

Description of the Chairman's Mark

**The Modernizing and Ensuring PBM
Accountability Act**

Scheduled for Markup
By the Senate Committee on Finance
On July 26, 2023

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SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

“Modernizing and Ensuring PBM Accountability Act”

SECTION 2. ARRANGEMENTS WITH PHARMACY BENEFIT MANAGERS WITH RESPECT TO PRESCRIPTION DRUG PLANS AND MA-PD PLANS.

Current Law

Medicare Part D is a voluntary outpatient prescription drug benefit, enacted in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA; P.L. 108-173), effective January 1, 2006. Congress designed Part D as a market-based program under which private insurers submit annual contract bids to the Centers for Medicare & Medicaid Services (CMS) to provide outpatient prescription coverage to Medicare beneficiaries. Medicare beneficiaries may buy stand-alone Part D plans (PDP) or obtain drug coverage through a Medicare Advantage (Part C) plan with a Part D component (MA-PD plan). All Part D plans must provide coverage at least as generous as the minimum standard benefit that defines the range of drugs covered by Medicare Part D and maximum enrollee cost-sharing, including deductibles and prescription co-insurance or copayments. Enrollee premiums are based on each plan’s annual cost for offering Part D benefits. Part D plan sponsors have latitude to alter plan benefit designs so long as their plans meet or exceed the standard benefit specified at SSA 1860D-2(b).

Part D plan sponsors (insurers) often contract with pharmacy benefit managers (PBMs) to design and administer Part D benefits. Since the inception of the program, Congress expected that PBMs, then already in use in the commercial insurance industry, would play a role in helping Part D plan sponsors control prices and plan costs. PBMs also perform a variety of other core functions for Part D sponsors, including developing plan formularies (lists of covered drugs and the conditions under which they are covered, including cost-sharing), contracting with networks of retail pharmacies to dispense drugs for set reimbursement from the plan sponsor, negotiating price concessions from pharmaceutical manufacturers, operating mail order and specialty drug pharmacies, and administering electronic payment systems that process billions of prescription drug claims each year. Initially, most plans contracted with independent PBMs, but more recently, many insurers that offer Part D plans have merged or affiliated with PBMs.

Federal statutes and regulations govern annual CMS contracting with Part D plan sponsors.¹ PBM contract terms and service agreements with Part D plan sponsors vary from sponsor to sponsor with regard to the specific level and type of compensation (i.e., fees vs. retention of volume-based rebates), whether a contract includes PBM performance incentives or Part D plan drug price guarantees, and definitional terms, among other items. The forms of compensation PBMs can generate from plan sponsors and entities in the supply chain related to prescription drugs dispensed under Part D are not determined in statute or regulation, and they have evolved considerably since the program’s inception by Congress in 2003.

Under current law, CMS has taken some steps to regulate some plan sponsor/PBM practices. Part D plans and their PBMs must report to CMS all price concessions that affect the price of Part D

¹ Part D contract regulations are at 42 CFR § 423.505.

drugs. The price data are used for program administration and payment. Generally, there are two main ways that drug price data are reported to CMS:

- One is a Prescription Drug Event (PDE) report that is generated whenever a beneficiary fills a prescription at a network pharmacy. The PDE includes information on the negotiated price, including the amount paid to the pharmacy for the drug, quantity dispensed, out-of-pocket spending by the beneficiary, and coverage by qualified third parties, such as other insurers.
- The second reporting method applies to price concessions that are not passed on to enrollees at the point of sale. These concessions are reported to CMS as direct and indirect remuneration, or DIR. DIR includes price concessions such as discounts, rebates, pharmacy fees and other price concessions or similar benefits from manufacturers, pharmacies or similar entities that are obtained by an intermediary organization such as a PBM with which the Part D plan sponsor has contracted.²

Provisions

These provisions would require that, beginning in plan year 2026, each Part D plan sponsor must have a written agreement with any PBM acting on its behalf under which the PBM agrees to meet the requirements outlined below. All of these requirements would apply to MA–PD plans, as well as PDPs.

These provisions also would define “pharmacy benefit manager” as any entity that acts as a price negotiator or group purchaser, manages the prescription drug benefits, processes and pays drug claims, performs drug utilization review, processes prior authorization requests, adjudicates drug plan appeals or grievances, contracts with network pharmacies, controls the cost of Part D covered drugs, or provides related services on behalf of a Part D plan. These provisions would define an “affiliate” as any entity owned by, controlled by, or related under a common ownership structure with a PBM.

I. Bona Fide Service Fees

This provision would require that a PBM and any affiliate of a PBM may not derive remuneration for services provided in connection with the use of Part D covered drugs, except in the form of bona fide service fees. The provision would define a “bona fide service fee” as a fee that reflects the fair market value for a bona fide, itemized service. A bona fide service fee would be required to be a flat dollar amount not based on the drug’s price or other related drug price benchmarks and factors. Remuneration would be subject to audit, including by the HHS OIG, to ensure adherence with these requirements.

Part D plan sponsors could continue to collect rebates, discounts, or price concessions that lower net costs for covered part D drugs. Nothing in this provision shall be construed as prohibiting a PBM from reimbursing entities that acquire prescription drugs for the ingredient cost of the products.³

²42 CFR §423.308.

³ In general, the ingredient cost is the amount paid by the pharmacy or wholesaler for the drug. It does not include pharmacy dispensing fees.

II. Transparency Regarding Guarantees and Cost Performance Evaluations

This provision would institute transparency standards for written agreements between Part D sponsors and PBMs. Specifically, the provision would require PBMs to define and apply drug and drug pricing terms in written agreements with plan sponsors in a transparent and consistent manner for purposes of calculating or evaluating PBM performance against pricing guarantees or similar cost performance measurements. PBMs would also have to identify any exceptions to such guarantees and provide a calculation of such guarantees using either the Wholesale Acquisition Cost (WAC) or an equivalent, in addition to any other benchmarks used.

III. PBM Data Reporting Requirements

This provision would set out new requirements for PBMs to annually report drug price and other information to Part D plans and to HHS. PBMs would be required to include several categories of information in their reports, including the following:

- Lists of all drugs covered;
- Information about dispensing of such drugs;
- Information about enrollee cost-sharing and access to generics and biosimilars if plans cover the brand-name drugs or biologic reference products;
- Information on other financial relationships between the PBM and other entities in the drug pricing supply chain;
- Information related to net and gross prices and total drug spending; and
- Information about the PBM's affiliates.

PBMs that are affiliated with a pharmacy must also report the following types of information:

- Information related to dispensing and costs by affiliate pharmacies;
- Information related to acquisition costs; and
- Information related to drugs subject to 340B arrangements.

This provision would also require PBMs or their affiliates to provide Part D plans with a written explanation of contracts or arrangements with a drug manufacturer (or affiliate) that makes rebates, discounts, payments, or other financial incentives related to the drug manufacturer's drug(s) contingent upon coverage, formulary placement, or utilization management conditions on other prescription drugs. The PBM would be required to provide this information shortly after the contract or arrangement with the drug manufacturer is finalized. The written agreement must be certified and would include information about the manufacturers and drugs subject to such arrangement.

IV. Confidentiality

This provision would bar the HHS Secretary from publicly disclosing information obtained from a Part D sponsor or PBM under the required agreements and reports that is not otherwise publicly available, except in limited circumstances, including:

- By the HHS Secretary to carry out this part;
- To the Government Accountability Office (GAO), the Congressional Budget Office (CBO) and the Medicare Payment Advisory Commission (MedPAC); and

- To permit oversight and enforcement by government agencies.

These agencies would not be permitted to report on or disclose the information in a way that would identify a specific supply chain stakeholder or prices for specific drugs.

V. Audit Rights

This provision would permit audits of a PBM, no less than once a year, if requested by a Part D sponsor, including to ensure the accuracy of drug price information reported under these provisions. The Part D plan sponsor would have the right to select the auditor. The PBM would be required to provide information to the auditor necessary to perform the audit and confirm the accuracy of PBM reporting, including information owned or held by a PBM's affiliate, in a timely manner. The HHS Secretary would be allowed to include reasonable restrictions on how the information is reported to prevent redisclosure.

VI. Enforcement

This provision would require a PBM to:

- Disgorge remuneration received by the PBM or an affiliate of such PBM in violation of the bona fide service fee requirements;
- Reimburse the Part D sponsor for any civil money penalty imposed on the sponsor due to the failure of the PBM to meet the requirements of these provisions; and
- Be subject to punitive remedies for breach of contract for failing to comply with the requirements of these provisions.

This provision would also require each Part D sponsor to provide the HHS Secretary an annual certification of compliance with the provisions outlined above, as well as such information as the Secretary determines necessary to carry out this subsection.

VII. Funding

This provision would provide \$20 million to CMS for FY 2026 and \$5 million to the HHS OIG. The funds would remain available until expended.

VIII. GAO Report on Certain Pricing Requirements

This provision would require GAO to conduct a study of federal and state reporting requirements for health plans and PBMs regarding the transparency of prescription drug costs and prices. Study results would be required to include recommendations for legislation and administrative actions to streamline and reduce burden with respect to the reporting requirements for health plans and PBMs.

SECTION 3. ENSURING FAIR ASSESSMENT OF PHARMACY PERFORMANCE AND QUALITY UNDER MEDICARE PART D.

Current Law

Part D plan sponsors and PBMs create contracted networks of retail pharmacies that dispense covered drugs for set reimbursement. Part D regulations⁴ require plan sponsors to have standard pharmacy contracts with reasonable and relevant terms and conditions of participation, and to allow any willing pharmacy to participate in a basic pharmacy network. Actual contract terms vary among Part D plans, however, meaning retail pharmacies, which often contract with multiple Part D plans, may have to navigate differing plan contract payment and other terms.

CMS regulations generally require Part D plan sponsors to report data to CMS regarding pharmacy performance.⁵ Thus, many plans and PBMs use quality measures to evaluate pharmacy performance in various areas, such as medication adherence and generic dispensing. In recent years, however, pharmacies have reported that quality measures imposed by plans and PBMs are unpredictable, sometimes irrelevant to the pharmacy, and measure outcomes over which pharmacies have limited control.⁶

Provision

This provision would require the HHS Secretary to institute standard Part D measures for assessing network pharmacy performance, starting in 2025. Under the provision, a Part D sponsor that wanted to institute fees, price concessions, or incentive payments based on network pharmacy performance would be able to do so only if the plan sponsor/PBM used performance measures that were: (1) established or adopted by the HHS Secretary; and (2) relevant to the pharmacy.

The HHS Secretary would be required to establish or adopt standardized pharmacy performance measures that were: (1) evidence-based and reasonable; and (2) focused on pharmacy performance related to patient health outcomes and other areas that pharmacies can impact, as determined by the Secretary. The Secretary's determination may be based on data and information from relevant stakeholders.

Rather than establishing some or all of the required performance measures, the Secretary may adopt measures endorsed by a multi-stakeholder consensus organization (such as the Pharmacy Quality Alliance), that has participation from pharmacies, health plans, PBMs, and CMS. The performance measure list would be subject to periodic evaluation and revision by the Secretary.

This provision would provide \$4 million to CMS in FY 2025 to carry out the provision. The

⁴ 42 CFR §423.505.

⁵ 42 CFR §423.514(a)(5).

⁶ Frier Levitt and the National Association of Specialty Pharmacy. “”Performance”Based DIR Fees: A Rigged System with Disparate Effect on Specialty Pharmacies, Medicare Part D Beneficiaries and the U.S. Healthcare System.” March 20, 2017. <https://communityoncology.org/research-publications/studies/performance-based-dir-fees-a-rigged-system-with-disparate-effect-on-specialty-pharmacies-medicare-part-d-beneficiaries-and-the-us-healthcare-system/>.

funds would remain available until expended.

SECTION 4. PROMOTING TRANSPARENCY FOR PHARMACIES UNDER MEDICARE PART D.

Current Law

Just as drug pricing and formulary coverage vary among Part D plans, pharmacy reimbursement from Part D plans also differs depending on formulary requirements, plan specifications, and a plan's negotiated price for a drug. Pharmacies dispense billions of Part D drugs each year, and payments from Part D plan sponsors are processed in real time at the point of sale through electronic systems that aggregate plan-specific data including the drug ingredient cost, dispensing fees, cost-sharing requirements, and other third-party sources of payment.

In recent years, CMS has noted a sharp rise in pharmacy fees and other price concessions that plan sponsors and PBMs have extracted from retail pharmacies after the point of sale and reported as DIR. Part D pharmacy DIR includes such things as administrative fees, network access fees, and fees for not meeting plan quality metrics. Part D plan sponsors may provide incentive payments to pharmacies for meeting specified goals, but CMS data indicate that fees have far outweighed additional compensation to pharmacies. According to CMS, pharmacy fees are the fastest-growing category of DIR, accounting for nearly 5% of gross Part D drug costs (\$9.5 billion) in 2020, compared to 0.01% (\$8.9 million) in 2010. The increase in fees, and the fact that they are imposed after the point of sale, have made it difficult for pharmacies to predict their total reimbursement for dispensing a drug.⁷ Differences in reporting of negotiated prices among Part D plans can also affect beneficiary cost sharing, CMS payments to plans, and according to CMS, can diminish competition between Part D plans.

In May 2022, CMS issued a final rule, effective in 2024, to help address the uncertainties in pharmacy reimbursement caused by PBM fee requirements. The rule changes the definition of "negotiated price" to include the lowest possible reimbursement that a network pharmacy will receive in total for dispensing a drug.⁸ Part D plan sponsors are required to take the rule change into account when submitting 2024 contract bids.

Provision

This provision would establish a process by which Part D sponsors provide their network pharmacies with comprehensive information about pricing of prescription drug claims. The new system would be required to take effect in 2025.

This provision would provide \$2 million for FY 2025 to CMS to carry out the provision. The funds would remain available until expended.

⁷ CMS, "Medicare Program: Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs," 87 *Federal Register*, May 2022, p. 1413, <https://www.federalregister.gov/d/2022-09375/p-1413>.

⁸ CMS, "Medicare Program: Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs," 87 *Federal Register*, May 2022.

SECTION 5. PREVENTING THE USE OF ABUSIVE SPREAD PRICING IN MEDICAID.

Current Law

State Medicaid programs reimburse statutorily defined retail community pharmacies for covered outpatient drugs (CODs) dispensed to Medicaid beneficiaries. The payment to retail community pharmacies has two components: an amount to cover the cost of acquiring the drug (ingredient cost) and an amount for the pharmacist's professional services in filling a prescription (dispensing fee).

The Patient Protection and Affordable Care Act (ACA, P.L. 111-148) required drug manufacturers that participate in the Medicaid drug rebate program to provide rebates on CODs that are dispensed to beneficiaries covered under a managed care organization (MCO) that contracts with the state Medicaid program. Most MCOs and other entities that provide Medicaid prescription drug benefits contract with PBMs to manage and administer the drug benefits. Generally, MCOs pay PBMs for drugs supplied to Medicaid beneficiaries based on a published price, such as a percentage of the average wholesale price (AWP), while PBMs separately determine payment to pharmacies. Even though the difference (spread) between MCO payments to PBMs and PBM payments to pharmacies may be small for individual drugs, it can be substantial when aggregated for all drugs.

Contracts between Medicaid MCOs and PBMs sometimes are based on the margin (spread) between the amount charged to the MCO for a COD and the amount paid by a PBM to the pharmacy provider.⁹ Effective April 2017, the Centers for Medicare & Medicaid Services required prescription drug benefits under fee-for-service Medicaid programs to use a drug pass-through pricing model, but this requirement does not apply to Medicaid MCOs. Under pass through pricing PBMs charge their MCO clients the actual amount it reimburses the pharmacy for CODs, then passes back all the rebates from manufacturers, and collects explicit administrative fees as income. Although CMS has issued spread pricing guidance,¹⁰ federal statute does not prohibit the use of spread pricing in contracts between Medicaid MCOs and PBM or other entities.¹¹

Provision

The provision requires a pass-through pricing model for covered outpatient drugs reimbursed under Medicaid, including when services are provided under contract with MCOs. This section would require payment for PBM services to be limited to the ingredient cost and a professional dispensing fee that is no less than the professional dispensing fee paid under fee-for-service

⁹ Centers for Medicare & Medicaid Services (CMS), Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program, 88 *Federal Register* 34249, May 26, 2023.

¹⁰ CMS, Center for Medicaid and CHIP Services Informational Bulletin, Medical Loss Ratio (MLR) Requirements Related to Third-Party Vendors, May 19, 2019.

¹¹ CMS, Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program, 88 *Federal Register* 34250, May 26, 2023.

through a state plan or waiver and passed through in their entirety to the dispensing pharmacy. The provision would allow an exception to the pass-through payment requirement for drugs purchased by 340B covered entities.

Payments to PBMs for administrative services would be limited to the fair market value of those services. PBMs and other entities would be required to make available to state Medicaid programs, and the Secretary upon request, all specified costs and payments related to CODs and accompanying administrative services.

This provision would also prohibit any form of spread pricing that exceeds the amount paid to pharmacies or providers on behalf of the state for purpose of claiming federal Medicaid matching payments. State Medicaid programs would be prohibited from making payments to certain specified health plans unless the contract between the state and the entity met the Medicaid rebate program and other prescription drug requirements.

This provision would apply to state Medicaid program contracts between MCOs, other specified entities, and PBMs with an effective date that begins 18 months after this law's enactment date.

SECTION 6. ENSURING ACCURATE PAYMENTS TO PHARMACIES UNDER MEDICAID.

Current Law

State Medicaid programs reimburse statutorily defined retail community pharmacies for covered outpatient drugs dispensed to Medicaid beneficiaries based on two components: (1) the cost of the medicine, the ingredient cost; and (2) a payment for the cost to the pharmacy of administering and filling a prescription (i.e., the professional dispensing fee). State Medicaid programs, subject to CMS approval, determine pharmacy ingredient payment rates, as well as professional dispensing fees.

For multiple source drugs with generic equivalent products, state Medicaid programs are subject to annual aggregate upper limits on payments. Prices available for multiple source drugs can vary widely, so upper payment limits ensure states pay competitive prices. State Medicaid programs are required to have a CMS-approved methodology to determine multiple source drug payments, including addressing the ingredient costs and pharmacy dispensing fees. Medicaid regulations require states to base the ingredient cost component for multiple source drugs on each product's actual acquisition cost (AAC). State Medicaid programs have discretion in determining AAC, such as using a state administered pharmacy survey to determine a drug's average cost or using the results of a national drug acquisition cost survey of retail community pharmacies authorized in Medicaid statute.

The Deficit Reduction Act of 2005 (DRA, P.L. 109-171) amended SSA Section 1927 by adding a new subsection (f) that required the Department of Health and Human Services Secretary (the Secretary) to retain a contractor to survey retail community pharmacies. To implement the survey, CMS contracted for the National Average Drug Acquisition Cost (NADAC) survey. NADAC is a monthly survey of acquisition costs paid for most covered outpatient drugs,

including multiple source and single source (brand name) drugs and biological products. CMS, through a contractor, surveys a national random sample of retail community pharmacies monthly and has been publishing NADAC data since November 2013. Pharmacy participation in NADAC is voluntary, but to provide a national estimate of average acquisition costs, it is important that the sample is representative of all geographic areas and different pharmacy types such as independent and chain pharmacies.

Provision

This provision would require the Secretary to survey retail community pharmacies drug prices in the 50 states and the District of Columbia to determine national average drug acquisition costs. Retail community pharmacies that receive payment related to the dispensing of CODs to individuals receiving benefits under Medicaid would be required to respond to the survey. The Secretary would be authorized to use a vendor to conduct the NADAC survey of Medicaid covered outpatient drugs. Information on national drug acquisition prices obtained through the NADAC survey would be publicly available, as would other specified information on the NADAC survey. The NADAC survey also would identify information on price concessions to the pharmacy.

The HHS Secretary may enforce noncompliance with the NADAC survey through monetary penalties or by fully or partially suspending Medicaid payments until the pharmacy complies. State Medicaid programs would be required to report additional information including the basis for setting drug dispensing fees as well as payment rates under Medicaid managed care plans.

This provision would be effective 18 months after this law's enactment date. The Secretary would receive a \$5 million appropriation in FY2024 and each fiscal year thereafter to conduct the NADAC survey.

SECTION 7. HHS OIG STUDY AND REPORT ON DRUG PRICE MARK-UPS IN MEDICARE PART D.

Current Law

The past several decades have seen rapid consolidation in the health care sector, including among PBMs. The early 2000s saw horizontal integration as freestanding PBMs merged. More recently, there has been vertical integration, with major PBMs now owned by, or affiliated with, retail pharmacy chains, insurers, and health care providers such as hospitals. As a result of the consolidation, the three largest PBMs were expected to account for nearly 80% of prescription claims processed in 2022.¹² In addition, some PBMs have entered into strategic agreements with insurers and retail pharmacies to provide certain services to insurers and retail pharmacies.

It can be difficult to determine the pricing structure and flow of funds within these vertically integrated entities. MedPAC's June 2023 report, however, included an analysis that suggested

¹² Adam J. Fein, "The Top Pharmacy Benefit Managers of 2022: Market Share and Trends for the Biggest Companies," *Drug Channels*, May 23, 2023, <https://www.drugchannels.net/2023/05/the-top-pharmacy-benefit-managers-of.html>.

vertically integrated organizations, such as pharmacy benefit managers affiliated with a health plan and at least one pharmacy channel, appear to be paying their affiliate pharmacies more than other pharmacies. Specifically, in comparing Part D payments between plan-sponsor-affiliated (vertically integrated) pharmacies and non-affiliated (non-vertically integrated) pharmacies, MedPAC found that in 71 percent of cases, plans incurred the highest average net drug costs for transactions with their pharmacy affiliates.¹³ Other recent studies have found that Part D may be overpaying for certain medicines relative to purchases made by entities such as Costco or the Mark Cuban Cost Plus Drug Company, potentially by billions of dollars.¹⁴

Provision

This provision would require the HHS OIG to study how vertical integration between Part D plans, PBMs, and pharmacies affects Part D plan negotiated prices (i.e., the prices Part D plans charge the Medicare program for drugs dispensed to Part D enrollees). The study would include an analysis of the following:

- Affiliate acquisition costs within vertically integrated entities;
- Transfer pricing and margin created between affiliates;
- The impact of such transactions on Part D; and
- Other issues determined to be relevant and appropriate by the Inspector General.

The Inspector General would submit the study under a specified timeframe to the Senate Finance and House Energy and Commerce and Ways and Means Committees. The provision would provide \$5.2 million to the HHS OIG for FY 2024 to carry out the provision, to remain available until expended.

SECTION 8. MEDICARE IMPROVEMENT FUND.

Current Law

The Medicare Improvements for Patient and Providers Act (MIPPA) established the Medicare Improvement Fund (MIF), available to the Secretary to make improvements under the original fee-for-service program under Parts A and B for Medicare beneficiaries. Under current law, \$180 million is available for services furnished during and after FY2022.

Provision

This provision would direct \$1.726 billion in savings to the MIF.

¹³ MedPAC June 2023 Report: https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_MedPAC_Report_To_Congress_SEC.pdf

¹⁴ Lalani, H. et al. (July 2022). “Potential Medicare Part D Savings on Generic Drugs From the Mark Cuban Cost Plus Drug Company.” *Annals of Internal Medicine*. Available at: <https://pubmed.ncbi.nlm.nih.gov/35724381/>; Trish, E. et al. (July 2021) “Comparison of Spending on Common Generic Drugs by Medicare vs Costco Members.” *JAMA*. Available at: <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2781810?guestAccessKey=89d9de51-fc11-4451-97aa-90b352b7867b>

APPENDIX. COMMON INSURANCE AND PRESCRIPTION DRUG TERMS

Biologics (Biological Products): Products derived from living organisms, which can include animal cells and microorganisms, often produced through the use of biotechnology in a living system, such as a cell, for the treatment of various medical conditions.

Brand-Name Drug: The Food and Drug Administration (FDA) defines a brand-name drug as a drug marketed under a proprietary, trademark-protected name.

Coinsurance: The percentage share that an enrollee in a health insurance plan pays for a product or service covered by the plan. An insurer could charge 10% coinsurance for a \$100 prescription drug, meaning the consumer's out-of-pocket cost would be \$10.

Co-payment: A fixed dollar amount that an enrollee in a health insurance plan pays for a product or service covered by the plan. For example, an insurer could charge a \$20 co-payment for a physician visit or a \$5 co-payment for a prescription drug.

Cost Sharing: Refers generally to health plan deductibles, coinsurance, or co-payments for drugs or services. Does not include plan premiums.

Deductible: The amount an enrollee is required to pay for health care services or products before his or her insurance plan begins to provide coverage. An enrollee in an insurance plan with a \$500 deductible would be responsible for paying for the first \$500 in health care services. In some insurance plans, the deductible does not apply to certain services, such as preventive care. Insurance plans vary regarding whether beneficiaries must meet a deductible for prescription drug coverage.

Formulary: A list of prescription drugs covered by an insurance plan. In an effort to control costs, insurers are imposing closed or partially closed formularies, which include a more limited number of drugs than traditional formularies.

Generic: A generic drug is identical to a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price.

Out-of-Pocket Costs: The total amount an insured consumer pays each year for covered health care services that are not reimbursed by an insurance plan. Out-of-pocket costs can include deductibles, co-payments, and coinsurance.

Pharmacy Network: A group of retail, mail-order, and specialty pharmacies that contract with PBMs and health insurers to dispense covered drugs at set prices. Network pharmacies also may provide other services under contract, such as monitoring patient adherence to drugs.

Specialty Drug: There is no one set definition of specialty drugs, although insurers and other health care payers often characterize them as prescription products requiring extra handling or

administration that are used to treat complex diseases, such as cancer. Biologics, or drugs derived from living cells, often are deemed specialty drugs.

Tiered Pricing: Insurers use tiered cost sharing for formulary drugs, meaning patients face lower co-payments or coinsurance for less expensive generic drugs and certain brand-name drugs designated by the plan as preferred drugs, based on the price the plan has negotiated with the manufacturer and the product's effectiveness. At the same time, patients are charged higher co-payments or coinsurance for more expensive drugs (including specialty drugs) or drugs the plan deems to be less effective.

Drug Price Terms

Average Wholesale Price (AWP): The AWP is a market-derived approximation of a drug's list price. It is typically higher than list price. The AWP is available from private publishers, such as Red Book and Medispan. It is not a regulated price measure.

Medicare Part D Negotiated Price: Part D sponsors must provide beneficiaries with access to negotiated prices for covered drugs at the point of sale that "take into account" any rebates, discounts, or other direct and indirect price concessions obtained by the plans (SSA §1860D-2(d)(1)(B)). Plan sponsors have some latitude to decide what price concessions to include in the negotiated price at the point of sale, and may choose to pass price concessions through to beneficiaries outside of negotiated prices, such as in the form of lower monthly plan premiums.

Wholesale Acquisition Cost (WAC): WAC, as defined in Medicare statute (SSA §1847A(c)(6)(B)), is a drug manufacturer's most recent monthly list price to U.S. wholesalers or direct purchasers, excluding prompt payment discounts or other discounts, rebates, or price reductions, as published in drug pricing compendia.