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 1014
INTRODUCER:	Senate Banking and Insurance Committee, Health Policy Committee and Senator Garcia
SUBJECT:	Pharmacy Benefit Managers
DATE:	March 27, 2014 REVISED:

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

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 1014 creates provisions governing pharmacy benefit managers (PBMs). A PBM contracts with plan sponsors, such as employers and insurers, to manage the cost and quality of the plans' drug benefits and may provide a variety of related services. Maximum-allowable cost (MAC) is the payment for the unit ingredient costs for off-patent prescription drugs (generics). The PBM or an insurer may develop a MAC list based on a proprietary survey of wholesale prices and other factors. The purpose of the MAC 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. The bill creates definitions of "maximum allowable cost," "plan sponsor," and "pharmacy benefit manager." The bill establishes criteria for a PBM to place a particular generic drug on a MAC list and may result in some drugs being removed from the MAC list and being subject to higher reimbursement rates. The bill sets out required provisions, disclosures, and conditions for contracts entered into between a pharmacy benefit manager and a pharmacy, and between a PBM and a plan sponsor related to drug pricing and claims adjudication.

According to the Division of State Group Insurance (DSGI) of the Department of Management Services, the implementation of this bill would negatively affect the State Employees' Health Insurance Trust Fund by approximately $12 million annually. The impact on local governments, insurers, and private sector employers that use PBMs for providing drug benefits for workers' compensation or health insurance is indeterminate at this time.

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, 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 disciplined for violations of applicable state or federal laws relating to a 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 and Pharmacies

Advances in pharmaceuticals have transformed health care over the last several decades. Many health care problems are prevented, cured, or managed effectively using prescription drugs. As a result, national expenditures for retail prescription drugs have grown from $120.9 billion in 2000

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

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, plan sponsors have looked for ways to manage the cost and quality of the plans' drug benefits, and have turned to pharmacy benefit managers (PBMs) who act as clearinghouses for plans, covered individuals, and retail pharmacies, and may provide a variety of related services. The range of services include 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. 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. [7] Recent industry mergers have reduced the number of large PBMs to two which together control 60 percent of the market and provide benefits for approximately 240 million people.[8]

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)[9] for brand-name drugs and at a Maximum Allowable Cost (MAC)[10] for generic drugs (and sometimes brand drugs that have generic versions), plus a dispensing fee.

The maximum-allowable cost (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 profits margins, and other factors. The federal government and state Medicaid programs use a similar tool. The purpose of the MAC pricing list is to ensure that the pharmacy or their buying groups are always 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

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[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.*
[7] 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).
[8] *Id.*
[9] 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.
[10] MAC is a price set for generic drugs and is the maximum amount that the plan sponsor will pay for a specific drug.

pharmacy purchases generic drugs at more favorable price, they will be more likely to make a profit.

The shift to generic drugs has saved consumers more than a $1 trillion over a decade, but it has adversely affected independent pharmacists according to recent news articles.[11] In 2000, about 50 percent of U.S. prescription drugs were generic. Now, generics represent about 84 percent of the market, according to IMS Health Incorporated. The increasing use of generics is pushing prescription-drug sales down. In response, drugstores want lawmakers to require the PBMs to share pricing information that would help drugstores negotiate bigger reimbursements and avoid dispensing drugs that are money losers. Some pharmacists contend that reimbursements are not covering the cost of the generic drug for about 10 percent of prescriptions--a rate that is growing because of reduced payments to pharmacies. The PBMs state that such legislation would allow pharmacies to know the amount of reimbursement for dispensed medications and could lead to pharmacies colluding against PBMs on pricing.[12]

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.[13] In addition, contracts generally specify whether and how the PBM will pass manufacturer rebates on to the health plan sponsors.[14] The contracts can also include performance guarantees, such as claims processing accuracy or amount of rebates received.[15]

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 Act of 2010, amending PPACA. The law[16] requires Medicare Part D plans and qualified health plan issuers who have their own PBM or contract with a PBM to report to the federal 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.

[11] Timothy W. Martin, *Drugstores Press for Pricing Data,* Wall Street Journal, March 27, 2013.
[12] *Id.*
[13] If the PBM owns the mail order or specialty pharmacy, claims processing fees may not be applied.
[14] Contracts may specify a fixed amount per prescription or a percentage of the total rebates received by a PBM.
[15] 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).
[16] 42 U.S.C. s. 1320b-23.

State and Federal Studies on Pharmacy Benefit Managers

Federal Studies

Concerns have been raised that a PBM that owns a pharmacy (whether retail or mail) may have a greater ability to influence which drugs are dispensed under the plans it administers than a PBM that does not own a pharmacy. If plan sponsor contracts with PBMs do not properly align the incentives of PBMs with those of the plans, this lack of alignment could create a conflict of interest. Potential conflicts of interest should be rare, however, if competition among PBMs provides plan sponsors with alternatives. At the request of Congress, the FTC collected aggregate data on prices, generic substitution and dispensing rates, savings due to therapeutic drug switches ("therapeutic interchange"), and repackaging practices. In response, the FTC analyzed data on PBM pricing, generic substitution, therapeutic interchange, and repackaging practices. The study examined whether PBM ownership of mail-order pharmacies served to maximize competition and lower prescription drug prices for plan sponsors. In its 2005 report based on the study, the FTC found, among other things, that the prices for a common basket of prescription drugs dispensed by PBM-owned mail order pharmacies were typically lower than the prices charged by retail pharmacies. The study also found competition affords health plans substantial tools with which to safeguard their interests.[17]

This 2005 FTC study continued the FTC's ongoing review of PBMs. The PBM practices were a particular focus of hearings on health care markets jointly conducted by the FTC and the Department of Justice Antitrust Division ("DOJ") in 2003 ("Health Care Hearings").[18] In 2004, the FTC and DOJ issued a report based on the hearings, a Commission-sponsored workshop, and independent research.[19] In addition, FTC staff have analyzed and commented on proposed PBM legislation in several states in 2006, 2007, and 2009.[20]

State Study

Pursuant to a legislative request, the Office of Program Policy Analysis & Government Accountability (OPPAGA) reviewed pharmacy benefit managers in a report released in 2007. The report addressed concerns relating to PBM business practices, actions by states, PBMs, and plan sponsors, and possible legislative options. Relevant portions of the report are summarized below.[21]

What concerns exist related to PBM business practices? In recent years, federal and state litigants and various stakeholders in the prescription drug industry have alleged that PBMs sometimes engage in unfair business practices that have resulted in excessive profits at the

[17] Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* (August 2005). Available at: http://wwwftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf (last visited March 24, 2014).
[18] *See* Hearings on Health Care and Competition Law and Policy, June 26, 2003, *available at* http://www.ftc.gov/ogc/healthcarehearings/030626ftctrans.pdf (last visited March 24, 2014).
[19] *See* Federal Trade Commission, and Department of Justice, *Improving Health Care: A Dose of Competition* (2004), available at http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf (last visited March 24, 2014).
[20] See, e.g., Letter from FTC staff to New York Senator James L. Seward (March 31, 2009), available at http://www.ftc.gov/os/2009/04/V090006newyorkpbm.pdf; Letter from FTC staff to New Jersey Assemblywoman Nellie Pou (Apr. 17, 2007), available at http://www.ftc.gov/be/V060019.pdf; Letter from FTC staff to Virginia Delegate Terry G. Kilgore (Oct. 2, 2006), available at http://wwwftc.gov/be/V060018.pdf (last visited March 24, 2014)
[21] Office of Program Policy Analysis & Government Accountability, *supra* note 7.

expense of health plan members, sponsors, or pharmacies. 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, such as incentives for increasing a manufacturer's drug sales 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.

In addition, some stakeholders allege that PBMs have illegally increased rebates by changing patient prescriptions to drugs that receive higher rebates. These business practices are illegal and may increase costs of plan sponsor if PBMs switch beneficiaries to higher cost drugs.[22] Drug switching, for non-clinical reasons, also may not be in the best interest of patients as changed prescriptions can potentially cause harm or result in higher out-of-pocket payments.

Litigants and stakeholders also allege that PBMs have excessively profited from the price spread created by the difference between pharmacy reimbursements and 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.

Historically, PBM contracts with health plan sponsors have not provided sponsors access to information on PBM transactions or negotiations with manufacturers and pharmacies. Some stakeholders assert that this lack of transparency increases the potential that PBMs may engage in 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. However, subsequent to the issuance of this report, PPACA was enacted, which requires specified plans and PBMs to report information to HHS, as described earlier in the analysis.

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 certain contractual issues.[23] In addition, two states had passed legislation to regulate PBMs by requiring licensure or oversight by state insurance departments or pharmacy boards. The PBMs, health plans sponsors, and other stakeholders have 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

[22] Federal and state anti-kickback laws classify payments in exchange for favorable treatment as illegal kickbacks.
[23] At least 21 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).

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.[24]

Some stakeholders claim that over time voluntary efforts[25] 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. 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 contracts that are more transparent, 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 contracts that are more transparent. If 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:

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

- "Maximum allowable cost" (MAC) 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 administrator, 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

[24] 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.

[25] 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).

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 provides that a contract between a PBM and a pharmacy, which includes MAC pricing, the PBM, must:

- Update MAC pricing information every 7-calendar days and establish a reasonable process for notice of updates; and
- Maintain a procedure to eliminate products from the MAC list or to modify the MAC pricing in a timely fashion so pricing remains consistent with pricing changes in the marketplace.

In order to place a prescription drug on the MAC list, the PBM must ensure a drug has at least two or more nationally available, therapeutically equivalent, multiple-source generic drugs that:

- Have a significant cost difference;
- Are listed as therapeutically and pharmaceutically equivalent or "A" or "B" rated in the United States Food and Drug Administration's most recent version of the Orange Book;
- Are available for purchase without limitations by all pharmacies in the state from national or regional wholesalers; and
- Are not obsolete or temporarily unavailable.

The new requirements for drugs to be eligible to for MAC list pricing may result in certain drugs being taken off the list and being subject to payment at a higher rate. Fewer drugs may qualify for the MAC list.

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 PBM must notify the plan sponsor as updates occur.
- Whether the PBM 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 the claim was adjudicated and make the adjustment effective for all similarly situated network pharmacies.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The bill may require cities or counties to spend funds or to take action requiring such expenditures. If the bill meets one of these requirements, cities and counties will have to comply with such provisions if the Legislature determines that it fulfills an important state interest.

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.

The United States Constitution and the Florida Constitution prohibit the state from passing any law impairing the obligation of contracts.[26] 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."[27]

If a law does impair contracts, the courts will assess whether the law is deemed reasonable and necessary to serve an important public purpose.[28] 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.[29]

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.

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[26] U.S. Const. art. I, § 10; art. I, s. 10, Fla. Const.
[27] *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).
[28] *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).
[29] *Pomponio v. Cladridge of Pompanio Condo., Inc.,* 378 So.2d 774 (Fla. 1980).

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The bill may result in a reduction in the number of drugs subject to the MAC list pricing. As a result, a pharmacist may receive a higher reimbursement for dispensed drugs that are removed from the MAC list and are subject to a reimbursement at a higher brand-like rate.

Due to changes in the criteria for drugs to be eligible for the MAC list, the bill may increase prices for some generic drugs removed from the MAC list and now subject to higher brand-like pricing. Employers and insurers may incur indeterminate additional costs for drugs that are removed from the MAC list. These costs could be shifted to policyholders as an increase in copayments for drugs removed the MAC list and now subject to brand pricing.

C. Government Sector Impact:

According to the Division of State Group Insurance (DSGI) of the Department of Management Services, this bill would negatively affect the State Employees' Health Insurance Trust Fund by approximately $12 million annually. There would be no impact to rebate collection.

The bill requires two or more therapeutically equivalent generics be available to include the generic drug on the MAC pricing list. The pharmacy benefit manager (PBM) for DSGI projected the negative fiscal impact to the trust fund based on the following:

- The DSGI's discount for generic drugs on the MAC pricing list at retail is approximately 75 percent. The discount for brand drugs is approximately 20 percent; moving generics off the MAC pricing list means the Department will lose the higher discount;
- The DSGI would be required to reimburse the PBM and its network retail pharmacies at a brand drug rate for all generic drugs dispensed that do not have two therapeutically equivalent generics in the market;
- The DSGI would lose significant savings while waiting for two generics to be available in the market;
- Any generics with an FDA rating other than "A" or "B" could not be added to the MAC pricing list;
- Over 2,058 "orphan" generic drugs – no other generic available – are currently on the market and would be removed from the MAC pricing list.

Additionally, the DSGI notes the bill:

- Requires that these two generics on the MAC list must have a "significant cost difference." A fiscal impact cannot be determined without a definition of this phrase.

- Removes all incentives for network retail pharmacies to dispense the least expensive therapeutic generic drug for the customer.
- May result in the member (state employee or retiree) paying the brand copayment to correspond to the higher brand pricing that the DSGI would pay.

According to the Division of Risk Management[30] of the Department of Financial Services (DFS), the fiscal impact on prescription drug costs for injured state workers is indeterminate at this time. The DFS spends approximately $11,000,000 per year for pharmacy benefits. The Division of Risk Management is contracted through January 1, 2017, with a PBM to manage prescription costs for injured state workers. Due to prohibitions in the state and federal constitution on impairment of contracts, it is unlikely any effects of this legislation would occur until expiration of the current contract. The fiscal impact on prescription costs for injured state workers is probably less of an impact than on state group health insurance since the provisions of s. 440.13(12)(c), F.S., prescribes a reimbursement amount at the average wholesale price plus $4.18 for a dispensing fee unless a lower rate has been negotiated for workers' compensation prescriptions. Since this section is not addressed by the bill, it is likely that workers' compensation medication would continue to be reimbursed at the statutory amount. The bill may limit a PBM's ability to negotiate rates below the statutory rate for workers' compensation drugs. According to DFS, many of the disclosure requirements provided in the bill are already required pursuant to the current state contract. It is most likely that additional regulatory requirements, such as updating the MAC list every 7 days and providing an appeal procedure, will increase the administrative costs for the PBM and result in higher state contracting costs after the current contract expires.

VI. Technical Deficiencies:

Some of the terms and conditions provided in the bill may be difficult to interpret, implement, or enforce by the stakeholders. For example, the bill provides that in order to place a drug on the MAC list, the drug must have at least two therapeutically equivalent, multiple-source generic drugs, which have a "significant cost difference" and are available for purchase "without limitations" by all pharmacies in the state from national or regional wholesalers. It is unclear how "significant" and "without limitation" would be determined. The bill requires PBMs to modify MAC pricing in a "timely fashion." It is unclear how this requirement would be determined.

The bill creates a new section in Chapter 465, F.S., relating to pharmacies. It is unclear whether the Board of Pharmacy or the Department of Health would have the authority to enforce the provisions of the bill.

VII. Related Issues:

The bill takes effect July 1, 2014, and may result in additional administrative costs for plans that operate on a calendar year basis. Plans may incur additional costs to notify employees and retirees of changes in the plan.

[30] Department of Financial Services, CS/CS/SB 1014 Fiscal Note (Mar. 27, 2014) (on file with the Senate Committee on Banking and Insurance).

VIII. Statutes Affected:

This bill creates 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/CS by Banking and Insurance on March 25, 2014:
The bill revises the criteria for a PBM to place a particular generic prescription drug on a maximum allowable cost list. The bill requires the drug to have at least two, instead of three, or more nationally available, therapeutically equivalent, multiple-source generic drugs that are listed as therapeutically and pharmaceutically equivalent or "A" or "B," instead of only "A," rated in the United States Food and Drug Administration's most recent version of the Orange Book.

CS by Health Policy on March 19, 2014:
Deletes the requirement for contracts between PBMs and pharmacies to be executed by January 1 annually.

- Deletes the contract requirement for PBMs to provide pharmacies with the basis and sources used to determine MAC pricing.
- Deletes the requirement for a PBM to contractually commit to providing a specified reimbursement rate for generic drugs.
- Deletes the definitions of "average wholesale price" and "AWP Discount."
- Makes a technical change to the definition of "plan sponsor," by replacing the word "administration" with "administrator."
- Reorganizes, without changing content, language related to conditions under which a PBM can place a drug on a MAC list.
- Clarifies the date for retroactive adjustment of payment when a pharmacy wins an appeal of a claim, as retroactive to the date the claim was adjudicated.

B. Amendments:

None.