

AWP (Average Wholesale Price) And Industry's Search for a Viable Replacement Pricing Benchmark

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AWP = Confusion

- Average Wholesale Price (AWP), despite its name, is not an *average* of anything, and does not reflect actual *wholesale* transaction *prices*
- A long-time joke in the industry is that AWP means “Ain’t What’s Paid”



AWP - A Brief History

- Originated in the California Medicaid program in the 1960s to standardize drug reimbursement
- Not defined by statute
- Functions as a benchmark undiscounted suggested retail list price for brand drugs
- Under attack, but still used to determine the amount of reimbursement paid to pharmacies for dispensing brand drugs



How is AWP Calculated?

- Historically, manufacturers reported AWP. Brands stopped reporting AWP principally due to litigation. Many generics still report AWP.
- Suggested Wholesale Price (SWP) generally is the same as AWP
- If no AWP or SWP is reported for a brand drug, $AWP = WAC \text{ (or Direct Price)} \times 1.20$



What is WAC?

- WAC, like AWP, is an undiscounted price
- Federal statute defines WAC as manufacturer's list price to wholesalers or direct purchasers, not including discounts and rebates
- WAC is the actual invoice price off the dock to wholesalers
- Some manufactures may use the term Net Wholesale Price (NWP)



Relationship Between WAC and AWP

- For brand drugs, $AWP = WAC \times 1.2$
- Similarly, AWP discounted by 16.7% equals WAC. $WAC = AWP \times .833$
- OIG Report 10/11 - Pharmacies' invoice prices for brand drugs were close to WAC, and were approximately 83% of AWP



AWP/WAC - Role of Pricing Compendia

- First Databank Blue Book (no AWP)
Thomson Reuters Red Book
Wolters Kluwer Medi-Span
- Compendia accumulate information for existing and new drugs, including pricing, clinical information, and regulatory documentation
- Confusion historically whether compendia surveyed wholesalers in order to calculate AWP: Surveys NOT currently conducted



Why is AWP Still Being Used?

- Long History of Use
- Administrative Ease
- Pharmacy Lobby (believe AWP reimbursement likely is greater than alternatives)
- Problems With Other Benchmarks



AWP Litigation Caused Brands and FDB To Stop Reporting AWP

- Lawsuits changed brand manufacturers' behavior (generics are different)
- Federal Court (Saris, J.) and various state courts held that AWP should be interpreted using its plain meaning
- Plain meaning is a fiction: manufacturers and pricing compendia never defined AWP using its plain meaning



Federal Court Adopted Three-Part Test for Manufacturer Liability

1. Did the manufacturer cause the publication of spreads over the 30% yardstick expected in the industry?
2. Did the manufacturer manipulate the spread? Were 50% of sales within 5% of WAC?
3. Did the manufacturer market the spread?



Epidemic of State AWP Litigation

- State Attorneys General hired contingency lawyers to pursue cases
- Contended that manufacturers caused State Medicaid agencies to overpay pharmacies by reporting undiscounted and inflated WAC and/or AWP prices
- No practical way for manufacturers to report prices that meet the contingency lawyers' alleged legal standard



AWP Litigation Almost Over

- First AWP lawsuit unsealed more than ten years ago (filed in the 1990s), but the cases never seem to end
- States contend that, as the sovereign, they are immune from statutes of limitations



AWP Litigation Big Success for Claimants

- Significant trial verdicts, principally against generics, many of which were upheld on appeal
- Beasley Allen, one of the contingency law firms representing eight states, recently reported nearly \$1 billion in settlements for 8 States, plus additional sums recovered from trial verdicts



Expect More Medicaid Fraud Cases

- "During the AWP litigation, our firm uncovered other fraudulent activity occurring in the Medicaid arena." Beasley Allen
4/1/2014
- Sympathetic plaintiff + unsympathetic defendant with deep pockets + complexity + contingency lawyers = Lawsuits



Minimize Risk – Do Not Report AWP

- May be easier said than done for generic manufacturers
- Brands already stopped reporting AWP
- WAC reporting continues, and use of WAC as a benchmark presents similar problems to AWP
- Federal statutory definition of WAC reduces litigation risk



Reimbursement Changes

- Search for a new benchmark
 - In 2005, Congress required Medicaid to switch to Average Manufacturer Price (AMP) for generic reimbursement
 - Federal Upper Limit (FUL) = AMP x 1.75
 - Still not implemented



Status of AMP Implementation

- CMS set July 2014 implementation
- Pharmacy groups seeking a one-year transition period, with some support from State Medicaid Directors
- State reimbursement methodology changes often require legislative action and a cost of dispensing study



Alternatives to AWP

- CMS and state Medicaid agencies want a new methodology (OIG July 2011)
- Two principal alternatives to AWP:
 - Use an alternative existing benchmark reported by manufacturers (WAC, AMP)
 - Reimburse based on pharmacy actual acquisition cost (AAC)
- All alternatives have problems



A National Solution?

- CMS engaged Myers & Stauffer to perform national scale acquisition cost survey
- Results: National Drug Acquisition Cost (NADAC)
- NADAC available at www.medicaid.gov
- Data updated weekly



A National Solution?

- To date—no State has adopted methodology using NADAC
- To date—no mandate from federal government directing states to use NADAC data
- Alabama, Oregon, and a handful of other states have implemented their own AAC programs



New York AAC

- First Databank began publishing draft NY AAC data in 2014, for use later this year
- "New York prices will represent the first and only AAC effort that seeks to identify true net costs" FDB 1/31/2014



Easy U&C Solution Ignored

- States currently have rules prohibiting reimbursement above a pharmacy's usual and customary (U&C) price
- U&C definitions vary, but enforcement using "most favored nation" definition likely solves most of the problem
- Political and other hurdles

