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 Appropriations

BILL:	CS/SB 662
INTRODUCER:	Appropriations Committee and Senator Hays
SUBJECT:	Workers' Compensation
DATE:	April 25, 2013
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Burgess	BI	**Favorable**
2.	Davlantes	Stovall	HP	**Favorable**
3.	Betta/Johnson	Hansen	AP	**Fav/CS**
4.				
5.				
6.				

I. Summary:

CS/SB 662 revises provisions relating to reimbursement for prescription medications under chapter 440, F.S., Florida's Workers' Compensation Law in the following manner:

It is estimated that the implementation of the bill would reduce workers' compensation insurance costs by 0.7 percent or approximately $20 million based on preliminary 2012 statewide workers' compensation insurance premium (insurers and self-insurers).[1]

The Division of Risk Management in the Department of Financial Services estimates that implementation of the bill would result in an estimated annual increase in prescription drug costs of $210,377 to the State Risk Management Program.

The bill:

- Revises the amount of reimbursement for prescription medications of workers' compensation claimants by providing that the reimbursement rate for repackaged or relabeled drugs dispensed by a dispensing practitioner would be capped at 112.5 percent of the average wholesale price (AWP), plus $8.00 for the dispensing fee.
- Maintains the reimbursement rate for other prescription medications at AWP plus $4.18 dispensing fee.
- Provides that the average wholesale price would be calculated by multiplying the number of units dispensed times the per-unit average wholesale price set by the original manufacturer of

[1] National Council on Compensation Insurers, Preliminary Estimate of the impact of the delete-all amendment(barcode 213550) to SB 662, April 22, 2013. On file with Banking and Insurance Committee staff.

the underlying drug dispensed, based upon the published manufacturer average wholesale price published in the Medi-Span Master Drug Database as of the date of dispensing.
- Provides an exception to the reimbursement schedule if the employer or carrier, or a third party acting on behalf of the employer or carrier, directly contracts with a provider seeking reimbursement at a lower rate.
- Prohibits a dispensing practitioner from possessing such medications unless payment has been made to the supplying manufacturer, wholesaler, distributor, or drug repackager within 60 days of the dispensing practitioner taking possession of the medication.

Chapter 440, F.S., generally requires employers and carriers to provide medical and indemnity benefits to workers who are injured due to an accident arising out of and during the course of employment. Medical benefits can include, but are not limited to, medically necessary care and treatment, and prescription medications. In Florida, the prescription reimbursement rate for dispensing physicians and pharmacies is the AWP plus a $4.18 dispensing fee, or the contracted rate, whichever is lower.[2]

This bill amends the following section of the Florida Statutes: 440.13.

II. Present Situation:

State and Federal Regulation of Prescription Drugs

Section 510 of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. s. 360, requires registered drug establishments to provide the Food and Drug Administration (FDA) with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. Drug products are identified and reported to the FDA using a unique, three-segment number, called the National Drug Code (NDC), which is a universal product identifier for human drugs. The current edition of the NDC Directory is limited to prescription drugs and insulin products that have been manufactured, prepared, propagated, compounded, or processed by registered establishments for commercial distribution.[3]

The term "repackaged" drugs refers to drugs that have been purchased in bulk by a wholesaler/repackager from a manufacturer, relabeled, and repackaged into individual prescription sizes that can be dispensed directly by physicians or pharmacies to patients. Repackagers of drugs are required to register and list all such drug products repackaged and relabeled with the FDA.

In Florida, the Department of Business and Professional Regulation (DBPR) regulates prescription drug repackagers. A permit as a prescription drug repackager is required for any person that repackages a prescription drug in Florida. The permit authorizes the wholesale distribution of prescription drugs repackaged at the establishment.

Rule 64F-12, F.A.C., defines "repackaging or otherwise changing the container, wrapper, or labeling to further the distribution" to mean:

[2] Section 440.13(12), F.S.
[3] *National Drug Code Database Background Information*, U.S. Food and Drug Administration. Found at: <http://www.fda.gov/drugs/developmentapprovalprocess/ucm070829

- Altering a packaging component that is or may be in direct contact with the drug, device, or cosmetic. For example, repackaging from bottles of 1,000 to bottles of 100.
- Altering a manufacturer's package for sale under a label different from the manufacturer. For example: a kit that contains an injectable vaccine from manufacturer A; a syringe from manufacturer B; alcohol from manufacturer C; and sterile gauze from manufacturer D; packaged together and marketed as an immunization kit under a label of manufacturer Z.
- Altering a package of multiple-units, which the manufacturer intended to be distributed as one unit, for sale or transfer to a person engaged in the further distribution of the product.[4]

According to the Workers' Compensation Research Institute, some states, such as Massachusetts, New York, and Texas prohibit physicians from dispensing drugs.[5] In Florida, s. 465.0276(1), F.S., authorizes physicians and pharmacies to dispense, as provided below:

> A person may not dispense medicinal drugs unless licensed as a pharmacist or otherwise authorized under this chapter to do so, except that a practitioner authorized by law to prescribe drugs may dispense such drugs to her or his patients in the regular course of her or his practice in compliance with this section.

To become a dispensing practitioner in Florida, a practitioner is required to register under s. 465.0276, F.S., with the applicable professional licensing board as a dispensing practitioner and pay a $100 fee.[6] Dispensing practitioners must comply with all laws and rules applicable to pharmacists and pharmacies including undergoing inspections. A practitioner registered under this section may not dispense a controlled substance listed in Schedule II or Schedule III in s. 893.03, F.S.[7]

Section 458.347, F.S., allows a supervising physician to delegate dispensing authority to his or her physician assistant (PA). No registration is required for a PA to dispense. The PA may prescribe under his or her supervising physician; however, a PA cannot prescribe controlled substances.

According to advocates of physician dispensers, there are some advantages for patients from physicians dispensing drugs. These benefits may include greater compliance by the patient in taking a drug dispensed directly by the physician, more convenience for patients residing in remote areas, and the benefit of prompt treatment.

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[4] The Rule provides that repackaging does not include:
a. Selling or transferring an individual unit which is a fully labeled self-contained package that is shipped by the manufacturer in multiple units, or
b. Selling or transferring a fully labeled individual unit, by adding the package insert, by a person authorized to distribute prescription drugs to an institutional pharmacy permit, health care practitioner, or emergency medical service provider for the purpose of administration and not for dispensing or further distribution.

[5] *Prescription Benchmarks for Massachusetts* by the Workers' Compensation Research Institute, March 2010.

[6] If the practitioner is dispensing complimentary packages of medicinal drugs, the practitioner is not required to register.

[7] *See* s. 465.0276(1)(b), F.S.

Health Care Providers in Florida's Workers' Compensation System

A health care provider rendering medical treatment and care to an injured employee must be certified pursuant to Rule 69L-29.002, F.A.C., by the Department of Financial Services (DFS) or deemed certified, pursuant to s. 440.13(1)(d), F.S., as a provider within a managed care organization licensed through the Agency for Health Care Administration. Section 440.13(1) (d), F.S., provides that a "certified health care provider" is a provider approved to receive reimbursement through the Florida workers' compensation system. A certified provider may be a physician, a licensed practitioner, or a facility approved by the DFS or a provider who has entered an agreement with a licensed managed care organization to provide treatment to injured employees. Generally, a certified health care provider must receive authorization from the insurer before providing treatment.

The DFS is authorized to investigate health care providers to determine whether they are complying with the provisions of chapter 440, F.S. In addition, the DFS may impose penalties and sanctions on health care providers for violations of chapter 440, F.S., such as engaging in a pattern or practice of overutilization or improper billing practices.[8]

Section 440.13(14), F.S., provides that fees charged for remedial treatment, care, and attendance, except for independent medical examinations and consensus independent medical examinations, may not exceed the applicable fee schedules adopted under ch. 440, F.S., and department rule. However, if a physician or health care provider specifically agrees in writing to follow identified procedures aimed at providing quality medical care to injured workers at reasonable costs, deviations from established fee schedules are allowed.

Reimbursement for Prescription Drugs in Workers' Compensation

Chapter 440, F.S., is Florida's workers' compensation law. The Division of Workers' Compensation within the DFS is responsible for administering ch. 440, F.S. Generally, employers/carriers are required to provide medical and indemnity benefits to a worker who is injured due to an accident arising out of and during the course of employment. For such compensable injuries, an employer/carrier is responsible for providing medical treatment, which includes, but is not limited to, medically necessary care and treatment and prescription drugs.[9]

The reimbursement method for a prescription medication to pharmacies and dispensing physicians is found in s. 440.13(12)(c), F.S. The reimbursement amount is the average wholesale price (AWP) of the drug plus $4.18 for the dispensing fee, unless the carrier has contracted for a lower amount. The AWP is comparable to a wholesaler's suggested price and the term, AWP, is not defined in ch. 440, F.S. Current law does not provide caps on reimbursements for repackaged or relabeled prescription drugs.

An NDC is assigned to each drug and used to identify the medication and the manufacturer or repackager of the medication. The original drug manufacturer creates an AWP for each drug. Drug repackagers purchase pharmaceuticals in bulk from the manufacturer, then relabel, and

[8] *See* s. 440.13(8) and (11), F.S.
[9] Section 440.13(2)(a), F.S.

repackage the drugs into individual prescription sizes. Although drug repackagers do not alter the drugs, they do sell them in different quantities. By repackaging a drug, a new NDC is created and a new AWP is assigned to the repackaged drug.

Costs of Prescription Drugs in the Workers' Compensation System

According to a recent Workers' Compensation Research Institute (WCRI)[10] report,[11] the average payment per claim for prescription drugs in Florida was $536, which was the second highest average prescription cost per claim among the 17 states in the study. [12] Between 2005-2006 and 2007-2008, the average prescription cost per claim increased 14 percent in Florida. Over the same period, prices per pill paid to physicians grew more rapidly than prices paid to pharmacies for the same prescription. In 2007-2008, the prices paid to physician dispensers for many common drugs were 40-80 percent higher than what was paid to pharmacies for the same drugs. For generic drugs, physicians were paid much higher prices per pill than pharmacies for the same prescription. According to the WCRI, this suggests that if physicians stop dispensing prescription drugs in response to a large price drop, more pharmacies would dispense the same prescriptions at a lower price, resulting in a decline in prescription costs.

III. Effect of Proposed Changes:

The bill amends s. 440.13, F.S., relating to reimbursement rates for prescription medications under chapter 440, F.S., by providing the following changes:

- Creates a new reimbursement schedule for repackaged or relabeled prescription medications dispensed by a dispensing practitioner and requires reimbursement at 112.5 percent of the average wholesale price (AWP), plus $8.00 for the dispensing fee.
- Maintains the reimbursement rate for other prescription medications at AWP plus $4.18 dispensing fee.
- Provides that the AWP is calculated by multiplying the number of units dispensed times the per-unit AWP set by the original manufacturer of the underlying drug dispensed by the practitioner, based upon the published manufacturer AWP published in the Medi-Span Master Drug Database as of the date of dispensing.
- Provides an exception to the reimbursement schedule if the employer or carrier, or a third party acting on behalf of the employer or carrier, directly contracts with a provider seeking reimbursement at a lower rate.
- Prohibits a dispensing practitioner from possessing such medications unless payment has been made to the supplying manufacturer, wholesaler, distributor, or drug repackager within 60 days of the dispensing practitioner taking possession of the medication.

[10] The Workers Compensation Research Institute is an independent, not-for-profit research organization providing information about public policy issues involving workers' compensation systems. Organized in late 1983, the WCRI does not take positions on the issues it researches.
[11] *Prescription Benchmarks for Florida, 2ND Edition,* by Workers' Compensation Research Institute, July 2011.
[12] The following states were included in the WCRI study: Florida, California, Tennessee, Indiana, Texas, Louisiana, Michigan, Minnesota, North Carolina, Iowa, Pennsylvania, Illinois, Maryland, Wisconsin, New Jersey, New York, and Massachusetts.

Under current law, the reimbursement amount is the average wholesale price (AWP) of the drug plus $4.18 for the dispensing fee, unless the carrier has contracted for a lower amount. The term, AWP, is not defined in ch. 440, F.S.

Presently, a National Drug Code (NDC) is assigned to each drug and used to identify the medication and the manufacturer or repackager of the medication. The original drug manufacturer creates an AWP for each drug. Drug repackagers purchase pharmaceuticals in bulk from the manufacturer, then relabel and repackage the drugs into individual prescription sizes. Although drug repackagers do not alter the drugs, they do sell them in different quantities. By repackaging a drug, a new NDC is created and a new AWP is assigned to the repackaged drug. Current law does not provide caps on reimbursements for repackaged or relabeled prescription drugs.

The act takes effect July 1, 2013.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The NCCI[13] estimates that the changes proposed in the bill to revise reimbursements for repackaged or relabeled prescription drugs would result in a savings of 0.7 percent or $20 million on overall workers' compensation costs for employers in Florida

C. Government Sector Impact:

The Division of Risk Management in the DFS estimates that implementation of the bill would result in an increase in recurring prescription drug costs of the state risk management program of $210,377 on an annual basis.

[13] In Florida, the National Council on Compensation Insurance (NCCI) is the rating and statistical organization that files rates on behalf of worker's compensation insurers in the state. The Office of Insurance Regulation licenses the NCCI.

The current contract with the DFS and Progressive contains repackaged drug pricing provisions. As the pharmacy benefits manager, Progressive, contracts on behalf of the DFS for a network of pharmacy providers. The repackaged drug price in the PBM contract allows the DFS to argue if reimbursement is disputed that this price controls what is paid to a dispensing physician under s. 440.13(12)(c) F.S., which provides:

> (c) As to reimbursement for a prescription medication, the reimbursement amount for a prescription shall be the average wholesale price plus $4.18 for the dispensing fee, except where the carrier has contracted for a lower amount. Fees for pharmaceuticals and pharmaceutical services shall be reimbursable at the applicable fee schedule amount. Where the employer or carrier has contracted for such services and the employee elects to obtain them through a provider not a party to the contract, the carrier shall reimburse at the schedule, negotiated, or contract price, whichever is lower. No such contract shall rely on a provider that is not reasonably accessible to the employee. (Underlining supplied for emphasis)

For the period of 6/1/11 to 5/31/12, the number of repackaged/relabeled drug transactions for the State Risk Management program was 9,259. Assuming an increase of $3.82 in the dispensing fee for each of those transactions, the total cost increase due to the increased dispensing fee is $35,369.

The total amount paid as the average wholesale price for these transactions, unaffected by any increase in the AWP due to repackaging or relabeling, was $1,400,071. According to the DFS, increasing that amount by 112.5 percent results in $1,575,079, an increase of $175,008.

The total of the $175,008 increase is a result of using 112.5 percent of AWP, and the increase of $35,369 is a result of raising the dispensing fee to $8.00, is an estimated yearly increase in drug costs of $210,377 to the State Risk Management Program.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Under the bill, section 440.13(12)(e), F.S., would prohibit a dispensing practitioner from possessing such medication unless payment has been made to the supplying manufacturer, wholesaler, distributor, or drug repackager within 60 days of the dispensing practitioner taking possession of the medication. It is unclear whether there is a specific sanction or penalty under chapter 440, F.S., that the DFS could impose on a dispensing practitioner for noncompliance with this provision.

VIII. Additional Information:

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

CS by Appropriations on April 23, 2013:

The committee substitute makes the following changes:

- Creates a new reimbursement schedule for repackaged or relabeled prescription medications dispensed by a dispensing practitioner and requires reimbursement at 112.5 percent of the average wholesale price (AWP), plus $8.00 for the dispensing fee.
- Maintains the reimbursement rate for other prescription medications at AWP plus $4.18 dispensing fee.
- Provides that the AWP is calculated by multiplying the number of units dispensed times the per-unit AWP set by the original manufacturer of the underlying drug dispensed by the practitioner, based upon the published manufacturer AWP published in the Medi-Span Master Drug Database as of the date of dispensing.
- Provides an exception to the reimbursement schedule if the employer or carrier, or a third party acting on behalf of the employer or carrier directly contracts with a provider seeking reimbursement at a lower rate.
- Prohibits a dispensing practitioner from possessing such medications unless payment has been made to the supplying manufacturer, wholesaler, distributor, or drug repackager within 60 days of the dispensing practitioner taking possession of the medication.

B. Amendments:

None.