What Is the Price Benchmark to Replace Average Wholesale Price (AWP)?

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An article on the front page of the Wall Street Journal on October 6, 2006, thrust into the public media the otherwise esoteric controversy concerning the use of average wholesale price (AWP) as the primary basis for reimbursements to pharmacies for pharmaceuticals in the United States. Although used widely for nearly 40 years, AWP had been criticized prior to this investigative report as unreliable, subject to manipulation, and not representative of the actual purchase price for pharmaceuticals. The Wall Street Journal article, based on a tentative settlement of litigation in which First DataBank (San Francisco, CA) and the McKesson Corporation (San Francisco, CA) were accused of unilaterally increasing AWPs, included the findings that (a) at least since 2003, AWP was not based on calculation of an “average” wholesale price but instead reflected the pricing of McKesson Corporation, a single drug wholesaler; and (b) AWP had undergone a systematic change beginning in 2001 when First DataBank had converted its markups of wholesale acquisition cost (WAC) to a common multiplier of 1.25, effectively increasing the AWP by 4% for AWPs that were previously calculated using a multiplier of 1.20.

In March 2009, the future of AWP became uncertain as a result of circumstances surrounding the court settlement of the litigation that had begun in 2005 against First DataBank. On March 17, 2009, U.S. District Court Judge Patti B. Saris approved the proposed settlement of 2 civil action lawsuits filed by private health plan payers of pharmaceuticals against the 2 largest publishers of AWP, First DataBank (along with wholesaler McKesson) and Medi-Span (Indianapolis, IN, subsidiary of Wolters Kluwer Health). On March 30, 2009, Judge Saris signed a final order and judgment certifying the class (of “Private Payor” purchasers) which settled 2 national class action lawsuits against the 2 largest publishers of AWP. As part of the formal settlement, Medi-Span and First DataBank agreed to adjust the markup factor used to calculate AWP downward to 1.20 times WAC “for any prescription pharmaceutical” that had “a mark up factor basis from WAC to AWP in excess of 1.20” for the 1,442 specific national drug code (NDC) numbers that were listed in the court complaint.

The “rollback” of AWP as a result of reducing the WAC/DP (direct price) multiplier to no more than 1.20 was implemented from the date of the judgment, as ordered. The same time, these AWP publishers voluntarily implemented price modifications to all products that had a WAC markup greater than 1.20. This decision expanded the list of NDC numbers from the 1,442 specified in the lawsuit to well over 50,000 items. The expanded list included both prescription and nonprescription (over-the-counter [OTC]) items, both active and inactive NDC numbers on the drug database, as well as a variety of markup factors. The adjusted AWPs had markup factors that ranged from 1.20 to 1.33. About two-thirds to three-fourths of the NDC numbers with adjusted AWPs had a pre-settlement WAC markup of 1.25.

This U.S. District Court decision on March 30, 2009, was also accompanied by separate announcements from the defendants Medi-Span and First DataBank that they would voluntarily discontinue publication of AWP. First DataBank announced that its voluntary discontinuation of publication of AWPs would be “no later than two years following the date that the Blue Book AWP adjustments noted above are implemented.” Medi-Span announced that it would discontinue publication of “current AWPs for all products in the Medi-Span files within approximately 2 years of March 30, 2009.” Therefore, according to these announcements by the 2 largest and most widely used publishers of drug price data, the voluntary discontinuation of publication of AWPs would occur on or before March 30, 2011, for Medi-Span and on or before September 26, 2011, for First DataBank.

It is important to note that the litigation and court decision did not address or affect the cost of the products (i.e., pharmacy purchase prices were unaffected by these AWP changes). Rather, the AWP rollback affected the AWPs published by the compendia and could have a secondary effect on reducing pharmacy reimbursement when based on AWP.

Two other drug database publishers of AWP with less market share, Gold Standard (Elsevier, Atlanta, GA) and Red Book, did not make announcements in 2009 that they would discontinue publication of AWP. On April 8, 2010, Thomson Reuters (New York, NY), the publisher of the Red Book, announced that it would continue to provide AWP in addition to other drug price information including WAC, DP, suggested retail price (SRP), and federal upper limit (FUL). Similarly, on May 18, 2010, Gold Standard announced that it too would continue to publish AWP, taking direct aim at the competition: “Gold Standard reports all drug pricing standards utilized and required within the industry, and we intend to continue doing so. … We understand the frustrations felt by those who rely on...
AWP and expect stability and dependability from their drug databases. We look forward to providing a reliable and flexible resource for pricing industry-wide, including AWP and any new benchmarks..."11

The countdown to discontinuation of AWP was interrupted on June 29, 2010, when Medi-Span reversed its earlier position and announced that “based on comments from our customers and other industry participants” it would “publish AWP (or a similarly determined benchmark price) until relevant industry or governmental organizations develop a viable, generally accepted alternative price benchmark to replace AWP.”12 This announcement of course left First DataBank in a difficult position as the only current publisher of AWP on record as planning to discontinue publication of AWP.

Effects on Payers of the AWP Rollback in 2009 and Payer Response

When Medi-Span and First DataBank “rolled back” the WAC/DP multiplier to no more than 1.20 on September 26, 2009, these 2 publishers voluntarily reduced the multiplier to no more than 1.20 for all NDC numbers for which the WAC or DP multiplier was greater than 1.20. For the NDC numbers where the former multiplier was 1.25, the AWP reduction was 4%,13 derived from dividing the 5-point reduction by the former multiplier 1.25. The overall effect on all brand AWPs was different for each payer, determined by the utilization and dollar mix of affected and unaffected NDC numbers. The overall effect was a reduction in composite brand AWP of less than 4% because of the dilution effect from the brand NDC numbers that were already priced at a multiplier of 1.20 prior to the rollback.

Pharmacy benefits management companies (PBMs) and payers could respond to the reduction in AWP with one or perhaps more than one strategy (Table 1). The strategic response to the AWP changes for each PBM or payer depended in part on the anticipated availability of AWP past the dates announced by Medi-Span and First DataBank. The authors determined, through discussions with representatives of many PBMs and health plans, that the following strategies were adopted prior to, and implemented concurrently with, the rollback that occurred in September 2009. Strategies 1 through 5 delivered a “cost neutral” effect, whereby the price of the drug remained constant to the payer and provider in spite of the change in the reference price (AWP). Strategy 5 resulted in a cost reduction to the payer and a lower reimbursement to the provider.

1. Readjust the multiplier to 1.25 (or other previous value) from the post September 26, 2009 multiplier of 1.20 for the NDC numbers that were adjusted downward to the 1.20 multiplier, thereby returning the AWP to its (legacy) value prior to the rollback.
2. Use the “new” reduced AWPs as received from Medi-Span and First DataBank and revise payer-provider contracts to reduce the size of the discount (e.g., 84% of AWP [AWP – 16%] revised to 87.5% of AWP [AWP – 12.5%]).
3. Revise payer-provider contracts using a new price benchmark (e.g., WAC + 5%).
4. Revise payer-provider contracts to incorporate multiple solutions, such as equating WAC plus to AWP minus (see example in Table 2).
5. Do nothing.

The variety of actions implemented across PBMs and payers has not been assessed and reported, understandably since the actions represent business decisions made in a competitive marketplace. However, some information is available that suggests that the strategic responses varied among PBMs and payers. For example, one large PBM-payer announced that it would “recontract the entire retail pharmacy network ... to maintain comparable aggregate pharmacy reimbursement and ensure that our networks remain stable.”14 This announcement suggests that this PBM-payer adopted strategy #2 (Table 1).

State Medicaid programs apparently did little or nothing in response to the rollback (i.e., reduction) of AWP prices in September 2009. For example, the state of Tennessee notified its TennCare pharmacy providers on September 18, 2009, that “At this time, there are no plans to change our pharmacy reimbursement methodology as a result of this ruling.”15 The result of doing nothing was reduced cost to the payer, at the

### Table 1: Alternative Business Strategies in Responding to the AWP Rollback

<table>
<thead>
<tr>
<th>Strategy Description – Example</th>
<th>Strategy Description – Example</th>
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<tbody>
<tr>
<td>If the former multiplier was 1.25 X WAC, the new reduced AWP is recalculated by using the pre September 26, 2009 ratio (e.g., 1.25 divided by 1.20)</td>
<td>If the former discount for brand drugs was 84% of AWP (i.e., AWP−16%), then the new discount might be 87.5% of AWP (AWP−12.5%).</td>
</tr>
<tr>
<td>WAC is used as the new price benchmark. If the former AWP discount was 16%, the new contract rate might be WAC + 5%.</td>
<td>WAC and AWP are used as the price benchmarks with the new AWP discount (e.g., AWP−12.5% = WAC + 5%).</td>
</tr>
</tbody>
</table>

AWP = average wholesale price; WAC = wholesale acquisition cost.
only be viewed as a temporary solution" because WAC prices “are currently available for many, but not all drugs” and because WAC “may be susceptible to the same concerns that rendered AWP ineffective.”

**Application of the Principle of Best Benchmark Criteria**

The announcement by the 2 most widely used publishers of AWP that they would discontinue publication, by March 2011 for Medi-Span and September 2011 for First DataBank, precipitated a great deal of discussion about the benchmark that might be used to replace AWP. The white paper from AMPAA-NASMD in November 2009 described a process that evaluated the characteristics of alternatives to AWP and included the note that unlike AWP, WAC has a definition in statute. Specifically, in the Social Security Act in the section pertaining to average sales price (ASP), WAC is defined in sub-section (c)(6)(B) as “the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.” Also indicative of widespread stakeholder interest in the issue, in 2010 the National Council for Prescription Drug Programs (NCPDP) convened a focus group “to discuss the options for a new benchmark to replace AWP.” The focus group met twice in early 2010 and again in May 2010, when it was identified as an NCPDP Special Committee.

**AMPAA-NASMD Recommendation for Alternative Price Benchmarks**

One of the early recommendations for an alternative price benchmark to replace AWP was rendered in November 2009 in a “white paper” from the American Medicaid Pharmacy Administrators Association (AMPAA) and the National Association of State Medicaid Directors (NASMD). AMPAA had formed a committee of 13 state Medicaid pharmacy directors that presented its findings from an initial meeting in October 2009 to a work group composed of AMPAA and NASMD members in November 2009. The AMPAA-NASMD work group recommended “a single national benchmark” based on “actual average acquisition cost.” Because national average actual acquisition cost (AAC) is not presently available, this AMPAA-NASMD work group recommended that “WAC accompanied by a well-designed MAC [maximum allowable cost] program may provide an interim alternative but should expense of the provider, (e.g., if the previous AWP-based reimbursement was $4.77 per unit, the new reimbursement was 4% lower or $4.58 per unit). The TennCare announcement did include a notice that specialty pharmacy rates would be revised and posted on or before September 23, 2009, because specialty pharmacy “rates are subject to a much deeper discount off of AWP and were implemented at a time after AWP had been inflated.”

Presumably, the business strategies adopted in 2009 to adjust to the reduction in AWP were developed in anticipation of events that would follow the rollback of AWP that occurred in September 2009. Although Medi-Span and First Databank were on record to discontinue publication of AWP as early as March 2011, a majority of PBMs and health plans either anticipated the continued availability of AWP or were unable to decide at that time on a suitable alternative pricing benchmark. The uncertainty surrounding the continued availability of AWP precipitated discussions by public and private stakeholders regarding possible replacement benchmarks and revised payment methods for pharmaceutical products.

**Table 2: Example of Calculation of Neutral Pricing for Pharmacy Reimbursement**

<table>
<thead>
<tr>
<th>NDC 00071-0156-23</th>
<th>Ingredient Cost</th>
<th>Dispense Fee</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AWP – 16% Example</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Lipitor 20 mg tablet</strong></td>
<td>Unit AWP</td>
<td>AWP at Quantity = 90</td>
<td>AWP Minus 16%</td>
</tr>
<tr>
<td>Pre 09.26.2009 AWP</td>
<td>$4.77144</td>
<td>$429.43</td>
<td>$360.72</td>
</tr>
<tr>
<td><strong>Unit WAC</strong></td>
<td><strong>WAC at Quantity = 90</strong></td>
<td><strong>WAC Minus 5.0%</strong></td>
<td></td>
</tr>
<tr>
<td>Pre 09.26.2009 WAC</td>
<td>$3.81711</td>
<td>$343.54</td>
<td>$360.72</td>
</tr>
<tr>
<td>Post 09.26.2009 WAC</td>
<td>$3.81711</td>
<td>$343.54</td>
<td>$360.72</td>
</tr>
</tbody>
</table>

Pre 09.26.09 AWP is derived from WAC multiplied by 1.25; post 09.26.09 AWP is derived from WAC multiplied by 1.20. AWP = average wholesale price; mg = milligrams; NDC = national drug code; WAC = wholesale acquisition cost.
What Is the Price Benchmark to Replace Average Wholesale Price (AWP)?

Actual Acquisition Cost (AAC)

AAC is the final price paid by the pharmacy provider after subtraction of all discounts. AAC prices are not reported or publicly available and would have to be determined by pharmacy self-report or audit of actual pharmacy invoices. Furthermore, using the AAC as an alternative to AWP would require determining whether the AAC is calculated per pharmacy site, per pharmacy chain, per pharmacy association buying group, or some other segmentation. AAC is purchaser (provider) specific and therefore not a benchmark. A variation could theoretically apply if AACs are combined and a mathematical mean or median value is determined for a group of like pharmacy providers. Such an “average” AAC, as recommended by the AMPAA-NASMD work group, could be determined for pharmacies by type (e.g., mail order, chain community pharmacy, independent community pharmacy) or by geographic region. For example, the state of Alabama Medicaid program in 2010 began posting the results of its audits of community pharmacy invoices in Alabama. The state of Alabama contracts with a third party to conduct audits of pharmacy invoices twice per year, for the invoice months of December and June, and each pharmacy in the state is required to participate once every 2 years. The third-party audit firm calculates an average AAC value for each generic code number (GCN [Formulation ID]; for each drug and strength by dosage form, such as fluoxetine 20 milligram [mg] capsules) separately for brand and generic drugs. The average AAC values are publicly available as part of the “Alabama State MAC List.” Average AAC values are presented in 2 lists, separately for brand drugs and for generic drugs, and as of June 2010, the 2 price lists include the notice that these average AAC values per unit are “not effective for current reimbursement.”

Assessment of AAC as a Benchmark.

At the present time, AAC fails nearly all of the best benchmark criteria. AAC is not readily available, and it is administratively complex and expensive to determine. Timeliness is problematic because AAC values that are determined from invoice prices at a given point in time are immediately outdated. Also, practical definitions of AAC would necessarily employ a method to calculate average or median AAC values because it would be unimaginable to administer a system that reimbur ses individual pharmacy providers based on their own individual AACs. Reimbursement based on pharmacy-specific AAC would also reduce the financial incentive for competitive buying because pharmacy-purchasers would simply pass on their cost of goods to payers. Although AAC has significant shortcomings, national AAC prices came one step closer to reality with the release on July 16, 2010, of a request for proposal issued by the Federal Business Opportunities office on behalf of the Centers for Medicare & Medicaid Services (CMS) for the conduct of “a monthly nationwide survey of retail community pharmacy prescription drug prices and the generation of publicly available pricing databases ... [to] afford State Medicaid agencies a valid array of covered outpatient drug prices from ingredient costs paid by retail community pharmacies to those prices available to the consumer.”

Average Manufacturer Price (AMP)

AMP is a manufacturer-reported price that was mandated by Congress as part of the Medicaid drug rebate program in the Omnibus Budget Reconciliation Act (OBRA 1990). AMP is defined in section 1927(k)(1)(B) of the Social Security Act as “the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade,” excluding “customary prompt pay discounts extended to wholesalers.” The Office of Inspector General (OIG) estimated in June 2005 that the median AMP was approximately 77% of AWP for single-source brand drugs, 72% of AWP for multiple-source brand drugs, and 30% of AWP for generic drugs. Prior to the Deficit Reduction Act of 2005 (DRA), AMP was used by CMS at the federal level to calculate manufacturer rebates owed to the Medicaid program. DRA required that CMS make the AMP data available to state Medicaid programs on a monthly basis beginning July 1, 2006, providing the opportunity for state Medicaid programs to use AMP as the basis for reimbursement. DRA 2005 also established AMP as the basis for determining the FUL amounts, calculated as 250% of the AMP for the drug with the lowest AMP, thereby replacing the former FUL calculation based on 150% of the

**TABLE 3** Best Benchmark Criteria and Alternative Price Benchmarks

<table>
<thead>
<tr>
<th>Best Benchmark Criteria</th>
<th>Alternative Price Benchmarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Accessible – readily available</td>
<td>AAC – actual acquisition cost</td>
</tr>
<tr>
<td>2. Timely</td>
<td>AMP – average manufacturer price</td>
</tr>
<tr>
<td>3. Administratively simple and efficient</td>
<td>ASP – average sales price</td>
</tr>
<tr>
<td>4. Comprehensive</td>
<td>AWP – average wholesale price</td>
</tr>
<tr>
<td>5. Durable (not an interim solution)</td>
<td>EAC – estimated acquisition cost</td>
</tr>
<tr>
<td>6. Stable (won’t produce more litigation)</td>
<td>FUL – federal upper limit</td>
</tr>
<tr>
<td>7. Easily understood</td>
<td>MAC – maximum allowable cost</td>
</tr>
<tr>
<td>8. Transparent and unambiguous</td>
<td>MLP – manufacturer list price</td>
</tr>
<tr>
<td>9. Auditable</td>
<td>WAC – wholesale acquisition cost</td>
</tr>
<tr>
<td>10. Not anticompetitive</td>
<td></td>
</tr>
<tr>
<td>11. Trustworthy</td>
<td></td>
</tr>
<tr>
<td>12. Acknowledges complexity of drug distribution system</td>
<td></td>
</tr>
</tbody>
</table>

aAWP may also be referred to as suggested wholesale price (SWP) when supplied by the manufacturer.
bMLP might replace AWP as a multiple of WAC and would be reported by the manufacturer rather than calculated by the publisher of drug price data.
cWAC may also be referred to as direct price (DP) or list price (LP).
What Is the Price Benchmark to Replace Average Wholesale Price (AWP)?

lowest published price. In July 2007, CMS issued final regulations that addressed the AMP provisions of the DRA including the definition of the “retail pharmacy class of trade” to include “sales including discounts, rebates, or other price concessions provided to [PBMs] for their mail order pharmacy purchases.” Medicaid reimbursement based on AMP for multiple-source (generic and brand) drugs was delayed by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Public Law 110-275). Improvements for Patients and Providers Act of 2008 (MIPPA) (generic and brand) drugs was delayed by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Public Law 110-275). Improvements for Patients and Providers Act of 2008 (MIPPA) (generic and brand) drugs was delayed by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Public Law 110-275).26

**Assessment of AMP as a Benchmark.** AMP is closely related to AAC and has an advantage in trustworthiness; it is unlikely to be overstated because (a) it is the basis of calculation of the amount of rebate owed to the Medicaid program by the pharmaceutical manufacturer, and (b) the chief executive officer of each drug manufacturer must attest to its authenticity. Weaknesses of AMP include lack of timeliness, lack of availability, and lack of fairness across classes of trade. However, the latter disadvantage of AMP may be overcome at least in part by its redefinition in the Affordable Care Act of 2010 (the combination of P.L. 111-148, the Patient Protection and Affordable Care Act [PPACA, enacted March 23, 2010], and P.L. 111-152, the Health Care and Education Reconciliation Act of 2010 [HCERA, enacted March 30, 2010]) to remove from the calculation of AMP certain discounts that were not available to all purchasers, such as discounts offered to mail order pharmacies. There appears to be future opportunity for AMP as a pharmaceutical price and reimbursement benchmark for private as well as public programs as a result of revision of the calculation method defined in the Affordable Care Act of 2010 and with anticipated public availability of AMP as early as January 2011. However, until that time, AMP remains unavailable, and questions about transparency cannot be answered until AMP becomes available in the marketplace. AMP also has the significant shortcoming of a lack of timeliness because it is determined retrospectively.

**Average Sales Price (ASP)**

ASP is calculated by CMS from manufacturer-reported prices for “sales to all purchasers,” excluding sales that are exempt from Medicaid “best price” and sales at “nominal charge.” ASP is based on actual transaction price data and includes virtually all discounts and rebates, defined as “net of any price concessions, such as volume discounts, prompt pay discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates other than those obtained through the Medicaid rebate program.” ASP is therefore a near-actual net purchase price. ASP replaced AWP as the basis for reimbursement for pharmaceuticals in Medicare Part B (primarily physician-administered injectables) on January 1, 2005, as a result of the 2003 Medicare Prescription Drug, Improvement, and Modernization Act (MMA) (Public Law 108-173), and the method of calculation of ASP changed on April 1, 2008. Payment to Medicare providers is 106% of ASP except for reimbursement at 104% of ASP, effective January 1, 2009, for Part B drugs that are separately reimbursable in hospital outpatient departments.

**Assessment of ASP as a Benchmark.** ASP is favorable by several best benchmark criteria including transparency and present use in the marketplace. However, it is not a reasonable replacement of AWP as a benchmark because of its limited scope. ASP is available only for Medicare Part B covered drugs, which account for only about 2% of outpatient prescriptions. ASP also fails best benchmark criteria because it is calculated retrospectively and therefore lacks timeliness. ASP values reported to CMS by manufacturers lag real-time transactions by 2 calendar quarters. ASP is also not specific to NDC numbers, making it impractical for use in pricing and reimbursement for prescription drug claims submitted using NDC numbers. The primary opportunity for ASP might lie in expanding the scope of ASP to more, if not all drugs, but this expansion is not anticipated at this time.

**Average Wholesale Price (AWP)**

AWP is a list price for drugs published in commercial publications (or drug price compendia). Two companies’ compendia (Medi-Span and First DataBank) are used as the basis of pricing most pharmacy claims in the United States. Two other recognized drug price data sources for drug price information including AWP are Red Book (Thomson Reuters) and Alchemy (Elsevier Gold Standard). When AWP is supplied by the manufacturer, it is identified by the drug price compendia as suggested wholesale price (SWP). If the manufacturer-labeler does not supply the compendia with an SWP, AWP is calculated by the compendia using a markup applied to the WAC or DP supplied by the manufacturer-labeler. The markup factor may be lower than 1.20 but not greater than 1.20 as a result of the AWP rollback that occurred on September 26, 2009; however, a manufacturer may supply an SWP that is greater than a markup of 1.20 times WAC/DP. Each AWP/SWP is specific to an 11-character (technically 10 characters with a “0” fill) NDC number that is composed of 3 segments to identify the (a) manufacturer or (re)labeler (4 or 5 characters); (b) product code (drug, strength, and dosage form and formulation; 3 or 4 characters); and (c) package code (1 or 2 characters).31

**Assessment of AWP as a Benchmark.** Although AWP survived for 40 years as the basis for pharmacy reimbursement of pharmaceutical ingredient cost, it was never intended to represent actual transaction prices in the marketplace. AWP is favorable according to many best benchmark criteria including the higher-value attributes of timeliness, accessibility, comprehensiveness, administrative simplicity, and low administrative cost. However, AWP is less favorable by the criteria of trustworthiness and transparency. Moreover, the business
strategy adopted by many PBMs and payers in 2009 that adjusted (restored) the “new” (post September 2009) AWP to the pre September 2009 AWP (strategy 1, Table 1) by introduc-
ing a “legacy” multiplier of WAC added to the complexity by creating multiple AWPs. The pejorative connotation associated with “AWP” is evident, including the description by U.S. District Court Judge Patti B. Saris in a court decision in June 2007 of a “flawed AWP system” that permitted defendant drug manufacturers to act “unfairly and deceptively by causing the publication of false and inflated average wholesale prices.”
This court decision referred to AWP as “ain’t what’s paid” and “fictitious” and introduced a “speed limit” for the margins between AWP and the actual purchase price. It is possible that some of the criticism of AWP could be overcome by adopting an alternate name, such as “manufacturer list price,” “standard list price,” or “reference price.”

**Estimated Acquisition Cost (EAC)**

EAC is the basis for state Medicaid reimbursement for covered outpatient drugs. Federal regulation 42 CFR 447.512 requires pharmacy reimbursement to be the lesser of (a) EAC plus “reasonable dispensing fees” or (b) the pharmacy “providers’ usual and customary charges to the general public.” Each state Medicaid agency determines EAC for pharmacy reimbursement, and EAC is defined in federal regulation 42 CFR 447.301 as “the [state Medicaid] agency’s best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.”

EAC is therefore intended to represent an actual transaction price that is an estimate of AAC. As of March 2010, 11 states used WAC (or direct price) in some way to reimburse pharmacy providers for pharmaceutical ingredient cost, including Rhode Island, which CMS lists as using WAC exclusively for reimbursement of brand and generic drugs, with no state MAC. As of March 2010, almost all of the remaining states and the District of Columbia used discounted AWP solely or primarily to determine EAC.

**Assessment of EAC as a Benchmark.** EAC is not a published price and is therefore not accessible or readily available. EAC is not used for transaction pricing, and its use for pharmacy reimbursement would require a methodology for its determination. Presumably, a survey of wholesalers or pharmacy purchasers would be necessary to determine EAC. The use of EAC for pharmacy reimbursement would have the drawbacks associated with AAC including administrative complexity, expense in price data collection, and prices outdated almost immediately upon determination (i.e., lack of timeliness).

**Federal Upper Limit (FUL)**

FULs are calculated and published by CMS and represent the maximum amount that state Medicaid programs can pay for multiple-source generic pharmaceuticals. FUL may also be referred to as federal MAC or FED MAC, CMS MAC, or even HCFA MAC (referring to the former name of CMS, Health Care Financing Administration). FUL was created in 1987, and prior to 2007, each FUL was calculated as 150% of the lowest price for a drug from “the prices published nationally in three drug pricing compendia” for drugs rated “A” in the U.S. Food and Drug Administration’s Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). The DRA of 2005 redefined the calculation of FUL as 250% of “the lowest AMP rather than 150 percent of the lowest published price for therapeutically equivalent products,” effective January 1, 2007. CMS started sending AMP data monthly to state Medicaid programs in July 2006, as required by DRA 2005, but states were not required to base reimbursement on these data. MIPPA (July 15, 2008) delayed implementation of FULs based on AMP to no earlier than October 1, 2009 and prevented CMS from making any AMP “publicly available” prior to that date. However, MIPPA was superseded by the Affordable Care Act of 2010, including redefinition of FUL as 175% of AMP, and redefinition of the calculation of AMP.

**Assessment of FUL as a Benchmark.** Although FUL prices are widely available, the products with FUL prices are not comprehensive. FULs are intended to serve as benchmark prices for multiple-source products (generic and brand) but are not applicable to single-source products. FUL prices are also not timely because they are determined retrospectively and updates are published infrequently.

**Maximum Allowable Cost (MAC)**

MAC is defined by individual PBMs or payers (commercial or governmental) for reimbursement of multiple-source drugs. Each formulation (e.g., tablet, capsule, or gram) of a drug and strength has a MAC price that is determined by the PBM or health plan from actual or estimated transaction prices in the marketplace and other price information such as FULs. Individual state Medicaid programs may maintain their own MAC price lists with MAC prices that are no greater than the FULs. MAC values may also be established for multiple-source drugs that do not have FULs. MAC price lists in the private sector are usually considered proprietary and are generally not available or accessible.

**Assessment of MAC as a Benchmark.** State MAC prices and FULs are accessible, but private sector MAC price lists are not accessible or readily available. MAC prices are not applicable or present for single-source drugs. MAC also falls short of best benchmark criteria for transparency and trustworthiness. However, MAC is well accepted in the private sector as a pro-competitive method for pharmacy reimbursement for multiple-source drugs.
Wholesale Acquisition Cost (WAC)

WAC is the list price for a pharmaceutical sold by a manufacturer to a wholesaler (e.g., McKesson, Amerisource Bergen [Valley Forge, PA], Cardinal Health [Dublin, OH]). WAC is determined by the manufacturer. The WAC price published by First DataBank, Medi-Span, and other providers of drug price data is the price supplied to them by the manufacturer of the pharmaceutical product. Alternate terms for WAC include: list price (LP), catalog price, wholesale net price, book price, and DP. Almost all single-source pharmaceuticals have WAC prices, but many generic pharmaceuticals, repackaged pharmaceuticals, and branded generics do not have a WAC price. There is no legal requirement for manufacturers to report WAC. However, certain current and evolving business practices make it advantageous for drug manufacturers to supply WAC prices. For instance, when WAC is used as a basis for pricing, the absence of a WAC becomes an obstacle to reimbursement determination and therefore a barrier to product use.

Because WAC is the basis for determining AWP for most brand drugs, commonly using a multiplier of either 1.20 or 1.25 (1.20 after September 26, 2009), WAC is lower than AWP and is closer to AAC. However, like AWP, WAC does not include many discounts such as rebates, volume purchases, and prompt payment. Unlike AWP, WAC is defined in federal statute and as noted previously, the statutory definition of WAC is “the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.”

Assessment of WAC as a Benchmark. WAC excels when assessed by best benchmark criteria for accessibility, administrative simplicity, and low administrative cost. WAC is closer to AAC than AWP, and as the basis for AWP, it is more transparent. WAC is not presently comprehensive, but the absence of WAC prices for some NDC numbers could be overcome because (a) currently approximately 98% of prescriptions dispensed can be priced using WAC or MAC as the price basis; (b) payment based on WAC would result in more widespread reporting of WAC by manufacturers, distributors, and repackagers; and (c) the WACs currently missing for some generic drugs can be easily managed with MAC pricing. Like AWP, WAC is not a transaction price, and AMPAA-NASMD argued that WAC would be as susceptible as AWP to inflation by manufacturers if WAC replaced AWP as the common price benchmark.

Alabama Medicaid Filed State Plan Amendment in 2010 to Replace AWP with Average AAC

The Alabama Medicaid Agency filed a State Plan Amendment (SPA) with CMS and announced in May 2010 that it expected to receive approval by mid-2010 to replace AWP in its “lower of” pharmacy reimbursement formula with “average acquisition cost” for both brand and generic drugs. The state also proposed in its SPA to increase the pharmacy dispensing fee from $5.40 to $10.64 per prescription, based on the results of a cost of dispensing survey that was conducted by an independent contractor. The Alabama Medicaid Agency pursued regulatory approval of the new pharmacy reimbursement formula through the Administrative Code process, which requires a public comment period. The announcement in May 2010 cited an anticipated implementation date of August 2010 following federal and state regulatory approval.

The Alabama Medicaid Agency (AMA) had motivation to aggressively pursue discontinuation of the use of AWP because of state court rulings regarding complaints filed by the State against 73 drug manufacturers in 2005 for inflating drug cost to the State through the use of AWP. Although 3 lower-court decisions favored the State, including an award of $215 million in February 2008, the Alabama Supreme Court in October 2009 overturned the lower-court rulings, reversing more than $275 million in awards, and criticized the AMA for having “actual knowledge of what the State now seeks to disavow, that is, that published AWP’s were not net prices,” since “1992 at the very latest.” The Alabama Medicaid Commissioner Carol Steckel said as part of the announcement in May 2010 that, “As AWP has been found to be inflated in both state and national litigation, our Agency must move away from fraudulent AWP pricing and toward reimbursement logic based on true estimated acquisition costs as mandated in federal guidelines.”

The details in the 8-to-1 ruling by the State of Alabama Supreme Court judges may have implications for other claimants who allege perpetration of fraud by pharmaceutical manufacturers in the use of AWP. Specifically, the Supreme Court judges found that the State’s own pharmacy reimbursement formula, which paid pharmacies the lower of WAC plus 9.2% or AWP minus 10.2%, was evidence that the State knew that AWP was not a “net price” as required by federal regulation in reimbursement of pharmacies based on EAC. The judges wrote: “The State concedes that ‘EAC is not a ‘list’ price or an ‘undiscounted price,’ but is a price paid.’ … Remarkably, the State has taken the position that AWP also means ‘an actual average price’ paid.” The judges stated in their concluding statement that the AMA’s “own surveys put the AMA on notice that the AWP benchmark was not a true representation of the prices actually paid by pharmacies in Alabama for drugs purchased from pharmaceutical wholesalers. The AMA’s reimbursement formula, which deducted 10% from the AWP, graphically codifies the AMA’s understanding that the AWP was not a true representation of the price paid by pharmacies in Alabama …The evidence is undisputed that the WAC was the primary basis for reimbursement by the AMA.”
Is a Replacement for AWP Necessary?
Although the AMPAA-NASMD work group concluded in November 2009 that “immediate action is necessary” because there was less than 2 years available before the “disappearance of AWP,” some PBMs and payers in the private sector apparently determined at the time that AWP may continue to be available in the foreseeable future. The crystal ball for these PBMs and payers who foresaw life after death for AWP was verified by 3 announcements of intention to continue publishing AWP that occurred in succession in April (by Thomson Reuters for Red Book), in May (by Gold Standard), and in June 2010 (by Medi-Span). The only uncertainty that remained just 15 months after the announcements by Medi-Span and First DataBank of voluntary discontinuation of AWP was if or when First DataBank would announce that it too will continue to provide AWP to its customers past September 2011.

Action by the State of Alabama to replace AWP was a milestone in the 40-year history of the use of AWP in reimbursement of pharmaceuticals in the United States. Ironically, AWP was originally developed in 1969 not by pharmaceutical manufacturers but rather by the State of California for pricing and reimbursement of pharmaceuticals dispensed by community pharmacies to Medi-Cal recipients.32 The history of AWP is also notable in the present search for a replacement because AWP was not intended to represent actual transaction prices but instead was created in part to represent average prices in the instances in which pharmaceutical manufacturers did not report actual prices.32

So, is a replacement for AWP necessary? The currently obvious answer is no, at least not in the short term. However, the energy that was created in the period from 2006 through the first half of 2010 will probably continue to propel discussion of alternate benchmark prices to replace AWP. There is demand from some payers for more transparent benchmark prices that better represent real-world business transactions. Some payers would like to move to a payment method that offers little if any gross margin on the drug product for the pharmacy provider, combined with a dispensing fee that more closely approximates average actual dispensing cost. However, in addition to its other shortcomings, cost-based pricing such as AAC fails to provide a strong incentive for competitive buying. WAC on the other hand is already used by at least 11 states for at least some components of Medicaid reimbursement to pharmacy providers, and some private payers already use WAC-based reimbursement; it seems likely that more payers will adopt WAC and abandon AWP. Furthermore, WAC is the benchmark price from which AWP is derived, for those products for which the manufacturer does not supply an SWP.

AWP has proven to be a type of Phoenix, perhaps not living 1,000 years as in the legend but longer than 40 years.
What Is the Price Benchmark to Replace Average Wholesale Price (AWP)?


What Is the Price Benchmark to Replace Average Wholesale Price (AWP)?


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