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:	SB 580
INTRODUCER:	Senators Garcia and Mayfield
SUBJECT:	Insurance Administrators
DATE:	March 31, 2017
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	**Pre-meeting**
2.			HP	
3.			AP	

I. Summary:

SB 580 amends the Insurance Code to require the licensure and regulation of pharmacy benefit managers (PBMs) by the Office of Insurance Regulation (OIR) as insurance administrators or third party administrators. A PBM contracts with a health plan or employer to administer or manage prescription drug benefits, which includes negotiating drug prices with pharmacies and drug manufacturers on behalf of health plans. In addition, a PBM may perform other administrative, clinical, and cost containment services, and process drug claims for the health plans. The bill requires the OIR to conduct quarterly audits of each PBM to determine compliance with ss. 465.1862, F.S., and 465.1865, F.S. The bill authorizes the OIR to impose administrative fines, and to suspend or revoke a certificate of authority of a PBM for violations of ss. 465.1862, F.S., and 465.1865, F.S.

The OIR will incur an estimated fiscal impact of $550,000 to implement the provisions of the bill.

II. Present Situation:

Prescription Drug Cost Containment

In 2014, spending on retail prescription drugs in the United States was approximately $298 billion.[1] In 2015, total retail prescription drug spending increased by 9 percent, reaching $325 billion. The significant growth in 2015 was attributed to certain cost drivers, such as, spending on new drugs, price growth for existing brand-name drugs, increased spending on generics, and a decrease in the number of expensive drugs whose patents have expired.[2]

[1] *See* HEALTH AFFAIRS 36, No. 1 (2017):166-176.
[2] *Id.*

Due to increasing health care expenditures, public and private employers and insurers continue to look for cost containment methods, including the reduction of prescription drug costs. Many employer-sponsored health plans and insurers contract with pharmacy benefit managers (PBMs). While PBMs provide pharmacy claims processing and mail-order pharmacy services to their customers, many provide additional services, including rebate negotiations with drug manufacturers, development of pharmacy networks, formulary management, prospective and retrospective drug utilization reviews, generic drug substitutions, and disease management programs. The PBM generally manages the list of preferred drug products (formulary) for each of its plan sponsors. The decision of plan sponsors to use PBMs to control pharmacy benefit costs, however, can shift business away from retail pharmacies.

Currently, the six largest PBMs represent over 90 percent of the market.[3] These companies are Express Scripts (29 percent), CVS Health (24 percent), UnitedHealth and Catamaran (22 percent), Prime (6 Percent), Humana (6 percent), Medimpact (5 percent), and others (7 percent).

Pharmacy Benefit Managers and Pharmacies

MAC Pricing List (Maximum Allowable Cost)

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)[4] for brand-name drugs and at a MAC[5] 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 profit margins, and other factors.

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.

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

[3] Trefis Team, *Insurance Companies Start to Bring PBM In-House: CVS Health's PBM Business Could Be Under Threat*, Forbes (Jul. 28, 2015) https://www.forbes.com/sites/greatspeculations/2015/07/28/insurance-companies-start-to-bring-pbm-in-house-cvs-healths-pbm-business-could-be-under-threat/#3177b45f8b7c (last viewed Mar. 30, 2017).
[4] 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.
[5] MAC is a price set for generic drugs and is the maximum amount that the plan sponsor will pay for a specific drug.

Act of 2010, amending PPACA. The law[6] 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.

Regulation of Insurers and Health Maintenance Organizations in Florida

The Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, HMOs, and other risk-bearing entities.[7] The Agency for Health Care Administration (agency) regulates the quality of care provided by HMOs under part III of ch. 641, F.S. Before receiving a certificate of authority from the OIR, an HMO must obtain a Health Care Provider Certificate from the agency.[8]

Insurance Administrators

An administrator,[9] also known as a third party administrator or TPA, must be licensed by the Office of Insurance Regulation (OIR). Third party administrators provide various administrative services for life and health insurers, health maintenance organizations (HMOs), self-insurance programs, and other types of insurers. Some of the services provided by TPAs include soliciting and making effective insurance coverage, collecting premiums, and adjusting and settling claims.

Administrators are subject to various regulatory requirements under ss. 626.88 - 626.894, F.S. For example, an administrator must make its books and records available to the OIR for examination, audit, and inspection and must maintain its business records for 5 years.[10] Administrators are also required to file annual, audited financial statements with the OIR.[11] Administrators must have a written agreement with an insurer containing specified provisions.[12]

The insurance company, and not the administrator, must be responsible for determining the benefits, rates underwriting criteria, and claims payment procedures.[13] A payment to the administrator of any premiums on behalf of the insured are deemed to have been received by the insurer and all premiums collected by an administrator on behalf of an insurer must be held by the administrator in a fiduciary capacity. If an administrator is collecting premiums for more than one insurer, the administrator must keep records clearly recording each insurer's accounts. The administrator law requires that a person who provides billing and collection services to HMOs on behalf of health care providers must comply with s. 641.3155, F.S., the prompt payment statute.

[6] 42 U.S.C. s. 1320b-23.
[7] Section 20.121(3)(a), F.S.
[8] Section 641.21(1), F.S.
[9] Section 626.88, F.S.
[10] Section 626.884, F.S.
[11] Section 626.89, F.S.
[12] Section 626.882, F.S.
[13] Sections 626.8817 and 626.882, F.S.

State Regulation of Pharmacies and Pharmacy Benefit Management Companies

Pharmacies and pharmacists are regulated under the Florida Pharmacy Act (act) in ch. 465, F.S. The Board of Pharmacy (board), created under the Department of Health (DOH), adopts rules to implement provisions of the act and takes other actions according to duties conferred on it by the act.[14] Each pharmacy is subject to inspection by the DOH and disciplined for violations of applicable laws relating to a pharmacy.[15]

Section 465.1862, F.S., provides that in a contract between PBMs and pharmacies, the PBM must update the maximum allowable cost (MAC) at least every 7 days and maintain a process that will 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.

Further, s. 465.1885, F.S., establishes the rights of a pharmacy when it is audited by a managed care plan, insurer, third-party payor, PBM, or an entity that represents companies or groups. These rights include:

- To have at least 7 days prior notice of each initial on-site audit with some exceptions;
- To have an on-site audit scheduled after the first 3 days of the month;
- To limit the audit period to 24 months after the date a claim is submitted to or adjudicated by the entity;
- To have an audit that requires clinical or professional judgment conducted by or in consultation with a pharmacist;
- To use the written and verifiable records of a hospital, physician, or other authorized practitioner to validate the pharmacy records in accordance with state and federal law;
- To be reimbursed for a claim that was retroactively denied for a clerical, typographical, scrivener's, or computer error, if the prescription was properly dispensed, unless the pharmacy has a pattern of such errors or fraudulent billing is alleged or the error results in actual financial loss to the entity;
- To receive the preliminary audit report within 120 days after the audit is concluded and to receive the final audit report within 6 months after receiving the preliminary report;
- To have 10 business days after the preliminary audit report is delivered to produce documentation to address a discrepancy or audit finding; and
- To have recoupment or penalties based on actual overpayments, not extrapolation.

The rights do not apply to audits that are based on a suspicion of fraud or wilful misrepresentation; audits of claims paid for by federally-funded programs; or concurrent reviews or desk audits that occur within 3 business days after transmission where no chargeback or recoupment is demanded.

Although PBMs are not subject to licensure in Florida, PBMs may obtain accreditation from various independent, external organizations that determine if certain national standards are being met. Some states, such as Connecticut, Georgia, Kansas, Kentucky, Louisiana, Maryland, New Mexico, and South Dakota, require PBMs to either register with state insurance regulators or be licensed as third-party administrators.[16]

[14] Sections 465.005 and 465.022, F.S.
[15] Sections 465.015 and 465.016, F.S.
[16] Joanne Wojcik, *States Try to Regulate Pharmacy Benefit Managers,* Business Insurance, August 22, 2010, *available at* http://www.businessinsurance.com/article/20100822/ISSUE07/308229997 and Steven Imber, *Pharmacy Benefit Manager*

III. Effect of Proposed Changes:

Section 1 revises the definition of an "administrator," to include PBMs, thereby requiring PBMs to be licensed and regulated by the OIR as a TPA.

Section 2 requires the OIR to conduct quarterly audits of each PBM, who holds a certificate of authority to act as an administrator, to determine whether the PBM is complying with the provisions of s. 465.182, F.S.

Section 3 provides that a violation of s. 465.1982, F.S., or s. 465.1885, F.S., is grounds for suspension or revocation of the certificate of authority of a PBM.

Section 4 authorizes the OIR to impose an administrative fine upon an administrator for a violation of s. 465.1862, F.S., or s. 465.1865, F.S., in an amount not to exceed $5,000 for each violation and up to an aggregate amount of $25,000 for all knowing and willful violations arising out of the same action.

Section 5 requires that, within 180 days after the effective date of this act, the OIR may not penalize a PBM, as defined in s. 465.1862(1), F.S., for operating as an administrator if the PBM applies for a certificate of authority within 90 days after the effective date of this act and is issued such certificate of authority within 180 days after the effective date of this act.

Section 6 directs the Division of Law Revision and Information to replace the phrase "the effective date of this act" wherever it occurs in this act with the date this act becomes a law.

Section 7 provides the act takes effective upon becoming a law.

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.

Face New Licensing Requirements, National Law Review, available at http://www.natlawreview.com/article/pharmacy-benefit-managers-face-new-licensing-requirements (last viewed Mar. 30, 2017).

B. Private Sector Impact:

The PBMs will incur additional expenses associated with obtaining a license as an administrator with the OIR and the costs of quarterly audits incurred by the OIR. The PBMs would also be required to file annual reports and audited financial statements with the OIR.

C. Government Sector Impact:

The implementation of the bill may impose a significant additional workload on the OIR staff due to the initial applications process, quarterly audits, and review of annual reports.[17] A preliminary survey indicated that there are approximately 36 PBMs that may be subject to licensure in Florida.

The OIR estimates the fiscal impact of the bill would be approximately $550,000. This estimate includes additional staffing of one actuary, one pharmacist, and two analysts.

VI. Technical Deficiencies:

The bill requires the OIR to audit licensed PBMs to determine compliance with s. 465.1862, F.S., which requires contracts between a PBM and pharmacy to contain certain contract provisions. However, the audit does not require the OIR to determine if the PBM is actually complying with the contractual provisions.

The bill requires the OIR to determine the PBM's compliance with s. 465.1885, F.S., relating to pharmacy rights during an audit by a managed care company, an insurance company, a third-party payor, a PBM, or other entity. It is unclear whether the OIR would have access to records of the audited pharmacy in order to verify whether the PBM's audit complied with the requirements of this section.

If the OIR will be regulating PBMs under the Insurance Code, the ch. 465, F.S., provisions may need to be transferred to the Insurance Code.

It is unclear what the intent of the term, "within 180 days after the effective date of this act" means on lines 185-186.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 626.88, 626.8805, 626.891, and 626.894.

[17] Office of Insurance Regulation, *SB 580 Analysis* (Feb. 10, 2017) (on file with Senate Banking and Insurance Committee1).

IX. Additional Information:

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

None.

B. Amendments:

None.