



Background and Implications of AWP Changes

An October, 2006 *Wall Street Journal* Story [How Quiet Moves by a Publisher Sway Billions in Drug Spending](#)¹ alerted the health care industry to a class action suit being settled in a Boston court room. At issue were allegations that First Databank (FDB), Medi-Span and McKesson conspired to inflate the Average Wholesale Price (AWP) of prescription drugs. A Final Order and Judgment approving the settlement has been entered. The ruling, together with other publisher-initiated changes to the calculation and publication of AWP, may drive major changes in prescription drug contracting and pricing methods for some, but not all, PBM clients.

A Brief History of AWP

Introduced in the late 1960's, AWP evolved as a means of standardizing prescription drug reimbursements for the California Medicaid Program. Prior to the establishment of AWP, pharmacies billed according to what each one charged for drugs, creating a system that was labor intensive and plagued by inconsistent pricing. The California Medicaid program began paying pharmacies a standardized price for each drug. Ultimately insurers and employers embraced the concept and AWP became a benchmark for drug pricing and contracting. It was not long before publishing AWP and other drug pricing data evolved into a business in its own right.

One publisher was First Data Bank. The firm, founded in 1977, surveyed pharmaceutical wholesaler companies to determine the list prices for drugs being sold to retail pharmacies. Using a proprietary process, FDB blended wholesaler list prices to create the "average wholesale price" or AWP associated with the package size of product, as identified by its national drug (NDC) code. Quickly, AWP became the basis of the costs that third party payors incurred for drug products. In 1998, FDB acquired Medi-Span, a competing drug pricing compendia. Pricing established by FDB applied to both references until the FTC forced the sale of Medispan by FDB.

AWP Litigation

From its inception, FDB described the AWP as a value calculated from a survey of wholesaler prices. This was widely accepted to be the case until investigations for the class action suit revealed that since at least 2001² only the prices of one wholesaler, McKesson, were collected and reported. In late 2001 and early 2002, McKesson changed its methodology for drug pricing for approximately 1400 NDC codes. Historically, wholesalers varied their drug mark-ups, applying a 20% increase over wholesale acquisition cost (WAC) to some manufacturers' products while others were increased at 25%. McKesson adopted a 25% mark-up for many popular medications that were previously increased only 20%. Because McKesson was the sole source of wholesaler prices in FDB's surveys, the action by McKesson raised AWP drug prices immediately.

FDB/Medi-Span Settlement Summary

Agree to reduce and maintain drug price mark-ups at a level that is no greater than 1.20 times WAC for 450 drugs (1400 NDCs) currently at that level or above beginning September 26, 2009.
Maintain a Data Room for analysis in potential drug pricing claims against other defendants
Make a total \$2.7 million payment to a Settlement Fund for distribution in a Court approved manner
Facilitate interviews with key personnel and make individuals available for testimony in cases involving other defendants
FDB/Medi-Span have announced plans to cease publication of AWP within 2 years. Again, action is taken independently and not due to court order.

Table 1



McKesson's pricing change had a profound negative impact on consumers, unions and other self-insured employers, health insurers and health and welfare plans including the government. As the situation was revealed, payers took action, ultimately leading to class action suits against FDB/Medi-Span and McKesson. The plaintiffs in the suit contend that FDB sought to curry favor with McKesson, hoping, among other things, that McKesson would utilize FDB as a pricing source for contract purposes.³ Furthermore, because pharmacy reimbursement is directly tied to the AWP, it was anticipated pharmacies would become the direct beneficiaries of the new methodology.

FDB Settlement and Subsequent Plans for Pricing Changes

While both parties have denied any wrong-doing, FDB and Medi-Span reached a settlement in this case and a Final Order and Judgment approving the settlement for FDB and Medi-Span was entered in the United States District Court for the District of Massachusetts on March 30, 2009 (see Table 1).

While the settlement dictates changes in AWP prices for only 1400 affected NDCs, FDB has announced additional planned changes to its pricing database. In September 2009, FDB will adjust prices for all products that have a WAC to AWP ratio of more than 120%. This announcement affects many more products that are impacted by the settlement. Furthermore, within 2 years of the settlement, FDB intends to cease publication of AWP as a price reference. Medispan has announced intentions to make changes to its database in a manner with the adjustments announced by FDB.

PBM's React to AWP Rollback

In considering the implications of the rollback, it comes as no surprise that PBMs have been proactively setting the stage to revise contracting terms in hopes of neutralizing the impact of the rollback and protecting their revenue stream. However, many third party payors are not in agreement with the PBMs. They object to contract revisions on the grounds that increased costs they incurred during the class action period should now be offset by savings generated from the rollback. Any contract revisions are likely to be driven by existing contractual agreements between the parties. Plan sponsors should proceed cautiously as many PBM proposals may result in higher prescription costs over time.

Suggestions floated by PBMs thus far include:

- Revising AWP discounts across the board to offset the impact of price rollbacks.
- Establishing a PBM based pseudo-AWP, using methodology similar to the current AWP.
- Transitioning to an alternative price benchmark such as WAC or AMP.

Most PBMs propose to restate drug discounts to account for the AWP changes, but maintain AWP as the pricing basis. One PBM proposes to base a revised discount upon the preceding twelve months of claims data, based on their book of business. Although the new discount amount would be calculated to maintain the same ingredient cost in aggregate as is currently paid, the impact will vary between clients and individuals prescriptions. Using the PBM's "book of business", aggregate prices will result in lower costs for some clients and higher costs for others. Another PBM offers to restate drug discounts on a client by client basis. The discount percentage for each plan served by the PBM would be based on each client's aggregate drug costs. There are some inherent limitations to this approach. First, drugs lose patent protection which, for blockbuster drugs may have significant impact on drug spending. Secondly, even without considering availability of lower cost generics, drug mix shifts and the mix that resulted in a particular projected discount may change over time, and may change from client to client.

In a unique program, one PBM is offering to establish its own AWP for pricing purposes. Under this PBM's methodology, the pricing discounts in clients' contracts would not change, but the price discounts for affected NDCs would no longer be based on a published AWP. Instead the PBM would develop a "proprietary AWP" to maintain the WAC/AWP differential before the AWP restatement. The PBM would be solely responsible for ongoing maintenance of the new "AWP," and the differential would be applied to WAC prices going forward. This method will require more maintenance of the drug pricing file by the PBM, but since the proprietary AWP will be applied only to those NDCs that change on September 26th, it seems to be a fair method of pricing adjustment for clients. The challenge for this PBM will be in bidding for new business. This PBM could not use its proprietary AWP in bidding new business because this will be completely out of sync with the rest of the PBM marketplace.

The final approach we've encountered involves those PBMs that have decreased the percentage discount by a flat amount, calculated to offset the 5% decrease in AWP. For example, PBMs have suggested simply using a factor of 4.1% for adjustment, which is essentially the ratio between the former mark up of 1.25 and the revised markup of 1.20. While this mathematically makes sense, it may not be equitable for all plans, as it fails to consider the historic impact of the inflated AWPs on drug costs or the individual client's drug mix.

What Should Payers Do?

As employers, health plans and retirement funds consider the preceding scenarios, we first offer a few general considerations. The prospect of contract renegotiation raises the question: is the client obligated to agree to any contract updates?

Restating of contracts is neither always necessary, nor is it often advisable. Most contracts will clearly indicate that the prices published in FDB or Medi-Span serve as the primary drug pricing sources. Some of these PBM contracts, particularly older or long range term agreements, are silent regarding any industry revisions in pricing terms or methodologies. For these organizations, negotiation of discount rates may be deferred until contract renewal. Of course, it is unlikely that PBMs will be willing to accept the upcoming AWP roll back without a corresponding decrease in the discount given to plans. As a result, even plans with contracts that do not outwardly warrant restatement are likely to be approached by a PBM interested in renegotiating terms.

More recently drafted contracts often include general language such as stating that 'relative economics' must be maintained. These agreements typically support PBM renegotiation interests by providing an avenue to initiate a contract revision. The motivation to include contract language protecting PBMs is based on this lawsuit, which has been in the settlement phase since 2006 and upon the legal action on pricing issues which predated the suit by several years. It is, therefore, reasonable to expect PBMs to have anticipated the settlement and to have included contract provisions aimed at mitigating the effects of any changes to AWP. Mary Ross, Director of Clinical and Consulting Services of APC notes:

"At APC we have advised clients to include language in PBM contracts that affords clients the right to review and approve potential changes as well as to have the authority to have a third party review contract amendments on its behalf." –Mary Ross

It is incumbent upon clients to carefully assess the current contracts with their PBMs. The first step is to ascertain whether the contract includes a right of refusal as a means by which plans can weigh in on how potential pricing scenarios play out. Agreements written with an eye to client interests are most likely to protect clients and may help them to avoid unnecessary contract renegotiation.

What if Our Agreement Seems to Warrant Contract Revision?

If it is determined that the contract terms justify modifying terms of the original agreement, we suggest clients proceed with caution. One of the most significant concerns facing a client would be entering into a contract in which all calculations for determining pricing terms, etc. are at the sole discretion of the PBM. APC President, Kim McDonough advises,

“Clients should retain the ability to independently review the methodology used to make any AWP discount adjustments and to independently verify the impact to client costs.” – Dr. Kimberly McDonough

Pricing adjustments and methodology should be clearly described in a contract amendment. Without clear contract language, clients will have no recourse regarding any disagreements on pricing.

Other Implications of Changing Pricing Methods to Consider

The pricing methodology upon which contracts are based carries other implications. As Nancy Hayden, APC’s Manager of Audit Services points out, the “proprietary AWP” method for contracting could result in a challenge from an audit perspective if both AWPs – the published metric and the proprietary metric – do not both appear on the claims file. This PBM has stated that there will be an indicator on the file when an AWP has been adjusted, but APC has not yet seen the file layout.

What Should a Plan Look for When Revising a Contract?

The preceding scenarios offer compelling arguments for plans to review their contract terms carefully to ensure price equity. Specifically:

- A pricing change must be based upon a transparent methodology and include a clear mechanism for measuring the impact of proposed contract changes. Only in this way is a plan assured of obtaining the prices to which it is entitled.
- Before agreeing to any contract revisions, a plan must conduct careful analyses that assess the proposal and clearly quantify and define the financial impact of proposed changes upon the plan.
- Plans should include contract language which includes the authority to have an independent third party to review any contract amendments on its behalf in an effort to assure revised methodologies are validated and fully protect the plans’ interests.

Caution is the key word in moving forward with any contract revision. For example, clients must quantify the effect of the planned AWP rollback. The true economic impact will vary based upon the drug utilization of each plan. A major consideration is that many of the drugs identified by the settlement as part of the AWP roll back have become or will soon become available as generic formulations. As a result, clients who subscribe to the seemingly equitable rollback of discounts to “offset” the AWP rollback by maintaining relative economics may pay less for a higher priced brand, but more for some other agents. In time, when the higher cost drug becomes available as a generic the client will lose the savings associated with the branded drug, while effectively paying a higher cost for other drugs in its product mix. Such a scenario might be demonstrated with a high volume, high cost drug soon to be available as a generic, such as Lipitor®.

Drug Name	Pre-Settlement AWP	Pre-Settlement Discount Price (discount of 10%)	Post-Settlement AWP	Post-Settlement Price (discount of 7.5%)
Lipitor®	\$100	\$90	\$95	\$87.88
Drug X **	\$100	\$90	\$100	\$92.50
Average Price		$\$90 + \$90 = \$180 / 2 = \90		$\$87.88 + \$92.50 = \$180.38$ $\$180.38 / 2 = \90.19
** Drug X Unaffected by AWP Rollback				

At the time of adjustment, relative economics have been preserved. However, in less than two years Lipitor will be available as a generic. The plan will save by purchasing the generic, but be left with the higher, more costly post settlement price for Drug X. In this case the price will be \$92.50 instead of \$90.

This is a fairly simple example, but it serves to demonstrate that contract revisions require time for analysis and negotiation. PBMs expecting clients to merely accept revised pricing contracts risk creating tension that could lead to litigation. Many plans possess the leverage and the inclination to “push back” and may do so. Keep in mind that as noted in the March 17, 2009 Memorandum and Order, “...pharmacies (both chain and independent) and PBMs reimbursed on the basis of AWP, were unjustly enriched when drug prices were fraudulently inflated during the scheme, yet they have not been asked to disgorge the profits.” Speaking in response to objections from pharmacy groups the judge points out “none of the pharmacies protested the windfalls they received when prices were unilaterally inflated by five percent.”⁴ The same can be said of PBMs. During the time that the AWP value was inflated, PBMs made no call to maintain “relative economics.” Therefore, as plans recognize the priority PBMs have placed on protecting themselves and pharmacies from a potential reduction of profit margins, they may be inclined to act. Another group of PBM clients may also be motivated to take action; those who were party to the original case. These clients may expect a financial settlement of some type and could reasonably anticipate that, if proceeds are not forthcoming from the legal settlement, they will look for restitution through their PBM.

Alternatives to AWP

Although the requirement that AWP no longer be published was removed as a requirement of the Class Action settlement, both Medi-Span and FDB announced plans to cease publication of the benchmark. Many analysts viewed McKesson’s settlement of its AWP class action suit as a major step toward the demise of the benchmark. Simultaneously, the Centers for Medicaid and Medicare Services (CMS) are in search of an acceptable, transparent contracting benchmark. Lastly, the court weighs in on this matter stating “Reliance on AWP is a trap for unwary and unsophisticated TPP purchasers and results in consumers paying unwarranted co-payments. Not only do FDB and Medi-Span have the right to make these changes, but in my view, after eight years of this MDL (Multi-District Litigation), rolling back AWP’s or phasing them out as a pricing benchmark is in the public interest and to the benefit of the class.” Judge Sarris then writes, “Objectors also complain that FDB will independently discontinue publishing AWP data for all drugs in the Blue Book within two years following the rollback. However, this decision is not part of the settlement agreement. Just as with the rollback itself, even if I could stop FDB and Medi-Span, I would not do so.”⁵ It appears there is consensus, there is a need for an alternative basis for drug contract pricing and several options have been offered up.

Some have suggested WAC, the Wholesale Acquisition Cost. The WAC is the manufacturer’s list price to wholesalers or other direct purchasers (excluding any applicable discounts.) The advantage of WAC is

that it is an existing and familiar value in the drug pricing arena. However, critics are skeptical of using it as a contracting benchmark because it is not a computed transaction price. Therefore it is vulnerable to manipulation and subject to many of the same criticisms lavished upon AWP.

Average Manufacturer Price (AMP) is a value sometimes mentioned as an alternative to AWP. AMP is a value, reported to the federal government by manufacturers, that reflects the actual sale price for pharmaceuticals, inclusive of discounts. AMP is based upon the product, rather than the NDC code, so pricing remains consistent across all package sizes. The AMP has less potential to be inflated or otherwise manipulated than other benchmark candidates. The Government Accountability Office (GAO) and the Office of the Inspector General (OIG) have recommended AMP be used as the basis for the development of the Federal Upper Limit (FUL) and for reimbursement of state costs related to prescriptions covered under the Medicare program.

While AMP files are used by CMS in the Medicaid program, these files are not currently available for public use. The publications, which should have been released as a result of the Medicare Modernization Act, have not been made public. Publication of the price reference, which should have occurred as a result of Medicare Modernization Act, has been contested by drug manufacturers, pharmacies and wholesalers, in part because there's disagreement on how AMP is defined. At issue for this proposal is that AMP is defined as the price wholesalers pay manufacturers for drugs to be distributed through "the retail class of trade." This definition is critical because as currently defined by CMS, this class of trade includes PBM and mail order pharmacies, Medicaid, Medicare Part D, the State Children's Health Insurance Program (SCHIP,) and the State Pharmaceutical Assistance Program. Opponents charge that the AMP calculation includes many transactions that have nothing to do with prices paid to wholesalers for drugs distributed to retail pharmacies. Interestingly, the hospitals, long term care pharmacy, federal supply schedule and prompt pay discounts aren't included in the AMP calculation.⁶ As is evident, the issue of using AMP is controversial from the outset. As a result, although it may be a valuable price standard, it is unlikely AMP will be accepted and available as a pricing benchmark in the near term.

In the meantime, pricing publishers have gotten into the business of offering alternatives. For example, Medi-Span is publishing an alternative benchmark, called the "Average WAC Pricing File™." The concept is likely to meet with resistance as the industry is likely to view another publisher generated price index with suspicion. The product is being promoted as a means of offering clients pricing and contracting alternatives. Additionally, Medi-Span is promoting several other alternatives to clients. These include a subscription to a service which generates another calculated price, like the Average Wholesale Price, (AAWP) based upon the WAC. Another for generics is considered similar to the Generic Equivalent Average Prices (GEAP) known as the Generic Equivalent Wholesale Acquisition Cost (GEWAC). The publisher appears to be promoting this concept as an alternative to WAC pricing, particularly for those generic NDCs without a WAC, as (manufacturers may opt not to publish a WAC for certain drugs.)

Another alternative that is gaining publicity is basing contracts upon a "cost plus" model. Wal-Mart and Caterpillar have moved forward with such a program and recently announced plans to expand the offering to several other companies.⁷ The concept is viewed favorably because it controls expenses and avoids the problems inherent in AWP based contracting. The potential issue with this approach is transparency. Certainly, invoice pricing might be used for a "cost," but extensive auditing would be required to identify discounts that might be offered separately and in order to confirm that "cost" was truly based upon final cost.

Looking Ahead

Few things are certain as we look ahead. It is clear that FDB and Medi-Span will roll back AWP on September 26, 2009 and that within two years a publisher generated “faux” AWP will cease to exist. It is certain that PBM contracting methodologies will be undergoing significant changes. The issues to resolve are many, but clients must protect their interests and be certain that terms are not adjusted without careful analysis. In particular, clients must proceed with caution when analyzing and subscribing to revised contract terms, particularly those involving a flat discount adjustment across all brands. Plans should avoid contracts in which all calculations for determining pricing and terms are at the sole discretion of the PBM. Clients must, as we’ve previously advised, include language in PBM contracts that affords the plan the right to review and approve changes, and have a third party of their choice review contract amendments to quantify and define the financial impact of proposed changes upon the plan. Finally, plans must assure that any contract revisions they agree to be clear, and include detailed methodology for calculating pricing benchmarks.

¹ *Martinez, B. Wall Street Journal Section A • Page 1 October 6, 2006*

² United States District Court, District of Massachusetts Second Amended Class Action Complaint Leave to File Granted November 22, 2006. *New England Carpenters Health Benefits fund et al. vs. First Databank, Inc and McKesson*. Case 1:05-cv-11148-PBS Document 174 Filed 11/30/2006 Page 44 of 95. Item 124 “Beginning sometime in late 2001 or early 2002, First Data, by agreement with McKesson, limited its purported “surveys” to McKesson and did not “survey” other wholesalers. First Data agreed to utilize for markup purposes data received from McKesson. At the same time and as part of a common plan, McKesson implemented a 5% increase in the WAC to AWP markup for hundreds of brand name drugs that it distributed.”

³ United States District Court, District of Massachusetts Second Amended Class Action Complaint Leave to File Granted November 22, 2006. *New England Carpenters Health Benefits fund et al. vs. First Databank, Inc and McKesson*. Case 1:05-cv-11148-PBS Document 174 Filed 11/30/2006 Page 8 of 95. Item 14 “ First Data agreed to this Scheme to curry favor with McKesson so that McKesson would utilize First Data as the pricing source it has in some of its contracts with pharmaceutical companies and others in the distribution chain, as well as in the pricing database that it provides to its customers, thereby increasing First Data’s business.”

⁴ United States District Court, District of Massachusetts Second Amended Class Action Complaint Memorandum and Order, March 17, 2009. *New England Carpenters Health Benefits fund et al. vs. First Databank, Inc and McKesson*. Case 1:05-cv-11148-PBS Document 720 Filed 03/17/2009 Page 14 of 17. “A more compelling case is made by IPC, the largest group purchasing organization for independent pharmacies. It submitted an amicus curiae brief stating that at a margin of 2.8%, many of its members “cannot absorb a 4-5% reduction in reimbursement for brand name pharmaceuticals, approximately 80% of prescription sales.” Brief of IPC [Docket No. 605] 7.) While these concerns should be weighed, the pharmacies (both chains and independent) and PBMs, reimbursed on the basis of AWP, were unjustly enriched when drug prices were fraudulently inflated during the scheme, yet they have not been asked to disgorge their profits. None of the pharmacies protested the windfalls they received when prices were unilaterally inflated by five percent. Further the pharmacies seem to have survived prior to the start of this fraudulent scheme, making it seem likely they will survive after it has been undone.

⁵ United States District Court, District of Massachusetts Second Amended Class Action Complaint Memorandum and Order, March 17, 2009. *New England Carpenters Health Benefits fund et al. vs. First Databank, Inc and McKesson*. Case 1:05-cv-11148-PBS Document 720 Filed 03/17/2009 Page 13 of 17. “Even if the Court infers that this rollback is the product of the earlier agreement between the parties, it was disclosed to the Court, and the Court has no interest in interfering with it. AWP has been exposed as a faux inflated price unrelated to actual drug prices. Reliance on AWP is a trap for unwary and unsophisticated TPP purchasers and results in consumers paying unwarranted co-payments. Not only do FDB and Medi-Span have the right to make these changes, but in my view, after eight years of this MDL (Multi-District Litigation), rolling back AWP or phasing them out as a pricing benchmark is in the public interest and to the benefit of the class.” Judge Sarris then writes, “Objectors also complain that FDB will independently discontinue publishing AWP data for all drugs in the Blue Book within two years following the rollback. However, this decision is not part of the settlement agreement. Just as with the rollback itself, even if I could stop FDB and Medi-Span, I would not do so.”

⁶ Virginia Department of Medical Assistance Services, November 1, 2008. Special Report on the Analysis of the Fiscal Year 2008 Fiscal Impact of the Implementation of “Average Manufacturer Price” Pages 1-2 of 3

⁷ Jones, Sandra M. Chicago Tribune, March 28, 2009. Drug prices: Wal-Mart/Caterpillar plan may drive down employer health-care costs. [Chicago Tribune](#)

