

**HOUSE OF REPRESENTATIVES  
FINAL BILL ANALYSIS**

<b>BILL #:</b>	CS/HB 605	<b>FINAL HOUSE FLOOR ACTION:</b>	
<b>SPONSOR(S):</b>	Health & Human Services Committee; Hudson and others	115 Y's	0 N's
<b>COMPANION BILLS:</b>	(CS/SB 662)	<b>GOVERNOR'S ACTION:</b>	Approved

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**SUMMARY ANALYSIS**

CS/HB 605 passed the House on May 1, 2013 as CS/SB 662.

Florida's workers' compensation law, ch. 440, F.S., provides medically necessary treatment and care for injured employees, including medications. Reimbursement for prescription drugs (generally to dispensing physicians and pharmacies) is the average wholesale price (AWP) plus a \$4.18 dispensing fee, or at a contract rate, whichever is lower. AWP is not defined in the workers' compensation law and does not have a universally accepted definition.

Prescription drug repackaging companies 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 then assigned a different AWP than the manufacturer's AWP, which is often substantially higher than the manufacturer's AWP. As such, the cost for a prescription filled with repackaged drugs in the workers' compensation system is generally much higher than it would have been if the prescription had been filled with the same drug that had not been repackaged. The overwhelming majority of repackaged drugs in Florida's workers' compensation system are dispensed by physicians who are authorized to dispense drugs at their office.

It is estimated that higher reimbursements for repackaged or relabeled drugs add \$27.3 million annually to workers' compensation costs. The Office of Insurance Regulation approved a workers' compensation rate filing that provides for an overall 6.1% increase in workers' compensation premiums effective January 1, 2013.

The bill provides for fee schedule reimbursement of prescription medication dispensed by a dispensing practitioner in the amount of 112.5 percent of the AWP, plus an \$8.00 dispensing fee. Reimbursement for repackaged or relabeled drugs is to be calculated by multiplying the number of units of the drug dispensed by the per-unit AWP set by the original manufacturer of the drug. The AWP is to be determined by the original manufacturer's published AWP as published in the Medi-Span Master Drug Database on the date the medication is dispensed, unless the employer or carrier, or an entity acting on behalf of the employer or carrier, such as a third party administrator of service company, has contracted for a lower amount. This AWP formula was included in HB 5603 (2010), which was vetoed by Governor Crist.

The bill prohibits possession of a prescription medication by a dispensing practitioner if payment for the prescription medication is not made within 60 days of the dispensing practitioner taking possession of the medications.

The bill appears to have an indeterminate fiscal impact on state and local government.

The bill was approved by the Governor on June 7, 2013, ch. 2013-131, L.O.F., and will become effective on July 1, 2013.

## I. SUBSTANTIVE INFORMATION

### A. EFFECT OF CHANGES:

#### Present Situation

#### Florida's Workers' Compensation Program

##### *Workers' Compensation Benefits<sup>1</sup>*

Chapter 440, F.S., is Florida's workers' compensation law. For work-related injuries, workers' compensation requires employers, or employers' insurance carriers, to pay for:

- Medically necessary remedial treatment, care, and attendance, including medicines,<sup>2</sup> medical supplies, durable medical equipment, and prosthetics.<sup>3</sup>
- Compensation for disability when the injury causes an employee to miss more than 7 days of work.<sup>4</sup>

The Division of Workers' Compensation (Division) within the Department of Financial Services (DFS) provides regulatory oversight of Florida's workers' compensation system.

To be eligible for payment under the workers' compensation law, health care providers who treat injured employees, except for emergency treatment, must apply for and be certified by the DFS and receive authorization from the insurer before providing treatment.<sup>5</sup> As of April 29, 2013, there were 37,122 certified health care providers in the workers' compensation system.<sup>6</sup>

##### *Reimbursement for Prescription Drugs in Workers' Compensation*

Reimbursement to pharmacies and dispensing physicians for prescription drugs in workers' compensation is provided for in s. 440.13(12)(c), F.S. Under current law, prescription drugs are reimbursed at the average wholesale price (AWP) plus a \$4.18 dispensing fee, or at a contract rate, whichever is lower.<sup>7, 8</sup> AWP is not defined in the workers' compensation statute and does not appear to have a universally accepted definition.<sup>9, 10</sup>

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<sup>1</sup> Whether an employer is required to have workers' compensation insurance depends upon the employer's industry (construction, non-construction, or agricultural) and the number of employees.

<sup>2</sup> Many workers' compensation insurers have implemented prescription drug programs (sometimes called "first fill" programs) designed to avoid out-of-pocket pharmacy expenses to injured employees for the initial prescription filled at the pharmacy as well as subsequent prescriptions. Under such a program, an injured employee may be given a form or card to show at a pharmacy to avoid out-of-pocket expense.

<sup>3</sup> Section 440.13(2) (a), F.S.

<sup>4</sup> Section 440.12(1), F.S.

<sup>5</sup> Section 440.13(3)(a), F.S.; Rule 69L-29.002, F.A.C.

<sup>6</sup> Florida Department of Financial Services, "Division of Workers Compensation Health Care Provider Directory," available at <https://apps.fldfs.com/provider/> (last viewed April 29, 2013).

<sup>7</sup> Fees for pharmaceuticals and pharmaceutical services must 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 must reimburse at the scheduled, negotiated, or contract price, whichever is lower. The contract may not rely on a provider that is not reasonably accessible to the employee. Section 440.13(12)(c), F.S.

<sup>8</sup> In response to inquiries received by the Florida Division of Workers' Compensation (Division) as to whether employers/carriers may appropriately deny authorization or reimbursement for prescription medication that is dispensed by a physician instead of a pharmacist, the DFS issued Informational Bulletin DFS-02-2009 on August 12, 2009. The bulletin informs, in part, that the Division is unaware of any specific provisions of the workers' compensation law that addresses the issue presented; available at: <http://www.myfloridacfo.com/wc/> (last viewed on April 26, 2013).

<sup>9</sup> See, for example, "Prescription Benchmarks for Florida, 2nd Edition," a 2011 study by the Workers' Compensation Research Institute (WCRI study) compared with "Impact of Physician-Dispensing of Repackaged Drugs on California Workers' Compensation, Employers Cost, and Workers' Access to Quality Care," a 2006 study conducted by Frank Neuhauser and colleagues for the California Commission on Health and Safety and Workers' Compensation (California study). The WCRI defines average wholesale price as:

## Physician Dispensing of Drugs

The authority for a physician to dispense medicinal drugs is found in s. 465.0276, F.S. Physician dispensing is regulated by the relevant licensing boards with the Department of Health. To dispense medicinal drugs, a physician must register with the applicable professional licensing board and pay a fee of \$100.<sup>11</sup> In addition, the physician must comply with all applicable statutes found in ch. 465, ch. 499, and ch. 893, F.S., all applicable rules, and federal laws regarding the dispensing of medicinal drugs.<sup>12</sup> Lastly, a physician must provide the patient with a written prescription and advise him or her, orally or in writing, that there is an option to have the prescription filled at the doctor's office or at a pharmacy.<sup>13</sup>

A physician may not dispense controlled substances listed in Schedule II and Schedule III, as provided in s. 893.03, F.S.<sup>14</sup> However, the following actions are exempted from the ban on physician dispensing:

- Dispensing complimentary medications in the normal course of practice without payment or remuneration;
- Dispensing a controlled substance listed in Schedule II or Schedule III in connection with the performance of a surgical procedure, limited to a 14 day supply;
- Dispensing a controlled substance listed in Schedule II or Schedule III pursuant to an approved clinical trial;
- Dispensing methadone in a methadone clinic licensed under s. 397.427, F.S.; and
- Dispensing a controlled substance listed in Schedule II or Schedule III in a hospice care facility licensed under part IV of ch. 400, F.S.<sup>15</sup>

Currently, there are 7,187 registered dispensing physicians in Florida.<sup>16</sup> The number of certified workers' compensation health care providers who are also authorized to dispense drugs is unknown.

## Relabeled or Repackaged Drugs

The term "repackage," used in the context of distributing drugs in Florida, means to repack or otherwise change the container, wrapping, or labeling to further the distribution of a drug, device, or cosmetic.<sup>17</sup> A "repackager" means a person who repackages a drug, device, or cosmetic, but specifically excludes

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"Published by First DataBank and Medi-Span ©. The AWP operates as an available price index that represents the most common wholesaler price charged to customers. The AWP does not necessarily represent the actual sales price in any single transaction. The payors may negotiate for lower prices. In workers' compensation systems, however, the AWP is often used as a price benchmark for pharmacy reimbursements of prescription drugs." [Note: On September 28, 2011, First DataBank discontinued publication of the "Blue Book Average Wholesale Price." See <http://www.firstdatabank.com/Support/drug-pricing-policy.aspx>.] The California study states that: "AWP is probably the most widely quoted pricing benchmark, but the least meaningful.... unlike what the name implies, the price has no relation to a wholesale price, average or otherwise. It is simply a price point established by the manufacturer, wholesaler, or repackager....The AWP...is typically much higher than the actual amounts that are paid by pharmacies and other wholesale drug purchasers...." Details on the WCRI study are available at <http://www.wcrinet.org/>. The California study is available at <http://www.dir.ca.gov/chswc/search/query.asp?SearchType=0> (last viewed April 26, 2013).

<sup>10</sup> The Florida Division of Workers' Compensation informs that in the event of a reimbursement dispute it would rely on the "Drug Topics Red Book," published by Thomson Reuters (New York) to determine the average wholesale price. The "Red Book" is listed as a reference source in the "Florida Workers' Compensation Health Care Provider Reimbursement Manual, 2008 Edition." The Reimbursement Manual is available at <http://www.myfloridacfo.com/wc/> (last viewed April 26, 2013).

<sup>11</sup> Section 465.0276(2)(a), F.S.; Rule 64B8-3.006, F.A.C. Registration is not required for dispensing complimentary medications in the normal course of practice without payment or remuneration.

<sup>12</sup> Section 465.0276(2)(b), F.S.; ch. 499, F.S., contains the Florida Drug and Cosmetic Act, administered by the DBPR; ch. 893, F.S., contains the Florida Comprehensive Drug Abuse Prevention and Control Act, which was significantly amended during the 2011 Regular Legislative session; see also ch. 2011-141, L.O.F.

<sup>13</sup> Section 465.0276(2)(c), F.S.

<sup>14</sup> Section 465.0276(1)(b), F.S.; see also s. 15, ch. 2011-141, L.O.F.

<sup>15</sup> Sections 465.0276(1)(b)1. through 6., F.S.

<sup>16</sup> Email correspondence from the Florida Department of Health on file with staff of the Health and Human Services Committee, dated March 15, 2013.

<sup>17</sup> Section 499.03(49), F.S.

pharmacies operating in compliance with pharmacy practice standards set out in ch. 465, F.S., and under applicable rules.<sup>18</sup> The term “repackaged” drugs refers to pharmaceuticals that have been purchased in bulk by a repackager from a manufacturer, relabeled, and repackaged into individual prescription sizes that can be dispensed directly by physicians to patients.

Rule 61N-1.001, 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 1000 pills to bottles of 100 pills.
- 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. This does not include:
  - Selling or transferring an individual unit which is a fully labeled self-contained package that is shipped by the manufacturer in multiple units, or
  - 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.

Repackagers may assign an AWP for a repackaged drug that differs from the AWP suggested by the original manufacturer of the drug.<sup>19</sup> Frequently, the AWP assigned by the drug repackager is significantly greater than the AWP suggested by the drug’s manufacturer. Thus, the cost of the repackaged drug, in terms of reimbursement paid by an insurer, is often significantly greater than it would have been if the prescription had been filled with the identical non-repackaged drug.

The Florida Department of Business and Professional Regulation (DBPR), which regulates prescription drug repackagers, reports that there are 28 licensed prescription drug repackagers in the state.<sup>20</sup>

### *The Cost of Repackaged or Relabeled Prescription Drugs to Florida’s Workers’ Compensation System*

The National Council on Compensation Insurance (NCCI) is the designated licensed rating and statistical organization for workers’ compensation in Florida. Among its responsibilities, NCCI collects data from workers’ compensation insurers in Florida and makes rate filings on the insurers’ behalf. The workers’ compensation rate filing for 2013 provides for an overall increase in workers’ compensation rates of 6.1%.<sup>21</sup>

Using 2011 data from the Division, the NCCI has estimated that reimbursements for repackaged or relabeled prescription drugs add \$27.3 million in annual costs to the workers’ compensation system.<sup>22</sup>

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<sup>18</sup> Section 499.003(50), F.S.

<sup>19</sup> United States Government Accountability Office, “Brand-Name Prescription Drug Pricing: Lack of Therapeutically Equivalent Drugs and Limited Competition May Contribute to Extraordinary Price Increases” (GAO-10-201, December 2009); available at <http://www.gao.gov/products/GAO-10-201> (last viewed April 26, 2013).

<sup>20</sup> Correspondence from the Department of Business and Professional Regulation, dated March 14, 2013 (on file with staff of the Health and Human Services Committee). The DBPR also reports that as of March 2013, there were 275 “out-of-state prescription wholesaler distributor” permits issued. Such distributors are able to repackage drugs. However, the DBPR does not collect information as to whether applicants for such permits repackage drugs, as it does not have legal authority to regulate repackaging outside of the state of Florida.

<sup>21</sup> Florida Office of Insurance Regulation, Office Statement, “OIR Approves Final Order for Workers’ Compensation Rates” (November 5, 2012), available at <http://www.floir.com/PressReleases/index.aspx> (last viewed April 26, 2013).

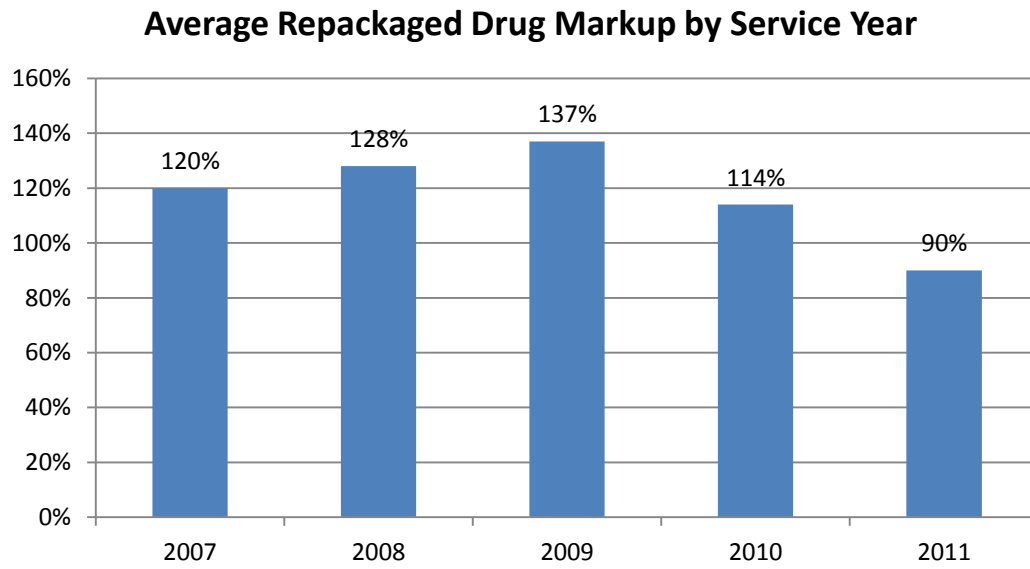
<sup>22</sup> National Council on Compensation Insurance, “Pricing of Workers Compensation Proposals 2013,” page 8 (on file with staff of the Health and Human Services Committee); see also National Council on Compensation Insurance, “Analysis of Florida Proposal to

Additional findings about Florida's workers' compensation system include the following:

- The 10 most frequently dispensed repackaged drugs have an average markup of 54% to 625%.<sup>23</sup>
- Physician-dispensed drugs account for 62% of all prescription drug dollars; the second highest percentage of the 23 states in one study.<sup>24</sup>

An analysis of CS/SB 662 by NCCI following passage of the bill estimates that the changes proposed in the bill would result in saving to the workers' compensation system of 0.7%, or \$20 million.<sup>25</sup>

The following chart illustrates the average markup of repackaged drugs from 2007 through 2011:<sup>26</sup>



Total workers' compensation system costs as a result of the markup on repackaged drugs were \$250 million over the last five years.<sup>27</sup> The following chart shows the annual system costs attributed to the markup of repackaged drugs from 2007 to 2011:<sup>28</sup>

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Revise Reimbursement for Repackaged or Relabeled Prescription Drugs Effective Upon Adoption," September 25, 2012, page 1 (on file with staff of the Health and Human Services Committee).

<sup>23</sup> *Id.* at page 12. The 10 drugs are Meloxicam, Carisoprodol, Lidoderm®, Tramadol HCL, Omeprazole, Gabapentin, Ranitidine HCL, Cyclobenzaprine HCL, Naproxen, and Lyrica.

<sup>24</sup> Workers Compensation Research Institute, Wang, D., "Physician Dispensing in Workers' Compensation," July 2012, page 8, table A.

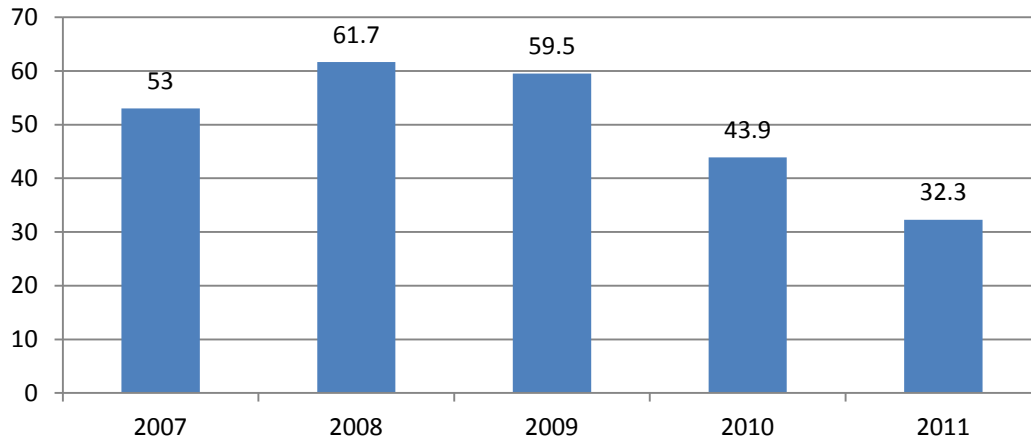
<sup>25</sup> National Council on Compensation Insurance, "Analysis of Florida Senate Bill (SB) 662 Proposed to be Effective July 1, 2013," May 1, 2013, page 4 (on file with staff of the Health and Human Services Committee).

<sup>26</sup> *See supra*, FN 22 at page 10.

<sup>27</sup> *Id.* at page 14.

<sup>28</sup> *Id.*

## Annual Workers' Compensation System Costs Due to Repackaged Drug Markup, in Millions



The Three Member Panel (Panel) Biennial Report for 2013 makes the following observation regarding reimbursement to physicians in the workers' compensation system who are repackaging and dispensing medications:

"...the current statutory benchmark of reimbursing prescription drugs at the Average Wholesale Price has led to a pricing environment that is not conducive to the self-execution of the workers' compensation system and does not provide reimbursement clarity and uniformity, which is a detriment to the payers and payees. The result has been a dramatic increase in the number of petitions for reimbursement dispute filed by physicians in FY 2011/2012 (up 872% over FY 2010/2011 from 1,308 to 12,718, respectively) primarily due to disputes involving physician dispensed medication."

The Panel believes that the Division will continue to see great numbers of petitions for reimbursement dispute being filed until a legislative and/or regulatory solution is achieved.<sup>29,30</sup>

### *Findings of the Workers' Compensation Research Institute<sup>31</sup>*

In July 2011, the Workers' Compensation Research Institute (WCRI) published "Prescription Benchmarks for Florida, 2nd Edition,"<sup>32</sup> a study that compares the cost, price, and use of pharmaceuticals in workers' compensation in Florida with 16 other states.<sup>33</sup> Among the study's findings on Florida:

<sup>29</sup> *Id.* at page 6.

<sup>30</sup> The three-member panel is comprised of the Chief Financial Officer, or the CFO's designee, and two members appointed by the Governor, subject to confirmation by the Senate. The two appointed members represent employers and employees, respectively. The panel determines statewide schedules of maximum reimbursement allowances for medically necessary treatment, care, and attendance provided by physicians, hospitals, ambulatory surgical centers, work-hardening programs, pain programs, and durable medical equipment under Florida's workers' compensation system. See s. 440.13(12), F.S.

<sup>31</sup> WCRI is an independent research organization that analyzes workers' compensation systems for states with which it contracts. WCRI provides information through studies and data collection efforts, and does not take positions on the issues it researches.

<sup>32</sup> WCRI study, *supra* note 7.

<sup>33</sup> The 17 states in the WCRI study are California, Florida, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, New Jersey, New York, North Carolina, Pennsylvania, Tennessee, Texas, and Wisconsin.

- For 2007/2008, the average payment per workers' compensation claim for prescription drugs was \$536, the second highest cost of the 17 states studied, and 45% higher than the median<sup>34</sup> of the states studied.<sup>35</sup>
- Between 2005/2006 and 2007/2008, the average cost per claim for prescription drugs in Florida increased by 14%, but remained relatively stable in the other study states.
- Higher and growing costs of prescription drugs in Florida were largely due to more frequent and higher-priced physician dispensing.
- Over a four-year period (from 2004/2005 through 2007/2008), the percentage of payments for physician-dispensed prescriptions increased from 17% to 46% of all prescription payments.
- In 2007/2008, for many common drugs, physicians were paid 40% to 80% more than pharmacies for the same prescription.
- 65% of physician-dispensed prescriptions were for pain medications.

Further, the WCRI study identifies and addresses two concerns that have been raised in response to proposals to eliminate higher reimbursements for repackaged drugs, and to provide the same rate of reimbursement for the same drug, whether it is repackaged or non-repackaged. The first concern is that prescription drug costs would increase. This position is based on the following assumptions: that physician dispensing would decrease and that physicians dispense generic drugs more frequently than pharmacies. For the most commonly dispensed drugs, the WCRI found that physicians and pharmacies almost always dispense generic drugs, and that physicians are paid much higher prices per pill than pharmacies for the same prescription.

A second concern with providing the same reimbursement for repackaged and non-repackaged drugs is that physicians would stop dispensing drugs, and patients who do not have prescriptions filled by their doctor are less likely to take their medicine as prescribed, which would be detrimental to the patient. For California, the 2011 WCRI study reports that physician dispensing decreased from 50% to 25% of all prescriptions immediately following enactment of a reform to provide the same reimbursement for repackaged and non-repackaged drugs.<sup>36</sup> In a subsequent study, "Physician Dispensing in Workers' Compensation," published in July 2012, the WCRI reports that three years after the California reform nearly half of all prescriptions in that state were dispensed by physicians.<sup>37</sup>

### **Effect of Proposed Changes**

The bill provides for fee schedule reimbursement of prescription medication dispensed by a dispensing practitioner in the workers' compensation system in the amount of 112.5 percent of the AWP, plus an \$8.00 dispensing fee. Reimbursement for repackaged or relabeled drugs is to be calculated by multiplying the number of units of the drug dispensed by the per-unit AWP set by the original manufacturer of the drug. The AWP is to be determined by the original manufacturer's published AWP as published in the Medi-Span Master Drug Database on the date the medication is dispensed, unless the employer or carrier, or an entity acting on behalf of the employer or carrier, such as a third party administrator of service company, has contracted for a lower amount.

The bill requires all claims for reimbursement of prescription medication dispensed by a dispensing practitioner in the workers' compensation system to include the National Drug Code (NDC) of the original manufacturer of the dispensed medication. This provision effectively eliminates the practice of creating a new NDC for a repackaged or relabeled prescription medication, which then, under current law, permits the establishment of a new, often exorbitant, AWP by the repackaging or relabeling dispensing practitioner.

<sup>34</sup> The Merriam-Webster Dictionary online defines median as "a value in an ordered set of values below and above which there is an equal number of values or which is the arithmetic mean of the two middle values if there is no one middle number...." See <http://www.merriam-webster.com/dictionary.htm>.

<sup>35</sup> WCRI study, *supra* note 7, informs that physician dispensing is not generally allowed in three of the states in its study - Massachusetts, New York, and Texas.

<sup>36</sup> Data from the first quarter of 2008. Subsequent dispensing patterns are not addressed in this study.

<sup>37</sup> See <http://www.wcrintet.org/>.

The bill deletes the requirement that the employer or carrier reimburse a provider who is not a party to an existing contract for pharmaceutical services at the lower amount of the fee schedule, negotiated, or contract price. The bill also deletes the prohibition against an employer or carrier reimbursing a dispensing practitioner at a contracted price with a provider who is not reasonably accessible to the injured worker. These provisions are consistent with the portion of the bill that requires reimbursement at the fee schedule rate unless the employer or carrier, or entity acting on behalf of the employer or carrier, directly contracts with the provider for a lower reimbursement amount.

The bill prohibits a dispensing practitioner from possessing prescription medication if payment for the medication is not made within 60 days of the dispensing practitioner taking possession of the medication. This provision will prohibit the current practice of a dispensing practitioner taking prescription medications on consignment and paying for the supply after they have been reimbursed.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

### A. FISCAL IMPACT ON STATE GOVERNMENT:

#### 1. Revenues:

None.

#### 2. Expenditures:

To the extent that repackaged drugs are dispensed by physicians to state government employees who suffer a workplace injury, the bill will lower the costs that state government pays for prescription drugs.

### B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

#### 1. Revenues:

None.

#### 2. Expenditures:

To the extent that repackaged drugs are dispensed by physicians to local government employees who suffer a workplace injury, the bill will lower the costs that local governments pay for prescription drugs. Also, for local governments that have procured workers' compensation insurance coverage, there may be a reduction in insurance premiums to reflect potential system-wide savings.

### C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Physicians that dispense prescription drugs under the workers' compensation system will continue to receive an \$8.00 dispensing fee for each prescription they fill, in addition to the fee schedule reimbursement amount of 112.5 percent of AWP, but will no longer derive additional income from current higher reimbursements.

### D. FISCAL COMMENTS:

The bill will result in significant savings to state and local governments and lower workers' compensation costs for Florida employers.