

..... AMCP GUIDE TO

Pharmaceutical Payment Methods

EXECUTIVE SUMMARY | VERSION 3.0

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 dynamics behind these changes

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AMCP GUIDE TO Pharmaceutical Payment Methods

This *AMCP Guide to Pharmaceutical Payment Methods, 2013 Update (Version 3.0)* builds on previous versions of the *Guide*, which were 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. and AMCP. The Academy intends to periodically update sections of the *Guide* as necessary. To view the full *Guide*, go to www.amcp.org/pharmaceutical-payment-guide

Release Date: April 2013

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About AMCP

The Academy of Managed Care Pharmacy (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 nearly 7,000 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. More news and information about AMCP can be obtained on its website, at www.amcp.org.

The methods by which the U.S. health care system pays for prescription drugs are changing because of

- Growth of healthcare as a percentage of GDP.
- Healthcare reform (The Patient Protection and Affordable Care Act, known as PPACA).
- Payer demands for price transparency.
- Increasing cost sharing by patients.
- The belief by many stakeholders that prescription drug prices and price increases should be moderated.
- Increasing Generic Dispensing Rates.
- Increase in specialty pharmaceuticals on the market, their increasingly high cost per course, and increasing specialty pharmacy penetration and utilization (in both the pharmacy and medical benefit).
- Undisclosed prescription drug rebates and discounts which may differ by type of purchaser.

The current 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 dispensing prescription drugs and providing pharmaceutical services. 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. The reality is much more complex, confounded by the two necessary components of a reimbursement formula: estimated ingredient cost and dispensing fee. Currently, reimbursement of the ingredient cost often subsidizes the dispensing fee, which can be confusing and which may generate calls for more transparency.

Thus, in an effort to reform the payment system and reduce drug expenditures, policymakers have made significant and proposed changes to the benchmarks used by public programs to pay for drugs, and, in some cases, have created new benchmarks altogether.

Federal government activity to reduce drug expenditures via payment system changes was a component of healthcare reform. PPACA included these changes that impact drug payment and payment methodologies:

- *Increased minimum Medicaid drug rebates* to 23.1% of the Average Manufacturer Price (AMP) for single source drugs, 13% of AMP for non-innovator multiple source

drugs, and 17.1% of AMP for blood clotting factors, all per unit or the difference between the AMP and the best price per unit and adjusted by the Consumer Price Index-Urban (CPI-U) based on launch date and current quarter AMP.

- *Cap on total rebate amount for innovator drugs* to 100% of the AMP.
- *Additional Medicaid Line Extension rebates* for oral solid dosage forms of single source or innovator multiple source drugs (e.g., new formulations such as extended release).
- *Extended Medicaid rebates to cover Medicaid patients in managed care organizations.*
- *A new formula for calculating the Federal Upper Reimbursement Limit (FUL).*
- *New definitions of AMP and multiple source drug.*
- *Expanded eligibility for Public Health Service 340B discounts.*
- *An FDA approval pathway for biosimilar biological products and Medicare Part B payment that would incentivize their use.*

Private payers have followed the government's lead but have not aggressively ventured out on their own to change their payment methods and benchmarks. As of the publication date of this Guide, AWP and manufacturer-determined Wholesale Acquisition Cost (WAC) remain widely used payment benchmarks for private insurance reimbursement to pharmacies, physicians, and other providers. 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. Despite the pushback on using AWP, this much-maligned benchmark continues to be available from a variety of sources.

Bundling of outpatient prescription drugs into payment for selected diagnoses and procedures is being tried on an expanded basis by Medicare for renal dialysis, hospice and on a limited, voluntary basis with Integrated Delivery Networks and some private payers. However, the tradition for outpatient treatment continues to be that drugs are a pass-through cost to be charged at the providers' actual or estimated acquisition price plus a pre-determined markup.

The U.S. drug purchasing and distribution system is complex and involves multiple transactions among a myriad of stakehold-

ers, including drug manufacturers, distributors, Group Purchasing Organizations, government entities, third-party payers, pharmacies (retail, mail order, specialty), pharmacy benefit managers, physicians, and patients. Changes in payment methods or benchmarks, and laws impacting pricing to government entities and government-specified entities, have 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 policy-makers better understand, evaluate and navigate the profound changes occurring in payment for prescription drugs in the United States. This 2013 update to the 2009 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.

Following the introduction (Section I), the *Guide* is presented in four main sections covering the following subject areas:

- **Payment Benchmarks.** Section II explains the drug payment benchmarks that have come into use over the past four 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 average wholesale price (AWP), average sales price (ASP), average manufacturer price (AMP), wholesale acquisition cost (WAC), maximum allowable cost (MAC), also referred to as maximum reimbursement amount (MRA), federal upper limit (FUL), national average retail price (NARP) and national average drug acquisition cost (NADAC).
- **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, clinics and hospitals. Discussed in this *Guide* are: Public payers such as Medicare, Medicaid, the Department of Defense, the Veterans Administration, and the Public Health Service's 340B program; private payers such as commercial insurers, self-funded employers and individual

patients; intermediaries including managed care organizations and pharmacy benefit managers; and providers such as hospitals, physicians, pharmacies and home health providers. 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 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 actual acquisition cost (AAC) and the surveys used to determine NADAC and NARP; the use of weighted average AMP for calculation of federal upper limit (FUL); the implications of ASP+6% payment under Medicare Part B; pricing transparency; the role of comparative-effectiveness research; orphan drugs; and bundling of provider payment for prescription drugs with payment for other related services.

Highlights

The following 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

Health plans cover pharmaceuticals under the "medical benefit" (typically drugs administered in a medical office or clinic setting, or administered through home health), and the "pharmacy benefit" (typically drugs dispensed by a retail, mail order or specialty pharmacy). Pharmaceuticals covered under the medical benefit and/or the pharmacy benefit component of a health plan typically have differing payment methods and use different pricing benchmarks.

Average Wholesale Price and Wholesale Acquisition Cost

Historically, AWP has been the generally accepted drug payment benchmark for most payers, primarily because it was readily available. However, in recent years AWP became recognized as

a “sticker price” that does not reflect the average wholesale price ultimately paid after subtraction of undisclosed price concessions.

AWP is related to WAC, although not by a standard multiplier. Historically, the relationship of AWP to WAC has been most commonly, though not always, characterized by one of the following equations, as determined by the publisher: $AWP = 1.20 \times WAC$, or $AWP = 1.25 \times WAC$ for branded pharmaceuticals. While multiple source generic drugs may have WACs from which AWP can be calculated, their reimbursement is typically based instead on maximum allowable cost.

However, WAC is not reflective of an actual acquisition cost for a wholesaler, because the WAC does not include 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 discounts and rebates negotiated between manufacturers and private payers (i.e., discounts and rebates are typically 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 and publishers alleging “gross inflation” of AWP for certain drugs and has led to the discontinuation of publishing or to a dramatic overhaul of its ‘definition’ by the remaining publishers of this widely used benchmark.

Recognition of the unreliability of AWP (or of its continued availability) 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 uncertainty of AWP as a basis for payment for pharmaceuticals in the United States became an issue for all stakeholders on March 17, 2009, with the decision by U.S. District Court Judge Saris on the proposed settlement in the two national class action lawsuits against First DataBank and McKesson. This decision resulted in the roll-back of the multiplier used to calculate AWP. The WAC multiplier of 1.25 (or greater than 1.20) was 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, an independent commercial publisher of drug pricing information, announced that it would discontinue publication of AWP no later than 2 years following implementation of the recalculated AWP — and has done so. Medi-Span made a similar announcement at the time, but ultimately reversed that decision, announcing that it will continue to publish AWP until there is a generally accepted alternative.¹ Truven Healthcare, publisher of *Redbook*, and Elsevier, publisher of *Gold Standard (ProspectoRx)* continue to publish AWP as of the publication date of this *Guide*.

While several independent publishers have proposed alternative pricing benchmarks, at the time of this publication, no comprehensive, transparent, and widely acceptable alternative to AWP has been identified.

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” [see Glossary in full *Guide*]).

Because ASP is a volume-weighted 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. ASP prices are based on manufacturer-submitted data that is two quarters in arrears, and do not include subsequent pricing changes. In general, small physician offices and regional specialty pharmacies buy small quantities 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.

From a payer perspective, ASP can also create misaligned incentives to dispense higher cost drugs due to a flat 6% mark-up in Medicare Part B (larger mark-ups are applied by some commercial health plans), when less expensive alternatives exist. Some commercial health plans have implemented a tiered mark-up on ASP, varying with compliance to health plan prescribing policies (for example, Blue Shield of California Professional fee Schedule. See: <https://www.blueshieldca.com/provider/claims/fee-schedules/home.sp>).

Average Manufacturer Price

Congress created Average Manufacturer Price (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. The Deficit Reduction Act of 2005 (DRA) mandated that AMP instead of AWP be used for the calculation of the FUL.

Like ASP, AMP represents an effort by the federal government to step away from AWP to an alternate benchmark price. In 2003, the AMP approximated 79% of AWP for brand name drugs with no generic equivalents. The Congressional Budget Office (CBO) estimated that the acquisition cost to retail pharmacies averages approximately 4% above the AMP for brand name drugs without generic equivalents.²

In March 2010, the Patient Protection and Affordable Care Act (PPACA, PL 111-148) changed the definition of AMP, to represent the average price paid to the manufacturer by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer. PPACA excluded certain payments and rebates or discounts provided to certain providers and payers from calculation of AMP, including wholesaler customary prompt pay discounts, certain bona fide services fees, manufacturer reimbursement for unsalable returned goods, and payments, rebates or discounts related to entities that do not conduct business as a wholesaler or retail community pharmacy.

Federal Upper Limit

The Deficit Reduction Act of 2005 (DRA) mandated that AMP instead of AWP be used for the calculation of the federal upper limit (FUL), 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. That is, Federal Medicaid matching funds to states are limited to payments that do not exceed the FUL in the aggregate for multiple-source drugs, plus a dispensing fee set by each state. The FUL list is created and maintained by CMS for use by states in their Medicaid Pharmacy programs, but it is also in the public domain for use by any entity.

Effective October 1, 2010, PPACA revised the Social Security Act to require HHS to calculate the FUL as no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly average manufacturer price (AMP) for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. In a study published October 2012, the Office of Inspector General reported that FUL amounts based on published prices were more than four times total pharmacy acquisition costs; and that AMP-based FULs were 61% lower than published price-based FULs at the median.³

CMS has proposed that FUL be a unit price calculated for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent,

meaning A-rated in the FDA Orange Book.⁴ Initially a FUL will not be published for any FUL group that does not contain at least three innovator and/or non-innovator drug products at the NDC-9 level, that are "A rated" with three monthly AMP prices with AMP units greater than zero reported and certified by manufacturers to calculate the weighted average of monthly AMPs.⁵

CMS has issued draft AMP-based FUL reimbursement files for review and comment, for multiple source drugs, including the draft methodology used to calculate the FULs.^{6,7} Because posted monthly AMP-based FULs fluctuated significantly month-to-month, CMS created an alternative methodology based on a rolling 3-month average of the monthly AMP-based FULs.⁸ However, the monthly and three month rolling average FUL files do not exactly match, because CMS does not have three months of data for all drugs, and because the older data may be less reflective of pharmacies' current purchase price. As of publication of this Guide, these results are posted on the CMS website for review and comment.⁹ Until the draft is finalized, CMS is using the prior formula of 150% of the lowest published price as an "interim methodology" to calculate FULs.³

Best Price

Medicaid best price was created by OBRA 90 and took effect January 1, 1991, in the calculation of rebates that manufacturers are required to pay to the states and the federal government for sales of single-source and multiple-source branded products to Medicaid beneficiaries. According to a Congressional Budget Office (CBO) report published in June 2005, best price for brand-name drugs approximates 63% of AWP.

Maximum Allowable Cost or Maximum Reimbursement Amount

Maximum allowable cost (MAC) is typically a reimbursement limit per individual multiple-source pharmaceutical, strength and dosage form. MAC price lists are established by health plans and PBMs for private sector clients and by many states for multiple-source pharmaceuticals paid for by their Medicaid and other state-funded programs. Private sector MACs usually are considered confidential. While clearly defined in FUL for Medicaid, there is no standardized private sector definition, methodology, update timing or market application for MAC.

Medicaid generic drug cost containment in some states is built around MAC programs. Those state Medicaid programs create their own lists of maximum reimbursement prices for generic drugs. As a general rule, state MAC lists include more drugs and establish lower reimbursements than the FUL list because they are not bound by the FUL three-drug/three-supplier rule, nor by the FUL payment methodology. For a drug on the FUL list, the state MAC can be lower but not higher than the FUL.

National Average Retail Price and National Average Drug Acquisition Cost

State Medicaid programs currently reimburse pharmacies for covered outpatient drugs based, in part, on the estimated acquisition cost (EAC), the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers. On February 2, 2012, in CMS-2345-P, CMS proposed replacement of EAC with estimated actual acquisition cost (AAC), and engaged (through competitive procurement) Myers & Stauffer (a private accounting firm) to provide state Medicaid agencies with acquisition costs and consumer purchase prices of covered outpatient drugs dispensed by pharmacies (not including specialty pharmacies), through a recurring pharmacy survey described in "Survey of Retail Prices: Payment and Utilization Rates and Performance Rankings".

The survey objectives are to collect data for calculation of National Average Retail Price (NARP), a monthly pricing database of actual drug prices provided voluntarily by independent and chain pharmacies in the United States, including for cash paying customers, customers with commercial third party insurance, and Medicaid customers. Another survey objective, established by CMS but not mandated in PPACA, is to collect data on the purchase prices of all Medicaid covered outpatient drugs dispensed by independent community pharmacies and chain pharmacies, for calculation of the National Average Drug Acquisition Cost (NADAC). As with AMP-based FUL, CMS has posted draft NARP and NADAC reimbursement files for review and comment by the public.¹⁰

Separately, some state Medicaid programs have implemented or are in the process of implementing an AAC-based reimbursement methodology. These states include Alabama, Oregon, Idaho, Iowa, Louisiana, California and New York.¹¹

Public Health Service 340B Price

Public Health Service (PHS or 340B) price (referred to as a '340B ceiling price') is the highest price that a '340B-covered entity' could be charged, and is equal to the price that the state Medicaid agency would pay absent any supplemental discount or rebate. However, 340B pricing can be better than Medicaid pricing because sales do not include retail pharmacy markups and because 340B providers usually negotiate sub-ceiling prices.¹²

340B ceiling prices for brand-name drugs were reported to average 51% of AWP. PPACA expanded the 340B program to include certain children's hospitals, freestanding cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals. PPACA exempted pharmaceutical manufacturers from having to provide discounts on orphan drugs to these newly

eligible entities, as proposed, if the drugs are used to treat diseases for which they received orphan-drug designation.

■ 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 payment made to the hospital. Similarly, drugs used in the hospital outpatient department for which the cost per day is \$80 or less (for CY 2013) 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. For CY 2013, CMS will pay acquisition and pharmacy overhead cost for hospital outpatient separately payable drugs and biologicals without pass-through status at ASP plus 6%. Part B prescription drugs administered in the physician office or clinic are also paid at ASP plus 6%.

The Federal Government's financial and budget issues have the potential to cause changes in reimbursement. For example, the Sequester of 2013 will result in reduction of Medicare Part B payment from ASP+6% to ASP+4% for claims on or after April 1st. However, as of the time of publication of this *Guide*, it is not possible to know if this change in reimbursement will be sustained or if there may be other changes in federal health services reimbursement. It is also impossible to know if these changes in federal reimbursement will influence or affect reimbursement by commercial entities that sometimes emulate government reimbursement methods.

For end stage renal dialysis, injectable and oral drugs with injectable equivalents administered in relationship to dialysis treatment are included in the Medicare per-dialysis prospective payment.¹³ The American Taxpayer Relief Act (H.R. 8), signed into law on January 1, 2013, included a delay in addition to the prospective payment of oral-only drugs related to dialysis treatment until January 1, 2016 (previously these drugs had been scheduled for addition to the prospective payment on January 1, 2014).¹⁴

On January 1, 2006, as a result of passage of the MMA, Medicare 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) or Medicare Advantage prescription drug plans that are integrated with a

medical plan (MA-PDs). 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.

Part D plans and MA-PDs may negotiate discounts and/or rebates with drug manufacturers. In late 2012, it was proposed that Part D drug sales for dual eligible and low income beneficiaries, together representing approximately 56% of Part D enrolled patients, be made subject to Medicaid statutory drug rebates. However no such change has been implemented as of the publication date of this *Guide*.¹⁵

Medicaid

Currently, every state Medicaid program includes an outpatient prescription drug benefit (also called a “pharmacy benefit”). As of July 1, 2011, 74.2% of Medicaid enrollees nationwide were enrolled in managed care plans, including health insuring organizations, commercial managed care organizations, Medicaid-only managed care organizations, Primary Care Case Management, prepaid inpatient health plans, prepaid ambulatory health plans, programs for all-inclusive care for the elderly and others. However health insuring organizations, commercial managed care organizations and Medicaid-only managed care organizations represented only 47% of this enrollee pool.¹⁶

Under fee-for-service Medicaid, most states pay pharmacies directly for the drugs dispensed to Medicaid beneficiaries, 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. Several states have implemented Average Actual Acquisition Cost (AAC)-based reimbursement as well.¹⁷ 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 and network. 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.

When pharmacy benefits are carved into Medicaid managed care contracts, CMS requires states to collect drug utilization data, for collection of statutory rebates from pharmaceutical manufacturers. However, in a study conducted in Q2 2011, the OIG found that 10 of 22 states using the carve-in approach did not collect rebates.¹⁸

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 differently than are drugs covered under the pharmacy benefit, using formulas that vary by state, that are based on AWP, WAC, or ASP. States are required to collect rebates for drugs administered in these settings also, but as of 2009, not all states were in compliance.¹⁹

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, the frequency with which they are updated, and network pharmacies at which they apply 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.²⁰ It has been suggested that P & T committees refocus to address value-based reimbursement and accountable care.²¹ Generic drugs are most commonly placed in the lowest formulary copayment tier, although some formularies list preferred generics on the lowest tier, and non-preferred generics on the second tier together with preferred brands. Private payers 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 for inpatient hospital, while hospital outpatient drugs are more commonly paid for separately if they exceed a specified cost threshold. Drugs administered in physician offices and clinics are usually paid separately based on AWP, WAC, or ASP.

Pilot programs are underway in several commercial settings to evaluate bundled payment mechanisms. A RAND Evidence-based Practice Center study published in August 2012 by the Agency for Healthcare Research and Quality concluded in part: "There is weak but consistent evidence that bundled payment programs have been effective in cost containment without major effects on quality."²² Private sector initiatives include, for example, United Healthcare's bundled payment pilot study in oncology.²³

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

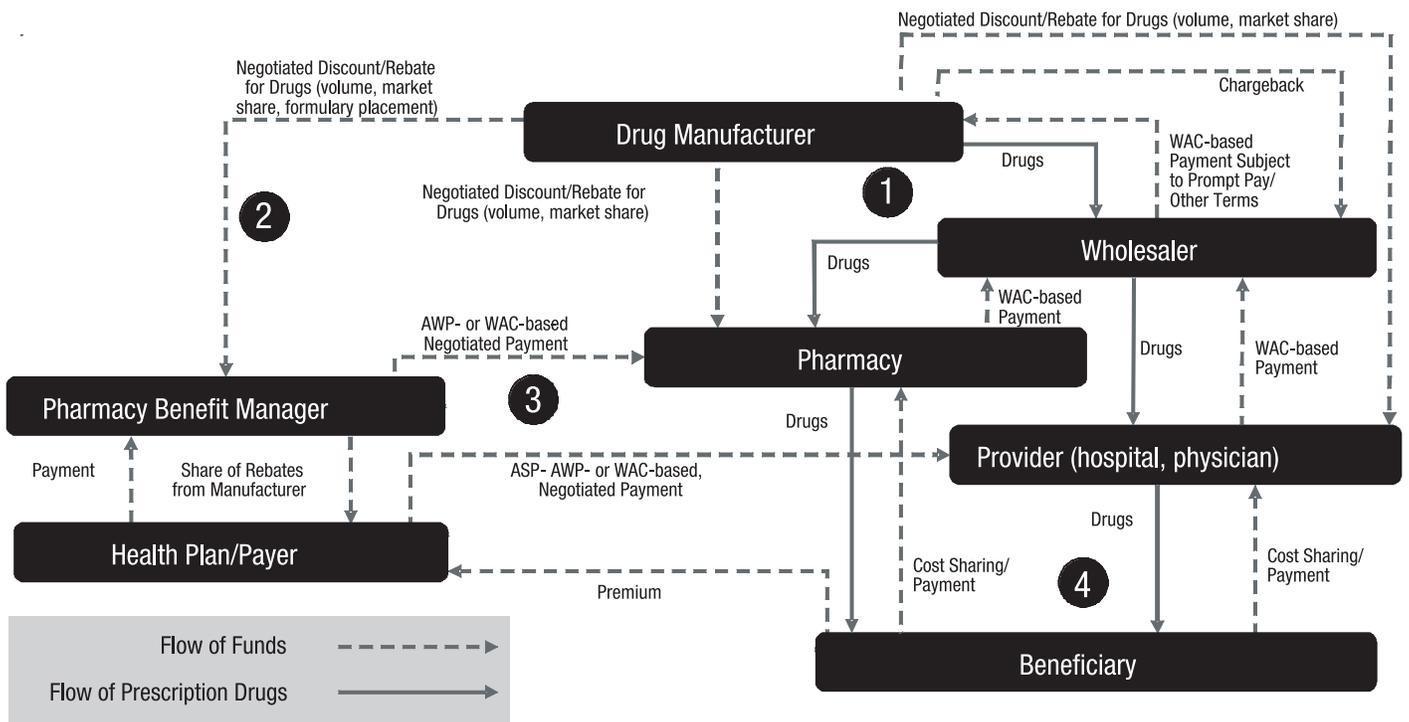
Any discussion of drug payment should consider the impact of channel of pharmaceutical distribution (e.g., hospital, physician, pharmacy) on both payment method and level.

- 1 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 custom-

ers' channel of distribution or class of trade, which may be administered by wholesalers or distributors or directly with the manufacturers.

- 2 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.
- 3 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.

EXHIBIT 1
Drug Distribution Model



4 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.

Recent Pharmaceutical Payment Milestones

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

■ Disclosures

There was no external funding for this research. The contributors, Howard Tag, JD, and Elan Rubinstein, PharmD, MPH, provide consulting services to clients that include professional associations, health plans, purchasers, providers, pharmaceutical, biological, and medical device manufacturers, and other health care entities.

..... TABLE 1
Pharmaceutical Payment Milestones: 2005–2013

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://www.gpo.gov/fdsys/pkg/PLAW-108publ173/pdf/PLAW-108publ173.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	<i>Wall Street Journal</i> 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 markup of WAC to determine AWP for a large number of drugs in 2002 was 1.25 instead of the typical 1.20, potentially 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. <i>Wall Street J.</i> October 6, 2006:A1. Available at: http://www.dc37.net/news/news_releases/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

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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.	<p><i>Retail pharmacy class of trade</i> 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.</p> <p><i>Sales, rebates, discounts, or other price concessions included in AMP.</i> Includes several non-retail pharmacy channels (see references).</p>	<p>Medicaid Drug Pricing Regulation. CMS Fact Sheet. 7/6/07.</p> <p>http://www.amcp.org/Work-Area/DownloadAsset.aspx?id=11424 and Section 447.504, Determination of AMP.</p> <p>http://www.gpo.gov/fdsys/pkg/CFR-2008-title42-vol4/pdf/CFR-2008-title42-vol4-sec447-504.pdf and Retail Pharmacy class of trade, <i>Federal Register</i> v72 #136, 7/17/07.</p> <p>http://www.gpo.gov/fdsys/pkg/FR-2007-07-17/html/07-3356.htm</p>
November 1, 2007	Judgments against two major brand-name drug manufacturers for “grossly inflating” the AWP 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 seven 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://wexlerwallace.us/files/00079404.pdf
July 2008	Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).	With a federal court injunction, results in <u>delay of</u> (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://www.gpo.gov/fdsys/pkg/PLAW-110publ275/pdf/PLAW-110publ275.pdf
December 31, 2008	CMS’s Medicare Part B drug Competitive Acquisition Program (CAP) postponed as of December 31, 2008.	<p>Postponed because of contractual issues with successful bidder.</p> <p>No official notice regarding if or when program may be restarted.</p>	http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/CompetitiveAcquisforBios/index.html

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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.gov/Regulations-and-Guidance/Guidance/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 Healthcare 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. <i>Health Policy Monitor</i> . 2009. Available at: http://hpm.org/en/Surveys/Johns_Hopkins_Bloomberg_School_of_Publ_H_-USA/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: https://oig.hhs.gov/oei/reports/oei-03-07-00350.pdf

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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 AWP.”	<p>Adjust AWP for approximately 1,400 NDCs to smaller gross margin (1.20xWAC rather than 1.25xWAC), effective September 26, 2009.</p> <p>Establish a reasonably accessible data repository of discoverable material regarding First DataBank drug price reporting practices.</p> <p>First DataBank independent of this court decision commits to discontinuation of publication of AWP within 2 years, on or before September 26, 2011.</p>	<p>U.S. District Court. District of Massachusetts. <i>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</i>. Civil Action No. 05-11148-PBS and Civil Action No. 07-10988-PBS. Available at:</p> <p>http://pacer.mad.uscourts.gov/dc/cgi-bin/recentops.pl?filename=saris/pdf/new+eng+carp+health+benefits+v+mckesson.pdf</p>
July 13, 2009	“Proposed Rule: Medicare Program: Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010” [CMS-1413-P], CMS proposed several changes to the Medicare drug Competitive Acquisition Program (CAP).	The Medicare Competitive Acquisition Program for Part B drugs has not been reinstated as of the 2013 publication date of this <i>Guide</i> .”	http://www.gpo.gov/fdsys/pkg/FR-2009-07-13/pdf/E9-15835.pdf
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.	(see March 17, 2009 above)	See March 17, 2009, above.
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.	<p>Temporary suspension of public availability of AMP.</p> <p>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).</p>	http://www.gpo.gov/fdsys/pkg/PLAW-110publ275/html/PLAW-110publ275.htm
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://publications.milliman.com/periodicals/health-perspectives/pdfs/health-perspectives-august-2009.pdf

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October 1, 2010	The Affordable Care Act modified the previous statutory provisions that establish a Federal Upper Limit (FUL) on multiple source drugs. Effective October 1, 2010, the Social Security Act was revised to require that the Secretary calculate FULs as no less than 175 percent of the weighted average (determined on the basis of manufacturer utilization) of the most recently reported monthly average manufacturer prices (AMP) for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis.	CMS posts ACA FUL and weighted average AMP to its website To minimize month-to-month fluctuations, CMS posts 3 month rolling average ACA FUL to its website.	http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/MethodologyGuide-AMP-BasedFULnew.pdf and http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Federal-Upper-Limits.html and http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/December-5-2012webinarpresentation.pdf
September 28, 2011	First DataBank discontinues publication of AWP. Medi-Span continues publication of AWP.	Only First DataBank discontinues publication of AWP	http://www.fdbhealth.com/policies/drug-pricing-policy/ and http://www.medispan.com/common/pdf/wkh_AWP_policy.pdf and http://www.medispan.com/Pricing-Policy-Update-2.aspx
June 2012	CMS publishes “Part I: Draft Methodology for Estimating National Average Retail Prices (NARP) for Medicaid Covered Outpatient Drugs”	CMS contracts with Myers & Stauffer to prepare a monthly report of the national average retail price (NARP) of Medicaid covered outpatient drugs by National Drug Code (NDC). Myers & Stauffer will also report the average drug price paid by cash, Medicaid, and third party insurance customers. NARP files posted to CMS website on monthly basis.	http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/NARPDraftMethodology.pdf and http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html
May 2012	CMS publishes “Part II: Draft Methodology for Calculating the National Average Drug Acquisition Cost (NADAC)”	See note regarding Myers & Stauffer for June 2012 NADAC posted to CMS website on weekly basis.	http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/NADACDraftMethodology.pdf and http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html
March 2013	President issues Sequestration order for Fiscal 2013, pursuant to Section 251A of the Balanced Budget & Emergency Deficit Control Act, as amended.	Sequestration interpreted to impact reimbursement for Medicare Part B prescription drugs, reducing reimbursement to ASP+4% for claims submitted on or after April 1, 2013.	http://www.gpo.gov/fdsys/pkg/FR-2013-03-06/html/

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