AMCP Academy of Managed Care Pharmacy®

AMCP Guide to Pharmaceutical Payment Methods

2009 UPDATE (VERSION 2.0)

EXECUTIVE SUMMARY

This *AMCP Guide to Pharmaceutical Payment Methods, 2009 Update (Version 2.0)* builds on the October 2007 *Guide*, which was created by the Academy of Managed Care Pharmacy Task Force on Pharmaceutical Payment Methods in conjunction with consulting firm Tag & Associates, Inc. The updated version incorporates revisions by Tag & Associates, Inc. The Academy intends to periodically update sections of the *Guide* as necessary. To view the full *Guide*, go to **www.amcp.org/page/PharmaceuticalPaymentMethodsIntro.**

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About AMCP

AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's 5,700-plus members develop and provide a diversified range of clinical, educational, and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit. For more information about AMCP, visit **www.amcp.org.**

The methods by which the U.S. health care system pays for prescription drugs have faced increasing scrutiny in recent years. Two key developments have emerged: (a) congressional enactment of important changes in the basis for payments for prescription drugs in the Medicare and Medicaid programs; and (b) a March 2009 decision in a federal class action lawsuit that alleged fraudulent manipulation of the dominant pricing benchmark (average wholesale price, AWP), used primarily as the basis for payment for brand-name prescription drugs.

The debate about prescription drug payment methods centers on determining the most appropriate basis for calculating how payers, including patients, government agencies, employers, and health plans, should pay pharmacies and other providers for drugs. Historically, payment for prescription drugs has been based on published prices that do not necessarily reflect the actual acquisition costs paid by providers, primarily pharmacies, physicians, and hospitals. This has led policymakers to believe that Medicare and Medicaid programs have paid more than is necessary for prescription drugs. Thus, in an effort to reform the payment system and reduce drug expenditures, policymakers have made significant changes to the benchmarks used by public programs to pay for drugs, and in some instances have created new benchmarks.

Private payers have followed the government's lead and begun to change their own payment methods and benchmarks. They can be expected to accelerate the change as a result of the settlement agreement approved in the March 2009 federal court decision. The settlement will result in the lowering of the AWP for more than 400 generic and brand-name drugs. In addition—and technically unrelated to the litigation and any appeals that may be taken—2 major price data reporting companies, First DataBank and Medi-Span, announced their intent to discontinue publication of AWP within 2 years of September 26, 2009. (At the time this report was prepared, there have been no similar announcements from Thomson Healthcare for Redbook or from Elsevier for Gold Standard [ProspectoRx], who are 2 other publishers of prescription drug prices). Furthermore, several manufacturers have announced that they will no longer provide either an AWP or a markup percentage on certain pharmaceuticals. Thus, by 2011, the AWP benchmark as we know it will no longer be widely available for use by public or commercial payers for payment of pharmaceutical products.

Today's prescription drug payment to pharmacies, physicians, and other providers is often determined by a formula based on the AWP benchmark. However, it is unclear how replacement of the AWP benchmark might affect provider payment for two reasons: (a) no widely available alternative benchmark has been selected, and (b) pharmacy benefit manager contracts with network pharmacies often include language to adjust payment under any new benchmark to maintain comparable pricing to the AWP standard.

The U.S. drug purchasing and distribution system is complex and involves multiple transactions among myriad stakeholders, including drug manufacturers, distributors, third-party payers, pharmacies, physicians, and patients. Any change in payment methods or benchmarks has significant implications for all stakeholders, affecting the payments and prices to and from each of these groups. Knowledge of the intricate distribution and payment systems for prescription drugs is essential to ensure that payment reform results in desired outcomes including fair and equitable payment to providers while avoiding unintended consequences such as reduced access to medically necessary drugs.

AMCP recognizes the need to help stakeholders and policymakers better understand, evaluate and navigate the profound changes occurring in payment for prescription drugs in the United States. This 2009 update to the *AMCP Guide to Pharmaceutical Payment Methods* offers a comprehensive examination of the methods and price benchmarks that have been used in the public and private sector to pay for pharmaceuticals in the United States, the changes that have occurred or are likely to occur in the future, and the forces that are behind these changes. AMCP has made every effort to make the *Guide* an unbiased presentation of information, issues, and implications.

The *Guide* is presented in 5 main sections including an introduction and the following 4 subject areas:

- **Payment Benchmarks.** Section II explains the drug payment benchmarks that have come into use over the past 4 decades, how and when they are used, and how they compare to one another. The benchmarks discussed in detail are those that have the greatest overall impact on pharmaceutical payment or are currently receiving the most scrutiny and discussion, including AWP, average sales price (ASP), average manufacturer price (AMP), wholesale acquisition cost (WAC), maximum allowable cost (MAC), and the federal upper limit (FUL).

- **Payers and Payment Methods.** Section III describes payment methods used by payers as well as manufacturers' price concessions related to product preference and acquisition across various settings of care such as community pharmacy, mail service pharmacy, physician offices, and hospitals. The payers discussed in this *Guide* include public payers such as Medicare, Medicaid, and the Public Health Service's 340B program, and private payers such as commercial insurers, self-funded plans, Taft-Hartley plans, and individual patient payments. Also covered are topics relevant to private health insurance, including benefit design, the use of formularies by private payers, and the relationship of these factors to the availability of rebates from drug manufacturers.

- **How Products, Services, and Payments Flow Through Channels of Distribution.** Section IV provides a detailed analysis of how drugs are purchased, distributed, and paid for by various entities within the pharmaceutical supply chain in the U.S. The purpose of this section is to examine the complexity of the drug distribution system as well as the multiple direct and indirect transactions that occur.

- **Select Issues and Implications for Stakeholders.** Section V explores the immediate and future issues and implications of the most significant changes to drug payment methods or benchmark prices that have been proposed or implemented in recent years. The topics evaluated in this section include the pending switch to the use of AMP by state Medicaid programs for drug payment; the ongoing implications of the implementation of ASP under Medicare Part B, and the implications that both of these changes may have for private payers in the pharmaceutical marketplace; pricing transparency; and bundling of provider payment for prescription drugs with payment of other related services

Highlights

The following key issues are discussed in this *Guide*. Please refer to the corresponding section in the *Guide* for a more detailed discussion of trends in drug pricing and payment.

Payment Benchmarks

Some health plans cover pharmaceuticals under the "medical benefit" (e.g., drugs administered in a medical office or clinic setting), while others may cover them under the "pharmacy benefit" (e.g., drugs dispensed by a pharmacist). Pharmaceuticals covered under either the medical benefit and/or the pharmacy benefit component of a health plan typically have differing payment methods and price benchmarks.

Average Wholesale Price and Wholesale Acquisition Cost

Historically, AWP was the generally accepted drug payment benchmark for many payers, primarily because it was readily available. However, in more recent years AWP became recognized as a "sticker price" that does not reflect the average wholesale price ultimately paid after discounts have been subtracted.

AWP is related to WAC, although not by a standard multiplier. Historically, the relationship of AWP to WAC has been most commonly characterized by one of the following equations, as determined by the manufacturer:

AWP = 1.20 x WAC, or
AWP = 1.25 x WAC

However, WAC is not an actual acquisition cost for a wholesaler, because the WAC does not include many of the discounts and price concessions that are offered by manufacturers. For sole-source branded pharmaceuticals, WAC more closely approximates the price that pharmacies pay to manufacturers or wholesalers than does AWP and, for this reason, often serves as the basis for negotiated discounts and rebates between manufacturers and private payers (i.e., discounts and rebates are based on WAC) for both medical and pharmacy benefit drugs. Manipulation of the so-called "spread" or differential between WAC and AWP has been the subject of lawsuits against pharmaceutical manufacturers alleging "gross inflation" of AWP for certain physician-administered drugs.

Recognition of the unreliability of AWP as a benchmark of real-world prices actually paid by pharmacies and other purchasers, including physicians has precipitated the search for other reference prices for payment purposes. The impending demise of AWP as a basis for payment for pharmaceuticals in the United States became more certain on March 17, 2009, with the decision by U.S. District Court Judge Saris on the proposed settlement in the 2 national class action lawsuits against First DataBank/ McKesson and Medi-Span. This decision will result in the rollback of the multiplier used to calculate AWP. The WAC multiplier of 1.25 (or greater than 1.20) will be reduced to 1.20 for the 1,442 National Drug Code (NDC) numbers referenced in the lawsuit, effective September 26, 2009, under order of the court in acceptance of the proposed settlement. First DataBank announced as an independent commercial publisher that it would do the following: (a) apply the 1.20 multiplier in calculating AWPs for all other NDCs whose AWPs were derived using a multiplier greater than 1.20, and (b) discontinue publication of AWP no later than 2 years following implementation of the recalculated AWPs. Medi-Span has made a similar announcement. When this *Guide* went to press, Thomson Healthcare, publisher of Redbook, and Elsevier, publisher of Gold Standard (ProspectoRx), had not announced similar changes.

Unless third-party reimbursement contracts with pharmacies are renegotiated, the practical results of this settlement and other changes to be implemented include (a) reduction in pharmacy gross margin on the affected drug prices paid under AWP discount-based third-party contracts, and (b) a proportionate reduction in beneficiary cost-share amounts that are based on coinsurance rather than dollar copayments.

Average Sales Price

As a result of the 2003 Medicare Prescription Drug, Improvement, and Modernization Act (MMA) (Public Law 108-173), ASP replaced AWP as the basis for payment for most drugs covered under Medicare's medical benefit—Medicare Part B—as of January 1, 2005. Unlike AWP, ASP is based on manufacturer-reported actual selling price data and includes the majority of rebates, volume discounts, and other price concessions offered to all classes of trade (excluded from the calculation of ASP are all sales that are exempt from "best price" and sales at "nominal price").

Because ASP is an average, some providers are able to obtain pharmaceuticals below this average selling price, while others are able only to purchase the drugs at a price that is above the average. Historically, small physician offices and specialty pharmacies buy at the least favorable prices and are unable to purchase some drugs at prices at or below the ASP prices or ASP-based payment amounts. Generally, large physician groups and hospitals are able to negotiate the best discounts and price concessions and are better positioned under the ASP payment system.

ASP values are publicly available on the federal government's Centers for Medicare & Medicaid Services (CMS) Web site, and private payers are therefore able to use ASP for payment of medical benefit drugs. Uptake of the ASP benchmark by commercial

sector has been slow but steady. Survey data from approximately 100 payers showed that, by the fall of 2008, about 44% of private payers used ASP as their primary payment benchmark for specialty therapies (accounting for more than half of covered members), but only 16% of payers depended exclusively on ASP and 37% had no ASP contracts.

Average Manufacturer Price

Congress created AMP as part of the Omnibus Budget Reconciliation Act (OBRA 1990) for the purpose of calculating rebates to be paid by manufacturers to states for drugs dispensed to their Medicaid beneficiaries. AMP was defined as the price available to the retail class of trade and reflected discounts and other price concessions afforded those entities.

In another effort by the federal government to eliminate AWP as a payment benchmark, the Deficit Reduction Act of 2005 (DRA) mandated that AMP instead of AWP be used for the calculation of the FUL. FUL is the maximum amount of pharmacy reimbursement for product costs for certain generic and multiple-source drugs that the federal government will recognize in calculating federal matching funds for payment to state Medicaid programs. Congress mandated that CMS follow a formal rulemaking process to outline a clear, consistent definition of AMP for manufacturers. In July 2007, CMS published a final rule that broadly defined the retail class of trade, including community pharmacies as well as mail-order pharmacies, physician offices, outpatient facilities, and other outlets that sell drugs to the general public. The rule did not include pharmacy benefit management companies (PBMs), 8 long-term care facilities, or federal drug benefit programs within the definition of "retail class of trade." This broad definition led to industry dissent and even legal challenges to AMP use. There is disagreement about the fairness of a single rate for reimbursement when all of the providers in the class cannot buy at similar rates; for example, community pharmacies serving walk-in patients that do not have access to purchase prices and discounts available to mail-order pharmacies.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Public Law 110-275) delayed the implementation of new Medicaid payment limits to retail pharmacies using the AMP for multiple-source (generic and brand) drugs and instructed the Secretary of the Department of Health and Human Services (DHHS) to suspend the publication of AMP data submissions to a public Web site through September 30, 2009. States may not switch to AMP-based pharmacy reimbursement prior to this time. It is anticipated that there will be efforts in the current Congress to either further delay or otherwise modify the statutory 2005 AMP mandate. In addition, there is pending litigation in the courts that upon resolution could affect AMP.

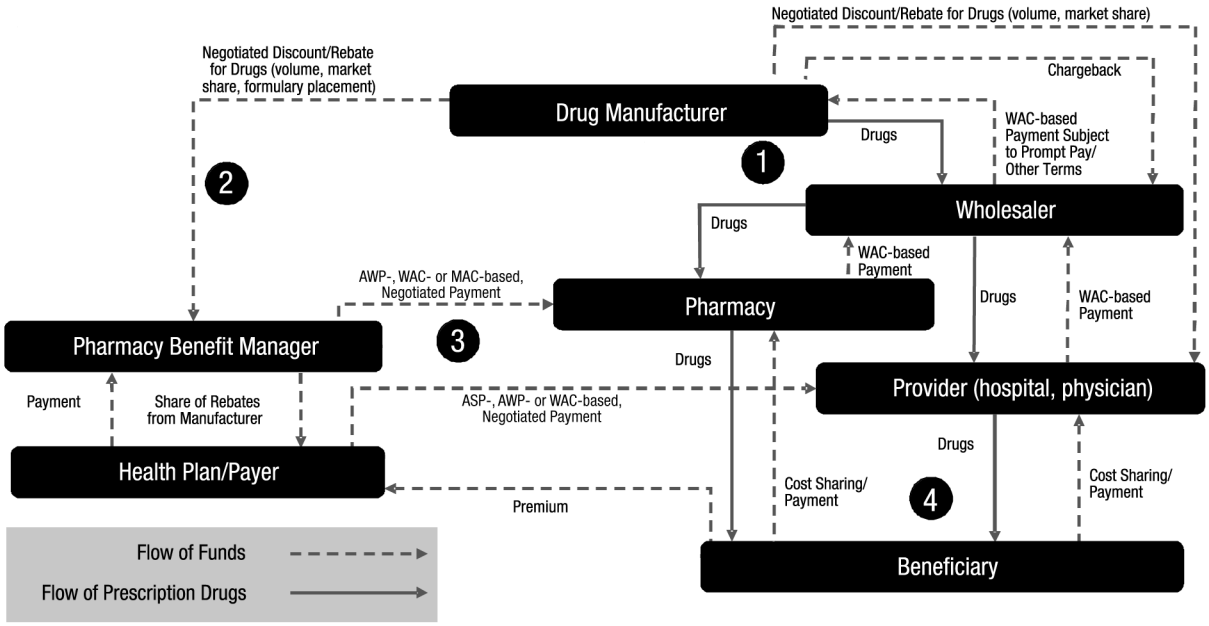
Payers and Payment Methods

Payment to providers for the drugs they administer or dispense varies depending on the payer and the site of care.

Medicare

Medicare's payment for drugs depends on the treatment setting. Drugs provided in the hospital inpatient setting typically do not receive separate payment, but instead their costs are accounted for in the diagnosis related group (DRG)-based prospective pay-

EXHIBIT 1 Drug Distribution Model



ment made to the hospital. Similarly, drugs used in the hospital outpatient department for which the cost per day is $60 or less (in 2009) are bundled into ambulatory payment classification (APC) reimbursement for the procedures with which they are used; there is no separate payment made for those drugs. Currently, drugs with a cost per day exceeding this threshold ($60) in the hospital outpatient department receive separate payment; as of January 1, 2009, the payment rate for the majority of these drugs is ASP plus 4%, and drugs with pass-through status will be paid at ASP plus 6%.

Most drugs administered in physicians' offices and thus covered by Medicare's Part B medical benefit also are paid using the formula ASP plus 6%. The Part B Competitive Acquisition Program (CAP), through which CAP-electing physicians obtained Part B drugs administered in their offices through a CMS-contracted CAP vendor, was postponed by CMS for 2009, effective December 31, 2008.

On January 1, 2006, as a result of passage of the MMA, Medicare also began to pay for outpatient pharmaceuticals dispensed at the pharmacy under Part D. Part D benefits are provided through stand-alone prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MA-PDs) that are integrated with a medical plan. These drug plans typically are offered by PBMs and commercial health plans. Subject to legislated mandates and to CMS guidelines and approval, each PDP and MA-PD sets its own premiums, benefit structures, drug formularies, pharmacy networks, and terms of payment. Thus, unlike the other components of Medicare where a standard payment formula typically exists, drug payment to pharmacies and member cost-share vary by individual plan under Part D through September 30, 2009, the planned publication of AMP data submissions on a public Web site.

Medicaid

Currently, every state Medicaid program includes an outpatient prescription drug benefit (also called a "pharmacy benefit"). As of June 30, 2007, 64.1% of Medicaid enrollees nationwide were enrolled in managed care plans. In that year, 20 Medicaid programs carved-out their pharmacy benefit, in whole or in part, from these managed care plans.

Under fee-for-service Medicaid, states usually pay pharmacies directly for the drugs dispensed to Medicaid beneficiaries, typically using a rate based on AWP or WAC for brand drugs and maximum allowable cost (MAC, based on federal and state upper limits) for multiple-source brand and generic drugs. If the beneficiary is enrolled in a Medicaid managed care plan, the state may pay the Medicaid managed care plan to cover pharmacy benefits for beneficiaries, or the state may choose to "carve out" the pharmacy benefit and pay for it directly under fee-for-service administered by the state. Under managed Medicaid without carve-out, each MCO negotiates with drug manufacturers for rebates and discounts and manages its own drug formulary. Under carve-out, the state pays pharmacies for prescription drugs directly and manages a statewide formulary that may include a preferred drug list (PDL) and supplemental rebates as well as rebates mandated by federal statute. Beneficiaries who are eligible for both Medicaid and Medicare ("dual eligibles") receive prescription drug benefits through the Medicare Part D outpatient drug benefit.

Every state Medicaid program, either directly or through managed Medicaid organizations, also pays for drugs that are utilized under the medical benefit (e.g., in the physician's office and clinic). Drugs covered under the medical benefit are typically paid for separately based on formulas that vary by state, but are based on AWP, WAC, or ASP.

Private Purchasers

Compared with public payers, there is less transparency in the payment methods used by private payers to pay for prescription drugs. For example, private payers use MAC price lists for multiple-source drugs; however, prices contained in these MAC lists, the methodology by which these lists are constructed, and the frequency with which they are updated, are not publicly disclosed. Similar to public payers, private payers use drug formularies to manage beneficiary prescription drug use and the cost of drugs paid for by the plan. Most formularies have copayment "tiers" that correspond to different levels of beneficiary cost sharing. The placement of drugs within copayment tiers is related to their relative safety, efficacy, and effectiveness as determined by health plan or PBM pharmacy and therapeutics (P&T) committees as well as their direct cost, including the price concessions that private payers can obtain from drug manufacturers. Generic drugs are commonly placed in the lowest copayment tier. Private payers also negotiate drug payment rates with pharmacy providers; historically, these rates have been based on AWP or WAC, and include MAC pricing for most generic drugs.

As in Medicare DRGs, private payers prefer to bundle payment for prescription drugs in DRG-based payments or in per-diem rates in the inpatient hospital setting, while hospital outpatient drugs are more commonly paid for separately if they exceed a specified cost threshold. Drugs administered in physician offices are usually paid for separately based on AWP, WAC, or ASP.

How Products, Services, and Payments Flow Through Channels of Distribution (see Exhibit 1)

Any discussion of drug payment should consider the impact of channel of pharmaceutical distribution (e.g., hospital, physician, pharmacy) on both payment method and level.

❶ The majority of drug manufacturers ship drugs directly to drug wholesalers or distributors, who then distribute the drugs to their end customers. Manufacturers enter into various forms of contracting arrangements, including discounts and rebates, with all of the entities within the pharmaceutical supply chain. Manufacturers typically offer different contracting arrangements, depending on customers' channel of distribution or class of trade, which may be administered by wholesalers or distributors or directly with the manufacturers.

❷ Health plans and PBMs also negotiate with manufacturers for discounts and rebates, primarily for single-source branded pharmaceuticals in competitive therapeutic categories purchased for the individuals enrolled in their plans or under their management, based on volume, market share, and formulary placement.

❸ Pharmacies receive payment from the health plan or PBM for the drugs dispensed to the plan members based on a reimbursement formula agreed to by the payer (or agent) and pharmacy. Physicians and other providers also negotiate with health plans for payments for the drugs they administer directly to beneficiaries. Drug payment may be bundled in some channels (e.g., DRGs for hospital inpatient and, depending on circumstances, APCs for hospital outpatient), or in other channels (e.g., pharmacy and physician office) drugs may be paid on the basis of individual prescriptions dispensed or administered.

❹ At the pharmacy counter or other point of sale, beneficiaries with health insurance that includes prescription benefit coverage will typically pay a cost-share to the pharmacy for the prescription drug. The cost-sharing type (e.g., copayment or coinsurance) and amount are set by the terms of that health plan member's benefit design. If the pharmacy plan is administered by a PBM, the PBM then bills the member's health plan or other payer an amount based on the payment formula stipulated in its provider service agreement, minus the beneficiary cost-share amount collected by the pharmacy. Individuals without health insurance or other coverage for the purchase of their prescription drugs or without the assistance of negotiated pricing through a "discount card" program must pay the pharmacy's or other provider's "usual and customary" (U&C) price to obtain their drugs.

Implications

Current and future drug payment reforms have implications for multiple stakeholders at all points across the channels of drug distribution. Issues that have yet to be resolved include: (a) how soon payers will shift away from AWP to other payment benchmarks; (b) how ASP has affected access to drugs under the Medicare Part B benefit; and (c) alternative pricing benchmarks that must shortly supplant AWP (and/or WAC). The *Guide* explores each of these topics, as well as others.

Recent Pharmaceutical Payment Milestones

The timeline (Table 1) summarizes recent events affecting payment of prescription drugs and provides hyperlinks to obtain further information.

Conclusion

After 4 decades of use as the basis for payment for pharmaceuticals in the United States, AWP lost favor because it was found to be subject to manipulation and an unreliable estimate of the actual purchase price. Federal legislation and related regulations have resulted in the use of ASP for reimbursement of Medicare Part B drugs since January 2005, and the use of AMP for calculating manufacturer rebates to state Medicaid programs since 1991. The extension of AMP as the basis for pharmacy reimbursement for multiple-source drugs has been postponed by litigation and related legislation. Economic and political factors will continue to drive the search for reliable bases for pharmaceutical payment, and federal policy seems likely to lead change in the private sector. We intend this updated *Guide* to serve as a resource in understanding the complexity of pharmaceutical payments and evaluating drug reform proposals and alternate payment methods.

Note on references and AMCP's interactive resource library— The references in the text of the *Guide* and in the list of references contain URL hyper-links to the source documents that are publicly available. In addition, on the AMCP Web site is an interactive resource library—a searchable interactive database of articles and documents that examine drug product payment methods in the United States. To view the interactive resource library, go to **www.amcp.org/page/PharmaceuticalPaymentMethodsandInteractiveResourceLibrary.**

TABLE 1 Pharmaceutical Payment Milestones: 2005-2011

Date	Description of Milestone Event	Key Points	References
January 1, 2005	Initiation of Average Sales Price for Medicare Part B medications, as a result of the 2003 Medicare Prescription Drug, Improvement, and Modernization Act (Public Law 108-173).	• CMS's effort to establish a new payment benchmark for prescriptions administered in physician office, clinic and hospital outpatient settings.	http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_bills&docid=f:h1enr.txt.pdf.
January 1, 2006	Initiation of Medicare Part D, administered by stand-alone PDPs and by MA-PDs with prescription drugs and services delivered primarily by community pharmacies.	• Competitive delivery model without centralized drug pricing, mandatory manufacturer rebates or community pharmacy reimbursement guidelines.	Medicare Part D Benefit Designs and Formularies 2006-2009. J Hoadley, for MedPAC. 12/5/08 http://www.medpac.gov/transcripts/MedPAC%20Formulary%20Presentation%20-%20Hoadley%2012-05-08%20revised.pdf
February 8, 2006	Deficit Reduction Act of 2005 establishes AMP as basis of Medicaid FUL calculation, and requires AMP to be publicly disclosed.	• CMS's effort to establish a new payment benchmark for prescriptions dispensed through pharmacy channels.	Deficit Reduction Act of 2005: Implications for Medicaid. 2/06. Kaiser Commission on Medicaid and the Uninsured. http://www.kff.org/medicaid/upload/7465.pdf
October 6, 2006	*Wall Street Journal* article reporting on litigation revealed for the first time that First DataBank took action in 2002 to increase the markup of AWP from WAC for certain brand-name drugs.	• First DataBank increased the markup of WAC to determine AWP for a large number of drugs in 2002 from 1.20 to 1.25, costing payers including consumers billions of dollars. • AWP was not based on actual surveys of drug wholesaler prices.	Martinez B. How quiet moves by a publisher sway billions in drug spending. *Wall Street J*. October 6, 2006:A1. Available at: http://www.dc37.net/news/newsreleases/2006/drugpricing_WallStJ.pdf
November 14, 2006	U.S. District Court for the District of Massachusetts, Judge P. Saris, granted preliminary approval to a settlement in class action re AWP with First DataBank.	• Public disclosure of disconnect between AWP and actual market prices.	Proposed Settlement by Judge Saris in CIVIL ACTION NO. 05-11148-PBS; *New England Carpenters Benefit Fund et al. vs. First DataBank-McKesson*. Available at: http://www.prescriptionaccess.org/docs/FDB-prelim-approval-order2.pdf
July 6, 2007	Deficit Reduction Act of 2005 definition of "retail pharmacy class of trade" for AMP calculation purposes, and of class of trade to be included in the AMP calculation.	• *Retail pharmacy class of trade* means any independent pharmacy, chain pharmacy, mail order pharmacy, or other outlet that purchases drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public. • *Sales, rebates, discounts, or other price concessions included in AMP.* Includes several non-retail pharmacy channels (*see* references).	Medicaid Drug Pricing Regulation. CMS Fact Sheet. 7/6/07. http://www.nasmd.org/issues/docs/AMP%20Reg%20CMS%20Fact%20Sheet%202007_07_06.pdf and Section 447.504, Determination of AMP. http://edocket.access.gpo.gov/cfr_2008/octqtr/pdf/42cfr447.504.pdf and Retail Pharmacy class of trade, *Federal Register* v72 #136, 7/17/07. http://fdsys.gpo.gov/fdsys/pkg/FR-2007-07-17/pdf/07-3356.pdf
November 1, 2007	Judgments against 2 major brand-name drug manufacturers for "grossly inflating" the AWPs of certain expensive physician-administered drugs (PADs).	• Public disclosure of disconnect between AWP and actual market prices with respect to particular products; preceded by about 7 years of allegations and settlements between several pharmaceutical manufacturers and state and federal prosecutors over inflating the "spread" between AWP and actual acquisition cost for physicians.	Memorandum and order by Judge Saris in: Re MDL 1456 and Civil Action No. 01-12257-PBS. Available at: http://www.prescriptionaccess.org/docs/AWP_damages_order_11-2-07.pdf
July 2008	Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).	• With a federal court injunction, results in delay of (a) expansion of the number of drugs subject to the FUL amounts, (b) change in the basis for the calculation of FUL amounts to AMP, and (c) requirement that CMS share AMP data with states.	http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ275.110.pdf
December 31, 2008	CMS's Part B drug CAP postponed as of December 31, 2008.	• Postponed because of contractual issues with successful bidder. • No official notice regarding if or when program may be restarted.	http://www.cms.hhs.gov/CompetitiveAcquisforBios/01_overview.asp#TopOfPage

TABLE 1 Pharmaceutical Payment Milestones
(continued from previous page)

January 2009	Hospital outpatient settings: Payment for non-pass-through drugs and biologicals in CY 2009 is made at a single rate of ASP+4%, which includes payment for both the acquisition cost and pharmacy overhead costs associated with the drug or biological. For pass-through drugs and biologicals in CY 2009, a single payment of ASP+6% is made to provide payment for both the acquisition cost and pharmacy overhead costs of these pass-through items.	• For CY 2009, separate drug payment in hospital outpatient settings reduced to ASP+4% for non-pass-through drugs and biologicals. • For CY 2009, pass-through drug payment continues at ASP+6%.	http://www.cms.hhs.gov/transmittals/downloads/R1702CP.pdf
January 2009	The American Recovery and Reinvestment Act of 2009 provides $1.1 billion funding for comparative effectiveness (CE) research through the Agency for Health Research and Quality (AHRQ) and the National Institutes of Health (NIH), and establishes the Federal Coordinating Council for Comparative Effectiveness.	• Objective is to increase research that compares treatment modalities. • The hope is that availability of CE research results will help care givers make best possible therapeutic choices. • Council is precluded from making coverage or reimbursement decisions.	Comparative Effectiveness. J Holzer, G Anderson. *Health Policy Monitor.* 2009. Available at: http://www.hpm.org/en/Surveys/Johns_Hopkins_Bloomberg_School_of_Public_Health/13/Comparative_Effectiveness_Research.html
February 2009	OIG release of comparison of community pharmacy reimbursement amounts for Medicare Part D plans versus Medicaid in the second half of 2009 for 40 single-source drugs and 39 multiple-source drugs with high expenditures.	• Analysis of "average unit reimbursement amount" including dispensing fee with ingredient cost. • Median 0.6% lower Part D reimbursement for single-source brand drugs. • Medicaid reimbursement exceeded Medicare Part D reimbursement by 10% or more for 28 of 39 multiple-source drugs and was 17% higher at the median for the 39 multiple-source drugs.	DHHS Office of Inspector General. Comparing pharmacy reimbursement: Medicare Part D to Medicaid. Report no. OEI-03-07-00350. February 2009. Available at: http://www.oig.hhs.gov/oei/reports/oei-03-07-00350.pdf
March 17, 2009	U.S. District Court judge approves settlement between drug price clearinghouses Medi-Span and First DataBank (with drug wholesaler McKesson) and plaintiff health plans alleging "fraudulent increase of AWPs."	• Adjust AWPs for approximately 1,400 NDCs to smaller gross margin (1.20 x WAC rather than 1.25 x WAC), effective September 26, 2009. • Establish a reasonably accessible data repository of discoverable material regarding First DataBank drug price reporting practices. • First DataBank independent of this court decision commits to discontinuation of publication of AWPs within 2 years, on or before September 26, 2011.	U.S. District Court. District of Massachusetts. *New England Carpenters Health Benefits Fund, et al. vs. First Databank, Inc., and McKesson Corporation; and District Council 37 Health and Security Plan vs. Medi-Span.* Civil Action No. 05-11148-PBS and Civil Action No. 07-10988-PBS. Available at: http://www.firstdatabank.com/Support/awp-communications.aspx
September 26, 2009	U.S. District Court judge issues final order and judgment in case of Medi-Span and First DataBank cases.	• Effective date of order.	http://www.firstdatabank.com/download/pdf/FinalJudgment.pdf
October 1, 2009	No longer blocked as of this date: (a) Medicaid implementation of AMP as FUL payment benchmark, and (b) CMS publication of AMP data on its Web site.	• TEMPORARY SUSPENSION OF UPDATED PUBLICLY AVAILABLE AMP DATA.—Notwithstanding clause (v) of section 1927(b)(3)(D) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(D), the Secretary of Health and Human Services shall not, prior to October 1, 2009, make publicly available any AMP disclosed to the Secretary. (MIPPA, Public Law 110-275, 7/15/08).	http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ275.110.pdf
By September 26, 2011	First DataBank and Medi-Span voluntarily cease publication of AWP no later than this date.	• Publication of other manufacturer-provided suggested pricing benchmarks, such as direct price and wholesale acquisition cost, are not affected.	http://www.firstdatabank.com/downloads/pricing/awpupdate031709.pdf and http://www.medispan.com/Common/PDF/CustomerLetter_April12009_FINAL.pdf

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