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 662
INTRODUCER:	Senator Hays
SUBJECT:	Workers' Compensation
DATE:	March 16, 2013
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Burgess	BI	**Pre-meeting**
2.			HP	
3.			AP	
4.				
5.				
6.				

I. Summary:

SB 662 revises requirements for determining the amount of reimbursement for prescription medications of workers' compensation claimants by providing that the reimbursement rate is the same for repackaged or relabeled drugs as for non-repackaged drugs, unless the carrier has contracted for a lower rate. Reimbursement for repackaged or relabeled drugs would be determined by multiplying the number of units of the drug dispensed by the per-unit average wholesale price (AWP) set by the original manufacturer of the drug (which may not be the manufacturer of the repackaged or relabeled drug), plus a $4.18 dispensing fee, unless the carrier has contracted for a lower amount. The bill expressly prohibits the price of repackaged or relabeled drugs from exceeding the amount that would otherwise be payable had the drug not been repackaged or relabeled. This provision would not apply in situations where the employer or insurer has contracted for a lower reimbursement amount.

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.[1]

It is estimated that the bill would reduce workers' compensation costs overall by 1.1 percent or $27 million.[2]

[1] Section 440.13(12), F.S.

[2] National Council on Compensation Insurers, Analysis of Florida Proposal to Revise Reimbursement for Repackaged or

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:

- 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]

Relabeled Prescription Drugs, February 20, 2013. On file with Banking and Insurance Committee Staff.
[3] *National Drug Code Database Background Information*, U.S. Food and Drug Administration. Found at: <http://www.fda.gov/drugs/developmentapprovalprocess/ucm070829
[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.

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.

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.

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.

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[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.

Reimbursement for Prescription Drugs in Workers' Compensation

Chapter 440, F.S., is Florida's workers' compensation law. The Division of Workers' Compensation within the Department of Financial Services 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.[8]

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 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)[9] report,[10] 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. [11] 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.

[8] Section 440.13(2)(a), F.S.
[9] 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.
[10] *Prescription Benchmarks for Florida, 2ND Edition,* by Workers' Compensation Research Institute, July 2011.
[11] 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.

III. Effect of Proposed Changes:

The bill amends s. 440.13, F.S., to require the same reimbursement rate for repackaged or relabeled drugs that currently exists for non-repackaged drugs in Florida. The bill provides that regardless of the location or the provider of a prescription to a claimant, the reimbursement amount is the average wholesale price, plus the $4.18 for the dispensing fee, unless the carrier has contracted for a lower amount.

If a drug has been repackaged or relabeled, the reimbursement amount is calculated by multiplying the number of units dispensed times the per-unit average wholesale price set by the original manufacturer of the underlying drug, which may not be the manufacturer of the repackaged or relabeled drug, plus a $4.18 dispensing fee, unless the carrier has contracted for a lower amount. The bill also provides that the price of the repackaged or relabeled drug may not exceed the amount otherwise payable if the drug had not been repackaged or relabeled.

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[12] estimates that the changes proposed in SB 662 to revise reimbursement rules for repackaged or relabeled prescription drugs would result in an impact of -1.1 percent or -$27.3 million[13] on overall workers' compensation costs for employers in Florida.[14]

[12] 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.

[13] Overall system costs are based on NAIC Annual Statement data as provided by A.M. Best including an estimate of self-insured premium. The estimated dollar impact of -$27.3M (million) is the percent impact displayed multiplied by A.M. Best 2011 written premium (preliminary) of $1,794M for Florida plus an estimate of the self-insured premium from the Florida Division of Workers Compensation for 2011 of $692M. This figure does not include the policyholder retained portion of

In Florida, drug costs represent 15.1 percent[15] of workers compensation (WC) medical costs. Repackaged or relabeled drug costs represent 24.3 percent of Florida's WC drug costs, or 3.7 percent (=24.3 x 15.1) of medical costs. Non-repackaged drugs represent 11.4 percent (=15.1 - 3.7) of medical costs.

In order to estimate the cost impact of this proposal, NCCI compared the paid amount of repackaged or relabeled drugs to the expected payment for drugs if they had been dispensed in their original packaging from the manufacturer (not repackaged or relabeled). A repackaged or relabeled indicator field from First Databank's *National Drug Data FileTM (NDDF), Descriptive and Pricing Data*, was used to distinguish repackaged or relabeled drugs from the drugs dispensed in their original packaging from the manufacturer within the Florida Workers Compensation Data licensed to NCCI.

Since HB 7095, effective July 1, 2011, bans dispensing of Schedule II and Schedule III controlled substances by a physician, these drugs were omitted from the cost impact analysis.

NCCI has assumed the difference between the current reimbursement for repackaged or relabeled drugs and the current reimbursement for the equivalent of these drugs that are not repackaged or relabeled to be a reasonable estimate of the cost impact due to the proposed rule.

The current and proposed reimbursements for each repackaged or relabeled drug were calculated as follows:

Current Cost = Average price per unit for repackaged or relabeled drug
x total units of repackaged or relabeled drug

Proposed Cost = Average price per unit for equivalent drug that is not repackaged or relabeled x total units of repackaged or relabeled drug

Where: *Units* = Total number of pills per prescription

Average price per unit = Total paid divided by total units

The current and proposed reimbursements are summed over all the transaction-level data to obtain total current and total proposed costs. The estimated direct impact on drug costs is the ratio of total proposed costs to total current costs. The impact on total prescription drugs due to the above proposals is summarized in the table below:

deductible policies, or adjustments for subsequent changes in premium levels. The use of premium as the basis for the dollar impact assumes that expenses and other premium adjustments will be affected proportionally to the change in benefit costs

[14] *Ibid.*

[15] Based on Florida Division of Workers' Compensation (DWC) data for Service Year 2011. This data would be on a calendar year basis – and include all 2011 medical provided on any open claim regardless of date of accident.

Type of Prescription Drug	Cost Distribution[16]	Impact
Repackaged	24.3%	-45.1%
Non-Repackaged	75.7	0.0
Total Prescription Drugs	100.0%	-10.9%

The above impact of -10.9 percent on total prescription drugs is then multiplied by the Florida percentage of medical costs attributed to prescription drug payments (15.1 percent) to arrive at the estimated impact of -1.6 percent on medical costs. The resulting impact on medical costs is multiplied by the percentage of Florida benefit costs attributed to medical benefits (68.4 percent[17]) to arrive at the estimated impact on Florida overall workers compensation system in costs of -1.1 percent or -$27.3 million.

C. Government Sector Impact:

State and local governments manage their workers' compensation risks by insuring or self-insuring. The impact on local government is indeterminate at this time. A local government that secures workers' compensation coverage would expect to experience a reduction in prescription drug costs to the extent that physicians dispense repackaged drugs to their employees. If a local government has contracted for a lower reimbursement rate, the bill would not affect that particular local government's costs.

Since the Division of Risk Management[18] in the Department of Financial Services has a contract provision regarding repackaged drug costs in its contract with its pharmacy benefits manager, it does not currently reimburse at the repackaged drug invoice price, and therefore the bill would not have a fiscal impact on the Division of Risk Management.[19]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

[16] Based on Florida Division of Workers' Compensation (DWC) data for Service Year 2011.
[17] Based on NCCI Financial Call data from Policy Years 2009 and 2010 projected to 1/1/2013. This estimated date is subject to change depending on the effective date of this proposal.
[18] The Division of Risk Management is responsible for the management of claims reported by or against state agencies for coverage under the self-insurance fund known as the "State Risk Management Trust Fund." Coverages provided through the trust fund include Workers' Compensation, Property, Fleet Automobile Liability, General Liability, Federal Civil Rights/Employment Discrimination and Court Awarded Attorney Fees.
[19] Department of Financial Services, Division of Risk Management Bill Analysis, February 15, 2013. On file with Banking and Insurance Committee staff.

VIII. Additional Information:

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

None.

B. Amendments:

None.