Supplements to the Journal of Managed Care Pharmacy are intended to support medical education and research in areas of clinical practice, health care quality improvement, or educational objectives. The references in the text of the Guide and in the list of references contain URL hyperlinks to the source documents that are publicly available. In addition, on the AMCP Web site is an interactive resource library—a searchable interactive database of articles and documents that examine drug product payment methods in the United States.2

**Pharmacists Accreditation and Credit Designation Statement**

The Academy of Managed Care Pharmacy is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. AMCP designates this continuing education activity for 2.0 contact hours of credit or .20 Continuing Education Units (CEUs). ACPE Universal Program Number: 233-000-09-028-H01-P.

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**About AMCP**

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

**Learning Objectives**

Upon reading this supplement, readers should be able to:

1. Describe the strengths, weaknesses and future prospects for AWP and WAC pricing benchmarks.
2. Differentiate the pricing benchmarks ASP and AMP.
3. Explain how the use of the newer benchmarks such as ASP and AMP may put particular types of providers at competitive disadvantage.
4. Describe common price limits such as FUL, MAC, and reference price.
5. Recognize how prescription drug characteristics (e.g., small molecule, biotechnology product, self-injectable, DME-supported infusible) affect access, coverage, third-party payment, and patient cost-sharing.
6. View federal program (including Medicare, Medicaid and 340B), private sector payer and PBM roles in the payment and management of prescription drugs dispensed or administered in different settings (e.g., by community pharmacies, hospital outpatient, physician office, home health).
7. Discuss the influence of provider incentives in the management of prescription drug utilization and cost.
8. Discuss how provider risk-sharing, pricing transparency, bundling, comparative effectiveness, and pharmacogenomics affect physician prescribing, cost, and patient access.

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EXECUTIVE SUMMARY

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

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

Private payers have followed the government’s lead and begun to change their own payment methods and benchmarks. They can be expected to accelerate the change as a result of the settlement agreement approved in the March 2009 federal court decision. The settlement will result in the lowering of the AWP for more than 400 generic and brand-name drugs. In addition—and technically unrelated to the litigation and any appeals that may be taken—2 major price data reporting companies, First DataBank and Medi-Span, announced their intent to discontinue publication of AWP within 2 years of September 26, 2009. (At the time this report was prepared, there have been no similar announcements from Thomson Healthcare for Gold Standard [ProspectoRx], who are 2 other publishers of price data.)

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

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

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

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

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

How Products, Services, and Payments Flow Through Channels of Distribution. Section IV provides a detailed
Executive Summary

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

Payment Benchmarks

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

Average Wholesale Price and Wholesale Acquisition Cost

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

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

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

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

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

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

Average Sales Price

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

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

ASP values are publicly available on the federal government’s Centers for Medicare & Medicaid Services (CMS) Web site, and private payers are therefore able to use ASP for payment of medical benefit drugs. Uptake of the ASP benchmark by commercial sector has been slow but steady. Survey data from approximately 100 payers showed that, by the fall of 2008, about 44% of private payers used ASP as their primary payment benchmark for specialty therapies (accounting for more than half of covered members), but only 16% of payers depended exclusively on ASP and 37% had no ASP contracts.7

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

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

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Public Law 110-275) delayed the implementation of new Medicaid payment limits to retail pharmacies using the AMP for multiple-source (generic and brand) drugs8 and instructed the Secretary of the Department of Health and Human Services (DHHS) to suspend through September 30, 2009, the planned publication of AMP data submissions on a public Web site. States may not switch to AMP-based pharmacy reimbursement prior to this time. It is anticipated that there will be efforts in the current Congress to either further delay or otherwise modify the statutory 2005 AMP mandate. In addition, there is pending litigation in the courts that upon resolution could affect AMP.

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

Medicare
Medicare’s payment for drugs depends on the treatment setting. Drugs provided in the hospital inpatient setting typically do not receive separate payment, but instead their costs are accounted for in the diagnosis related group (DRG)-based prospective payment made to the hospital. Similarly, drugs used in the hospital outpatient department for which the cost per day is $60 or less (in 2009) are bundled into ambulatory payment classification (APC) reimbursement for the procedures with which they are used; there is no separate payment made for those drugs. Currently, drugs with a cost per day exceeding this threshold ($60) in the hospital outpatient department receive separate payment; as of January 1, 2009, the payment rate for the majority of these drugs is ASP plus 4%, and drugs with pass-through status will be paid at ASP plus 6%.10,11

Most drugs administered in physicians’ offices and thus covered by Medicare’s Part B medical benefit also are paid using the formula ASP plus 6%. The Part B Competitive Acquisition Program (CAP), through which CAP-electing physicians obtained Part B drugs administered in their offices through a CMS-contracted CAP vendor, was postponed by CMS for 2009, effective December 31, 2008.12

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

Medicaid
Currently, every state Medicaid program includes an outpatient prescription drug benefit (also called a “pharmacy benefit”). As of June 30, 2007, 64.1% of Medicaid enrollees nationwide were enrolled in managed care plans.13 In that year, 20 Medicaid
Compared with public payers, there is less transparency in the payment methods used by private payers to pay for prescription drugs. For example, private payers use MAC price lists for multiple-source drugs; however, prices contained in these MAC lists, the methodology by which these lists are constructed, and the frequency with which they are updated, are not publicly disclosed. Similar to public payers, private payers use drug formularies to manage beneficiary prescription drug use and the cost of drugs paid for by the plan. Most formularies have copayment “tiers” that correspond to different levels of beneficiary cost sharing. The placement of drugs within copayment tiers is related to their relative safety, efficacy, and effectiveness as determined by health plan or PBM pharmacy and therapeutics (P & T) committees as well as their direct cost, including the price concessions that private payers can obtain from drug manufacturers.15

Generic drugs are commonly placed in the lowest copayment tier. Private payers also negotiate drug payment rates with pharmacy providers; historically, these rates have been based on AWP or WAC, and include MAC pricing for most generic drugs.

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

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

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

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

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

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

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

Implications

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

Recent Pharmaceutical Payment Milestones

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

Conclusion

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

DISCLOSURES

There was no external funding for this research. The contributors, Howard Tag, JD, and Elan Rubinstein, PharmD, MPH, provide consulting services to clients that include professional associations, health plans, purchasers, providers, pharmaceutical, biological, and medical device manufacturers, and other health care entities.
### Table 1: Pharmaceutical Payment Milestones: 2005-2009

<table>
<thead>
<tr>
<th>Date</th>
<th>Description of Milestone Event</th>
<th>Key Points</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 6, 2006</td>
<td>Wall Street Journal article reporting on litigation revealed for the first time that First DataBank took action in 2002 to increase the markup of AWP from WAC for certain brand-name drugs.</td>
<td>• First DataBank increased the markup of WAC to determine AWP for a large number of drugs in 2002 from 1.20 to 1.25, costing payers including consumers billions of dollars. • AWP was not based on actual surveys of drug wholesaler prices.</td>
<td>Martinez B. How quiet moves by a publisher sway billions in drug spending. Wall Street J. October 6, 2006. A1. Available at: <a href="http://www.dc37.net/news/newsreleases/2006/drugpricing_WallStJ.pdf">http://www.dc37.net/news/newsreleases/2006/drugpricing_WallStJ.pdf</a></td>
</tr>
<tr>
<td>November 14, 2006</td>
<td>U.S. District Court for the District of Massachusetts, Judge P. Saris, granted preliminary approval to a settlement in class action re AWP with First DataBank.</td>
<td>• Public disclosure of disconnect between AWP and actual market prices.</td>
<td>Proposed Settlement by Judge Saris in Civil Action No. 05-11148-PBS, New England Carpenters Benefit Fund et al. vs. First DataBank-McKesson. Available at: <a href="http://www.prescriptionaccess.org/docs/FDB-prelim-approval-order2.pdf">http://www.prescriptionaccess.org/docs/FDB-prelim-approval-order2.pdf</a></td>
</tr>
<tr>
<td>July 6, 2007</td>
<td>Deficit Reduction Act of 2005 definition of “retail pharmacy class of trade” for AMP calculation purposes, and of class of trade to be included in the AMP calculation.</td>
<td>• Retail pharmacy class of trade means any independent pharmacy, chain pharmacy, mail order pharmacy, or other outlet that purchases drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public. • Sales, rebates, discounts, or other price concessions included in AMP. Includes several non-retail pharmacy channels (see references).</td>
<td>Medicaid Drug Pricing Regulation. CMS Fact Sheet. 7/6/07. <a href="http://www.nasmd.org/issues/docs/AMP%20Reg%20CMS%20FactSheet%202007_07_06.pdf">http://www.nasmd.org/issues/docs/AMP%20Reg%20CMS%20FactSheet%202007_07_06.pdf</a> and Section 447.504, Determination of AMP. <a href="http://eDocket.access.gpo.gov/cfr_2008/octqtr/pdf/42cfr447.504.pdf">http://eDocket.access.gpo.gov/cfr_2008/octqtr/pdf/42cfr447.504.pdf</a> and Retail Pharmacy class of trade, Federal Register v72 #136, 7/17/07. <a href="http://fdsys.gpo.gov/fdsys/pkg/FR-2007-07-17/pdf/07-3356.pdf">http://fdsys.gpo.gov/fdsys/pkg/FR-2007-07-17/pdf/07-3356.pdf</a></td>
</tr>
<tr>
<td>November 1, 2007</td>
<td>Judgments against 2 major brand-name drug manufacturers for “grossly inflating” the AWPs of certain expensive physician-administered drugs (PAs).</td>
<td>• Public disclosure of disconnect between AWP and actual market prices with respect to particular products, preceded by about 7 years of allegations and settlements between several pharmaceutical manufacturers and state and federal prosecutors over inflating the “spread” between AWP and actual acquisition cost for physicians.</td>
<td>Memorandum and order by Judge Saris in: Re MDL 1456 and Civil Action No. 01-12257-PBS. Available at: <a href="http://www.prescriptionaccess.org/docs/AWP_damages_order_11-2-07.pdf">http://www.prescriptionaccess.org/docs/AWP_damages_order_11-2-07.pdf</a></td>
</tr>
<tr>
<td>July 2008</td>
<td>Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).</td>
<td>• With a federal court injunction, results in delay of (a) expansion of the number of drugs subject to the FUL amounts, (b) change in the basis for the calculation of FUL amounts to AMP, and (c) requirement that CMS share AMP data with states.</td>
<td><a href="http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_laws&amp;docid=f:publ275.110.pdf">http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_laws&amp;docid=f:publ275.110.pdf</a></td>
</tr>
<tr>
<td>December 31, 2008</td>
<td>CMS's Medicare Part B drug Competitive Acquisition Program (CAP) postponed as of December 31, 2008.</td>
<td>• Postponed because of contractual issues with successful bidder. • No official notice regarding if or when program may be restarted.</td>
<td><a href="http://www.cms.hhs.gov/CompetitiveAcquisitionBios/01_overview.asp#TopOfPage">http://www.cms.hhs.gov/CompetitiveAcquisitionBios/01_overview.asp#TopOfPage</a></td>
</tr>
<tr>
<td>Date</td>
<td>Description of Milestone Event</td>
<td>Key Points</td>
<td>References</td>
</tr>
<tr>
<td>-----------</td>
<td>-----------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>January 2009</td>
<td>Hospital outpatient settings: Payment for non-pass-through drugs and biologicals in CY 2009 is made at a single rate of ASP + 4%, which includes payment for both the acquisition cost and pharmacy overhead costs associated with the drug or biological. For pass-through drugs and biologicals in CY 2009, a single payment of ASP + 6% is made to provide payment for both the acquisition cost and pharmacy overhead costs of these pass-through items.</td>
<td>• For CY 2009, separate drug payment in hospital outpatient settings reduced to ASP + 4% for non-pass-through drugs and biologicals. • For CY 2009, pass-through drug payment continues at ASP + 6%.</td>
<td><a href="http://www.cms.hhs.gov/transmittals/downloads/R1702CP.pdf">http://www.cms.hhs.gov/transmittals/downloads/R1702CP.pdf</a></td>
</tr>
<tr>
<td>January 2009</td>
<td>The American Recovery and Reinvestment Act of 2009 provides $1.1 billion funding for comparative effectiveness (CE) research through the Agency for Healthcare Research and Quality (AHRQ) and the National Institutes of Health (NIH), and establishes the Federal Coordinating Council for Comparative Effectiveness.</td>
<td>• Objective is to increase research that compares treatment modalities. • The hope is that availability of CE research results will help care givers make best possible therapeutic choices. • Council is precluded from making coverage or reimbursement decisions.</td>
<td>Comparative Effectiveness. J Holzer, G Anderson. Health Policy Monitor. 2009. Available at: <a href="http://www.hpm.org/en/Surveys/Johns_Hopkins_Bloomberg_School_of_Public_Health/13/Comparative_Effectiveness_Research.html">http://www.hpm.org/en/Surveys/Johns_Hopkins_Bloomberg_School_of_Public_Health/13/Comparative_Effectiveness_Research.html</a></td>
</tr>
<tr>
<td>February 2009</td>
<td>OIG release of comparison of community pharmacy reimbursement amounts for Medicare Part D plans versus Medicaid in the second half of 2009 for 40 single-source drugs and 39 multiple-source drugs with high expenditures.</td>
<td>• Analysis of “average unit reimbursement amount” including dispensing fee with ingredient cost. • Median 0.6% lower Part D reimbursement for single-source brand drugs. • Medicaid reimbursement exceeded Medicare Part D reimbursement by 10% or more for 28 of 39 multiple-source drugs and was 17% higher at the median for the 39 multiple-source drugs.</td>
<td>DHHS Office of Inspector General. Comparing pharmacy reimbursement: Medicare Part D to Medicaid. Report no. OEI-03-07-00350. February 2009. Available at: <a href="http://www.oig.hhs.gov/oei/reports/oei-03-07-00350.pdf">http://www.oig.hhs.gov/oei/reports/oei-03-07-00350.pdf</a></td>
</tr>
<tr>
<td>March 17, 2009</td>
<td>U.S. District Court judge approves settlement between drug price clearinghouses Medi-Span and First DataBank (with drug wholesaler McKesson) and plaintiff health plans alleging “fraudulent increase of AWPs.”</td>
<td>• Adjust AWPs for approximately 1,400 NDCs to smaller gross margin (1.20 x WAC rather than 1.25 x WAC), effective September 26, 2009. • Establish a reasonably accessible data repository of discoverable material regarding First DataBank drug price reporting practices. • First DataBank independent of this court decision commits to discontinuation of publication of AWPs within 2 years, on or before September 26, 2011.</td>
<td>U.S. District Court. District of Massachusetts. New England Carpenters Health Benefits Fund, et al. vs. First Databank, Inc., and McKesson Corporation; and District Council 37 Health and Security Plan vs. Medi-Span. Civil Action No. 05-11148-PBS and New England Carpenters Health Benefits Fund, et al. vs. First Databank, Inc., and McKesson Corporation; and District Council 37 Health and Security Plan vs. Medi-Span. Civil Action No. 07-10988-PBS. Available at: <a href="http://www.firstdatabank.com/Support/awp-communications.aspx">http://www.firstdatabank.com/Support/awp-communications.aspx</a></td>
</tr>
<tr>
<td>July 13, 2009</td>
<td>“Proposed Rule: Medicare Program: Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010” [CMS-1413-P]. CMS proposed several changes to the Medicare drug Competitive Acquisition Program (CAP).</td>
<td>The date of possible reinstatement of the Medicare CAP for Part B drugs was not known at the time that this 2009 update to the AMCP Guide was completed.</td>
<td>Available at: <a href="http://www.oig.hhs.gov/oei/reports/oei-03-07-00350.pdf">http://www.oig.hhs.gov/oei/reports/oei-03-07-00350.pdf</a></td>
</tr>
<tr>
<td>September 26, 2009</td>
<td>U.S. District Court judge issues final order and judgment in case of Medi-Span and First DataBank cases.</td>
<td>• Effective date of order (see March 17, 2009 above)</td>
<td><a href="http://www.firstdatabank.com/downloads/pdf/FinalJudgment.pdf">http://www.firstdatabank.com/downloads/pdf/FinalJudgment.pdf</a></td>
</tr>
<tr>
<td>October 1, 2009</td>
<td>No longer blocked as of this date: (a) Medicaid implementation ofAMP as FUL payment benchmark, and (b) CMS publication of AMP data on its Web site.</td>
<td>• TEMPORARY SUSPENSION OF UPDATED PUBLICLY AVAILABLE AMP DATA — Notwithstanding clause (v) of section 1927(b)(3)(D) of the Social Security Act (42 U.S.C. 1395r–8(b)(3)(D)), the Secretary of Health and Human Services shall not, prior to October 1, 2009, make publicly available any AMP disclosed to the Secretary. (MIPPA, Public Law 110-275, 7/15/08)</td>
<td><a href="http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&amp;docid=f:publ275.110.pdf">http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&amp;docid=f:publ275.110.pdf</a></td>
</tr>
<tr>
<td>By September 26, 2011</td>
<td>First DataBank and Medi-Span voluntarily cease publication of AWP no later than this date.</td>
<td>• Publication of other manufacturer-provided suggested pricing benchmarks, such as direct price and wholesale acquisition cost, are not affected.</td>
<td><a href="http://www.firstdatabank.com/downloads/pricing/awpupdate031709.pdf">http://www.firstdatabank.com/downloads/pricing/awpupdate031709.pdf</a> and <a href="http://www.medispan.com/Common/PDF/CustomerLetter_April2009_FINAL.pdf">http://www.medispan.com/Common/PDF/CustomerLetter_April2009_FINAL.pdf</a></td>
</tr>
</tbody>
</table>
I. Introduction

Prescription pharmaceuticals are unlike any other segment of the health care marketplace in the complexity and variation of how the finished goods are priced to intermediate and final purchasers in the channels of distribution and ultimately how much is paid when the product is dispensed or administered to the patient. In response to a growing need by all stakeholders for detailed information on this complex topic, the Academy of Managed Care Pharmacy (AMCP) has produced this 2009 update to its 2007 AMCP Guide to Pharmaceutical Payment Methods.

For many years and until recently, pharmaceutical prices increased at rates that far exceeded other segments of health care and propelled increases in pharmaceutical spending. However, IMS Health, a provider of market data to pharmaceutical and health care industries, reported that 2008 annual U.S. prescription dollar sales slowed to an annual increase of 1.3%, with growth in the number of dispensed prescriptions of 0.9%, and projected a decline in dollar sales of 1% to 2% in 2009. IMS projected that the pharmaceutical market would recover with the economy in future years, but “an unprecedented level of potential patent expirations in 2011 and 2012 will curb sales growth.” In the private sector, the Milliman Medical Index suggests that the pharmacy costs of preferred provider organization (PPO) health plans have moderated somewhat in recent years (see Exhibit I-1).

Another concern is the increasing cost of new pharmaceutical treatments. The following chart shows monthly and median costs of cancer drugs at the time of approval by the U.S. Food and Drug Administration (FDA), from 1965 through 2008 (see Exhibit I-2).

The federal government has responded to escalated spending on pharmaceuticals by becoming increasingly involved in pricing and payment dynamics. The interest of Congress in pharmaceutical payment, supported by research and investigations by its committees and agencies (e.g., Government Accountability Office [GAO], Congressional Budget Office [CBO], MedPAC, Congressional Research Service, and the House Committee on Energy and Commerce) and federal executive agencies, has led to extraordinary changes in the manner and methods by which federal programs pay for prescription pharmaceuticals.

The new administration and the 111th Congress (January 2009 through January 2011) are almost certain to consider and likely enact a wide range of policies that will affect payment methods for pharmaceuticals and the pharmaceutical industry directly. Possible actions include:

- Accelerate access to affordable follow-on biologic drugs (also known as “biosimilars” or generic biologicals) through the establishment of a regulatory pathway for their approval administered by the FDA.
- Promote programs that increase consumer access to generic drugs.
- Restrict drug companies from delaying access to generic drugs by prohibiting brand name manufacturers from reformulating existing products into new products to restart, extend, or otherwise prolong their patent protection, a process known as “ever-greening,” and prohibiting anticompetitive agreements and collusion between brand name and generic drug manufacturers intended to keep generic drugs off the market.
- Increase the Medicaid drug rebate for brand-name drugs from

EXHIBIT I-1 Milliman Medical Index Annual Rate of Increase in Costs by Component of Medical Care

<table>
<thead>
<tr>
<th>Component of Medical Care</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>7.8%</td>
<td>7.1%</td>
<td>9.4%</td>
<td>6.2%</td>
<td>10.6%</td>
</tr>
<tr>
<td>Inpatient</td>
<td>8.2%</td>
<td>6.5%</td>
<td>8.8%</td>
<td>7.1%</td>
<td>9.1%</td>
</tr>
<tr>
<td>Outpatient</td>
<td>5.7%</td>
<td>7.6%</td>
<td>6.2%</td>
<td>8.3%</td>
<td>9.5%</td>
</tr>
<tr>
<td>Physician</td>
<td>7.7%</td>
<td>8.1%</td>
<td>8.7%</td>
<td>9.6%</td>
<td>9.9%</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>5.1%</td>
<td>6.2%</td>
<td>6.7%</td>
<td>7.0%</td>
<td>8.0%</td>
</tr>
</tbody>
</table>


Notes:
1. Average medical spending for typical American family of 4 covered by an employer-sponsored PPO program.
2. 7.6% Average medical spending for typical American family of 4 covered by an employer-sponsored PPO program.
15.1% to 23.1% of the average manufacturer price (AMP), eliminate best price provisions, apply the additional rebate to new drug formulations, and allow states to collect rebates on drugs provided through Medicaid managed care organizations.

Other changes may also affect pharmaceuticals, such as funding for comparative effectiveness research and dissemination of the results, which may result in reduced access and reduced payments for certain pharmaceuticals in public and private sector plans.

In the commercial sector, a purchaser’s net cost for prescription drugs is often a function of class of trade (COT)-based price concessions to the list price. Pharmaceutical manufacturers may, at their discretion, group their customers by COT and offer certain price concessions to some COTs and not to others. The following schematic shows 1 view of COTs. However, each pharmaceutical manufacturer may categorize its customers differently (see Exhibit I-3). 24

This Guide offers a comprehensive overview as well as a selected focus on details concerning the most important changes to pharmaceutical payment. The 4 main subject areas are:

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

AMCP intends this Guide to be an unbiased presentation of information, issues, and implications. The Guide is neither an expression of AMCP policy, nor does it intend to advocate any position on behalf of AMCP or its members on any issue contained herein.

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**EXHIBIT I-2**

**Monthly and Median Costs of Cancer Drugs at the Time of Approval by the FDA, 1965-2008**

Shown are costs for 1 month of cancer treatment for a person who weighs 70 kg or has a body-surface area of 1.7 m². The line indicates median prices during a 5-year period. Prices have been adjusted to 2007 dollars and reflect the total price for the drug at the time of approval, including both the amount of Medicare reimbursement and the amount paid by the patient or by a secondary payer. (For details about the costs of individual drugs, see the Supplementary Appendix, available with the full text of this article at NEJM.org)


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**EXHIBIT I-3**

**Example of Pharmaceutical Classes of Trade**

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 providers for pharmaceuticals. For approximately 40 years, AWP was the widely used basis for reimbursement of providers for the delivery of pharmaceuticals to patients.

The disparity between AWP and pharmacy actual acquisition cost has increased over time. Janet Rehnquist, former Inspector General of the Department of Health and Human Services, stated, in 2002 testimony to the Senate Committee on Finance: “We estimated that the actual generic drug acquisition cost was a national average of 65.93% below AWP. Our previous estimate, based on calendar year 1994 pricing data, showed a discount of 42.45% below AWP for generic drugs. As a result, this review showed an increase of 55.31% in the average discount below AWP for generic drugs from 1994 to 1999.”

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 Fall 2006.

At that time, the discovery process in a national class action lawsuit 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 1.25) between AWP and wholesale acquisition cost (WAC) for nearly all brand drugs. Through the discovery process in the litigation, it was learned that “beginning in 2001, First DataBank (FDB) and McKesson reached a secret agreement to raise the margin between WAC and AWP from its standard 20% to 25% for more than 400 drugs. McKesson communicated their new 25% WAC to AWP markups to FDB, which then published AWPs with the new markups.”

Today, every government and private payer is considering or has already made fundamental changes in its pharmaceutical reimbursement methods. 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. (The implementation of AMP as a pricing benchmark and posting of AMP to the CMS Web site are on hold at least through October 1, 2009). Over the years, government, providers, manufacturers, and data publishers have created a wide range of benchmarks and price references that they and their customers continue to use, but there often seems to be little agreement on the meaning and use of much of the terminology. For example, AWP has not been defined in law other than in recent case law. Other benchmarks, such as AMP, have been defined in different ways for different purposes, creating small but significant differences in meaning depending on the user or purpose.

The following section provides a description of benchmarks that are receiving special attention for public policy reasons.

### II. Payment Benchmarks

#### Average Wholesale Price

Created in the 1960s, AWP was the first generally accepted standard pricing benchmark for payment of prescriptions dispensed through retail channels and of pharmaceuticals administered in the medical office by the majority of payers because this information was readily available from several suppliers. At that time, AWP was considered to be an appropriate estimate of the actual acquisition cost (AAC).

In recent years, AWP has been referred to as “essentially a sticker price and does not directly correspond to any actual market transaction.” It is not an average of prices charged by wholesalers to providers, but is rather a price reported by drug manufacturers to publishing companies like FDB and Medi-Span. Pharmacies and other providers have been able to purchase brand pharmaceuticals at net prices below AWP, and the pharmacy reimbursement rates reflect some of the difference between AAC and AWP. For the past 25 years or more, price competition has resulted in ever-larger AWP discounts in provider service agreements between pharmacy providers and payers (health plans/PBMs). For example, the average reimbursement rate for community pharmacies for brand drugs declined from AWP minus 13.2% plus a dispensing fee of $2.25 per prescription in 1998 to AWP minus 16.1% plus a dispensing fee of $1.73 in 2008, and reimbursement to mail order pharmacies for brand drugs declined from AWP minus 17.1% in 1998 to AWP minus 20.2% in 2008.

With the advent of ASP as a benchmark for pharmaceuticals payable under Part B, Medicare’s use of AWP ended on January 1, 2005, for all but a handful of pharmaceuticals. Medicaid soon followed, with a change in reimbursement for generic pharmaceuticals from an AWP-based formula to one that relies on AMP. However, this change to AMP-based reimbursement has not been implemented as of the publication date of this update to the Guide. (see AMP discussion below).

In a recent development of particular significance, a final Memorandum and Order was issued on March 17, 2009, in the national class actions against First DataBank, McKesson, and Medi-Span in U.S. District Court for the District of Massachusetts, which requires First DataBank and Medi-Span to “roll back from 1.25 to 1.20 the wholesale average cost to AWP markup for all of the 1,442 NDCs affected by the fraudulent scheme” no earlier than 6 months following entry of the final judgment. In response to this ruling, First DataBank reiterated its intention to apply a 1.20 factor in calculating AWPs for all other NDCs whose AWPs were previously set based on a factor greater than 1.20, and to discontinue publication of AWP no later than 2 years.
following implementation of these changes. Medi-Span has made a similar announcement. As of press time for this Guide, Thomson Healthcare, publisher of Redbook; and Elsevier, publisher of Gold Standard (ProspectoRx), have not announced similar changes.3,33,36

**Average Sales Price**

Most drugs covered by Medicare Part B, mainly physician-administered infusions and injections, are currently reimbursed at 106% of ASP. As of January 1, 2009, Part B drugs separately covered in the hospital outpatient setting are paid at 104% of ASP. ASP is based on the manufacturer’s actual selling price, which includes almost all forms of rebates and discounts reported to the federal government’s Centers for Medicare & Medicaid Services (CMS).

Section 1847A(c) of the Act, as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, defines ASP as a manufacturer’s sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions, such as volume discounts, prompt pay discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates other than those obtained through the Medicaid drug rebate program. Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of “best price” in the Medicaid drug rebate program.37

Following is the formula used by CMS beginning April 1, 2008, to calculate volume-weighted ASP:37

\[
\text{Volume-Weighted ASP} = \frac{\sum \text{ASP for NDC Billing Units in NDC} \times \text{Number of NDCs Sold}}{\sum \text{Number of NDCs Sold}}
\]

There is a lag of 2 calendar quarters between the time when sales reflected in the ASP occur and the time when these sales are reported to CMS for ASP calculation and posting. The change in average sales price, which could be the result of loss of a brand’s patent protection and market entry of generic competitors, is thus not immediately reflected in the posted ASP. As a consequence, ASP-based reimbursement may be either too high or too low, until manufacturer-submitted data to CMS reflect this change in net market price.

For example: The innovator brand of irinotecan lost patent protection in late February 2008, and by the following month, generic versions accounted for 86% of sales with an average price of $40.66. But during March, the innovator brand’s average price remained almost 3 times higher than the generic, and the Q1 2008 Payment Amount (ASP + 6%) was $126.31. The impact of generic price and volume only became apparent in Q4 2008 ASPs.38

ASP has proven to be substantially lower than AWP, the former benchmark for Part B reimbursement. In a 2005 study, the Office of Inspector General (OIG) of the Department of Health and Human Services (DHHS) found that, in the aggregate for all pharmaceuticals reviewed, “ASP is 49% lower than AWP at the median.”39

The Medicare Payment Advisory Commission (MedPAC) found that, from 2004 to 2005 when the payment rate changed to 106% of ASP, total claims volume and charges for each medical specialty reviewed (including pharmaceuticals, pharmaceutical administration, evaluation and management visits, tests, and other procedures) increased, but spending on pharmaceuticals decreased. The decline in expenditures for pharmaceuticals ranged from 1% for rheumatology to 52% for urology. Overall, total Part B pharmaceutical spending (considering price and volume changes) fell from $10.9 billion in 2004 to $10.1 billion in 2005.40 By 2007, total Part B pharmaceutical spending had increased to $11 billion.37

**Impact on Provider Practices.** ASP is a volume-weighted average.41 A provider whose acquisition cost is above the median will be adversely affected, while those entities below the median will benefit. In the MedPAC study noted above,40 most physicians reported that they were able to purchase most of their oncology pharmaceutical agents at the Medicare payment level. However, all physicians reported that pharmaceutical profit margins are slim, and that some products cannot be purchased at the payment rate. Many physicians also reported that they have increased efficiencies in their practices in response to lower pharmaceutical payments.

One concern with ASP-based reimbursement is that it may undermine manufacturers’ incentives to compete on price for single-source, therapeutically equivalent products. ASP also may discourage use of less expensive multiple-source products when a therapeutically equivalent brand is available at a higher ASP. Given the same 6% markup on all products, the one with the highest dollar ASP provides the highest provider margin in dollars.

**Average Manufacturer Price**

Like ASP, average manufacturer price (AMP) represents an effort by the federal government to step away from AWP to an alternate benchmark price. If legal challenges against it are overcome and Congress makes no further changes, AMP will become the benchmark for Medicaid reimbursement for generic pharmaceuticals and will be poised to become an important factor in reimbursement of single-source products in public and private markets.

In 2003, the AMP approximated 79% of AWP for brand name drugs with no generic equivalents. The Congressional Budget Office (CBO) estimated that the acquisition cost to retail pharmacies averages approximately 4% above the AMP for brand name drugs without generic equivalents.42 In other words, the CBO report supports the argument that community (retail) pharmacies typically purchase brand drugs for prices
II. Payment Benchmarks

<table>
<thead>
<tr>
<th>Components of AMP Calculation</th>
<th>Included Sales/Discounts</th>
<th>Excluded Sales/Discounts</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Mail-order pharmacy (including those operated by a PBM)</td>
<td>• PBMs</td>
</tr>
<tr>
<td></td>
<td>• Specialty Pharmacy</td>
<td>• Discounts and rebates to third-party payers (see list in column at left)</td>
</tr>
<tr>
<td></td>
<td>• Home-infusion providers</td>
<td>• Sales and discounts to HMOs/MCOs that purchase or take possession of drugs</td>
</tr>
<tr>
<td></td>
<td>• 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 organization [MCOs] that do not take possession of or purchase drugs)</td>
<td>• Hospitals where drug is used in inpatient setting or site of use cannot be determined</td>
</tr>
<tr>
<td></td>
<td>• Hospitals where outpatient setting use can be documented</td>
<td>• Long-term care (LTC) facilities, including nursing home pharmacies</td>
</tr>
<tr>
<td></td>
<td>• Home health providers</td>
<td>• Hospices (inpatient and outpatient)</td>
</tr>
<tr>
<td></td>
<td>• Outpatient facilities (including clinics, surgical centers, ambulatory care centers, dialysis centers, and mental health centers)</td>
<td>• Manufacturer coupons redeemed by consumer or other entity in which full value of coupon is passed on to consumer</td>
</tr>
<tr>
<td></td>
<td>• Direct patient sales</td>
<td>• Voucher programs</td>
</tr>
<tr>
<td></td>
<td>• Wholesalers(^4)</td>
<td>• Manufacturer drug discount cards</td>
</tr>
<tr>
<td></td>
<td>• Retail pharmacies</td>
<td>• Patient assistance programs</td>
</tr>
<tr>
<td></td>
<td>• Manufacturers who act as wholesaler and do not repackaged/ rebrand under purchaser’s NDC, including private labeling agreements</td>
<td>• Free goods not contingent on any purchase requirement</td>
</tr>
<tr>
<td></td>
<td>• Any other price concession to retail COT</td>
<td>• Nominal prices for specified entities(^5)</td>
</tr>
</tbody>
</table>

Note: See exclusions in column at right

\(^4\)Except for sales that can be documented as being subsequently sold to excluded entities.

\(^5\)Including Medicaid rebates paid to states under the National Rebate Agreement and authorized state supplemental rebate agreements.

\(^6\)See “nominal price exception (or exclusion)” in the Glossary.


above AMP, an average of AMP plus 4%.

AMP, like ASP, is based on manufacturer reported sales data. AMP was created in the early 1990s following enactment of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) as the basis for calculation of manufacturer rebates on outpatient pharmaceuticals dispensed to Medicaid beneficiaries. OBRA 90 required that pharmaceutical manufacturers enter into rebate agreements with CMS and pay quarterly rebates to the states to obtain Medicaid coverage and payment. The statutorily mandated rebate amounts are calculated based on the AMP, defined as follows:\(^3\)

AMP means, with respect to a covered outpatient drug of a manufacturer, including those sold under an NDA approved under Section 505(c) of the federal Food, Drug, and Cosmetic Act (FFDCA) for a calendar quarter, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade. AMP shall be determined without regard to customary prompt pay discounts extended to wholesalers. AMP shall be calculated to include all sales and associated discounts and other price concessions provided by the manufacturer for drugs distributed to the retail pharmacy class of trade unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation.

AMP data are treated by the federal government as proprietary and confidential, but will become public if legal challenges are overcome.

The Deficit Reduction Act of 2005 (DRA) mandated that AMP instead of AWP be used for the calculation of the federal upper limit (FUL), the maximum amount of pharmacy reimbursement for product costs for certain generic and multiple-source drugs that the federal government will recognize in calculating federal matching funds for payment to state Medicaid programs. Congress mandated that CMS follow a formal rulemaking process to outline a clear, consistent definition of AMP for manufacturers. In July 2007, CMS published a final rule that broadly defined the retail class of trade, including community pharmacies as well as mail-order pharmacies, physician offices, outpatient facilities, and other outlets that sell drugs to the general public. The rule did not include PBMs, long-term care facilities, or federal drug benefit programs within the definition of “retail class of trade.”

Two changes for Medicaid benchmark prices contained in the DRA were subsequently put on hold by litigation and legislation: (a) adoption of AMP as the new reference price for generic drug reimbursement and requiring the AMP be calculated for all pharmaceuticals—both generic and brand name; and (b) reporting of AMP to the states and public on a monthly basis. As a result, AMP, which was developed and used only for Medicaid rebate calculations, would have become an important reference price for calculation of FULs. The DRA did not change Medicaid AWP-based reimbursement for brand-name drugs, but states would have had the option to use AMP.
Components of AMP, but subject to change, are shown in Exhibit II-1.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), enacted July 15, 2008, prohibited CMS from taking any action, before October 1, 2009, to impose FULs based on AMPs for multiple-source drugs established under 42 CFR 447.514(b). Thus, under current law, the existing methodology for calculation of FUL, described below, will continue, at least through September 30, 2009, for purposes of federal financial participation.

Under 42 CFR § 447.332, CMS is to establish a federal upper limit amount for a drug when: (a) all formulations of a drug have been rated as therapeutically equivalent by [FDA], and (b) at least 3 suppliers of the drug are listed in current editions (or updates) of published compendia of cost information for drugs available for sale nationally. The Omnibus Budget Reconciliation Act of 1990 (OBRA ’90) established new criteria requiring a drug to be included on the FUL when 3 or more versions of a drug had been rated therapeutically and pharmaceutically equivalent by FDA, regardless of the ratings of other versions. FDA designates drugs that are therapeutically equivalent as “A-rated.”

Federal regulation (42 CFR § 447.332) sets the FUL amount at 150% of the published price for the least costly, therapeutically equivalent product that can be purchased by pharmacists in quantities of 100 tablets or capsules plus a reasonable dispensing fee. If the drug is not typically available in quantities of 100 or if the drug is a liquid, the FUL amount is based on a commonly listed size.

Because economic conditions have increased the pressure on state Medicaid budgets, the payment reductions enacted in 2005 and suspended through September 2009 are likely to receive renewed interest by a Congress and administration intent on lowering health care expenditures.

**Best Price**

Medicaid best price was created by OBRA 90 and took effect January 1, 1996, in the calculation of rebates that manufacturers are required to pay to the states and the federal government for sales of single-source and multiple-source branded products to Medicaid beneficiaries.47 Best price therefore applies to brand-name and not generic drugs, and is defined as the “lowest price available from the manufacturer during the rebate period to any entity in the United States in any pricing structure (including capitated payments).” Best price includes “rebates, discounts and other price concessions provided by the manufacturer to any entity unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by status or regulation from the rebate calculation.” Among exclusions from best price calculations are free goods and manufacturer sales at “nominal prices” (see Glossary; generally defined as manufacturer sales at less than 10% of AMP). For Medicaid rebates for brand-name drugs, best price is applied when the price to a purchaser is less than the price with the mandatory discount plus any penalties (i.e., greater than 15.1% of AMP plus the Consumer Price Index [CPI] penalty). According to a Congressional Budget Office (CBO) report published in June 2005, best price for brand-name drugs approximates 63% of AWP.48

Some providers and health plans have criticized best price as a barrier to the negotiation of lower prices between manufacturers and private-sector customers because a manufacturer is reluctant to create a new best price in the Medicaid market. Opponents of best price have repeatedly, but thus far unsuccessfully, urged Congress to repeal or modify the best price provision.49,50 And, in December 2008, the CBO suggested elimination of the best price provisions, saying that “although many manufacturers offer large discounts to private purchasers, the best price provision discourages manufacturers from offering discounts larger than the flat rebate because such discount automatically triggers a larger rebate to Medicaid.”42

**Wholesale Acquisition Cost**

Wholesale acquisition cost (WAC) is the manufacturer’s reported list price for a prescription pharmaceutical for sale to wholesalers.50 Each manufacturer establishes its own WAC by using its own formula. Price-reporting services, such as FDB and Medi-Span, publish WAC prices supplied to them by manufacturers in their pharmaceutical information databases. Pharmaceutical contracts between manufacturers and private payers typically use AWP or WAC as the reference price.51

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

Like AWP, WAC is a suggested price that often does not represent what a wholesaler or end provider actually pays for the pharmaceutical, because WAC does not include manufacturer incentives such as rebates, volume purchase agreements, and prompt-payment discounts. However, unlike AWP, 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.52

WAC is a lower price than AWP because it is applied earlier in the distribution process. Some Medicaid programs use WAC as an alternative to AWP in their reimbursement formula. In the FDB system, AWP and WAC are related in a constant ratio for each manufacturer in which AWP is 1.20 or 1.25 (or some other factor) times WAC. Because of the proportionate
Matching funds to states are limited to payments that do not exceed the FUL in the aggregate for multiple-source drugs, plus a dispensing fee set by each state.

**Public Health Service**

Public Health Service (PHS or 340B) is the highest price that a “340B-covered entity” could be charged and is equal to the price that the state Medicaid agency would pay absent any supplemental discount or rebate. The price could be negotiated lower by the 340B entity. 340B entities include PHS-funded clinics and disproportionate-share hospitals (DSHs). Patients of a covered 340B entity, including non-Medicaid patients, may receive drugs purchased at the 340B discount price. The benefit of this preferred pricing may be realized by the patient, the payer, the 340B entity, or shared among the parties. 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.54 As of 2009, there are 13,817 340B covered entities in the United States, with more joining each year.55 340B prices for brand-name drugs were reported to average 51% of AWP (see Exhibit II-2).

**Comparison of Benchmark Prices**

Exhibit II-2, from a 2005 CBO study, shows how selected benchmark prices relate to each other. The exhibit includes DoD’s Military Treatment Facility Average Price, VA Average Price, Price Available to the “Big Four,” Federal Ceiling Price, 340B Ceiling Price, Medicaid Net Manufacturer Price, Federal Supply Schedule Price, Best Price, Nonfederal Average Manufacturer Price, and Average Manufacturer Price. Each price is compared to the list price (AWP) as a percentage. The exhibit highlights the variations in pricing across different entities and programs, with some prices reaching as high as 79% of the list price.

The relationship between WAC and AWP, entities that establish the WAC effectively establish the AWP published by FDB and thus 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.53

**Maximum Allowable Cost or Maximum Reimbursement Amount**

Maximum allowable cost (MAC) is typically a reimbursement limit per individual multiple-source pharmaceutical entity, strength, and dosage form (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 many states for multiple-source pharmaceuticals paid for by their Medicaid and other state-funded programs. Private sector MACs usually are considered confidential.

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

**Federal Upper Limit**

FUL is a unit price calculated and published by CMS for each drug entity, strength, and dosage form. Federal Medicaid matching funds to states are limited to payments that do not exceed the FUL in the aggregate for multiple-source drugs, plus a dispensing fee set by each state.

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**II. Payment Benchmarks**

**EXHIBIT II-2** Estimated Prices Paid to Manufacturers, Relative to List Price (AWP), for Brand-Name Drugs Under Selected Federal Programs, 2003

Source: CBO. Prices for brand-name drugs under selected federal programs. June 2005.58

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DoD’s Military Treatment Facility Average Price: 41%
VA Average Price: 42%
Price Available to the “Big Four”: 49%
Federal Ceiling Price: 50%
340B Ceiling Price: 51%
Medicaid Net Manufacturer Price: 51%
Federal Supply Schedule Price: 53%
Best Price: 63%
Nonfederal Average Manufacturer Price: 79%
Average Manufacturer Price: 79%
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 benchmarks include the following:

- At 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 actual transaction price should accurately reflect the most common selling price, while a benchmark based on average net acquisition cost should represent the most common prices for wholesalers or providers as purchasers. How accessible, transparent, and accurate are the benchmark values for all stakeholders?

AWP and WAC have been used as drug payment benchmarks because they were readily accessible from Medi-Span, Redbook, and First DataBank. However, AWP has been shown to have almost no relevance to the net price of 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 generally represent the price of a drug purchased from a wholesaler, and WAC does not generally represent the actual cost to the wholesaler.56

- How will different stakeholders be affected by the change? For example, if average actual transaction 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 methods? For example, how would use of AMP as a pricing benchmark 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 method? 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 Methods

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 may involve a different reimbursement formula. As a result, providers must be keenly aware of their payer “mix,” the portion of total revenue attributable to each type of payer. Payers have an important economic stake in the treatment setting in which a particular drug is prescribed or administered.

Medicare

Background

Medicare, established in 1965 as 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), 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 methods for prescription drugs. In general, the payment method will depend on the treatment setting.

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

Medicare’s Influence on Prescription Drug Payment

Private health insurance pays the largest portion of prescription drug costs, and available data show that this remains the case despite introduction of Medicare Part D in 2006. As of 2007, private health insurance paid 43.6% and public funds (i.e., Medicare, Medicaid, and other public funds) paid 35.5% of drug costs, and available data show that this remains the case despite introduction of Medicare Part D in 2006. As of 2007, private health insurance paid 43.6% and public funds (i.e., Medicare, Medicaid, and other public funds) paid 35.5% of prescription drug sales in retail outlets, while beneficiary out-of-pocket paid the balance.

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

Hospital Outpatient Departments

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

Drugs and radiopharmaceuticals whose cost per day is $60 or less (in 2009) are “packaged” or “bundled” into APCs for the procedures in which they are used, meaning that there is no separate reimbursement for those drugs. Drugs, which CMS calls “specified covered outpatient drugs” (SCODs), and radiopharmaceuticals exceeding the $60 threshold receive separate payment through drug-specific APCs. As of January 1, 2009, the payment amount is ASP plus 4%, significantly below the physician office payment rate of the ASP plus 6%. Drugs eligible for transitional pass-through payment are paid at ASP plus 6%. CMS may change these payment rates annually.

Physician Offices

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

The MMA also created a drug Competitive Acquisition Program (CAP) as an alternative way for physicians to acquire physician-administered drugs. CAP was postponed by CMS as of January 1, 2009, because of contractual issues with the successful bidders. In the rule Medicare Program: Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010, CMS-1413-P, CMS proposed several changes to the drug CAP, but did not propose a date for restart of this program. Thus, as of the date this update to the Guide was finalized, it is not known whether, when, or with what changes the program may be reinstated.

With CAP, Medicare reimbursement was made to the CAP vendor and not to the physician. The goal of the program was to increase competition for Part B drugs. It was reasoned that CAP vendors, which would purchase large quantities of drugs, would be able to negotiate lower prices with drug manufacturers and produce Medicare savings. CAP would provide smaller practices, unable to purchase drugs at the Medicare payment rate, with another way to acquire drugs for administration in their offices.

Under the CAP, organizations such as wholesalers and specialty pharmacies submitted bids to Medicare to become designated vendors for Part B drugs. Each year, physicians chose 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 dispensed drugs to CAP-electing physician offices on a prescription-by-prescription basis. Medicare paid the vendors directly, and the vendors billed patients for required copayments.

By law, Medicare’s first year payment for CAP drugs was based on the average of vendor bids, but could not 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%. As the drug Competitive Acquisition Program (CAP) as an alternative way for physicians to acquire physician-administered drugs.

Pharmacy-Dispensed Medicare Part B Drugs

The vast majority of Part B drugs are administered in a physician’s office or HOPD; however, some drugs dispensed by retail or mail-order pharmacies for self-administration also are part of
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 PDP and MA-PD plans are determined through a competitive bidding process, and enrollee premiums are also tied to plan bids.

Pharmacy-Dispensed Medicare Part D Drugs

Part D is administered by private-sector entities, either stand-alone Prescription Drug Plans (PDPs) or Medicare Advantage–Prescription Drug plans (MA-PDs). These plans compete for enrollees on the basis of annual premiums, benefit structures, specific formulary drugs, pharmacy networks, and quality of services. PDPs and MA-PDs are typically PBMs and commercial health plans. Approximately 14% of Part D enrollees nationwide are dual eligibles (i.e., enrolled in both Medicare and Medicaid) who are automatically enrolled in Part D and randomly assigned to Part D plans (see Exhibit III-1).

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 PDP and MA-PD plans are determined through a competitive bidding process, and enrollee premiums are also tied to plan bids.

Medicare Payment to PDPs

For 2009, Part D enrollees who are not dual eligibles pay an average of $364 per year in premiums, which is about 25% of the expected Medicare Part D benefit expenditures per person (see Exhibit III-2).

CMS subsidizes the remaining 75% of the cost of standard coverage for all types of beneficiaries. That average subsidy takes 3 forms:

- Direct subsidy: A monthly prospective payment. This component of Medicare Part D spend is estimated at $19.9 billion in 2009.
- 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 (see Exhibit III-3). By using risk

The Part B benefit. Examples are immunosuppressives to prevent organ transplant rejection and some oral cancer drugs. The reimbursement rate for retail or mail-order pharmacy-dispensed Part B drugs is currently ASP plus 6%.

Pharmacy-Dispensed Medicare Part D Drugs

Part D is administered by private-sector entities, either stand-alone Prescription Drug Plans (PDPs) or Medicare Advantage–Prescription Drug plans (MA-PDs). These plans compete for enrollees on the basis of annual premiums, benefit structures, specific formulary drugs, pharmacy networks, and quality of services. PDPs and MA-PDs are typically PBMs and commercial health plans. Approximately 14% of Part D enrollees nationwide are dual eligibles (i.e., enrolled in both Medicare and Medicaid) who are automatically enrolled in Part D and randomly assigned to Part D plans (see Exhibit III-1).
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. For 2009, reinsurance subsidizes amounts above beneficiary cost of $6,153.75, and spend is estimated to be $9.6 billion.

- Also, for those plans that enroll low-income beneficiaries, Medicare pays some of their enrollees’ cost sharing and premiums. For 2009, the cost for this subsidy is estimated at $21.1 billion.

The 2003 Medicare Prescription Drug, Improvement, and Modernization Act (MMA) (Public Law 108-173) established risk corridors partly to protect PDPs from higher than expected costs, but also to recoup excessive payments. Risk corridors were defined in the statute as “specified percentages above and below the target amount.” The target amount is defined as total payments adjusted, and reduced by total administrative expenses assumed and separated from the medical care cost component. For the same reason, PDPs also may be less motivated than MA-PDs by a manufacturer claim justifying a higher-net-priced drug being offset by reduced utilization of other health care system resources, such as hospitalization, emergency room or physician office visits.

CRS reports that while manufacturers do not provide rebates for generics, rebates for individual branded drugs may be as high as 20% to 30%.72 The average PDP rebate was 9.6% of total prescription drug costs in 2007, and was expected to remain approximately 9.5% for several years.73

In a study published in February 2009, the OIG found that while Part D and Medicaid pharmacy reimbursement for single source drugs was similar, Medicaid reimbursement for multiple-source drugs was 17% higher at the median than in Part D for 39 multiple-source drugs studied. However, the OIG study does not “compare total program expenditures and does not examine the impact of rebates or post-point-of-sale price concessions.” The OIG concluded that “federal upper limits and Medicaid reimbursement amounts are still based on published prices, which previous OIG work has found to result in inflated payments for multiple-source drugs.” In its response, CMS concurred with these findings and conclusion.74

### PDP Report to CMS of “Lock-In price” Versus “Pass-Through Price.” Part D plan sponsors are required to report drug costs (the “negotiated price”) to CMS, but current rules allow the Part D plan to report the amount paid to the PBM (the “lock-in price” or, alternatively, to report the amount that the PBM actually paid to the pharmacy (the “pass-through price”).75 “Under the lock-in approach, a Part D plan agrees to pay a PBM a set rate for a particular drug. The PBM then negotiates with pharmacies to obtain the lowest possible price for the drug, which often is lower than the amount the PBM receives from the plan.”75 As of January 1, 2010, CMS has ruled that while Part D sponsors may continue to use the lock-in model, they must report as “negotiated price” the price actually paid to pharmacies. CMS will then consider as an administrative cost any difference between the price paid by the Part D plan sponsor to the PBM, and the price paid by the PBM to the pharmacy. The negotiated price is used to determine beneficiary cost-share as well as any CMS reinsurance or risk corridor payments.75

### Pharmaceutical Manufacturer Price Negotiations. The law creating the Medicare Part D drug benefit specifically prohibited CMS from negotiating prices directly with manufacturers. Part D price negotiations with manufacturers are handled by PDPs and MA-PDs. There have been efforts in Congress to pass legislation which would allow Medicare to negotiate price concessions directly with pharmaceutical manufacturers for Part D, in

### Plan Liability Under Risk Corridor Provisions

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<tr>
<th>Risk Corridor</th>
<th>Plan Liability for Costs Above and Below Target</th>
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<tr>
<td>2006-2007</td>
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<tr>
<td>Costs below 95% of the target</td>
<td>80% refund</td>
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<tr>
<td>Costs between 95% and 97.5% of the target</td>
<td>75% refund</td>
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<td>Costs between 97.5% and 102.5% of the target</td>
<td>Full risk</td>
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<td>Costs between 102.5% and 105% of the target</td>
<td>Risk for 25% of amount</td>
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<tr>
<td>Costs over 105% of the target</td>
<td>Risk for 20% of amount</td>
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<tr>
<td>2008-2011</td>
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<tr>
<td>Costs below 90% of the target</td>
<td>80% refund</td>
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<td>Costs between 90% and 95% of the target</td>
<td>50% refund</td>
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<td>Costs between 95% and 105% of the target</td>
<td>Full risk</td>
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<tr>
<td>Costs between 105% and 110% of the target</td>
<td>Risk for 50% of amount</td>
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<tr>
<td>Costs over 110% of the target</td>
<td>Risk for 20% of amount</td>
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the belief that greater discounts could be gained. To date, these efforts have been unsuccessful; however, this issue may be reconsidered during the 111th Congress.76

Medicare Part B or Part D. Medicare payment for more than a dozen categories of pharmaceuticals, including immunosuppressive agents used for transplant patients, parenteral nutrition, intravenous immune globulin (IVIG), and hepatitis C vaccine, could be made under either Part B or Part D. Whether payments fall under either Part B or Part D depends on such factors as diagnosis, route of administration, location of treatment, and whether the drug is self-administered. Whether payment is made under either Part B or Part D determines the payment method used and, thus how much is paid.77

Protected Therapeutic Classes. Plans are allowed to develop formularies that exclude certain drugs from coverage, although they are required to have at least 2 formulary drugs for each therapeutic category. However, pursuant to CMS guidance, plans are required to include in their drug formularies “all or substantially all” drugs in 6 protected classes (“six classes of clinical concern”: immunosuppressant for prophylaxis of organ transplant rejection, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic).78 “Substantially all” does not include multiple-source brand drugs, extended-release products when the immediate-release product is included, or dosage forms that do not provide a unique route of administration (e.g., tablets vs. capsules). The intent of this policy was to ensure that Medicaid beneficiaries who use these drugs would not be discouraged from enrolling in certain Part D plans and would not experience interruption in therapy. Plans may not implement prior authorization or step therapy requirements to steer beneficiaries currently taking a drug to preferred alternatives within these protected classes,78 but plans may use prior authorization or step therapy for patients who are new to the drug therapy.

A provision in the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008, when implemented through regulations, is expected to result in modifications to the CMS guidance that established the “six classes of clinical concern.” The MIPPA provision requires the Secretary of DHHS to establish a regulatory process that identifies classes of drugs used to treat major or life-threatening conditions where access is needed to multiple drugs in that class because of unique chemical actions and pharmacological effects, and to require formularies of Medicare Part D drug plan sponsors to include all drugs in the classes that are identified unless a particular drug (or drugs) is excepted through a formal rulemaking process. A survey of Part D plan administrators conducted in 2008 found an estimated $511 million in lost rebates associated with the current protected 6 classes for 25.4 million Part D members and an estimated $3.4 billion in additional lost rebates if protections were expanded to 4 additional drug classes (antihyperlipidemics, proton-pump inhibitors, antidiabetics, and antihypertensives).79

Least Costly Alternative
Least costly alternative (LCA) is a Medicare payment policy that originally was created for durable medical equipment (DME) and has been extended by CMS interpretation to non-DME services, including drugs and biologicals.80 LCA is essentially a reference price system. Products deemed to be therapeutic alternatives are grouped together under a LCA policy statement. The least costly product, with cost measured as the Medicare reimbursement rate, becomes the reference price for all products covered by the LCA policy. All LCA products are covered; however, regardless of which product is used, the provider is reimbursed as if the least costly product was used. Most of the drug payment impact has occurred for a class of prostate cancer treatments known as GnRH (or LHRH) agonists and for inhaled drugs to treat respiratory disease.

LCA is a policy that Medicare applies under its evaluation of whether a particular service is “reasonable and necessary.”81 LCA policy making occurs in a decentralized way through regional contractors who process claims. As a result, LCA policies are not uniform throughout the United States.82

In a federal district court decision involving an inhaled drug, the court held that CMS cannot use LCA to set payment for the inhaled drug because Medicare payment is established by statute and LCA runs contrary to the clear and plain language of the statute.83 Subsequent to the decision, Medicare contractors withdrew their use of LCA for the inhaled drug but have kept LCA in place for the GnRH agonists. However, the Medicare Payment Advisory Commission has concluded that this district court decision may affect Medicare contractors’ ability to apply LCA policy to any drug.84

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. 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.85

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 FDA are not covered. No DME is required to trigger the benefit. As a practical matter, the benefit is available only when IVIG is administered by the patient or a caregiver because no payment is available for home health clinical services. Reimbursement is paid at ASP plus 6%.86
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%.56

CMS has determined that Part D sponsors that offer Medicare Advantage prescription drug plans may provide Part D home infusion drugs as part of a bundled service, as a mandatory supplemental benefit under Part C. CMS’s rationale is that, for Part D sponsors electing to do this, it will “…improve benefit coordination of home infusion therapy between Part C and Part D. This improved benefit coordination promotes continuity of care and cost avoidance of more expensive institutional care by facilitating continuous access to home infusion drugs, as well as the costs of administration and supplies associated with that therapy.”77

Medicaid

Background

Medicaid is a program financed jointly by federal and state governments that provides medical and long-term care (LTC) to many of the nation’s most vulnerable lower-income individuals, especially mothers and children, seniors, and individuals with disabilities. Medicaid programs, which accounted for more than 21% of state spending in 2007, are under pressure nationwide as a result of reduced state revenues in the face of increased demand because of reduced availability of employer health insurance coverage and, starting in late 2008, increased layoffs in response to the worsening economy.87

Eligibility rules for Medicaid vary widely from state to state, and eligibility is 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, and subject to waivers of law.88,90

State spending on Medicaid is matched by the federal government. The federal financing share—Federal Medical Assistance Percentage (FMAP)—is determined each year based on each state’s average per capita income level, compared with the national income average. States with a higher per capita income level are reimbursed a smaller share of their costs. By law, the FMAP cannot be lower than 50% or higher than 83%. In fiscal year 2008, the FMAPs varied from 50% to 76.29%, and averaged 56.7%. For children in the State Children’s Health Insurance Program (SCHIP), the federal government pays an enhanced FMAP which averages about 70%.90

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 the state pays capitation to the managed Medicaid organization for the beneficiary’s care. State-specific payment formulas including ingredient cost calculation, whether a MAC list applies, dispensing fee amount, and beneficiary cost-share amount are accessible on the CMS Web site.91

More than 60% of Medicaid beneficiaries are now enrolled in some type of managed care program, ranging from traditional managed care models (such as health maintenance organizations [HMOs]) to less rigid networks with select providers.92

Dual Eligibles

Medicaid beneficiaries who also qualify for Medicare are known as dual eligibles. Before enactment of the Medicare prescription drug benefit, dual eligibles received their outpatient medications from Medicaid. The MMA changed that process; as of January 1, 2006, dual eligibles receive their prescription drugs primarily through the Medicare benefit (i.e., through PDPs and MA-PDs). This change affected approximately 16% of Medicaid beneficiaries and 42% of Medicaid prescription drug spending.93 Many of the affected beneficiaries receive LTC in nursing facilities.94,95,96

Rebates

The actual cost to Medicaid for prescription drugs is reduced by manufacturers’ rebates that are paid to the states and shared with the federal government. In addition to rebates on branded drugs covered under Medicaid pharmacy benefit programs, the Federal Deficit Reduction Act of 2005 (DRA) requires all state Medicaid agencies to collect rebates from drug manufacturers for physician-administered drugs.97 At this time, rebates extend only to drugs purchased by states on a FFS basis.

When states purchase drugs through managed care programs, the managed care organizations (MCOs) are permitted to negotiate their own discounts and rebates, and the federal mandate for rebate payments does not apply.

Each calendar quarter, for each unit of drug covered by a state Medicaid FFS program, each manufacturer must pay either a basic rebate based on a percentage of the AMP or a rebate based on the best price available to wholesalers and other customers. The unit rebate amount (URA) is calculated as follows:98

- 11% of AMP for “non-innovator” multiple-source (generic) drugs
- a minimum of 15.1% of AMP for brand (“innovator” brand-name multiple-source and single-source) drugs in which the URA is calculated from 2 factors:
  1. “basic URA” defined as the greater of (a) 15.1% of the AMP or (b) AMP minus best price, plus
  2. “additional URA” defined as the “Baseline AMP divided by the Baseline Consumer Price Index-Urban (CPI-U)” and multiplied by the quarterly CPI-U (i.e., additional URA applies if the drug’s AMP has increased from a baseline faster than the Consumer Price Index).

Many states have negotiated with manufacturers for supplemental rebates over and above the basic and additional rebate based on the position of products on state prescription drug lists (PDLs).99

It is anticipated that the 111th Congress will consider a number of options to generate health care savings, including a
In July 2007, CMS published a final rule along with a comment period to more fully describe the DRA changes. The final rule defines the “retail class of trade” to include any independent pharmacy, chain pharmacy, mail-order pharmacy, or other outlet that purchases drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public. Sales to hospitals for inpatient use, to LTC facilities, to PBMs, and to federal programs other than Medicaid are excluded from the retail class of trade.

Private Purchasers

Private purchasers (also known as “payers” and “plan sponsors”) provide the bulk of health insurance coverage in the United States for people younger than 65 years of age. As of 2007, almost 68% of Americans younger than 65 years of age were enrolled in privately sponsored health care insurance, of which approximately 88% was employer based, and the balance was direct purchased (see Exhibit III-4).
**III. Payers and Payment Methods**

### Average Copayments Among Covered Workers Facing Prescription Drug Copayments, 2000-2008

<table>
<thead>
<tr>
<th>First-tier drugs, often called generic</th>
<th>2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Copayments</td>
<td>$8</td>
<td>$8</td>
<td>$9</td>
<td>$9*</td>
<td>$10*</td>
<td>$10</td>
<td>$11</td>
<td>$11</td>
<td>$10</td>
</tr>
<tr>
<td>Second-tier drugs, often called preferred</td>
<td>$15</td>
<td>$16*</td>
<td>$18*</td>
<td>$20*</td>
<td>$22*</td>
<td>$23*</td>
<td>$25*</td>
<td>$25</td>
<td>$26</td>
</tr>
<tr>
<td>Third-tier drugs, often called nonpreferred</td>
<td>$29</td>
<td>$28</td>
<td>$32*</td>
<td>$35*</td>
<td>$38</td>
<td>$40*</td>
<td>$43</td>
<td>$43</td>
<td>$46*</td>
</tr>
<tr>
<td>Fourth-tier drugs</td>
<td>b</td>
<td>b</td>
<td>b</td>
<td>b</td>
<td>$59</td>
<td>$74</td>
<td>$59</td>
<td>$71*</td>
<td>$75</td>
</tr>
<tr>
<td>Second-tier drugs, often called preferred</td>
<td>NSD</td>
<td>23%</td>
<td>24%</td>
<td>23%</td>
<td>25%</td>
<td>27%</td>
<td>26%</td>
<td>26%</td>
<td>25%</td>
</tr>
<tr>
<td>Third-tier drugs, often called nonpreferred</td>
<td>28%</td>
<td>33%</td>
<td>40%</td>
<td>34%*</td>
<td>34%</td>
<td>38%</td>
<td>38%</td>
<td>40%</td>
<td>38%</td>
</tr>
<tr>
<td>Fourth-tier drugs</td>
<td>b</td>
<td>b</td>
<td>b</td>
<td>b</td>
<td>30%</td>
<td>43%*</td>
<td>42%</td>
<td>36%</td>
<td>28%</td>
</tr>
<tr>
<td>Average Coinsurance</td>
<td>b</td>
<td>b</td>
<td>b</td>
<td>b</td>
<td>b</td>
<td>b</td>
<td>b</td>
<td>b</td>
<td>b</td>
</tr>
</tbody>
</table>

| First-tier drugs, often called generic | 18%  | 18%  | 18%  | 18%  | 18%  | 19%  | 19%  | 21%  | 21%  |
| Second-tier drugs, often called preferred | NSD  | 23%  | 24%  | 23%  | 25%  | 27%  | 26%  | 26%  | 25%  |
| Third-tier drugs, often called nonpreferred | 28%  | 33%  | 40%  | 34%* | 34%  | 38%  | 38%  | 40%  | 38%  |
| Fourth-tier drugs                     | b    | b    | b    | b    | 30%  | 43%* | 42%  | 36%  | 28%  |

*Estimate is statistically different from estimate for the previous year shown (P < .05).
*Fourth-tier drug copayment or coinsurance information was not obtained prior to 2004.
NSD = Not Sufficient Data.

### Structure of Privately Sponsored Health Coverage

A 2008 annual employer survey demonstrated that 2% of covered workers were enrolled in conventional insurance plans, 20% in HMOs, 58% in PPOs, 12% in point-of-sale (POS) plans, and 8% in high-deductible health plans associated with savings options (HDHP/POS). 106

Employer-sponsored coverage for beneficiaries enrolled in these plans may be fully insured or self-insured (“self funded”) and governed under the Employee Retirement and Income Security Act (ERISA) of 1974. 107, 108 In a fully insured plan, the employer pays a per employee premium to the insurance company, which is then both responsible and at risk for provision of health coverage in accordance with policy provisions. In contrast, the employer acts as its own insurer in a self insured plan, with final authority for establishing coverage policies, and for paying providers directly or through a third-party administrator for provision of health products and services. In 2008, 88% of workers in firms with 3-199 employees were in fully insured plans, and 89% of workers in firms with 5,000 or more employees were in self-insured plans. 106 Exhibit III-4 shows insurance coverage for 2006 and 2007.

### Benefit Design

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

- Under which part of the insurance benefit (e.g., medical, pharmacy) the drug will be paid and, within these broad categories, whether it will be “carved in” or “carved out” (contracted, managed, and paid separately) under a sub-benefit (e.g., mental health, or home health).
- The type and amount of the patient’s cost-sharing responsibility and whether it will be a coinsurance percentage, a copayment dollar amount, or an amount equal to the charged amount that exceeds a maximum reference price that the plan will pay.
- Whether the benefit will be subject to requirements such as drug formulary, formulary tiers, prior authorization, drug-specific coverage policies, maximum dispensed amount (quantity or days supply), and/or mandatory mail order or other pharmacy network restrictions.
- Whether there is a deductible and/or a maximum annual payable amount (i.e., stop-loss for the member or for the drug plan) for the pharmacy benefit, separately from any deductible or maximum annual payable amount that may apply to other specific portions of the benefit or to the overall benefit.

### Use of Formularies

A formulary is a list of drugs in a pharmacy benefit that are designated as preferred or nonpreferred by the pharmacy and therapeutics (P & T) committee of the health plan or PBM based on effectiveness, safety, and cost considerations. Many health plans have tiered formularies, with drugs categorized by copayment or coinsurance levels, in which nonpreferred drugs may be covered but with a higher cost-share for members. Member cost-share at the point of service is a fixed-dollar copayment or a percentage of drug cost (i.e., coinsurance). These copayment and coinsurance levels are intended to influence utilization, typically to encourage a shift from expensive brand-name nonpreferred drugs to less expensive, therapeutically equivalent generic and therapeutic alternatives. These member cost-share requirements at the point of service also help finance the pharmacy benefit.

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...
III. Payers and Payment Methods

EXHIBIT III-6

Median Cost-Sharing for a Month’s Supply of a Prescription Drug Has Risen Among PDPs, 2006-2009

<table>
<thead>
<tr>
<th></th>
<th>PDPs</th>
<th>MA-PDs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2006</td>
<td>2007</td>
</tr>
<tr>
<td>Copay</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Generic</td>
<td>$5</td>
<td>$5</td>
</tr>
<tr>
<td>Preferred brand-name drug</td>
<td>$28</td>
<td>$28</td>
</tr>
<tr>
<td>Nonpreferred brand-name drug</td>
<td>$55</td>
<td>$60</td>
</tr>
<tr>
<td>Specialty-tier coinsurance</td>
<td>25%</td>
<td>30%</td>
</tr>
</tbody>
</table>

PDP (prescription drug plan), MA-PD (Medicare Advantage-Prescription Drug [plan]). Calculations are weighted by enrollment. 2009 values were calculated using 2008 enrollment. Generic copay values are for all plans that use dollar copays. Copay values for preferred and nonpreferred brand-name drugs are only for plans that use those tiers. PDPs exclude employer-only groups and plans offered in U.S. territories. MA-PDs exclude demonstration programs, 1876 cost plans, employer-only groups, special needs plans, and plans offered in U.S. territories. Specialty tiers apply to expensive products and unique drugs and biologics for which enrollees may not appeal for lower cost sharing.


may be therapeutically equivalent to it. By creating the ability to steer utilization toward a particular drug that has clinical equivalence or preference to others in the class, the plan can offer a drug manufacturer a higher market share in exchange for a lower purchase price or a higher rebate that also achieves a lower net price. A formulary with fewer clinically therapeutic alternatives in a preferred tier or larger patient-based financial incentives will increase this leverage.

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

Typically, formularies have 3 or 4 cost-share tiers, with generic drugs often placed in the first tier, preferred brand drugs placed in a second tier, and nonpreferred 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 has the highest cost-share (i.e., copayment amount or coinsurance percentage).

Patient cost sharing has steadily increased since 2000, primarily for more expensive drugs. Exhibit III-5 shows average patient copayment amounts in commercial plans.

Beneficiary cost sharing is somewhat different in the Medicare Part D setting, but generally follows the same pattern as for commercial plans (see Exhibit III-6).

Traditional and Transparent Pricing

In recent years, some PBMs have emphasized transparency in customer relations, including “transparent” pricing in their payer contract offers. PBM traditional pricing for retail and mail-order pharmacy is typically offered on the basis of the AWP benchmark for single-source branded pharmaceuticals, and proprietary MAC or MRA for multiple-source pharmaceuticals. Contracts may guarantee the overall value of the MAC or MRA as a percentage AWP discount, although this guarantee is difficult to validate because MAC details typically are not shared with PBM clients. Some contracts guarantee the AWP-discount value of all multiple-source products, whether or not they are on the MAC list. A dispensing fee typically applies.

In contrast, PBM transparent pricing for retail and mail-order pharmacy specifies that the actual PBM payments to pharmacy providers are passed through to the payer without markup or alteration. This form of pricing generally does not specify a particular AWP-discount price that will be charged to the payer for single-source branded pharmaceuticals, but may guarantee the overall claims value in terms of an average AWP discount. The reason for the absence of a specified AWP discount is that PBM pharmacy network contracts are negotiated individually and may vary among pharmacy providers, so that the PBM cannot offer the payer a single pricing formula in advance (but an average AWP discount paid can be offered after the fact, in a reconciliation process).

Specialty pharmaceuticals are often priced differently to payers. Individual specialty pharmaceuticals may be listed in the contract, priced on an AWP-discount basis that may differ depending on whether the payer opts for an exclusive provider arrangement with the specialty pharmacy, or for an open provider model in which the patient also may obtain specialty pharmaceuticals from network retail pharmacies. A MAC may apply for multiple-source products. Specialty pharmaceuticals not individually priced may be subject to an across-the-board AWP discounted price. A dispensing fee may apply.

Contracts with pharmacy providers typically include “lower of” provisions in which the PBM or plan sponsor pays no more than what would be paid by a pharmacy customer paying out-of-pocket without pharmacy benefit coverage. Contractual “lower of” provisions may have become more important in recent years as a result of the community pharmacy “generic price war.”
Prescription Drug Rebates

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

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

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 drugs perceived to be without therapeutically interchangeable alternatives and for breakthrough drugs, because manufacturers perceive no need to negotiate prices to obtain favorable formulary status for these products. Rebates are also rare for generic drugs or for multiple-source brand-name drugs when generics have been available for a long period of time.

The extent to which drug manufacturer rebates are shared among 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 the employer and PBM (or health plan), 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 a lower share of rebates.

Rebates and other price concessions to health plans and PBMs have no direct impact on payments to contracted pharmacies. However, in an AMP- or ASP-benchmarked system in which payment is a markup on 1 of these benchmarks, rebates and other price reductions that lower the overall reportable selling price also lower the pharmacy’s allowable cost and net margin of profit (assuming that no change occurs in pharmacy acquisition cost and the dispensing fee remains constant).

Patient Expenditures for Pharmaceuticals

For a typical family of 4 covered by an employer-sponsored PPO, one medical index estimates that a patient’s out-of-pocket cost-share for prescription drug costs in 2008 is approximately 27.4% of total drug costs. According to the index, the actuarial value of annual pharmacy cost for a family of 4 in this scenario is $2,302 of a total annual medical cost of $15,609 paid by or on behalf of the typical family.

While average Medicare beneficiary cost-share for prescriptions is lower as a result of the Part D benefit, it remains significant, particularly for beneficiaries who reach the “doughnut hole.”

According to a CBO report, “average prices for patented drugs in other industrialized countries are 35% to 55% 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.”

Importation of a prescription drug (or reimportation, if it is manufactured in the United States) is generally not lawful for individuals or commercial entities such as pharmacies or wholesalers. However, P.L. 109-295 (enacted in 2006) allows U.S. residents to transport up to a 90-day supply of qualified drugs from Canada to the United States. The U.S. government reportedly does not consistently stop individuals from purchasing drug products abroad. Internet sales and personal importation through physical travel to Canada totaled about $700 million in sales in 2003, or 0.3% of total U.S. prescription sales, and about the same dollar value of prescription drugs is estimated to have entered the United States from the rest of the world.

Because of the price difference, some people without prescription drug insurance have used drug importation to reduce their prescription drug cost. Yet, safety considerations exist. Key findings of the DHHS Task Force on Drug Importation are as follows: “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.”

People without prescription drug insurance or with inadequate coverage may be eligible for prescription drug discount cards, offered by county government, pharmacy benefit managers, community pharmacies, and others. Discount cards typically are honored only at certain community pharmacies, may reduce the purchase price of all pharmaceuticals purchased or only of generics, and may be fee-based or free to those meeting eligibility criteria.

Relationship of Provider to Payment Method

The payment method varies by provider type in the private sector as it does in the public sector. However, in the private sector, payment methods are far more variable than in the public sector. Because payment methods 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 for the ingredient cost component based on a percentage discount or markup on a benchmark, typically AWP or WAC, respectively, for single-source brand drugs. For multiple-source drugs, payment is usually subject to a purchaser-defined MAC price list. A negotiated fee is paid for professional services including dispensing. Some purchasers make an additional payment to the community pharmacy for work expended in gaining substitution with a preferred product when a nonpreferred product was prescribed. Purchasers also may offer payment to community pharmacies for the provision of medication therapy management (MTM) or disease management (DM) professional services.

This product-based reimbursement formula in community pharmacy is expressed as an ingredient cost calculation plus dispensing fee, such as the following:

- AWP\(-X\% + \text{x.xx}\)
- WAC\(+X\% + \text{x.xx}\)
- MAC\(+x.xx\) (for multiple-source drugs)

A May-June 2008 survey of 223 employers representing about 15 million members showed that average community pharmacy reimbursement for brand drugs was AWP minus 16.1%, plus an average dispensing fee of $1.73.33

Community pharmacy reimbursement also is typically subject to a “lower of” provision in which the pharmacy provider is not
paid more than the submitted price or submitted drug cost, the submitted U&C price or the contractual amount.

**Providers of Specialty Injectables.** Drug payment for specialty injectables, as well as beneficiary cost-share responsibility for these products, depends on the benefit under which the injectable is covered as well as the provider dispensing or administering the product. Specialty injectables, including self-administered and office-administered injectables, may be included in a payer’s pharmacy benefit and/or covered through the medical benefit. When covered under the pharmacy benefit, injectables are subject to payers’ drug formularies, as with other pharmaceuticals paid through that benefit. Most medical benefits lack the description of benefits language or capability of claims processing systems to support product positioning as preferred or nonpreferred, which precludes the opportunity to earn meaningful product discounts from rebates.

As shown in Exhibit III-7, based on a survey conducted...
A significant portion of the commercial marketplace has shifted from AWP-based reimbursement to ASP-based reimbursement (see Exhibit III-9).

**Hospital Inpatient and Outpatient.** Because per diem and prospective payment are the most frequently used payment methods in these settings, separate payment for drugs in the inpatient hospital setting seldom occurs. However, most hospital outpatient drugs are reimbursed separately 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 reimbursed separately. The business failure of several physician practice management organizations (organizations that own or

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**EXHIBIT III-11** ASP-Based Reimbursement in the Physician-Office Setting

**Key Findings:**
- Increased adoption of rates above +6% has fueled the transition to ASP technology

**Injectables Index Data**

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<thead>
<tr>
<th></th>
<th>Fall 2007</th>
<th>Spring 2008</th>
<th>Fall 2008</th>
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<tbody>
<tr>
<td>ASP</td>
<td>35.4%</td>
<td>41.0%</td>
<td>44.1%</td>
</tr>
<tr>
<td>Other</td>
<td>65%</td>
<td>59%</td>
<td>56%</td>
</tr>
<tr>
<td>ASP=35.4%</td>
<td>45.8% of covered lives</td>
<td>58.8% of covered lives</td>
<td>57.3% of covered lives</td>
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<tr>
<td>Other=65%</td>
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<td>43.1%</td>
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<td>n=99</td>
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**Oncology Index Data**

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<tr>
<th></th>
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<th>Winter 2008</th>
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<tbody>
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<td>ASP</td>
<td>36.0%</td>
<td>36.0%</td>
</tr>
<tr>
<td>Other</td>
<td>64%</td>
<td>64%</td>
</tr>
<tr>
<td>ASP=36.0%</td>
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<td>n=100</td>
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</tbody>
</table>

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during December 2008 of health plans representing commercial, MA-PD (Medicare Advantage with prescription drug) and managed Medicaid lines of business, commercial coverages are split between a flat and a tiered cost-share for specialty drugs under the pharmacy benefit, but typically require no cost-share for specialty drugs 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.

Commercial health plan payment formulas for specialty pharmaceuticals typically differ by provider type and by payer, as shown in Exhibit III-8.
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. A concept proposed by Prometheus Payment—that of physician-based, severity-adjusted, evidence-based case rates—may soon be tested, but case rates initially will not include prescription drugs. Outside of staff model health plans as of 2003, office-administered drugs typically were paid on a FFS formula, with AWP as a common basis and formulas ranging from AWP plus 10% to AWP minus 20%.

Web-based surveys of payers and of oncologists have shown significant uptake of the ASP benchmark in the commercial sector, as shown in the following slides from the Zitter Group. As of the time of this survey, more than 40% of payers surveyed, representing almost 60% of commercially covered lives, had adopted the ASP benchmark, most commonly at a 6% markup. Survey of oncologists provides very similar findings (see Exhibit III-10 and 11).

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

**Home Health.** Private purchasers pay home health professional services on a per diem, per-visit or per episode basis. In the commercial sector, prescription drugs administered in the home setting are paid separately to home-infusion pharmacies on a FFS basis. In the Medicare program, infusion therapy is paid according to the Medicare Durable Medical Equipment Prosthetic, Orthotics, and Supplies fee schedule. Based on a managed care survey performed in December 2008, the reimbursement for specialty pharmacy products in home health care was based predominantly on AWP (see Exhibit III-12).
The complexity of drug payment can be made more comprehensible by diagrams that show the multitude of entities that are involved in various distribution channels. The 2 principal models of drug payment and pharmacy benefit financing in the U.S. health care system in 2009 are:

- Pharmacy benefit other than Medicare prescription drug benefit (see Exhibit IV-1); and
- Medicare prescription drug benefit (see Exhibit IV-2).

Key stakeholder relationships are highlighted in these schematics. Only the first instance of each stakeholder relationship is shown. The relationships are described below.

1. **Payer carve-out to PBM.** 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. With the exception of Medicare Part D (see Exhibit IV-2), PBMs generally do not take financial risk 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 usually centers on AWP, WAC, MAC or pharmacy U & C price. PBMs also may receive payment for services from manufacturers now defined as bona fide service fees. Insurers retain all rebates for their insured business and share rebates with self-insured customers at an amount negotiated as part of the ASC agreement.

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

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

A self-insured employer may participate in a group purchasing organization (GPO) that can build preferred relationships with vendors, including PBMs, mail-order, and specialty pharmacies, based on price concessions, services, and service guarantees. The Human Resource Policy Association’s Transparency in Drug Purchasing Solutions (TIPPS) initiative is an example of such an organization.112,129

3. **Health plan to PBM arrangements.** 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. **Relationship between PBM and network pharmacies.** PBMs generally do not take financial risk 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 usually centers on AWP, WAC, MAC or pharmacy U & C price. PBMs also may receive payment for services from manufacturers now defined as bona fide service fees. Insurers retain all rebates for their insured business and share rebates with self-insured customers at an amount negotiated as part of the ASC agreement.

5. **Manufacturer to PBM relationships.** 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 contracted performance targets.

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

Pharmacy purchase of drug inventory. Community, specialty, and other types of pharmacies may purchase drugs directly from wholesalers, or may join GPOs to generate increased negotiating leverage by combining purchase volume. GPOs may offer members owned or affiliated wholesaler-distributor service arrangements. GPO fees typically are up to 3%
Patient assistance programs assist patients in meeting cost-share. Patient assistance programs (PAPs), sponsored by manufacturers and administered by service providers, PBMs, and charitable organizations, are available to help eligible individuals meet the cost of medications when patients are without pharmacy benefit coverage and/or meet specific, sponsor-defined financial criteria. The Partnership for Prescription Assistance (PPARx, www.pparx.org) is an example of a referral service to
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 recouped by the government. Employers and unions that sponsor retiree benefits that offer no less than the Medicare drug benefit qualify for a Retiree Drug Subsidy.69,70

Patient relationship to their health plan. 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 employee's share of the monthly health insurance premium is deducted from salary by the employer.

CMS contracts with Part D and MA-PD providers. 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 recouped by the government. Employers and unions that sponsor retiree benefits that offer no less than the Medicare drug benefit qualify for a Retiree Drug Subsidy.69,70

Medicare beneficiary relationships to PDP and MA-PD providers. Most Part D beneficiaries must pay a monthly premium to the Part D sponsor. The MMA requires that beneficiary premiums must reflect 25.5% of the national average standardized bid across all Part D plans.71 Low-income beneficiaries pay less or no premium, cost-share and deductible.
V. Issues and Implications for Stakeholders

### Actual Transaction Price as the Basis of Drug Payment

**Issue**

In light of the March 17, 2009, Memorandum and Order referred to earlier (see Section II, Payment Benchmarks), and both First DataBank’s and Medi-Span’s subsequent announcements, it appears that AWP will no longer be widely published by the end of 2011. Consequently, payers will replace AWP as the basis for payment. It is possible that the new benchmark will be a measure of actual transaction price, at the manufacturer level possibly based on CMS’s leadership in developing ASP and AMP, or at the provider level based on actual acquisition cost (AAC).

In Medicaid, change to AMP, if implemented according to the Deficit Reduction Act of 2005, would apply only to multiple-source drugs. However, AMP is intended to be publicly available according to the 2005 Act, and could be applied by government and commercial payers beyond the mandated use specified in the DRA.

WAC also has been suggested as a possible replacement for AWP, because it more closely approximates actual transaction price for single-source-branded products, because it currently exists in most published pricing references, and because it will continue to be published for the foreseeable future. However, WAC has not been a viable option heretofore because many drugs, particularly multiple-source drugs, do not have published WAC prices, and because WAC does not approximate actual transaction price for many single source branded drugs in competitive therapeutic classes and for the vast majority of multiple-source drugs.137

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

**Implications**

- Pharmaceutical manufacturers may reconsider rebates currently offered for preferred formulary placement and attainment of market share targets, because it may be necessary to calculate AMP net of such payment. Pharmaceutical manufacturers and other stakeholders in the channels of distribution may reconsider fees paid in light of whether they qualify as exempt bona fide service fees.

- Third-party payers may benefit from replacement of AWP with an actual transaction price benchmark because the new benchmark would provide transparency both with respect to acquisition cost and markup. In addition, such a benchmark may enable payers 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 an actual transaction price benchmark 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. Without upward adjustment of product markups or increases in dispensing fees for pharmacy services, there may be adverse effects on access as a result of reduced pharmacy participation in provider networks.

- 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 ASP and AMP, it is the end provider of services, not the manufacturer, whose gross margin is most affected.

- Use of a simple ASP plus some percentage, absent any additional controls, creates the financial incentive for prescribers to select a higher-cost, higher-dollar product versus a lower-cost, lower-dollar product. For example, 6% of a drug with a $500 ASP for a provider-purchaser has a $30 margin, while a therapeutic alternative with a $100 ASP has only a $6 margin.

- As noted in a recent statement on AWP reform from the Biotechnology Industry Association (BIO), “If changes to AWP are made, these changes should take into account the professional services of physicians and other providers that accompany the administration of covered products,” and offers the following in explanation: “Some provider organizations have presented evidence that their members are not being adequately reimbursed for their professional services and that any differential between AWP and provider acquisition cost goes to make up this gap.” In this and in similar cases, movement from AWP to an actual transaction price benchmark will necessitate valuation and fair separate compensation for services related to provider drug handling and administration. Similarly, use of an actual transaction price for drug ingredient cost in community and mail-order pharmacies will precipitate pressure for upward adjustment of dispensing/administrative fees.

- Medicare’s ASP 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 and who therefore do not qualify for or are unable to earn particular discounts or rebates. This reimbursement formula also has forced physicians to be more vigilant about collecting full patient cost sharing. As a result, manufacturers report increasing demand for coinsurance assistance from Patient Assistance Programs (PAPs). In addition, patient service levels can be affected negatively in some cases where physicians no longer acquire the medication because of insufficient reimbursement.

- An actual transaction price benchmark could disadvantage community pharmacies in several ways. First, it may 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 may be 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. Also, if the actual transaction price benchmark is calculated on data that is several months old, and if this benchmark becomes the basis for current payment purposes (as is true for ASP), then this may misrepresent a current transaction price to the disadvantage of the purchaser.

- MCOs that adopt payment methods benchmarked to an actual transaction price 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 method is appropriate to ensure that providers are recovering at least their AAC? Total drug payment to service providers 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?

- Pharmaceutical manufacturers must understand that pricing benchmarks such as WAC are necessary to make the delivery system work. Similarly, payers require some method or benchmark to evaluate competitive offers/bids, to validate contract terms, adjudicate drug claims, and control, monitor, and track their trend in pharmacy-benefit spending.

Public Disclosure of an Actual Transaction Price

Issue

Medicare ASPs are publicly available information. If implemented in accordance with the 2005 DRA, AMP will also become publicly available (AMP is currently confidential).

Implications

- AMP would become the new statutory benchmark for Medicaid reimbursement of multiple-source drugs only. AMP disclosure, however, would apply to single-source and multiple-source drugs. As a result, states would have the information needed to move from AWP to AMP for single-source drug reimbursement, if they so desire.

- General availability of routinely updated actual transaction price benchmarks, such as AMP and ASP, may supplant “list” price benchmarks in the private sector, well before publication of AWP ceases.

- Public disclosure of actual transaction prices should enable increased specificity and transparency in the calculation of private payer rebates. Private-sector MAC price lists often are established without reliable information about the AACs of multiple-source brand drugs, so an important implication for the publication of AMP prices is the potential for use in MAC pricing.

- 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. If true, then public disclosure of actual transaction price may result in a narrowing of the range of net prices offered into the marketplace.

Bundling (Combining) Drugs With Services

Issue

Combining drug reimbursement with related clinical services transfers the drug’s economic responsibility and risk from the payer to the provider. Medicare has used this technique for managing hospital inpatient (diagnosis-related group [DRG]) and outpatient (APC) drug spending, other acute care services (e.g., skilled nursing facilities [SNFs]), and dialysis services (composite rate). In the private sector, some medical groups have received per member per month (PMPM) capitation payments inclusive of shared financial risk for prescription drugs, and most private health plans pay for inpatient services using a per diem or DRG rate that includes drugs.

Packaging has been proposed in other settings (such as primary care in a medical home setting), across settings (such as hospital and post-discharge care) and with particular disease severity refinements to more accurately reflect provider cost and ability to manage risk. The following shows one view of how primary care services in the “medical home” setting might be packaged (see Exhibit V-1).

Implications

- If prescription drug cost and financial risk are packaged together with clinical pharmacy services and delegated to the provider together, then it may follow that drug formulary maintenance and exceptions authority are also delegated to the at-risk provider. This would provide the at-risk provider with the responsibility and tools needed to manage that risk.

- Public disclosure of actual transaction prices improves payers’ ability to package drugs with services because it permits the payer to negotiate with more confidence regarding providers’ costs. Therefore, public disclosure of actual transaction prices may encourage packaging of prescription drugs with other health care services. Providers may seek additional compensation for drug-related professional services if there is loss of revenue on the drug component of payment.
V. Issues and Implications for Stakeholders

### Pricing Transparency

**Issue**

In the private sector, increasing pressure has been placed on PBMs by many stakeholders including drug plan sponsors, government agencies and consumer organizations, to disclose pricing concessions and rebates. Furthermore, increasing penetration of high-deductible Consumer Driven Health Care plans will lead to increased beneficiary price sensitivity and demand for greater pharmaceuticals price transparency. Many PBMs have increased pricing transparency 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 fund 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 when they were funded through the margin between the amount paid to the pharmacy provider and the amount charged to the drug plan sponsor. New billable services likely will evolve to replace the lost revenue.
- Some PBMs’ “transparent pricing” offers amount to a pass-through cost to the drug plan sponsor of the PBMs’ individually negotiated network pharmacy payments. However, the PBM may be unwilling to disclose underlying pricing with these pharmacies, and may be unable in advance to estimate the weighted average of its pricing in AWP-discounted terms. Therefore, the payer may perceive this as less transparent than a contractually specified AWP-discounted pricing formula.
- In a recent report, the CBO has observed that “the markets for some health care services are highly concentrated, and increasing transparency in such markets could lead to higher, rather than lower, prices.” In particular, “In health care, reduced competition might result if more transparent pricing revealed the prices negotiated between insurers and providers, especially in concentrated markets.”

### Prescription Drug Risk-Adjusted Premium

**Issue**

Medicare Part D PDPs are at financial 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, 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. A fundamental problem was the absence of a contract relationship between PBMs and prescribers to permit PBMs to have some influence over prescribing behavior.

PBM performance ratings can be adversely affected by higher drug expenditures even if the spending for drugs is associated with lower costs elsewhere in the health care system. An example of consequences of looking at benefit costs in “silos” includes the introduction of the histamine-2 antagonists for ulcer treatment in the 1970s. These drugs eliminated the need for surgical intervention for many patients but resulted 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, without regard to utilization or cost impact to other aspects of the health benefit.
- 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

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**EXHIBIT V-1** Payment System Alternatives – Patient-Centered Medical Home

<table>
<thead>
<tr>
<th>Payment System Today</th>
<th>Transitional Payment System</th>
<th>Ideal Payment System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fees for Face-to-Face Physician Visits</td>
<td>Fees for Face-to-Face Physician Visits</td>
<td>Simple Comprehensive Payment to Cover Visits and Calls with Physicians, RN Care Managers, Testing, etc.</td>
</tr>
<tr>
<td>Fees for Diagnostic Testing, etc.</td>
<td>Fees for Diagnostic Testing, etc.</td>
<td>+ Bonus/Penalty Based on Use of ER, Hospital</td>
</tr>
<tr>
<td>No Payment for MD Phone Contacts</td>
<td>Fees for MD Phone Contacts</td>
<td>+ Bonus/Penalty Based on Use of ER, Hospital</td>
</tr>
<tr>
<td>No Payment for RN Care Managers, etc.</td>
<td>Fees for RN Care Managers, Inc.</td>
<td>+ Bonus/Penalty Based on Use of ER, Hospital</td>
</tr>
<tr>
<td>No Penalty for High Rates of Hospitalization</td>
<td></td>
<td>+ Bonus/Penalty Based on Use of ER, Hospital</td>
</tr>
</tbody>
</table>

• Pharmacists have demonstrated effectiveness in helping patients manage their out-of-pocket costs for prescription drugs and pharmacy services.146,147,148
• Reference pricing: Set a drug's payment rate no higher than the cost of currently available treatments unless evidence shows that the drug improves beneficiaries' outcomes.
• Payment for results: Link a drug's payment to beneficiaries' outcomes through risk-sharing agreements with manufacturers.
• Bundling: Create payment bundles for groups of clinically associated products and services.

Note: MedPAC has served in an advisory capacity, but in 2009 as part Congressional debate regarding health care prices, possibly reducing trend (i.e., growth in benefit cost over time).

Implications
• Concern exists that despite the report language that accompanied ARRA, comparative-effectiveness research may be used by insurers or by the government primarily to deny coverage for more expensive treatments or to ration care.
• Comparative effectiveness methods and standards can be controversial. For example, controversy exists about the validity of inferring causation about treatments and other health interventions based on observational data. Another issue is whether comparative effectiveness should address cost: For example, is an incremental benefit always “worth it”? Who will decide and on what basis and with what input will that decision be made?153
• That the results of comparative-effectiveness research may be applied in ways which incorporate payment is substantiated in a June 2009 MedPAC Report to the Congress:44

“To help improve the value of Medicare spending, we discuss three pricing strategies that use information about a drug’s clinical effectiveness when paying for it under Part B and Part D:

- Reference pricing: Set a drug’s payment rate no higher than the cost of currently available treatments unless evidence shows that the drug improves beneficiaries’ outcomes.
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Use of Comparative-Effectiveness Research
Findings to Guide Benefits, Access, and Payment

Issue
A total of $1.1 billion of the $787 billion economic stimulus bill approved by Congress in February 2009 (Public Law 111-5, the American Recovery and Reinvestment Act of 2009 [ARRA]) provided significant one-time funding for comparative-effectiveness research to evaluate drugs, medical devices, surgery, and other treatments. The funding is available through September 30, 2010. Although the focus of the funding of this research is to be on clinical effectiveness, incorporating evaluation of cost-effectiveness is not precluded, although the result of any comparative-effectiveness research is not to be used to mandate coverage, reimbursement, or other policies for any public or private payers. Since 2005 and with a much smaller budget, the Agency for Healthcare Research and Quality has sponsored comparative-effectiveness research.150,151 Many state Medicaid programs, private payers, and provider groups sponsor similar efforts.152 The 111th Congress is considering several proposals that would establish an ongoing, long-term program that would foster and coordinate comparative-effectiveness research and disseminate the findings associated with the research to all stakeholders (e.g., consumers, government, payers, providers, and manufacturers).

Implications
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• Comparative effectiveness methods and standards can be controversial. For example, controversy exists about the validity of inferring causation about treatments and other health interventions based on observational data. Another issue is whether comparative effectiveness should address cost: For example, is an incremental benefit always "worth it"? Who will decide and on what basis and with what input will that decision be made?153
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"To help improve the value of Medicare spending, we discuss three pricing strategies that use information about a drug’s clinical effectiveness when paying for it under Part B and Part D:

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Note: MedPAC has served in an advisory capacity, but in 2009 as part Congressional debate regarding health care prices, possibly reducing trend (i.e., growth in benefit cost over time).
care, there was a proposal in draft legislation to create an independent Medicare Advisory Council (IMAC) from the current MedPAC. IMAC would have authority to make recommendations to the President, and this change would transform MedPAC into a policy-making entity.154

- Others argue that cost-effectiveness information will instead lead to improved quality, better outcomes, more efficient, and less variable delivery of care.

- An important challenge in application of comparative-effectiveness research will be the balance of societal and population needs versus unique patient circumstances at the point of care delivery. To some, this suggests the need to consider the meaning of rationing.155

- Challenges include dissemination of this information to patients, advocacy groups and providers, implementation of decision support tools at the point of care delivery, and widespread and consistent application of electronic medical records technology.

- The $1.1 billion funding of comparative-effectiveness research in ARRA (2009) quite likely portends the adoption of a permanent and possibly centralized structure in the United States for establishing priorities and policies, and coordinating these research activities.

### Pharmaceutical Manufacturer Acceptance of Risk for Desired Therapeutic Outcomes

**Issue**

Pharmaceutical manufacturers are experimenting with accepting risk for the therapeutic outcome of their drugs in exchange for insurance coverage that would otherwise be denied or restricted. Published reports describe arrangements between private insurers and manufacturers of diabetes and osteoporosis drugs that place the manufacturer at risk for treatment costs attributed to failure of the drug to achieve the stated therapeutic goals. The arrangements are similar to one between a U.S. oncology drug manufacturer and the United Kingdom's National Health System.156

**Implications**

- These arrangements reflect the increasing cost sensitivity of the marketplace and the need for cost to be justified by value to obtain access for a more expensive drug in a crowded therapeutic category. Arrangements like these could become more common in response to even greater cost pressure throughout the next decade.

- Should risk for desired therapeutic outcomes be considered a warranty, a type of insurance, providers’ assumed risk in prescribing and managing a particular therapeutic course, or a combination of these?257 For example, which of these might be the best description of the Medicare “never events” policy?258

- Acceptance of financial risk for therapeutic outcomes presents extraordinary challenges to pharmaceutical manufacturers.

The success of these programs will depend on resolution of several issues such as those shown below:

- Significant variation in patient response should be expected over time, particularly for patients with multiple medical problems, subject to multiple therapeutic interventions, including the targeted drug therapy for which the manufacturer is at risk. In observational data, it may prove difficult to link specific drug treatment causally to a particular outcome for a particular chronically ill patient population, much less for a particular patient.

- Assuming economic risk for a health outcome is the equivalent of insuring patient care, albeit for a targeted purpose. Pharmaceutical manufacturers do not have experience as insurers, nor is the manufacturer business model set up for this purpose. Investors in pharmaceutical stocks anticipate risk in research and development, but do not anticipate risk related to outcome of therapy.

- A manufacturer could hire or contract to obtain necessary risk assessment and management expertise. Doing so will entail a certain cost. An additional cost is incurred in underwriting outcome risk, which manufacturers might retain internally or seek through a third-party insurance policy. These costs could be financed through increasing product price or result in lower manufacturer profitability.

- It is not clear how state insurance regulators will respond to manufacturer-sponsored outcome risk arrangements. Will this be considered insurance subject to capital requirements and regulation?

- Smaller manufacturers may be financially unable to underwrite outcome risk programs, even if their products are ideal candidates, leaving them at a competitive disadvantage to larger manufacturers of competing products.

- These arrangements may become less about financial risk and more about market entry and market positioning, in that nimble manufacturers may be able to use effectiveness guarantees to create payer preference and market barriers to equally or more efficacious products. Such guarantees also could be used on a direct-to-consumer basis by manufacturers, in an effort to circumvent a product’s formulary status.

- These considerations suggest that health outcome risk assumption by pharmaceutical manufacturers will require careful study before becoming a routine part of the payer-manufacturer relationship.

### Pharmacogenomics

**Issue**

A goal of pharmacogenomics is to “provide clinicians with tools to assess risks and benefits associated using available medicines for particular patients to select therapies and treatments tailored to each patient. In so doing, pharmacogenomics should enable direct management of individual patient-drug response
for many conditions.” One example is HER2/neu testing of metastatic breast cancer patients to determine potential responsiveness to Herceptin.159 Another is the use of KRAS testing to determine whether Erbitux or Vectibix would be beneficial in the treatment of colorectal cancer in particular patients.160

**Implications**

- Although costs will be associated with the performance of pharmacogenomic tests, drug ingredient and associated costs also would be saved by avoiding administration of drugs where tests show particular patients would be poor responders, and for particular patients for whom particular drugs would be unsafe.
- Consistent application of pharmacogenomic tests in appropriate cases would make more likely that patients identified as good candidates for particular drug therapy would be offered that therapy, if otherwise clinically indicated.
- Today’s health information technology infrastructure is not well suited to support informed use of pharmacogenomic tests and use of prescription drugs dependent on the outcome of those tests at the point of care.159
- It will be important for payers to develop coverage policies and tracking systems to link availability and results of particular pharmacogenomic tests to the utilization of particular pharmaceuticals for patients meeting specified clinical conditions.
VI. Conclusion

Pharmaceutical payment is complex, made more so by factors such as the historical combination of reimbursement of pharmacy professional services with payment for pharmaceutical products, the number of entities involved in the distribution of pharmaceuticals, and the more than 10,000 unique drugs with vastly different prices distributed among the drug categories of brand, generic, and multi-source. In addition, a complex relationship exists between the use of pharmaceuticals and of other medical resources in particular therapies, related to a host of factors, including site of care delivery, the type of prescriber, method and amount of payment, benefit design, payer coverage policies, results of practice guidelines and comparative-effectiveness reviews, patient medical condition, patient cost-share responsibility, and patient preference.

Today, biologics and injectable drugs that were at one time covered primarily in the medical benefit often have been transferred to the pharmacy benefit, and these 2 health benefit categories have used much different payment methods. Pharmaceuticals and biotechnology therapeutics, and their associated costs, are increasingly visible and of concern to public and private third-party payers. As a result of direct-to-consumer advertising and increased cost-sharing, they have become increasingly visible and of concern to patients as well. What may be less evident to both, representing a major challenge for future development, is these products’ value for money.

It is also clear that, after more than 40 years of using AWP as the primary benchmark for determining pharmaceutical payment, this benchmark has been manipulated and does not approximate the actual acquisition cost to the end dispenser of the drug. The search continues for a replacement for AWP for pharmaceutical payment that will encourage delivery of high-quality products and stimulate efficient delivery of pharmacy products and services without reducing access for patients. Understanding pharmaceutical payment and the factors that affect payment is an important step in achieving the aforementioned goals.

AMCP hopes that the information in this Guide will ultimately prove to be “quality data that informs the debate” and thus leads to better decisions. The Academy welcomes your feedback about this Guide, which can be submitted at: http://www.amcp.org/amcp.ark?p=1529B561.
### VII. Acronym List

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

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
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<tbody>
<tr>
<td>PAB</td>
<td>Pharmacy Affairs Branch</td>
</tr>
<tr>
<td>PAP</td>
<td>patient assistance program</td>
</tr>
<tr>
<td>PBM</td>
<td>pharmacy benefit manager</td>
</tr>
<tr>
<td>PDL</td>
<td>Preferred Drug List</td>
</tr>
<tr>
<td>PDP</td>
<td>prescription drug plan</td>
</tr>
<tr>
<td>PERS</td>
<td>PERS Public Employees' Retirement System (e.g., California Public Employees' Retirement System [CalPERS])</td>
</tr>
<tr>
<td>PHS</td>
<td>Public Health Service</td>
</tr>
<tr>
<td>PMPM</td>
<td>per member per month</td>
</tr>
<tr>
<td>PMPY</td>
<td>per member per year</td>
</tr>
<tr>
<td>POS</td>
<td>point of sale or point of service</td>
</tr>
<tr>
<td>PPARx</td>
<td>Partnership for Prescription Assistance</td>
</tr>
<tr>
<td>PPO</td>
<td>preferred provider organization</td>
</tr>
<tr>
<td>PPS</td>
<td>prospective payment system</td>
</tr>
<tr>
<td>PSAO</td>
<td>Pharmacy Services Administrative Organization</td>
</tr>
<tr>
<td>PSO</td>
<td>provider-sponsored organization</td>
</tr>
<tr>
<td>RP</td>
<td>reference price</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
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<tbody>
<tr>
<td>SCHIP</td>
<td>State Children's Health Insurance Program</td>
</tr>
<tr>
<td>SCOD</td>
<td>specified covered outpatient drug</td>
</tr>
<tr>
<td>SNF</td>
<td>skilled nursing facility</td>
</tr>
<tr>
<td>SPAP</td>
<td>State Pharmaceutical Assistance Program</td>
</tr>
<tr>
<td>TIPPS</td>
<td>Transparency in Drug Purchasing Solutions</td>
</tr>
<tr>
<td>TMAC</td>
<td>therapeutic maximum allowable cost</td>
</tr>
<tr>
<td>TPA</td>
<td>third-party (claims) administrator</td>
</tr>
<tr>
<td>TrOOP</td>
<td>true out-of-pocket (Medicare Part D)</td>
</tr>
<tr>
<td>U&amp;C</td>
<td>usual and customary (price)</td>
</tr>
<tr>
<td>UCR</td>
<td>usual, customary, and reasonable</td>
</tr>
<tr>
<td>URA</td>
<td>unit rebate amount</td>
</tr>
<tr>
<td>VA</td>
<td>Department of Veterans Affairs (Veterans Administration)</td>
</tr>
<tr>
<td>WAC</td>
<td>wholesale acquisition cost</td>
</tr>
<tr>
<td>WAMP</td>
<td>widely available market price</td>
</tr>
</tbody>
</table>
340B Ceiling Price See Public Health Service 340B Ceiling Price.

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 & 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.

authorized generic Drug approved by the FDA that the brand manufacturer subsequently chooses to market (or have marketed under sale or license) by generic name. The brand-name drug and the authorized generic are chemically identical.

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. In June 2005, the OIG estimated the median AMP at 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. Before the enactment of the Deficit Reduction Act of 2005 (DRA), AMP data were used by the Centers for Medicare & 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) Section 303(c) of the Medicare Modernization Act (MMA) revised the drug payment methodology by creating a new pricing system based on a drug’s ASP. Effective January 2005, Medicare began paying for the vast majority of Part B covered drugs and biologicals using a drug payment methodology based on the ASP. In accordance with section 1847A of the Social Security Act (the Act), manufacturers submit the ASP data for their products to CMS on a quarterly basis. These data include the manufacturer’s total sales (in dollars) and number of units of a drug to all purchasers in the United States in a calendar quarter (excluding certain sales exempted by statute), with limited exceptions. The sales price is net of discounts such as 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 Act). CMS updates ASP drug pricing files for Medicare Part B drugs on a quarterly basis. Medicare Part B drugs and biologicals not paid on a cost or prospective payment basis are paid based on the ASP methodology, and payment to providers is 106% of the ASP, less applicable beneficiary deductible and coinsurance.

average wholesale price (AWP) List prices for drugs reported by pharmaceutical manufacturers and published in commercial clearinghouses such as Redbook, Medi-Span, First DataBank, and Elsevier Gold Standard (ProspectoRx). Each price is specific to the drug, strength, dose form, package size, and manufacturer or (re)labeler. Each price is specific to an 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), plus or 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. Best price 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. Best price includes cash discounts, free goods that are contingent on purchase, volume discounts, and rebates.
The Deficit Reduction Act 2005 changed the manufacturer price reporting requirements for AMP and best price effective January 1, 2007, to include the price of the authorized generic.

**Big 4** See federal Big 4.

**biological product (biologic)** Includes a wide range of products such as vaccines, blood and blood components, allergens, 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, 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 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. Most commonly, a bundle of services is combined with drugs at a designated price, as in the case of ambulatory payment classifications (APCs) or diagnosis-related groups (DRGs). Alternatively, drug sales to providers from manufacturers may determine the net price of individual drugs in the bundle based on the on the sales volume of all drugs in the bundle.

**capitation** Method of payment for health services in which a health care provider is paid a fixed amount, usually prospectively, for each person on the provider’s patient roster, regardless of the quantity or nature of services actually provided.

**carve-out pharmacy benefit** Prescription and pharmacy services insurance coverage that is financially and administratively separated from the primary health care plan and typically administered under contract by a separate company, such as a pharmacy benefits manager (PBM). When care is capitated, a carve-out is a service or package of services not provided within the contract. Thus, it is carved out from the per member per month (PMPM) payment rate. A carve-out benefit also may 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 & 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, customers such as buyers of pharmaceuticals that share similar profiles and attributes may be categorized into a COT to 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. The business practice of offering various price discounts by COT was challenged by chain pharmacies in the 1990s. The U.S. Court of Appeals for the Seventh Circuit decided in July, 1999 (In re Brand Name Prescription Drugs Antitrust Litigation, No. 99-1167, 186 F.3d at 788), 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.

**comparative effectiveness** Whereas most randomized controlled trials (RCT) compare active drug with placebo, comparative-effectiveness research compares clinical outcomes of alternative active drug therapies for the same condition. It is thought that results from comparative-effectiveness research may better inform health care decisions, reduce variability in care delivery, improve quality of care, improve efficacy, and improve efficiency.

**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) method (“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, and was postponed after December 31, 2008.

consumer-driven health plan (CDHP; also consumer-driven health care [CDHC]) Plans that include health spending accounts into which employers or individuals may contribute pre-tax dollars to be used for health care purchases. CDHPs are based in part on the theory that a beneficiary who is in control of their health care dollars will choose wisely how to spend and will be a good shopper for value and quality.

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 health plan member benefits, such as a fixed dollar amount for each prescription received (e.g., in a 3-tier pharmacy copayment design, $5 for a generic prescription, $15 for a preferred brand-name prescription, and $30 for a non-formulary product).

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

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

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

Diagnosis Related Group (DRG) Used in Medicare's prospective payment system and by other public and private payers. DRGs classify patients into groups based on the principal diagnosis, treatments and other relevant criteria. Hospitals are paid the same amount for each case classified in the same DRG, regardless of the actual cost of treatment (but with provision for cost-outlier cases).

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 wholesale acquisition cost (WAC), 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.

doughnut hole Coverage gap in Medicare Part D prescription drug coverage, within which beneficiary is responsible for 100% of prescription drug cost. Coverage resumes when total prescription drug expenses reach $5,916.25 (in 2009; indexed to the CPI), after which Medicare pays 95% of beneficiary's prescription drug costs through the end of the calendar year.

estimated acquisition cost (EAC) Federal regulations (at 42 CFR § 447.512) require, with certain exceptions, that each State Medicaid agency's reimbursement for covered outpatient drugs not exceed (in the aggregate) the lower of the estimated acquisition cost for drugs plus a reasonable dispensing fee or the provider's usual and customary charge to the public for the drugs. Estimated Acquisition Cost represents 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). As of March 2007, WAC was used in some way by 11 state Medicaid programs, but AWP was the predominant basis of pharmacy provider reimbursement for drug acquisition cost.

federal Big 4 The 4 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 4 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 4—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 & Medicaid Services (CMS) as the maximum amount that a state Medicaid program can pay for a drug. Sometimes called fed-eral upper limit (FUL) Price calculated and published by the Centers for Medicare & Medicaid Services (CMS) as the maximum amount that a state Medicaid program can pay for a drug. Sometimes called federal upper limit (FUL)

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., nonformulary 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 Nonpreferred (i.e., nonformulary) 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 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,” on scientific evaluations. The FDA Orange Book provides ratings of equivalence [A-rated] and non-equivalence for generic substitution. 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.

**VIII. Glossary**

**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 1 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 1 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 & Medicaid Services (CMS) to supplement CPT codes and include physical services not included in CPT as well as nonphysician 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 also are 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. MAC 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 by taking advantage of competitive pricing among multiple-source drugs.

Medicaid State-operated and administered program that is funded jointly 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 & 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 older than 65 years of age 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 posthospital services for individuals aged 65 years or older 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.
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) also are allowed to accept Medicare risk. A Medicare Advantage offering pharmacy benefits is called an MA-PD.

MedPAC
The Medicare Payment Advisory Commission (MedPAC) is an independent Congressional agency established by the Balanced Budget Act of 1997 (P.L. 105-33) to advise the U.S. Congress on issues affecting the Medicare program. The Commission’s statutory mandate is broad: In addition to advising the Congress on payments to private health plans participating in Medicare and providers in Medicare’s traditional fee-for-service program, MedPAC is also tasked with analyzing access to care, quality of care, and other issues affecting Medicare.\(^{164}\)

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

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

National Drug Code (NDC)
Defined officially as a 10-character number by the FDA but commonly implemented in claims administration systems as an 11-character number. The NDC number is divided into 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 discounts 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

nominal price and nominal price exception (or exclusion)
Nominal price pertains to manufacturer reporting to CMS of AMPS for Medicaid rebate purposes and includes any price less than 10% of the AMP in the same quarter for which the AMP is computed. The final rule implementing the Deficit Reduction Act of 2005 (DRA), CMS-2238-FC, limited the nominal price exception for manufacturer reporting of AMPS to CMS to a smaller list of purchasers: 340B-eligible entities, intermediate care facilities for the mentally retarded, and state-owned or state-operated nursing facilities. [See: Centers for Medicare & Medicaid Services. Medicaid Drug Rebate Program. Medicaid drug pricing regulation: a summary. July 6, 2007.]

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 4 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 & 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 (U.S. Department of Health and Human Services and Food and Drug Administration), also known as the Orange
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.” 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.

patient assistance program (PAP) Program administered by a pharmaceutical company or its agent 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 practice to promote better and more efficient patient outcomes.

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 pays medical or pharmacy claims 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. PBMs 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 provide Medicare Part D benefits 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 10, 30, or 60 days subsequent to product delivery.

prospective payment Payment received before care is delivered. 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 pharmaceutical use by a covered person or purchases by a provider.

reference price 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 Reference Price.

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-FC168 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.

self-insurance: See administrative services only.

single-source brand Drug under patent protection that is sold under a brand name and is thus available from only 1 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 (e.g., hospital, physician office, pharmacy, patient’s home).

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 (e.g., rheumatoid arthritis, multiple sclerosis, hemophilia). 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 1 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, heartburn, or depression), requiring beneficiaries to use an equally effective, lower-cost drug before 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) before coverage of the second-line drug.

supplemental rebate A Congressional Research Report in 2008 showed that in 2005 (the year prior to implementation of Medicare Part D and the transfer of dual eligible beneficiaries from Medicaid to Medicare) 22 states collected a total of $1.3 billion (federal share $719 million) in Medicaid rebates not required under federal law.100

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 (also known as the Orange Book), drug products are considered to be therapeutically equivalent only if they are pharmaceutical equivalents and can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling. Drug products are considered pharmaceutical equivalents if they contain the same active ingredient(s), are of the same dosage form and route of administration, and are identical in strength or concentration.

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

**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 themselves 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.

**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 or other provider would charge a cash-paying customer without the benefit of insurance provided through a payer or intermediary with a contract with the provider.

**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 commonly is discounted, but would be the purchase price net of discounts, rebates, and price concessions routinely available to prudent purchasers.
IX. References


8. Pharmacy benefit management (PBM) companies provide administrative services under the pharmacy benefit, such as contracting with a network of pharmacies including mail service, developing and managing formularies, establishing payment levels for provider pharmacies, adjudicating pharmacy claims, operating pharmacy and member call center/help desk, and providing data reporting.


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


IX. References


75. DHHS Centers for Medicare and Medicaid Services. Medicare clarifies negotiated prices under Part D. January 6, 2009. Available at: http://www.cms.hhs.gov/apps/media/pressrelease.aspx?Counter=73329&IntPaperID=231&srchType=2&srchOpt=0&srchData=p-10&checkDate=0&checkKey=2&srchType=2&numDays=0&srchOpt=0&srchData=p-10&checkDate=0&checkKey=2&srchType=2&srchData=p-10&checkDate=0&checkKey=2&srchType=2&srchData=p-10&checkDate=0&checkKey=2&srchType=2&checkDate=0&checkKey=2&srchType=2&checkDate=0&checkKey=2. Accessed July 27, 2009.


IX. References
AMCP Guide to Pharmaceutical Payment Methods, 2009 Update (Version 2.0)

Pharmacists Accreditation and Credit Designation Statement

The Academy of Managed Care Pharmacy is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. AMCP designates this continuing education activity for 2.0 contact hours of credit or .20 Continuing Education Units (CEUs). ACPE Universal Program Number: 233-000-09-028-H01-P.

Release Date: August 1, 2009
Expiration Date: August 1, 2011

This is a knowledge-based learning activity.

Target Audience: Pharmacists

For questions regarding the accreditation of this activity, please contact the AMCP Education and Meetings Department at 800.827.2627, ext. 604.

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The posttest worksheet is provided to assist you in marking your answers prior to entering the online CE center for submission; these pages cannot be submitted for CE credits.

In order to receive CE credit for this activity, you must complete the following forms online:

1. Posttest for this program, “AMCP Guide to Pharmaceutical Payment Methods, 2009 Update (Version 2.0)” accessible at the AMCP.org CE/CME Center. You must receive a score of 70%. You will have 2 opportunities to pass the posttest.

2. Activity Evaluation Form

Upon successful completion of this activity, you will automatically receive your CE, statement as proof of completion. Your CE credits will be archived and tracked for you on the AMCP.org CE/CME Center site. All information is kept confidential.

To complete this continuing pharmacy education activity, go to www.amcp.org (CE/CME Center) to access the posttest and evaluation.
1. Which of the following is true regarding WAC?
   a. The price most commonly paid by community pharmacies for prescription drugs
   b. Will no longer be available after September 2011
   c. Includes discounts negotiated by wholesalers with manufacturers
   d. Is related to AWP by a common multiplier for both brand and generic drugs
   e. None of the above

2. The percentage difference between AWP and AAC is the largest for:
   a. Branded drugs
   b. Multiple-source brand drugs
   c. Multiple-source generic drugs
   d. There is not a significant difference between AWP and AAC for brand, multiple-source brand or multiple-source generic drugs

3. ASP refers to which of the following:
   a. The benchmark price now published by many price sources to replace AWP
   b. Community pharmacy prices for consumers without insurance
   c. Selling price data reported by pharmaceutical manufacturers including most discounts and rebates
   d. Estimated selling price for physician-administered drugs
   e. Prices for hospital outpatient drugs

4. Which of the following best describes the relationship of ASP and AMP?
   a. Under current rules, all prescription drugs will have AMPs, but ASPs will be publicly available only for prescription drugs covered through Medicare Part B.
   b. Both ASP and AMP represent manufacturers’ actual transaction prices.
   c. Neither ASP nor AMP include wholesaler or distributor markups applied to manufacturers’ actual transaction prices.
   d. Comparison of ASP and AMP for prescription drugs that have both prices cannot be made at this time, because AMPs are not publicly available.
   e. All of the above.

5. A March 2009 District Court ruling in a national class action lawsuit against First DataBank and McKesson required a change in the relationship between AWP and WAC on drugs covered in the suit to:
   a. The average markup on WAC that prescription drug wholesalers rely on, as determined by an annual survey of wholesalers
   b. The specific markup on WAC that the pharmaceutical manufacturer recommends
   c. A fixed markup of 1.20 times WAC
   d. A fixed markup of 1.25 times WAC
   e. A fixed markup of either 1.20 or 1.25 times WAC

6. Although currently on hold through the end of September 2009, the Deficit Reduction Act of 2005 required AMP to be used by state Medicaid programs in the calculation of:
   a. The federal upper limit (FUL) on payment for multi-source drugs only in the pharmacy benefit
   b. Payment for brand-name drugs only in the pharmacy benefit
   c. FUL for multi-source drugs and payment for brand-name drugs in the pharmacy benefit
   d. Payment for multi-source and brand-name drugs in the pharmacy benefit and for drugs administered in the physician’s office

7. Which of the following is true of the “basic” Medicaid unit rebate amount (URA)?
   a. Flat 15.1% of AMP for generic (multiple-source “non-innovator”) drugs
   b. Flat 15.1% of AMP for single-source and “innovator” multiple-source drugs
   c. Flat 15.1% of AMP for all drugs
   d. Greater of 15.1% of AMP or AMP minus best price for single-source and “innovator” multiple-source drugs
   e. The best price reported by manufacturers for all drugs

8. Which of the following sales is excluded from Medicaid Best Price reporting for pharmaceutical manufacturers?
   a. Nonprofit HMOs
   b. Any nonprofit entity
   c. Mail order pharmacies
   d. Long-term care facilities
   e. Veterans Affairs
9. According to the Office of Inspector General, the ASP developed by CMS to replace AWP as the benchmark for payment of Medicare Part B prescription drug claims, is:
   a. About 57% lower than AWP at the median
   b. About 49% lower than AWP at the median
   c. About 24% lower than AWP at the median
   d. About 13% lower than AWP at the median

10. An office-based physician prescribing a prescription drug covered by Part B to a Medicare beneficiary would enjoy a higher gross margin in which of the following scenarios, assuming that the Medicare beneficiary cost-share is collected in full and that no deductible applies:
   a. A multisource generic injectable with an ASP of $100
   b. A multisource brand injectable with ASP of $200
   c. A single source brand injectable with an ASP of $300
   d. All of the above yield about the same gross margin to the physician

11. The Congressional Budget Office found which of the following to have the largest AWP discount for brand-name drugs in 2003?
   a. Federal ceiling price (FCP)
   b. 340B ceiling price
   c. Best price
   d. AMP
   e. Department of Defense military treatment facility average price

12. In the private sector, pharmaceutical manufacturers may offer prompt pay, formulary and tier placement, therapeutic class market share and other performance-based price concessions to purchasers. The availability of certain price concessions to private sector purchasers may be determined by:
   a. The provider’s class of trade
   b. How aggressively the purchaser maximizes the prescribing and dispensing of preferred products
   c. The purchasing power of the group purchasing organization (GPO) to which the provider belongs
   d. Whether the prescription drug has therapeutic alternatives which prescribers may consider interchangeable
   e. All of the above

13. As of January 2009, the Medicare program pays for most prescription drugs administered in the hospital outpatient setting that are not bundled into ambulatory payment classification (APC) on the basis of ASP plus:
   a. 2%
   b. 3%
   c. 4%
   d. 5%
   e. 6%

14. For a typical family of 4 covered by an employer-sponsored PPO, one medical index estimates that a patient’s out-of-pocket cost-share for prescription drugs in 2008 was:
   a. Approximately 19%
   b. Approximately 27%
   c. Approximately 33%
   d. Approximately 41%

15. The best estimate by a Medicaid agency of the actual cost for a drug acquired by a pharmacy and other providers describes which of the following:
   a. EAC
   b. ASP
   c. WAC
   d. MAC
   e. AMP

16. The Public Health Service 340B program requires manufacturers participating in the Medicaid program to extend the same pricing, net of mandated Medicaid rebates, to entities enrolled in the 340B program. Is it permissible for entities enrolled in the 340B program to negotiate with pharmaceutical manufacturers for discounts that are greater than mandated by the 340B program?
   a. Yes
   b. No

17. Which of the following best describes the Medicare Part D provision for the “Six Classes of Clinical Concern” (also referred to as “Protected Classes”):
   a. Plan sponsors must not deeply discount payment for these drugs
   b. Prevents plan sponsors from applying prior authorization or step therapy for new or existing users of these drugs
   c. Requires plan sponsors to include all drugs in these 6 classes on drug formularies
   d. Includes drugs for asthma and diabetes
   e. Permits exclusion of multiple-source brand drugs
18. Which of the following factors is NOT used to determine whether a category of pharmaceutical may be paid under Medicare Part B or Part D for a Medicare beneficiary?
   a. Diagnosis
   b. Route of administration
   c. Location (setting) of treatment
   d. Whether the drug is a small molecule or a biological
   e. Whether the drug is self-administered

19. The Medicare program pays for drugs infused through durable medical equipment (DME), such as parenteral nutrition administered by an infusion pump, on the basis of which of the following payment formulas in 2009:
   a. 95% of AWP
   b. ASP + 6%
   c. ASP + 4%
   d. WAC + 5%
   e. Usual and customary charge

20. Which of the following pricing strategies was NOT discussed in a June 2009 Report to the Congress by the Medicare Payment Advisory Commission (MedPAC) for the application of clinical effectiveness information to improve the value of Medicare spending?
   a. Reference pricing: Set a drug's payment rate no higher than the cost of currently available treatments unless evidence shows that the drug improves beneficiaries’ outcomes
   b. Drug formulary: List a drug in tiers of the formulary in accordance with its value as demonstrated through clinical effectiveness research
   c. Payment for results: Link a drug's payment to beneficiaries' outcomes through risk-sharing agreements with manufacturers
   d. Bundling: Create payment bundles for groups of clinically associated products and services
   e. None of the above

To complete this continuing pharmacy education activity, go to www.amcp.org (CE/CME Center) to access the posttest and evaluation.