

WORKERS' COMPENSATION PHARMACY FEE SCHEDULES:

THE IMPACT OF THE DISCONTINUATION OF AVERAGE WHOLESALE PRICE

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<u>Objectives:</u>

The focus of this paper is to provide an overview of the Average Wholesale Price (AWP) litigation and settlements and their impact on pharmacy fee schedules in workers' compensation and to discuss potential financial and operational implications for the Workers' Compensation Pharmacy Benefit Management (PBM) industry.

Synopsis:

Since 2005, several lawsuits have been filed against certain drug companies as well as the pharmacy industry's two primary benchmark pricing sources: First DataBank, Inc., ("FDB") and Medi-Span, for alleged inflation of Average Wholesale Price (AWP). The basis for these separate but related lawsuits is the methodology used to calculate the AWP of over 400 drugs, representing 1,442 national drug codes (NDC). The lawsuits contend that specific parties intentionally reported false and inflated AWPs via printed and electronic databases for financial gain. The named litigants deny allegations that they knowingly affected prices or altered pricing methodologies for financial gain and have denied wrongdoing. However, FDB and Medi-Span both settled out of court, paying approximately \$2 million in settlements to date. Independent of the lawsuits, FDB and Medi-Span agreed to stop publishing AWP within a two-year period post March 2009.

In part, the lawsuits allege that AWPs were unlawfully inflated from 20% to 25% above the mark-up from Wholesale Acquisition Cost (WAC). FDB and Medi-Span both calculated AWP as a function of WAC, thus the increase from a 20% surcharge to a 25% surcharge effectively increased AWP by approximately 4%. The increase primarily affected brand name prescription drugs purchased or

dispensed between 8/1/01 and 3/15/05, including, but not limited to Lipitor, Claritin, Prozac, Nexium, Plavix, Allegra, Wellbutrin, Ambien, Prilosec, Zantac, Valtrex, Zyprexa, Celebrex, Imitrex, Risperdal, Seroquel, and Neurontin. As part of the settlement, the near-term method for changing pricing is as follows:

- First DataBank and Medi-Span will adjust AWPs for any drug identified in the action(s) that was marked up beyond 120% of WAC or 120% of Medi-Span's Direct Price.
- In addition to the 1,442 NDCs involved in the AWP settlement, the same reduction will be applied to all NDCs in excess of 120% markup.

The court-directed settlement required First DataBank and Medi-Span to change their pricing methodology within 180 days from effective date of final judgment, which falls on 9/26/09. While identifying a new pricing benchmark was not part of the resolution, many pharmacy industry stakeholders believe that the long-term solution will include such a benchmark.

The ramifications for FDB, Medi-Span and the entire workers' compensation pharmaceutical industry will not be fully realized for many years as new pricing benchmarks are established, but short-term implications will have an immediate impact on the industry.

Pricing discussion

To gain a better understanding of the AWP settlement's impact, the following model is presented to explain relationship between WAC and AWP:

Based on the WAC price of \$100 for a product, the pre-9/26/09 formula is as follows:

- WAC = \$100; AWP = \$125
- Markup from WAC to arrive at AWP is 25%, i.e., \$100 x 1.25 = \$125 AWP
- Discount from AWP to arrive at the WAC price is 20%, i.e., \$125 x (1 .
 20) = \$100 WAC.

Using the same \$100 WAC price, the proposed settlement would change the relationship to:

- WAC = \$100; AWP = \$120 (\$5 or 4.1% reduction in AWP used in this scenario)
- The markup for WAC to arrive at AWP is 20%, i.e., \$100 x 1.20 = \$120 AWP.
- The discount from AWP to arrive at WAC is 16.67%, i.e., \$120 x (1 . 1667) = \$100 WAC.

Example:

In this example, a PBM's buy rate for brand drugs is AWP - 15% + \$2.50 dispensing fee.

Assuming the pharmacy's acquisition cost is equal to WAC, then the gross profit dollars generated by dispensing this prescription under the current WAC/AWP relationship is:

Revenue of \$125 x (1 - 0.15) + \$2.50 = \$108.75 - \$100 cost = \$8.75 gross margin.

Under the proposed settlement, the gross profit generated from the prescription under the same reimbursement model is:

Revenue of \$120 x (1 - 0.15) +\$2.50 = \$104.50 - \$100 cost = \$4.50 gross margin.

The pharmacy's gross margin in this example decreases by \$4.25 or 48%.

Reaction from the Market:

The National Association of Chain Drug Stores (NACDS) opposes the First DataBank/Medi-Span settlement, stating in a March 25, 2009 press release that the court ruling by Judge Patti B. Saris of the U.S. District Court District of Massachusetts will adversely affect pharmacies by reducing AWPs to 120% of wholesale acquisition cost (WAC).

NACDS has already filed a legal brief disputing the validity of cost savings and the impact of the settlement contending it was based on "inaccurate" economic analysis which would unfairly affect retail pharmacies. NACDS contends that pharmacies that are unable to renegotiate private-sector reimbursement contracts face a net 4 percent reduction in AWP-based reimbursement. (Source: www.nacds.org / Drug Topics E-News, 3/25/09). Notably, the large group/Medicare PBMs have all committed to "cost neutrality" in their financial relationships with retail pharmacies.

CompPharma is currently investigating this suit to determine if it would be appropriate to support NACDS' actions.

Additional commentary from the marketplace is included below:

• CVS' written statement to its investors: "In the event AWPs were

suddenly reduced in a material way for particular products, obviously we would renegotiate the discount or dispensing fee. Virtually all of our commercial agreements are 'at-will' agreements, which can be renegotiated freely." (Source: DrugTopics.com website, accessed 6/4/09.)

 John Rector, Vice President and Senior Counsel to the National Community Pharmacists' Assoc.: "From our sector's point of view, there are some very problematic aspects of the settlement," said Rector. "As part of the settlement, First DataBank will make available all the documents that it has relevant to the AWP issue, which could lead to new litigation. First DataBank is held harmless and nobody else is. Who knows what data they have?" (Source: DrugTopics.com website, accessed 6/7/09.)

At this time, it appears that WAC is the most "acceptable" known pricing benchmarks. The relationship between AWP and WAC identifies a 4% margin loss to pharmacies, a loss pharmacies contend must be resolved via contract renegotiations between PBMs and payers so that pharmacies maintain their current profitability.

Considerable publicity surrounding AWP lawsuits and settlements has nurtured speculation in the regulatory and payer communities about the potential for cost savings due to reductions in AWP. There are numerous reports of state Medicaid regulators refusing to renegotiate prices with retail pharmacies despite the pending change in AWP methodology.

In the workers' compensation sector, many in the payer community (carriers / employers) expect budgetary cost savings based on the AWP settlement. This expectation is diametrically opposed to the pharmacy provider community's determination not to accept lower margins from the PBMs. In fact, the pharmacies want to be made whole. Retail pharmacies and other drug suppliers have clearly indicated they are not willing to absorb margin reductions related to the re-formulation of AWP or its subsequent replacement.

Because some workers comp payers expect to pay less for drugs while pharmacies expect to receive the same amount they always did, PBMs are caught in the middle. As a result, in some instances workers' compensation PBMS are being asked to absorb the margin reductions, decreasing their already slim operational budgets.

As AWP disappears from the landscape, workers' compensation regulators and legislators in the 33 states that have fee schedules tied to an AWP methodology (and others that may soon develop Rx fee schedules) are looking for price benchmark alternatives. Several states have moved to base their workers' compensation drug fee schedule on Medicaid, with California the most telling

example. The appeal of Medicaid is it is simple to understand and easy for the regulators to implement. The problems with Medicaid as the basis for a workers' compensation fee schedule are significant, yet subtle, and require an understanding of the financial and operational relationships among various entities involved in the provision of workers' compensation pharmacy care, such as transaction processes, pharmacy cost drivers, and medical claims management. None of these topics apply in the Medicaid arena, nor are they thoroughly understood by most state regulators and legislators.

Pharmacy Contracting Ramifications:

The entire pharmacy industry landscape will change due to the demise of AWP as a pricing mechanism. Most pharmacies, dispensing entities, PBMs, and payers are in the process of re-assessing pricing parameters and in many cases they are re-negotiating managed care and third-party contracts.

The uniform challenge for negotiating parties lies in defining financial equality and understanding the significance of other factors impacting pharmacy contracting and reimbursement. In workers' compensation pharmacy, generic utilization hovers around 63% nationally (Source Health Strategy Associates' Fifth Annual Survey Report of Prescription Drug Management in Workers' Compensation) and profitability margins of usual and customary (U&C) pricing, although dwindling, is highly valued by pharmacy providers. During the past several years the generic product market experienced notable growth. providing pharmacies with sufficient profitability to offset losses incurred by Pharmacies have felt considerable pressure to escalating brand discounts. maintain their market share due to a growing acceptance by competitors of more aggressive discounts. The instability of the workers' compensation industry, caused by economic factors, plan design parameters and now the uncertainty of a new pricing benchmark have heightened pharmacy providers' resolve to defend operational profitability.

Long-Term Impact on Pharmacy Reimbursement:

AWP, as it is known today, will likely not exist two years in the future. Alternate pricing methodologies are currently being considered, but there is no clear indication of their replacement(s). Methodologies under consideration include Wholesale Acquisition Cost (WAC), Direct Price (DP), Suggested Wholesale Price (SWP), Blue Book AWP (BBAWP), and Alternative Benchmark Price (ABP). While each has specific positive characteristics, they each also have problems, which make it difficult to predict which methodology will become the benchmark on which most workers' compensation fee schedules will be based. It is entirely possible that different states will adopt different methodologies, with obvious significant implications for PBMs, payers, and retail pharmacies. Following is a brief description of each methodology, highlighting specific problems of each. Wholesale Acquisition Cost (WAC): Previously referred to as net wholesale price. Published by First DataBank and Medi-Span, WAC represents the manufacturers' published catalog or list price of a drug product to wholesalers. For purposes of this discussion on drug pricing policy, the term "manufacturer" includes manufacturers, repackagers, private labelers and other suppliers.

Problems:

- WAC does not represent actual transaction prices and does not include prompt pay or other discounts, rebates or reductions in price.
- First DataBank does not perform any independent investigation or analysis of actual transaction prices for purposes of reporting WAC.
- First DataBank relies on manufacturers to report or otherwise make available the values for the WAC data field.
- Not all products currently have a WAC price.

Direct Price (DP), as published by First DataBank, represents the manufacturers' published catalog or list price for a drug product to non-wholesalers.

Problems:

- Direct Price does not represent actual transaction prices and does not include prompt pay or other discounts, rebates or reductions.
- First DataBank does not perform any independent investigation or analysis of actual transaction prices for purposes of reporting Direct Price.
- First DataBank relies on manufacturers to report, or otherwise make available, the values for the Direct Price data field.

Suggested Wholesale Price (SWP), as published by First DataBank, represents the manufacturers' suggested price for a drug product from wholesalers to their customers (i.e., retailers, hospitals, physicians and other buying entities).

Problems:

- SWP is a suggested price and does not represent actual transaction prices.
- Reliance on manufacturers to report or otherwise make available the values for the SWP data field.

Blue Book AWP (BBAWP), as published by First DataBank, is intended to represent an average of wholesalers' catalog or list prices for a drug product to their customers (i.e., retailers, hospitals, physicians and other buying entities).

Problems:

- For purposes of publishing BBAWP, First DataBank has "frozen" the last average wholesale mark-up previously provided to First DataBank through the wholesaler survey process and will no longer update that mark-up. Upon receipt of a change in drug pricing from a manufacturer, this mark-up is applied against the WAC or, if a WAC is not available, the Direct Price, with the resulting value populating the BBAWP field.
- For those drug products generally not distributed through the wholesaler sales channel, the BBAWP data field will reflect the same value as the Direct Price data field.
- For those manufacturer product lines for which wholesalers historically accepted the manufacturer's Suggested Wholesale Price, First DataBank will continue to populate the Blue Book AWP and the Suggested Wholesale Price data fields with the same value.
- For those drug manufacturers and lines of products for which First DataBank does not maintain a historical mark-up (e.g., new manufacturers), BBAWP will be determined by applying a standardized mark-up of 25% for prescription drugs and 23% for over-the-counter drugs over the manufacturer's WAC, or WAC is not available, over the manufacturer's Direct Price. To the extent that neither the WAC nor the Direct Price is available, First DataBank will populate the BBAWP and the Suggested Wholesale Price data fields with the same value. For those drug products generally not distributed through the wholesaler sales channel, the BBAWP data field will reflect the same value as the Direct Price data field. (Medi-Span's logic was not available.)

Alternative Benchmark Price (ABP). Commencing on or about March 31, 2005, First DataBank began publishing an additional data field as an alternative benchmark to BBAWP. This Alternative Benchmark Price is based solely upon a manufacturer's WAC or, if the WAC is not available, the manufacturer's Direct Price.

Problems:

 The Suggested Wholesale Price (SWP) is not based on the Alternative Benchmark Price, regardless of whether such value historically was accepted by wholesalers. First DataBank calculates the Alternative Benchmark Price by applying standardized mark-ups to the manufacturer's WAC or Direct Price, as follows:

Prescription drugs. For prescription drugs, First DataBank utilizes a standardized mark-up of 25% over the manufacturer's WAC or, if a WAC is not available, over the manufacturer's Direct Price.

Over-the-counter drugs. For over-the-counter drugs, First DataBank utilizes a standardized mark-up of 23% over the manufacturer's WAC or, if a WAC is not available, over the manufacturer's Direct Price.

An Alternative Benchmark Price is not published for any drug product for which a manufacturer fails to report or otherwise make available the WAC or Direct Price.

A list of manufacturers and the relevant products that do not report or make available a WAC or Direct Price is available at: http://www.firstdatabank.com/support/rcs/policies/pricing/.

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Conclusion:

Pharmaceutical expenses amount to between 15% (WCRI data) and 19% (NCCI data) of total workers' compensation medical expenses, which is approximately \$4 billion to \$5.6 billion annually. The majority of these drugs are managed by and processed through workers' compensation PBMs, which use clinical resources, contractual terms, and other operational expertise to help control payers' total drug costs.

Fee schedules will change over the next two years. The basis for that change, and the methodology used, will have more impact on PBMs than any other entity. If, for example, a Medicaid-equivalent fee schedule becomes popular, PBMs' margins will evaporate, revenues will fall, and in many states, PBMs will not longer be able to operate.

If workers' compensation PBMs fail or stop doing business in a state, injured employees will face access issues. Pharmacies, uncertain of the patient's eligibility or the payer of the prescription, may require the claimant to pay out of pocket or go without the medication, creating anxiety and potentially leading to an increase in litigation. Without PBMs to negotiate pharmacy prices and monitor utilization, payers will pay higher costs for medications. Without PBMs providing clinical services, claimants seeing several doctors will likely receive several prescriptions for the same ailment. When PBMs take over older claims, they routinely identify claimants who are taking two or three different kinds of anti-depressants, pain medications, sleeping aides, or anticonvulsants. When all medication invoices are processed through the workers' compensation PBM, a clinician can work with all the physicians to reduce the number of prescriptions, dramatically cutting the cost of the claim.

The workers' compensation PBM can also search for potentially harmful combinations of prescriptions and alert the physicians before a problem surfaces. Since drugs may interact negatively with each other, side effects can occur, and PBMs can actually save lives. This clinical service prevents costly treatment for side effects from inappropriate combination of medications.

However, if regulators and legislators understand the value delivered by workers' compensation PBMs and the need for these PBMs to have enough margin to operate effectively in a state, employers and other payers will see drug costs controlled and claimants will have unfettered access to the medications needed to facilitate recovery

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Joseph Paduda, president of CompPharma, is available for speaking engagements and media interviews on this subject. For more information, contact Helen Knight, 813-837-1701 or hknight@comppharma.com