

First DataBank/Medispan/McKesson AWP “Rollback” Litigation and Settlement Overview

What follows is an overview of the lawsuit, settlement and the various PBM pricing strategies employed as a result of the First DataBank (FDB) and Medispan Average Wholesale Price (AWP) calculation methodology changes that occurred on September 26, 2009.

Overview

This case began with lawsuits filed in June 2005 and February 2006 by members of the Prescription Access Litigation (PAL) coalition alleging that AWP publisher FDB and the drug wholesaler McKesson carried out an illegal scheme from 2002 to 2005 to raise the price of prescription drugs.

The lawsuits claim that in 2002 FDB and McKesson began setting the Wholesale Acquisition Cost (WAC)-to-AWP markup to 25 percent for more than 400 brand-name drugs. Those drugs previously had only a 20% percent WAC-to-AWP markup.

Soon after the original lawsuit was filed, the other predominant AWP publisher Medispan was named as a defendant to the suit.

Final Order and Judgment

On March 17, 2009, Judge Patti B. Saris of the United States District Court for the District of Massachusetts issued a memorandum and order giving final approval to the Amended and Restated Settlement Agreements dated May 28, 2008 and July 15, 2008. On March 30, 2009, Judge Saris issued the final order and judgment certifying the class for purposes of settlement, approving of the class action settlement and dismissing the action with prejudice.

Key provisions of the settlement included:

- FDB and Medispan to adjust the WAC-to-AWP markup for all of the 1,442 NDC numbers affected from a markup factor in excess of 1.20 to 1.20 (i.e., the “rollback”).

- FDB and Medispan to make the adjustment 180 days from the entry of final judgment, effectively scheduling the rollback event for 12:00 a.m. Saturday, September 26, 2009.
- FDB and Medispan to establish a centralized data repository (FDB data room and Medispan data room) to facilitate reasonable access to discoverable material concerning drug price reporting practices.
- FDB and Medispan to pay \$2.7 million into the settlement fund for the benefit of the settlement classes (\$2.1 million from FDB and \$600,000 from Medispan). Separately, the plaintiffs resolved their claims with co-defendant McKesson for \$350 million, making the combined settlement pool \$352.7 million.

Despite the final provision of the settlement that limited the scope of the rollback to only 1,442 drugs, FDB and Medispan expanded their WAC-to-AWP adjustment from the original 1,442 products to ALL products with a markup factor in excess of 1.20. Here are statements from both companies:

*Excerpt from First DataBank’s
Press Release dated March 31, 2009:*

“Independent of the settlement and on the same schedule as the Blue Book AWP adjustment noted above, First DataBank will apply the same 1.20 markup factor to all other NDCs whose Blue Book AWP is set based upon a markup to WAC or Direct Price in excess of 1.20.”

*Excerpt from Medispan's
Press Release dated April 1, 2009:*

"Independent of the amended settlement, Wolters Kluwer Health's Medispan will implement editorial policy changes that would apply the same adjustments required by the settlement to all other NDCs in the Medispan files whose AWP is determined by a markup factor to the product's WAC or Direct Price (DP) in excess of 1.20 at the time of the adjustment."

Despite the Final Judgment, Many Organizations Unsuccessfully Attempted to Stop the Rollback

Many industry associations objected to the settlement. Here is a re-cap of their arguments:

- Because both FDB and Medispan announced plans to voluntarily roll back the AWP on thousands of NDCs beyond the 1,442 directly required by the proposed amended agreement, NACDS, FMI, LTCPA and ASCP objected, contending FDB's and Medispan's voluntary rollback is a "collusive end-run" around the Court's concerns. In response, FDB and Medispan claimed there "simply is no agreement or quid pro quo with Settlement Class Counsel or others concerning FDB's separate and independent editorial decisions regarding the future publication of" Blue Book AWP.
- NACDS, FMI, PCMA and others objected that the AWP rollback is punitive to innocent non-parties and threatens the viability of certain pharmacies because it will impose "very substantial transaction costs" and administrative burdens on retail drug chains and PBMs.
- Various organizations representing independent pharmacies objected in stating that with an independent pharmacy's average margin of 2.8%, many "cannot absorb a 4 to 5% reduction in reimbursement for brand-name pharmaceuticals, approximately 80% of prescription sales."
- NCPA filed an objection that some NDCs have been improperly included in the settlement.

Pharmacy's Demand from PBMs in the Face of Rollback

In a word, neutrality. Pharmacies refused to have their bottom line adversely affected by the AWP rollback. They contended that the purported inflation of AWP was offset by decreasing levels of reimbursement that they were forced to accept by managed care organizations like PBMs. This is supported by evidence of the discounts on prescription drugs observed over time. In the early 2000s it was not uncommon to see average PBM-negotiated pharmacy reimbursements in the range of AWP – 10 to 12%. In 2009, the average discounts ballooned to AWP – 15% or more. This is an indication that the market responded to the inflation of AWP through greater negotiated discounts off AWP. Now that AWP values are adjusted back down from the rollback, so too must the effective discount off AWP paid to the pharmacies. Pharmacies demanded the same reimbursement post-rollback as they had pre-rollback and it was the PBM's task to accomplish this and explain any changes in drug cost calculation methodology to stakeholders.

The PBM Response to the AWP Rollback

How did PBM organizations adjust pricing methodology to account for the AWP rollback and keep pharmacies and payers "cost neutral"?

Three models employed by PBMs attain the "neutrality" demanded by pharmacies.

• AWP discount adjustment method, employed by Serve You:

- > Using a conversion table, the PBM pays the pharmacy and charges the payer a new, lower discount off AWP that would correspond to the same reimbursement or charge as before the rollback.
- > Example of AWP adjustment pricing: A drug with a WAC of \$80 will have an AWP of \$100 pre-rollback (80 times 1.25) and an AWP of \$96 post-rollback (80 times 1.20). If a pharmacy is reimbursed at AWP – 15% pre-rollback, their reimbursement will be \$85. To obtain the same reimbursement of \$85 after the AWP has been "rolled back" to \$96, the reimbursement must be adjusted to AWP – 11.46%.

- **WAC re-contracting method:**

- > This option involves re-contracting the network with discounts based off of WAC and not AWP.
- > The primary concern with this option is that not all drugs have a WAC.
- > Example of WAC-based pricing: A PBM has re-contracted with a chain of pharmacies at a reimbursement rate of WAC + 4%. Therefore, for a drug with a WAC of \$80, the pharmacy will be reimbursed \$83.20. This corresponds to an effective discount off AWP of 16.8% pre-rollback.

- **Factor Method:**

- > This option involves the creation and periodic updating of a database that effectively retains pre-rollback AWP prices by maintaining the markup factor over WAC for those legacy products whose markup factor is > 1.20.
- > One large PBM has pursued an option similar to this by essentially creating and maintaining their own AWP database.
- > This option enables PBMs to continue to offer the same discounts the market is accustomed to (i.e., they can continue to sell discounts of AWP – 15% instead of an equivalent discount of AWP – 11.46%).
- > Example: A drug with a WAC price of \$80 will have an AWP of \$100 pre-rollback and an AWP of \$96 post-rollback. Under the factor method, after the AWP is adjusted to \$96 on September 26, 2009, by Medispan, the PBM will re-adjust the AWP back to \$100 via creation and maintenance of a separate database. Price neutrality will be achieved because pharmacies will be reimbursed and clients will be charged based upon the \$100 benchmark price. Therefore, under AWP – 15% pricing, the reimbursement or charge will continue to be \$100 – 15%, or \$85.

FAQ

Q1: How does this affect the price paid for prescription drugs? If the lawsuit contends that consumers have been paying too much for prescription drugs due to these fraudulent actions, why are you telling us that we must continue to pay the same price?

A1: On your behalf, a PBM negotiates discounts on prescription drugs filled at network pharmacies. Consequently, you pay an amount below a pharmacy's Usual and Customary (U&C) or cash price for most prescriptions. In the years since the alleged fraudulent markup action began, the discounts obtained by your PBM on your behalf have risen steadily. In the early 2000s, typical PBM-negotiated discounts were in the AWP – 10 to 12% range. Today, discounts are typically AWP – 15% or greater. The deeper AWP discounts PBMs are able to obtain on your behalf today are the result of market forces adjusting for the increased markup factor that has been in place since 2002. Now that the inflated markup factor used to calculate AWP has gone away, discounts have returned to levels not seen since earlier last decade. For example, a discount that is AWP – 15% pre-rollback will correspond to an effective post-rollback discount of AWP – 11.46% after the markup is reduced. It should be the goal of the PBM to continue to maintain excellent discounts for valued clients—discounts that network pharmacies will accept.

Q2: Has there been any disruption at the Point of Service? Is this action transparent to the members?

A2: Claim adjudication systems were updated, tested and ready before September 26, 2009, and claims processed correctly on and after that date with no member disruption.

Q3: Does this action apply to mail order pharmacy claims (and affect mail order pharmacy discounts) as well?

A3: If the mail order claim prices at a discount off AWP and is included on the rollback list, then it will be affected by the rollback. If the mail order claim prices according to a Maximum Allowable Cost (MAC) list, it will not be affected.

Q4: How many products are affected or "rolled back?"

A4: All NDC numbers whose AWP is calculated by a markup factor over WAC in excess of 1.20 were rolled back, which amounted to in excess of 18,600 NDC numbers.

Q5: What are PBMs doing to address statements made by FDB and Medispan that they will cease the updating/publication of AWP two years post settlement date (i.e., in March of 2011)?

A5: While Medispan originally indicated that they would stop publishing AWP within two years of the final settlement date, they have since revised this policy and will continue to publish AWP for the foreseeable future. This is contrary to the stance taken by FDB, who has not backed down on its commitment to discontinue the publishing of AWP. Their latest statement includes the following: "First DataBank will also independently discontinue publishing the Blue Book AWP data field for all drugs no later than two years following the date that the Blue Book AWP adjustments noted above are implemented." Accordingly, it is important to determine which pricing source a PBM uses, and if they use FDB what their plan is moving forward. Serve You uses Medispan.

(Serve you.)

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