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 Health Regulation Committee

BILL:	SB 668
INTRODUCER:	Senator Hays
SUBJECT:	Workers' Compensation Medical Services
DATE:	February 14, 2012 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Burgess	BI	**Fav/1 amendment**
2.	Wilson	Stovall	HR	**Pre-meeting**
3.			BC	
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	☐	Statement of Substantial Changes
B. AMENDMENTS.....	☐	Technical amendments were recommended
	☐	Amendments were recommended
	☒	Significant amendments were recommended

I. Summary:

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 average wholesale price (AWP) plus a $4.18 dispensing fee, or the contracted rate, whichever is lower.

Prescription drug repackagers are licensed by the Department of Business and Professional Regulation. Drug repackagers purchase pharmaceuticals in bulk from the manufacturer and repackage the drugs into individual prescription sizes. The repackaged drugs are assigned a new National Drug Code and can be assigned a new, higher AWP than the original manufacturer's AWP.

The bill revises requirements for determining the amount of reimbursement for prescription medications of workers' compensation claimants by providing that the reimbursement amount is the same for repackaged or relabeled drugs as for non-repackaged drugs. Reimbursement for repackaged or relabeled drugs would be determined by multiplying the number of units of the

drug dispensed by the per-unit 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.

It is estimated that the bill would reduce workers' compensation costs overall by 2.5 percent.

This bill substantially 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.[1]

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.[2]

[1] *National Drug Code Database Background Information*, U.S. Food and Drug Administration. Found at: <http://www.fda.gov/drugs/developmentapprovalprocess/ucm070829> (Last visited on February 14, 2012).
[2] The Rule provides that repackaging does not include:

Dispensing Practitioners

According to the Workers' Compensation Research Institute, some states, such as Massachusetts, New York, and Texas prohibit physicians from dispensing drugs.[3] 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.[4] 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.[5]

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.

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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.

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

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

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

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 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.[6]

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, FS. 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

Workers Compensation Research Institute (WCRI) Findings

According to a recent WCRI[7] report, 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.[8] [9] 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

[6] Section 440.13(2)(a), F.S.

[7] 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.

[8] *Prescription Benchmarks for Florida, 2ND Edition*, by Workers' Compensation Research Institute, July 2011.

[9] 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.

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.

National Council on Compensation Insurance

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 NCCI is licensed by the Office of Insurance Regulation. The NCCI provided the following data related to drug repackaging costs:[10]

- Markup on Florida repackaged drugs ranges up to 679 percent above the same drug in a non-repackaged format.
- Physician dispensed drugs have grown from 9 percent of the drug costs in 2003 to 50 percent of the drug costs in 2009.
- Florida has the highest rate of physician-dispensed drugs of 46 states studied.
- Most repackaged drugs are dispensed by physicians.

Division of Risk Management, Department of Financial Services

The Division of Risk Management within the Department of Financial Services administers the State of Florida's self-insurance program for property and casualty risk, which includes workers' compensation coverage.[11] The program covers executive, legislative, and judicial branches of Florida government and state universities and is funded by yearly assessments to participating state agencies. In 2011, the division identified medical costs, including pharmacy, as a claims cost driver.[12] A recent study by the division identified total repackaged drug costs of $1.2 million for the 2010 fiscal year.[13]

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

[10] NCCI presentation to the Three Member Panel, November 16, 2011.
[11] Ch. 284, F.S.
[12] *Florida's Risk Management Program Initiatives to Address Program Cost Drivers,* Presentation by staff of the Department of Financial Services to the House Subcommittee on General Government Appropriations, February 8, 2011.
[13] Fiscal Analysis of SB 910 by the Department of Financial Services, November 21, 2011. (On file with the Senate Banking and Insurance Committee).

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, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The NCCI estimates that the implementation of SB 668 would result in an impact of minus 2.5 percent, or approximately $62 million in savings, on the overall workers' compensation costs in Florida. In order to estimate the cost impact of this proposal, the NCCI compared the cost of repackaged or relabeled drugs to the cost of drugs dispensed in its 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 its original packaging from the manufacturer within the Florida Workers' Compensation Data licensed to NCCI.

The NCCI looked at generic and non-generic drugs separately. As an example, acetaminophen is the generic medication for the brand name drug Tylenol. The NCCI looked at the reimbursement amounts for acetaminophen in physician's offices and in pharmacies, and determined the average markup for acetaminophen. Then, the NCCI looked at the reimbursement amounts for Tylenol in physicians' offices and in pharmacies, and determined the average markup for Tylenol.

If the bill were enacted, the NCCI estimated percentage reduction in physician dispensed drugs would be 57 percent. According to the 2011 Annual Report of the Division of Workers' Compensation, physician dispensed drug costs were $63.2 million for service year 2010. Using the $63.2 million figure provided by the division, the total dollar savings in physician dispensed drugs would be $36 million ($63.2 million x -57 percent). In the Florida January 1, 2012 workers' compensation rate filing, total benefit costs represented 57.8 percent of the premium dollar. Therefore, the reduction in physician dispensed drugs would result in a premium savings of $62 million ($36 million/.578).

The overall decrease in costs attributable to the reduction in the costs of repackaged and relabeled drugs would benefit employers securing workers' compensation coverage. The Office of Insurance Regulation anticipates issuing a rate reduction order prospectively from the effective date of the new law, July 1, 2012.

The bill would continue to allow the repackaging of prescription drugs, but it would limit and reduce the reimbursement amount to the AWP of the original manufacturer, plus the $4.18 dispensing fee.

C. Government Sector Impact:

According to the Division of Risk Management of the Department of Financial Services, implementation of this bill would result in an estimated recurring cost savings of $1 million per fiscal year for the state.

The bill would also result in an indeterminate amount of annual savings to local governments.

VI. Technical Deficiencies:

None.

VII. Related Issues:

In 2010, HB 5603 was vetoed by Governor Crist. That bill would have continued to allow the repackaging and relabeling of drugs, but it would have limited the reimbursement amount to the AWP of the original manufacturer, plus the $4.18 dispensing fee.

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:

Barcode 666350 by Banking and Insurance on January 19, 2012:
The amendment provides that a sick or injured employee is entitled to the choice in the selection of a dispensing practitioner to fill prescriptions for medicines required under

ch. 440, F.S. Current law provides that a sick or injured employee has a choice in the selection of the pharmacy or pharmacist.
(WITH TITLE AMENDMENT)