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:	SB 1014
INTRODUCER:	Senator Garcia
SUBJECT:	Pharmacy Benefit Managers
DATE:	March 18, 2014 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Peterson	Stovall	HP	**Pre-meeting**
2.			BI	
3.			AGG	
4.			AP	

I. Summary:

SB 1014 creates a new section of law titled "Pharmacy benefit managers." The bill creates definitions of "average wholesale price (AWP)," "AWP discount," "maximum allowable cost," "plan sponsor," and "pharmacy benefit manager." The bill sets out required provisions and conditions for contracts entered into between a pharmacy benefit manager (PBM) and a pharmacy and between a PBM and a plan sponsor related to drug pricing and pharmacy reimbursement.

II. Present Situation:

Pharmacy Regulation

Pharmacies and pharmacists are regulated under the Florida Pharmacy Act (the Act) found in ch. 465, F.S.[1] The Board of Pharmacy (the board) is created within the Department of Health (DOH) to adopt rules to implement provisions of the Act and take other actions according to duties conferred on it in the Act.[2]

Several pharmacy types are specified in law and are required to be permitted or registered under the Act:

- Community pharmacy – a location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.
- Institutional pharmacy – a location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medical drugs are compounded,

[1] Other pharmacy paraprofessionals, including pharmacy interns and pharmacy technicians, are also regulated under the Act.
[2] Section 465.005, F.S.

dispensed, stored, or sold. The Act further classifies institutional pharmacies according to the type of facility or activities with respect to the handling of drugs within the facility.

- Nuclear pharmacy – a location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold, excluding hospitals or the nuclear medicine facilities of such hospitals.
- Internet pharmacy – a location not otherwise permitted under the Act, whether within or outside the state, which uses the internet to communicate with or obtain information from consumers in this state in order to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state.
- Non-resident pharmacy – a location outside this state which ships, mails, or delivers, in any manner, a dispensed drug into this state.
- Special pharmacy – a location where medicinal drugs are compounded, dispensed, stored, or sold if such location is not otherwise defined which provides miscellaneous specialized pharmacy service functions.

Each pharmacy is subject to inspection by the DOH and discipline for violations of applicable state or federal law relating to pharmacy. Any pharmacy located outside this state which ships, mails, or delivers, in any manner, a dispensed drug into this state is considered a nonresident pharmacy, and must register with the board as a nonresident pharmacy.[3,4]

Pharmacy Benefit Managers

Advances in pharmaceuticals have transformed health care over the last several decades. Many health care problems are prevented, cured, or managed effectively for years through the use of prescription drugs. As a result, national expenditures for retail prescription drugs have grown from $120.9 billion in 2000 to 263.3 billion in 2012.[5] Health plan sponsors, which include commercial insurers, private employers, and government plans, such as Medicaid and Medicare, spent $216.5 billion on prescription drugs in 2012 and consumers paid $46.8 billion out of pocket for prescription drugs that year.[6]

As expenditures for drugs have increased, health plan sponsors have looked for ways to control that spending. Among other things, they have turned to pharmacy benefit managers (PBMs), which are third party administrators of prescription drug programs. PBMs initially emerged in the 1980s as prescription drug claims processors. PBMs now provide a range of services including developing and managing pharmacy networks, developing drug formularies, providing mail order and specialty pharmacy services, rebate negotiation, therapeutic substitution, disease management, utilization review, support services for physicians and beneficiaries, and processing and auditing claims.

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[3] Section 465.0156, F.S.
[4] However, the board may grant an exemption from the registration requirements to any nonresident pharmacy which confines its dispensing activity to isolated transactions. *See* s. 465.0156(2), F.S.
[5] Centers for Medicare and Medicaid Services, *National Health Expenditures Web Tables, Table 16, Retail Prescription Drugs Aggregate, Percent Change, and Percent Distribution, by Source of Funds: Selected Calendar Years 1970-2012, available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/tables.pdf (last visited March 17, 2014).
[6] *Id.*

Health plan sponsors contract with PBMs to provide specified services, which may include some or all of the services described. Payments for the services are established in contracts between health plan sponsors and PBMs. For example, contracts will specify how much 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)[7] for brand-name drugs and at a Maximum Allowable Cost (MAC)[8] for generic drugs, plus a dispensing fee. Contracts also generally include fees for processing claims submitted by pharmacies (usually based on a rate per claim) and fees for providing services such as disease management or utilization review.[9] In addition, contracts generally specify whether and how the PBM will pass manufacturer rebates on to the health plan sponsors.[10] The contracts can also include performance guarantees, such as claims processing accuracy or amount of rebates received.[11]

In 2007, there were approximately 70 PBMs operating in the United States and managing prescription drug benefits for an estimated 95 percent of health beneficiaries nationwide.[12] Industry mergers in recent years have cut the number of large PBMs to two which together control 60 percent of the market and provide benefits for approximately 240 million people.[13]

Office of Program Policy Analysis and Government Accountability (OPPAGA) Report on Pharmacy Benefit Managers

Pursuant to a legislative request, the OPPAGA reviewed pharmacy benefit managers in a report released in 2007. This report addresses four questions.

- What role do PBMs play in the prescription drug industry?
- What concerns exist related to PBM business practices?
- How have states, PBMs, and health plan sponsors addressed these concerns?
- What options could the Legislature consider to address PBM business practices?

Relevant portions of the report are excerpted below.[14]

What role do PBMs play in the prescription drug industry?

PBMs are sometimes referred to as the middlemen in the prescription drug market because they act as intermediaries between health plan sponsors and drug manufacturers and pharmacies. PBMs negotiate with drug manufacturers and pharmacies on behalf of plan sponsors. These negotiations include provisions for cash rebates that drug manufacturers pay for drugs placed on health plan sponsor formularies (lists of approved drugs for prescribing) and the volume of these

[7] 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.
[8] MAC is a price set for generic drugs and is the maximum amount that the health plan will pay for a specific drug.
[9] If the PBM owns the mail-order or specialty pharmacy, claims processing fees may not be applied.
[10] Contracts may specify a fixed amount per prescription or a percentage of the total rebates received by a PBM.
[11] Information contained in this analysis has been excerpted in detail from a February 2007 report prepared by the Office of Program Policy Analysis & Government Accountability. (Office of Program Policy Analysis & Government Accountability, *Legislature Could Consider Options to Address Pharmacy Benefit Manager Business Practices*, Report No. 07-08 (Feb. 2007), *available at* http://www.oppaga.state.fl.us/MonitorDocs/Reports/pdf/0708rpt.pdf (last visited March 17, 2014).
[12] *Id.*
[13] Office of Program Policy Analysis & Government Accountability, *Research memorandum: Pharmacy Benefit Managers* (December 2, 2013) (on file with the Senate Health Policy Committee).
[14] Office of Program Policy Analysis & Government Accountability, *supra* note 11.

drugs that are used by health plan beneficiaries. PBMs also contract with pharmacies on behalf of plan sponsors to establish how pharmacies will be reimbursed for prescriptions they dispense to health plan sponsor beneficiaries.

What concerns exist related to PBM business practices?

In recent years, federal and state litigation as well as various stakeholders in the prescription drug industry have alleged that PBMs sometimes engage in unfair business practices that may not be in health plan sponsors' or their beneficiaries' best interests. These allegations cite unfair business practices that have resulted in excessive profits at the expense of health plan sponsors or pharmacies. The confidential and proprietary nature of PBM contracts and financial arrangements with drug manufacturers and pharmacies creates the opportunity for PBMs to engage in unfair business practices.

Although PBMs save health plan sponsors money by managing prescription drug costs, litigation, as well as stakeholders representing health plan sponsors, allege that PBMs have excessively profited by illegally accepting secret monetary incentives from drug manufacturers that are not shared with health plan sponsors. To manage prescription drug costs, PBMs negotiate rebates with manufacturers for drugs placed on health plan formularies as well as on the volume of drugs used by beneficiaries of the health plan sponsor. PBMs also manage costs by substituting, when clinically appropriate, a beneficiary's prescription for a more cost-effective drug, i.e., a less expensive but therapeutically equivalent brand-name or generic drug.

However, lawsuits assert that some PBMs have illegally accepted secret rebates or payments from manufacturers that are not shared with health plan sponsors, such as incentives for increasing a manufacturer's drug sales. Also, some stakeholders allege that PBMs have illegally increased rebates by changing patient prescriptions to drugs that receive higher rebates. These business practices are not only illegal but can also increase health plan sponsor costs if PBMs switch beneficiaries to higher cost drugs.[15] Drug switching, for non-clinical reasons, also may not be in the best interest of patients as changed prescriptions can potentially cause them harm or result in higher out-of-pocket payments.

Lawsuits and stakeholders also allege that PBMs have excessively profited from the price spread created by the difference between pharmacy reimbursements and health plan sponsor drug prices. Ideally, health plan sponsors should pay drug prices to the PBMs that are comparable to the prices that PBMs reimburse pharmacies. However, some stakeholders allege that PBMs have realized high profits by charging health plan sponsors significantly higher drug prices than prices at which they reimburse pharmacies. For example, in 2002 one PBM made a profit of $200 for each prescription of a generic version of Zantac, a drug for acid reflux, it sold on behalf of a health plan sponsor. It did this by charging the health plan sponsor $215 per prescription while only reimbursing network pharmacies $15.

Many of these issues arise because historically, PBM contracts with health plan sponsors have not provided sponsors access to information on PBM transactions or negotiations with manufacturers and pharmacies. PBMs consider this information to be confidential and proprietary. However, this lack of transparency increases the potential that PBMs may engage in

[15] Federal and state anti-kickback laws classify payments in exchange for favorable treatment as illegal kickbacks.

unfair business practices that can prevent health plan sponsors and pharmacies from receiving a fair share of the profits realized by PBMs in their negotiations with drug manufacturers.

How have states, PBMs, and health plan sponsors addressed these concerns?

As of December 2006, three states and the District of Columbia had passed legislation that addresses these issues by requiring contract transparency.[16] Another 28 states, including Florida, had considered but not passed similar legislation. In addition, two states had passed legislation to regulate PBMs by requiring licensure or oversight by state insurance departments or pharmacy boards. PBMs, health plans sponsors, and other stakeholders have also taken steps to change business practices and increase transparency.

To create more transparency in their business practices, PBMs have begun to offer health plan sponsors contracts that provide more transparency than traditional contracts. These contracts give health plan sponsors access to information about contractual and financial arrangements with drug manufacturers and pharmacies. Some PBMs also will negotiate contracts that establish drug prices for health plan sponsors equal to the price at which PBMs reimburse pharmacies. In addition to these voluntary steps, the provisions of settled lawsuits require defendant PBMs to adhere to specific transparency practices.[17]

Some stakeholders claim that over time voluntary efforts[18] combined with the effect of litigation will reduce the need for regulation. However, because the more transparent contracts generally require PBMs to pass on more rebates to health plan sponsors, potentially reducing profits, PBMs have increased their administrative fees for transparent contracts. In addition, the more transparent contracts require health plan sponsors to accept greater risk because these contracts do not guarantee specific amounts of drug rebates. Health plan sponsors could also experience greater administrative costs because of the increased monitoring needed to ensure transparency. As such, some health plan sponsors are reluctant to negotiate more transparent contracts, in part, because they prefer contracts with lower fixed costs and guaranteed rebates.

What options could the Legislature consider to address PBM business practices?

In 2007, the OPPAGA suggested that prior to considering statutory actions, the Legislature may wish to give market forces time to further influence efforts by PBMs, health plan sponsors, and other stakeholders to change PBM business practices and establish more transparent contracts. If

[16] At least twenty-one states and the District of Columbia have now enacted laws imposing some form of regulation on pharmacy benefit managers, including: Arkansas, Connecticut, Florida (Medicaid audits), Georgia, Indiana, Iowa, Kansas, Kentucky, Maryland, Mississippi, Missouri, New Mexico, North Carolina, North Dakota, Oklahoma, Rhode Island, South Dakota, Tennessee, Texas, Utah, Vermont, and the District of Columbia. (National Community Pharmacy Association, *Laws that Provide Regulation of the Business Practices of Pharmacy Benefit Managers*, *available at* http://www.ncpanet.org/pdf/leg/leg_pbm_business_practice_regulation.pdf (last visited March 17, 2014).

[17] For example, the settlement agreement between 20 state attorneys general against Medco arising from litigation in 2003 prohibits Medco from soliciting drug switches when the net drug cost of the proposed drug exceeds the cost of the prescribed drug. It also requires Medco to disclose financial incentives for switching drugs.

[18] For example, URAC, an independent accrediting organization that promotes health care quality now accredits PBMs. According to its website, URAC's PBM Accreditation standards cover the organization's contract terms and pricing structures; ensure access to drugs and pharmacies; provide for drug utilization management, formulary management, patient safety and customer service; and create a process for PBM outcomes measurement and quality improvement. (URAC, *Pharmacy Benefit Management*, https://www.urac.org/accreditation-and-measurement/accreditation-programs/all-programs/pharmacy-benefit-management/ (last visited March 17, 2014).

the Legislature wishes to enact statutory provisions to regulate PBMs, the OPPAGA suggested it could consider options adopted in other states, which include establishing transparency guidelines or licensing or certifying PBMs.

III. Effect of Proposed Changes:

SB 1014 creates a new section of law titled "Pharmacy benefit managers." The bill defines terms used in the law as follows:

- "Average wholesale price" means the published or suggested cost of pharmaceuticals charged to a pharmacy by a large group of pharmaceutical wholesalers.
- "AWP Discount," also known as the generic effective rate, means the negotiated amount a plan sponsor pays to pharmacies for the ingredient cost of a prescription and commonly expressed as a percentage of AWP.
- "Maximum allowable cost" means the upper limit or maximum amount that an insurance or managed care plan will pay for generic, or brand-name drugs that have generic versions available, which are included on a PBM-generated list of products.
- "Plan sponsor" means an employer, insurer, managed care organization, prepaid limited health service organization, third-party administration, or other entity contracting for pharmacy benefit manager services.
- "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; assuring audit compliance; and providing management reports.

The bill requires PBMs to contract with pharmacies annually on or before January 1. The bill requires the contracts to include the methodology and sources used to determine MAC pricing; update pricing weekly and provide notice of updates; and maintain a procedure for eliminating products from the list or modifying the MAC pricing timely so pricing remains consistent with pricing changes in the marketplace.

In order to put a prescription drug on the MAC list, the PBM must ensure that:

- A drug has at least three or more nationally available, therapeutically equivalent, multiple-source generic drugs that have a significant cost difference;
- Products are listed as therapeutically and pharmaceutically equivalent or "A" rated in the United States Food and Drug Administration's most recent version of the Orange Book; and,
- The product is available for purchase without limitations by all pharmacies in the state from national or regional wholesalers and may not be obsolete or temporarily unavailable.

The bill requires a PBM to disclose to the plan sponsor:

- The methodology and sources used to determine MAC pricing between the PBM and the plan sponsor. The plan sponsor must be notified as updates occur.
- Whether the PMB uses a MAC list for drugs dispensed at retail but not for drugs dispensed by mail order.

- Whether the PBM is using the identical MAC lists to bill the plan sponsor that it uses to reimburse network pharmacies and, if not, to disclose the pricing differences.

The bill requires that contracts between PBMs and pharmacies contain:

- A process for appealing, investigating, and resolving disputes regarding MAC pricing, which limits the right to appeal to 90 calendar days following the initial claim; requires the dispute to be resolved within 7 days; and requires the PBM to provide contact information of the person who is responsible for processing the appeal.
- A requirement that if the 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.
- A requirement that if the appeal is upheld, the PBM must make an adjustment retroactive to the date of adjudication and make the adjustment effective for all similarly situated network pharmacies.

The bill requires a PBM, by contract, to commit to providing a particular aggregate average reimbursement rate for generics or a maximum average AWP discount on multi-source generics as a whole. The AWP discount amount must be based on the AWP published by a nationally available compendia. The bill requires that the aggregate average rate for reimbursement be calculated using the actual amount paid to the pharmacy, excluding the dispensing fee; prohibits reimbursement calculated solely according to the amount allowed by the plan; and requires reimbursement to be calculated including all generics dispensed, regardless of whether they are subject to MAC pricing.

The bill has an effective date of July 1, 2014.

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:

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.
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The United States Constitution and the Florida Constitution prohibit the state from passing any law impairing the obligation of contracts.[19] 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."[20]

If a law does impair contracts, the courts will assess whether the law is deemed reasonable and necessary to serve an important public purpose.[21] 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.[22]

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:

Indeterminate.

C. Government Sector Impact:

Indeterminate.

VI. Technical Deficiencies:

It appears that on line 36 the word "administration" should be "administrator."

The requirement on lines 48 – 51 to contract by January is unclear in its intended application and could create problems in the event a pharmacy benefit manager is required to replace or add pharmacies in the network in order to satisfy access criteria.

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[19] U.S. Const. art. I, § 10; art. I, s. 10, Fla. Const.
[20] *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).
[21] *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).
[22] *Pomponio v. Cladridge of Pompanio Condo., Inc.,* 378 So. 2d 774 (Fla. 1980).

On line 65, it is unclear what would be a significant cost difference.

Lines 66 – 73, which create paragraphs (b) and (c), appear intended to modify language that is set out in paragraph (a). The paragraphs also introduce the term "product" instead of "drug." The lines should be redrafted for consistency and clarity.

Lines 107 – 108 should be revised to clarify that the adjustment is retroactive to the date the claim was adjudicated.

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

None.

B. Amendments:

None.