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REPORT

Medicaid

Drug Spending and the Average Wholesale Price: Removing the AWP Albatross From Medicaid's Neck

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Introduction

State budgets are straining under the weight of Medicaid spending.[1] Congressional representatives and the Bush administration are proposing deep cuts and drastic changes to federal funding of the Medicaid program. The greatest increase in Medicaid spending in the past 10 years has been on outpatient prescription drugs, which grew from 5 percent of Medicaid spending in 1992 to 11 percent in 2003.[2] The

[1] States' general fund support for Medicaid in 2006 is predicted to increase 26 percent more than overall state general fund spending, with 21 states facing Medicaid funding increases greater than 10 percent. *State Budget & Tax Actions 2005: Preliminary Report*, National Conference of State Legislatures, http://ncsl.org/programs/fiscal/presbta05.htm (accessed Aug. 24, 2005).

[2] Brian Bruen and Arunabh Ghosh, *Medicaid Prescription Drug Spending and Use*, Kaiser Commission on Medicaid and the Uninsured, June 2004, 4.

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amount spent on prescription drugs increases every year, as the price of drugs continues to outpace inflation.[3] Centers for Medicare & Medicaid Services actuaries estimate that in 2005 Medicaid drug spending will top $40 billion and account for 18 percent of total national drug spending, making Medicaid the largest single purchaser of drugs in the nation.[4] Congress and state governments are trying to address Medicaid budget shortfalls by restricting Medicaid eligibility, cutting benefits and covered services, and increasing copayments and premiums. However, such approaches ignore one of the greatest contributors to the growing Medicaid expenditure on prescription drugs: the manipulation of the pricing benchmark on which virtually the entire Medicaid drug payment system relies—the Average Wholesale Price (AWP). It is estimated that the pharmaceutical industry overcharges Medicaid an estimated $1 billion a year through AWP inflation. Replacing the use of AWP with a more verifiable benchmark could save Medicaid at least $5.2 billion over five years.[5] With Congress looking to cut more than $10 billion over five years from federal Medicaid spending, switching from AWP to a more accurate pricing basis could achieve over half this savings target.

AWP is a reference price printed in commercial price publications such as the *Blue Book* and the *Red Book*. It is used by 48 state Medicaid programs and the overwhelming majority of private third-party payors as the basis upon which they pay for prescription drugs. Despite its dominant position, AWP is a term that has not been defined in law or regulation, and it has no empirical basis in actual market transactions.[6] In fact, critics ranging from consumer advocates to congressional representatives to the federal Office of the Inspector General (OIG) allege that the AWP is a fictitious figure, invented out of whole cloth by drug companies to increase their market share. Manufacturers report ''wholesale'' pricing data (both AWP and Wholesale Acquisition Cost, or WAC, which is supposed to represent the average price paid by wholesalers to manufacturers) for their drugs to the *Blue Book* and other publications. These publications essentially reprint the information the manufacturers have given them, with no verification of the accuracy of the data. Thus, AWP bears no relationship to any actual price paid by anyone.[7] Yet most states and private health insurers continue to base their reimbursement formulas on a fixed discount from AWP (e.g. AWP minus 10 percent), largely because no alternative, more accurate data source for drug pricing is available.

The resulting Medicaid payment system is easily gamed by providers and manufacturers, provides reimbursements that often bear little relation to the cost to providers of acquiring medications, and results in dramatic overpayments for drugs. The OIG estimates that overpayments due to inaccuracies in AWP totaled $1.5 billion in 1999 alone, and Department of Health and Human Services Secretary Michael Leavitt stated that reforming the system would save the federal government approximately $15 billion and state governments roughly $11 billion over the next 10 years.[8]

Momentum for reforming this system has been building for several years. A nationwide class action lawsuit against 19 of the largest drug manufacturers is proceeding in federal court,[9] and many state attorneys general have filed their own suits to recoup Medicaid overpayments resulting from inflated AWPs.[10] California's attorney general recently expanded that state's AWP lawsuit to include 39 drug companies as defendants.[11] The Medicare Prescription Drug, Improvement, and Modernization Act (the Medicare Modernization Act) changed the reimbursement formula for physician-administered drugs covered under Medicare Part B from AWP to a new, presumably more transparent benchmark called the ''Average Sales Price'' (ASP). In the past two years, two different congressional committees have held hearings on AWP, and the Bush administration included a proposal in its fiscal year 2006 budget to switch Medicaid to an ASP-based reimbursement system. CMS, the National Governors Association, and the House Committee on Energy and Commerce have proposed changes to Medicaid drug reimbursement that would do away with AWP. With the drug industry under fire and Medicaid spending under the microscope, the time is ripe for federal reform of AWP.

This paper will provide context on this issue by outlining how and why AWP inflation occurs, why states have not been able to address the issue on their own,

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[3] Price inflation for prescription drugs averaged 7.4 percent a year from 1993-2003, while overall inflation averaged 2.5 percent. *Prescription Drug Trends: A Fact Sheet*, Kaiser Family Foundation, June 2004.

[4] Stephen Heffler, Sheila Smith, Sean Keehan, Christine Borger, M. Kent Clemens, and Christopher Truffer, ''U.S. Health Spending Projections, 2004-2014,'' *Health Affairs*, Feb. 23, 2005.

[5] The Bush administration estimates that its proposal to replace AWP with ''Average Sales Price'' (ASP – see ___) would save $5.4 billion over five years. The Congressional Budget Office estimates that the savings would be $5.2 billion over five years. *See ''Testimony of Dennis G. Smith, Director Center For Medicaid And State Operations In The Centers For Medicare & Medicaid Services On Medicaid Oversight Before The Senate Finance Committee'' June 28, 2005* http://finance.senate.gov/hearings/testimony/2005test/DStest062805.pdf (accessed Aug. 25, 2005).

[6] Dawn M. Gencarelli, *Average Wholesale Price for Prescription Drugs: Is There a More Appropriate Pricing Mechanism?* NHPF Issue Brief No. 775, Washington, D.C.: National Health Policy Forum, June 7, 2002, 3; Steven Schondelmeyer and Marion Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices, Final Report*, Abt Associates Inc., Contract No. 500-00-0049, Task Order 1, Prepared for CMS, Aug. 30, 2004, 14-15. Some manufacturers claim that AWP is actually determined by the price compendia publishers or wholesalers. However, even when publishers or wholesalers calculate AWP, it is generally as a fixed percentage (usually 20-25 percent) above WAC, which is set by manufacturers.

[7] Schondelmeyer and Wrobel, 21. A frequently repeated joke says that AWP stands for ''Ain't What's Paid.''

[8] HHS Office of the Inspector General, Testimony of George Reeb Before the House Committee on Ways and Means Subcommittee on Health, Oct. 3, 2002, 4; Federal Drug Discount and Compliance Monitor, vol. 2 no. 2, February 2005, 10.

[9] *In re Pharmaceutical Average Wholesale Price Litigation*, (D. Mass.) MDL No. 1456. Members of the PAL coalition, which one of the authors of this article coordinates, are plaintiffs in this lawsuit.

[10] These include Alabama, California, Connecticut, Florida, Illinois, Kentucky, Massachusetts, Missouri, New York, Ohio, Pennsylvania, Wisconsin, and others.

[11] ''Drugmakers inflated prices, Calif. suit claims,'' Julie Schmit, *USA Today*, Aug. 26, 2005 http://www.usatoday.com/money/industries/health/drugs/2005-08-25-calif-ag-usat_x.htm (accessed Aug. 26, 2005).

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and why federal reform is necessary to solve the problem.

How the Structure of the Market for Prescription Drugs and Current Reimbursement Policy Lead to AWP Inflation

Problems with AWP inflation stem from current drug reimbursement policies and the structure of the prescription drug market, in which nearly all providers and payors negotiate to purchase or reimburse for drugs at a certain percentage below AWP, plus a fixed dispensing fee. For state Medicaid programs, these AWP-based formulas usually are written into law.[12] All but two states reimburse pharmacies for drugs at AWP minus a percentage that varies from 5 percent to 20 percent (the average is 10.6 percent).[13]

Despite the fact that AWPs are self-reported and not based on any actual sales figures or pricing data, the determination of AWP is fairly consistent for the majority of the more than 60,000 individual drug products on the market. For most brand-name drugs, AWP is usually 20 percent to 25 percent above the Wholesale Acquisition Cost (WAC). This does not mean that AWPs are accurate, since WACs also are self-reported and unverified. However, it does at least partly explain why Medicaid programs and private health plans continue to trust and rely upon AWP figures.

The fixed reimbursement formulas based on AWP used by Medicaid programs give drug manufacturers strong incentives to inflate the AWPs they report to commercial publishers and to sell drugs to pharmacies, hospitals, and doctors' offices at lower prices (the ''Actual Acquisition Cost''). By creating a ''spread'' between what these providers pay to acquire drugs and the reimbursements they receive, drug manufacturers can create a financial incentive for providers to prescribe, purchase, or carry their products over competitors'. This incentive can be used to increase market share.[14] Institutional purchasers are able to retain this spread as profit, and thus can be tempted to purchase a particular drug because of the size of the spread rather than its clinical effectiveness, or (in the case of competing but equally effective drugs) its cost savings to the ultimate payor (e.g. Medicaid, private health plans, or a cash-paying patient). In fact, some companies have explicitly promoted their drugs to doctors or pharmacies based on the additional profits those purchasers can make from the spread, a practice known as ''marketing the spread.''[15]

Since AWPs are self-reported by manufacturers to the pricing publications and subject to no review or auditing, the AWP-based reimbursement system allows drug manufacturers to dictate the price at which providers will be reimbursed. Such an unregulated system all but invites fraud. By paying for drugs based on AWP, state Medicaid programs are essentially signing a blank check for their prescription drugs. ''Spreads,'' at their most extreme, can reach into the thousands of percentage points. The national class action lawsuit challenging AWP alleges individual spreads of 1,382 percent (Methylprednisolone Sodium Succinate), 7,574 percent (Vancomycin Hydrochloride), 12,531 percent (Gentamicin Sulfate), and 15,671 percent (Dextrose Sodium Chloride).[16]

Marketing the spread is a logical response to the structure of the drug market, in which there is a disconnect between those who pay for drugs (Medicaid, private insurers, and patients) and those who determine which drugs will be prescribed (physicians, as well as pharmacies, who, in the case of generic drugs, decide which of several competing generic brands to carry[17]). Drug manufacturers naturally direct most of their competitive energy and marketing dollars toward physicians, who determine which drug will be purchased.[18] However, because physicians and pharmacies do not pay the final bill, they are insulated from the effects of AWP inflation, as are the majority of patients, who pay a copayment for their drugs. Under this system, manufacturers have no incentive to reduce the overall cost of the drug. Rather, they are encouraged to increase the cost in order to maximize the spread. This system increases the overall cost to Medicaid and the health care system as a whole while adding nothing of value.

The competitive aspect of AWP inflation has been documented in a number of government and private reports on the subject. For example, the OIG found in a 1999 study that the acquisition costs to pharmacies for a sample of brand-name drugs covered under Medicaid averaged 21.84 percent below AWP, while generics averaged 65.93 percent below AWP.[19] In 2004, the Congressional Budget Office reported that the acquisition costs to pharmacies for generic drugs, as a percentage of Medicaid reimbursements, were both much lower

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[12] See, e.g., Fla. Stat. § 409.908(14) (''The Medicaid maximum allowable fee for ingredient cost will be based on the lower of: average wholesale price (AWP) minus 15.4 percent, Wholesaler Acquisition Cost (WAC) plus 5.75 percent, the Federal Upper Limit (FUL), the State Maximum Allowable Cost (SMAC), or the usual and customary (UAC) charge billed by the provider.''), and Minn. Stat. § 256B.0625, subd. 13 (''The actual acquisition cost of a drug shall be estimated by the commissioner, at Average Wholesale Price minus 12 percent'').

[13] The remaining states reimburse pharmacies at a fixed markup from Wholesale Acquisition Cost (WAC), another widely available list price. See Gencarelli, 19; Reeb Testimony, 3.

[14] Congressional Budget Office, *Medicaid's Reimbursements to Pharmacies for Prescription Drugs*, December 2004, 2; Schondelmeyer and Wrobel, 8.

[15] Perhaps the most famous—and infamous—example of this concerned the prostate cancer drug, Lupron, manufactured by TAP Pharmaceuticals. Federal prosecutors and state attorneys general reached the largest-ever health care fraud settlement with TAP, worth $875 million in damages and penalties, to resolve allegations of marketing the spread. A nationwide class action lawsuit brought by consumers and third-party payors resulted in a $150 million civil settlement.

[16] *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 263 F.Supp.2d 172, 178 (D. Mass., 2003).

[17] AWP inflation is particularly acute in the generic drug market.

[18] Ben Harder, ''Pushing Drugs: How Medical Marketing Influences Doctors and Patients,'' *Science News* July 30, 2005; Vol. 75. According to IMS Health data quoted in the article, manufacturers spent $21.7 billion on detailing and free samples in 2003, compared with $3.2 billion on direct to consumer advertising.

[19] Office of the Inspector General, Department of Health and Human Services, Testimony of George Reeb Before the House Committee on Ways and Means Subcommittee on Health, Oct. 3, 2002, 4.

than the percentage for brand-name drugs and much more variable. While acquisition costs for brand-name drugs remained constant at 85 percent of Medicaid reimbursements, the acquisition costs of generics fluctuated between 26 percent and 36 percent of what Medicaid reimbursed pharmacies.[20]

Competition is clearly an important factor that leads manufacturers to discount prices to providers through rebates. In some cases, it has led drug manufacturers to conspire with providers to illegally inflate AWPs. In 2000, Bayer agreed to pay the federal government and 47 states $14 million to settle allegations that the company illegally inflated AWPs to market the spread on its drugs to physicians and pharmacists, causing them to submit inflated claims to state Medicaid programs.[21] In 2001, TAP Pharmaceuticals agreed to pay the federal government $875 million to resolve criminal and civil charges that it illegally inflated the AWP for Lupron, a cancer drug covered by Medicare, to encourage doctors and pharmacies to submit false claims.[22]

The Lack of Transparency and Accurate Price Data Make AWP Inflation Possible

The practice of reporting inflated and inaccurate AWPs is made possible by a lack of transparency in drug pricing and sales, and the fact that there is no accurate market price information available to states and other payors. The large number of actors in the chain of drug distribution and financing, the various discounts and rebates that drug prices are subject to, and the secrecy surrounding nearly all transactions and prices makes the actual price of any particular drug at any point in the distribution chain difficult, if not impossible, to determine. This lack of transparency makes it impossible to determine the actual acquisition cost of providers, which in turn makes it impossible to set accurate reimbursements.

As in many markets, individual negotiated sales prices of drugs are held confidentially. However, the prescription drug market is unique in that there are no pricing indices that provide accurate, aggregate market price information. List price data published in the *Red Book* and the *Blue Book* are the most accessible data, but are unreliable since they are not based on actual market transactions.[23] Despite this fact, Medicaid programs and private health plans continue to regard AWP as a reliable benchmark. Such payors are caught in a Catch-22—they must rely on the AWP data because no real alternatives exist but cannot verify its accuracy. An alternative form of information is pharmacy point-of-sale data, which can be purchased from firms such as IMS Health. These data are based on cash register transactions from a large sample of retail pharmacies and are primarily used by drug manufacturers to track drug sales and market share.[24] However, these data do not capture the numerous time-delayed rebates that reduce the ultimate net price paid for a given drug.[25]

Price comparison and benchmark methods used in other industries, such as looking at ''shadow'' prices in a secondary market, or empirically determining prices through buyer surveys, are not feasible with drugs due to the large number of drug products (60,000+) and the unique nature of the pharmaceutical market. The Prescription Drug Marketing Act of 1988 requires drugs to be sold through licensed wholesalers, restricts the resale of medications, and prevents the sale of drugs between health care providers.[26] The regulation of the supply chain, combined with the number of players in that chain, makes the type of price comparison common to other industries nearly impossible. Along with patent protection that gives manufacturers a monopoly (and thus complete control over price) over ''single source'' brand-name drugs, this absence of a secondary market allows drug manufacturers to price discriminate by setting different prices for different customers or classes of customers. While necessary for drug safety, these laws heighten the market's lack of transparency.

The federal government maintains a number of price databases, but many of them, such as direct purchase data held by the Veterans Health Administration, are not available to states or contain prices well below what the private providers reimbursed by states can attain. Even those that are relevant to state drug programs are not available to states, however. For example, CMS collects ''Average Manufacturer Price'' (AMP) data from drug manufacturers to calculate the Medicaid drug rebate, which manufacturers are required to pay to states under the Medicaid program.[27] AMP is defined as the average net price paid to manufacturers by wholesalers, and it is calculated based on manufacturer reporting of sales data that is subject to audit by CMS.[28] AMP is considered to be more accurate than AWP, but it only includes sales to wholesalers, and it most likely does not capture all forms of rebating.[29]

While this information is used by CMS to calculate payments made to states, states are not able to access this data, even to verify that they are receiving the correct rebates. Instead, the system places CMS between states and manufacturers, and the agency operates much like a pharmaceutical benefits manager (PBM), calculating manufacturer discounts based on client utilization. The underlying AMP data are held confidential by CMS. In general, the current state-federal regulatory structure tends to limit price transparency: even though the use of AMP as a benchmark would result in more accurate reimbursements than AWP, states cannot use the price because the data is kept secret.

With data from public agencies unavailable, Medicaid agencies and private payors are forced to rely on private data sources and limited publicly available government data. The main problem with both private

[20] CBO December 2004, 4-5.
[21] Gencarelli, 11.
[22] Ibid.
[23] Schondelmeyer and Wrobel, 21.
[24] Schondelmeyer and Wrobel, 22.
[25] Interview with Professor Meredith Rosenthal Jan. 4, 2005; Schondelmeyer and Wrobel, 22.
[26] Food and Drug Administration, Prescription Drug Marketing Act: Report to Congress, June 2001. (See Appendix E for Act specifics).
[27] The rebate is equal to the lower of 15.1 percent of the Average Manufacturer's Price (AMP) or the difference between the AMP and the manufacturer's ''best price.'' See Gencarelli, 8; William H. von Oehson, *Pharmaceutical Discounts Under Federal Law: State Program Opportunities*, Oakland, Calif.; Public Health Institute/Pharmaceuticals and Indigent Care, 2001, 12.
[28] Office of the Inspector General, Department of Health and Human Services, *State Strategies to Contain Medicaid Drug Costs,* OEI-05-02-00680, October 2003, 9; Gencarelli, 8-9.
[29] Interview with Dawn Gencarelli, Nov. 1, 2004; Gencarelli, 8; OIG State Strategies, 9.

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price data and government databases is that they fail to account for the complex system of time-delayed rebates that drug companies pay health plans, physicians, pharmacies, and PBMs in return for certain levels of utilization, market share, or other incentive schemes. These rebates lower the net price, often significantly, that buyers pay for drugs, but because they are paid after the time of actual purchase, they do not appear on sales invoices and are difficult to tie to individual purchases or drug products.[30] Until recently, data collection methods employed by the federal government have not been able to account for these rebates, and states are unable to collect data on their own due to staff and resource limitations, the enormous volume of drug products, the resistance of both buyers and sellers to providing data, and the overall complexity of the market.[31]

The need for better data and a better payment system

The discussion above suggests that in order to create more accurate drug reimbursements through the Medicaid program, we need to either change the way drugs are paid for or generate more accurate and accessible drug price information. Without help from the federal government, however, states, which actually set drug reimbursements, are not in a position to do either.

The View From the States[32]

The ability of state Medicaid officials to set more accurate reimbursement prices is severely limited. Under federal law, states must pay for drugs according to the providers' ''Estimated Acquisition Cost'' (EAC), which is defined as the state'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 the drug most frequently purchased by providers.''[33] Based on these vague instructions, each state must determine its own EAC, without guidance or accurate price information from the federal government.

States follow two general patterns when setting their EACs that relate to the two major drug categories: those with and without competition (generic or ''multisource'' drugs and brand-name drugs, respectively). For unique brand-name drugs, nearly all states rely on a standard, statutorily fixed formula based on a percentage discount from AWP, although some use a markup from WAC.[34] States generally do not alter their basic EAC formula for these drugs because they assume that the relationship between AWP or WAC and the price they are paying is normal (which is true for most drugs). As long as AWP markup is consistent for the vast majority of drugs, Medicaid program officials feel confident that their reimbursement formulas at least get them in the neighborhood of the pharmacies' Actual Acquisition Cost (AAC). This creates a danger if individual manufacturers seek to game the system by inflating their AWPs. Those drugs for which manufacturers have significantly inflated the AWP are like needles in a haystack. Because there is no easy way to determine whether a particular AWP is accurate or inflated, Medicaid programs and health plans are not able to determine whether that AWP is a needle or a piece of hay.

Since the ''spread'' between AWP and AAC is generally greater for generic drugs than it is for brand-name drugs, many states treat generics differently by creating a parallel reimbursement system based on Federal Upper Limit (FUL) prices and state-set Maximum Allowable Cost (MAC) prices. The FUL caps the reimbursement for certain generic drugs at 150 percent of the published price for the least costly therapeutically equivalent drug.[35] In other words, states will pay no more than 150 percent of the price of the cheapest available generic. States also are allowed to set their own MACs for generic drugs, and roughly half of states do, because the FUL list only contains about 400 drugs and does not offer the savings many states desire.[36] States have to improvise when setting MACs. For example, some states receive price information over the phone from a small number of pharmacies that voluntarily report their acquisition costs on an as-needed basis and some states use MAC lists developed by other states.[37] Despite the need to improvise, states report that setting the MAC results in substantial savings, ranging from $1 million to $45 million a year (in 2001).[38]

States face strong resistance to changes in drug reimbursement formulas from pharmacies, physicians, and drug manufacturers, but the biggest barrier to more accurate reimbursement is lack of information. Virtually all states base their drug reimbursement on AWP price information purchased from First Databank (the *Blue Book*), a commercial price publisher. This information arrives electronically and includes AWP and WAC list prices as reported by manufacturers. States stick with AWP because they do not have access to more accurate information and they do not have the capacity to collect it themselves. They also are generally unaware of the extent of the inflation of spreads on certain drugs.

Although some states try to supplement the information they receive from First Databank through surveys of pharmacies and other informal data collection methods, very few engage in systematic price data collection. One important exception is Texas, which requires all manufacturers whose drugs are covered by the state's pharmacy program to report a host of price information, including AWP, WAC, and other pricing points. Starting in 2001, the state also began requiring companies to report their AMP. [39]

Although Texas is cited as a model for price data collection, the state continues to face obstacles to obtaining accurate information. This is because most manufacturers do not report transaction prices to the

[30] Interview with Professor Meredith Rosenthal, Jan. 4, 2005. *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*, Prepared for the Kaiser Family Foundation by The Health Strategies Consultancy LLC, March 2005, 16-17.

[31] Schondelmeyer and Wrobel, 23.

[32] Much of the information in this section is based on interviews the authors conducted with state Medicaid officials. Because officials in some states did not wish to be identified, citations for much of this information are not included.

[33] 42 CFR § 447.301.

[34] OIG State Strategies, 8; Gencarelli, 19.

[35] Gencarelli, 7.

[36] HHS Office of the Inspector General, *Addition of Qualified Drugs to the Medicaid Federal Upper Limit List*, December 2004, 2; OIG State Strategies, 12.

[37] OIG State Strategies, 13.

[38] OIG State Strategies, 13.

[39] Schondelmeyer and Wrobel, 23; 29; OIG State Strategies, 10.

program—they report the same list prices provided to First Databank. In addition, only 25 percent of companies complied with the AMP reporting requirement in the first year; the next year, only 16 percent did.[40] State officials believe companies are reluctant to divulge this information for fear that it will place them at a competitive disadvantage. Texas is one of 10 states that has brought suit against drug manufacturers for AWP manipulation and false claims, and reports that the only manufacturers who report accurate transaction prices are the ones that have been sued.[41]

Even if these problems with compliance did not exist, however, it is unlikely that most states could replicate the Texas program because they lack the capacity or resources. The Texas program employs 60-100 people—other states employ as few as two or three. Thus, even if states were guaranteed accurate results, the burden of collecting data is so great that many would prefer to focus their efforts on other strategies they believe will yield greater savings.

Federal Reform Efforts

So far, states have been left on their own to contend with the serious flaws in the Medicaid payment system, but recent attention focused on reforming Medicaid and a number of recent proposals for reforming the way Medicaid pays for drugs may offer states some relief.

In 2005, Congress replaced AWP in the Medicare Part B payment methodology with the Average Sales Price (ASP).[42] Drugs covered by Part B (mainly physician-administered drugs) will be reimbursed at a rate of ASP plus 6 percent. Unlike AWP, ASP is based on actual manufacturer-submitted data and includes all forms of rebates, including ''volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement and chargebacks.''[43] In a recent report, the Office of the Inspector General (OIG) compared ASP and AWP for over 2,000 drug codes and found a significant difference between the two prices. They found that, at the median, ASP was 26 percent below AWP for sole source brand drugs, 30 percent below AWP for multi-source brand drugs, and 68 percent less than AWP for generic drugs.[44]

The Bush administration favors similarly replacing AWP with ASP in the Medicaid program. In the president's FY 2006 budget, the administration proposed reforming the current Medicaid drug reimbursement system by requiring drug manufacturers to submit ASP data and limiting the federal government's Medicaid match to 6 percent above ASP.[45] Similarly, Rep. Joe Barton (R-Texas), chairman of the House Energy and Commerce Committee, has promised to introduce legislation that ''would bring drug reimbursements more in line with what it actually costs pharmacies and other health care providers to purchase these drugs.''[46]

The National Governors Association recently submitted a proposal to curb Medicaid spending that placed drug payment reform at the top of the list. While the NGA proposal supports finding an alternative to AWP, the proposal emphasizes that reforms must go beyond simply altering the reference price. In addition to replacing AWP, the proposal recommends changes to the Medicaid drug rebate and enhancements to states' ability to negotiate with drug manufacturers and to adopt price-saving techniques employed by private plans to reduce drug costs.[47] The Medicaid Commission created by the Department of Health and Human Services recently issued its recommendations for cutting $10 billion from federal Medicaid spending over the next five years. In that report, the commission recommended replacing AWP with AMP for Medicaid, on the grounds that the use of AMP, unlike the use of ASP, would allow states the discretion to set appropriate dispensing fees. The Bush administration's budget proposes to do away with the separate dispensing fee and instead cap federal Medicaid matching funds for drugs at the same ASP plus 6 percent formula used by Medicare Part B.

Possible Pitfalls to Using ASP or AMP for Medicaid Drug Reimbursement

What the proposals above have in common is that they would replace the use of AWP with the use of a benchmark based on actual sales data (either ASP or AMP) for state Medicaid programs across the board.

Such a switch, whether to ASP or AMP, would undoubtedly produce savings,[48] but it also would present obstacles. Both ASP and AMP data submitted to CMS remain confidential.[49] Drug companies are sure to strenuously resist any efforts to make these data public, on the notion that price data are ''trade secrets'' and that revealing them would place manufacturers at a competitive disadvantage. One possibility would be to use this data to calculate reimbursement, but to have those calculations centrally performed by CMS, thus preserving the confidentiality of the data. CMS already performs a similar function in calculating rebates that manufacturers owe to states. However, having CMS calculate reimbursements is a task of a wholly different order. It would require CMS to take on even more of a PBM-like role than it currently does with the calculation of rebates. This would be a mammoth task given the sheer volume of Medicaid pharmacy purchases, and would add an additional layer of bureaucracy to an already overcomplicated system.

Even if CMS were able to assume this role, serious doubts exist as to whether CMS has the resources or

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[40] Interview with Texas Medicaid Official.

[41] Interview with Texas Medicaid Official.

[42] Medicare Modernization Act, Section 303 (Pub. L. No. 108-173), 42 U.S.C. 1395w-3a.

[43] CMS. Medicare Program: Manufacturer Submission of Manufacturer's Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals. Final Rule. 42 CFR Part 414. Sept. 16, 2004. *Federal Register* vol. 69 no. 179, 55763.

[44] Office of the Inspector General, *Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price,* OEI-03-05-00200, June 2005, 8. http://oig.hhs.gov/oei/reports/oei-03-05-00200.pdf (accessed Aug. 26, 2005).

[45] CMS, *Restructuring Medicaid Pharmacy Payments to Use Average Sales Price Methodology*, http://www.cms.hhs.gov/faca/mc/Medicaid_Pharmacy_Payments.pdf (accessed Aug. 26, 2005).

[46] House Energy and Commerce Committee, Press Release ''CBO Report Confirms Medicaid Abuses Uncovered by Committee,'' http://energycommerce.house.gov/108/News/12172004_1415.htm (accessed Aug. 16, 2005).

[47] *Medicaid Reform: A Preliminary Report from the National Governors Association,* June 15, 2005 http://www.nga.org/Files/pdf/0506medicaid.pdf (accessed Aug. 1, 2005), 3.

[48] *See note 43.*

[49] Medicare Modernization Act, Section 303(i)(4)(D), 42 U.S.C. 1396r-8(b)(3)(D).

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willingness to adequately monitor and audit pricing data submitted to it by drug companies.[50] Such data are only as useful as they are accurate. The Government Accountability Office issued a report in February 2005, finding CMS's oversight of drug companies' submitted data on Medicaid ''best prices'' to be sorely lacking.[51] Given the deficiencies in CMS's enforcement and auditing of drug company ''best price'' data, states and policymakers should be wary of CMS's ability to audit either ASP or AMP data. Without adequate verification and auditing, neither ASP nor AMP data will be a significant improvement over AWP. While the theoretical threat of an audit and even possible prosecution can be expected to improve the accuracy of such data somewhat, CMS's track record cannot be expected to render AMP and ASP reliable and accurate. Thus, even if AMP or ASP data were provided to states for them to process their own pharmacy claims, the lack of assurance of the accuracy of that data would leave states in a position little better than that in which they currently find themselves.

The Challenge of Compensating Pharmacies Fairly

Pharmacies claim that switching to ASP or AMP would have a negative impact on their bottom line, since many of them rely on the profits from AWP spreads. But it makes little sense to pay pharmacies anything above an accurate estimate of the actual acquisition cost (whether measured by AMP or ASP) plus a fixed fee to compensate them for the costs of dispensing a particular prescription. Any sensible replacement for AWP should strive to approximate AAC as closely as possible, and then guarantee the pharmacy a reasonable profit based on a fixed dispensing fee, or at least on a fee that does not increase as the cost of the drug increases. The current use of fixed dispensing fees by state Medicaid programs and most private plans acknowledges that there are fixed costs associated with a pharmacy filling any given prescription—labor, occupancy and the like. In the current pharmaceutical market, the costs to a pharmacy of filling one prescription as opposed to another vary little, if at all. The tasks that once made filling some prescriptions more labor-intensive and costly to a pharmacy (e.g. compounding) are largely a thing of the past. It does not require more effort or expense for a pharmacist to fill a bottle with, for example, a 30-day supply of an expensive brand-name Calcium Channel Blocker than with a 30-day supply of a generic antihypertensive diuretic costing pennies a day. Thus, the proposal to use ASP plus 6 percent, with the additional 6 percent standing in lieu of a fixed dispensing fee, does not make much sense. There is no justification for a reimbursement formula that increases compensation to pharmacies based on the ''spread.''

Further, doing away with the ability of states to establish a fixed dispensing fee deprives them of the ability to account for regional cost differences (i.e. it is no doubt more expensive to fill a prescription in, say, New York City, than in many other places). Finally, having Medicaid use the exact same formula and reimbursement rate that Medicare uses for Part B-covered drugs (ASP plus 6 percent) fails to acknowledge and account for the differences between pharmacies (reimbursed by Medicaid) and hospitals/doctors' offices (reimbursed by Medicare Part B). When Medicare pays for a drug under Part B, it often also is paying for an entire package of services for which Medicare compensates the doctor or hospital—the visit itself, tests to determine the need for the treatment or appropriate dosage, the administration of the drug (say, an injection or IV), and then finally the drug itself. Thus, the doctor or hospital is not only receiving the ASP plus 6 percent payment for the drug—they also are receiving payment for these other services. Pharmacies, by contrast, under the administration's proposal, only receive the payment of ASP plus 6 percent. It makes sense for the reimbursement to pharmacies to acknowledge this difference. The best way to do that is by providing a fixed dispensing fee.

Choosing a New Benchmark: ASP, AMP, or WAC?

Thus, any reform to AWP should strive to track AACs as closely as possible and include a fair dispensing fee that compensates pharmacies adequately without encouraging them to favor more expensive drugs. The remaining question is which alternative benchmark to use. ASPs are closer to AACs than AMPs because they represent actual purchases made by pharmacies, hospitals, and other dispensers of medications—in other words, purchases made by the same types of entities that Medicaid programs will be reimbursing.[52] AMPs, by contrast, represent sales at least one level up in the distribution chain, from the manufacturer to the wholesaler. However, this fact alone does not render AMP an inappropriate reimbursement benchmark. If it can be shown that markups from the wholesaler to the pharmacy are fairly standard and consistent across the drug market (i.e. AAC is generally AMP plus X percentage), then a formula that used AMP plus some percentage would not necessarily be inaccurate or inappropriate.

Any benchmark is an approximation, and care must be taken to ensure that it tracks AAC as closely as possible. Despite these obstacles, both of these benchmarks would be improvements over AWP, since they are at least based on actual sales data at some point in the distribution chain, rather than being arbitrary inventions of the industry's imagination. A more accurate and transparent pricing system, using either ASP or AMP, actually can help pharmacies by bringing the true costs of dispensing medication to light and ensuring that fees remain adequate.

The National Association of Chain Drug Stores, the trade group representing the largest pharmacy chains,

[50] But since all this data is confidential, there is no way of determining its accuracy. States have no choice but to rely on CMS's calculation of their rebates. If states similarly had to rely on CMS for their pricing benchmark data, deficiencies in CMS's auditing and oversight would be even more problematic.

[51] The report stated that ''CMS conducts only limited checks for reporting errors in manufacturer-reported drug prices. Furthermore, the agency does not generally review the methods and underlying assumptions that manufacturers use to determine best price and AMP.'' *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States*, GAO-05-102, http://www.gao.gov/new.items/d05102.pdf (accessed Aug. 11, 2005).

[52] Pharmacies argue that ASPs capture sales to institutions such as hospitals that get better prices than retail pharmacies are able to negotiate, and thus that an ASP-based reimbursement system will not fairly compensate them.

recently proposed replacing AWP with WAC for brand-name drugs.[53] WAC, like AWP, is not an actual market price and is at risk of being artificially inflated (particularly if it becomes the reimbursement benchmark for Medicaid). Like AMP, it purports to measure prices between wholesalers and manufacturers, but unlike AMP, it is not reported to CMS nor is it auditable by them. Whatever benchmark is used must be one that CMS can audit and verify. Without the threat of monitoring and enforcement, the incentive and temptation to inflate the chosen benchmark is too great (and that incentive does not disappear even with the threat of enforcement). WAC is not an adequate replacement for AWP.

Finally, although both ASP and AMP are based on actual sales and pricing data, they are not immune to manipulation and outright fraud. In July 2004, Schering-Plough paid $345.5 million to settle a case brought against it by federal prosecutors and state attorneys general.[54] That case alleged that Schering-Plough engaged in a complex fraud to avoid reporting certain sales of its allergy drug Claritin to CMS under its ''best price'' reporting obligations.[55] Similar schemes are possible under an ASP or AMP system. ASP encompasses all of the sales a manufacturer makes of a particular drug, including all time-delayed discounts and rebates. If a drug company gives a certain private buyer a particularly great deal, that price is factored into the ASP, and thus brings the ASP down. That reduction in turn would reduce the reimbursement amount paid by Medicaid. A drug manufacturer, for example, could ''game'' an ASP-based system by failing to report or attempting to hide certain lower-priced sales of its drugs in order to prevent its ASP, and thus its reimbursements under either Medicare Part B or state Medicaid programs, from being lowered.

This is only the most obvious type of fraud and obfuscation possible under such a system. Any reimbursement scheme presents opportunities for ''gaming the system,'' an area in which the pharmaceutical industry has demonstrated itself to be endlessly innovative. Regardless of what benchmark is used, the system will only work as intended with aggressive and adequately funded auditing, enforcement, and prosecution by CMS and other federal agencies.

Conclusion

It is abundantly clear that the current AWP-based reimbursement system is fundamentally broken. Rising drug spending in Medicaid programs is robbing states of funds that would otherwise go to medical treatment or expanded coverage, is placing pressure on the Medicaid program as a whole, and is adding to states' overall budget problems. Overpayments as a result of AWP reimbursement are contributing significantly to this rising cost. States cannot effectively replace or reform their Medicaid reimbursement formulas alone, but require federal involvement and intervention. An across-the-board replacement of AWP for state Medicaid programs with a formula using ASP or AMP offers significant savings potential, but should include a fair dispensing fee to adequately compensate pharmacies. Further, the system will function as intended only as long as enforcement and auditing are thorough and robust. Possibilities for fraud exist even in an ASP- or AMP-based system, and any federal reform efforts must include adequate resources, as well as political will, for CMS to aggressively police the accuracy of the data used as a benchmark.

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[53] *See Medicaid Reform Recommendations from NACDS–Executive Summary* http://www.nacds.org/user-assets/pdfs/newsrelease/MedicaidCommissionExec.PDF (accessed August 26, 2005).

[54] ''Schering Case Demonstrates Manipulation of Drug Prices,'' *New York Times,* July 31, 2004.

[55] Manufacturers are required to report their ''best prices,'' which are used to calculate states' Medicaid rebates. The ''best price'' is defined as ''the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States,'' excluding prices given to certain governmental and charitable programs. 42 U.S.C. 1396r-8(c)(1)(C).

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