

AMCP GUIDE TO

# Pharmaceutical Payment Methods

COMPREHENSIVE EDITION ■ VERSION 1.0

**AMCP**  
Academy  
of Managed  
Care Pharmacy®

AMCP TASK FORCE ON DRUG PAYMENT METHODOLOGIES ■  
OCTOBER 2007 ■

This *AMCP Guide to Pharmaceutical Payment Methods* was created by the Academy of Managed Care Pharmacy Task Force on Pharmaceutical Payment Methods in conjunction with the consulting firm of Tag & Associates. It was approved for publication by the Academy's Board of Directors in September 2007. The Academy intends to periodically update sections of the *Guide* as necessary.

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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](http://www.amcp.org).

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## Executive Summary

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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 *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:

- **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).
- **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 the *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.
- **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.
- **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. Evaluated topics 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 sections highlight key issues discussed in the *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, but 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 contain many of the 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 Centers for Medicare and Medicaid Services (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 pharmacy benefit managers (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 managed 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**

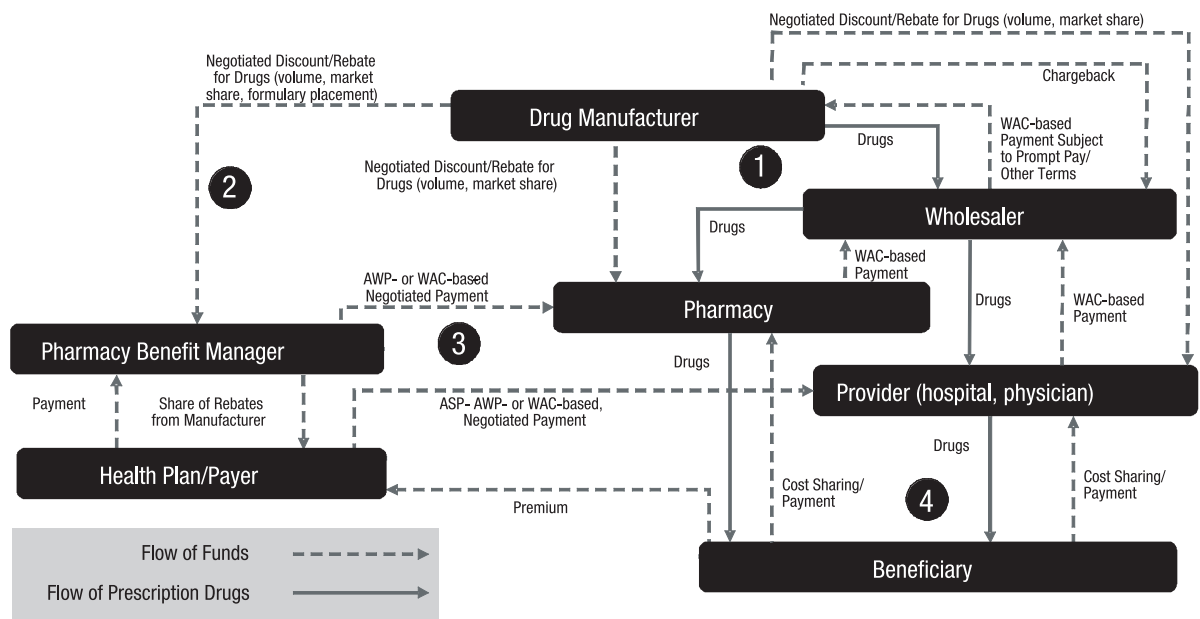
Compared with public payers, private payers have less transparency in their payment methods for prescription drugs. For example, private payers use MAC price lists for multiple-source drugs that are not accessible. Like public payers, private payers use drug formularies—a list of drugs covered by the 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.

**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.

**EXHIBIT 1** Drug Distribution Model



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 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 drugs are purchased and paid for.

**Note:** The references in the *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>.

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## I. Introduction

Prescription pharmaceuticals 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

stakeholders<sup>1</sup> for detailed information on this complex topic, the Academy of Managed Care Pharmacy (AMCP) 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.<sup>1</sup> As shown in Exhibit I-1, projections made in 2005 suggested that this pattern would continue through 2014.<sup>2</sup>

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.<sup>3</sup>

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 federal offices, led to extraordinary changes in how large federal programs pay manufacturers and providers for prescription pharmaceuticals.

In the past 2 years, pharmaceutical pricing benchmarks, used by payers to form the basis of payment, have been subject to greater pressure for change than in the previous 2 decades. Changes that began with Medicare in 2005 are spreading rapidly among government payers and are being closely examined by private health plans. Each year for the next several years, a steady evolution is expected toward the goals of pharmaceutical payment simplification, reliable benchmarks, and price transparency.

To understand where U.S. prescription pharmaceutical payment methodology is heading, it will help to understand where it is currently, how it got there, and what forces are moving it in new directions. This *Guide* offers a comprehensive overview as well as a selected focus on details concerning the most important segments and developments. It is organized into 4 main sections:

1. Payment Benchmarks
2. Payers and Payment Methodologies
3. How Products, Services, and Payments Flow Through Channels of Distribution
4. Issues and Implications for Stakeholders

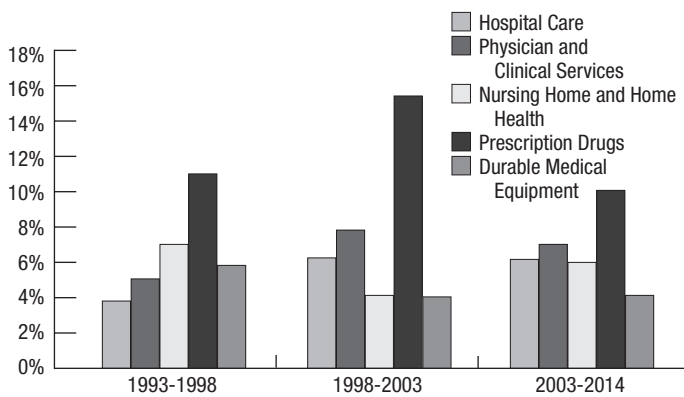
This *Guide* is intended to be an unbiased presentation of information, issues, and implications. The *Guide* is not an expression of AMCP policy, nor is it intended to advocate any position on behalf of AMCP or its members on any issue.

*Notes: 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.*

*An acronym list and a glossary to assist the reader appear at the end of this Guide.*

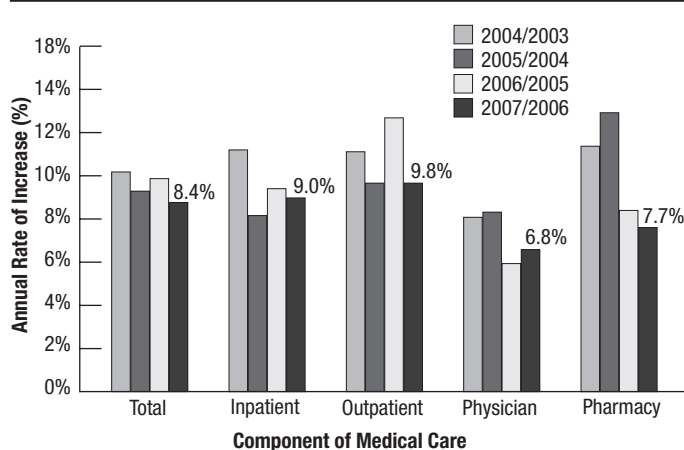
<sup>1</sup>Stakeholders including payers and their consultants and representatives, vendors in the channels of distribution, health professionals, policy makers, patient associations, and professional associations.

**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.

## II. Payment Benchmarks

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.<sup>4,5</sup>

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.

To help stakeholders understand and evaluate these changes, this Section explains

- the benchmarks that have come into use over the past 4 decades,
- how and when they are used, and
- how they compare with and affect one another.

### Variation in Use of Terms and Their Significance

Over the years, governments, 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. Benchmarks may or may not be defined in law; AMP is so defined, while AWP is not.

This Section lists the most frequently used terms and their generally accepted definitions. Benchmarks are detailed that have greater overall impact on pharmaceutical payment or are currently receiving the most scrutiny and discussion.

### Most Frequently Used Benchmarks

#### ■ Average Wholesale Price (AWP)

AWP was the first generally accepted standard pricing benchmark for the majority of payers because this information was readily available from several suppliers.<sup>6</sup> AWP was reportedly created in the 1960s by the California Medicaid program as a means by which to standardize a basis for the pharmaceutical cost component of

pharmacy reimbursement. It was subsequently adopted by other Medicaid programs, and several publishers made a business of collecting, calculating, and disseminating AWP data.<sup>5</sup> At that time, AWP was considered to be an appropriate estimate of the actual acquisition cost (AAC).

More recently, however, the legitimacy of AWP has been called into question by numerous analysts. AWP has been referred to as “essentially a sticker price and does not directly correspond to any actual market transaction.”<sup>7</sup> For the past several years, pharmacies and other provider customers have generally been able to purchase pharmaceuticals at a net cost below AWP.

### Payers Seek Alternatives to AWP

Through at least the early 1980s, product cost reimbursement was commonly 100% of AWP. By the mid-1980s, however, AWP discounts of 5–10% were common; by the mid-1990s, AWP discounts were as much as 15% (i.e., reimbursement would be 85% of AWP).

Through 2004, almost every U.S. government and private payer used AWP as its primary benchmark for reimbursement. Supported by data from Congressional Budget Office (CBO) reports, Office of Inspector General (OIG) studies from the Department of Health and Human Services (DHHS), and Department of Justice (DOJ) investigations analyses, Congress and the Administration ended Medicare’s use of AWP effective January 1, 2005, for all but a handful of pharmaceuticals.<sup>viii</sup> In the Deficit Reduction Act of 2005 (DRA), the Medicaid federal upper limit (FUL) reimbursement for generic pharmaceuticals was changed from an AWP-based formula to one that relies on AMP, with an original effective date of July 1, 2007. In addition, a succession of studies, lawsuits, and government enforcement actions demonstrate growing payer dissatisfaction with AWP as a basis for reimbursement.<sup>9</sup>

Under a pending settlement in the case of *New England Carpenters Health Benefits Fund v. First DataBank Inc.* (D. Mass., No. 1:05-CV-11148-PBS, settlement agreement filed 10/6/06), 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.<sup>10</sup> In May 2007, Wolters Kluwer, publisher of *Medi-Span*, announced that it had entered into a similar settlement agreement with plaintiffs, pending court approval.<sup>11</sup> 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)

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) changed the way that Medicare pays for pharmaceuticals under the physician fee schedule. Effective January 1, 2005, ASP replaced AWP as the Medicare Part B payment benchmark. Pharmaceuticals covered by Part B (mainly physician-administered pharmaceuticals) are reimbursed at 106% of ASP

(ASP plus 6%) unless market survey data trigger a downward adjustment (see discussion under “Widely Available Market Price”).

Not all drugs have published ASPs. Only those drugs that are part of the Medicare Part B benefit have ASPs that are reported to and published by the Federal government’s Centers for Medicare and Medicaid Services (CMS). Unlike AWP, ASP is based on manufacturer-reported actual selling price data and includes all forms of rebates, volume discounts, prompt-pay discounts, cash discounts, free goods that are contingent on any purchase requirement, and chargebacks.

Manufacturers report ASP values by using national drug code (NDC) numbers. Currently, each manufacturer must provide CMS with the ASP and sales volume for each of its NDC numbers on a quarterly basis. To do this, manufacturers collect purchasing information supplied to them by wholesalers and other customers to integrate with their own sales reports. As currently constructed, the reporting process creates a lag of at least 2 quarters between implementation of a pharmaceutical price change and a corresponding adjustment in the ASP-based reimbursement for that pharmaceutical.

Although manufacturers submit ASP data by NDC numbers, the Medicare component of CMS does not currently use NDCs to reimburse Medicare providers for Part B pharmaceuticals. Instead, CMS uses Healthcare Common Procedure Coding System (HCPCS) Level II codes. For this reason, NDCs are “crosswalked” to the HCPCS codes via a data file published by CMS.<sup>12</sup> The net result is that ASP is not directly linked to payment in the Medicare program. The impact of this process is discussed in Section III, “Payers and Payment Methodologies.”

### **Impact of ASP on Pharmaceutical Costs**

ASP has proven to be substantially lower than AWP. In a June 2005 study, the DHHS Inspector General found that in the aggregate for all pharmaceuticals reviewed, “ASP is 49% lower than AWP at the median.”<sup>13</sup> The greatest difference between ASP and AWP was observed in generic pharmaceuticals. ASP is approximately 74% of AWP for single-source brands, approximately 70% of AWP for multiple-source brands, and 32% of AWP for generic pharmaceuticals.<sup>13</sup>

In the MMA, Congress directed the Medicare Payment Advisory Commission (MedPAC) to study the impact of implementation of ASP on beneficiary access and quality of care. Focusing on oncology services, MedPAC issued its first report in January 2006 and a second report 1 year later regarding services provided by urologists, rheumatologists, and infectious disease specialists. When the payment rate changed per MMA to 106% of ASP from 2004 to 2005, MedPAC found that total claims volume and charges for each medical specialty reviewed (including pharmaceuticals, pharmaceutical administration, evaluation and management visits, laboratory tests, and other medical procedures) increased, but spending on pharmaceuticals decreased. The decline in expenditures for pharmaceuticals ranged from 1% for rheumatology to 52% for urology, with much

of the reduction being attributable to lower prices. Overall, total Part B pharmaceutical spending (considering price and volume changes) fell from \$10.9 billion in 2004 to \$10.1 billion in 2005.<sup>14</sup>

Although data are not available to document net savings to the Medicare program as a result of the change to ASP-based payment, there is evidence of lower net cost for specific drugs. According to the Court’s Findings of Fact and Conclusions of Law in the pharmaceutical industry AWP litigation, “even with the increase in administration fees paid to doctors, Medicare has had overall cost savings from the decrease in drug expenditures for Zoladex, Taxol, Remicade, Procrit, and albuterol. The total reimbursement for a typical administration of Zoladex, including both product cost and administration fee, fell from \$451.56 in 2002 to \$226.48 in 2005 under the new ASP system. Looking at those same 2 years, the cost of a typical dose of Taxol dropped from \$1785.16 to \$428.07, Remicade from \$2,035.15 to \$1,703.09, Procrit from \$150.65 to \$131.96, and albuterol from \$109.74 to \$71.63.”<sup>15</sup>

### **Impact on Provider Practices**

Because ASP is a volume-weighted average,<sup>16</sup> any provider whose acquisition cost is above the median will be adversely impacted, while those below the median will benefit. The acquisition cost for many pharmaceuticals varies significantly by class of trade (COT), purchase volume, and ability to influence product market share in competitive therapeutic classes. Anecdotal evidence suggests that small physician offices often buy at the least favorable prices, while large physician groups and hospitals, which commonly access contracts through group purchasing organizations (GPOs), have historically been able to negotiate the best discounts and price concessions.

In the MedPAC study noted above,<sup>14</sup> most physicians reported that they were able to purchase the majority 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. Physicians purportedly have used pharmaceutical profit margins to cover operating costs associated with common delays in the payment process and perceived underpayment for services and procedures associated with pharmaceutical administration. Physicians, particularly oncologists (who buy the most pharmaceuticals), reported spending considerable time and staff resources seeking the best deals for pharmaceuticals. Many also reported that they have increased efficiencies in their practices in response to lower pharmaceutical payments.<sup>14</sup>

The following structural problems with ASP were reported to MedPAC by physicians, hospital administrators, wholesalers, manufacturers, and consultants.<sup>14</sup>

**Data lags.** The current ASP payment rate is set based on transaction prices from the previous 2 quarters. Thus, if manufacturers raise prices in subsequent quarters, purchasers may have difficulty purchasing products at the Medicare payment rate until the ASP catches up. (This provider complaint was also associ-

ated with changes to the reported AWP prices previously used by payers.) Physicians reported that data lag was their biggest problem with the new payment method. (It should be noted that when prices are falling, as may happen when generic versions of a pharmaceutical become available, the combination of falling prices and data lag may create temporary reimbursements that are higher than the purchase price.) Additionally, physicians reported that price increases are smaller but more frequent with the ASP program than with the previous AWP payment system.

**Gap between manufacturers' reported ASP and average physician purchase price.** ASP is based on the payments that manufacturers receive for their products. When manufacturers sell directly to a physician, the average amount received is the average amount paid by the physician. However, pharmaceuticals often pass through a larger distribution chain. Wholesalers, specialty pharmacies, health maintenance organizations (HMOs), and GPOs may be involved in pharmaceutical shipping, storing, handling, and price negotiations. Each link in the distribution chain receives payment for administrative services. When a gap appears between the price that manufacturers receive and report and the purchase price paid by providers, ASP may be lower than the average provider purchase price. This can occur in 2 ways:

- ASP may include discounts that are not received by all purchasers.
- ASP does not reflect wholesaler fees for administrative services that physicians or other purchasers pay.

For example, discounts to physician purchasers vary depending on the volume of product purchased. Larger practices that purchase substantial quantities receive the deepest discounts. If a large practice or purchasing group dominates the customer base for a given pharmaceutical, as is often the case, the average discount will be higher—and the ASP lower—than the discount experienced by smaller customer groups.

Manufacturers may also offer prompt-pay discounts to wholesalers or other large purchasers who pay for their purchases within a specified time frame. Although these discounts are small in percentage terms, they are an important source of revenue for wholesalers and typically are not passed on to the final purchaser, such as a physician. Prompt-pay discounts lower the ASP because they reduce the revenue that manufacturers receive for their products. When these discounts are included in the ASP calculation but are not passed on to purchasers, including physicians, Medicare's ASP may fall below the average price paid by physicians.

Similarly, wholesalers may mark up the price they charge to physicians to include allowances for wholesaler profit, handling, and shipping costs. The manufacturer does not receive more money for its product and therefore does not include these fees when calculating ASP. Thus, these markups may result in pharmaceutical prices that exceed the ASP reported by

manufacturers. In MedPAC's interviews, many physicians listed older generic pharmaceuticals as examples of products that they could not purchase at the Medicare payment rate.<sup>14</sup>

**State and local taxes.** In some parts of the country, physicians report that they pay state or local taxes on acquisition of Part B pharmaceuticals. However, these taxes are not reimbursed by payers because they are not recognized as an acquisition cost.<sup>14</sup>

**Bundling.** Some manufacturers offer provider discounts for one of their products contingent on purchases of 1 or more other products, which is referred to as "bundling." The effect of pharmaceutical bundling on providers can perhaps best be illustrated through example. Suppose that 2 competing pharmaceuticals, named A and B, are similar products that compete for market share in a therapeutic class. Although the shift to ASP has resulted in lower payment rates for both products, volume and expenditures continued to increase in 2005. In this example, the manufacturer of A also makes C, a lifesaving pharmaceutical with no effective competition. The manufacturer provides a significant incentive discount on product C to purchasers who buy A instead of B. These discounts result in a lower ASP for C as well as a lower Medicare payment rate. If a physician prefers B and therefore does not purchase A, the physician loses money each time a patient is treated with C because Medicare's payment rate for C is lower than the price that physicians must pay if they do not obtain the bundled discount.<sup>14</sup>

Another concern with ASP-based reimbursement is that it may undermine manufacturers' incentives to compete on price for single-source, therapeutically equivalent products. ASP may also discourage use of multi-source products when a therapeutically equivalent brand is available. For example, a \$60 dollar margin exists on a drug with an ASP of \$1,000, but only a \$30 margin on a drug with an ASP of \$500.

If reduction in a physician's acquisition cost is perfectly matched by reduction in reimbursement for the pharmaceutical component, the physician will have no incentive to use the lower-priced pharmaceutical and the manufacturer will have no incentive to reduce price; rather, the manufacturer may have an incentive to raise the price under ASP-based reimbursement. Thus, an indirect contracting model with specialty pharmacies/pharmacy benefit managers (PBMs) (such as CMS's Competitive Acquisition Program [CAP], described in detail in Section III) that is not empowered to design restrictive formularies is likely to be ineffective at fostering price competition between manufacturers.<sup>17</sup>

### ■ 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.

Similar to ASP, AMP 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 states to obtain Medicaid coverage and payment. The statutorily mandated rebate amounts—11% for multiple-source pharmaceuticals and at least 15.1% for single-source products—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.

Despite the rebates, Medicaid 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.<sup>18</sup> 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 and Subsequent Rule Making

In 2005, Congress implemented the OIG recommendations with enactment of the DRA.<sup>19</sup> The DRA's 2 sweeping changes for Medicaid benchmark pricing were (a) adoption of AMP as the new RP for generic pharmaceutical reimbursement and (b) requiring the AMP for all pharmaceuticals—both generic and brand name—to be reported to the states and public on a monthly basis. 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 maximum allowable cost (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.<sup>20</sup> Exhibit II-1 lists those components that the final rule states must be included and excluded in the AMP calculation.

### EXHIBIT II-1 Components of AMP Calculation<sup>21</sup> (as of July 2007)

Included Sales/Discounts	Excluded Sales/Discounts
<ul style="list-style-type: none"> <li>• Mail order pharmacy (including those operated by a PBM)</li> <li>• Specialty pharmacy</li> <li>• Home-infusion providers</li> <li>• Sales of drugs reimbursed by third-party payers (including Medicare Part D, Medicare Advantage Prescription Drug [MA-PD] plans, qualified retiree prescription drug plans [PDPs], State Children's Health Insurance Programs [SCHIPs], state pharmaceutical assistance programs [SPAPs], Medicaid programs, and HMOs/managed care organizations [MCOs] that do not take possession of or purchase drugs)</li> <li>• Hospitals where outpatient setting use can be documented</li> <li>• Home health providers</li> <li>• Physicians</li> <li>• Outpatient facilities (including clinics, surgical centers, ambulatory care centers, dialysis centers, and mental health centers)</li> <li>• Direct patient sales</li> <li>• Wholesalers*</li> <li>• Retail pharmacies</li> <li>• Manufacturers who act as wholesalers and do not repackage/relabel under purchaser's NDC, including private labeling agreements</li> <li>• Any other price concession to retail COT</li> </ul>	<ul style="list-style-type: none"> <li>• PBMs</li> <li>• Discounts and rebates to third-party payers (see list in column at left)**</li> <li>• Sales and discounts to HMOs/MCOs that purchase or take possession of drugs</li> <li>• Hospitals where drug is used in inpatient setting or site of use cannot be determined</li> <li>• Long-term care (LTC) facilities, including nursing home pharmacies</li> <li>• Hospices (inpatient and outpatient)</li> <li>• Manufacturer coupons redeemed by consumer or other entity in which full value of coupon is passed on to consumer</li> <li>• Voucher programs</li> <li>• Manufacturer drug discount cards</li> <li>• Patient assistance programs</li> <li>• Free goods not contingent on any purchase requirement</li> <li>• Nominal prices*** for specified entities</li> <li>• Customary prompt-pay discounts</li> <li>• Returned goods and replacement products</li> <li>• Veterinarians</li> <li>• Prisons</li> <li>• Sales outside the United States</li> <li>• State, county, and municipalities</li> <li>• Indian Health Service (IHS), Department of Veterans Affairs (VA), qualified state home, Department of Defense (DoD), Public Health Service (PHS), 340B entities, Federal Supply Schedule (FSS), depot prices including Tricare, and other approved federal agencies</li> <li>• Bona fide service fees</li> <li>• Wholesalers whose drug is distributed to the nonretail COT</li> <li>• Wholesalers whose drug is relabeled under the wholesaler's NDC number</li> </ul>

Note: See exclusions in column at right

\* Except for sales that can be documented as being subsequently sold to excluded entities.

\*\* Including Medicaid rebates paid to states under the National Rebate Agreement and authorized state supplemental rebate agreements.

\*\*\* See "nominal price exception (or exclusion)" in the Glossary.

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 long-term care (LTC) facilities, to PBMs, and to federal programs other than Medicaid are excluded from the retail class of trade.

Calculation of AMP includes all price concessions, discounts (other than customary prompt-pay discounts), and rebates. Manufacturer payments for bona fide services are not included.

### ■ Wholesale Acquisition Cost (WAC)

WAC is the manufacturer’s reported list price for a prescription pharmaceutical for sale to wholesalers.<sup>22</sup> Each manufacturer establishes its own WAC using its own formula. FDB includes manufacturers, repackagers, private labelers, and other suppliers within the term *manufacturer* in its policy for determining the origin of WAC prices.<sup>23</sup> 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.<sup>24</sup>

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, chargebacks, 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.*<sup>25</sup>

WAC has been an important benchmark price for several reasons. It is lower 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 in contracts with PBMs and health plans.<sup>26</sup>

### ■ Maximum Allowable Cost (MAC)

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 PBMs for private-sector clients and by individual states for multiple-source pharmaceuticals dispensed by their Medicaid and other state-funded programs. As of September 2006, 42 state Medicaid programs had a MAC program.<sup>27</sup>

Some state Medicaid departments may create and administer their own MAC lists, utilize private consultant firms, or delegate the function to PBMs. No standardized definition for MAC exists; states use a variety of formulae, including WAC-based and FUL-based approaches, as well as market surveys targeting distributors and pharmacies.

MAC prices are often lower than the FUL established by CMS for Medicaid payment. A recent study concluded that MAC prices on average (unweighted) for top Medicaid generic pharmaceuticals are 49% below those specified by the old FUL formula (lowest published price plus 150%).<sup>27</sup>

MAC lists are also routinely used in the private sector. PBMs typically apply MAC pricing for generic pharmaceuticals and multiple-source brand pharmaceuticals dispensed by community pharmacies. Principal differences among MAC lists are (a) the MAC value or price for each drug and strength (generic code number (GCN) in the FDB system) and (b) the number of drugs (GCNs) with MAC prices. Some PBMs maintain multiple MAC lists, differing in the number of generics listed and in pricing aggressiveness, with prices often below the state-established Medicaid MAC prices. MAC is reportedly less common in mail order pharmacy reimbursement.

### Other Benchmarks

#### ■ Actual Acquisition Cost (AAC)

A pharmaceutical’s AAC will vary from one customer to another depending on the terms that the customer has negotiated with the manufacturer and distributor.

#### ■ Best Price (BP)

Best price 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 an entity exceeds the discount earned by application of the mandatory discount plus any penalties (i.e., greater than 15.1% of AMP plus Consumer Price Index [CPI] penalty). BP approximates 63% of AWP.<sup>28</sup> Medicare Part D, Medicaid, and other government purchasers are excluded from this calculation. The final rule implementing the DRA includes authorized generics in the

calculation of the BP, as follows:

“...we have revised the authorized generic provision to include in the best price of the brand drug, transfer prices and other fees paid for authorized generics by the secondary manufacturer to the primary manufacturer, unless such prices or fees are excluded by statute or regulation or fall within the definition of a bona fide service fee...”<sup>20</sup>

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.

Exhibit II-2 depicts the components of Medicaid’s BP calculation.

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

**EXHIBIT II-2** Medicaid Best Price Components<sup>20</sup>

Included Sales/Discounts	Excluded Sales/Discounts
<ul style="list-style-type: none"> <li>• Wholesalers</li> <li>• Retailers</li> <li>• PBM-operated mail order pharmacies or PBM price concessions designed to adjust prices at the retail or provider level</li> <li>• Providers</li> <li>• Nonprofit entities</li> <li>• Sales directly to patients from the manufacturer</li> <li>• Mail order pharmacies</li> <li>• Outpatient clinics</li> <li>• Manufacturers who act as wholesalers and do not repackage/relabel under purchaser’s NDC, including private labeling agreements</li> <li>• Entities that repackage/relabel under purchaser’s NDC, including private label, if that entity is also an HMO or other nonexcluded entity</li> <li>• Manufacturer coupons in which full value is not passed to consumer</li> <li>• Authorized generic drugs sold by primary manufacturer</li> <li>• Government entities in the United States, except as excluded (see column at right)</li> <li>• Prompt-pay discounts</li> <li>• Returned goods</li> </ul>	<ul style="list-style-type: none"> <li>• IHS, VA, qualifying state homes, DoD, PHS, 340B entities, FSS, depot prices, or other approved federal agencies</li> <li>• PBMs</li> <li>• Rebates or supplemental rebates to Medicaid agencies</li> <li>• SPAPs</li> <li>• Medicare Part D plans, MA-PDs, and qualified retiree PDPs</li> <li>• Nominal prices* to specified entities</li> <li>• Manufacturer coupons in which full value is passed to consumer</li> <li>• Manufacturer-sponsored drug discount program</li> <li>• Goods provided free of charge under a manufacturer’s patient assistance program (PAP)</li> <li>• Free goods not contingent on any purchase requirement</li> <li>• Bona fide service fees</li> </ul>

Note: See exclusions in column at right

\* See “nominal price exception (or exclusion)” in the Glossary.

repeatedly, but thus far unsuccessfully, urged Congress to repeal the BP provision.<sup>29</sup>

**Direct Price (DP)**

Some manufacturers who sell their pharmaceuticals directly to community pharmacies and clinicians as well as to wholesalers have established a direct price in addition to a WAC. For some manufacturers, DP is the same as WAC, while DP may be slightly higher than WAC for other manufacturers. Due to different levels of discounts across drug products and specific COTs, DP does not generally have a reliable relationship to AAC.<sup>30</sup>

**Estimated Acquisition Cost (EAC)**

Estimated acquisition cost is a state Medicaid agency’s best estimate of the price generally paid by pharmacies for a drug. This figure is meant to represent a calculation of the AAC across all pharmacies.

The federal government does not specify how EAC should be calculated. Individual states have developed their own methods, with most using a discount off the AWP. The average reduction from AWP for all states that use an EAC methodology is approximately 12%.<sup>31</sup>

**Federal Ceiling Price (FCP)**

Federal ceiling price is the maximum price that manufacturers can charge the Department of Veterans Affairs (VA), Department of Defense (DoD), Public Health Service (PHS), and Coast Guard—known as the “Big Four”—for brand-name drugs. FCP is mandated by law to be 24% lower than the previous fiscal year’s nonfederal average manufacturer prices (non-FAMPs) minus an additional discount if the non-FAMP rises faster than inflation (see the following discussion of non-FAMP).<sup>32</sup> FCP cannot exceed the previous year’s inflation-adjusted Federal Supply Schedule (FSS) price. FCP approximates 50% of AWP.<sup>28</sup>

**Federal Supply Schedule (FSS)**

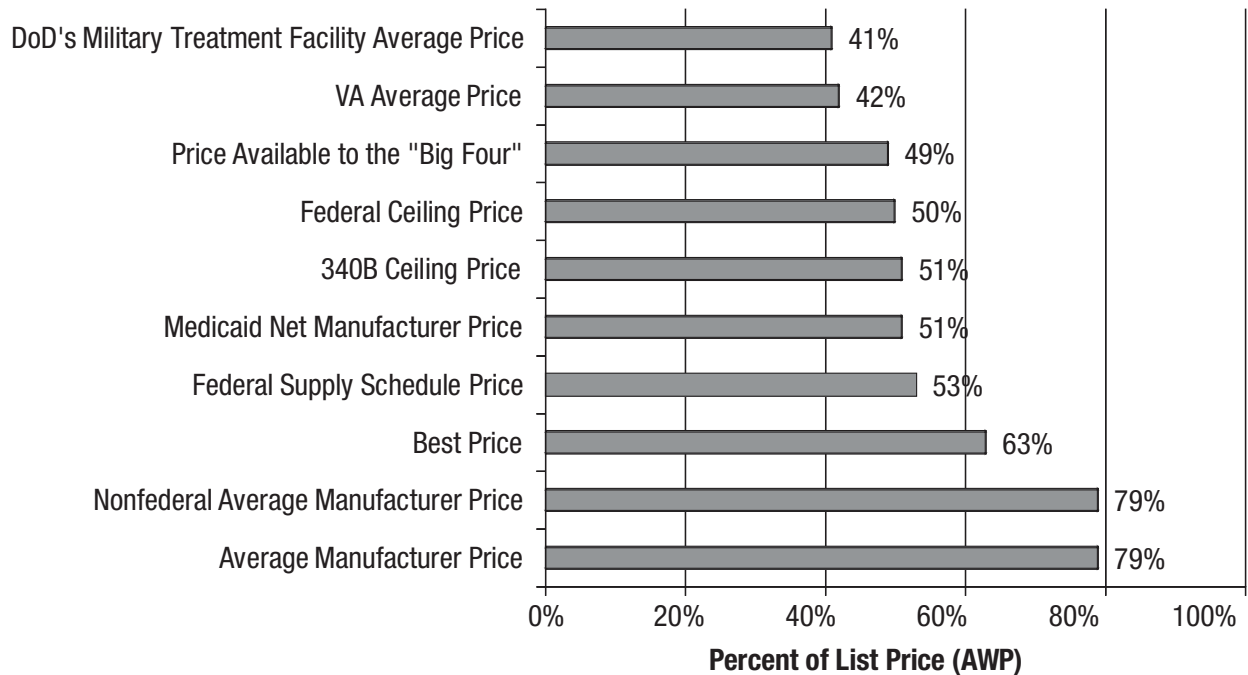
FSS is a price negotiated with manufacturers by the VA on the basis of the prices that manufacturers charge their most-favored commercial customers under comparable terms and conditions. During a multi-year contract period, FSS prices may not increase at a rate higher than the inflation in the general U.S. economy. FSS price approximates 53% of AWP.<sup>28</sup>

**Federal Upper Limit (FUL)**

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. As of January 1, 2007, the FUL for multiple-source pharmaceuticals is set at 250% of the AMP for the least costly of the products within a given multiple-source designation that also meets specified regulatory criteria.<sup>33</sup> The previous formula set the FUL at 150% of the lowest published price—be it AWP, WAC, or DP—in any of the 3 national drug-pricing compendia

**EXHIBIT II-3**

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.

(FDB, Medi-Span, and Red Book).<sup>34</sup> The statutory definition of *multiple-source pharmaceutical* has also been revised in the DRA to require the existence of only 2 rather than 3 therapeutically and pharmaceutically equivalent products.

In some cases, utilization of the FUL system has increased net cost to state Medicaid programs due to the disparity in the rebates paid by innovator and multi-source manufacturers.

**■ Nonfederal Average Manufacturer Price (Non-FAMP)**

Non-FAMP is used to calculate the maximum price that manufacturers can charge the Big Four for brand-name drugs. Non-FAMP is the average price paid to the manufacturer by wholesalers (or others who purchase directly from the manufacturer) for drugs distributed to nonfederal purchasers, taking into account any cash discounts or similar price reductions given to those purchasers, but not taking into account any prices paid by the federal government. The non-FAMP does not reflect rebates paid by the manufacturer to third-party payers. It approximates 79% of AWP.<sup>28</sup>

**■ Public Health Service (PHS or 340B)**

340B is a ceiling price that is calculated by the Pharmacy Affairs Branch (PAB), formerly the Office of Pharmacy Affairs (OPA). It is

the highest price that a 340B entity could be charged and is equal to the price that the state Medicaid agency would pay absent any supplemental discount or rebate. 340B entities include PHS-funded clinics and disproportionate-share hospitals (DSHs) (referred to as “covered entities”). 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.<sup>35</sup> The price could be negotiated lower by the 340B entity. 340B prices are reported to be approximately one-half (49%) of AWP.<sup>28,36</sup>

**■ Reference Price (RP)**

Reference pricing limits pharmaceutical plan reimbursement of “interchangeable” medicines to a reference price, which is typically equal to the price of the lowest-cost interchangeable pharmaceutical. Any cost above that limit is assumed by the patient.<sup>37</sup> Interchangeability in the context of the RP has been stated as follows: “If there is no evidence that one drug is more effective or has fewer toxic effects than another lower-priced drug (within a specific drug class), then the extra cost should not be covered by a publicly funded drug-benefit plan.”<sup>38</sup>

The Foundation of Managed Care Pharmacy sponsored a survey of managed care pharmacy experts during the summer of 2006.<sup>39</sup> Approximately one-third of respondents stated that implementation of reference-based pricing is very likely, likely, or somewhat likely within the next 3 years.

**Therapeutic Maximum Allowable Cost (TMAC)**

A related benchmark is therapeutic maximum allowable cost, an intervention used by managed care organizations (MCO), that establishes a defined benefit dollar amount per therapeutic procedure or indication. A TMAC can be established for any medical procedure (e.g., joint replacement) or any pharmacological indication (e.g., cholesterol reduction).<sup>40,41</sup> Similar to MAC in which a single maximum payment rate is established for generic-equivalent products, TMAC involves calculation of a single maximum payment rate from multiple reported costs for therapeutically equivalent products or procedures.

For example, a TMAC for low-density lipoprotein (LDL) cholesterol reduction might be set at \$0.50 per day of pharmaceutical therapy based on marketplace prices, such as \$0.40 to \$0.50 for generic simvastatin, a benchmark pharmaceutical in the class of LDL cholesterol reduction. TMAC is derived from reported and marketplace costs and involves clinical judgment about the price point that will permit the vast majority of patients to achieve the desired therapeutic outcome(s).

**Usual and Customary Price (U&C)**

Usual and customary price—also known as “retail” or “cash” price—is the undiscounted price that individuals without drug coverage would pay at a retail pharmacy.<sup>42</sup>

**Widely Available Market Price (WAMP)**

Widely available market price is a concept established by Congress in 2003 as part of the MMA. It is an alternative method used to monitor market prices of Part B pharmaceuticals and allow downward adjustment of reimbursement.<sup>43</sup>

Creation of WAMP interjected a new federal government office into the price benchmarking process—the OIG of the DHHS. The OIG is directed to conduct market price surveys to determine the WAMP. If the OIG finds that the ASP exceeds the WAMP or the Medicaid AMP by a threshold percentage (currently 5%), then CMS must substitute the lesser of (a) the WAMP or (b) 103% of the AMP as reimbursement for that pharmaceutical instead of 106% of the ASP.<sup>43</sup>

**Comparison of Benchmark Prices**

Exhibit II-3, from a 2005 CBO study, illustrates how selected benchmark prices compare with both AWP and with one another.

Another comparison was prepared by the OIG in 2005. For a sample of NDCs, the OIG analyzed the median percentage differ-

ences between ASP and AWP for single-source, multi-source, and generic brands. The OIG found that ASP is 26% below AWP at the median for more than 700 single-source brand NDCs, and ASP is 30% below AWP at the median for more than 200 multi-source brand codes. The difference between ASP and AWP was greatest for generic pharmaceuticals, with ASP being 68% less than AWP at the median for more than 1,100 generic NDCs.<sup>13</sup>

Another OIG report calculated overall median, average, and weighted average comparisons for AMPs as shown in Exhibits II-4 and II-5.<sup>6</sup>

**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 best price benchmarks include:

- 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

**EXHIBIT II-4** Median, Average, and Weighted Average Reduction (%) from Average Wholesale Price to AMP

	Median	Average	Weighted Average*
Single-source brands	23%	25%	24%
Multi-source brands	28%	40%	36%
Generics	70%	65%	74%

\* Weighted by Medicaid expenditures.  
Source: Office of Inspector General. Medicaid drug price comparisons: average manufacturer price to published prices. Department of Health and Human Services; June 2005. OEI-05-05-00240. Available at: <http://oig.hhs.gov/oei/reports/oei-05-05-00240.pdf>. Accessed September 4, 2007.

**EXHIBIT II-5** Median, Average, and Weighted Average Percent Reduction (%) from Wholesale Acquisition Cost to AMP

	Median	Average	Weighted Average*
Single-source brands	4%	7%	6%
Multi-source brands	8%	19%	20%
Generics	40%	39%	59%

\* Weighted by Medicaid expenditures.  
Source: Office of Inspector General. Medicaid drug price comparisons: average manufacturer price to published prices. Department of Health and Human Services; June 2005. OEI-05-05-00240. Available at: <http://oig.hhs.gov/oei/reports/oei-05-05-00240.pdf>. Accessed September 4, 2007.

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.<sup>15</sup>
- 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 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?

### III. Payers and Payment Methodologies

#### 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.

This section describes reimbursement methodologies by payer and treatment setting for Medicare, Medicaid, the PHS 340B program, and private insurers. Medicaid will be examined in less detail because, as a result of Medicare’s assumption of primary drug coverage for individuals who are dually eligible for both Medicare and Medicaid, the Medicaid share of the total prescription drug market has been significantly reduced, having been estimated to have dropped from 19% in 2004 to 12–14% in 2007.<sup>27</sup>

Other government programs, such as VA health care benefits, use a manufacturer contracting process to obtain drugs for their beneficiaries rather than a provider reimbursement system. Therefore, these programs are not described in this paper.

Private insurer payment methodologies tend to be less complex than government programs. Because of proprietary contract negotiations, private insurance payments and methodologies are less transparent. As a result, less consistent information is available about private payers than government programs.

#### 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.<sup>44</sup>

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

Over the years, Congress has created a variety of exceptions and special payment rules to accommodate certain political and public

health interests without fundamentally revising a Medicare benefit program. As a result, special payment rules exist for certain drugs in some of the aforementioned settings.

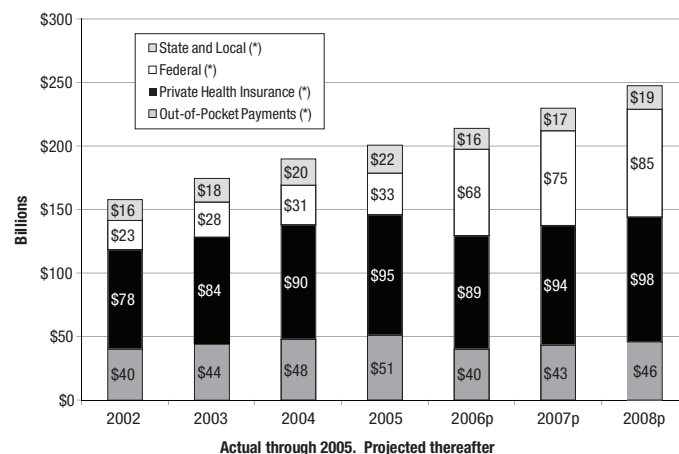
##### Medicare’s Influence on Prescription Drug Payment

Until 2006, private health insurance paid the largest portion of prescription drug costs. However, by 2007, it is projected that the introduction of the Medicare Part D outpatient prescription drug benefit established by 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.<sup>45</sup>

In 2005, the U.S. pharmaceutical market was estimated at \$201 billion, of which public payments accounted for approximately \$55 billion and private health insurance accounted for \$95 billion. By 2007, CMS Office of the Actuary estimates total prescription drug expenditures of \$230 billion, with \$92 billion from public sources and \$94 billion from private health insurance. By 2008, prescription drug expenditures are projected at \$248 billion, with \$103 billion attributed to public programs and \$98 billion to private health insurance.<sup>45</sup>

Between 2003 and 2007, Medicare transitioned from being a payer with modest influence on prescription drug payment to

**EXHIBIT III-1** Prescription Drug Expenditures by Source of Funds



(\*) Launch of Medicare Part D on January 1, 2006, is projected to have reduced state drug expenditures, representing the shift of Medicaid/Medicare dual eligibles to Part D, and to have shifted both private out-of-pocket and private health insurance expenditures for covered beneficiaries to Part D. The Part D program drives the projected increase in federal share of prescription drug expenditures between 2005 and 2006.

Source: Office of the Actuary. National Health Expenditures projections 2006-2016. Centers for Medicare and Medicaid Services. Based on the 2005 version of the National Health Expenditures released in January 2007. Available at: [http://www.cms.hhs.gov/NationalHealthExpendData/03\\_NationalHealthAccountsProjected.asp#TopOfPage](http://www.cms.hhs.gov/NationalHealthExpendData/03_NationalHealthAccountsProjected.asp#TopOfPage). Accessed September 1, 2007.

becoming one of the most important in the United States and, by extension, the world. In 2003, Medicare was responsible for \$2.4 billion, or 1.4%, of U.S. prescription drug costs. By 2007, it is projected that Medicare's share of these costs will have risen to \$51 billion or over 22% of total.<sup>45</sup> Exhibit III-1 illustrates sources of prescription drug expenditures during the first years of this decade.

Fundamental reasons for the shift in influence are contained in the MMA.<sup>46</sup> This Act made 3 sweeping changes: the first affected primarily drugs dispensed through retail outlets, the second transitioned prescription drug coverage of dual eligibles (i.e., those enrolled in both Medicare and Medicaid) to Medicare, and the last affected drugs administered by clinicians in physician office and hospital outpatient settings.

- A prescription drug benefit (Part D) was enacted, effective January 1, 2006. Its structure is unlike anything seen in the private insurance market or from other government payers. Most beneficiaries, excepting dual eligibles, have significant cost sharing up to a catastrophic threshold. Commercial entities that operate the benefit are at economic risk.
- Prescription drug coverage for Medicare/Medicaid dual eligibles became the responsibility of Medicare. Dual eligibles do not pay premiums and are only responsible for copayments.
- Payment for clinician-administered as well as a handful of covered self-administered drugs (Part B) are now based on the manufacturers' actual net selling price rather than AWP. This new ASP became effective in physician offices in 2005 and hospitals in 2006.

The following section discusses provider reimbursement aspects of Medicare Part B, Part D, and other benefits.<sup>47</sup>

## ■ Hospital Inpatients

### *Prospective Payment System (PPS)*

Prospective payment system is a method of reimbursement in which Medicare payment is based on a predetermined, fixed amount. The payment amount for a particular service is derived based on the classification system of that service (e.g., diagnosis-related groups [DRGs] for inpatient hospital services). Separate PPS schedules for reimbursement to acute inpatient hospitals, home health agencies, hospice, hospital outpatient, inpatient psychiatric facilities, inpatient rehabilitation facilities, LTC hospitals, and skilled nursing facilities (SNFs) are used by CMS.

### *Diagnosis-Related Groups (DRGs)*

Under the hospital inpatient PPS payment schedule, each inpatient admission is assigned a DRG category. Each DRG is assigned a payment weight based on the average resources used to treat Medicare patients in that DRG. Pharmaceuticals receive no separate Medicare reimbursement when they are provided to hospital inpatients; their cost is included in the lump sum DRG prospective payment made to the hospital.<sup>48</sup>

Exceptions to the system of no separate payment for pharma-

ceuticals exist for hemophilia clotting factor and also for a limited period of time (usually 2–3 years) for certain new technologies. Clotting factor is separately reimbursed using the same formula (106% of ASP) as is found in the outpatient setting (see “Hospital Outpatient Departments” and “Physician Offices”). New technologies, including drugs, can receive separate reimbursement under the Medicare statute if, “based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate.”<sup>49</sup> The hurdles in demonstrating inadequate payment are so high that the sepsis treatment Xigris® (drotrecogin alpha) is, to date, the only drug to receive the special payment.<sup>50</sup> If a new technology add-on payment is approved, Medicare pays approximately 50% of the cost of the drug in excess of the full DRG payment for 2 or 3 years.

## ■ 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.

### *Ambulatory Payment Classification (APC)*

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.<sup>51</sup> 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%. Newly introduced SCODs may have a different payment amount for several months based on the WAC or AWP until ASP data are available.<sup>52</sup>

## ■ Physician Offices

Policy makers had long agreed that Medicare did not pay accurately for Part B drugs or the clinical services to administer those drugs.<sup>53</sup> Under the AWP payment methodology, administration of prescription drugs “incident to” physician services generated high profit margins for oncologists, urologists, and other physicians. Some authorities believe that the financial incentives created by this profitability played a large and problematic role in treatment decisions, that is, prescribers responded to these high margins by tending to administer more drug therapy (and more expensive drugs) than might be medically necessary.<sup>30</sup>

### *Average Sales Price (ASP)*

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; determination of how ASP is calculated and reported is described in Section II, “Payment Benchmarks.”

**Competitive Acquisition Program (CAP)**

The MMA created the CAP as an alternative way for physicians to acquire physician-administered drugs.<sup>54</sup> 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: 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%.<sup>55</sup> Other potential CAP vendors either did not bid or withdrew bids because they did not believe they could earn an adequate margin under the CAP payment amount and procedures.

The 2007 CAP physician election period extended from October 1 to December 1, 2006. Approximately 2,400 physicians (almost 200 oncology and internal medicine groups with practicing oncologists) elected the CAP during the most recent election period.<sup>56</sup> Physicians in specialties with the highest Medicare Part B drug spending, particularly oncology, were reported to be least likely to enroll in the program.

**Least Costly Alternative (LCA)**

CMS has the statutory authority to apply a cost-control tactic named Least Costly Alternative to virtually any Part B drug or device. Thus far, LCA has been used most often to reduce payments for hormone-suppressing treatments for advanced prostate cancer, with the price of goserelin—the therapeutic LCA—being the reimbursement benchmark for 5 other nongeneric products. Physicians are allowed to use any of the 6 drugs; however, they will typically be reimbursed as if they had used the least expensive one.<sup>57</sup>

LCA has historically been implemented by Medicare contractors (local carriers) via local coverage decisions or medical review policies<sup>58</sup> rather than by CMS through a national coverage determination. Local implementation has caused some inconsistencies with how the LCA is enforced from one state to another.

**Pharmacy-Dispensed Medicare Part B Drugs**

The vast majority of Part B drugs are administered in a physician’s office or in an 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%.

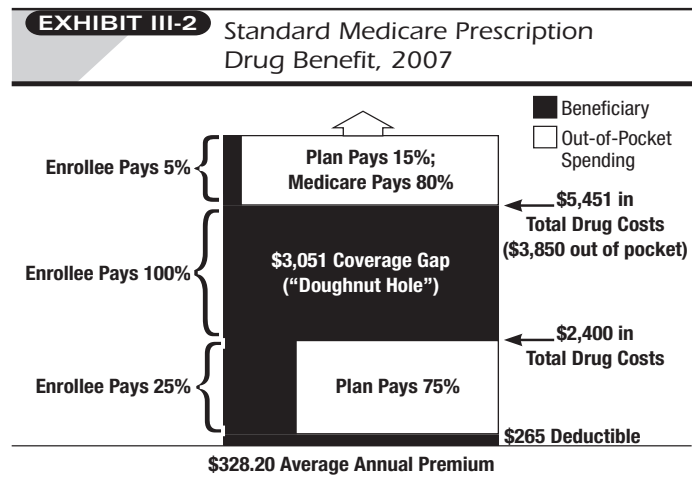
**Pharmacy-Dispensed Medicare Part D Drugs**

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 who are automatically enrolled in Part D and randomly assigned to Part D plans.<sup>59</sup>

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.<sup>60</sup>

**Part D Benefits**

The standard benefit for calendar year 2007 is shown in Exhibit III-2 and in the following list; participants may also purchase additional benefits.



NOTE: Annual premium amount based on \$27.35 national average monthly beneficiary premium (CMS, August 2006). Amounts for premium, coverage gap, and catastrophic coverage threshold rounded to nearest dollar. SOURCE: Kaiser Family Foundation illustration of standard Medicare drug benefit, updated with Part D benefit parameters for 2007 (from CMS, OACT, May 22, 2006).

- \$265 deductible
- Coverage for 75% of allowable drug expenses up to a benefit limit of \$2,400
- \$3,850 catastrophic limit on “true out-of-pocket (TrOOP) spending” (or \$5,451 in total drug expenses for enrollees without supplemental drug coverage)
- 5% coinsurance for drug spending above the catastrophic limit

TrOOP refers to a feature of Part D in which only certain types of spending on behalf of the beneficiary count toward the catastrophic threshold: the beneficiary’s own out-of-pocket spending; that of a family member or official charity; supplemental drug coverage provided through qualifying State Pharmaceutical Assistance Programs (SPAPs) or Part D’s low-income subsidies; and, under CMS’s demonstration authority, supplemental drug coverage paid for with Medicare Advantage rebate dollars. Beneficiaries must also adhere to their plan’s formulary, prior authorization (PA), and formulary exceptions processes to receive TrOOP credit for their out-of-pocket spending.

After the deductible, enrollees with standard benefits pay a 25% coinsurance on the first \$2,400 of prescription drugs. They then pay a 100% coinsurance for drug spending greater than \$2,400 but less than the catastrophic threshold, which is sometimes referred to as the “donut hole.”

Most plans also offer alternative coverage structures. For example, a plan can offer a deductible lower than \$265 or use tiered copayments rather than coinsurance—provided that the alternative benefit meets certain tests of actuarial equivalence. Also, plans may offer additional drug coverage that supplements the standard benefit; however, Medicare payments to plans do not subsidize such supplemental coverage.

### 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.<sup>60,61</sup>

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.<sup>62</sup>

Since the enactment of Part D, Medicare policy makers and others have considered moving some or all Part B drugs into the Part D benefit. In total, there are 13 categories of drugs for which separate payment is made under Part B: drugs furnished “incident to” a physician’s service, separately billable ESRD drugs, separately billable drugs provided in HOPDs, durable medical equipment (DME) supply drugs, other drugs covered as supplies, drugs used in immunosuppressive therapy, blood clotting factors, certain vaccines, antigens, parenteral nutrition, certain oral drugs used in cancer treatment, separately billable drugs provided in comprehensive outpatient rehabilitation facilities, and IVIG provided in the home. As of this writing, no proposals are on the table to move Part B drugs into the Part D benefit.

### State Pharmaceutical Assistance Programs (SPAPs)

Numerous state governments play an important role by offering direct pharmaceutical assistance benefits to eligible residents. As of January 2007, 42 states established or authorized some type of SPAP to provide prescription drug coverage or assistance, primarily to low-income elderly or persons with disabilities who do not qualify for Medicaid. Most programs use state funds to subsidize a portion of the costs, usually for a defined population that meets enrollment criteria.

A majority of these programs are recognized within the MMA and are termed State Pharmaceutical Assistance Programs or “SPAPs” in the federal law.<sup>63</sup> In the past 5 years, a growing number of states also offer pharmaceutical discount programs that do not involve state subsidies, but instead consolidate a state’s purchasing power to lower the retail price of prescription drugs.<sup>64</sup>

### Ambulatory Surgical Centers (ASCs)

ASCs are facilities that perform only ambulatory surgery. Approved procedures generally are limited to those that are provided in hospital inpatient settings but that also can be performed safely in outpatient facilities.

Each of the more than 2,400 procedures approved for payment in an ASC is classified into 1 of 9 prospective payment groups based on its cost—not clinical—similarity. Drugs administered for the procedure are packaged or bundled into the prospective payment. Regardless of cost, no separate drug reimbursement is made to ASCs.<sup>65</sup>

### ■ Dialysis Services

Regardless of age, individuals with ESRD who are entitled to receive Social Security benefits also receive all Medicare Part A and Part B benefits. Due to the scarcity of kidneys available for transplantation, most beneficiaries with ESRD (77%) receive maintenance dialysis.

Medicare submits a predetermined payment to dialysis facilities for each dialysis treatment. The prospective payment, or “composite rate,” is intended to cover the bundle of services and supplies, including certain drugs that are routinely required.

Technological advances have changed the provision of dialysis care since the composite rate was established. Consequently, the composite rate currently excludes several injectable drugs—such as erythropoietin, vitamin D, and iron—that have diffused widely into medical practice over the past decade. Providers are paid separately for these drugs at ASP plus 6%, which is a financial incentive for dialysis providers to administer and bill for them. CMS is considering a broader bundled payment system that includes injectable drugs and other items currently excluded from the outpatient dialysis bundle. The MMA mandated performance of a demonstration project to evaluate a composite rate that includes injectable drugs.<sup>66</sup>

Beneficiaries pay a 20% copayment for both composite rate services and separately billable drugs associated with dialysis services.<sup>67</sup>

### ■ 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 admin-

istered by the patient or a caregiver because no payment is available for home health clinical services. Reimbursement is paid at ASP plus 6%.<sup>68</sup>

**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%.<sup>69</sup>

### ■ Skilled Nursing Facilities (SNFs)

Beneficiaries who need short-term skilled care, such as nursing or rehabilitation services, on an inpatient basis following a hospital stay of at least 3 days are eligible to receive covered services in SNFs. The Medicare SNF benefit covers skilled nursing care and rehabilitation services, as well as other goods and services, and pays facilities a PPS per diem rate for each day of care up to 100 days.

The SNF per diem prospective payment rate is based on the “resource utilization group” for the particular beneficiary. The PPS includes drugs that are ordinarily furnished by the facility for the care and treatment of inpatients, whether the drugs are routinely stocked by the SNF or must be obtained for patients from an outside source, such as a community pharmacy. A small number of Part B drugs are excluded from PPSs and can be billed separately (e.g., pneumococcal, influenza, and hepatitis B vaccines).<sup>70-72</sup>

## Medicaid

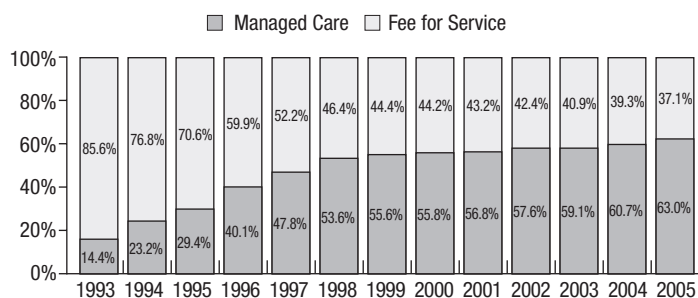
### ■ Background

Medicaid is a program financed jointly by federal and state governments that provides medical and long-term care to many of the nation’s most vulnerable lower-income individuals, especially mothers and children, seniors, and individuals with disabilities. Eligibility rules for Medicaid are complex and 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.<sup>73</sup>

State spending on Medicaid is matched by the federal government. The federal financing share is called the Federal Medical Assistance Percentage (FMAP). The FMAP averages 57%, varying from a 50% floor to a high in 2007 of 75.8% for the state of Mississippi. The federal match varies based on per capita income in the state relative to the national average, with states below the national average receiving a higher FMAP.<sup>31</sup>

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, in which case there are 2 primary scenarios: the state pays the Medicaid health plan a premium based on risk and cost categories that includes a pharmacy component, or the state “carves out” the OPD benefit and is thereby

**EXHIBIT III-3** Managed Care Enrollment as a Percent of Total Medicaid



Source: CMS. Medicaid managed care enrollment report: summary statistics as of June 30, 2005. DHHS. Available at <http://www.cms.gov/MedicaidDataSourcesGenInfo/Downloads/mmcer05.pdf> Accessed September 23, 2007.

entitled to statutory rebates. Carved-out OPD benefits from Medicaid health plans have become more common in recent years because states have been enticed to carve out to earn large statutory rebate revenues plus supplemental rebates based on product placement on states' Preferred Drug Lists (PDLs). As shown in Exhibit III-3, more than 60% of Medicaid beneficiaries are now enrolled in some type of managed care program, ranging from traditional managed care models (HMOs) to less rigid networks with select providers.<sup>31</sup>

### ■ 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 practice; as of January 1, 2006, dual eligibles received 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.<sup>74</sup>

One result of this shift in coverage and payment for prescription drugs from Medicaid to Medicare was the loss of mandatory drug manufacturer rebates for Medicaid drug program expenditures for dual eligibles. However, the reduction in this expense for brand-name pharmaceutical manufacturers was offset by rebate contracts negotiated individually by PDPs and MA-PDs associated with drug formulary inclusion and position.

### ■ Long-Term Care (LTC) Pharmacies

Because of a provision in the MMA, dual eligible beneficiaries receiving LTC in nursing facilities have Medicare Part D as their primary source of prescription drug coverage, even though Medicaid pays for other services. Prior to January 1, 2006, dual eligible nursing home beneficiaries were covered for prescription

drugs by their state Medicaid program.

Most nursing facilities contract with a single pharmacy provider, called an LTC pharmacy, which is located off-site from the many nursing homes it serves. When an LTC pharmacy receives a prescription order from a nursing facility, it fills the order for delivery in unit-dose packages.

Before the change in 2006, LTC pharmacies were highly influential in determining which drugs were dispensed within the facilities they serviced.<sup>75</sup> Many LTC pharmacies developed prescribing guidelines that functioned like drug formularies to encourage prescribers and consultant pharmacists to choose certain preferred drugs. This business practice enabled LTC pharmacies to maintain rebate relationships with pharmaceutical manufacturers because of their ability to influence medication regimens.<sup>76</sup>

Medicare Part D plans have lessened the influence of LTC pharmacies over the choice of drugs in nursing facilities. LTC pharmacies must now contract with Part D drug plans to provide pharmacy services for their Medicare beneficiaries who are nursing facility residents. These residents are subject to the plan's formulary and cost-management controls rather than the LTC pharmacy guidelines. Like all dual eligible beneficiaries, nursing home residents can switch drug plans on a monthly basis to provide greater flexibility in matching their changing needs to Part D plan formularies.

### ■ Prescription Drug Rebates

The actual cost to Medicaid for prescription drugs is reduced by manufacturers' rebates that are paid to the states, the benefit of which is shared with the federal government through lower FMAP payments due on net state Medicaid expenditures. Rebates extend only to drugs purchased by states on an FFS basis. When states purchase drugs through managed care programs, the MCOs are permitted to negotiate their own discounts and rebates, and the federal mandate for rebate payments from brand and generic drug manufacturers does not apply.

Medicaid rebates were created by Congress in the OBRA 90, effective January 1, 1991, and amended in 1992 and 1993. Under the rebate statute, also known as the "best price" statute, a manufacturer must enter into a rebate agreement with CMS in order for its drugs to be eligible for Medicaid reimbursement. Each quarter, for each unit of drug covered by a state FFS Medicaid program, the manufacturer must pay either a basic rebate (basic unit rebate amount [URA]) based on a percentage of the AMP or a rebate based on the BP available to wholesalers and other customers. Also, a manufacturer may be required to pay an additional rebate (additional URA) if the AMP of a single-source or innovator multiple-source product has increased from a baseline faster than the Consumer Price Index – Urban (CPI-U).

Since January 1996, rebate amounts have been calculated for each drug and strength (e.g., Lipitor 10 mg) according to the following formula for all 50 states (except Arizona) and the District of Columbia.

**EXHIBIT III-4** Estimated Average Unit Rebate Received by Medicaid for Brand-Name Prescription Drugs 1991-2003

(As a percentage of average manufacturer price)

	Basic Rebate	Additional Rebate	Total <sup>a</sup>
2003	19.6	11.7	31.4
2002	19.9	10.5	30.4
2001	20.3	9.1	29.3
2000	20.2	8.8	28.9
1999	20.0	9.0	29.0
1998	19.9	8.3	28.2
1997	19.9	8.6	28.6
1996	20.5	7.6	28.0
1995	21.5	8.3	29.9
1994	22.6 <sup>b</sup>	*	*
1993	24.2	*	*
1992	25.4	*	*
1991	20.3	*	*

Notes: Average rebate percentages for each quarter are weighted by that quarter's volume of sales to Medicaid. The annual figures are four-quarter averages for each year, except as noted. All estimates are based on manufacturer-reported prices from the Centers for Medicare and Medicaid Services.

\* = estimate not available.

<sup>a</sup> Basic and additional rebate estimates may not sum in totals because of rounding.

<sup>b</sup> Represents the first two quarters only.

Source: Congressional Budget Office.

- “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 components<sup>77</sup>:
  1. Basic URA—The greater of (a) 15.1% of the AMP or (b) AMP minus BP.
  2. Additional URA—Divide the baseline AMP (AMP for the first quarter after a drug's market date) by the baseline CPI-U (CPI-U for the month prior to the first quarter after a drug's market date), and multiply the resulting number by the quarterly CPI-U.
 The following table in Exhibit III-4 illustrates the sum of the basic and additional rebates.<sup>78</sup>

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.

Physician-administered drugs are covered under the rebate program; however, fewer than one-half of states surveyed by the DHHS

OIG collect rebates on these drugs. To collect the rebates, states must identify the drugs by their NDCs and provide units-paid data to the drug company. Unlike self-administered drugs, which are typically billed to the state with NDCs, physician-administered drugs are most often billed with HCPCS procedure codes.

States have been slow to introduce NDC requirements into their physician claims systems, but are now required to do so under the DRA. CMS's final rule implementing the DRA mandates state that, as of January 1, 2007, claims for physician-administered single-source drugs must use NDC codes. On January 1, 2008, claims for the 20 most expensive multiple-source drugs must also comply.<sup>20</sup>

Many states have negotiated with manufacturers for supplemental rebates over and above the basic and additional URA based on the position of products on state PDLs.<sup>79</sup> In 2002, 4 states collected approximately \$0.3 billion in supplemental rebates.<sup>80</sup> Payment of supplemental rebates is based on actual performance relative to product market share growth—a similarity between Medicaid PDLs and private-sector formularies. States' reliance on PDLs has increased substantially in recent years; now, almost all states either have PDLs in place or are planning to introduce them.<sup>81</sup>

**■ Bulk Purchasing Pools**

Supplemental rebates can also arise from several states acting collectively in one of several multi-state bulk purchasing pools. Not all purchasing pools serve Medicaid programs. Medicaid supplemental rebate agreements that arise from purchasing pool arrangements must be approved by CMS.<sup>82</sup>

**■ Reimbursement Methodology Prior to 2007**

The Medicaid program has experienced a rapid increase in spending for prescription drugs. In a 2004 study, the CBO found that the average annual increase over 5 years was 18% and that the total markup for the 5-year period increased by nearly 60%, rising from \$8.70 to \$13.80 per prescription. Policy makers at both the federal and state levels are revising reimbursement methodologies to reduce Medicaid drug spending growth.<sup>83</sup>

The CBO has attributed much of the increase in the average markup of prescription drugs to the use of relatively new generic drugs. For those generic drugs that appeared on the market during the study years, Medicaid reimbursed pharmacies on average approximately \$46 per prescription in 2002, of which about \$14 went for the purchase of the drug itself. Pharmacies and wholesalers retained the remainder, or markup, of nearly \$32 per prescription. By comparison, the markup on older generic drugs was approximately \$10 and was about \$14 on brand-name drugs.<sup>83</sup>

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 (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.<sup>84</sup>

Costs for brand-name drugs that have no generic substitutes (single-source drugs) are typically reimbursed at a rate equal to the AWP minus about 10–15% plus a dispensing fee. The payment formula is more complicated for many multiple-source drugs, which include generic drugs and their brand-name counterparts. These drugs are subject to a FUL when there are 3 or more interchangeable generic drug versions approved by the FDA (“Approved Drug Products with Therapeutic Equivalence Evaluations,” Orange Book) and the drug has at least 3 suppliers listed in current editions of national compendia.<sup>85</sup> Prior to January 1, 2007, the FUL was set at 150% of the lowest published price of a therapeutically and biologically equivalent drug.

States also have the latitude to set an upper boundary on reimbursement, or MAC, that differs from the FUL, as well as to set a MAC for a multiple-source drug that does not yet have a federal limit. Because of that flexibility and a desire to contain Medicaid costs, some states have MAC programs that include more drugs than are found on the federal list, and some states are also more aggressive in setting price limits by setting MACs that are lower than FULs.

### ■ Deficit Reduction Act of 2005 (DRA) Changes Medicaid Reimbursement Methodology

Responding to the CBO findings cited previously, Congress changed the RP from “published price” (i.e., AWP) to AMP in the DRA, effective January 1, 2007. The FUL reimbursement formula is now 250% of the AMP for the LCA “when at least two suppliers (e.g., manufacturers, wholesalers, repackagers, or relabelers) list the drug in a nationally available pricing compendia” (emphasis added).<sup>19</sup> Previously, FULs were applied to multiple-source prescription drugs that the FDA considered to have at least 3 therapeutically equivalent versions and at least 3 manufacturers or suppliers.

Prior to enactment of the DRA, AMP was an RP developed and used only for Medicaid rebate calculations. In a significant public policy shift, AMP has become an RP for reimbursement.

In CMS-2238-FC,<sup>20</sup> CMS finalized the calculation of AMP at the nine-digit NDC for the FUL calculation. In accordance with the DRA amendments, CMS will no longer take the individual 11-digit NDC and the most commonly used package size into consideration when computing FUL.

The FUL will be established only by using an Orange Book “A”-rated drug. However, CMS will continue its current practice of applying the FUL to all drug formulations, including those drug versions not proven to be therapeutically equivalent (e.g., B-rated drugs).

The FUL is calculated by using the lowest AMP that is not less than 30% of the next-highest AMP for that drug. If it is less than 30%, the FUL is calculated by using the next-lowest AMP. When the FUL group only includes the innovator single-source drug and the first new generic in the market, including an authorized generic, the 30% rule would not apply.<sup>20</sup>

### ■ Revising AMP

In addition to substituting AMP for AWP in the FUL formula, the DRA and CMS-2238-FC also changed the way that AMP is computed by manufacturers, as well as requiring monthly and quarterly calculations.

Medicaid rebate provisions in existence since 1990 defined AMP as “the average price received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade.” The statute has no definition of “retail pharmacy class of trade.” CMS has issued guidance in the past that has been superseded by the definitions in the final rule. The final rule defines the “retail pharmacy class of trade” to include sales to entities that dispense drugs to the general public, such as chain and independent community pharmacies and mail order pharmacies.

Pharmaceutical manufacturers, especially single-source drug manufacturers, define retail class of trade as community pharmacies, but typically exclude mail order pharmacies from the class. Mail order pharmacies typically receive larger discounts from manufacturers than are given to community pharmacies because manufacturers believe they can more effectively impact drug volume, drug market share, or both. As a result, Medicaid’s AMP reimbursement to community pharmacies could result in underpayment because it incorporates discounts that community pharmacies do not receive.

Among the items included in the AMP calculation are all forms of price concessions to entities within the retail pharmacy class of trade, as well as all fees except those paid for bona fide services. Bona fide service fees mean fees paid by a manufacturer to an entity that represent fair market value for a bona fide, 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 are not passed in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Excluded from the AMP calculation are (partial list): customary prompt-pay discounts defined as “discounts off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified time;” sales to federal programs other than Medicaid; sales to LTC facilities, including nursing home pharmacies; and direct sales to hospitals, HMOs, and wholesalers in which the drug is relabeled under that distributor’s NDC number. A more complete list of the components of the revised AMP calculation is found in Exhibit II-1.

For bundled sales, AMP (and BP) must be adjusted. A bundled sale is defined as “an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or drugs of different types (that is, at the nine-digit NDC level) or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary) or where the resulting

discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside of the bundled arrangement.<sup>70</sup> This definition expands the existing definition of bundled sale in several respects, including extending a “bundle” to discounts conditioned on purchases of a different package size of the same drug. Manufacturers are required to allocate discounts proportionately to the dollar value of the units of each drug sold under a bundled arrangement. For bundled sales in which multiple drugs are discounted, the aggregate value of all discounts in the bundled arrangement is proportionately allocated across all of the drugs in the bundle.

### ■ Public Access to AMP

Historically, AMP has been treated as proprietary and confidential information by manufacturers and the government. One of the more far-reaching effects of the DRA was to open that data to the public on an ongoing basis. The first monthly AMP reporting period under the new regulation is October 2007. Later in the year, CMS will begin publishing the following information on a public Web site: labeler code, product code, package size code, calendar month and year of the most recently reported AMP, and AMP per-unit per-product code for the month and year covered based on sales. If a drug is distributed in multiple package sizes, only one weighted AMP will be posted for the product and will be the same for all package sizes, which will have very significant implications for brand-name and generic manufacturers.

- **Brand-name** manufacturers may see states and perhaps even private payers move to replace AWP and WAC with AMP as the benchmark price for brand drug reimbursement. Because AWP and WAC were the only prices readily accessible by payers, they have continued to use it despite its flaws. AMP has the advantage of being closer to the actual selling price and subject to government sanction for reporting errors.

Pharmaceutical contracts between manufacturers and private purchasers are likely to result in lower negotiated prices, with AMP replacing WAC as the benchmark in part because the full measure of Medicaid and other government discounts will be more transparent to private purchasers.

- **Generic** manufacturers are concerned that the intention 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 could threaten the viability of the generic industry. At the very least, lower generic drug prices are likely to result for Medicaid and other public purchasers linked to Medicaid pricing.

## Public Health Service (PHS) 340B Program

### ■ Background

One avenue of federal funding that is generating attention is the 340B program, which was established by the Veterans Healthcare

Act of 1992. The primary objective of 340B is to provide access to outpatient medications at discounted rates to federal purchasers and certain grantees of federal agencies that provide care to vulnerable populations.

The Medicaid rebate program requires that the manufacturer of a drug must pay a rebate to Medicaid based on the manufacturer’s “best price” for that drug. As a result, pharmaceutical companies ended deep discounts in the non-Medicaid market to avoid establishing even lower “best prices.” When manufacturers began to raise their prices, Medicaid savings achieved through the rebate program were offset by increased government spending on drugs purchased by other federal- and state-supported providers. To correct this situation, Congress enacted Section 340B of the Public Health Service Act in November 1992, which requires pharmaceutical manufacturers participating in the Medicaid program to enter into a second agreement to provide discounts on covered outpatient drugs purchased by specified government-supported facilities, called “covered entities,” that serve the nation’s most vulnerable patient populations.<sup>86</sup>

The 340B program is administered by the Pharmacy Affairs Branch, which is located within the Health Resources and Services Administration (HRSA) within the DHHS.<sup>87</sup>

### ■ Covered Entities

The definition of covered entities includes certain high Medicaid (disproportionate-share) hospitals, as well as specified federal grantees including certain federally qualified health centers (FQHCs); FQHC “look-alikes;” state-operated acquired immunodeficiency syndrome (AIDS) drug assistance programs; Ryan White Comprehensive AIDS Resource Emergency (CARE) programs; tuberculosis, black lung, family planning, and sexually transmitted disease clinics; hemophilia treatment centers; public housing primary care clinics; homeless clinics; urban Indian clinics, and Native Hawaiian health centers. Over 10,000 participating covered entity sites and close to 600 pharmaceutical companies are affected by the law.

### ■ Payment

Covered entities are entitled to receive 340B discounts on all covered outpatient drugs, regardless of the patient’s payer status and whether the drug is intended for self administration or administration by a clinician. The 340B discount is equal to the AMP reduced by a rebate percentage that is equivalent to the Medicaid rebate amount. Covered entities receive a minimum discount of 15.1% for brand-name prescription drugs and 11% for generic and over-the-counter (OTC) drugs. They are entitled to an additional discount if the price of the drug has increased faster than the rate of inflation. In addition, covered entities are free to negotiate discounts that are lower than the maximum allowable statutory price. A drug purchased under Section 340B and dispensed to a Medicaid beneficiary is not subject to both a 340B discount and a Medicaid rebate.

Based on several price comparison studies, 340B prices are, on average, between 45% and 50% of AWP. Another survey found 340B prices to be 24% lower than prices available to GPOs.<sup>86</sup>

Section 340B prohibits the resale or transfer of discounted outpatient drugs to anyone other than a patient of the covered entity. Manufacturers have the right to audit the records of the covered entities to protect against diversion.

### Impact of Coding on Payment

For pharmaceuticals dispensed through retail and mail order pharmacies, coding using NDC numbers is the link to payment of the correct amount. In these settings, coding is seldom used to implement payment policy; filing a claim with the correct NDC code is a straightforward mechanical process for obtaining payment for that product.

Yet for drugs administered in outpatient treatment settings such as physician offices and HOPDs, coding can be a critical component of the payment equation. Typically, these products are infused, injected, or implanted by a physician, nurse, or other clinician licensed to perform the procedure. Payments for these products are sometimes determined by their NDCs, but they are more often determined by HCPCS Level II drug codes (primarily “J-codes”).

HCPCS codes are created and managed by CMS. Medicare, Medicaid, and many private payers use HCPCS codes to determine payment for drugs that are covered under the medical benefit

(Medicare Part B). Private health plans are gradually moving to replace their HCPCS systems with NDC codes, but as of this writing, HCPCS codes are used by the majority for medical benefit drugs. CMS has also directed state Medicaid agencies to utilize the NDC for physician and other provider billings and payments.

### Impact on ASP Payment

HCPCS Level II codes for clinician-administered (Medicare Part B) drugs are assigned, revised, and managed by CMS. A drug without an appropriately descriptive HCPCS code faces major obstacles for reimbursement by Medicare and the many other government and private payers who also use HCPCS codes for payment.

HCPCS codes are generally revised once per year, effective January 1. New products launched since inception of the previous code list are assigned to existing codes unless the new product (1) “performs a significantly different function” or (2) “operates differently” and evidences a “significant therapeutic distinction” from currently coded products. If the new product is launched at a higher price than the therapeutic alternatives, its payment will be lowered by the weighted average prices of the other products in the group. Likewise, payments for all other products will increase slightly because of the new product’s higher price. When a provider’s choice of product is influenced by the margin, the net effect can be to make the older products more economically attractive.

### Private Purchasers

#### Overview

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. However, as shown in Exhibit III-1, implementation of the Medicare Part D pharmacy benefit has resulted in a significant shift in funding from private purchasers and Medicaid to the Medicare program for eligible populations. Most privately insured Americans obtain care through relatively open provider network arrangements, such as PPOs and managed care point-of-sale (POS) plans.

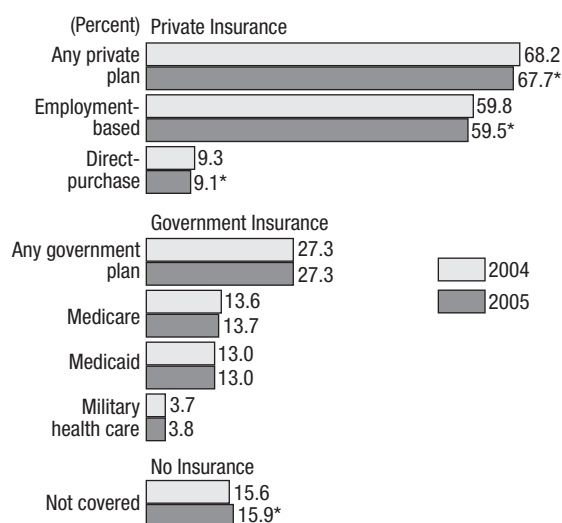
#### Share of Market by Type of Purchaser

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-5).<sup>88</sup>

#### Structure of Privately Sponsored Health Coverage

The Kaiser Family Foundation/Health Research and Education Trust (KFF/HRET) annual employer survey demonstrated that, in 2006, 3% of covered workers were enrolled in conventional insurance plans, 20% in HMOs, 60% in PPOs, 13% in POS plans, and 4% in high-deductible health plans associated with savings options (HDHP/SO).<sup>89</sup>

**EXHIBIT III-5** 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-6** Percentage of Covered Workers in Partially or Completely Self-Funded Plans by Firm Size, 1999-2006\*

	1999	2000	2001	2002	2003	2004	2005	2006
3-199 Workers	13%	15%	17%	13%	10%	10%	13%	13%
200-999 Workers	51	53	52	48	50	50	53	53
1,000-4,999 Workers	62	69	66	67	71	78	78	77
5,000 or More Workers	62	72	70	72	79	80	82	89
ALL FIRMS	44%	49%	49%	49%	52%	54%	54%	55%

\* Test found no statistical difference from estimate for the previous year shown at  $p < .05$ . Source: KFF/HRET. Employer health benefits. 2006 annual survey. Available at: <http://www.kff.org/insurance/7527/upload/7527.pdf>. Accessed September 4, 2007.

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.<sup>90,91</sup> As shown in Exhibit III-6, the prevalence of self insurance varies with employer size. Overall, 55% of covered workers are in self-insured plans.

Self-insured employers may self-administer some or all of the provision of health benefits for their beneficiaries including “carving out” pharmacy benefits, making decisions regarding benefit coverage, deciding coverage exceptions, and defining provider networks. In addition, self-insured employers are exempt from state-based coverage mandates. In contrast, employers that offer fully insured health coverage are removed and insulated from these operational decisions, having delegated them to a health plan through the purchase of insurance, but they are subject to state-based coverage mandates.

### Benefit Design

Less uniformity and transparency can be found in the benefit designs and provider arrangements of private purchasers than in public payer programs, discussed earlier in this section. Drug manufacturers’ pricing toward and relationships with private-sector providers and private payers are believed to be more variable than in the public sector, but are generally opaque to outside view. These factors outline the highly complex private-sector marketplace in which prescription drugs are available.

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:

- Whether and how a drug is “covered” for a given patient. A non-covered drug may not be subject to price determination according to a payer–provider contract.

- 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.

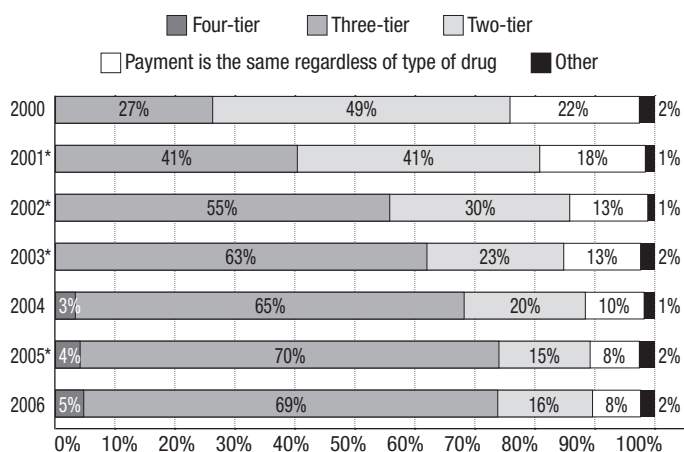
From health plan and PBM perspectives, formularies are used as tools to manage care and cost. By placing a drug on its formulary, the PBM or health plan may have increased leverage with the manufacturer of that drug and with manufacturers of drugs that may be therapeutically equivalent to it. By creating 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.

Because a formulary listing may affect the sales of a branded drug, pharmaceutical manufacturers compete to ensure that their products are preferentially included on these formularies. This typically includes an offer of payments to PBMs to obtain formulary status and/or rebates for market share targets achieved through PBM community pharmacy networks.<sup>92</sup> Often, product national market share is the baseline that must be exceeded, the assumption being that the pharmaceutical company did the work to get the product to the national market share and the PBM or health plan did the work to move product market share beyond the national market share.<sup>93</sup>

For these reasons, formularies, formulary tiering, tier-based copayments, and coinsurance levels are some of the most important benefit design features in use today to customize reimbursement and determine patient financial responsibilities for specific drugs.<sup>94</sup> Purchasers’ use of formularies appears to have reached a saturation point at 92%, according to one recent survey, up from 54% of respondents in 1995 and 74% of respondents in 1999.<sup>95</sup>

Although drug formularies involve the contracted pharmacies within a purchaser’s administration, pharmacies are typically not

**EXHIBIT III-7** Distribution of Covered Workers Facing Different Cost-Sharing Formulas for Prescription Drug Benefits



\* Distribution is statistically different from distribution for the previous year shown at  $p < 0.5$ . No statistical tests were conducted between 2003 and 2004 due to the addition of a new category.

Note: Fourth-tier drug cost-sharing 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.

involved in decision-making regarding formulary content or copayment amounts and generally do not share in the economic rewards of these programs.

### Drug Formulary Types, Structure, and Prevalence

Formularies typically 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-7 demonstrates that, since 2000, an increasing percentage of insured workers are in plans with 3- and 4-tiered formularies rather than 2-tiered formularies.

Exhibits III-8 and III-9 show the prevalence of tiered formularies plus the average patient copayment amounts and coinsurance percentages associated with those tiers. Note that patient cost-sharing amounts have steadily increased since 2000.

### Formulary Control Mechanisms

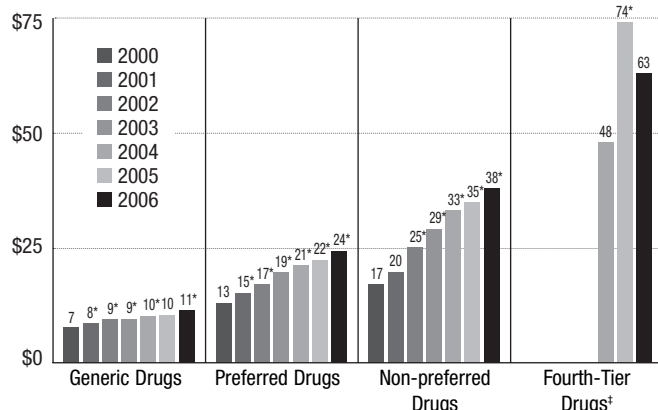
PBMs and health plans may have only one drug formulary, but apply different benefit designs and utilization management tools to it to accomplish their customers' objectives. There are 3 primary types of drug formulary benefit designs: incentive, open, and closed. A recent survey showed that 82% of employers relied on

incentive formularies, 16% relied on open formularies, and only 2% used closed formularies.<sup>95</sup>

Prior to the introduction of pharmacy benefit designs that added financial incentives (copayment tiers) for members to use preferred drugs, only 2 formulary types were tied to benefit design: open and closed. An open formulary allows prescribers and members to use non-formulary drugs without financial penalty. Open formularies typically have a single copayment amount regardless of drug type (brand or generic) or a 2-tiered copayment structure (one for brand and one for generic). A closed formulary commonly requires preauthorization for non-formulary drugs and sometimes involves a financial penalty for the patient. Health plans with closed formularies, particularly staff model health plans, often cover non-formulary drugs only by exception.<sup>96</sup> In these scenarios, members must pay the full retail price if they purchase a drug that is not listed on the formulary. Plans with closed formularies often have an appeals process to address special circumstances in which non-formulary drugs may be used.<sup>97</sup>

The third benefit design type applied to drug formularies is the incentive method, sometimes referred to as "selective" or "partially closed," containing a drug list in which some drug categories are restricted or closed without reimbursement for non-formulary drugs unless proven medically necessary via PA. More recently, multiple copayment-tiered (incentive) formularies emphasize full choice, but often create significant financial incentives in the form of high copayment/coinsurance (e.g., \$50 or 50%) for the use of non-formulary drugs.

**EXHIBIT III-8** Among Covered Workers Facing Prescription Drug Copayments, Average Copayments, 2000 - 2006

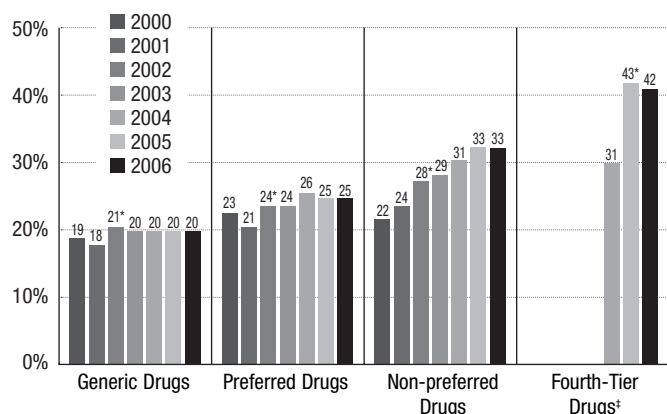


\* Estimate is statistically different from estimate for the previous year shown at  $p < 0.5$ .

† 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.

**EXHIBIT III-9** Among Covered Workers Facing Coinsurance for Prescription Drugs, Average Coinsurance, 2000 - 2006



\* Estimate is statistically different from estimate for the previous year shown at  $p < 0.05$ .

‡ Fourth-tier drug coinsurance information was not obtained prior to 2004.

Note: Averages do not include covered workers who do not have a coinsurance for prescription drugs.

Source: KFF/HRET. Employer health benefits. 2006 annual survey. Available at: <http://www.kff.org/insurance/snapshot/chcm050206oth.cfm>. Accessed September 4, 2007.

### ■ Use of Coinsurance Instead of Copayment

In contrast to copayments in which a flat dollar amount (or series of different amounts based on tiers) is established for a drug claim, coinsurance establishes a percentage of the allowed drug cost as the patient's responsibility. Tiered coinsurance rates are sometimes established for brands and generics or for preferred and non-preferred drugs. Copayment and coinsurance approaches differ in that coinsurance amounts are automatically larger for more expensive drugs.

Because beneficiaries pay a higher share of more expensive drugs, one advantage for payers of a coinsurance approach over copayments is that they are more sensitive to the actual cost of the drug and therefore more receptive to considering lower-cost alternatives. Also, some plan managers choose this approach because coinsurance increases automatically as the cost of drugs increases, eliminating the need to continually adjust copayment amounts upward over time—a step that can contribute to member dissatisfaction.

One concern with the coinsurance design is that it is likely to be based on a price that may not be the final transaction price. Coinsurance is based on the health plan- or PBM-negotiated retail transaction price, usually before any rebates are taken into account. If the final paid amount is reduced by rebates or other considerations outside the retail transaction, then the beneficiary's share of the payment is actually higher than the nominal coinsurance amount. In addition, coinsurance may be less popular with patients because the amount owed is unpredictable.

### ■ Prescription Drug Rebates

Two fundamental concepts surround drug manufacturer rebates. First, rebates amount to a reduction in drug price that occurs after the drug is dispensed, whereas price discounts are obtained as part of the acquisition of the drug. Second, rebates can be categorized as (a) "access" fees for formulary status that are generally calculated as a simple percentage of the WAC or direct price of the drug (e.g., 2–5%) or (b) volume-based ("performance") rebates that are based on the number of units of the drug dispensed by NDC number.

The link between drug formulary tiers and manufacturer rebates is important in understanding the true net program cost of a drug. 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, they 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 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 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 (with the exception of those with mail order or specialty pharmacies) 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. Specific information on rebate agreements and amounts are considered to be proprietary information.

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.<sup>98</sup>

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 the dispensing fee remains constant).

**■ Prescription Drug Bundling**

CMS defines a bundled sale as “an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or some other performance requirement (e.g., the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement.”<sup>20</sup>

Some manufacturers have preferred to negotiate on a bundle of drugs, using their breakthrough drugs as leverage to get others on formularies, while health plans and PBMs prefer a drug-by-drug negotiation.<sup>99</sup> An example of bundling involves products in 2 therapeutic classes. In one drug class are several equally efficacious generic or therapeutic alternatives, including the manufacturer's product. In the other drug class, the manufacturer has a product with a significant clinical or therapeutic advantage over competing drugs. In this latter drug class, the superior product's manufacturer may not offer a significant rebate or other price concession on the product alone. But the manufacturer may bundle the superior product with another of its products that is more easily substituted, providing a significant rebate on both in exchange for preferred brand status for both.

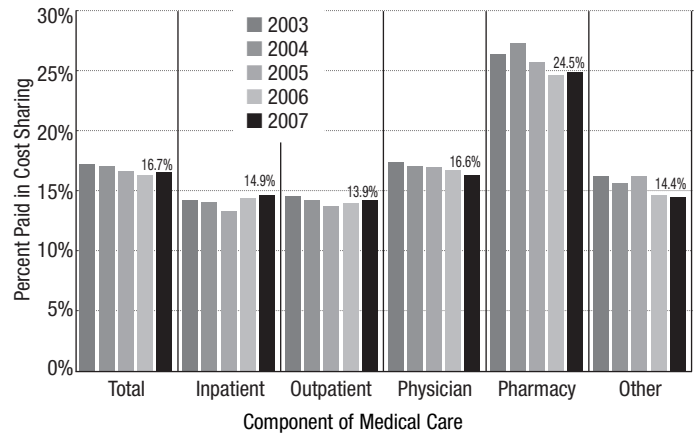
**■ Patient Expenditures for Pharmaceuticals**

The Milliman Medical Index 2007 states that, for a typical American family of 4 covered by an employer-sponsored PPO program, a patient's out-of-pocket cost share for prescription drug costs is approximately 24.5% (Exhibit III-10). According to the Index, the actuarial value of annual pharmacy cost for a family of 4 in this scenario is \$2,081; therefore, the average annual family cost share for prescription drugs in 2007 is \$510.<sup>3</sup>

If the average family with PPO coverage has less than 25% out-of-pocket cost sharing for prescription drugs, Americans with other types of coverage have a much higher overall level of cost sharing, as shown in Exhibit III-11.

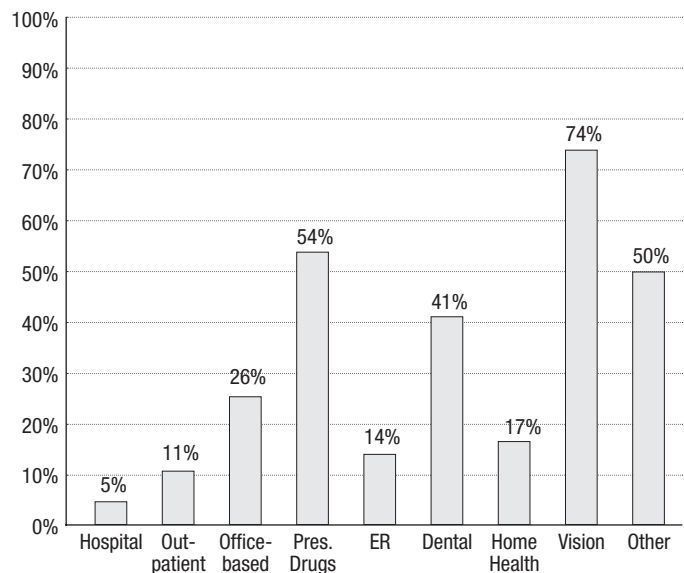
Medicare beneficiaries covered under the Part D drug benefit also face significant cost sharing: “We estimate that quarterly out-of-pocket payments for a Part D enrollee with average prescription spending will vary from a low of \$163 in the second and third quarters of 2006 to a high of \$590 in the fourth quarter of 2007. By contrast, the average beneficiary in the high spender cohort is projected to face quarterly out-of-pocket payments that vary from

**EXHIBIT III-10** Milliman Medical Index Consumer Share of Medical Costs for Family of Four Covered by an Employer-Sponsored Preferred Provider Organization 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.

**EXHIBIT III-11** Average Share Paid Out-of-Pocket by People with Health Spending, by Type of Service, All People, 2003



Source: Kaiser Family Foundation. Distribution of out-of-pocket spending for health care services. May 2006. Available at: <http://www.kff.org/insurance/snapshot/chcm0502060th.cfm>. Accessed September 4, 2007.

\$401 in the second quarter of 2008 to \$1,391 in the third and fourth quarters of that year. Finally, the average catastrophic spender is projected to face out-of-pocket obligations that range from a high of \$2,276 in the second quarter of 2006 to a low of \$95 in the fourth quarter of 2007.<sup>100</sup>

Uninsured and underinsured patients may save on the purchase of prescription drugs in several ways. A relatively new Internet-based offering is the reverse auction, in which “participating, licensed pharmacies compete to provide the required prescription at the lowest total price.”<sup>101</sup> One analysis reports that purchasing a 60- to 90-day supply, comparison shopping, and pill splitting are ways in which cash patients can “save 96% on a cardiovascular drug.”<sup>102</sup>

Some cash patients have used drug importation to reduce prescription drug cost, despite quality concerns. For example, 2 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.”<sup>103</sup>

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.”<sup>102</sup> Another government report states that “U.S. drug buyers—families, HMOs and insurance companies, etc.—may get a discount much less than the full difference between U.S. prices and foreign prices. U.S. drug buyers may obtain discounts of only 20% or less, with the rest of the difference between U.S. and foreign prices going to commercial importers that find less expensive drugs abroad and import them in compliance with applicable safety regulations.”<sup>103</sup>

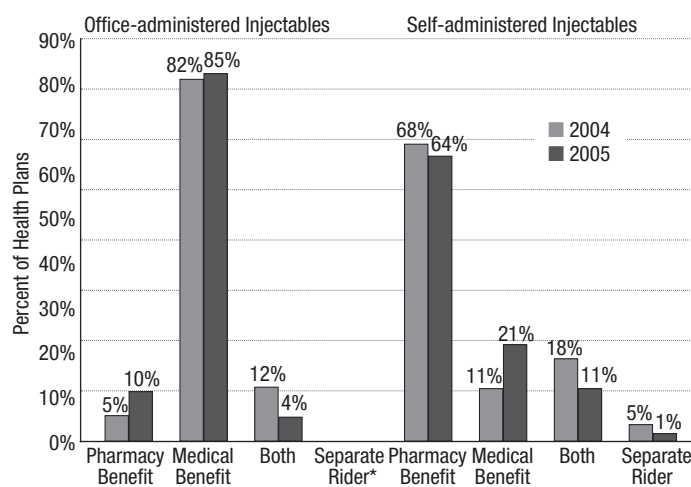
### Relationship of Provider to Payment Methodology

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-

**EXHIBIT III-12** Coverage of Injectables: Pharmacy vs. Medical Benefit



\* Office-administered is 0% for 2004 and 2005.

Source: Serono injectables digest, 2nd edition. Rockland, MA: Serono, Inc.; 2006.

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%.<sup>95</sup>

#### 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 as shown in Exhibit III-12. 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.<sup>20</sup> 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.<sup>105</sup>

### ***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.<sup>106</sup> Medical group capitation with limited drug risk continues, but is not common.<sup>107</sup> 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.<sup>108</sup> 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%.<sup>109</sup>

In a survey conducted during 2005, the average physician reimbursement rate for specialty drugs was AWP minus 8%.<sup>105</sup> This survey found that 7% of health plans reimburse unspecified J-code agents at full AWP, 27% reimburse at a percentage of billed charges, 30% reimburse at a percentage off the AWP, and 1% reimburse at a percentage plus AWP. In another 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%.<sup>110</sup>

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%.<sup>111</sup>

For cost-control reasons, private payers are increasingly requiring 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 diem<sup>112</sup> 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. As such, each should be individually examined—a daunting task at best.

Variance in the basic structure of relationships between payer, purchaser, and provider has led to inconsistent use of nomenclature to describe these situations. This *Guide* will briefly consider the variability in meaning and use of terms related to the entity who pays for health care services by using words such as final payer, payer, purchaser, plan sponsor, and intermediary.

For example, consider the distinction between the terms “final payer” and “intermediary.” The former may refer to an employer or government entity that ultimately pays for health care services and the latter to a company contracted to the final payer to perform certain tasks such as provider contracting, provider network management, and claims payment.

From the perspective of a contracted provider, the intermediary may be the final payer if it is a health plan and the program is a fully insured health benefit. Alternatively, the intermediary may subcontract to another entity that, depending on the payment terms, providers may view as the final payer. Many entities are often involved in a contractual chain; therefore, from a provider perspective, it is often not clear what role each of these entities plays.

For this reason, the *Guide* uses the term “purchaser” without attempting to tease out the many possible variations that this term may connote under different circumstances. Also, the *Guide* attempts to reduce complexity by describing payer distribution characteristics that are important to understand as a basis and then depicting the flow of products, services, and payments in 4 important situations. Payment flow varies by stakeholder.

### Class of Trade

The AAC paid by providers for drugs may vary between providers in different COTs and between providers in the same COTs.<sup>113</sup> AAC disparities are due to the availability of different price concessions to providers in different COTs, the procurement pathway that a drug takes through the channels of distribution, and the extent to which providers are able to take advantage of or meet the criteria for offered price concessions. Examples of price concessions include prompt-pay discounts as well as volume-based, market share target, or bundled price concessions.

Some types of price concessions may be offered to all COTs, such as those based on prompt pay and purchase volume; for brand products, a manufacturer may offer other price concessions. Offer of these price concessions may reflect physician, health plan, or PBM agreements to prescribe or develop benefits or policy based on a drug's functional or therapeutic equivalence and the extent to which price concessions will influence formulary position,

copayment/coinsurance levels, access controls, and/or market share. For example, as a result of differential access to price concessions, medical offices that purchase office-administered drugs will often pay some of the lowest prices, while community pharmacies, including high-volume chain pharmacies, will often pay some of the highest prices.

### Stakeholders in the Channels of Distribution

The following charts depict the flow of drugs, dollars, and services in the U.S. health care system within the context of 4 important distribution channels:

- Pharmacy benefit (other than Medicare prescription drug benefit),
- Medicare prescription drug benefit,
- Hospital inpatient and outpatient, and
- Medical office.

Each of these channels is represented in schematic drawings shown in Exhibits IV-1 through IV-3 and Exhibit IV-6. 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 within each schematic 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.

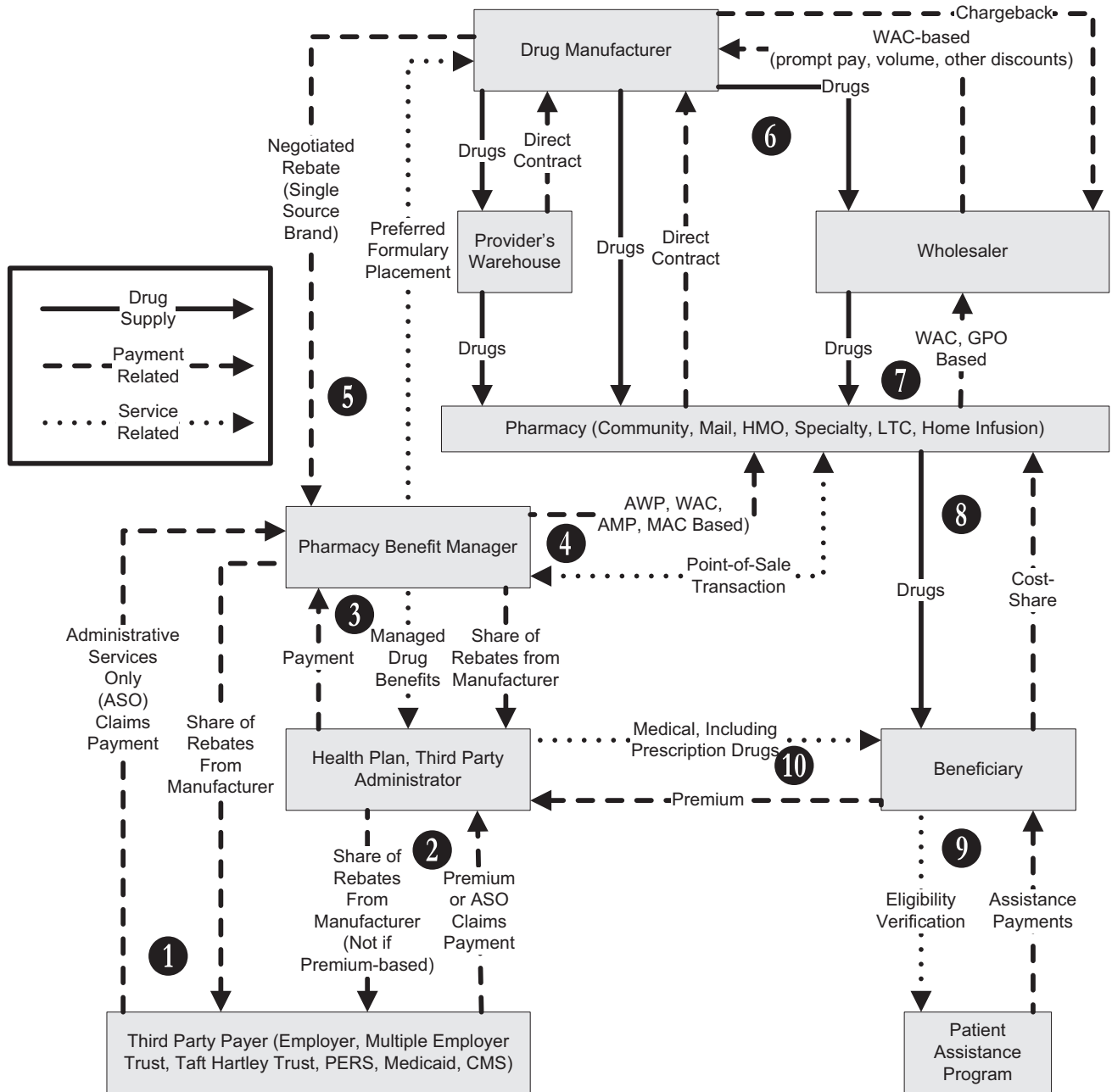
A survey conducted by Hewitt Associates in 2005 suggested that only 5% of self-insured employers provide “a customized design” or “build-your-own” plan for prescription drugs.<sup>114</sup> This suggests that while employers could be instrumental in customizing their contracted pharmacy benefit programs, 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 U&C. 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,<sup>115</sup> 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.<sup>116</sup> 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

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



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 manage-

ment of the benefit, which is called an administrative services contract. Insurers retain all rebates for their insured business and share rebates with self-insured customers at an amount negotiated as part of all such agreements.

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.<sup>117</sup>

A self-insured employer may participate in a 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.<sup>118</sup>

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.<sup>119</sup>

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. As a case in point, in 2004 testimony before a Congressional committee, a Wal-Mart representative 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."<sup>120</sup>

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 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.<sup>95</sup>

⑨ 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](http://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.<sup>121</sup>

⑩ Workers electing health benefits through a group may be required to pay a portion of the premium cost in addition to any deductibles, copayments, and coinsurance that the benefit design may stipulate. The 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.<sup>89</sup>

⑪ 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.<sup>60</sup>

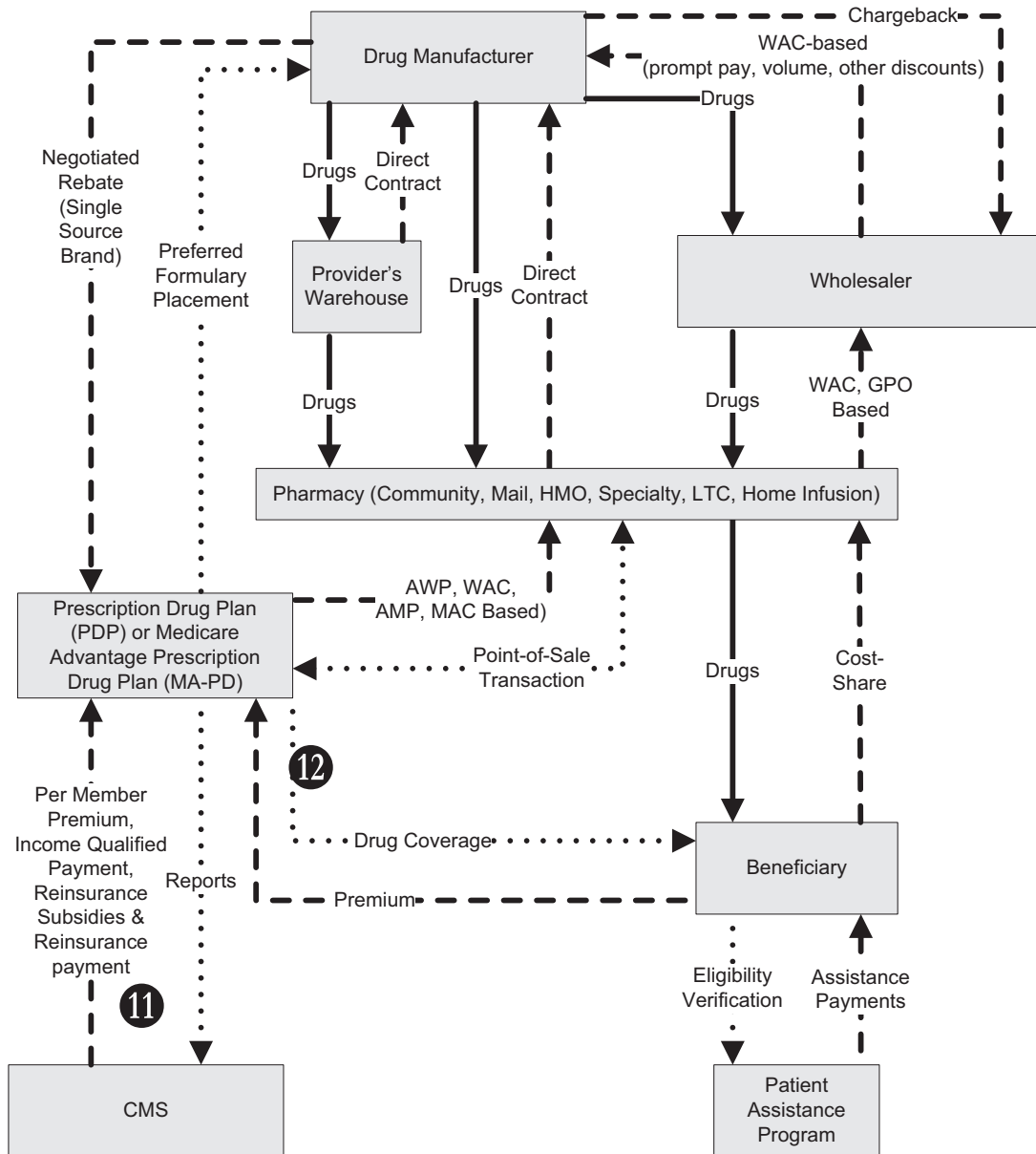
⑫ Most Part D beneficiaries must pay a monthly premium to the Part D provider. The MMA requires that beneficiary premiums must reflect 25.5% of the national average standardized bid across all Part D plans.<sup>61</sup>

⑬ Indemnity products, as well as charge-based patients, dominated private insurance from the 1960s through the mid-1980s. Hospitals were typically paid on the basis of negotiated discounts off billed charges as defined by hospitals' chargemasters, including drugs administered in hospital inpatient and outpatient settings.

Every hospital maintains a chargemaster that lists billable procedures and the hospital's list price. As private payers began moving away from charge-based payment toward fixed-price arrangements, hospitals responded by increasing list prices to the shrinking pool of charge-based patients (for inpatient hospital services), resulting in a growing disparity between billed charges and actual receipts.<sup>122</sup> This approach is exemplified by the following hypothetical situation depicted in Exhibit IV-4.<sup>123</sup>

Today, private-sector payers purchase hospital services on the basis of discounted charges, negotiated per diem rates, or packaged rates patterned after Medicare's DRGs. Discounted charges

**EXHIBIT IV-2** Medicare Prescription Drug Benefit



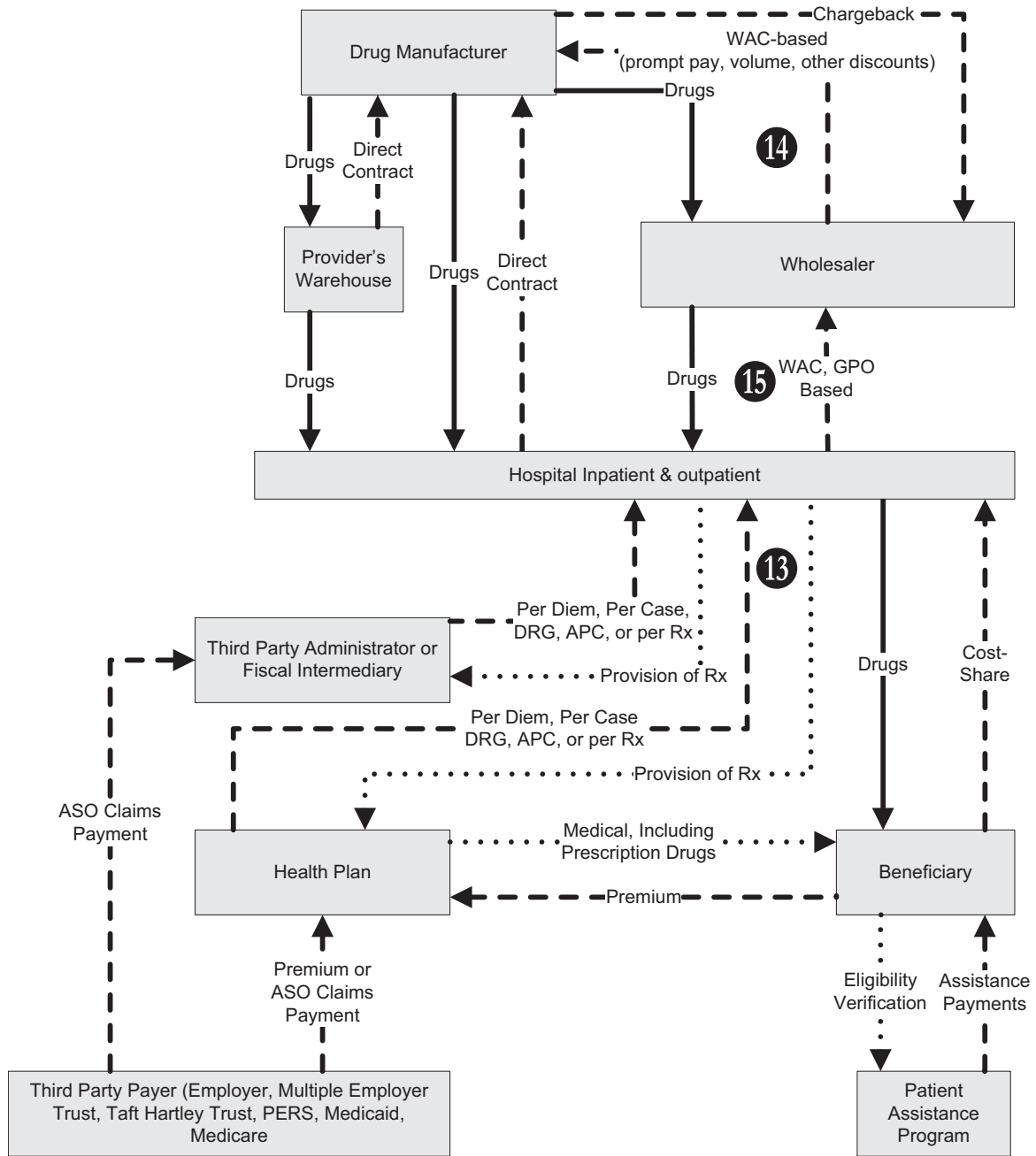
are more common in payment of outpatient services.<sup>124</sup> Prescription drugs are incorporated in the package rate, per diem, or DRG fixed-price structures, which may be subject to outlier adjustment.

Which payment system would payers prefer for inpatient hospital services? One writer's opinion is that "the 'best' hospital payment system, from an employer's perspective, has a manageable number of negotiable prices, linked to aggregated sets of clinically appropriate services. The ideal system would also be trans-

parent enough to enable the payer to know both which services are bundled within a particular price and how actual service use, quality, and prices compare across hospitals."<sup>125</sup> Health economist Uwe Reinhardt, looking at hospital pricing from the perspective of consumer-driven health care, states the challenge to be "...how the prices charged by hospitals could be revealed to prospective patients in ways they could digest and act upon as 'consumers.'"<sup>126</sup>

⑬ Manufacturers, wholesalers, and GPOs interface to facilitate

**EXHIBIT IV-3** Hospital Inpatient and Outpatient



drug purchase arrangements as depicted in Exhibit IV-5.

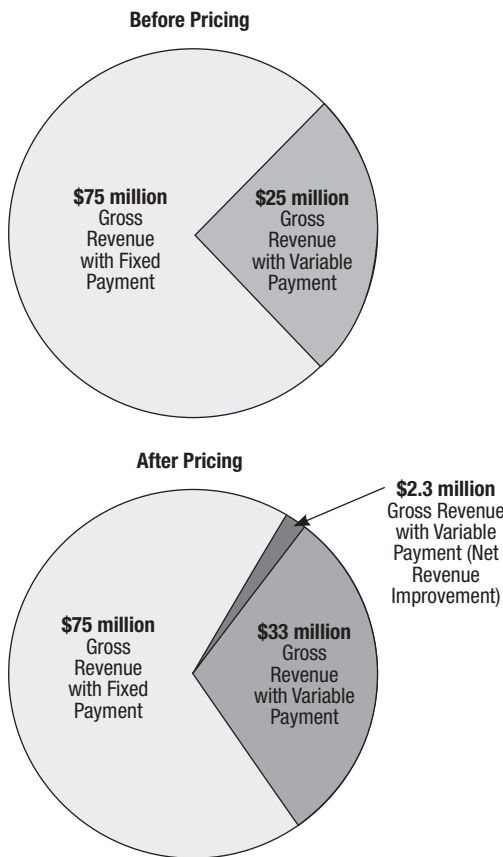
15 The first known hospital GPO was the Hospital Bureau of New York, founded in 1910. By the early 1970s with the establishment of Medicaid and Medicare, 40 hospital GPOs existed in the United States. GPO-contracted purchases were estimated to be

more than \$200 billion dollars in 2005. Almost 90% of hospitals, nursing homes, and other healthcare organizations procure a large part of their supplies through GPOs, which typically earn 3% of the value of their purchased products and supplies through negotiated contracts. GPOs attempt to influence customer and supplier

**EXHIBIT IV-4** Effect of Hospital Price Adjustment

The results of effective pricing can be significant. Take, for example, one hospital with about \$100 million in gross revenue per year, where \$75 million is paid on a fixed basis and \$25 million is paid on a percent-of-charge basis. The finance department wanted to increase net revenue but limit individual procedure price changes to plus or minus 15 percent and remain gross-revenue neutral.

By lowering prices in primarily fixed-payment revenue and raising prices in primarily percent-of-charge payment revenue, the percent-of-charge payment revenue is increased to \$33 million. The hospital gained about \$2.3 million in net revenue while holding its gross revenues constant.

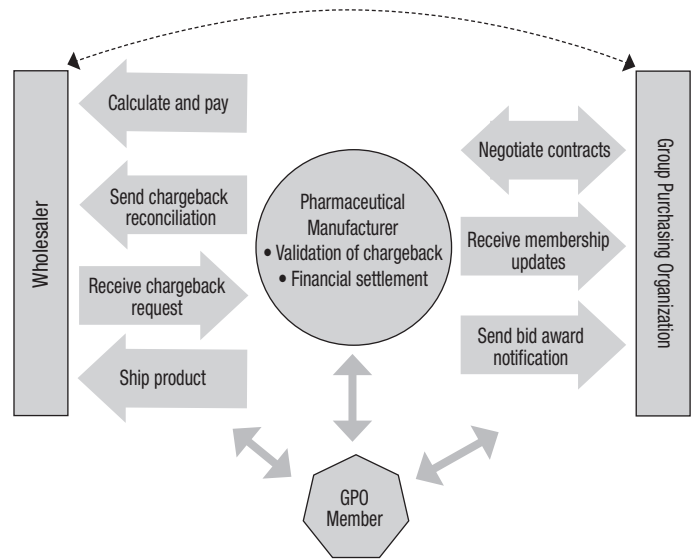


Source: Healthcare Financial Management Association. Strategic price setting: ensuring your financial viability through price modeling. June 2004. Available at: [http://www.hfma.org/NR/rdonlyres/6F2AF75F-4618-4F80-BCFF-09764F0D4A31/0/3M\\_StrategicPriceSetting.pdf](http://www.hfma.org/NR/rdonlyres/6F2AF75F-4618-4F80-BCFF-09764F0D4A31/0/3M_StrategicPriceSetting.pdf). Accessed September 4, 2007.

behavior through tied contracts, sole-source buying, and customer use of bundled products and services.<sup>127</sup>

Hospitals may qualify for drugs available under the 340B program on the basis of being owned and operated by a unit of state or local government and by maintaining a disproportionate-share adjustment percentage of at least 11.75%. A private nonprofit hospital must also demonstrate to the PAB that it is contracted with a government entity to provide a specified amount of indigent care.

**EXHIBIT IV-5** How Manufacturers, Wholesalers, and GPOs Interact



Source: Alexandria, VA: Tag & Associates.

Obtaining 340B entity status may be challenging for some providers. Legislation has been enacted in California to facilitate private nonprofit hospital participation in 340B by requiring a standard contract and reports of charity care to the state.<sup>128</sup>

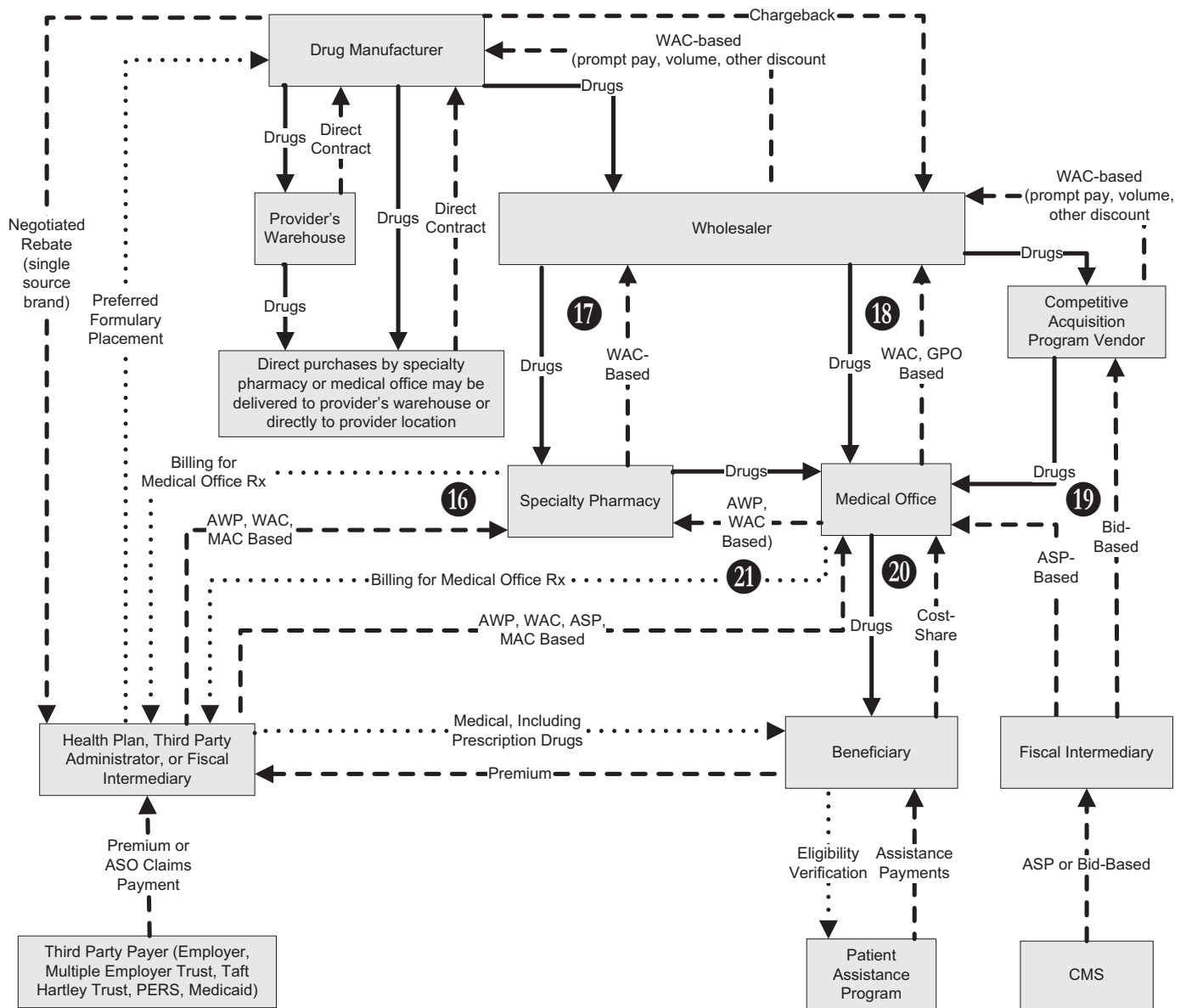
Drug manufacturers typically will offer significant discounts to GPOs as a means of familiarizing physicians with their drug products. Most outpatient insurance programs have not mandated that patients be switched to formulary agents; as such, hospital sales have been used to drive market share.

<sup>16</sup> Payers may contract with specialty pharmacies to deliver office-administered prescription drugs to contracting physician offices and to subsequently bill, on a payer-negotiated basis, either to the payer directly or to physician offices (which in turn bill the payer). The payment methodology for this process is most likely based on AWP or WAC, although ASP-benchmarked payment may become more common in the future.

<sup>17</sup> Specialty pharmacies purchase drugs from wholesalers or directly from manufacturers. Manufacturers typically place specialty pharmacies in the retail class of trade and offer similar pricing arrangements. Currently, some specialty pharmacies act as distributors to facilitate compliance with FDA-mandated record keeping and training requirements.<sup>129</sup> In some cases, payments are made to the specialty pharmacy for the drug product and dispensing and/or drug administration fees are paid to the end-service provider by either the specialty pharmacy or third-party payer.

<sup>18</sup> Medical groups acquire drugs from wholesalers, distributors,

**EXHIBIT IV-6** Medical Office



and directly from manufacturers. Special pricing may be available from manufacturers for single-source and multi-source branded drugs based on volume or market share attained within the medical group. Price arrangements may address a single drug or combine the purchases of several drugs. Price reductions that are based on achieved sales or market share are calculated quarterly or less frequently. The contract may be administered by the manufacturer or the wholesaler. If administered by the manufacturer, back-end

price concessions would be paid to the medical group as a rebate. If administered by the wholesaler, the difference between wholesaler's cost and contract price is then charged back to the manufacturer. Drugs may also be purchased through a specialty pharmacy that administers a drug discount purchase program on behalf of a drug manufacturer or that has negotiated a volume purchase or market share agreement.

19 For treatment of Medicare beneficiaries in the traditional

program, physicians may elect to obtain office-administered drugs through a CMS-contracted CAP vendor or continue with buy and bill. Physicians electing CAP receive drugs from the CAP vendor, who is paid a contracted rate by the fiscal intermediary of CMS.

Physicians who choose to buy and bill for treatment of Medicare beneficiaries in the traditional program are reimbursed at ASP plus 6%. While ASP-based payment has had a significant impact on oncology office profitability, it is important to note that ASP has had a different impact on payment for office-administered drugs. For example, carboplatin is a chemotherapeutic agent with multiple generic alternatives that is administered by intravenous infusion. For this product, the net medical oncology office margin per treatment (Medicare only) has been estimated at \$1,353 in 2004, \$653 in Q2 of 2005, and \$30 in Q1 of 2006.<sup>130</sup> In contrast, for branded products, ASP-based payment has often not resulted in such a large negative change.

④ Medicare beneficiaries without secondary coverage may find their access to provider-administered prescription drugs altered. According to a MedPAC study, Medicare beneficiaries without supplemental coverage may be transferred to HOPDs and face higher copayments primarily because provider offices may be unwilling to accept the financial risks associated with collecting patients' required copayments. However, if beneficiaries who cannot pay the cost sharing in physician offices then go to HOPDs for chemotherapy infusion, they are also unlikely to be able to pay the higher cost sharing at these institutions. The difference is that patients' unpaid bills from a HOPD would become bad debt and, in this setting, Medicare pays 70% of a hospital's bad debt.<sup>131</sup>

④ Prior to managed care, providers were most often paid on an FFS basis. As medical costs increased in the 1970s and 1980s, health plans moved away from indemnity coverage toward HMOs. HMOs, in turn, often contracted on a prospective capitated basis with medical groups or independent practice associations (IPAs), and some of these arrangements included drugs.<sup>132</sup>

## V. Issues and Implications for Stakeholders

This section explores the issues and implications of the most significant changes and trends in prescription drug payment methodologies. Note that there are other implications in addition to those mentioned.

### ■ 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.<sup>133</sup> 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.<sup>14,134</sup>
- 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 for provider services has 2 principal components: 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?

—Impact on site of service should also be considered. For example, when drug reimbursement amounts for IVIG were reduced but the product acquisition cost remained unchanged, some physicians referred patients to HOPDs for infusions, thus resulting in higher costs for the payer.

## ■ Public Disclosure of Net Manufacturer Price

### Issue

Medicare ASPs are publicly available information. The DRA and the final rule also require public 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 AAC. 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 service transfers the drug’s economic responsibility and risk from the payer to the provider. Medicare has used this technique for managing hospital inpatient (DRG) and outpatient (APC) drug spending, other acute care services (e.g., 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 due to the loss of revenue on the drug component of payment while packaging may change prescribing behavior, the net dollar impact of this process is difficult to quantify.

## ■ 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 because 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 PSAOs experimented with risk-based payment and capitation,<sup>135</sup> 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,<sup>136</sup> 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.<sup>135</sup> 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.

## ■ Expanded Pharmacy Services and Pay for Performance

### Issue

With the MMA as a catalyst, the following market trends provide fertile ground for the expansion of pharmacy and pharmacist services to the total care of the patient: self care, consumer-driven health care benefit designs, Internet-based medical information, medication therapy management, vaccination services, provider electronic medical record systems, and email connectivity between providers, patients, and other stakeholders.

### Implications

- The current trend in expansion of pharmacy services in an effort to obtain better patient outcomes from spending on drug costs may mesh with the coincident trend in pay-for-performance (P4P) initiatives. The result will likely be performance bonuses for pharmacy providers for patient outcomes (e.g., blood pressure control, target lipid levels, hemoglobin A1c targets for patients with diabetes) and perhaps renewed efforts to push some financial risk to pharmacy providers.
- According to publicly available data, P4P bonuses have been less than 2% of pay for physicians. For example, the California Pay for Performance Program accounted for approximately 1.5% of total physician income in California in 2005.<sup>138</sup> It may prove nec-

essary that P4P bonuses represent a larger portion of provider and hospital income to drive meaningful practice changes.

- If drug compliance increases due to successfully applied pharmacy services, drug spending could increase while total health care costs decrease. However, payers—particularly employers and benefit managers—must be shown how and why increased drug spending should be welcomed.

## ■ 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 all office-administered drugs used in the practice 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.<sup>139</sup>

## ■ New Business Models

### Issue

Drug-related gross margins of PBMs, medical groups, and pharmacies in the channels of drug distribution will experience downward pressure on profit margins when government and private-sector payers migrate to benchmarks based either on net manufacturer price or provider AAC.

### Implications

New business models will evolve to manage the price pressure from payers. CVS-Caremark is an example of the merger of one of the largest pharmacy providers with one of the largest PBMs. Other examples of evolving business models include (a) *community pharmacy*: specialty pharmaceutical services center and infusion suite housed in a pharmacy-based urgent care center; (b) *PBM*: support for the transition of private payer billing by NDC number for prescription drugs administered in physician offices that are now billed on the basis of far less detail via the CMS-1500 form and HCPCS codes, with a tie-in to the drug supply by PBM-owned specialty pharmacy resources; and (c) *prescriber*: a medical group may develop a freestanding infusion suite and market it aggressively to third-party payers.

## 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 the *Guide* will ultimately prove to be “quality data that informs the debate” and therefore leads to better decisions. The Academy welcomes your feedback about the *Guide*, which can be submitted at <http://www.amcp.org/amcp.ark?p=1529B561>.

## Acronyms

Acronym	Definition	Acronym	Definition
AAC	actual acquisition cost	HCPCS	Healthcare Common Procedure Coding System
AIDS	acquired immunodeficiency syndrome	HDHP/SO	high deductible health plan with savings option
AMCP	Academy of Managed Care Pharmacy	HMO	health maintenance organization
AMP	average manufacturer price	HOPD	hospital outpatient department
APC	ambulatory payment classification	HRSA	Health Resources and Services Administration
ASC	ambulatory surgical center		
ASO	administrative services only	IHS	Indian Health Service
ASP	average sales price	IPA	independent practice association
AWP	average wholesale price	IVIG	intravenous immune globulin
BP	best price	KFF/HRET	Kaiser Family Foundation/Health Research and Educational Trust
CAP	Competitive Acquisition Program (for drugs and biologicals)	LCA	least costly alternative
CARE	Comprehensive AIDS Resource Emergency	LDL	low-density lipoprotein
CBO	Congressional Budget Office	LTC	long-term care
CDHC	consumer-directed health 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		
DHHS	Department of Health and Human Services	NDC	national drug code (11-character)
DME	durable medical equipment	non-FAMP	nonfederal average manufacturer price
DoD	Department of Defense		
DOJ	Department of Justice	OBRA 90	Omnibus Budget Reconciliation Act of 1990
DP	direct price	OIG	Office of Inspector General (of the Department of Health and Human Services)
DRA	Deficit Reduction Act of 2005	OPA	Office of Pharmacy Affairs
DRG	diagnosis-related group	OPD	outpatient prescription drug
DSH	disproportionate-share hospital	OPPS	outpatient prospective payment system
		OTC	over-the-counter
EAC	estimated acquisition cost	P4P	pay for performance
EPO	exclusive provider organization	PA	prior authorization
ERISA	Employee Retirement and Income Security Act of 1974	PAB	Pharmacy Affairs Branch
ESRD	end-stage renal disease	PAP	patient assistance program
		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		
FMAP	Federal Medical Assistance Percentage	PHS	Public Health Service
FQHC	federally qualified health center	PMPM	per member per month
FSS	Federal Supply Schedule	POS	point of sale or point of service
FUL	federal upper limit	PPARx	Partnership for Prescription Assistance
		PPO	preferred provider organization
GCN	generic code number (6-character, First DataBank)	PPS	prospective payment system
GPI	generic product identifier (14-character, Medi-Span)		
GPO	group purchasing organization		

Acronym	Definition
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

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**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.<sup>ii</sup> 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 F3d at 788<sup>iii</sup>), 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

<sup>ii</sup> 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.

<sup>iii</sup> 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 reducing 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** A 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 is divided into 3 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).<sup>iv</sup>

**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."<sup>v</sup> 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."<sup>vi</sup> 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.<sup>vii</sup>

**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.

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

<sup>v</sup> Available at: <http://www.fda.gov/cder/ob/>. Accessed September 4, 2007.

<sup>vi</sup> 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.

<sup>vii</sup> 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<sup>viii</sup> 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.

**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.

**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.

**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.

<sup>viii</sup> 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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