



AMCP Guide to
Pharmaceutical Payment Methods

EXECUTIVE EDITION

AMCP Task Force on Drug Payment Methodologies

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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 5,000 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.

AMCP GUIDE TO

Pharmaceutical Payment Methods

EXECUTIVE EDITION



AMCP TASK FORCE
ON DRUG PAYMENT METHODOLOGIES



OCTOBER 2007

AMCP Guide to Pharmaceutical Payment Methods

EXECUTIVE SUMMARY

The methods by which the U.S. health care system pays for prescription drugs have been subject to much attention and increased scrutiny in recent years. In particular, groundbreaking legislation has been enacted and regulations implemented that have changed the basis for payment for prescription drugs in the Medicare and Medicaid programs, and a number of precedent-setting court cases are likely to result in further modifications to drug payment methods used by public and private payers. These developments will have significant implications for many stakeholders beyond public and private payers; they will affect consumers' access to drugs, payment to pharmacists and other providers of drugs, and spending for the health care system as a whole.

Recent debate centers on determining the most appropriate basis for calculating how payers, including government, employers, and health plans, should pay pharmacists and other providers for drugs. Historically, payment for prescription drugs has been based on benchmark prices that do not necessarily reflect the actual acquisition costs paid by providers, primarily pharmacists, physicians and hospitals. This has led policymakers to believe that Medicare and Medicaid have paid more than is necessary for prescription drugs, contributing to excess spending in public programs. Thus, in an effort to reform the payment system and reduce drug expenditures, policymakers have made changes to the benchmarks used by public programs to pay for drugs. Private payers are beginning to follow their lead by changing their own payment methods and benchmarks.

However, the drug purchasing and distribution system within the United States is highly complex and involves multiple transactions among myriad stakeholders, including drug manufacturers, distributors, third-party payers, pharmacists, 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 in order to ensure that payment reform results in desired outcomes such as fair and equitable payment to providers while avoiding unintended consequences such as reduced access to drugs.

The Academy of Managed Care Pharmacy (AMCP) recognized 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 *AMCP Guide to Pharmaceutical Payment Methods* offers a comprehensive examination of the methodologies and price benchmarks that have been used in the public and private sector to pay for pharmaceuticals in the U.S., 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 organized into 4 main sections:

1 Payment Benchmarks: This section 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 with and interact with 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), and Maximum Allowable Cost (MAC).

2 Payers and Payment Methods: This section 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, 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, as well as private payers. 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 manufacturer drug rebates.

3 How Products, Services, and Payments Flow Through Channels of Distribution: This section 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.

4 Select Issues and Implications for Stakeholders: This section 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 the 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.

Highlights

The following highlight key issues 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

Pharmaceuticals may be covered by a health plan under its "medical benefit" (e.g., drugs administered by a physician), while others are covered under the "pharmacy benefit" (e.g., drugs dispensed by a pharmacist). Medical and pharmacy benefit drugs are not only covered under separate components of a health plan, they also have different payment methods and price benchmarks.

Average Wholesale Price (AWP) and Wholesale Acquisition Cost (WAC)

Historically, Average Wholesale Price (AWP) was the generally accepted drug payment benchmark for many payers because it was readily available. However, AWP is now thought of as a “sticker price,” in that it rarely if ever reflects the average wholesale price actually paid after discounts have been subtracted. Related to AWP is Wholesale Acquisition Cost (WAC), which is the “list price” set by manufacturers for each product. AWP is typically set at approximately 20% to 25% above WAC. However, like AWP, WAC does not represent what a wholesaler actually pays for the drug because the WAC does not include many of discounts and price concessions that are offered by manufacturers. In fact, WAC serves as the basis for negotiated discounts and rebates between manufacturers and private payers (i.e., discounts and rebates are subtracted from WAC) for both medical and pharmacy benefit drugs.

While most payers base provider payment rates on AWP or WAC for drugs covered under the pharmacy and medical benefits, this is starting to change. Given the growing recognition that neither AWP nor WAC represents the true cost of the product to purchasers, particularly for generic drugs, several new drug payment benchmarks have been created that will likely result in a discontinuation of the use of these benchmarks.

Average Sales Price (ASP)

As a result of the Medicare Modernization Act (MMA), Average Sales Price (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 upon manufacturer-reported actual selling price data and includes the majority of rebates, volume discounts, and other price concessions offered to all classes of trade.

Because ASP is an “average,” some providers may be 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 buy at the least favorable prices and are unable to purchase some drugs at prices at or below the 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.

Because ASP values are publicly available on the CMS website, private payers are able to use ASP for payment of medical benefit drugs. Uptake beyond Medicare has been slow but steady. This trend is likely to continue and accelerate in upcoming years.

Average Manufacturer Price (AMP)

Average Manufacturer Price (AMP) was created by Congress in 1990 for the purpose of calculating rebates to be paid by manufacturers to states for drugs dispensed to their Medicaid beneficiaries. It 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 federal upper limit (FUL), the maximum amount of federal matching funds the federal government will pay to state Medicaid programs for eligible generic and multiple source drugs. Under DRA, FULs are now set at 250% of a drug's AMP.

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 to include 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 PBMs, long term care facilities, or federal drug benefit programs within this definition.

Because AMP values will now be reported monthly and will be available publicly on CMS' website, states may choose to expand AMP-based payment beyond FUL-eligible drugs to all drugs covered under the pharmacy benefit. Private payers may also choose to use AMP as the basis for pharmacy payment.

■ Payers and Payment Methodologies

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

Medicare

Medicare's payment for drugs depends upon 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 whose cost per day is \$55 or less (in 2007) are bundled into the ambulatory payment classification (APC) payment for the procedures with which they are used; there is no separate payment made for those drugs. Currently, drugs exceeding this threshold in the hospital outpatient department receive separate payment; the payment rate for the majority of these drugs is ASP plus 6%.

Most drugs administered in physicians' offices and hence covered by Medicare's Part B medical benefit are also paid using the ASP plus 6% formula. However, physicians who elect to participate in the Part B Competitive Acquisition Program (CAP) do not bill for Part B drugs administered in their offices. Instead, the CAP vendor bills directly, at ASP plus 4.4%.

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 via private sector drug plans known as stand-alone prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MA-PDs). These plans are typically offered by PBMs and commercial health plans; each sets its own premiums, benefit

structures, drug formularies, pharmacy networks, and terms of payment. Therefore, unlike the other components of Medicare where a standard payment formula typically exists, under Part D drug payment varies by individual plan.

Medicaid

Currently every state Medicaid program includes an outpatient prescription drug, or pharmacy, benefit. Under fee-for-service Medicaid, states usually pay pharmacies directly for the drugs dispensed to Medicaid beneficiaries, typically using a rate based upon 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 – referred to as dual eligibles – receive prescription drug benefits through the Medicare Part D outpatient drug benefit.

Every state Medicaid program, either directly or through man-

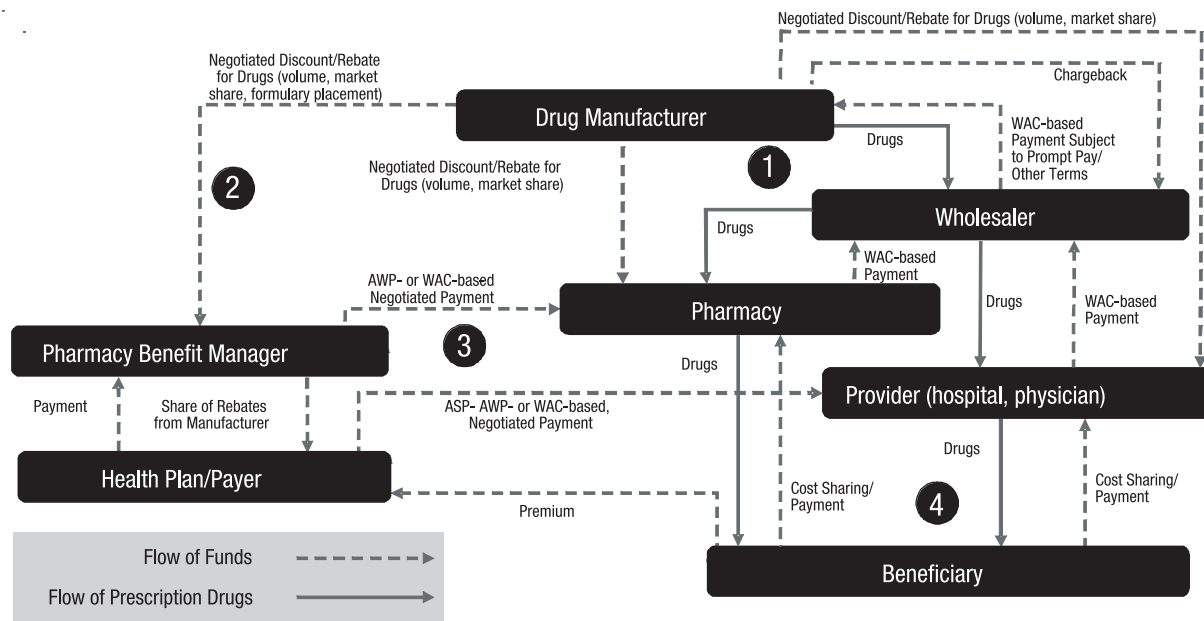
aged Medicaid organizations, also pays for drugs that are utilized under the medical benefit (e.g., in the physician’s office). Drugs covered under the medical benefit are typically paid for separately based upon formulas that vary by state, but are typically based on AWP, WAC or ASP.

Private Purchasers

Compared with public payers, private payers have less transparency in their payment methods for prescription drugs. For example, private payers use MAC price lists for multiple-source drugs that are not accessible. Like public payers, private payers use drug formularies – a list of drugs covered by the plan – 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 those copayment tiers is related to their relative safety, efficacy, and effectiveness as determined by pharmacy and therapeutics (P&T) committees as well as to their cost based in part on the price concessions that private payers can obtain from drug manufacturers. Generic drugs typically are placed on the lowest copayment tier. Private payers also negotiate drug payment rates with pharmacy providers; historically these rates have been based on AWP or WAC.

As in Medicare, private payers typically do not provide separate payment for drugs used in the inpatient hospital setting, while hospital outpatient drugs are paid for separately if they exceed a specified cost threshold. Drugs administered in physician offices are usually paid for separately based upon AWP, WAC or ASP.

EXHIBIT 1 Drug Distribution Model



■ How Products, Services, and Payments Flow Through Channels of Distribution

Any discussion about changes to the drug payment system should consider the pharmaceutical distribution system and the meaning of the many prices at each point in the supply chain.

① The majority of drug manufacturers ship drugs directly to drug wholesalers or distributors, who in turn then distribute the drugs to their end customers including pharmacies, hospitals, and physician offices. Manufacturers enter into various forms of contracting arrangements, including discounts and rebates, with all of the entities within the pharmaceutical supply chain.

② Health plans and pharmacy benefit managers (PBMs) also negotiate with manufacturers for discounts and rebates based upon volume, market share, and formulary placement for pharmaceuticals purchased for the individuals enrolled in their plans. PBMs are entities that provide administrative services under the pharmacy benefit, such as contracting with a network of pharmacies, developing and managing formularies, establishing payment levels for provider pharmacies, and adjudicating pharmacy claims.

③ Pharmacies receive payment from the health plan or PBM for the drugs dispensed to the plan beneficiaries based on a set formula agreed to by the plan and pharmacy. Physicians and other providers also negotiate with health plans for payments for the drugs they administer directly to beneficiaries.

④ At the pharmacy counter or other point of sale, beneficiaries with health insurance coverage will typically pay a copayment or some form of cost sharing to the pharmacy for the prescription drug. The cost sharing amount is set by the terms of that beneficiary's health insurance plan. Individuals without health insurance or other coverage for the purchase of their prescription drugs must pay the pharmacy's or other provider's "usual and customary" price to obtain their drugs.

■ Implications

Current and future drug payment reforms will have implications for multiple stakeholders at all points across the drug distribution system. Issues that have yet to be resolved include whether and to what extent payers will shift away from AWP to other payment benchmarks, how ASP has affected access to drugs under the Medicare Part B benefit, and how public disclosure of AMP may impact the range of drug prices offered in the market. Each of these topics, as well as others, is explored in the *Guide*.

Conclusion

The environmental changes and imperatives of the current political climate that are driving change in pharmaceutical payment are described in detail in *AMCP's Guide to Pharmaceutical Payment Methods*. As policymakers and stakeholders seek to navigate pharmaceutical pricing and payment policy issues, the *Guide* will serve as a resource in providing a foundation for developing and evaluating drug payment reforms. The *Guide* brings together in a single document information and analysis to assist anyone interested in learning more about how prescription drugs are purchased and paid for.

Note: The references in this *Guide* contain URL addresses to the source documents that are publicly available. In addition, a searchable interactive database offering access to articles and documents that examine drug product payment systems in use in the United States was developed by the Academy and is posted on the AMCP website at: <http://www.amcp.org/amcp.ark?p=264A8FA5> <<https://mail.amcp.org/exchweb/bin/redir.asp?URL=http://www.amcp.org/amcp.ark?p=264A8FA5>>.

I. INTRODUCTION

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Prescription pharmaceuticals¹ are unlike any other segment of the health care marketplace in both the complexity and variation of how the finished goods are priced to intermediate and final purchasers in the channels of distribution and how much is actually paid when the product is dispensed or administered to the patient. In response to a growing need by all stakeholdersⁱⁱ for detailed information on this complex topic, the Academy of Managed Care Pharmacy has produced this *AMCP Guide to Pharmaceutical Payment Methods*.

For many years and until recently, pharmaceutical prices are reported to have increased at rates that exceeded other health care spending.¹ As shown in Exhibit I-1, projections made in 2005 suggested that this pattern would continue through 2014.²

However, in the private sector, the Milliman Medical Index suggests that the pharmacy costs of preferred provider organization (PPO)-based health plans have moderated somewhat in recent years, as shown in Exhibit I-2.³

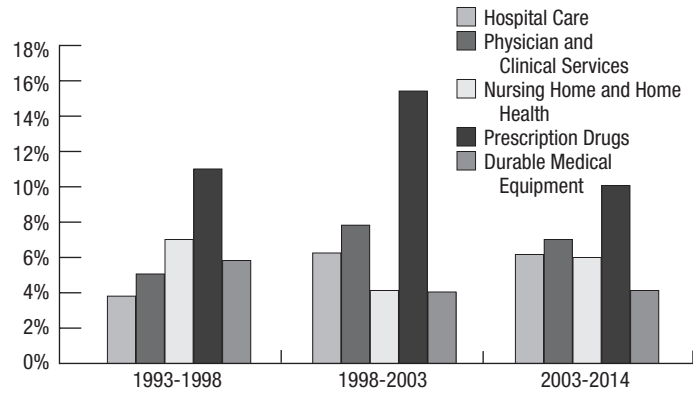
The federal government has responded to escalating cost by becoming increasingly involved in pricing and payment dynamics. The interest of Congress in pharmaceutical payment, supported by research and investigations by other federal offices, led to extraordinary changes in how large federal programs pay manufacturers and providers for prescription pharmaceuticals.

This *Guide* offers a comprehensive overview as well as a selected focus on details concerning the most important changes to pharmaceutical payment. It is organized into 4 main sections:

- Payment Benchmarks
- Payers and Payment Methodologies
- How Products, Services, and Payments Flow Through Channels of Distribution
- Issues and Implications for Stakeholders

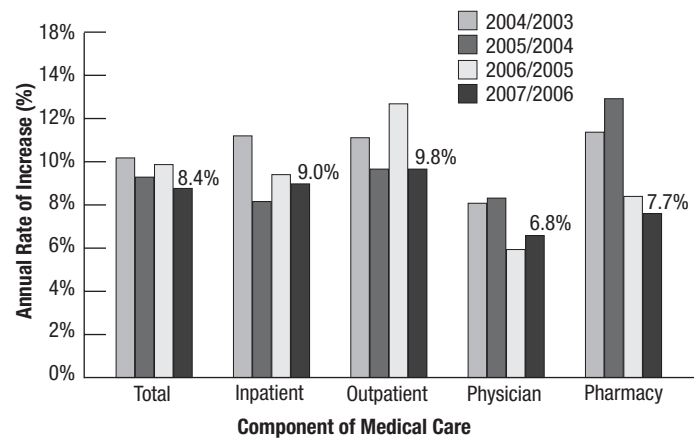
AMCP intends this *Guide* to be an unbiased presentation of information, issues, and implications. The *Guide* is not an expression of AMCP policy, nor is it intended to advocate any position on behalf of AMCP or its members on any issue contained herein.

EXHIBIT I-1 Average Annual Percent Growth in Health Expenditures for Selected Spending Categories, 1993-2014



Source: American Association of Retired People (AARP). *Reimagining America: AARP's blueprint for the future*. 2005. Available at: <http://www.aarp.org/research/blueprint/>. Accessed September 4, 2007.

EXHIBIT I-2 Milliman Medical Index Annual Rate of Increase in Cost by Component of Medical Care (*)



(*) Average medical spending for typical American family of 4 covered by an employer-sponsored PPO program.

Source: Milliman Inc. *Milliman medical index 2007*. May 2007. Available at: <http://www.milliman.com/expertise/healthcare/products-tools/mmi/pdfs/milliman-medical-index-2007.pdf>. Accessed August 26, 2007.

¹ The terms “pharmaceutical(s)” and “drug(s)” are used interchangeably throughout the paper, reflecting the usage in the government and nongovernment publications quoted and referenced throughout the paper. Unless stated otherwise, “pharmaceutical(s)” and “drug(s)” include biologicals.

ⁱⁱ Stakeholders including payers and their consultants and representatives, vendors in the channels of distribution, health professionals, policymakers, patient associations, and professional associations.

A crisis of confidence in the reliability of average wholesale price (AWP) as the appropriate benchmark for calculating payment for pharmaceuticals came to a head in 2006–2007 as it became increasingly evident that AWP bore little resemblance to the actual price paid by the pharmacy provider for the pharmaceutical. For approximately 40 years, AWP was the widely used basis for reimbursement of providers for the delivery of pharmaceuticals to patients. While consultants and observers had more recently referred to AWP as “ain’t what’s paid,” particularly for generic drugs, and the federal government had substituted average sales price (ASP) for AWP when handling provider reimbursement in Medicare Part B for drugs administered in physician offices, the death knell for AWP as a basis for pharmaceutical reimbursement did not occur until the Fall of 2006. At that time, the discovery process in litigation revealed that (a) there was no “average” in AWP, and (b) the primary source of AWP had unilaterally adopted a common margin of 20% (otherwise known as markup of 25%) between AWP and wholesale acquisition cost (WAC) for all brand drugs.^{4,5}

Today, every government and private payer is considering or has already made fundamental changes in its pharmaceutical reimbursement methodologies. The federal government has spearheaded efforts in this area by creating ASP and average manufacturer price (AMP), both new pricing benchmarks based on manufacturer net price.

Over the years, government, providers, manufacturers, and data publishers have created a wide range of benchmarks and price references that they and their customers continue to use. For some terms, there is no absolute uniformity in or agreement on their meaning. A benchmark might not be defined in law, such as AWP, or a benchmark might be defined in different ways for different purposes, such as AMP, thereby creating small but significant differences in meaning depending on the user or purpose.

The following section provides a description of benchmarks that are receiving special attention for public policy reasons. A more comprehensive list is contained in the Comprehensive Edition of the *Guide*, available at <http://www.amcp.org/amcp.ark?p=1529B561>.

Benchmarks

■ Average Wholesale Price (AWP)

Created in the 1960s, AWP was the first generally accepted standard pricing benchmark for the majority of payers because this information was readily available from several suppliers.⁶ At that time, it was considered to be an appropriate estimate of the actual acquisition cost (AAC).

AWP has been referred to as “essentially a sticker price and does not directly correspond to any actual market transaction.”⁷ For the past several years, pharmacies and other provider customers have generally been able to purchase pharmaceuticals at a net cost below AWP.

Medicare’s use of AWP ended on January 1, 2005, for all but a handful of pharmaceuticals.⁸ Medicaid soon followed, with a change in reimbursement for generic pharmaceuticals from an AWP-based formula to one that relies on AMP.

In 2007, under a settlement pending in a federal court case, First DataBank (FDB), the largest publisher of pharmaceutical pricing data, agreed to stop publishing AWP within 2 years of the court’s approval of the settlement based on the condition that its competitors also stop publishing AWP data.⁹ Wolters Kluwer, publisher of Medi-Span, announced that it had entered into a similar settlement agreement with plaintiffs, pending court approval.¹⁰ Many believe that, if given final approval by the court, this settlement agreement will mark the end of AWP as a benchmark.

■ Average Sales Price (ASP)

Most drugs covered by Medicare Part B, mainly physician-administered infusions and injections, are reimbursed at 106% of ASP. ASP is based on the manufacturer’s actual selling price, which includes almost all forms of rebates and discounts reported to the federal government’s Centers for Medicare and Medicaid Services (CMS).

ASP has proven to be substantially lower than AWP, the former benchmark for Part B reimbursement. In a 2005 study, the Office of Inspector General (OIG) of the Department of Health and Human Services (DHHS) found that, in the aggregate for all pharmaceuticals reviewed, “ASP is 49% lower than AWP at the median.”¹¹

The Medicare Payment Advisory Commission (MedPAC) found that, from 2004 to 2005 when the payment rate changed to 106% of ASP, total claims volume and charges for each medical specialty reviewed (including pharmaceuticals, pharmaceutical administration, evaluation and management visits, tests, and other procedures) increased, but spending on pharmaceuticals decreased. The decline in expenditures for pharmaceuticals ranged from 1% for rheumatology to 52% for urology. Overall, total Part B pharmaceutical spending (considering price and volume changes) fell from \$10.9 billion in 2004 to \$10.1 billion in 2005.¹²

Impact on Provider Practices

ASP is a volume-weighted average.¹³ A provider whose acquisition cost is above the median will be adversely impacted, while those entities below the median will benefit. In the MedPAC study noted above,¹² most physicians reported that they were able to purchase most of their oncology pharmaceutical agents at the Medicare payment level, but all reported that pharmaceutical profit margins are slim and that some products cannot be purchased at the payment rate. Many also reported that they have increased efficiencies in their practices in response to lower pharmaceutical payments.¹²

One concern with ASP-based reimbursement is that it may undermine manufacturers’ incentives to compete on price for

II. Payment Benchmarks

single-source, therapeutically equivalent products. ASP may also discourage use of multi-source products when a therapeutically equivalent brand is available.

■ Average Manufacturer Price (AMP)

AMP represents another effort by the federal government to step away from AWP to an alternate benchmark price. AMP is beginning its implementation as the benchmark for Medicaid generic pharmaceutical reimbursement and is poised to become an important influence for reimbursement of single-source products.

AMP, like ASP, is based on manufacturer reported sales data. AMP was created in the early 1990s following enactment of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) as the basis for calculation of manufacturer rebates on outpatient pharmaceuticals dispensed to Medicaid beneficiaries. OBRA 90 required that pharmaceutical manufacturers enter into rebate agreements with CMS and pay quarterly rebates to the States to obtain Medicaid coverage and payment. The statutorily mandated rebate amounts are calculated based on the AMP, defined by Section 1927 of the Social Security Act as the average price paid to the manufacturer by wholesalers in the United States for a pharmaceutical distributed to the retail pharmacy class of trade, after deducting customary prompt-pay discounts. Until recently, AMP data were treated by the federal government as proprietary and confidential.

Two changes for Medicaid benchmark prices are becoming effective in 2007: adoption of AMP as the new RP for generic drug reimbursement and requiring the AMP for all pharmaceuticals—both generic and brand name—to be reported to the states and public on a monthly basis. As a result, AMP, which was developed and used only for Medicaid rebate calculations, will soon become an important RP for other purposes. Medicaid reimbursement for brand-name drugs continues to be AWP based, but states have the option to use AMP.

Included within the calculation of AMP are any and all price concessions, discounts (other than customary prompt-pay discounts), and rebates. Manufacturer payments for bona fide services are not included. Final rules implementing the new Medicaid RP rules become effective October 1, 2007.

■ Best Price (BP)

Best price (BP) is considered by federal and state governments in the calculation of rebates that manufacturers are required to pay for sales of single-source and multi-source branded products to Medicaid beneficiaries. BP is applied when the price to a purchaser exceeds the discount earned by application of the mandatory discount plus any penalties (i.e., greater than 15.1% of AMP plus the Consumer Price Index [CPI] penalty). BP approximates 63% of AWP.¹⁴

BP can be a limiting factor in contract negotiations between manufacturers and private payers if the manufacturer uses it as

a rationale for not increasing a discount offered to a private payer. However, what may be overlooked in this type of negotiation is that the BP that will trigger a larger Medicaid rebate was calculated using a different benchmark (AMP) than the negotiated rebate to the private payer, which typically used WAC as the benchmark.

Some providers and health plans have criticized BP as a barrier to the negotiation of lower prices between manufacturers and private-sector customers because a manufacturer may not want to create a new BP in the Medicaid market. Opponents of BP have repeatedly, but thus far unsuccessfully, urged Congress to repeal the BP provision.¹⁵

■ Wholesale Acquisition Cost (WAC)

WAC is the manufacturer's reported list price for a prescription pharmaceutical for sale to wholesalers.⁶ Each manufacturer establishes its own WAC using its own formula. Price-reporting services, such as FDB and Medi-Span, publish WAC prices supplied to them by manufacturers in their pharmaceutical information databases. Most pharmaceutical contracts between manufacturers and private payers use WAC as the RP.¹⁶

The terms *list price*, *catalog price*, *wholesale net price*, and *book price* are used by some manufacturers as synonyms for WAC. Almost all single-source pharmaceuticals have a WAC price, but many generic pharmaceuticals, repackaged pharmaceuticals, or "house brands" do not because there is no legal requirement to report a WAC.

Like AWP, WAC is a suggested price that often does not represent what a wholesaler or end provider actually pays for the pharmaceutical because WAC does not include manufacturer incentives such as rebates, volume purchase agreements, and prompt-payment discounts. Unlike AWP, however, WAC is statutorily defined in the U.S. Code:

*The term "wholesale acquisition cost" means, with respect to a pharmaceutical or biological, the manufacturer's list price for the pharmaceutical or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of pharmaceutical or biological pricing data.*¹⁷

WAC is a lower price than AWP because it is applied earlier in the distribution process. Some Medicaid programs use WAC as an alternative to AWP in their reimbursement formula. In the FDB system, AWP and WAC are related in a constant ratio for each brand-drug manufacturer in which AWP is 1.20 or 1.25 times WAC. Due to the proportionate relationship between WAC and AWP, entities that establish the WAC effectively establish the AWP published by FDB and thereby impact payer reimbursement in AWP-based payment systems that use FDB data. In the private sector, WAC is the basis for many manufacturer rebate calculations.¹⁸

II. Payment Benchmarks

■ Maximum Allowable Cost (MAC)

Maximum allowable cost (MAC) is typically a reimbursement limit per individual pharmaceutical and strength (e.g., \$0.50 per fluoxetine 20-mg capsule). MAC price lists are established by health plans and pharmacy benefit managers (PBMs) for private-sector clients and by many states for multiple-source pharmaceuticals dispensed by their Medicaid and other state-funded programs.

No standardized definition for MAC exists; states and private payers use a variety of formulae, including WAC-based and FUL-based approaches, as well as market surveys targeting distributors and pharmacies.

■ Federal Upper Limit (FUL)

Federal upper limit (FUL) is a price calculated and published by CMS as the maximum amount that a state Medicaid program can pay for a multiple-source (generic) drug.

■ Public Health Service (PHS or 340B)

340B 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. The price

could be negotiated lower by the 340B entity. 340B entities include Public Health Service (PHS)-funded clinics and disproportionate-share hospitals (DSHs). Patients of a covered entity, including non-Medicaid patients, may receive drugs purchased at the 340B discount. However, covered entities are not permitted to resell or transfer outpatient drugs purchased at the 340B discount to individuals who are not patients of the covered entity.¹⁹ 340B prices are reported to be approximately one-half (49%) of AWP.^{14,20}

Comparison of Benchmark Prices

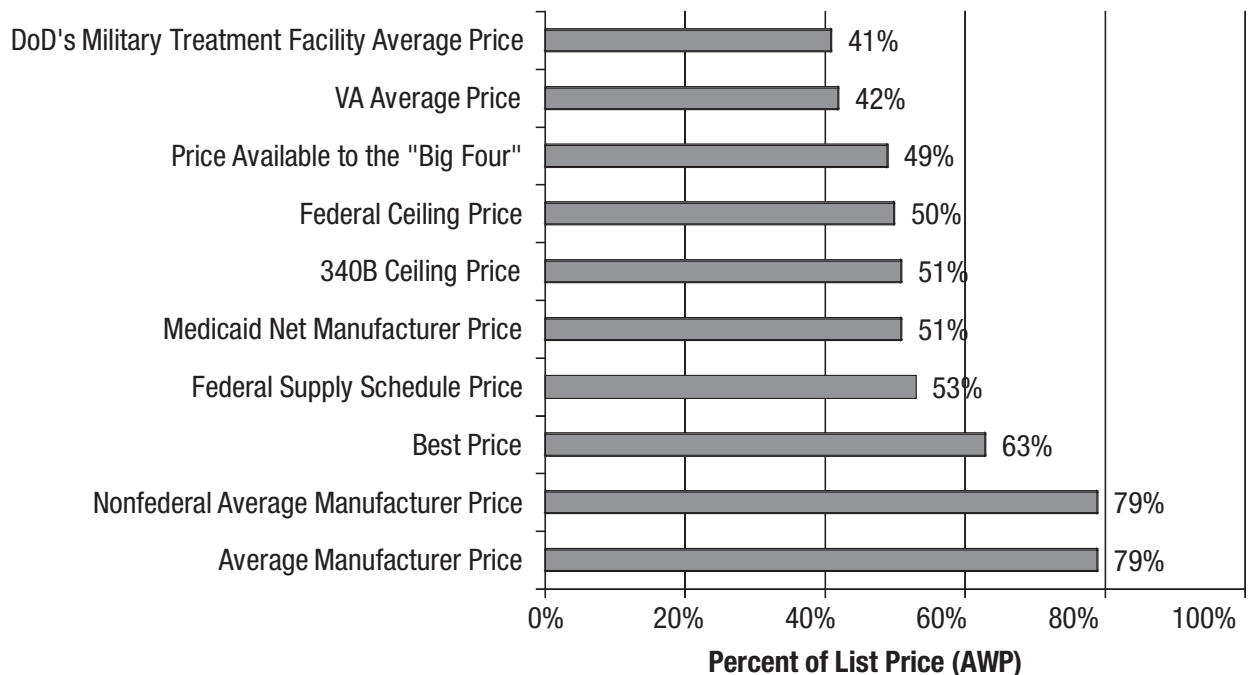
Exhibit II-1, from a 2005 Congressional Budget Office (CBO) study, illustrates how selected benchmark prices compare with both AWP and with one another.

■ Benchmarks and the Goal of Appropriate Payment

The "best" benchmark will be defined by its purpose and accuracy in defining a common value at a given point in the chain of drug distribution. By these 2 criteria, the best benchmark may be different for government versus private payers. Some factors that should be considered when defining BP benchmarks include:

EXHIBIT II-1

Estimated Prices Paid to Manufacturers, Relative to List Price (AWP), for Brand-Name Drugs Under Selected Federal Programs, 2003



Source: Congressional Budget Office. Prices for brand-name drugs under selected federal programs. Congress of the United States; June 2005. Available at: <http://www.cbo.gov/ftpdocs/64xx/doc6481/06-16-PrescriptDrug.pdf>. Accessed September 4, 2007.

II. Payment Benchmarks

- What point in the distribution chain is the benchmark the most accurate determination of the common true price? For example, a benchmark based on average net manufacturer price should accurately reflect the most common selling price, while a benchmark based on average net acquisition cost should represent the most common prices for wholesalers or providers as purchasers.
- How accessible, transparent, and accurate are the benchmark values for all stakeholders? AWP and WAC have been used as drug payment benchmarks because they were readily accessible from Medi-Span, Redbook, and FDB. However, AWP has been shown to have almost no relevance to most generic drugs, and WACs have not been readily accessible in all cases. Also, these terms cannot be interpreted literally; that is, AWP does not always represent the price of a drug purchased from a wholesaler, and WAC does not always represent the actual cost to the wholesaler.²¹
- How will different stakeholders be affected by the change? For example, if average net manufacturer price is used as a benchmark for calculation of provider compensation, is there recognition of the cost that is added in the process of transferring the product from manufacturer to provider, representing the value added as the product passes through the channels of distribution?
- What are the consequences for other payment methodologies? For example, how will use of AMP for provider reimbursement affect Medicaid rebates and rebate-discount negotiations between private payers and pharmaceutical manufacturers?
- What will be necessary for individual payers to monitor, modify, and administer the new payment methodology? For example, how much will the benchmark vary among smaller versus larger providers or among various classes of trade (COTs)? How can these variations be monitored and adjusted if desired to best represent actual price for different types of purchasers? What administrative burden will be incurred by monitoring the reasonableness of prices for different types of purchasers?

Introduction

Payment to providers for the prescription drugs that they administer and dispense varies depending on the payer and the site of care. Each combination of payer and site of care involves a different reimbursement formula. As a result, providers must be keenly aware of their payer “mix,” the portion of total revenue attributable to each type of payer. Payers have an important economic stake in the treatment setting in which a particular drug is prescribed or administered.

Medicare

■ Background

Established in 1965, Medicare is a federal health insurance program available to individuals who fall into 1 of 3 specified categories defined by age, disability, or end-stage renal disease (ESRD). The majority of individuals become eligible for Medicare by virtue of attaining age 65.²²

Medicare has several statutory benefit programs: Part A (hospital insurance), Part B (medical insurance), Part C (Medicare Advantage), and Part D (prescription drug coverage). Each program has unique rules governing coverage and payment methodologies for prescription drugs. In general, the payment methodology will depend upon the treatment setting:

- Hospital inpatient
- Hospital outpatient department (HOPD)
- Physician office
- Dialysis facility
- Ambulatory surgical center (ASC)
- Home via home health provider
- Home via retail pharmacy

■ Medicare’s Influence on Prescription Drug Payment

Private health insurance pays the largest portion of prescription drug costs. However, by 2007, it is projected that the introduction of the Medicare outpatient prescription drug benefit established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) will have equalized prescription drug expenditures in the public and private health insurance sectors and that thereafter the public sector will pay the majority of these costs.²³

The following is a brief overview of Medicare payment in selected treatment settings.

■ Hospital Outpatient Departments (HOPDs)

Medicare reimburses hospital outpatient services by using the outpatient prospective payment system (OPPS). Under the OPPS, CMS classifies services into ambulatory payment classifications (APCs) on the basis of clinical and cost similarity. All services within an APC maintain the same payment rate.

Drugs and radiopharmaceuticals whose cost per day is \$55 or

less (in 2007) are “packaged” or “bundled” into APCs for the procedures in which they are used, meaning that there is no separate reimbursement for those drugs.²⁴ Drugs (referred to by CMS as specified covered outpatient drugs or SCODs) and radiopharmaceuticals exceeding the \$55 threshold receive separate payment via drug-specific APCs. Payment amount is typically the same as the physician office payment rate of the ASP plus 6%.

■ Physician Offices

Following passage of the MMA, Congress and CMS reduced payments for drugs and increased payments for intravenous infusions and other drug administration services. Using AWP as the drug reimbursement benchmark was replaced by ASP. Payment for most physician office drugs is ASP plus 6%. Determination of how ASP is calculated and reported is described in Section II, “Payment Benchmarks.”

The MMA also created a competitive acquisition program (CAP) as an alternative way for physicians to acquire physician-administered drugs.²⁵ With CAP, Medicare reimbursement is made to the CAP vendor and not to the physician. The goal of the program is to increase competition for Part B drugs. It was reasoned that CAP vendors, who would purchase large quantities of drugs, could negotiate lower prices with drug manufacturers and produce Medicare savings. Smaller practices that are unable to purchase drugs at the Medicare payment rate would have another way to acquire drugs and could continue to administer drugs in their offices.

Under the CAP, organizations such as wholesalers and specialty pharmacies submit bids to Medicare to become designated vendors for Part B drugs. Each year, physicians choose whether to purchase and bill for all Part B drugs administered in their office in the traditional way or to participate in the CAP. Vendors purchase and dispense drugs to physician offices on a prescription-by-prescription basis. Medicare pays the vendors directly, and the vendors bill patients for required copayments.

By law, Medicare’s payment for CAP drugs cannot exceed ASP plus 6%. The CAP was implemented on July 1, 2006, with BioScrip (based in Elmsford, NY) as the sole designated vendor. At program launch, payment under the CAP contract to BioScrip was ASP plus 4.4%.²⁶

■ Pharmacy-Dispensed Medicare Part B Drugs

The vast majority of Part B drugs are administered in a physician’s office or hospital outpatient department (HOPD); however, some drugs dispensed in pharmacies for self administration are also part of the Part B benefit. Examples are immunosuppressives to prevent organ transplant rejection and some oral cancer drugs. The reimbursement methodology for pharmacy-dispensed Part B drugs is identical to that for other Part B drugs—ASP plus 6%.

■ Pharmacy-Dispensed Medicare Part D Drugs

On January 1, 2006, the Medicare outpatient drug benefit known

as Part D was initiated. Although it is a government program, Part D is administered by private-sector entities, either stand-alone Prescription Drug Plans (PDPs) or Medicare Advantage–Prescription Drug plans (MA-PDs). These plans compete for enrollees on the basis of annual premiums, benefit structures, specific formulary drugs, pharmacy networks, and quality of services. PDPs and MA-PDs are typically PBMs and commercial health plans. Approximately 14% of Part D enrollees nationwide are dual eligibles (i.e., enrolled in both Medicare and Medicaid) who are automatically enrolled in Part D and randomly assigned to Part D plans.²⁷

There is no direct Medicare “reimbursement” for Part D drugs. Revenue for MA-PDs and PDPs comes from beneficiary premiums and cost sharing via copayments or coinsurance, as well as from Medicare subsidy and reinsurance payments. Medicare payments to plans are determined through a competitive bidding process, and enrollee premiums are also tied to plan bids.²⁸

Medicare Payment to PDPs

For 2007, Part D enrollees who are not dual eligibles pay an average of \$328 per year in premiums, which is about 25% of the expected Medicare Part D benefit expenditures per person. CMS subsidizes the remaining 75% of the cost of standard coverage for all types of beneficiaries. That average subsidy takes 2 forms:

- Direct subsidy: A monthly prospective payment.
- Individual reinsurance: If a beneficiary exceeds the catastrophic threshold, CMS subsidizes 80% of drug spending above the threshold, and the plan is at risk for the remaining 20%.

Medicare establishes “risk corridors” to limit a plan’s overall losses or profits. By using risk corridors, Medicare limits a plan’s potential loss (or gain) by financing some of the higher-than-expected costs (or recouping excessive profits). These corridors are scheduled to widen, meaning that plans should bear more insurance risk over time. Also, for those plans that enroll low-income beneficiaries, Medicare pays some of their enrollees’ cost sharing and premiums.^{28,29}

Because PDPs are at risk for the drug costs of their beneficiaries, they are primarily concerned with controlling drug spending within the parameters of appropriate therapeutic use of these agents. Thus, PDPs may be less motivated by manufacturer rebates on products that, overall, might increase spending compared with therapeutic alternatives.

Price Negotiations

The law creating the Medicare Part D drug benefit specifically prohibited CMS from negotiating prices directly with manufacturers. Part D negotiations with manufacturers are handled by PDPs.

Part B vs. Part D

Medicare payment for more than one dozen categories of pharmaceuticals could be made under Part B or Part D including immunosuppressive agents used for transplant patients, parenteral nutrition,

intravenous immune globulin (IVIG), and hepatitis C vaccine. Whether payments fall under Part B or Part D depends on such factors as diagnosis, route of administration, location of treatment, and whether the drug is self administered.²⁸ Whether payment is made under Part B or Part D determines the payment methodology used and, therefore, how much is paid.

Home Health Providers

Although Medicare does not separately reimburse for most prescription drugs that could be administered by home health providers, certain exceptions exist.

Durable medical equipment (DME). Medication that is necessary to the function performed by otherwise-covered DME is also covered by Medicare and separately reimbursed. Examples include parenteral nutrition administered by an infusion pump, heparin administered in a home dialysis system, or albuterol in a nebulizer. Payment for most drugs used in conjunction with DME is set at ASP plus 6%. Drugs used with infusion equipment are paid at 95% of the AWP.

Intravenous immune globulin (IVIG). When administered in the home of a person with primary immune deficiency, IVIG is covered when the physician determines that home administration is medically appropriate. However, other indications for which IVIG is approved by the Food and Drug Administration (FDA) are not covered. No DME is required to trigger the benefit. As a practical matter, the benefit is only available when IVIG is administered by the patient or a caregiver because no payment is available for home health clinical services. Reimbursement is paid at ASP plus 6%.³⁰

Injectable osteoporosis drugs. These products are covered for women who have sustained bone fractures who are unable or unwilling to self-inject. Reimbursement is also paid at ASP plus 6%.³¹

Medicaid

Background

Medicaid is a program financed jointly by federal and state governments that provides medical and long-term care (LTC) to many of the nation’s most vulnerable lower-income individuals, especially mothers and children, seniors, and individuals with disabilities. Eligibility rules for Medicaid vary widely from state to state. They are linked to income as well as other factors, such as family or disability status. Each state decides how to structure benefits, eligibility, service delivery, and payment rates within guidelines established by federal law.³²

State spending on Medicaid is matched by the federal government. The federal financing share averages 57% and varies from a 50% floor to a high in 2007 of almost 76%.

Every Medicaid program includes an outpatient prescription drug (OPD) benefit. States pay pharmacy providers directly on a

fee-for-service (FFS) basis unless the beneficiary is enrolled in a managed care arrangement. More than 60% of Medicaid beneficiaries are now enrolled in some type of managed care program, ranging from traditional managed care models (such as health maintenance organizations [HMOs]) to less rigid networks with select providers.³³

■ Dual Eligibles

Medicaid beneficiaries who also qualify for Medicare are known as dual eligibles. Prior to enactment of the Medicare prescription drug benefit, dual eligibles received their outpatient medications from Medicaid. The MMA changed that process; as of January 1, 2006, dual eligibles receive their prescription drugs primarily through the Medicare benefit (i.e., through PDPs and MA-PDs). This change affected approximately 16% of Medicaid beneficiaries and 42% of Medicaid prescription drug spending.³⁴ Many of the affected beneficiaries are receiving LTC in nursing facilities.

■ Rebates

The actual cost to Medicaid for prescription drugs is reduced by manufacturers' rebates that are paid to the states and shared with the federal government. Rebates extend only to drugs purchased by states on an FFS basis. When states purchase drugs through managed care programs, the managed care organizations (MCOs) are permitted to negotiate their own discounts and rebates, and the federal mandate for rebate payments does not apply.

Each quarter, for each unit of drug covered by a state FFS Medicaid program, the manufacturer must pay either a basic rebate based on a percentage of the AMP or a rebate based on the BP available to wholesalers and other customers. Rebate amounts are as follows:

- "Non-innovator" multiple-source products—11% of the AMP per unit
- "Innovator" brand-name, single-source, or multiple-source products—the sum of the following two components³⁵:
 1. The greater of (a) 15.1% of the AMP or (b) AMP minus BP.
 2. An additional rebate if the product's AMP has increased from a baseline faster than the Consumer Price Index—Urban (CPI-U).

As a result of the Medicaid rebate law, pharmaceutical companies no longer had an incentive to offer discounts to private-sector purchasers of more than 15.1% of the AMP because those discounts also triggered larger Medicaid rebates. Many states have negotiated with manufacturers for supplemental rebates over and above the basic and additional rebate based on the position of products on state Prescription Drug Lists (PDLs).³⁶

Community pharmacy reimbursement typically includes both drug and dispensing components. Following federal guidelines, states reimburse pharmacies for Medicaid prescriptions on the basis of an estimate of the ingredient cost of the drug Estimated Acquisition Cost (EAC) plus a dispensing fee—both of which vary among the states. States determine how they will

calculate EAC. In most states, the AWP figures prominently into the formula.³⁷

Costs for single-source drugs are typically reimbursed at a rate equal to AWP minus approximately 10–15% plus a dispensing fee.

The payment formula for multiple-source drugs, which include generic drugs and their brand-name counterparts, is subject to a FUL. The FUL reimbursement formula is 250% of AMP for the least costly alternative (LCA) "when at least 2 suppliers (e.g., manufacturers, wholesalers, repackagers, or relabelers) list the drug in a nationally available pricing compendia."³⁸

States also have the latitude to set an upper boundary on reimbursement, or MAC, that is lower than the FUL, as well as to set a MAC for a multiple-source drug that does not yet have a FUL.

■ Revising AMP

Despite rebates paid to Medicaid programs, expenditures for prescription pharmaceuticals continued to be a major concern to the Administration, Congress, and states. The OIG of the DHHS reported that AWP-based Medicaid pharmaceutical reimbursements far exceed pharmacies' AAC and recommended that Medicaid should base reimbursement on pricing data that more accurately reflect AAC.³⁹ These data were primarily based on multi-source (generic) pharmaceutical pricing; further evaluation will be needed to determine the applicability of these data to innovator and single-source pharmaceutical products.

Deficit Reduction Act of 2005 (DRA) and Subsequent Rule Making

In 2005, Congress implemented the OIG recommendations with enactment of the Deficit Reduction Act (DRA).³⁸ Monthly manufacturer reporting began in March 2007 (retroactive to January 1), and release of prices to the public will begin later in the year.

Generic drugs will continue to be reimbursed at the FUL price unless a state has established a lower MAC. Prior to DRA implementation, the FUL was determined based on 150% of the lowest published price (based on the manufacturer's reported price, generally AWP) of all qualified Orange Book–equivalent pharmaceuticals. The DRA changed that number to 250% of AMP.

Even though reimbursement for Medicaid single-source brand pharmaceuticals continues to be AWP based, states have the option to use AMP when setting Medicaid reimbursement amounts for brand-name drugs.

In July 2007, CMS published a final rule along with a comment period to more fully describe the DRA changes.⁴⁰ The final rule defines the "retail class of trade" to include 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 to hospitals for inpatient use, to LTC facilities, to PBMs, and to federal programs other than Medicaid are excluded from the retail class of trade.

Private Purchasers

Private purchasers (also known as “payers” and “plan sponsors”) provide the bulk of health insurance coverage in the United States for those under the age of 65. As of 2005, almost 68% of Americans under the age of 65 were enrolled in privately sponsored health care insurance, of which approximately 88% was employer based, and the balance was direct purchased (see Exhibit III-1).⁴¹

Structure of Privately Sponsored Health Coverage

A 2006 annual employer survey demonstrated that 3% of covered workers were enrolled in conventional insurance plans, 20% in HMOs, 60% in PPOs, 13% in point-of-sale (POS) plans, and 4% in high-deductible health plans associated with savings options (HDHP/SOs).⁴²

Employer-sponsored coverage for beneficiaries enrolled in these plans may be fully insured or self insured (also referred to as “self funded”) and governed under federal legislation known as the Employee Retirement and Income Security Act (ERISA) of 1974.^{43,44} Fifty-five percent of covered workers are in self-insured plans.

Benefit Design

Private purchasers use the benefit design to impact payment for all forms of pharmaceuticals. Benefit design can be used to determine payment levels in several ways:

- Under which part of the insurance benefit (e.g., medical, pharmacy) the drug will be paid and, within these broad categories, whether it will be “carved in” or “carved out” under a sub-benefit (e.g., mental health, home health).
- The type and amount of the patient’s cost-sharing responsibility and whether it will be a coinsurance percentage or copayment dollar amount.
- Whether there is a deductible and/or a maximum annual payable amount for the pharmacy benefit.

Use of Formularies

A formulary is a list of covered drugs chosen by a health plan or a PBM’s pharmacy and therapeutics committee based on effectiveness, safety, and cost considerations. Many health plans have tiered formularies, with drugs categorized by copayment or coinsurance levels. A copayment is a fixed dollar-amount payment; coinsurance is a fixed percentage of drug cost. These copayment and coinsurance levels are intended to incentivize a shift in utilization, often from expensive brand-name drugs to less expensive, therapeutically equivalent generic and therapeutic alternatives.

From health plan and PBM perspectives, formularies are used as tools to manage care and cost. By placing a drug on its formulary, the PBM or health plan may have increased leverage with the manufacturer of that drug and with manufacturers of drugs that may be therapeutically equivalent to it. By creating the ability to steer utilization toward a particular drug that has clinical equivalence to others in the class, the plan can offer a drug manufacturer a higher market share in exchange for a lower price or a higher rebate that also achieves a lower price. A formulary with fewer clinically therapeutic alternatives in a preferred tier or larger patient-based financial incentives will increase this leverage.

Formularies, formulary tiering, tier-based copayments, and coinsurance levels are some of the most important benefit design features in use today to customize payment and determine patient financial responsibilities for specific drugs.⁴⁵ Although drug formularies involve the contracted pharmacies within a purchaser’s administration, pharmacies are typically not involved in decision-making regarding formulary content or copayment amounts and generally do not share in the economic rewards of these programs.

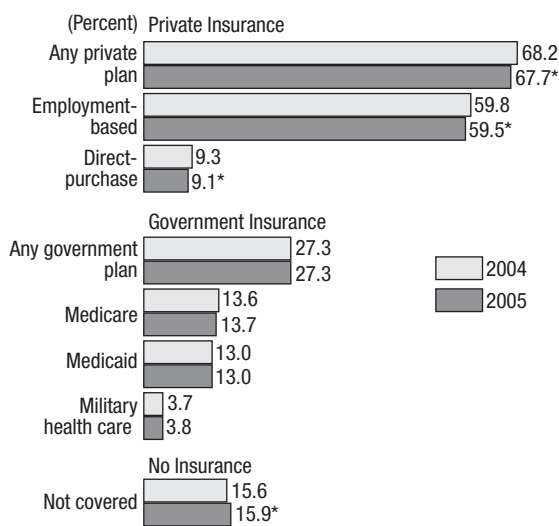
Typically, formularies have 3 or 4 tiers, with generic drugs often placed in the first tier, preferred brand drugs placed in a second tier, and non-preferred brand drugs placed in a third tier. If the formulary has a fourth tier, it is usually reserved for expensive injectable and specialty drugs and would have the highest copayment amount or coinsurance percentage.

Exhibit III-2 shows average patient copayment amounts. Note that patient cost sharing has steadily increased since 2000.

Prescription Drug Rebates

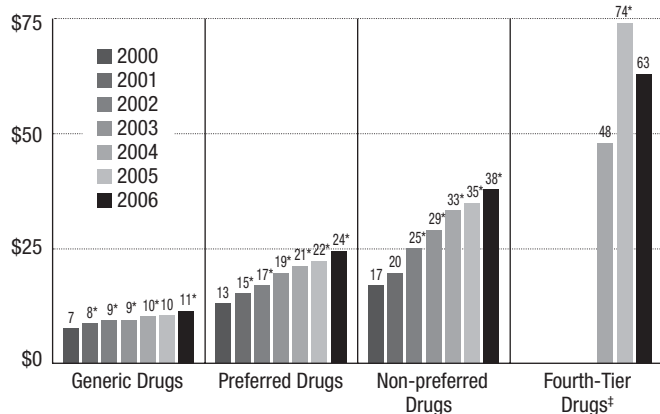
The link between drug formulary tiers and manufacturer rebates is important in understanding the true net program cost of a drug.

EXHIBIT III-1 Coverage by Type of Health Insurance 2004 and 2005



* Statistically different at the 90-percent confidence level.
 Source: U.S. Census Bureau. *Income, poverty and health insurance coverage in the U.S.: 2005*. August 2006. Available at: <http://www.census.gov/prod/2006pubs/p60-231.pdf>. Accessed September 4, 2007.

EXHIBIT III-2 Average Copayments Among Covered Workers Facing Prescription Drug Copayments (2000-2006)



* Estimate is statistically different from estimate for the previous year shown at $P < 0.05$.
 † Fourth-tier drug copayment information was not obtained prior to 2004.
 Source: KFF/HRET. Employer health benefits. 2006 annual survey. Available at: <http://www.kff.org/insurance/7527/upload/7527.pdf>. Accessed September 4, 2007.

Rebates may be based on utilization of a specific drug by enrollees of a health plan or PBM or based on the market share of that drug compared with other drugs in a therapeutic class. In some cases, rebates are based on changes in the share of drugs rather than the absolute share. Rebates may also be based on inclusion of a drug on a restrictive formulary. The rebate provides the purchaser (or its contracted intermediary, such as a PBM or health plan) with an incentive to put the branded drug on the second (preferred brand) tier rather than the third (non-preferred) or higher copayment tier. The purchaser may also have an incentive, negotiated or operational, to limit the number of other branded products in the same therapeutic class assigned to the preferred copayment tier so as to increase the unit rebate for one preferred drug.

Although health plans and PBMs often do not take possession of drugs, drug manufacturers pay rebates directly to them based on performance with the volume, share, formulary placement, and other terms, generally on a quarterly basis.

More generous rebates are often available for branded drugs that treat conditions for which an alternative therapeutically equivalent generic or brand-name treatment is available. Large rebate percentages are less likely to be offered for new or breakthrough drugs because manufacturers perceive no need to negotiate prices to obtain favorable formulary status for these products. Rebates are also less likely for generic or brand-name drugs when generics have been available for a long period of time.

The extent to which drug manufacturer rebates are shared between PBM, health plan, and purchaser is a matter of considerable attention and debate. As intermediaries between employers or

health plans and pharmacy providers, PBMs vary in the extent to which rebates are shared with client purchasers. The amount shared depends on negotiation of all variables in the contract between employer and PBM, including variables such as retail pharmacy network discounts and administrative fees. For example, an employer may desire to pay a higher administrative fee and receive more rebates or pay a lower administrative fee and share lower rebates.

Rebates and other price concessions to health plans and PBMs have no direct impact on payments to contracted pharmacies. However, in an AMP- or ASP-benchmarked system in which payment is a markup on one of these benchmarks, rebates and other price reductions that lower the overall reportable selling price also lower the pharmacy's allowable cost and net margin of profit (assuming that no change occurs in pharmacy acquisition cost and the dispensing fee remains constant).

■ Patient Expenditures for Pharmaceuticals

For a typical family of 4 covered by an employer-sponsored PPO, one medical Index estimates that a patient's out-of-pocket cost share for prescription drug costs in 2007 is approximately 25% of total drug costs. According to the Index, the actuarial value of annual pharmacy cost for a family of 4 in this scenario is \$2,081 and cost share is \$510.³ However, in 2003 across all types of coverage, the average cost-sharing percentage was significantly higher.⁴⁶

According to a CBO report, "Average prices for patented drugs in other industrialized countries are 35 to 55 percent lower than in the United States." However, "while an individual can fill a prescription in another country and realize savings reflecting the full difference in price, the same would not be true for the health care system as a whole."⁴⁷

Because of the price difference, some people without prescription drug insurance have used drug importation to reduce their prescription drug cost. Yet, safety considerations do exist. Key findings of the DHHS Task Force on Drug Importation are: "There are significant risks associated with the way individuals are currently importing drugs; and it would be extraordinarily difficult and costly for 'personal' importation to be implemented in a way that ensures the safety and effectiveness of the imported drugs."⁴⁸

■ Relationship of Provider to Payment Methodology

Payment methodology varies by provider type in the private sector as it does in the public sector. In the private sector, however, payment methodology is far more variable than in the public sector. Because payment methodologies are held in confidence by the contracting parties, little is known publicly about individual payment arrangements, how these arrangements compare across provider types, or trends in these arrangements over time.

Community Pharmacy

A community pharmacy is generally paid on the basis of a percentage markup or markdown on a benchmark, typically AWP or WAC

for single-source brands. Payment is usually subject to a purchaser-defined MAC schedule for multi-source products and includes a fee for professional services, including dispensing. Some purchasers make an additional payment to the community pharmacy for work in gaining substitution of a preferred product when a non-preferred product was prescribed. Purchasers may also offer payment to community pharmacies for the provision of medication therapy management or disease management services. A Fall 2005 employer survey showed that average community pharmacy brand reimbursement was AWP minus 15% and that average mail service brand reimbursement was AWP minus 21.9%.⁴⁹

Providers of Specialty Injectables

Drug payment for specialty injectables, as well as beneficiary cost-share responsibility for these products, depends on the benefit under which the injectable is covered as well as the provider dispensing or administering the product. Specialty injectables—including self-administered and office-administered injectables—may be included in a payer's pharmacy benefit and/or covered through the medical benefit. When covered under the pharmacy benefit, injectables are subject to payers' drug formularies, as with other pharmaceuticals paid through that benefit. Most medical benefits lack the legal language or systems capability to support product preferencing, which inhibits generic or rebate possibilities.

One study found that 64% of injectables covered under the pharmacy benefit were subject to a tiered copayment differential in 2005 and 36% were not, including 6% with a zero copayment.⁴⁰ In contrast, only 15% of HMO plans and 15% of PPO plans surveyed in 2005 applied separate cost-sharing (either copayment or coinsurance) requirements to injectables covered under the medical benefit.

Purchasers contract with several types of specialty injectable providers. For the medical benefit, providers typically include office-based physicians, outpatient hospital, and home health agencies, while pharmaceutical benefit providers typically include community, mail order, and specialty pharmacies.

Payment formulas typically differ for these providers. In 2005, average payment ranged from a high of AWP minus 7% for an outpatient hospital to a low of AWP minus 16% for specialty pharmacies, with physician offices receiving AWP minus 8%. In this survey, home health pharmacies dispensing specialty pharmaceuticals received AWP minus 11% and community pharmacies received AWP minus 14% for dispensing these products.⁵⁰

Hospital Inpatient and Outpatient

Because per diem and prospective payment are the most frequently used payment methodologies in these settings, separate payment for drugs in the inpatient hospital setting seldom occurs. However, most hospital outpatient drugs are separately reimbursed if they exceed a predetermined cost threshold, which is negotiated between the hospital and the payer.

Physician Office Drugs

Unless the physician has entered into a capitation arrangement, most physician-administered drugs are separately reimbursed. The failure of several physician practice management organizations (organizations that own or manage physician practices) in the late 1990s may have been partly due to drug risk in the face of double-digit cost increases during this time period.⁵¹ Medical group capitation with limited drug risk continues, but is not common.⁵² A concept proposed by Prometheus Payment—that of physician-based, severity-adjusted, evidence-based case rates—may soon be tested, but case rates will not initially include prescription drugs.⁵³ Outside of staff model health plans as of 2003, office-administered drugs were typically paid on an FFS formula, with AWP as a common basis and formulas ranging from AWP plus 10% to AWP minus 20%.⁵⁴ In a 2005 survey, average physician “buy and bill” reimbursement for specialty drugs was AWP minus slightly more than 15% and, by 2007, the average payment declined to AWP minus 19%.⁵⁵

ASP-based payment is being introduced for oncology drugs by some payers and is being considered for other therapeutic areas. A recent study states that 36% of surveyed payers use an ASP-based methodology for oncology. Of the payers using ASP, 51% based their reimbursement on ASP plus 6%, and 27% reported rates between ASP plus 9% and ASP plus 18%.⁵⁶

For cost-control reasons, some private payers require direct supply of physician office drugs by a specialty distributor under contract with the payer. In this scenario, the physician does not buy and bill for the drug, but rather the drug is shipped to the physician office by the supplier who bills the payer a negotiated price. The physician bills only for the professional services required to administer the drug.

Home Health

Private purchasers pay home health professional services on a per-visit basis, while prescription drugs administered in the home setting are paid separately to home-infusion pharmacies on a per diem⁵⁷ or FFS basis.

IV. How Products, Services, and Payments Flow Through Channels of Distribution

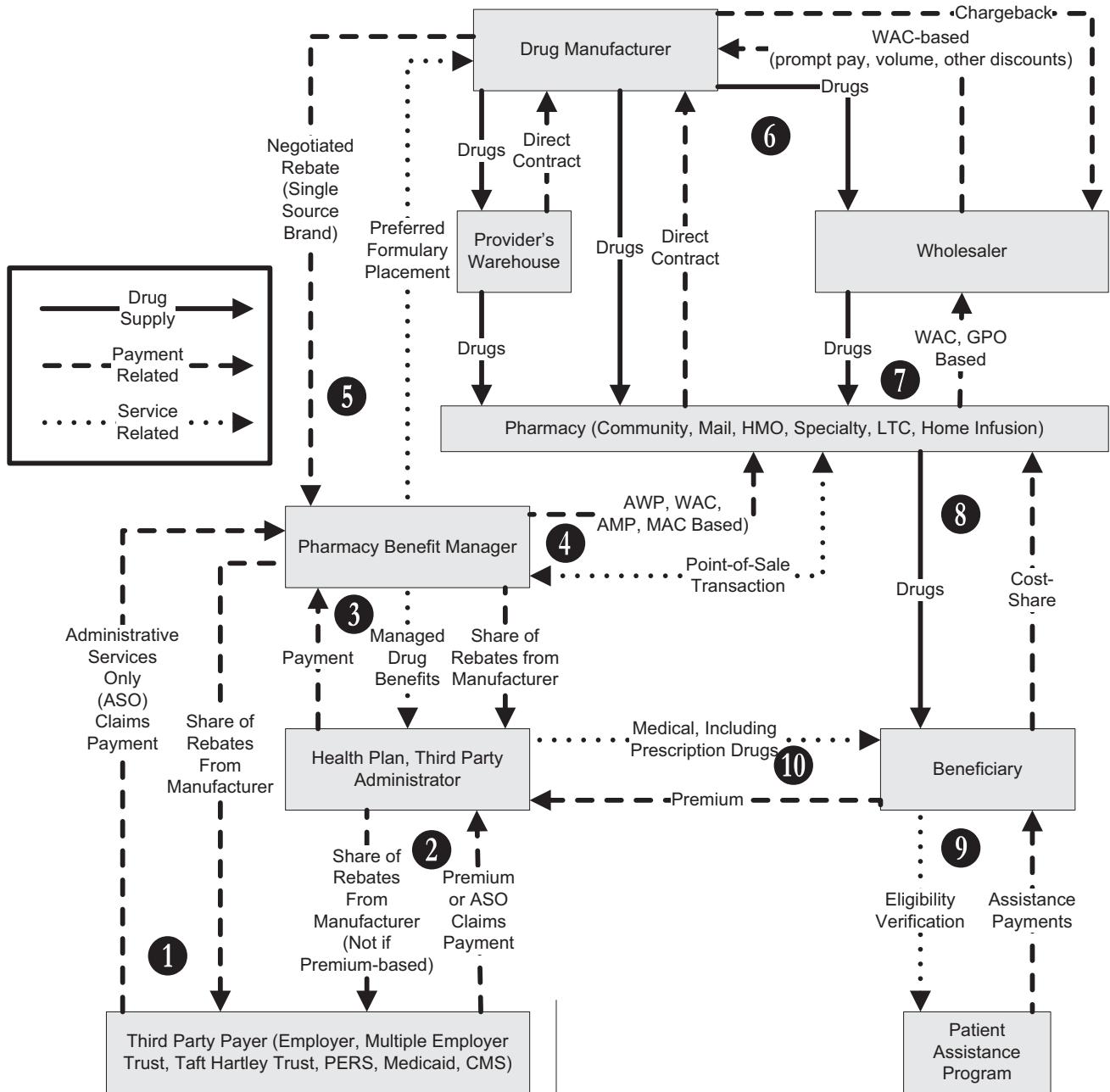
Introduction

The complexity of drug payment results in part from the fact that distribution, related services, and payment vary with each payer type. The charts that follow depict the flow of

drugs, dollars, and services in the U.S. health care system within the context of 2 important distribution channels:

- Pharmacy benefit (other than Medicare prescription drug benefit); and
- Medicare prescription drug benefit.

EXHIBIT IV-1 Pharmacy Benefit (other than Medicare prescription drug benefit)



IV. How Products, Services, and Payments Flow Through Channels of Distribution

Key stakeholder relationships in these situations are highlighted, and the first instance of each stakeholder relationship is shown but not repeated in other schematics. The relationships are described below.

① A self-insured and self-administered private-sector or government purchaser may carve out pharmacy benefits from the overall health plan and contract directly with a PBM for their provision.

A survey conducted by Hewitt Associates in 2005 suggested that only 5% of self-insured employers provide “a customized design” or “build-your-own” plan for prescription drugs.⁵⁸ This suggests that while employers could be instrumental in customizing their contracted pharmacy benefit programs, few choose to do so, instead deferring to vendors’ standard offerings. However, anecdotal reports suggest that there may be an increase in this self-insured employer activity.

With the exception of Medicare Part D (see Exhibit IV-2), PBMs do not take risks for prescription drug cost and utilization. Drugs supplied through pharmacies based on a PBM contract are paid on a negotiated basis, and the contract formula typically centers on AWP, WAC, or pharmacy usual and customary (U&C) price. PBM contractual elements may include performance guarantees, rebate share, and administrative services (such as claims adjudication, network management, drug utilization review, member communication, and member ID cards).

In recent years, specialty drugs have been an increasing concern to payers due to their high cost, high year-over-year trend,⁵⁹ and the robust pipeline of biotechnology products in clinical trials that may exhibit similar cost patterns. Despite payer concerns, a recent survey suggests payer willingness to compensate (via lower discounts on AWP) various levels of specialty pharmacy service above simple dispensing.⁶⁰ These specialty pharmacy providers may also receive payment for services from manufacturers now defined as bona fide service fees.

② Employers may purchase a premium-based (insured) benefits package from a health plan that includes prescription drug coverage. By doing so, the payer delegates full financial risk to the health plan for provision and management of the benefit. Self-insured employers assume this financial risk themselves and pay health plans or PBMs an administrative fee for the provision and management of the benefit, which is called an Administrative Services Contract (ASC). Insurers retain all rebates for their insured business and share rebates with self-insured customers at an amount negotiated as part of the ASC agreement.

State Medicaid programs may contract with health plans (MCOs) for their beneficiaries (managed Medicaid), including provision of prescription drugs. While the drug portion of the premium may now reflect EAC pricing, Medicaid adoption of AMP is likely to reduce this amount. Drug sales for state Medicaid beneficiaries enrolled in health plans are not subject to statutory rebates.⁶¹

A self-insured employer may participate in a group purchasing

organization (GPO) that can build preferred relationships with vendors, including PBMs, mail order, and specialty pharmacies, based on price concessions, services, and service guarantees. The Human Resource Policy Association’s Transparency in Drug Purchasing Solutions (TIPPS) initiative is an example of such an organization.⁶²

③ A health plan or third-party administrator (TPA) may contract with a PBM to provide pharmacy benefits to beneficiaries. The drug payment basis is typically a percentage of AWP or WAC for the ingredient cost, plus a dispensing fee and perhaps other fees, such as an administrative fee. Agreements may require disclosure of manufacturer rebates received by the PBM as well as sharing of a portion of the rebate.

④ PBM provider networks may include several types of pharmacies and pharmacist services including community, mail, health plan (staff and group models), specialty, LTC, and home infusion. PBMs may contract directly with pharmacies or through Pharmacy Services Administrative Organizations (PSAOs), or they may own these entities outright. According to one study, “PSAOs improve contracting efficiency for independent pharmacies, and allow them to contract with PBMs at discount rates that are comparable to those received by larger retail chains.” Pharmacies are paid on a formula basis, typically the lower of a contract price or the U&C price. The contract price is the sum of the discounted AWP or WAC plus a dispensing fee, and MAC is typically used for pricing the ingredient cost for multi-source drugs. The actual payment to the pharmacy is the lower of the contract price or U&C price minus the member cost share amount.⁶³

⑤ PBMs, health plans that offer pharmacy benefits, PDPs, and MA-PDs develop drug formularies and negotiate manufacturer drug price concessions relative to coverage policy, formulary placement of specific drugs, beneficiary cost share, and utilization management procedures. Manufacturer rebates also typically reflect the plan’s ability to achieve volume, market share, and other negotiated targets.

⑥ Manufacturers may sell drugs directly to pharmacies through drug wholesalers or to warehouses owned by drug chains. Large pharmacy chains may self-warehouse, but may be unable to negotiate manufacturer discounts below WAC for single-source branded drugs. The retail (community pharmacy) class of trade is typically not offered market share rebates on single-source branded drugs. In testimony before a Congressional committee in 2004, a Wal-Mart executive stated: “For branded drug products, Wal-Mart has little or no ability to negotiate discounts below the published WAC. Wal-Mart has no greater leverage for branded drug products than any other retail class of trade pharmacy provider.”⁶⁴

⑦ Smaller community pharmacies may join GPOs to generate increased negotiating leverage by combining purchase volume.

⑧ Beneficiaries pay a per-prescription cost share as stipulated in the benefit design, depending on coverage and formulary tier of

IV. How Products, Services, and Payments Flow Through Channels of Distribution

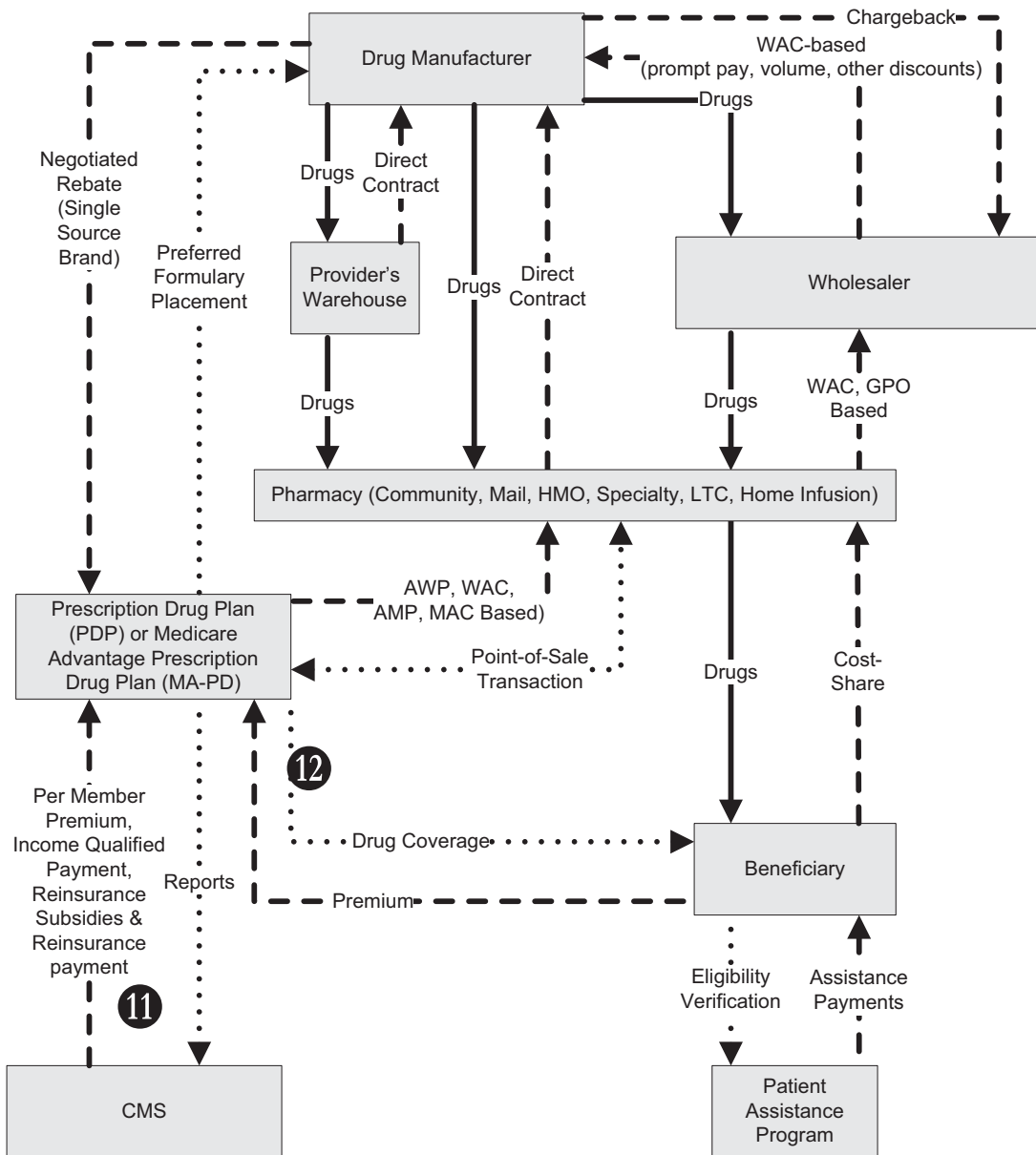
the dispensed drug. In addition, the beneficiary may be responsible for meeting an annual out-of-pocket deductible that may apply to all health benefits costs or be specific to the pharmacy benefit.⁴⁹

⑨ Patient assistance programs (PAPs)—sponsored by manufacturers and administered by service providers, PBMs, and charitable organizations—are available to help eligible individuals cover the cost of medications when patients are without pharmacy benefit

coverage and/or meet financial criteria. The Partnership for Prescription Assistance (PPARx, www.pparx.org) is an example of a referral service to assistance resources. The PPARx estimates that drug manufacturer-sponsored PAP programs filled more than 22 million prescriptions in 2004, with a wholesale value of over \$4 billion.⁶⁵

⑩ Workers electing health benefits through a group may be required to pay a portion of the premium cost in addition to any

EXHIBIT IV-2 Medicare Prescription Drug Benefit



IV. How Products, Services, and Payments Flow Through Channels of Distribution

deductibles, copayments, and coinsurance that the benefit design may stipulate. The Kaiser Family Foundation/Health Research and Educational Trust (KFF/HRET) survey, based on a representative sample of large and small U.S. employers, found that 98% of insured workers have prescription drug benefits and that, with respect to cost sharing, the most common formulary types are 3-tiered (69% of insured workers) and 2-tiered (16% of insured workers) formularies.⁴²

① CMS pays the Part D provider in 3 ways. The first is a direct risk-adjusted (according to health and demographic characteristics) premium subsidy, the second is a low-income subsidy, and the last is a reinsurance subsidy. An annual reconciliation may result in additional payments to the provider or in payment owed to the government.²⁸

② Most Part D beneficiaries must pay a monthly premium to the Part D provider. The MMA requires that beneficiary premiums must reflect 25.5% of the national average standardized bid across all Part D plans.²⁹

■ Net Manufacturer Price as the Basis of Drug Payment

Issue

In the private insurance world, AWP may well be phased out as the most popular price reference. Consequently, payers will replace AWP as the basis for payment with an alternate benchmark(s) that more closely approximates the manufacturer's actual ASP (referred to here as "net manufacturer price") and the provider's AAC. In Medicare, the change affects primarily provider-administered drugs; in Medicaid, the change currently applies only to multiple-source drugs.

WAC has been suggested as one possible replacement for AWP because WAC currently exists in most published pricing references. WAC does not, however, approximate either the provider's AAC or the manufacturer's ASP for many drugs, particularly multiple-source products.⁶⁶ AMP has also been discussed as a possible alternative to AWP.

It is noteworthy that the changes to benchmark RPs for determining provider reimbursement focus primarily on the manufacturer's actual selling price rather than the provider's AAC for the product.

Implications

- Health plans may benefit from replacement of AWP with net manufacturer price benchmarks because the new benchmarks would invariably lower prescription drug component expenditures. In addition, these benchmarks may enable health plans to more effectively leverage their market power in negotiating price concessions with pharmaceutical manufacturers.
- Payment to community, mail order, and specialty pharmacies on the basis of net manufacturer price benchmarks may result in reduction in the gross margins of these pharmacies, the extent of which would depend on the level of markup and additional fees paid.
- For PBMs that own and operate pharmacy businesses, such as specialty and mail order pharmacies, the benefit of reduction in drug payments is somewhat offset by the potential loss in revenue from reduced reimbursement for their pharmacy businesses. PBMs that do not own pharmacies appear to be advantaged by the new benchmarks because there is no offsetting revenue loss.
- Replacing AWP with ASP has been shown to be an effective method to significantly reduce drug payments for Medicare. ASP, however, does not lower the cost of drugs between the manufacturer and distributor or the manufacturer and provider; there is some evidence that it may raise the actual cost. Replacing AWP with AMP in Medicaid may have the same result. With both changes, it is the end provider of services, not the manufacturer, who is most affected.
- Use of a simple ASP plus some percentage, absent of any additional controls, creates the financial incentive for providers to select a higher-cost, higher-dollar product versus a lower-cost,

lower-dollar product. For example, 10% of a drug with a \$500 ASP for a provider-purchaser has a \$50 margin, while a therapeutic alternative with a \$100 ASP has a \$10 margin.

- Use of ASP in a sliding scale may blunt some of the effect of a flat ASP plus some percentage. For example, ASP plus 10% could be married with a minimum product cost margin of \$30, which is equivalent to an ASP of \$300. Alternatively, the percentage added to the ASP could remain flat at 10% until the drug's ASP reaches \$500, at which point the percentage added to ASP could drop to 8%; when ASP reaches \$1,000, it then could drop further to 6% and so on.
- Variation in ASP reimbursement at the product level within a class of therapeutic options could also address the implications noted here. Similar to copayment incentives to consumers, reimbursement incentives could be designed to support lower-cost product usage. For example, ASP plus 20% for a preferred, lower-priced product could yield a higher margin for the provider than ASP plus 6% for a non-preferred, higher-priced therapeutic alternative.
- Medicare's ASP plus 6% reimbursement formula has made it difficult for some providers to recover their full acquisition cost, mainly those who purchase physician-administered drugs in small quantities. It has also forced physicians to be more vigilant about collecting full patient cost sharing. As a result, manufacturers report increasing demand for coinsurance assistance from PAPs.^{12,67}
- A net manufacturer price benchmark could disadvantage community pharmacies in several ways:
 - A net manufacturer price benchmark does not reflect pharmacy acquisition cost, such as when including wholesaler prompt-pay discounts that may not be passed on to the purchaser;
 - Smaller community pharmacies are less able to obtain the net price concessions available to larger purchasers or other types of purchasers that are more capable of moving product market share; and
 - Use of net manufacturer price benchmarks calculated on data several months old for current payment purposes exposes purchasers to more recent price changes.
- MCOs that adopt payment methodologies benchmarked to manufacturers' net selling prices should carefully consider the immediate and long-term effects on providers and patients. Careful consideration of how overall provider services and relationships will change as a result of any drug payment policy changes should include the impact on access to care and the ability of providers to supply quality services.
 - For example, if ASP or AMP is determined to be a better benchmark than AWP, what change in payment methodology is appropriate to ensure that providers are recovering at least their AAC?
 - Total drug payment to service providers has 2 principal com-

ponents: the drug product and the professional services associated with dispensing or administering the product. Because providers rely on total compensation to meet their costs for the product and professional services, reduction in the reimbursement amount for one component will likely create pressure to increase the amount of reimbursement for the second component. How should total compensation ensure that providers maintain a reasonable profit?

■ Public Disclosure of Net Manufacturer Price

Issue

Medicare ASPs are publicly available information. Changes in Medicaid law require disclosure of Medicaid AMPs (AMP was formerly confidential).

Implications

- AMP becomes the new statutory benchmark for Medicaid reimbursement of multiple-source drugs only. AMP disclosure, however, applies to single-source and multiple-source drugs. As a result, states will have the information needed to move from AWP to AMP for single-source drug reimbursement if they so desire.
- General availability of routinely updated net manufacturer price benchmarks, such as AMP and ASP, may supplant “list” price benchmarks in the private sector.
- Public disclosure of net manufacturer prices should enable increased specificity and transparency in the calculation of private payer rebates and MAC programs’ price limits. An important implication for the publication of AMP pricing is the potential for use in MAC creation. Private-sector MACs are often established without reliable information about a drug’s AACs. For example, a published AMP would likely facilitate the MAC based on a percentage markup on AMP.
- Multiple-source drug manufacturers are concerned that the intent of CMS to publish manufacturer-specific AMPs for generic drugs rather than a blended AMP for all drugs in the class will create a downward price spiral that threatens the viability of the generics industry. Public disclosure of net manufacturer price may result in a narrowing of the range of net prices offered into the marketplace.

■ Packaging of Drugs with Services

Issue

Combining drug reimbursement with related professional services transfers the drug’s economic responsibility and risk from the payer to the provider. Medicare has used this technique for managing hospital inpatient (diagnosis-related group [DRG]) and outpatient (APC) drug spending, other acute care services (e.g., skilled nursing facilities [SNFs]), and dialysis services (composite rate). In the private sector, some medical groups in California receive per member per month (PMPM) capitation payments inclusive of

limited drug risk, and most private health plans pay for inpatient services using a per diem or DRG rate that includes drugs.

Implications

- Public disclosure of manufacturers’ actual selling prices improves a payer’s ability to package drugs with services because it permits the payer to negotiate with more confidence regarding the provider’s costs. Therefore, public disclosure may encourage packaging, which may or may not reduce the total expenditure. Providers will likely seek additional compensation for drug-related professional services if there is loss of revenue on the drug component of payment.

■ Pricing Transparency

Issue

In the private sector, increasing pressure has been placed on PBMs to eliminate undisclosed pricing concessions and rebates. In response, many PBMs have increased the transparency of such arrangements to their clients, reportedly including increased pass-through of manufacturer rebates.

Implications

- At the same time that some payers, most notably Medicare, are packaging services with drugs, the drive to greater pricing transparency may make it difficult for intermediaries and pharmacies to underwrite the provision of some drug administration-related services within the lower net drug price that is paid.
- Pricing transparency may force PBMs to offer, price, and cost-justify drug-related services previously made available at no extra charge then they were funded through the drug margin.

■ Prescription Drug Risk-Adjusted Premium

Issue

Part D PDPs are at risk for some of their beneficiary drug utilization. From the mid-1980s through the 1990s, some PBMs and PSOs experimented with risk-based payment and capitation,⁶⁸ but little of this remained by the end of the decade. One disadvantage of PBM capitation was insufficient data necessary to estimate the cost of the pharmacy benefit,⁶⁹ and a fundamental problem was the absence of a contract relationship between PBMs and prescribers.

PBM performance ratings are adversely affected by higher drug expenditures even if the spending for drugs is associated with lower costs elsewhere in the health care system.⁷⁰ For example, introduction of the histamine-2 antagonists for ulcer treatment in the 1970s eliminated the need for surgical intervention for many patients, resulting in the transfer of a medical cost to the pharmacy benefit.

Implications

- PDPs, which are at partial risk for their beneficiaries’ drug costs, are motivated to control net drug spending. To this end, PDPs seek to maximize beneficiary selection of generics and preferred

brands. Drug formulary-related manufacturer rebates support this PDP objective to the extent that they contribute to reduction in net drug spending.

- Primary tools for influencing drug utilization and choice in PDPs are formulary design, coverage policy, variations in cost sharing, and utilization management, such as step therapy. However, as it is structured, the Part D drug benefit limits the influence of PDPs over prescribing behavior, patient prescription demand, and patient compliance with physician instructions.
- Compared with PDPs, some MA-PDs are better able to use these tools because the same entity that offers the PDP provides comprehensive health insurance. Second, because MA-PDs hold financial risk for the total care of the patient, they are more likely to be receptive to the use of a higher-cost drug if it produces cost savings elsewhere in the system.

■ Impact of Medicare CAP on Buy and Bill for Office-Administered Drugs

Issue

In 2006, CMS initiated a CAP whereby physicians may elect to receive office-administered drugs from a CMS-contracted vendor. Physicians must elect to participate in the CAP for all physician-administered products used in their practice. Under this program, the CAP vendor bills the Medicare fiscal intermediary for the dispensed drug, minus the patient cost share, and bills the patient cost share directly to the Medicare beneficiary.

Implications

- If the CAP is successful in the Medicare environment, private-sector CAP-like solutions may emerge using PBM-type programs to influence the selection of office-administered drugs.
- If private payers adopt a net manufacturer price benchmark for buy-and-bill payment of office-administered drugs, provider gross margin for these drugs may fall, which may reduce prescriber resistance to implementation of CAP-like drug delivery models.

■ Beneficiary Cost Shift

Issue

The current trend in benefit design toward consumer-directed health care (CDHC) increases beneficiary exposure to additional costs in the form of health care premiums, deductible, and beneficiary cost share. For health plans and employers, the trend toward CDHC has a 2-fold advantage: (a) transfer of more financial risk to the beneficiary and (b) increased beneficiary sensitivity to health care prices.

Implications

- Higher beneficiary cost is likely to result in increased cost sensitivity when using medical benefits, including pharmacy services and prescription drugs.

- Pharmacy providers can help beneficiaries in CDHC plans to reduce out-of-pocket cost by therapeutic selection of generic and single-source brand drugs.
- If beneficiary cost exposure and access are not equivalent across treatment settings, care delivery may migrate to settings that expose the beneficiary to the lowest cost. To minimize this occurrence, payers may harmonize drug controls and cost share between medical and pharmacy benefits.
- There will likely be increased demand for PAPs for low-income beneficiaries who are in the “donut hole” of no coverage for Medicare Part D prescription plans.
- Pharmacists have demonstrated effectiveness in helping patients manage their out-of-pocket costs for prescription drugs and pharmacy services.⁷¹

Conclusion

Pharmaceutical payment is an especially complex topic, with no single entity or stakeholder group held accountable. Simplification is certainly achievable, but is limited by the realities of a complex health care delivery system, broad economic implications, and questions of fundamental fairness to the stakeholders most affected by each change.

Clinicians, elected and appointed government leaders, business executives, and patients all seek lower health care expenditures with no adverse impact on quality, access, and technology development. When compromises are required, the success of the final decision will depend on the quality of the data available to inform the debate.

Understanding pharmaceutical payment and the factors that affect payment is an important step in achieving the aforementioned goals. AMCP hopes that the information in this *Guide* will ultimately prove to be “quality data that informs the debate” and therefore leads to better decisions. The Academy welcomes your feedback about this *Guide*, which can be submitted at: <http://www.amcp.org/amcp.ark?p=1529B561>.

Acronym List

Acronym	Definition	Acronym	Definition
AAC	actual acquisition cost	GPI	generic product identifier (14-character, Medi-Span)
AIDS	acquired immunodeficiency syndrome	GPO	group purchasing organization
AMCP	Academy of Managed Care Pharmacy	HCPCS	Healthcare Common Procedure Coding System
AMP	average manufacturer price	HDHP/SO	high deductible health plan with savings option
APC	ambulatory payment classification	HMO	health maintenance organization
ASC	ambulatory surgical center	HOPD	hospital outpatient department
ASO	administrative services only	HRSA	Health Resources and Services Administration
ASP	average sales price	IHS	Indian Health Service
AWP	average wholesale price	IPA	independent practice association
BP	best price	IVIG	intravenous immune globulin
CAP	Competitive Acquisition Program (for drugs and biologicals)	KFF/HRET	Kaiser Family Foundation/Health Research and Educational Trust
CARE	Comprehensive AIDS Resource Emergency	LCA	least costly alternative
CBO	Congressional Budget Office	LDL	low-density lipoprotein
CDHC	consumer-directed health care	LTC	long-term care
CMP	competitive medical plan	MA-PD	Medicare Advantage–Prescription Drug Plan
CMS	Centers for Medicare and Medicaid Services	MAC	maximum allowable cost
COT	class of trade	MCO	managed care organization
CPI-U	Consumer Price Index – Urban	MedPAC	Medicare Payment Advisory Commission
CPT	current procedural terminology	MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
CRS	Congressional Research Service	NDC	national drug code (11-character)
DHHS	Department of Health and Human Services	non-FAMP	nonfederal average manufacturer price
DME	durable medical equipment	OBRA 90	Omnibus Budget Reconciliation Act of 1990
DoD	Department of Defense	OIG	Office of Inspector General (of the Department of Health and Human Services)
DOJ	Department of Justice	OPA	Office of Pharmacy Affairs
DP	direct price	OPD	outpatient prescription drug
DRA	Deficit Reduction Act of 2005	OPPS	outpatient prospective payment system
DRG	diagnosis-related group	OTC	over-the-counter
DSH	disproportionate-share hospital	P4P	pay for performance
EAC	estimated acquisition cost	PA	prior authorization
EPO	exclusive provider organization	PAB	Pharmacy Affairs Branch
ERISA	Employee Retirement and Income Security Act of 1974	PAP	patient assistance program
ESRD	end-stage renal disease	PBM	pharmacy benefit manager
FCP	federal ceiling price	PDL	preferred drug list
FDA	Food and Drug Administration	PDP	prescription drug plan
FDB	First DataBank	PERS	Public Employees' Retirement System (e.g., California Public Employees' Retirement System [CalPERS])
FFS	fee for service	PHS	Public Health Service
FMAP	Federal Medical Assistance Percentage		
FQHC	federally qualified health center		
FSS	Federal Supply Schedule		
FUL	federal upper limit		
GCN	generic code number (6-character, First DataBank)		

Acronym List

Acronym	Definition
PMPM	per member per month
POS	point of sale or point of service
PPARx	Partnership for Prescription Assistance
PPO	preferred provider organization
PPS	prospective payment system
PSAO	pharmacy services administrative organization
PSO	provider-sponsored organization
RP	reference price
SCHIP	State Children's Health Insurance Program
SCOD	specified covered outpatient drug
SNF	skilled nursing facility
SPAP	State Pharmaceutical Assistance Program
TIPPS	Transparency in Drug Purchasing Solutions
TMAC	therapeutic maximum allowable cost
TPA	third-party (claims) administrator
TrOOP	true out-of-pocket
U&C	usual and customary price
UCR	usual, customary, and reasonable
URA	unit rebate amount
VA	Department of Veterans Affairs (Veterans Administration)
WAC	wholesale acquisition cost
WAMP	widely available market price

Glossary

Based in part on the AMCP Glossary of Managed Care Terms, ©2004

actual acquisition cost (AAC) Final cost of the pharmaceutical to the pharmacy or other health care provider after all discounts, rebates, and other price concessions are taken into account.

administrative services only (ASO) An arrangement in which a plan hires a third party to deliver administrative services to the plan, such as claims processing and billing, but the plan bears the financial risk for claims. This is common in self-funded (also known as self-insured) health care plans.

allowed charge Price for a product or service negotiated between the provider and the health plan or other payer or its intermediary. The difference between the allowed charge and the provider's usual and customary (U&C) price is the "contractual discount."

ambulatory payment classification (APC) Method used by the Centers for Medicare and Medicaid Services (CMS) to implement prospective payment for ambulatory procedures. The APC clusters many different ambulatory procedures into groups for purposes of payment. Both APCs and diagnosis-related groups (DRGs) represent groups of patients that are clinically alike and have roughly the same resource consumption. The APC is used in a similar fashion to the way in which DRGs are used for payment for inpatients; however, APCs depend on the procedures performed, whereas DRGs depend on the diagnoses treated.

average manufacturer price (AMP) Average price paid to a pharmaceutical manufacturer by wholesalers for drugs distributed to retail pharmacies, net of prompt-pay ("cash") discounts. AMP was a benchmark created by Congress in 1990 in calculating rebates owed Medicaid by pharmaceutical manufacturers. The Federal Supply Schedule (FSS) and 340B prices, as well as prices associated with direct sales to health maintenance organizations (HMOs) and hospitals, are excluded from AMP under the Medicaid rebate program. The Office of Inspector General (OIG) in June 2005 estimated the median AMP to be approximately 77% of the average wholesale price (AWP) for single-source brand drugs, 72% of AWP for multiple-source brand drugs, and 30% of AWP for generic drugs. Prior to the enactment of the Deficit Reduction Act of 2005 (DRA), AMP data were used by the Centers for Medicare and Medicaid Services (CMS) primarily for purposes of the Medicaid drug rebate program, and disclosure of AMP data was forbidden except in certain narrow circumstances. The DRA stipulated that AMPs were to be made available to state Medicaid programs, that they were to be used to calculate federal upper limit (FUL) amounts for certain multiple-source drugs, and that states could use them to help set other reimbursement rates. In July 2007, CMS issued final regulations addressing the AMP provisions of the DRA.

average sales price (ASP) New system created by federal and state government prosecutors in settlements with pharmaceutical manufacturers TAP and Bayer to ensure more accurate price reporting. ASP is the weighted average of all nonfederal sales to wholesalers and is the net price after subtraction of chargebacks, discounts, rebates, and other benefits tied to the purchase of the drug product, whether paid to the wholesaler or retailer.

average wholesale price (AWP) List prices for drugs reported by pharmaceutical manufacturers and published in commercial clearinghouses such as Red Book, Medi-Span, and First DataBank. Each price is specific to the drug, strength, dose form, package size, and manufacturer or (re)labeler. There is an AWP value for each 11-character national drug code (NDC) number that is comprised of the first 5 characters for the manufacturer or labeler, 4 characters for the drug and strength, and 2 characters for the package size.

benchmark (also: benchmark price) Government and other payers generally establish their payment for prescription drugs through formulas that start with a benchmark price. Some benchmarks are proprietary and not publicly available. For example, a state may set its Medicaid reimbursement rate at a benchmark price, such as average wholesale price (AWP) or wholesale acquisition cost (WAC), minus a percentage. Some payment rates are subject to limits, such as through a maximum allowable cost (MAC) mechanism.

best price (BP) Lowest price available to any wholesaler, retailer, provider, health maintenance organization (HMO), nonprofit entity, or the government. BP excludes prices to the Indian Health Service (IHS), Department of Veterans Affairs (VA), Department of Defense (DoD), Public Health Service (PHS), 340B-covered entities, Federal Supply Schedule (FSS) and state pharmaceutical assistance programs (SPAPs), depot prices, and nominal pricing. BP includes cash discounts, free goods that are contingent upon purchase, volume discounts, and rebates.

Big Four See federal Big Four.

biological product (biologic) Includes a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or they may be living entities, such as cells and tissues. Biologics are isolated from a variety of natural sources—human, animal, or microorganism—and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research and may be used to treat a variety of medical conditions for which no other treatments are available.

bona fide services Fee paid to an “entity” for an itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement and that is not passed in whole or in part to a client or customer of an entity, whether or not the entity takes title to the pharmaceutical.

book price See list price.

bundled (also: packaged, bundling) Packaging of drugs of different types for the purpose of provider payment, sometimes including provider services. For example, in the context of drug sales to providers from manufacturers, the net price of individual drugs in the bundle may be contingent on the sales volume of other drugs included in the bundle. In another use of the term, a bundle of services may be combined at a designated price, as in the case of ambulatory payment classifications (APCs) or diagnosis-related groups (DRGs).

carve-out pharmacy benefit Prescription and pharmacy services insurance coverage that is removed from the primary health care plan and typically administered by a separate company, such as a pharmacy benefits manager (PBM), under contract. When care is capitated, a carve-out is a service or package of services not provided within the contract. It is therefore carved out from the per member per month (PMPM) payment rate. A carve-out benefit may also be created when a provider cannot or will not provide some segment of care or is unavailable during periods of time when care may still be needed, such as urgent care.

case rate Flat fee paid for services based on patient characteristics, such as diagnosis. For this fee, the provider covers all of the services the patient requires for a specific period of time.

catalog price See list price.

Centers for Medicare and Medicaid Services (CMS) Formerly known as the Health Care Financing Administration (HCFA). This federal agency is responsible for administering Medicare and overseeing states’ administration of Medicaid.

chargeback (also: charge-back) Discounts handled through wholesalers. Manufacturers negotiate discounted prices with some purchasers who buy through wholesalers. Wholesalers can deliver the drugs at discounted prices, inform the manufacturers, and then request reimbursement from the manufacturers.

class of trade (COT) Under federal law, all businesses that sell to the same type of customer must be eligible to receive similar pricing concessions, such as discounts and special offers. Most pharmaceutical companies have developed lists of similar customers and grouped them into different COTs. A manufacturer may have broad categories of COTs for most of its products (e.g., acute care, nonacute care, retail), but may allow a specific business unit to add an additional segment, such as long-term care (LTC), rather than include that sector in the nonacute COT.ⁱⁱⁱ The business practice of offering various price discounts by COT was challenged by chain pharmacies in the 1990s. The U.S. Court of Appeals for the Seventh Circuit decided in July, 1999 (*In re Brand Name Prescription Drugs Antitrust Litigation*, No. 99-1167, 186 F.3d at 788^{iv}), that the practice was not anticompetitive, and price concessions made by drug manufacturers by COT continue to this day.

coinsurance Percentage of the costs of medical services paid by the patient, usually at the point of care. This is a characteristic of indemnity insurance and preferred provider organization (PPO) plans. The coinsurance amount is often 20% of the cost of medical services after the deductible is paid.

Competitive Acquisition Program (CAP, and prescription drug CAP) Section 303 (d) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required implementation of a CAP for Medicare Part B drugs and biologicals not paid on a cost or prospective payment system basis. CAP is an alternative to the average sales price (ASP) methodology (buy and bill) for acquiring certain Part B drugs that are administered incident to a physician’s services. CAP was implemented on July 1, 2006.

Consumer Price Index – Urban (CPI-U) Measure of the average change over time in prices paid by urban consumers for a market basket of consumer goods and services. The all-urban consumers group represents about 87% of the total U.S. population. It is based on the expenditures of almost all residents of urban or metropolitan areas including professionals, self employed, poor, unemployed, and retired persons as well as urban wage earners and clerical workers. Not included in the CPI-U are the spending patterns of persons living in rural nonmetropolitan areas, farm families, persons in the Armed Forces, and those in institutions, such as prisons and mental hospitals.

copayment The cost-share amount charged to an insured member for products or medical services, usually at the point of care. Copayment amounts are typically specified in the description of

ⁱⁱⁱ U.S. Federal Trade Commission, Bureau of Competition. Connecticut Hospital Association (CHA) advisory opinion letter. December 20, 2001. Available at: <http://www.ftc.gov/opa/2001/12/chaadvisopinletter.shtm>. Accessed April 24, 2007.

^{iv} Available at: <http://www.projectposner.org/case/1999/186F3d781>. Accessed September 1, 2007.

health plan member benefits, such as a fixed dollar amount for each prescription received (e.g., in a 3-tier pharmacy copayment design, \$5.00 for a generic prescription, \$15.00 for a preferred brand-name prescription, and \$30.00 for a non-formulary product).

cost-based reimbursement Payment made by a health plan or payer to health care providers based on the actual costs incurred in the delivery of care and services to plan beneficiaries. This method of paying providers is still used by some plans; however, cost-based reimbursement has largely been replaced by prospective payment and other payment mechanisms in Medicare and Medicaid.

cost sharing (also: see copayment, coinsurance) Method of reimbursement for health care services that holds the patient responsible for a portion or percentage of the charge, with an attending strategy to serve as a means of managing utilization; normally includes an annual deductible amount.

deductible Fixed amount of health care dollars of which a person must pay 100% before health benefits begin. Plans may include annual deductibles ranging from a few hundred to a few thousand dollars. Once the deductible is reached, the plan then pays up to 100% of approved amounts for covered services provided during the remainder of that benefit year.

direct price (DP) Manufacturer's published catalog or list price for a pharmaceutical product to nonwholesalers. DP may or may not include standard volume discounts available to nonwholesaler customers. Similar to average wholesale price (AWP), DP may not represent actual selling prices because it does not include important price adjustments, such as prompt pay, or other discounts, rebates, or reductions.

disproportionate-share hospital (DSH) Hospital with a disproportionately large share of low-income patients. Under Medicaid, states augment payment to these hospitals. Medicare inpatient hospital payments are also adjusted for this added burden.

estimated acquisition cost (EAC) State Medicaid agency's estimate of the price generally paid by pharmacies for a pharmaceutical. This figure is often meant to represent a calculation across all pharmacies of the mean or median actual acquisition cost (AAC).

federal Big Four Four largest purchasers of pharmaceuticals within the federal government: Department of Veterans Affairs (VA), Department of Defense (DoD), Public Health Service (PHS), and Coast Guard. These 4 federal agencies have the right to purchase their pharmaceuticals from the Federal Supply Schedule (FSS), as does every other federal agency. However, the Big Four often obtain pricing below the FSS on brand-name drugs because

these drugs are subject to a maximum statutory price called the federal ceiling price (FCP).

federal ceiling price (FCP) Maximum price that manufacturers can charge for Federal Supply System (FSS)-listed brand-name drugs to the Big Four—Department of Veterans Affairs (VA), Department of Defense (DoD), Public Health Service (PHS), and Coast Guard—even if the FSS price is higher. The FCP must be at least 24% below the nonfederal average manufacturer price (non-FAMP). FCP prices are not publicly available.

Federal Supply Schedule (FSS) Collection of multiple-award contracts used by federal agencies, U.S. territories, Indian tribes, and other specified entities to purchase supplies and services from outside vendors. FSS prices for the pharmaceutical schedule are negotiated by the Department of Veterans Affairs (VA) and are based on the prices that manufacturers charge their “most-favored” nonfederal customers under comparable terms and conditions. Because terms and conditions can vary by drug and vendor, the most-favored customer price may not be the lowest price in the market. FSS prices are publicly available.

federal upper limit (FUL) Price calculated and published by the Centers for Medicare and Medicaid Services (CMS) as the maximum amount that a state Medicaid program can pay for a multiple-source (generic) pharmaceutical.

formulary List of drugs considered by physicians and pharmacy staff of a health care organization as preferred for use in treating patients served by the organization.

open or unrestricted formulary List of preferred drugs that is not necessarily tied to member cost share. An open formulary may have a single copayment or coinsurance amount for all drugs or, more typically, is associated with 2-tiered copayment in which there is a copayment (e.g., \$5.00) for all generic drugs and a higher copayment (e.g., \$20) for all brand drugs whether listed on the formulary or not. Therefore, physicians prescribing from an open formulary are not restricted in the products they may prescribe.

closed formulary Exclusive lists of covered drugs that limit prescribers and health plan members to only some of the commercially available products in each therapeutic class. Drugs not listed as preferred (i.e., non-formulary drugs) are not covered by the payer. Patients without prior authorization (PA) typically pay 100% of the provider's charge for non-formulary drugs.

partially closed/incentive formulary Non-preferred (i.e., non-formulary) drugs have a higher member cost share, such as

found in multiple-copayment tiers (e.g., 3-tiered copayment designs). A 4-tiered copayment design may have a generic drug (tier 1) copayment, preferred drug (tier 2) copayment, non-preferred drug (tier 3) copayment, and the highest copayment or coinsurance (50%) for cosmetic or other “lifestyle” drugs or perhaps a 4th cost-share tier (e.g., 20%) for injectable or other specialty pharmaceuticals.

generic drug Identical to a brand-name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. Before approving a generic drug product, the Food and Drug Administration (FDA) requires many rigorous tests and procedures to ensure that the generic drug can be substituted for the brand-name drug. The FDA bases evaluations of substitutability, or “therapeutic equivalence,” of generic drugs on scientific evaluations. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand-name product. Drug products evaluated as “therapeutically equivalent” can be expected to have equal effect and no difference when substituted for the brand-name product.

global price (also: global fee) Total prospectively determined amount that is paid for a specific set of services, such as obstetrical services that encompass prenatal, delivery, and postnatal care.

group purchasing organization (GPO) Organization that pools purchasers working together to provide larger potential purchases of particular goods and/or services and therefore lower unit costs.

health maintenance organization (HMO) Form of health insurance in which its members and/or members' employers prepay a premium for the HMO's health services, which generally include inpatient and ambulatory care. For the patient, it means reduced out-of-pocket costs (i.e., no deductible), no paperwork (i.e., insurance forms), and only a small copayment for each office visit to cover the paperwork handled by the HMO. There are several different types of HMOs.

group model The HMO contracts with a physician group, which is paid a fixed amount per patient to provide specific services. The administration of the group practice then decides how the HMO payments are distributed to each participating physician. This type of HMO is usually located in a hospital or clinic setting and may include a pharmacy. These physicians usually do not have any fee-for-service (FFS) patients.

hybrid model Combination of at least 2 managed care organizational (MCO) models that are melded into a single health plan. Because its features do not uniformly fit one model, it is called a hybrid.

independent practice association (IPA) model The IPA contracts with independent physicians who work in their own private practices and see fee-for-service (FFS) patients as well as HMO enrollees. Physicians belonging to the IPA may accept financial risk that the care needed by patients for whom they are responsible will fall within a pre-established per member per month (PMPM) budget.

network model Network of group practices under the administration of one HMO.

point-of-service (POS) model Sometimes referred to as an “open-ended” HMO. The POS model is one in which the patient can receive care by physicians who are either contracted with the HMO or who are not contracted. Physicians not contracted with the HMO who see an HMO patient are paid according to the services performed. Thus, the patient has an incentive to use contracted providers due to the fuller coverage offered for contracted care.

staff model All physicians in a staff model HMO are in a centralized site where all clinical and perhaps inpatient and pharmacy services are offered. The HMO holds the tightest management reigns in this setting because none of the physicians traditionally practice on an independent fee-for-service (FFS) basis. Physicians are more likely to be employees of the HMO in this setting because they are not in a private or group practice.

Healthcare Common Procedure Coding System (HCPCS) Federal coding system for medical procedures. The HCPCS includes current procedural terminology (CPT) codes (Level I), national alpha-numeric codes (Level II), and local alpha-numeric codes (Level III). National codes are developed by the Centers for Medicare and Medicaid Services (CMS) to supplement CPT codes and include physical services not included in CPT as well as non-physician services such as ambulance, physical therapy, and durable medical equipment (DME). Local codes are developed by local Medicare carriers to supplement the national codes. J-codes are a subset of the HCPCS Level II code set used to identify certain drugs and other items.

home-infusion pharmacy Pharmacy specializing in supplying members with home-infusion therapy medications and supplies.

house brand Private-labeled prescription drugs, repackaged for sale. *See* repackaged.

inpatient Pertaining to the treatment of patients admitted to a hospital bed.

intermediary Entity contracted to a purchaser for provision of products and/or services to beneficiaries or providers, with a purchaser-defined level of authority in the handling of this responsibility and responsibility to the purchaser for performance.

list price Published price that is not an actual transaction price. Certain pharmaceutical transactions, such as setting payment rates to pharmacies, may be based on list prices. The average wholesale price (AWP) and the wholesale acquisition cost (WAC) are examples of list prices.

long-term care (LTC) Services ordinarily provided in a skilled nursing, intermediate care, personal care, supervisory care, or elder care facility.

mail service option Pharmacy benefit specifying that all or certain drugs, such as maintenance drugs, may be obtained from a designated mail service pharmacy, usually provided in a 2- or 3-month supply.

managed care organization (MCO) Generic term applied to a managed care plan. They are also called health maintenance organizations (HMOs), preferred provider organizations (PPOs), and exclusive provider organizations (EPOs), although the MCO may not conform exactly to any of these formats.

maximum allowable cost (MAC) Cost management program that sets upper limits on the payment for equivalent drugs available from multiple manufacturers. It is the highest unit price that will be paid for a drug and is designed to increase generic dispensing, ensure that the pharmacy dispenses economically, and control future cost increases.

Medicaid State-operated and administered program that is jointly funded by the federal and state governments. Medicaid provides medical benefits for certain indigent or low-income persons in need of health and medical care. The program is authorized by Title XIX of the Social Security Act. Within broad federal guidelines, states determine the benefits covered, program eligibility, rates of payment for providers, and methods of administering the program.

Medicare National program of health insurance operated by the Centers for Medicare and Medicaid Services (CMS) on behalf of the federal government since its creation by Title XVIII—Health Insurance for the Aged in 1965 as an amendment to the Social Security Act. Medicare provides health insurance benefits primarily to persons over the age of 65 and others who are eligible for Social Security benefits and covers the cost of hospitalization, medical care, prescription drugs, and some related services.

Part A Insurance program (also called Hospital Insurance program) that provides basic protection against the costs of hospital and related post-hospital services for individuals aged 65 or over who are eligible for retirement benefits under the Social Security or Railroad Retirement System. Part A pays for inpatient hospital, skilled nursing facility (SNF), and home health care. The Hospital Insurance program is financed from a separate trust fund and primarily funded with a payroll tax levied on employers, employees, and the self-employed.

Part B Medicare component that provides benefits to cover the costs of physicians' professional services, whether the services are provided in a hospital, physician's office, extended-care facility, nursing home, or insured's home.

Part C Previously called Medicare+Choice when it was created by the Balanced Budget Act of 1997, it is now called Medicare Advantage. (See Medicare Advantage.)

Part D The Medicare component that provides benefits to cover the costs of outpatient prescription drugs (OPDs). Benefits commenced on January 1, 2006, and will be administered through private health plans.

Medicare Advantage Previously called Medicare+Choice, legislation in which Medicare expanded the number of eligible private and public entity risk contractors as part of the Balanced Budget Act of 1997. Current health maintenance organizations (HMOs) and competitive medical plans (CMPs) are automatically transitioned to Medicare Advantage but must comply with new rules, while provider-sponsored organizations (PSOs) are also allowed to accept Medicare risk. A Medicare Advantage offering pharmacy benefits is termed an MA-PD.

multiple-source brand Refers to the brand version of a drug when it is available in both brand-name and generic versions from a variety of manufacturers.

multiple-source drug Drug available in both brand-name and generic versions from a variety of manufacturers.

National Drug Code (NDC) Defined officially as a 10-character number by the FDA but commonly implemented in claims administration systems as an 11-character number. The NDC number is divided into three segments: the first 5 characters for the labeler (which may or may not be the manufacturer), 4 characters for the drug and strength, and the last 2 characters to describe the package size.

net price Price, after concessions are deducted, paid at different levels of the channels of prescription drug distribution (e.g., purchaser to provider, provider to wholesaler, and wholesaler to manufacturer).

net product revenue (for calculation of average sales price)

Sum of a manufacturer's volume discounts, prompt-pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927 of the Social Security Act) for the most recently available 12-month period associated with all sales included in the average sales price (ASP) reporting requirements as stated in the April 6, 2004, interim final rule. However, the manufacturer then calculates a percentage by using this summed amount as the numerator and the corresponding total sales data (i.e., the total in dollars for the sales subject to the ASP reporting requirement for the same 12-month period) as the denominator. This results in a 12-month rolling average price concession percentage of total price concessions (12-month)/total sales (12-month). This percentage is then applied to the total in dollars for the sales subject to the ASP reporting requirement for the quarter being submitted to determine the price concession amount for the quarter. The price concession amount is then applied as a reduction to the total sales dollar amount, and that result (i.e., total sales (quarter) minus [price concession percentage x total sales (quarter)]) is the numerator used in calculating the quarterly ASP for that national drug code (NDC) (excerpted from CMS-1380-F).^v

nominal price exception (or exclusion) This final rule implementing the Deficit Reduction Act of 2005 (DRA), CMS-2238-FC, limits the "nominal pricing" exception to 340B-eligible entities, intermediate care facilities for the mentally retarded, and state-owned or state-operated nursing facilities.

nonfederal average manufacturer price (non-FAMP) Average price paid to a manufacturer by wholesalers for drugs distributed to nonfederal purchasers. Under federal law, the Big Four are entitled to discounts on brand-name drugs of at least 24% off the non-FAMP. Non-FAMP is not publicly available.

Omnibus Budget Reconciliation Act of 1990 (OBRA 90) Medicaid Drug Rebate Program created by the Omnibus Reconciliation Act of 1990 (OBRA 90) that added Section 1927 to the Social Security Act, effective January 1, 1991. The law requires that manufacturers enter into an agreement with the Centers for Medicare and Medicaid Services (CMS) to provide rebates for their drug products that are paid for by Medicaid. Manufacturers that

do not sign an agreement with CMS are not eligible for federal Medicaid coverage of their product(s). Except for statutory limitations, state Medicaid programs must provide coverage and reimbursement for all covered outpatient drug products manufactured by companies that have entered into a rebate agreement with CMS.

Orange Book *Approved Drug Products with Therapeutic Equivalence Evaluations*, 27th Edition (U.S. Department of Health and Human Services and Food and Drug Administration, 2007), commonly referred to as the "Orange Book."^{vi} Publication that identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act. Patent listings can be found in this online book, which is updated daily.

own use Term developed in case law that is related to class of trade (COT) pricing in the pharmaceutical industry. The Non-Profit Institutions Act (15 U.S.C.A. Section 13c), enacted 2 years after the Robinson-Patman Act, exempts "purchases of their supplies for their own use by ... hospitals, and charitable institutions not operated for profit."^{vii} Because of the broad institutional function of a health maintenance organization (HMO), any sale of drugs to a member falls within the basic function of the HMO; therefore, the purchase of drugs by an HMO for dispensing to its members is for its "own use" and within the Non-Profit Institutions Act exemption. Hospitals and health systems that operate ambulatory care pharmacies that dispense drugs to patients who are not hospital or health system employees or members typically maintain separate prescription drug inventories so as not to violate the "own use" exemption.^{viii}

patient assistance program (PAP) Program administered by a pharmaceutical company that provides financial assistance with prescription drug costs. PAPs offer free and discounted prescription drugs to those who qualify.

patient cost share See cost share, copayment, and coinsurance.

pay for performance Use of provider payment incentives to encourage and reinforce the delivery of evidence-based medicine to promote better and more efficient patient outcomes.

^v Available at: <http://www.cms.hhs.gov/MMAUpdate/MMU/ItemDetail.asp?ItemID=CMS034048>. Accessed September 4, 2007.

^{vi} Available at: <http://www.fda.gov/cder/ob/>. Accessed September 4, 2007.

^{vii} U.S. Federal Trade Commission. FTC staff advisory opinion - Henry County Memorial Hospital (letter). April 10, 1997. Available at: <http://www.ftc.gov/bc/adops/henry.htm>. Accessed April 24, 2007.

^{viii} U.S. Federal Trade Commission, Bureau of Competition. Connecticut Hospital Association (CHA) advisory opinion letter. December 20, 2001. Available at: <http://www.ftc.gov/opa/2001/12/chaadvisopinletter.shtm>. Accessed April 24, 2007.

payer (also: purchaser, plan sponsor, third-party payer, insurer)

Public or private organization that pays or insures health or medical expenses on behalf of beneficiaries or recipients who pay a premium for this coverage in all private and some public programs. The payer then pays bills on behalf of covered individuals, which are called third-party payments.

payment rate With respect to a purchaser-to-provider transaction, net amount paid for the product and/or service rendered.

per diem reimbursement Reimbursement to an institution (usually a hospital) based on a set rate per day rather than on charges accrued. Per diem reimbursement can be varied by service (e.g., medical/surgical, obstetrics, mental health, intensive care) or can be uniform regardless of intensity of services.

pharmacy benefit management (PBM) companies Organizations that manage pharmaceutical benefits for managed care organizations (MCOs), other medical providers, or employers. PBMs contract with clients who are interested in optimizing the clinical and economic performance of their pharmacy benefit. PBM activities may include some or all of the following: benefit plan design, creation/administration of retail and mail service networks, claims processing, and managed prescription drug care services such as drug utilization review, formulary management, generic dispensing, prior authorization (PA), and disease and health management.

plan sponsor *See* payer.

preferred drug list (PDL) Used interchangeably with “formulary,” a listing of medications that beneficiaries may readily access through their health plans. Non-PDL medications may not be accessible, may carry a higher cost-share amount, or may be accessible only if prior authorization (PA) is obtained.

Preferred Provider Organization (PPO) A PPO plan has a network of providers that have agreed to contractually specified reimbursement for covered benefits with the organization offering the plan; and provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and is offered by an organization that is not licensed or organized under state law as an HMO.

prescription drug plan (PDP) Standalone PDPs, covered under Medicare Part D, that are offered to beneficiaries in a traditional fee-for-service (FFS) Medicare program and to beneficiaries in Medicare Advantage plans that do not offer a prescription drug benefit.

price concession Discount or rebate offered with respect to the purchase of a product or service, conditional upon the purchaser's compliance with terms and conditions of the offer.

price transparency Disclosure of price-related information by an entity to persons or organizations outside of that entity.

prior authorization (PA) Sometimes called “prior approval.” The physician or pharmacy must generally request approval from the health plan through a designated process to obtain coverage for the beneficiary and reimbursement to the provider.

private insurer *See* payer.

prompt-pay discount Discount provided for the payment of an invoice within a designated time, often 30–60 days subsequent to product delivery.

prospective payment Payment received before care is actually needed. It gives the provider organization a financial incentive to use fewer resources because they are allowed to keep the difference between what is prepaid and what is actually used.

provider Any supplier of services (i.e., physician, pharmacist, case management firm).

provider acquisition cost Estimate of the actual acquisition cost (AAC) of providers.

provider purchase price The actual acquisition cost (AAC) of providers.

Public Health Service (PHS) 340B ceiling price Calculated by the Office of Pharmacy Affairs (OPA) within the Department of Health and Human Services (DHHS), maximum price that manufacturers can charge covered entities participating in the 340B Drug Pricing Program of the PHS. The 340B discount is calculated by using the Medicaid rebate formula and is deducted from the manufacturer's selling price rather than paid as a rebate. Compared with a drug's average manufacturer price (AMP), covered entities receive a minimum discount of 15.1% for brand-name drugs and 11% for generic and over-the-counter (OTC) drugs and are entitled to an additional discount if the price of the drug has increased faster than the rate of inflation. Covered entities are free to negotiate discounts that are lower than the maximum allowable statutory price (i.e., subceiling prices).

published price *See* list price.

purchaser *See* payer.

rebate Monetary amount returned to a payer from a prescription drug manufacturer based on use by a covered person or purchases by a provider.

reference price (RP) Limits reimbursement for a group of drugs with similar therapeutic application but different active ingredients to the price of the lowest-cost drug within the group (the reference standard). Patients may purchase drugs other than the reference product, in which case they pay the difference between the retail price and the RP.

reimbursable (also: reimbursement) Process by which health care providers receive payment for their services is sometimes referred to as “reimbursement.” Because of the nature of the health care environment, providers are often reimbursed by third parties who insure and represent patients. A product or service that a health care provider administers to a patient and for which necessary approvals have been given becomes reimbursable.

repackaged Prescription drug taken from its original manufacturer container and placed into another labeled container for dispensing.

retail class of trade CMS-2238-FC^{ix} defines the retail pharmacy class of trade as that sector of the drug marketplace, similar to the marketplace for other goods and services, that dispenses drugs to the general public and includes all price concessions related to such goods and services. Prices of sales to nursing home pharmacies (long-term care [LTC] pharmacies) are to be excluded, but sales and discounts to mail order pharmacies are to be included.

single-source brand Drug under patent protection that is sold under a brand name and is thus available from only one manufacturer (or occasionally from other manufacturers under license from the patent holder). No generic version is available.

site of care Site at which health care services and products are administered to the patient.

specialty pharmacy Pharmacy that dispenses generally low-volume and high-cost medicinal preparations to patients who are undergoing intensive therapies for illnesses that are generally chronic, complex, and potentially life threatening. These therapies often require specialized delivery and administration.

stakeholder A party of interest. With respect to prescription drugs, stakeholders include but are not limited to purchasers, group purchasing organizations (GPOs), wholesalers, pharmaceutical manufacturers, providers, and patients.

step therapy A health plan or pharmacy benefit manager (PBM) may require a beneficiary to try one drug before the plan will pay for another drug. A principal purpose of step therapy is to reduce the average cost for treating a given condition (e.g., hypertension or heartburn), requiring beneficiaries to use an equally effective, lower-cost drug prior to coverage of a higher-cost, second-line drug. The health plan or other payer may require evidence of therapeutic failure (e.g., intolerance due to side effects) prior to coverage of the second-line drug.

therapeutically equivalent product Drug products containing different chemical entities that should provide similar treatment effects as well as the same pharmacological action or chemical effect when administered to patients in therapeutically equivalent doses. Per the *Approved Drug Products with Therapeutic Equivalents*, 27th Edition (also known as the Orange Book), drug products are considered to be therapeutic equivalents only if they are pharmaceutical equivalents and can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling. Drug products are considered pharmaceutical equivalents if they contain the same active ingredient(s), are of the same dosage form and route of administration, and are identical in strength or concentration.

therapeutic maximum allowable cost (TMAC) Managed care intervention that establishes a defined benefit dollar amount per therapeutic procedure or indication, such as \$0.75 per day of drug therapy for heartburn based on the omeprazole over-the-counter (OTC) price or \$0.50 per day of therapy for allergic rhinitis based on the market price of loratadine OTC in 2007.

third-party administrator (TPA) Organization that provides administrative services to group benefit plans that may include premium accounting, claims adjudication and payment, claims utilization review (e.g., for medical necessity), maintenance of employee eligibility records, and negotiations with insurers that provide stop-loss protection for large claims individually (“specific”) or collectively (“aggregate”). TPAs do not assume insurance risk.

third-party payer (also: third-party carrier) Public or private organization (such as Blue Cross and Blue Shield, Medicare, Medicaid, commercial insurer, self-insured employer, Taft-Hartley Trust, or Multiple Employer Trust) that pays for or underwrites coverage for health care expenses for an individual or group. The individual enrollee generally pays a premium for coverage in all private and some public health insurance programs, and the organization pays claims on the patient’s behalf.

^{ix} Available at: <http://www.cms.hhs.gov/MedicaidGenInfo/Downloads/CMS2238FC.pdf>. Accessed September 4, 2007.

traditional community pharmacy Any place under the direct supervision of a pharmacist where the practice of pharmacy occurs or where prescription orders are compounded and dispensed other than a hospital pharmacy, limited service pharmacy, or mail service (mail order) pharmacy.

usual and customary (U&C) price The price for a given drug or service that a pharmacy would charge a cash-paying customer without the benefit of insurance provided through a payer or intermediary with a contract with the pharmacy.

usual, customary, and reasonable (UCR) Amount determined to be “reasonable” (acceptable) by comparing the U&C charges among providers in a given geographic region. UCR prices are commonly used by traditional health insurance companies as the basis for physician reimbursement.

VA national contract price Price obtained by the Department of Veterans Affairs (VA) through competitive bids from manufacturers for select drugs in exchange for their inclusion on the VA formulary. Because the VA is entitled to federal ceiling prices (FCPs) under federal statute, VA national contract prices are even lower than FCP prices and are often the lowest prices in the nation.

volume purchase agreement Manufacturer agreement to sell prescription pharmaceuticals at a given price that is subject to additional discounts or rebates conditional on the purchase of a fixed quantity of product over a defined time period.

wholesale acquisition cost (WAC) Price paid by a wholesaler for a drug purchased from the wholesaler’s supplier, typically the manufacturer of the drug. Publicly disclosed WAC amounts may not reflect all available discounts, such as prompt-pay (cash) discounts.

wholesaler Firm involved in logistics function (assembling, sorting, and redistributing) in the channel of distribution for pharmaceuticals. Wholesalers purchase goods from manufacturers and redistribute them to purchasers, who may be pharmacies, physicians, or other types of providers.

widely available market price (WAMP) Price that a prudent physician or supplier would pay for the drug or biological, taking into account the discounts, rebates, and other price concessions routinely made available for such drugs or biologicals. WAMP would not be a list price that is commonly discounted, but would be the purchase price net of discounts, rebates, and price concessions routinely available to prudent purchasers.

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