharmacists have alleged that PBMs use contract clauses to restrict the flow of pricing information to patients. In a statement prepared for the U.S. House Committee on Oversight and Government Reform, the National Community Pharmacists Association asserted that pharmacies have been subject to "take it or leave it" contracts with PBMs that include "clauses that restrict their (pharmacists) ability to communicate with patients".[23]

In practice, restricting a pharmacist from conveying pricing information to a patient may result in an insured patient paying a higher price for a drug than a patient without pharmacy benefits. In circumstances where the retail price of a drug is less than a patient's applicable cost-share, the patient could pay the lower price if the pharmacist were allowed to proactively offer the drug at that price.[24]

Regulation of PBMs in Florida

PBMs are not regulated by the State of Florida. However, the Pharmacy Practice Act, chapter 465, F.S., regulates pharmacies and includes standards that guide the prescribing and dispensing of prescription drugs. Section 465.1862, F.S., in the Pharmacy Practice Act, subjects contracts between PBMs and pharmacies to certain requirements. Contracts between PBMs and pharmacies must include obligations that the PBM update Maximum Allowable Cost (MAC) pricing at least every seven days and maintain a process that will, in a timely manner, eliminate drugs from MAC lists or modify drug prices to remain consistent with changes in pricing data used in formulating MAC prices and product availability.[25]

Section 465.025, F.S., in the Pharmacy Practice Act, requires pharmacists in receipt of a prescription for a brand name drug to substitute a less expensive generic drug, unless requested otherwise by the purchaser. This requirement does not apply in cases where a generic is unavailable or is not included in a pharmacy's formulary. [26]

The Department of Health (DOH), in conjunction with the Board of Pharmacy, implements the Pharmacy Protection Act; however, the MAC list requirements of s. 465.1862 and the generic substitution requirements of s. 465.025, F.S., are only enforceable against the pharmacy. DOH and the Board do not have authority to enforce this requirement against PBMs.

---

[20] Barlas, Stephen. "Employers and Drugstores Press for PBM Transparency: A Labor Department Advisory Committee Has Recommended Changes." *Pharmacy and Therapeutics* 40.3 (2015): 206–208. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4357353/ (last accessed January 22, 2018.

[21] See, for example, *Megan Schultz v. CVS Health Corporation*, 17-cv-359, U.S. District Court for the District of Rhode Island (Providence).

[22] Feeley, Jef and Hopkins, Jared S. "CVS Health Is Sued Over 'Clawbacks' of Prescription Drug Co-Pays." *Bloomberg*. August 8, 2017. Available at https://www.bloomberg.com/news/articles/2017-08-08/cvs-health-is-sued-over-clawbacks-of-prescription-drug-co-pays (last accessed December 20, 2017).

[23] National Community Pharmacists Association. *Statement for the Record: National Community Pharmacists Association*. U.S. House Committee on Oversight and Government Reform. February 4, 2016. Available at http://www.ncpa.co/pdf/ncpa-ogr-statement.pdf (last accessed December 21, 2017).

[24] *Supra* note 12.

[25] S. 465.1862, F.S. and U.S. Department of Health and Human Services. *Medicaid Drug Pricing in State Maximum Allowable Cost Programs*. Report of the Office of Inspector General. August 2013. Available at https://oig.hhs.gov/oei/reports/oei-03-11-00640.pdf (last accessed January 11, 2018). MAC price lists set the upper limit amount that a PBM plan will reimburse a contracted pharmacy for generic drugs and some brand-name drugs with generic versions, known as multi-source brands.

[26] S. 465.025, F.S.

Regulation of PBMs in Other States

Florida is not unique in its lack of regulation related to PBMs. Generally, state regulation of PBMs has been aimed at improving the transparency of PBM operations, and can be categorized in two ways:

1) Licensure or registration requirements for PBMs; and,
2) Patient protections, price transparency requirements, or prohibitions on certain practices by PBMs.[27]

While this categorization is not intended to be a comprehensive accounting of the actions taken by states to regulate PBM practices, it is reflective of a nationwide trend that has emerged in the past several years. States enacting regulations of PBMs are as follows.[28]

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)

Effect of Proposed Changes

Regulation of Pharmacy Benefit Managers

CS/CS/HB 351 creates a new registration program for PBMs. The Financial Services Commission would, by rule, create an application form and set registration and renewal fees, not to exceed $500. PBMs would register with OIR by submitting a completed application form and fee for registration. Specifically, PBMs would be required to submit identifying information on the organization itself and each officer and director within the organization.

In addition, the PBM seeking registration must report any changes in this information to OIR within 60 days of changes having occurred. The bill sets the term of registration at two years.

The bill also repeals an existing section[29] of the Pharmacy Practice Act that requires PBMs to update MAC pricing lists at least every seven days as a condition of contracts entered into with pharmacies. The bill moves this requirement and associated definitions to the Insurance Code for enforcement purposes. In effect, the bill consolidates statutory requirements related to PBMs into the sections of the Insurance Code that regulate contracts between health plans and their subcontractors. The bill dictates that OIR has the authority to oversee aspects of contracts between PBMs and their clients, and not the Board of Pharmacy.

The bill requires contracts between PBMs and insurers or HMOs to include a prohibition on PBM practices that may limit the ability of a pharmacy or pharmacist to communicate with patients. Each contract must prohibit PBMs from disclosing to a patient whether his or her cost sharing obligation under an insurance benefit exceeds the retail price of a drug, and whether a more affordable alternative drug may be available. These prohibitions would prevent PBMs from taking actions that limit the ability of pharmacists to share cost-related information.

---

[27] PBM Watch. "Pharmacy Benefit Manager Legislation". Available at http://www.pbmwatch.com/pbm-legislation.html (last accessed December 21, 2017).
[28] 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 accessed December 21, 2017) 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 accessed December 21, 2017).
[29] S. 465.1862, F.S.

The bill requires contracts between PBMs and insurers or HMOs to include specific limits on the cost sharing that will be incurred by patients at the point of sale. Each contract must specify that a patient's cost share shall equal the lower of the following prices:

- The applicable cost sharing obligation under a patient's insurance; or,
- The retail (or "cash") price of the drug prescribed.

This requirement would prohibit PBMs from applying any mechanisms that would prevent a patient from paying the lowest applicable price for a particular drug.

Pharmacy Practice Act

The bill revises the Pharmacy Practice Act to create an affirmative duty for a pharmacist to communicate to a patient the availability of a less expensive, generically equivalent drug if one exists and whether the patient's cost sharing obligation exceeds the retail price of a drug in the absence of prescription drug coverage.

The bill applies to contracts entered into on renewed on or after July 1, 2018.

The bill has an effective date of July 1, 2018.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   OIR would experience an insignificant indeterminate increase in revenue in the form of registration fees paid by PBMs. This revenue would be used to cover the costs of the PBM registration program.

2. Expenditures:

   There will be an insignificant negative fiscal impact to the Office of Insurance Regulation associated with the registration of PBMs required in the bill. As the number of PBMs doing business in the state is small, the costs are expected to be insignificant and readily absorbed by the Office.

   According to a bill analysis by the Division of State Group Insurance (DSGI), the bill will have no impact on the State Employee Health Insurance Program.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   The bill may have a significant indeterminate fiscal impact on local government health plans, many of which contract with PBMs for pharmacy benefits. Those PBMs may experience a reduction in rebates from pharmaceutical manufacturers due to changes in the bill and may also lose some leverage in negotiating price concessions from pharmaceutical manufacturers. To the extent that

these costs are passed from impacted PBMs to their clients, local governments would incur additional costs.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill may have a significant indeterminate negative fiscal impact on health insurers, HMOs, and PBMs. To the extent that these entities must take action to comply with the new registration and contracting requirements in the bill, they will incur additional costs.

D. FISCAL COMMENTS:

None.