

Assessing the First DataBank Settlement

Dramatic Shake-Up or Status Quo?

by Joshua Golden

First DataBank (FDB) is the prescription drug industry's largest publisher of average wholesale price (AWP) data, which is used to derive drug prices at the consumer end of the U.S. drug distribution system. In 2006, FDB agreed to a tentative legal settlement after allegations it engaged in questionable activities that cost millions of consumers and third-party payers an extra \$7 billion between August 2001 and March 2005. The potential impact of the proposed settlement is projected to be far-reaching; however, settlement details still require final approval by the court.

The skyrocketing cost of health care ranks near the top of any benefit administrator's list of "things that keep me up at night." In the first half of this decade, consumers and plan sponsors alike watched helplessly as prescription drug prices soared a whopping 17% per year. Beyond increasing utilization, why were new to market drug prices so out of control? Could research and development costs really be to blame for meds costing \$5, \$10, \$20 or more per pill? Granted, it's not cheap to develop drugs that ease symptoms, cure diseases and, in some cases, actually save lives. But the price increases had many in the industry wondering whether other factors were contributing to price inflation.

Then, in 2004, information surfaced about some potentially questionable activities by First DataBank (FDB), based in San Bruno, California. A unit of the Hearst Corporation, FDB is the prescription drug industry's largest publisher of AWP data.

The commonly accepted practice had been to set the AWP 20% higher than the drug wholesaler's acquisition cost. In 2002, however, health plans who re-

lied on FDB's list noticed it had begun revising its AWP's on hundreds of brand-name drugs, so that the markup was nearly always 25%. These increases were met with anger from plan sponsors, who demanded an explanation. They never received a satisfactory answer and FDB soon found itself inundated with subpoenas related to a class action lawsuit brought in Massachusetts by several union funds on behalf of a class of private (i.e., nongovernmental) payers. The lawsuit alleged that FDB wrongfully inflated the markup factor used to determine its Blue Book AWP, as it pertained to numerous brand-name prescription drugs.

The story unfolded in a Boston court. FDB, which had long claimed that its prices reflected a survey of national wholesalers, had taken to relying on the input of just one wholesaler in recent years. When that wholesaler began inflating the prices it reported, millions of consumers and third-party payers (health plans, insurers, etc.) found themselves unknowingly paying more for the drugs in question. They paid up to \$7 billion more between August 2001 and March 2005, according to the *Wall Street Journal*.

Without admitting any wrongdoing, FDB agreed

to a tentative legal settlement in the fall of 2006. The proposed settlement terms required FDB to roll back many of the prices on its published list by 5%. The company also initially agreed to stop publishing AWP data altogether two years after the settlement went into effect. In exchange, it wouldn't be required to pay any damages to the plaintiffs.

WEIGHING THE IMPACT

The potential impact of the proposed settlement was projected to be far-reaching and dramatic. An economist hired by the plaintiffs estimated the savings in U.S. drug costs at \$4 billion for 2007 alone. But others in the industry argued that the supply chain had already "absorbed" the AWP increases through a steady increase in the AWP discounts offered to payers and distributors.

Meanwhile, pharmacy benefit manager Express Scripts issued a statement on the proposed settlement, in which it claimed that the "abrupt change brought about by this settlement has the potential to disrupt the distribution chain for the 8,500 prescription drugs subject to the terms of the settlement . . . Forced changes to the pricing components of contracts have the potential to hamper the distribution of medicines in the short-term until supply chain issues and contractual uncertainties are resolved."

For their part, plan sponsors were left wondering how the settlement would impact them. How would it affect their benefit plan? Would it require a modification to the relationship with their PBM? Would they have to fundamentally change the contract with their PBM with regard to the way drugs were priced in their arrangement? Would the contract be opened to renegotiation, or would the PBM simply impose the changes by mandate?

These are all good questions that demonstrate that plan sponsors are taking a proactive approach to this matter. Even before the dust has settled on the class action settlement with FDB, plan sponsors are actively seeking to understand how this pricing shake-up will affect their day-to-day interactions with their PBM and what impact it may have on their plan participants.

Initially, plan sponsors were thought to be impacted in two primary ways:

- In the near term, the rollback in the calculation of the AWP would result in a reduction in the published value for many commonly used drugs. Since many clients have negotiated AWP-based discount guarantees with their PBMs, it was expected that PBMs would approach clients either

to request or mandate that currently contracted discount guarantees be adjusted downward to make up for the rollback.

- Long term, FDB's agreement to cease publication of the AWP created the very real possibility that AWP would be phased out completely as a pricing index. A change in the methodology used to calculate drug prices could trigger a PBM's right to modify pricing under many contractual agreements.

But those predictions were made in response to the proposed settlement. As with many corporate cases, particularly those with such potentially broad-reaching ramifications, this one has been held up in court for well over a year after the initial ruling. A "fairness hearing" was held in January 2008 during which the court was expected to issue a ruling on the proposed settlement. Instead, the presiding judge delayed the ruling, citing lingering concerns over the specific terms of the settlement. This, in turn, delayed the implementation of any of the settlement terms until the court was able to arrive at a final ruling.

In more recent developments, FDB announced publicly on June 2, 2008 that the proposed settlement had been amended. The terms of the amended settlement would require FDB to move forward with the AWP rollback within 90 days of the approval of the settlement (although the list of impacted drugs has been significantly reduced), and would also require the company to pay \$1 million into a fund to benefit the settlement class.

Meanwhile, FDB confirmed that it intended to cease publishing AWP data within two years of the settlement date, even though the settlement no longer requires that. While this does not preclude other data providers from continuing to publish this benchmark, it does represent a change in direction for the biggest player in the drug data industry.

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TAKING ACTION

The verdict may still be out on the final terms of the AWP settlement, but that doesn't mean plan sponsors shouldn't be taking action right now. While plan sponsors wait to see where everything stands when the dust clears, there are steps they can take and important questions to consider as they manage benefits into the next year:

- **Review Contracts**—The vast majority of contracts contain clauses giving the PBM the right to adjust pricing on a “fair and equitable basis.” At the very least, they give the PBM the right to reopen the contract for renegotiation. Obviously, the latter is far preferable for a plan sponsor. Keep this in mind when negotiating new contracts, too. Make sure any new contract includes the right to evaluate and approve any kind of pricing changes the PBM or health plan wants to make in the event of any major changes to AWP. Above all else, be careful to not grant them the unilateral right to make sweeping changes at their own discretion.
- **Seek Help**—Few organizations are armed with the data or knowledge to evaluate the complex questions that are going to arise. If needed, consider turning to knowledgeable, experienced experts for help. For evaluations of any AWP pricing adjustments, consider seeking out a consulting firm that regularly receives AWP data file updates from a consolidator like First DataBank.
- **Stay Tuned**—The situation surrounding the settlement is fluid. Keep a watchful eye on the progress of the court case and be mindful of the pending AWP rollback.

Meanwhile, on July 14, 2008, the court overseeing the settlement process issued an order granting preliminary approval of the newest version of the proposed settlement and announced a fairness hearing for early December 2008. Many industry experts expect the court to reach a final decision on the settlement at that hearing.

In the short term, we face the matter of the rollback. If it does occur, which appears likely, it will rock the boat for any company engaged in a contract with a health plan or PBM. Specifically, it will affect the AWP-based pricing guarantees already in place with these strategic partners. Chances are, PBMs will need to contact plan sponsors to inform them of needed contract adjustments in order to account for the adjustment that the PBM will experience.

RECONSIDERING AWP

The lawsuit against FDB has called into question the appropriateness of AWP as the industry's primary pricing benchmark.

Originally devised by the California Medicaid program in the 1960s as a means of standardizing pharmacy reimbursement, AWP has long been criticized as an arbitrary measurement that can easily be manipulated because it is set by the manufacturers themselves. With no rules to guide them, they can essentially make the AWP whatever they want. Consider what happened with H.P. Acthar Gel, an injectable antiseizure medication crucial in the treatment of children with a rare and severe form of epilepsy. When the manufacturer's market research suggested that plan sponsors would pay significantly more for the drug, its price soared from \$1,600 to

\$23,000 per vial, according to a recent *New York Times* article.¹

Truth be told, there are those in the industry who have been hoping AWP would go away. They view it as an archaic, outdated measure. E.M. Kolassa, CEO and managing partner of Medical Marketing Economics, a consulting firm in Oxford, Mississippi, recently told the *Wall Street Journal* that AWP is “a vestige of a drug-distribution system that disappeared in the early 1980s.” In an official written statement about the FDB settlement, Medco, the largest U.S. PBM, stated; “Everyone knows AWP does not represent a true ‘average’ of anything and is an artificial benchmark.” An old and oft-used industry joke suggests that AWP stands for “ain't what's paid.”

Clearly, AWP is far from an ideal benchmark. It's rarely an accurate representation of what drugs really cost. What's more, at this point it is hardly an independent metric because it is tied directly to another benchmark—wholesale acquisition cost (WAC)—in that AWP is almost always based on a markup from WAC.

As far as how much time AWP has remaining in its tenure, opinions vary widely. It is important to note, however, that if AWP does go away, the industry has a unique opportunity to implement a new pricing benchmark that does a better job of tracking industry pricing dynamics and is not just another arbitrary “sticker price.”

EVALUATING THE ALTERNATIVES

Since AWP came under the microscope as a result of the FDB case, there has been an increasing interest in alternative benchmarks that more accurately represent the true costs of drugs. So far, the PBM vendor community has not presented a coordinated

solution, leaving many wondering just what will take AWP's place, if it does go by the wayside.

For the long term, a new industry benchmark must be developed after careful evaluation and appropriate consensus among the industry, policy makers and all affected parties. The author believes the chosen methodology should meet the following criteria:

- Standardized at the national level
- Updated with sufficient frequency
- Widely available (either in the public domain or commercially)
- Good potential for longevity
- Widely accepted by the vendor community
- Applicable for generic/brand drugs and retail/mail channels
- Provides good coverage for all NDCs (has no data "gaps")
- Not susceptible to high variability in measuring generic prices.

At this time, two alternative pricing methodologies appear to have the greatest likelihood of taking AWP's place:

1. WAC—Reported by manufacturers, WAC is the catalog or "list" price for drugs distributed to wholesalers and pharmacies. Updated daily and readily available to the private sector in commercially available databases, WAC is a marginally better representation of true acquisition cost when compared to AWP.

Still, there are considerations—most notably, WAC does not represent the actual transactional price at the wholesaler level because such transactions may include discounts, rebates or other pricing incentives. What's more, like AWP, WAC is set "arbitrarily" by manufacturers, with no review by any regulated oversight process. In addition, WAC is not available for all drugs. A recent analysis by Hewitt Associates suggests that over 9% of ge-

neric drugs lack a published WAC price. Where it is available for a generic, it varies widely among manufacturers. In part, that's because generic firms often discount their actual net price to the pharmacy to compete with other generics, but do not always reflect these discounts in lower AWP or WAC list prices.

2. Average Manufacturer Price (AMP)—Also reported by manufacturers, AMP is the supposed average price at which a drug is sold directly to retail pharmacies. Rather than being prospective and arbitrary, AMP is data-driven and retrospective, representing a true tracking of historical data. As such, it is a much more robust, reliable means of evaluating data than AWP. It's far from perfect, however, as AMP information lags the market by months and is currently not readily accessible outside of the government. What's more, recently proposed federal regulations provide for monthly and quarterly updates only, making it a bit slow for tracking dynamic drug prices in the private sector. AMP also faces harsh criticism by the retail pharmacy industry, with accusations that it underestimates actual acquisition costs, thus threatening profit margins for the retailers.

Obviously, there is no quick and easy solution to the dilemma surrounding prescription drug pricing methodologies. Like AWP, each potential replacement benchmark has its own share of benefits and drawbacks. Either way, this is certainly not the end of the AWP debate. ◀

Endnote

1. Freudheim, Milt. The Middleman's Markup, query.nytimes.com/gst/fullpage.html?res=940DEED6143DF93AA25757C0A96E9C8B63&scp=1&sq=acthar+gel&st=nyt, (April 19, 2008).

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