

Average Wholesale Price for Prescription Drugs: Is There a More Appropriate Pricing Mechanism?

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OVERVIEW — *This paper defines the average wholesale price (AWP), which has become an important benchmark for prescription drug pricing and reimbursement. The paper briefly explains the AWP's various uses in the pricing of prescription drugs, highlights some of the problems that have emerged as a result of the way it is reported and used, and explores some of the possibilities for reform. The paper also contains a glossary of commonly used terms, as well as an appendix that lists the state Medicaid reimbursement formulas.*

Average Wholesale Price for Prescription Drugs: Is There a More Appropriate Pricing Mechanism?

Prescription drug pricing has moved center stage in a health care industry that is becoming more and more complex. With the inclusion of new groups of stakeholders, more varied incentive systems, greater competition, and more complicated benefit structures, the “true” cost of prescription drugs has grown increasingly elusive. Drug prices are subject to various types of discounts and rebates, seen and unseen, on both the public and private side. Each drug sold by a manufacturer, therefore, is subject to multiple prices, and little is known publicly about this pricing information. In addition, the issue of drug pricing has implications for other payment systems, such as the Medicare resource-based relative value scale (RBRVS) for physician reimbursement and the state Medicaid reimbursement formulas for prescription drugs. In certain instances where providers or pharmacies believe they are inadequately compensated for administering or dispensing prescription drugs, an inflated average wholesale price (AWP) is relied upon to make up the difference. From a policy perspective, therefore, the AWP is part of a larger pricing infrastructure that requires examination. The continued debate about the establishment of a comprehensive Medicare prescription drug benefit has only intensified policymakers’ focus on drug prices.

At a time when health care costs are climbing and prescription drug spending is increasing at double-digit rates,¹ both public and private payers are under pressure to find ways to control outlays. As part of this effort, significant scrutiny has focused on the appropriateness of the AWP as a mechanism for prescription drug reimbursement. Over the last several years, the AWP has been the subject of investigations, litigation, and legislative proposals. Though imperfect, the AWP has come to represent a starting point for determining prescription drug reimbursement for public and private payers. As it has evolved, however, many argue that it has moved so far from the actual acquisition prices for prescription drugs that it fails to serve as a meaningful benchmark. Attempts at payment reform inevitably raise significant concerns about the potential impact on payment systems and stakeholders.

WHAT IS THE AWP AND WHY IS IT IMPORTANT?

The AWP, or average wholesale price, of prescription drugs was intended to represent the average price at which wholesalers sell drugs to physicians,

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pharmacies, and other customers. In practice, it is a figure reported by commercial publishers of drug pricing data, such as First DataBank and Thomson Medical Economics. According to the *Red Book*, published by Thomson Medical Economics, the pricing information is “based on data obtained from manufacturers, distributors, and other suppliers.”² This pricing information is then sold to government entities, private insurance companies, and other purchasers of prescription drugs.

The AWP has often been equated with a “sticker price” or “list price,” as those terms are used in the automobile industry. It has become an important prescription drug pricing benchmark for payers throughout the health care industry. Payments are typically based on AWP minus some percentage. Despite its name, however, the AWP is not an accurate reflection of actual market prices for drugs. As noted, it is a price derived from self-reported manufacturer data for both branded and generic drugs. There are no requirements or conventions that the AWP reflect the price of any actual sale of drugs by a manufacturer, or that it be updated at established intervals. It is not defined in law or regulation, and it fails to account for the deep discounts available to various payers, including certain federal agencies, providers, and large purchasers, such as HMOs. Consequently, the AWP has been the subject of great criticism and scrutiny.

According to the U.S. General Accounting Office (GAO), the AWP may be neither “average” nor “wholesale.”³ In addition, a recent investigation by the U.S. Department of Justice (DOJ) and the National Association of Medicaid Fraud Control Units (NAMFCU), which involved the collection of actual wholesale pricing information, indicated that some drug manufacturers report inflated average wholesale pricing information.⁴ Because the AWP is part of the reimbursement formula used in Medicare Part B and by many state Medicaid programs, any increase in the published AWP can increase the billions of dollars that federal and state governments pay for prescription drugs. Medicare beneficiaries, who are responsible for 20 percent coinsurance for the drugs covered under Part B, would also bear an increased financial burden.

Some manufacturers argue that they do not set the AWP for their drugs and are therefore not in a position to inflate these prices. They maintain that the commercial publishers of drug pricing data independently assess and report a drug’s AWP. Despite these claims, it is clear that the manufacturers must provide some level of pricing data to commercial publishers to enable them to publish AWP lists.

MEDICARE

As Congress struggles with proposals to develop an outpatient Medicare prescription drug benefit for seniors,⁵ significant attention has been paid to the high cost of prescription drugs and the mechanisms employed to determine the government reimbursement rate. Though Medicare does

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not have a comprehensive outpatient prescription drug benefit, Medicare Part B does cover approximately 450 drugs and biologicals.

The following categories of outpatient drugs are covered under Medicare Part B:

- Drugs that are not self-administered⁶ and that are furnished “incident to” a physician’s service, such as prostate cancer drugs.
- Certain self-administered oral cancer and antinausea drugs.
- Certain drugs used as part of durable medical equipment or infusion devices, such as inhalation drugs used with a nebulizer.
- Immunosuppressive drugs, which are used following organ transplants.
- Erythropoietin (EPO), which is the most costly drug for Medicare and is used primarily to treat anemia in patients with end-stage renal disease or cancer.
- Osteoporosis drugs furnished to certain beneficiaries by home health agencies.
- Vaccines for diseases such as influenza, pneumonia, and hepatitis.

These drugs are typically provided in the hospital outpatient setting, dialysis centers, or the doctor’s office, and are purchased directly by the physician or provider.⁷

In 1999, Medicare spent almost \$4 billion on outpatient drugs,⁸ with 82 percent of that cost attributable to 35 drugs, primarily cancer, inhalation therapy, and oral immunosuppressive medications. It is clear, therefore, that even a slight inflation in the cost of these drugs can result in significantly higher aggregate spending by the government.

Drugs provided in a physician’s office accounted for over 75 percent of Medicare spending for outpatient drugs in 1999. Three specialties, hematology/oncology, medical oncology, and urology, which bill Medicare primarily for drugs used in the treatment of cancer, represented 80 percent of total Medicare payments to physicians for drugs.⁹ Physicians are also paid under the Medicare physician fee schedule for services associated with drug administration.

Reimbursement for Medicare Part B prescription drugs has undergone significant change over the years. Prior to use of the AWP as a pricing benchmark, Medicare Part B drugs were reimbursed on the basis of the physician’s acquisition cost. That system was eventually replaced with one based on 100 percent of the AWP, and then to the lower of the estimated acquisition cost (EAC) or 95 percent of the AWP. EAC is often determined by subtracting a percentage discount from a drug’s AWP. Finally, on January 1, 1998, as a result of the Balanced Budget Act of 1997 and in an effort to bring down costs, Medicare Part B began to reimburse covered brand-name drugs at 95 percent of the AWP. For multisource drugs—drugs with generic equivalents or brand-name drugs with at least

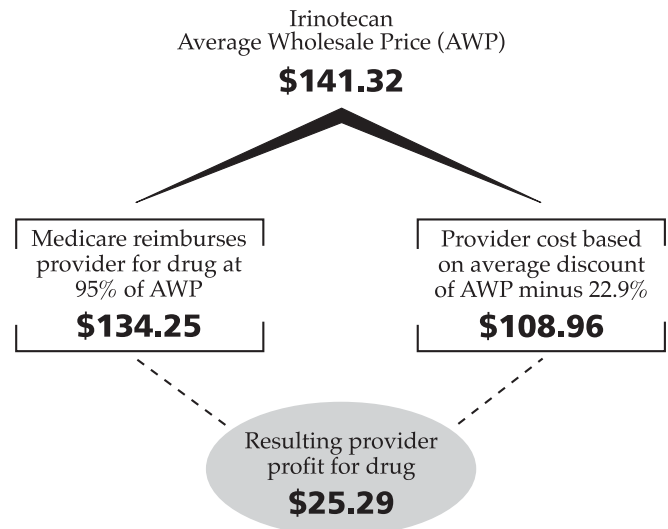
one competing product—reimbursement is 95 percent of the lower of (a) the median AWP of all generic forms of the drug and (b) the lowest brand-name product's AWP.¹⁰

A recent report indicated that the drug industry's published wholesale prices, which serve as the basis for Medicare payments to providers, are significantly higher than the providers' actual acquisition costs. Physicians are able to obtain Medicare-covered drugs at prices significantly below current Medicare payments. According to a September 2001 GAO report, the average discount from the AWP for most physician-administered drugs ranged from 13 percent to 34 percent; two oncology drugs, in particular—Dolasetron mesylate and Leucovorin—had discounts of 65 percent and 86 percent, respectively.¹¹ As a result of this disparity between the AWP and the providers' actual cost, providers are able to benefit financially from these transactions. (See Figure 1 for an example of this pricing structure.) In certain instances, drug manufacturers may make even deeper discounts available to providers, in exchange for the providers' willingness to prescribe their drugs over those of their competitors. The result is a wide range of unknown prices being paid for prescription drugs by providers, who are then reimbursed a fixed amount by Medicare, leading to widely varying profit margins for different doctors.

Providers argue that they need these additional profits to compensate for the lack of adequate payments for the administration of these drugs under the Medicare physician payment system, the RBRVS. Administration of Part B drugs often involves additional costs resulting from special storage, handling, and preparation requirements for these drugs. The president of the American Society of Clinical Oncology (ASCO), Larry Norton, M.D., stated in testimony that the Medicare reimbursement for chemotherapy services is insufficient to adequately cover the cost of furnishing such services. ASCO estimates that the Medicare reimbursement covers approximately 25 percent of the total costs of chemotherapy procedures.¹² The society supports a reduction in Medicare payment for drugs but not without a simultaneous increase in physician payments for related services.

Other nonphysician health care providers and suppliers who provide beneficiaries with covered drugs for infusion and inhalation therapies using durable medical equipment (DME) and with blood clotting factor for hemophilia also claim that the overpayment on the drugs allows them to provide critical administrative and support services to beneficiaries. Those services are otherwise not covered by Medicare.

FIGURE 1
Medicare Payment vs. Provider Cost for Part B Outpatient Prescription Drugs: An Example



Source: Based on information from U.S. General Accounting Office, Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost, September 2001 (GAO-01-1118), Washington, D.C.

In response to this issue of provider overpayment, the Health Care Financing Administration (HCFA, now the Centers for Medicare and Medicaid Services, or CMS), in the U.S. Department of Health and Human Services (DHHS) issued a memorandum in September 2000 that authorized the use of reduced prices that more accurately reflected provider acquisition costs for reimbursement of Medicare-covered drugs.¹³ The memo states: "These data are from wholesalers' catalogs that list the prices at which the wholesaler sells the respective products. The DOJ has indicated that these are more accurate wholesale prices for these drugs." After significant protest by oncology providers, however, HCFA notified Congress that it would not move forward with its effort to implement revised average wholesale pricing data.

Other Medicare suppliers also purchase drugs at prices that are significantly lower than the AWP. Pharmacy suppliers, who provide two types of drugs—drugs administered through DME and covered oral drugs—were the predominant billers for ten of the high-expenditure and high-volume drugs analyzed by GAO. Discounts for two of these drugs were 78 percent and 85 percent, according to GAO.¹⁴

MEDICAID

The increasing cost of prescription drugs is playing a major role in the dismal outlook for state Medicaid budgets across the country. Prescription drugs constitute a rapidly growing component of total Medicaid spending. Although coverage of outpatient prescription drugs is an optional benefit, all Medicaid programs currently offer prescription drug coverage to their Medicaid enrollees.¹⁵ Medicaid drug expenditures grew at an average annual rate of 18.1 percent between 1997 and 2000, which is more than two times the 7.7 percent annual growth in total Medicaid spending. Drug spending accounted for nearly 20 percent of the increase in Medicaid spending for this period.¹⁶

Medicaid payments for outpatient prescription drugs include three components: *acquisition costs*, *dispensing fees*, and a *rebate*. The acquisition costs cover the ingredients, or the drug itself, while the dispensing fee covers the pharmacist's costs of filling the prescription. The rebate is a mechanism for reducing the effective price of the drug below the traditional acquisition cost.

Acquisition Costs

Federal Medicaid law does not dictate the amount that a state may pay for the drug itself. It does, however, place limits on what the federal government will match. These limits differ for brand-name drugs and generic drugs. For brand-name drugs or for generic drugs with fewer than three generic versions the reimbursement is the lower of (a) the pharmacist's usual and customary charge to the general public and (b)

the drug's estimated acquisition cost.¹⁷ The EAC is a state's estimate of the price generally paid by providers for the drug. States generally use a drug's AWP to calculate its EAC. Most states pay for drugs at a percentage discount below a drug's published AWP.¹⁸ Information compiled by the National Pharmaceutical Council indicates that the reimbursement formulas for state Medicaid agencies range from AWP minus 4 percent in Wyoming to AWP minus 15.1 percent (for pharmacies with more than five stores) in Michigan. (See Appendix 1 for a complete list of the state Medicaid reimbursement formulas.) The average is 10.31 percent below AWP, according to the DHHS Office of Inspector General (OIG). The difference between the pharmacy's cost of obtaining the drug and the reimbursement amount is retained by the pharmacy.¹⁹ According to people within the pharmacy industry, this difference enables pharmacies to cover their costs in states where dispensing fees are inadequate to cover the pharmacy's dispensing costs (which average between \$7 and \$8).

In 1987, Medicaid regulations established the federal upper limit (FUL), which set limits on the amount that Medicaid could reimburse for drugs with three or more generic versions.²⁰ The goal of the FUL was to enable the federal government to recognize savings by taking into account market prices. The payment ceiling for this group of drugs is set at 150 percent of the published price for the least costly therapeutic equivalent that can be purchased by pharmacists in quantities of 100 tablets or capsules.²¹ States may set their own payment ceilings for these drugs, provided they do not exceed the federal payment limit.²²

An August 2001 report by the OIG found that the average acquisition cost paid by pharmacies for brand-name drugs in 1999 was 21.84 percent below AWP. The same report estimated that the Medicaid program could have saved as much as \$1.08 billion if reimbursement had been based on an average discount of 21.84 percent below AWP. The OIG recommended that CMS require states to bring pharmacy reimbursement for brand-name drugs more in line with these actual acquisition costs.²³

Representatives of community pharmacists and chain drug stores had concerns with the methodology and findings of the OIG report and commissioned a study by researchers at the Center for Pharmacoeconomics Studies at the University of Texas at Austin. The center's study identified problems with various aspects of the OIG report, including the categorization of drugs as "brand-name" or "generic" and the use of a disproportionate number of prices from urban chain pharmacies.²⁴ In response to the concerns expressed by these groups, the OIG indicated in early 2002 that it will conduct additional analysis of Medicaid pharmacy pricing data, using a different methodology, as advocated by the concerned groups.²⁵ The results of this analysis were not yet available at the time of this writing.

An investigation by the DOJ and the National Association of Medicaid Fraud Control Units found that some drug manufacturers were reporting inflated

Most states pay for drugs at a percentage discount below a drug's published AWP.

AWPs. As a result of this finding, the DOJ and NAMFCU collected actual wholesale pricing information for 51 drugs, which led to the calculation of revised wholesale prices for those drugs. These revised prices were provided to state Medicaid programs. According to a September 2001 report by the OIG, 30 states use at least some of the revised prices in their drug reimbursement calculations.²⁶ These revised prices, while providing some short-term savings for a limited number of drugs, do not solve the underlying problem of accountability or accuracy of the AWP. CMS continues to explore administrative and legislative solutions to the problem of state overpayment for Medicaid prescription drugs.

Dispensing Fees

In addition to the cost of the drug itself, state Medicaid agencies pay pharmacies a dispensing fee to cover the costs of filling each prescription. According to CMS regulations, the fee must be “reasonable,” though this term is not defined. Each state negotiates and sets its own dispensing fee, leading to wide variation in these fees across the states. A summer 2000 survey commissioned by the Kaiser Commission on Medicaid and the Uninsured and conducted by Health Systems Research, Inc., indicated that dispensing fees range from \$2.50 per prescription in New Hampshire to between \$3.69 and \$15.70 per prescription in Illinois.²⁷

Medicaid Rebates

To fully understand Medicaid reimbursement for prescription drugs, it is important to understand the Medicaid Drug Rebate Program and the pricing mechanisms on which it is based. In response to concern about the increasing cost of prescription drugs for Medicaid beneficiaries, the Medicaid Drug Rebate Program was implemented as part of the Omnibus Budget Reconciliation Act of 1990. This program requires drug manufacturers to sign a rebate agreement with the federal government in order to receive payment for outpatient prescription drugs provided to Medicaid beneficiaries. In exchange, states must cover all Food and Drug Administration-approved prescription drug products manufactured by a company that has signed a drug rebate agreement.²⁸ This process imitates what occurs with large private purchasers, who negotiate discounts in exchange for the placement of particular drugs on their formularies.

The Medicaid rebate amounts are established by federal statute and differ for brand-name and generic drugs. They are determined as follows: For brand-name drugs, reimbursement requires (a) a rebate that is the greater of 15.1 percent of the average manufacturer’s price (AMP) or the difference between the AMP and the manufacturer’s “best price”²⁹ and (b) an additional rebate for any product whose price increased by more than the Consumer Price Index (CPI-U) since July 1, 1990 (see Figure 2 for an example of Medicaid drug reimbursement). AMP is the average price paid to manufacturers by wholesalers (after all discounts, including

Each state negotiates and sets its own dispensing fee, leading to wide variation in these fees across the states.

manufacturer rebates) for a particular dosage form and strength of a prescription drug distributed solely to the retail pharmacy class of trade. The AMP is not a published price. It is calculated by the manufacturer and submitted to CMS for purposes of calculating the Medicaid rebate. The government holds it confidentially, to protect the proprietary nature of the deals negotiated between manufacturers and their best customers. AMP is subject to government audits, making manufacturers accountable for its accuracy. As noted later in the “Reform Options” section, President Bush’s 2003 budget contains a proposal that would replace the AMP with the AWP in the Medicaid rebate calculation. The “best price” was intended to represent the lowest price offered to any other customer, excluding Federal Supply Schedule (FSS) prices, prices to state pharmaceutical assistance programs, and prices for certain other purchasers. In an industry with a proliferation of complex relationships and financing arrangements, however, many question whether the “best price” truly captures the myriad discounts and rebates that exist.

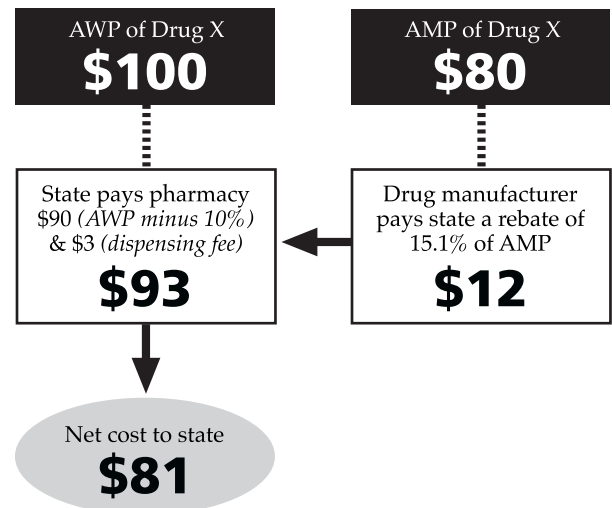
The combined effect of the minimum rebate and the best-price provision guarantees a larger rebate to the government for those drugs for which the best customers are receiving a particularly favorable price. However, it does not actually provide Medicaid with the same low price the best private customers pay. Medicaid’s net price after the rebate is higher because its payment to the pharmacy, which is based on the “AWP minus x” formula, is higher than the AMP. A “best price” rebate based on the difference between the best price and the AMP leaves a higher net price. For generic drugs, reimbursement requires a rebate of 11 percent of each product’s AMP.³⁰

OTHER PUBLIC AND QUASI-PUBLIC PROGRAMS

340B Drug Discount Program

Following implementation of the Medicaid Drug Rebate Program, drug manufacturers had a disincentive to provide deep discounts to non-Medicaid purchasers because the manufacturers would then be required to extend such discounts to Medicaid. Some drug manufacturers chose to raise their “best prices,” thereby increasing the cost to other federal- and state-supported providers. In response, Congress enacted Section 340B of the Public Health Service Act in November 1992, which requires drug manufacturers who participate in the Medicaid program to enter into an agreement with the secretary of health and human services. Under this

FIGURE 2
Medicaid Drug Reimbursement Example



Assumptions:

- A state Medicaid reimbursement formula of AWP minus 10%.
- No state “usual or customary” standard for drug reimbursement.
- A dispensing fee of \$3.00.
- The difference between the drug’s AMP and the manufacturer’s “best price” is not greater than 15.1 percent of the drug’s AMP.
- The drug is not a generic, which would have a rebate of 11% of AMP.

agreement, the manufacturer agrees to provide discounts on drugs purchased by “covered entities” that serve vulnerable patient populations. “Covered entities” include certain high-volume disproportionate share hospitals, as well as specified grantees of the Public Health Service, including certain federally qualified health centers, state-operated AIDS drug assistance programs, public housing primary care clinics, and homeless clinics.

As a condition for participation in Medicaid, the law requires manufacturers to charge covered entities a price for covered outpatient drugs that will not exceed an amount determined by a statutory formula. For most drugs, the discount is the AMP, reduced by a rebate percentage equivalent to the Medicaid rebate amount. (As noted above, that rebate amount is 15.1 percent of AMP for brand-name drugs and 11 percent of AMP for generic drugs.) These discounts are similar to those received by the Medicaid program, but these facilities may negotiate even deeper discounts.

Federal Supply Schedule

Prices paid to manufacturers by the Department of Veterans Affairs (VA), other federal agencies, and certain other entities, such as Indian tribal governments, are set by the FSS for pharmaceuticals. The FSS, which is administered by the VA, is a list of pharmaceutical products and prices that are available to federal entities. Under the Veterans Health Care Act of 1992, manufacturers must make drugs available to covered entities at the FSS price as a condition of eligibility for Medicaid reimbursement.³¹ In addition, manufacturers must sell brand-name drugs that are included in the FSS to the VA, Department of Defense, Public Health Service, and Coast Guard at prices that are at least 24 percent below the nonfederal average manufacturer price, a ceiling price that is lower than the FSS price for many drugs.³² The FSS is derived from actual market transaction data reported by drug manufacturers. Generally, the FSS price may not be higher than the lowest contractual price charged by the manufacturer to any nonfederal purchaser. The VA routinely uses competitive bidding to obtain lower drug prices. According to GAO, this results in prices that are approximately one-third lower than FSS prices. The FSS price is not included in a manufacturer’s “best price” for purposes of calculating the Medicaid rebate.

Enabling Medicare beneficiaries to purchase drugs at FSS prices has, on different occasions, been raised as a possible means of lowering drug costs for this population. Of significant concern, however, is the impact this would have on other purchasers and, ultimately, on the FSS prices themselves. As the number of purchasers with access to FSS prices for prescription drugs increased, manufacturers would inevitably be driven to offset this decrease in revenue with price increases for nonfederal purchasers. This in turn would drive up FSS prices, which are benchmarked against nonfederal purchaser prices.

Manufacturers must make drugs available to covered entities at the FSS price as a condition of eligibility for Medicaid reimbursement.

PRIVATE PAYERS

Private payers, especially large-volume purchasers, are able to negotiate deep discounts with drug manufacturers. Many private payers, including employers and managed care organizations, often contract with pharmacy benefit managers (PBMs) to manage prescription drug benefits for their enrollees. PBMs serve as intermediaries between these third-party payers and drug manufacturers, retail pharmacies, pharmacists, and wholesalers.³³ PBMs base their pharmacy reimbursements on the AWP for brand-name drugs. While they do not actually purchase drugs, except in the case of mail-order business, PBMs are able to negotiate discounts with retail pharmacies and provide incentives for pharmacists' use of less costly generics and on-formulary drugs. They also negotiate with wholesalers for mail-order services and drug manufacturers, who are eager to ensure that their products are included in drug formularies and to encourage the use of their drugs over their competitors' drugs.³⁴ The main streams of revenue for PBMs are manufacturer rebates and the difference between their drug acquisition costs and sales costs for mail-order prescription drugs. PBMs contract with drug manufacturers for rebates that range between 2 percent and 20 percent of a drug's AWP.³⁵

LITIGATION

In addition to significant attention by federal government agencies, drug company pricing practices have also come under attack within the court system. The issue of AWP manipulation can be found in several noteworthy legal actions. These cases will undoubtedly have an impact on future discussions of this issue.

- Bayer Corporation, in September 2000, agreed to pay \$14 million to the United States and 47 states to settle allegations under the federal False Claims Act. The allegations contend that beginning in the early 1990s, Bayer falsely inflated its AWPs, causing physicians, pharmacists, and home health companies to submit fraudulently inflated reimbursement claims to the state Medicaid programs.
- TAP Pharmaceutical Products, Inc., agreed in October 2001 to pay \$875 million to resolve criminal and civil liabilities in connection with its alleged fraudulent drug pricing and marketing conduct with regard to Lupron, a prostate cancer drug. In its case against TAP, the U.S. Government alleged that TAP set its AWP of Lupron far higher than the price for which wholesalers or distributors actually sold the drug, resulting in falsely inflated prices. As part of its settlement agreement, TAP also agreed to report to the OIG, on a quarterly basis, its average sales price (ASP) for all of its products reimbursed by the government.
- The Nevada attorney general filed suit against 12 drug companies, alleging that the companies engaged in deceptive trade practices by manipulating or misstating their drugs' AWPs, leading states, consumers, and others to significantly overpay for drugs.

Private payers are able to negotiate deep discounts with drug manufacturers.

■ The Montana attorney general filed suit against 18 drug companies on February 25, 2002, alleging that they illegally misstated the average wholesale prices of their medications. The attorney general alleges that the drug companies engaged in Medicaid fraud, caused false claims to be made to the state, and participated in deceptive trade practices by manipulating or misstating the average wholesale price of drugs, causing the state, consumers, and others to grossly overpay for prescription drugs.

■ A coalition of consumer groups filed suit in December 2001 against 28 drug companies for manipulating the AWP of drugs covered by Medicare. The lawsuit charges that, since 1993, the companies have engaged in “a pattern and practice” of selling drugs to physicians at prices well below the reimbursement cost charged to Medicare, resulting in violations of consumer laws and racketeering statutes. The plaintiffs estimate that Medicare and individual consumers using the drugs were overcharged more than \$800 million in 2000 alone.

PRESCRIPTION DRUG PRICING REFORM

Experts caution that any attempt to change the current reimbursement system for prescription drugs and, in particular, reliance on the AWP as a pricing benchmark, must be done with careful consideration of the many policy implications. The AWP is utilized across many different settings, and changes in the use of this benchmark are likely to produce varying results in each setting. Policymakers and legislators are considering several questions as they contemplate AWP reform. These include the following:

- How will each stakeholder—purchaser, pharmacy, provider, PBM, drug manufacturer, wholesaler, and patient—benefit or be negatively affected by this change?
- What types of incentives would be created if a new prescription drug pricing benchmark were to be used?
- What is the potential for manipulation of any proposed benchmark?
- Will the proposed system rely on data that can be audited? Who will be responsible for such audits? Are there sufficient resources?
- How, and how often, will these data be updated?
- How can accountability be assured without requiring drug manufacturers to divulge proprietary pricing information?
- What are the implications of making the AMP public?
- To whom will any potential discounts flow?
- How can government and consumer savings be assured?
- What will be the impact on other related payment systems, for example, RBRVS and diagnosis-related group, or DRG? Should the reform of these systems also be contemplated?
- What administrative costs and burdens will be associated with an alternative pricing mechanism?

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Pricing and Reimbursement Reform Options

Different recommendations have been made for the legislative and regulatory reform of the prescription drug reimbursement system. One such recommendation is the adjustment of the percentage below AWP at which Medicaid and Medicare reimburse prescription drugs, making it more reflective of actual acquisition costs. Some experts caution, however, that merely lowering the percentage below AWP at which prescription drugs are reimbursed perpetuates the existing problem by creating incentives for continued AWP manipulation. GAO has recommended that CMS bring reimbursement rates for Medicare Part B-covered drugs more in line with provider acquisition costs and evaluate expanding competitive bidding approaches to setting payment levels.³⁶

As noted previously, attempts to bring Medicare drug reimbursement rates more in line with market prices have been met with much resistance from providers. Oncologists, in particular, argue that the higher drug payments they receive for chemotherapy drugs are needed in order to compensate them for the inadequate payments they receive from Medicare for the services they provide in administering the drugs.³⁷

Another proposed reform is the replacement of the AWP with a different reportable figure. For example, the House Energy and Commerce Committee has proposed requiring drug manufacturers to report a new figure, the average sales price, that reflects the true cost of purchasing prescription drugs, including manufacturer-provided rebates, charge backs, and other discounts to purchasers. Medicare reimbursement would then be based on this new ASP. This new system would replace use of the AWP.³⁸

While the ASP proposal appears to replace the AWP with a figure that is more closely aligned with the actual cost of prescription drugs, the appropriateness of such a figure, like AWP, will hinge on the manner in which it is calculated, reported, and employed. The "true cost" of drugs varies widely within the industry, making a standard price difficult to capture. For example, some rebates are designed in such a way that they are not tied to a particular drug, perhaps to avoid having them count in the Medicaid "best price" determination. Given the intense legislative debate currently taking place around the establishment of a comprehensive Medicare prescription drug benefit and the sensitivity of prescription drug pricing to the many stakeholders involved, the details (for example the relationship between ASP and AMP) necessary to fully evaluate the different legislative proposals have not been made publicly available.

A third option for reform would be to move to a competitive bidding process, a reform that has been recommended by the majority staff of the House Ways and Means Committee. The AWP system of Medicare drug reimbursement would be replaced entirely. Contract entities would competitively bid with CMS to provide covered drugs. Physicians would purchase drugs through these entities at the best possible price in order to retain the difference between their cost and the reimbursement rate

from CMS. The CMS payment would be based on the average of all the bids by contract entities for a particular drug. Physicians would continue to receive an additional payment for the administration of the drug.

While the idea of injecting greater competition into the Medicare drug reimbursement system would seem like one that would garner significant support, efforts to use competitive pricing within the Medicare program in the past have not been successful.³⁹ One exception to this has been the Medicare DME competitive bidding demonstration, which has experienced some success.

And finally, included in Bush's proposed 2003 budget is a provision that would alter the way in which the Medicaid drug rebate is calculated. As discussed above, the rebate is currently calculated from the difference between the manufacturer's "best price" and the AMP. The budget proposal would substitute the AWP for the AMP, making it more reflective of how states purchase drugs. This would eliminate the need for two distinct pricing mechanisms within one system, one for state Medicaid reimbursement formulas and the second for calculation of the Medicaid rebate. According to the budget proposal, this change would generate \$290 million in savings for 2003 and \$5.5 billion over five years. With the Medicaid rebate calculation tied to a drug's AWP, manufacturers would arguably have an incentive to keep AWP's lower, whereas a higher AWP would increase the reimbursement received by pharmacies. Removing the AMP from the Medicaid rebate calculation also eliminates the accountability and auditability that comes with the use of a figure that is highly proprietary and reported directly by manufacturers to the federal government.

CONCLUSION

The AWP, a pricing mechanism that by most accounts is seriously flawed and not widely understood, plays a pivotal role in the overall prescription drug pricing and reimbursement systems. It has become a critical benchmark for key stakeholders, despite its inability to accurately reflect the "true cost" of drugs. Yet, as we have seen, the true cost of a given drug depends on the various discounts, rebates, and reimbursement formulas available to a particular purchaser—both public and private. Other alternatives to the AWP may suffer from similar flaws, namely, being subject to manipulation and not closely aligned with real market transaction prices. The creation of an appropriate payment mechanism for prescription drugs, therefore, will need to involve a careful balance between protecting the proprietary nature of drug pricing information and ensuring the accuracy of, and accountability for, the information on which such a payment mechanism is based.

The AWP has become a critical benchmark for key stakeholders, despite its inability to accurately reflect the true cost of drugs.

GLOSSARY

Average Manufacturer's Price (AMP)—AMP is the average price paid to manufacturers by wholesalers (after discounts) for a particular dosage form and strength of a prescription drug distributed solely to the retail pharmacy class of trade. The AMP is not a published price. It is calculated by the manufacturer and submitted to CMS for purposes of calculating the Medicaid rebate.

Average Sales Price (ASP)—As defined in the TAP Corporate Integrity Agreement, ASP is the average of all final sales prices charged for the product in the United States to all purchasers, excluding those sales that are exempt from inclusion in the “best price” for Medicaid drug rebate purposes.

Average Wholesale Price (AWP)—AWP is a figure that is reported by commercial publishers of drug pricing data, based on wholesale pricing information provided to them by drug manufacturers. This published pricing information is purchased by government entities, private insurance companies, and other purchasers and serves as the basis for prescription drug reimbursement. The AWP has often been equated with a “sticker price” or “list price.”

Estimated Acquisition Cost (EAC)—The EAC is a state's estimate of the price generally paid by providers for a particular drug. Most states use a drug's AWP to calculate the drug's EAC.

Federal Supply Schedule (FSS)—The FSS is derived from actual market transaction data reported by drug manufacturers. Generally, the FSS price may not be higher than the lowest contractual price charged by the manufacturer to any nonfederal purchaser. Prices paid to manufacturers by the Department of Veterans Affairs (VA), other federal agencies, and certain other entities, such as Indian tribal governments, are set by the FSS.

Federal Upper Limit (FUL)—The federal payment ceiling that applies to drugs with three or more generic versions. The FUL is set at 150 percent of the published price (in any of the published compendia of cost information for drugs) for the least costly therapeutic equivalent that can be purchased by pharmacists in quantities of 100 tablets or capsules.⁴⁰

Maximum Allowable Cost (MAC)—MACs represent upper limit prices that an insurer or health plan will reimburse for generically available or multiple source medications. This typically follows the initiative for reimbursement by the Medicare or Medicaid program when more than two generic drugs are available in the marketplace.⁴¹

Wholesale Acquisition Cost (WAC)—The manufacturer's charge to the wholesaler to purchase the drug. The WAC is a published price and does not generally reflect any rebates or discounts. It is often referred to as the “catalogue” price.

ENDNOTES

1. Growth of prescription drug spending at retail outlets exceeded that of other health services by a wide margin, increasing 17.3 percent in 2000, the sixth consecutive year of double-digit growth. See Katharine Levit, Cynthia Smith, Cathy Cowan, Helen Lazenby, and Anne Martin, "Inflation Spurs Health Spending In 2000," *Health Affairs*, 21, no. 1 (2002): 172.
2. Medical Economics Staff, *Red Book*, 106th ed. (Montvale, N.J.: Thomson Medical Economics, 2002), 169.
3. William J. Scanlon, "Medicare Part B Drugs: Program Payments Should Reflect Market Prices," testimony before the Subcommittee on Health and the Subcommittee on Oversight and Investigations, U.S. House Committee on Energy and Commerce, September 21, 2001 (GAO-01-1142T), U.S. General Accounting Office, Washington, D.C., 4; accessed May 20, 2002, at <http://www.gao.gov/new.items/d011142t.pdf>.
4. Thomas Scully, testimony before the Senate Finance Committee, Subcommittee on Health, hearing on Reimbursement and Access to Prescription Drugs under Medicare Part B, U.S. Senate, March 14, 2002, Washington, D.C.; accessed May 20, 2002 at <http://finance.senate.gov/hearings/testimony/031402tstest.pdf>.
5. Medicare Part A currently covers prescription drugs administered during a Medicare-covered inpatient stay. In this setting, drug costs are bundled into the diagnosis-related group (DRG) payment so the AWP is not an issue for the government.
6. A program memorandum issued on May 15, 2002, by the Centers for Medicare and Medicaid Services provided guidance for carriers to assist them in determining whether a drug or biological is "not usually self-administered by the patient," as outlined in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA). The memo states that drugs will be excluded from Medicare coverage if they are administered by the patient more than 50 percent of the time. See Centers for Medicare and Medicaid Services, Program Memorandum to Intermediaries/Carriers, "Medicare Payment for Drugs and Biologicals Furnished Incident to a Physician's Service" (Transmittal AB-02-072, CMS-Pub. 60AB), U.S. Department of Health and Human Services, Washington, D.C., May 15, 2002; accessed June 12, 2002, at <http://www.hcfa.gov/pubforms/transmit/AB02072.pdf>.
7. Scully, testimony.
8. Scanlon, *Medicare*, 4.
9. Scanlon, *Medicare*, 4.
10. Scanlon, *Medicare*, 5.
11. Scanlon, *Medicare*, 6.
12. Larry Norton, testimony before the Senate Committee on Finance, Subcommittee on Health, March 14, 2002, Washington, D.C.
13. Centers for Medicare and Medicaid Services, Program Memorandum to Intermediaries/Carriers, "An Additional Source of Average Wholesale Price Data in Pricing Drugs and Biologicals Covered by the Medicare Program" (Transmittal AB-00-86, HCFA-Pub. 60AB), U.S. Department of Health and Human Services, Washington, D.C., September 8, 2000; accessed May 20, 2002, at <http://www.hcfa.gov/pubforms/transmit/AB0086.pdf>.
14. Scanlon, *Medicare*, 7.
15. Brian K. Bruen, "Medicaid and Prescription Drugs: An Overview," Kaiser Commission on Medicaid and the Uninsured, Washington, D.C., October 2000, 2; accessed May 20, 2002, at <http://www.kff.org/content/2000/2202/mcaidandrx.pdf>.
16. Andy Schneider and Linda Elam, "Medicaid: Purchasing Prescription Drugs," Kaiser Commission on Medicaid and the Uninsured, Washington, D.C., January 2002, 1.
17. Office of Inspector General (OIG), "Medicaid Pharmacy—Actual Acquisition Cost of Brand Name Prescription Drug Products" (A-06-00-00023), U.S. Department of Health and Human Services, Washington, D.C., August 2001; accessed May 20, 2002, at <http://oig.hhs.gov/oas/reports/region6/60000023.htm>.
18. In some states, reimbursement is based on the lower of (a) the AWP minus some percentage or (b) the "usual and customary" charge to the public for the drug.

19. Schneider and Elam, "Medicaid: Purchasing," 17.
20. Health Care Financing Administration, "Federal Upper Limit on Drugs"; accessed May 20, 2002, at <http://www.hcfa.gov/medicaid/drugs/drug10.htm>.
21. Schneider and Elam, "Medicaid: Purchasing," 17.
22. Schneider and Elam, "Medicaid: Purchasing," 17.
23. OIG, "Medicaid Pharmacy."
24. Center for Pharmacoeconomics Studies, *A Review of the HHS Office of Inspector General Report: Medicaid Pharmacy—Actual Acquisition Cost of Brand Name Prescription Drug Products*, University of Texas at Austin, December 2001.
25. Thomas D. Roslewicz, Deputy Inspector General for Audit Services, U.S. Department of Health and Human Services, letter to Lawrence Kocot of the National Association of Chain Drug Stores, Washington, D.C., undated.
26. Office of Inspector General (OIG), "Medicaid's Use of Revised Average Wholesale Prices" (OEI-03-01-00010), U.S. Department of Health and Human Services, Washington, D.C., September 2001; accessed May 20, 2002, at <http://www.hhs.gov/oig/oei>.
27. Renee Schwalberg et al., "Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey and Selected Case Study Highlights," Kaiser Commission on Medicaid and the Uninsured, Washington, D.C., October 2001, 24.
28. Bruen, "Medicaid," 4.
29. National Pharmaceutical Council, "Pharmaceutical Benefits under State Medical Assistance Programs," National Pharmaceutical Council, Reston, Virginia, 2000.
30. Bruen, "Medicaid," 4.
31. U.S. Department of Health and Human Services, "Report to the President: Prescription Drug Coverage, Spending, Utilization, and Prices," Washington, D.C., April 2000; accessed May 20, 2002, at <http://aspe.hhs.gov/health/reports/drugstudy/>.
32. U.S. General Accounting Office (GAO), *Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes*, GAO Report (GAO/HEHS-00-118), Washington, D.C., August 2000.
33. Robin J. Strongin, "The ABCs of PBMs," Issue Brief No. 749, National Health Policy Forum, Washington, D.C., October 27, 1999, 2.
34. Veronica V. Goff, "Pharmacy Benefit Managers: A Model for Medicare?" Issue Brief No. 765, National Health Policy Forum, Washington, D.C., July 9, 2001, 3.
35. Goff, "Pharmacy," 3.
36. U.S. General Accounting Office, *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost*, September 2001 (GAO-01-1118), Washington, D.C., 5; accessed June 6, 2002, at <http://www.gao.gov/new.items/d011118.pdf>.
37. Norton, testimony.
38. Rep. W. J. "Billy" Tauzin and Rep. Michael Bilirakis, letter to Thomas Scully, administrator, Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services, Washington, D.C., November 14, 2001; accessed on June 4, 2002, at http://energycommerce.house.gov/107/letters/11142001_421.htm.
39. See Nora Super Jones, "Medicare Competitive Pricing: Lessons Being Learned in Phoenix and Kansas City," Issue Brief No. 750, National Health Policy Forum, Washington, D.C., November 8, 1999. Some analysts are of the opinion that competitive bidding may work but could be administratively burdensome. It may also be subject to manipulation by manufacturers and could lead to the unavailability of certain drugs.
40. Schneider and Elam, "Medicaid: Purchasing," 17.
41. F. Randy Vogenberg and Joanne Sica, *Managing Pharmacy Benefits* (Brookfield, Wis.: International Foundation of Employee Benefit Plans, 2001), 153.

Appendix 1: Pharmacy Payment and Patient Cost Sharing

| State | Dispensing Fee | Ingredient Reimbursement Basis | Copayment |
|---------------|---|---|---|
| Alabama | \$5.40 | AWP- 10%; WAC+9.2% | \$0.50 - \$3.00 |
| Alaska | \$3.45 | AWP-5% | \$2.00 |
| Arizona* | - | - | - |
| Arkansas | \$5.51 | AWP-10.5% | \$0.50 - \$3.00 |
| California | \$4.05 | AWP-5% | \$1.00 |
| Colorado | \$4.00 | AWP-11% or WAC+18%, whichever is lowest | G: \$0.75, B: \$3.00 |
| Connecticut | \$4.10 | AWP-12% | None |
| Delaware | \$3.65 | AWP-12.9% | None |
| DC | \$3.75 | AWP-10% | \$1.00 |
| Florida | \$4.23-\$4.73 | AWP-13.25%; WAC+7% | None |
| Georgia | \$4.63 + \$0.50 for G or P | AWP-10% | G/P: \$0.50, B/NP: \$0.50 - \$3.00 |
| Hawaii | \$4.67 | AWP-10.5% | None |
| Idaho | \$4.94 (\$5.54 for unit dose) | AWP-12% | None |
| Illinois | G: \$5.10, B: \$4.00 | AWP-11% | \$1.00 |
| Indiana | \$4.00 | AWP-10% | \$0.50 - \$3.00 |
| Iowa | \$5.17 | AWP-10% | \$1.00 |
| Kansas | \$4.50 | AWP-10%, IV AWP-50%, blood AWP-30% | \$2.00 |
| Kentucky | \$4.50 | AWP-10% | None |
| Louisiana | \$5.77 | AWP-13.5% (AWP-15% for chains) | \$0.50 - \$3.00 |
| Maine | \$3.35 (+extra fees for compounding) | AWP-10% | \$0.50 - \$3.00 |
| Maryland | \$4.21 | Lowest of :WAC+10%, direct+10%, AWP-10% | \$1.00 |
| Massachusetts | \$3.00 | WAC+10% | \$0.50 |
| Michigan | \$3.72 | AWP-13.5% (1-4 stores), AWP-15.1% (5+stores) | \$1.00 |
| Minnesota | \$3.65 | AWP-9% | None |
| Mississippi | \$4.91 | AWP-10% | \$1.00 |
| Missouri | \$4.09 | AWP-10.43%, WAC+10% | \$0.50 - \$2.00, \$5.00 for some 1115 pop. |
| Montana | \$2.00 - \$4.20 | AWP-10%, direct price for some labelers | G: \$1.00, B: \$2.00 |

continued

Appendix 1 (cont.)

| State | Dispensing Fee | Ingredient Reimbursement Basis | Copayment |
|----------------|--|--|--|
| Nebraska | \$3.84 - \$5.05 | AWP-10% | \$1.00 |
| Nevada | \$4.76 | AWP-10% | None |
| New Hampshire | \$2.50 | AWP-12% | G: \$0.50, B: \$1.00 |
| New Jersey | \$3.73 - \$4.07 | AWP-10%, WAC+30%, AAC for injectables | None |
| New Mexico | \$4.00 | AWP-12.5% | None (except CHIP and working disabled) |
| New York | B: \$3.50 G: \$4.50 | AWP-10% | G: \$0.50, B: \$2.00 |
| North Carolina | \$5.60 | AWP-10% | \$1.00 |
| North Dakota | \$4.60 | AWP-10% | None |
| Ohio | \$3.70 | AWP-11% | None |
| Oklahoma | \$4.15 | AWP-12.0% | \$1.00 - \$2.00 |
| Oregon | Retail: \$3.50 Inst./ NF: \$3.80 | AWP-13% | None |
| Pennsylvania | \$4.00 | AWP-10% | \$1.00 (\$2.00 for GA) |
| Rhode Island | OP: \$3.40, LTC: \$2.85 | WAC+5% | None |
| South Carolina | \$4.05 | AWP-10% | \$3.00 |
| South Dakota | \$4.75 (\$5.55 for unit dose) | AWP-10.5% | \$2.00 |
| Tennessee* | - | - | - |
| Texas | (EAC+\$5.27)/ 0.98 & delivery fee | AWP-15% or WAC+12%, whichever is lowest | None |
| Utah | \$3.90-\$4.40 (based on area) | AWP-12% | \$1.00, max. \$5.00/mo. |
| Vermont | \$4.25 | AWP-11.9% | \$1.00 - \$2.00 |
| Virginia | \$4.25 | AWP-9% | \$1.00 |
| Washington | \$4.14-\$5.12 (based on annual # of Rx) | AWP-11% | None |
| West Virginia | \$3.90 (+ extra \$1.00 for compounding) | AWP-12% | \$0.50 - \$2.00 |
| Wisconsin | \$4.88 (to a maximum \$40.11) | AWP-11.25% | \$1.00, max. \$5/ recip./ pharm./mo. |
| Wyoming | \$5.00 | AWP-11% | \$2.00 |

WAC = Wholesalers' Acquisition Cost; AWP = Average Wholesale Price; EAC = Estimated Acquisition Cost; AAC = Actual Acquisition Cost; G = Generic; B = Brand Name; OP = Outpatient; LTC = Long-Term Care; P = Preferred; NP = Nonpreferred.

*Within federal and state guidelines, individual managed care and pharmacy benefit management organizations make formulary/drug decisions.

Source: As reported by state drug program administrators in the 2001 National Pharmaceutical Council Survey.