PCMA

Glossary of Drug Pricing Terms

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Contents

List of Common Abbreviations

ABBREVIATION	DEFINITION
AAC	Average Acquisition Cost
ACA	Affordable Care Act
AMP	Average Manufacturer Price
ASP	Average Sales Price
AWP	Average Wholesale Price or Any Willing Pharmacy
BER	Brand Effective Rate
CAHPS	Consumer Assessment of Healthcare Providers and Systems
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CER	Comparative Effectiveness Research
CMR	Comprehensive Medication Review (Part of MTM)
CMS	Centers for Medicare & Medicaid Services
COC	Certificate of Coverage
DEA	Drug Enforcement Agency
DIR	Direct and Indirect Remuneration
DOL	Department of Labor
DUR	Drug Utilization Review
EDI	Electronic Data Interchange
EOB	Explanation of Benefit
ePA	Electronic Prior Authorization
EPCS	Electronic Prescribing for Controlled Substances
ERISA	Employee Retirement Income Security Act
FDA	Food and Drug Administration
FFS	Fee-for-Service
FSA	Flexible Spending Account
GER	Generic Effective Rate
GPI	Generic Product Identifier
GPO	Group Purchasing Organization
HDHP	High-Deductible Health Plan
HEDIS	Healthcare Effectiveness Data and Information Set
HIPAA	Health Insurance Portability and Accountability Act
HRA	Health Reimbursement Arrangement

ABBREVIATION	DEFINITION
HSA	Health Savings Account
IRA	Inflation Reduction Act
MAC	Maximum Allowable Cost
MAF	Manufacturer Administrative Fee
MA-PDP	Medicare Advantage-Prescription Drug Plan
MCO	Managed Care Organization
MDRP	Medicaid Drug Rebate Program
MLR	Medical Loss Ratio
MPR	Medication Possession Ratio
MTM	Medication Therapy Management
NADAC	National Average Drug Acquisition Cost
NCPDP	National Council for Prescription Drug Programs
NCQA	National Committee for Quality Assurance
NDC	National Drug Code
NPI	National Provider Identifier
OOP	Out-of-Pocket
OTC	Over-the-Counter
P&T	Pharmacy and Therapeutics (as in P&T Committee)
PA	Prior Authorization
PBM	Pharmacy Benefit Manager
PDP	Part D Prescription Drug Plan
PCMH	Patient Centered Medical Health/Homes
PCP	Primary Care Provider
PHS	Public Health Service
PHSA	Public Health Service Act
PQA	Pharmacy Quality Alliance
PSAO	Pharmacy Services Administrative Organizations
QL	Quantity Limit
QRS	Quality Rating System
RFP	Request for Proposal
RTBT	Real-Time Benefit Tools
UM	Utilization Management
URAC	Utilization Review Accreditation Commission
WAC	Wholesale Acquisition Cost

Drug Pricing Terms

#

340B Contract Pharmacy – A pharmacy under contract with a 340B covered entity to dispense drugs on behalf of the 340B covered entity. The use of an individual contract pharmacy or multiple contract pharmacies is voluntary, and a covered entity should first determine its needs for pharmacy services and the appropriate distribution mechanism for those services when deciding whether or not to utilize a contract pharmacy. Information on contract pharmacies can be found here: HRSA.gov- Contract Pharmacy

340B Covered Entity – Eligible 340B covered entities are defined in statute and include health centers designated by Health Resources and Services Administration (HRSA), an agency within the Public Health Service (PHS) of the U.S. Department of Health and Human Services (HHS), as well as Ryan White clinics and State AIDS Drug Assistance programs, Medicare/Medicaid Disproportionate Share Hospitals, children's hospitals, and other safety net providers. A full listing can be found here: HRSA.gov

340B Drug Pricing Program – This program was established with the intent of helping certain hospitals and other facilities—known as covered entities—acquire drugs at discounted prices from manufacturers, which would, in turn, allow those entities to pass the savings along to vulnerable patients, improving their access to drugs. The program was created through the Veterans Health Care Act of 1992, which added Section 340B to the Public Health Service Act (PHSA) and is administered by HRSA. Medicaid eligibility and 340B participation are linked, but the programs are separate, and federal law prohibits duplicate discounts (i.e., mandated Medicaid rebates do not apply to drugs obtained at 340B pricing).

A

Abbreviated New Drug Application (ANDA) – An Abbreviated New Drug Application (ANDA) contains data for the review and ultimate approval of a generic drug product. Generic drug applications are called "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, a generic applicant must scientifically demonstrate that its product is bioequivalent (i.e., meaning that it has the same amount of active ingredient, and performs essentially identically to the innovator drug). Once approved, an applicant may manufacture and market the generic drug product to provide the public with a safe, effective, low-cost alternative.

Affordable Care Act (ACA) – ACA, also known as Obamacare, is the comprehensive health care reform legislation enacted in 2010 that makes insurance more affordable for low- to moderate-income Americans. The ACA marketplace, called the Exchange, is where ACA health plan sponsor offerings are sold.

Average Acquisition Cost (AAC) – AAC is the average of the actual price—net of all rebates and discounts—paid to the wholesaler for acquiring the drug.

Alternative Funding Program – A plan design option in which health plan sponsors (see definition under "plan sponsor") lower costs by excluding coverage for certain, typically very high-cost, specialty medications. Working with the plan sponsor, alternative funding vendors inform patients that their benefits have changed and direct them to seek their medications from manufacturer patient assistance programs (PAPs). If a patient is not eligible for a manufacturer's PAP, the patient may pay out of pocket (OOP), try to find funding through a foundation, have to rely on a secondary insurer (Medicare or Medicaid), or not receive treatment.

Any Willing Pharmacy (AWP) – A policy that allows an interested pharmacy that is willing to accept the network participation terms and conditions of the plan sponsor to participate as an in-network contract pharmacy. AWP also refers to policies requiring PBMs and health plan sponsors to include such a pharmacy in their networks. This policy limits the use of performance-based metrics to assess the pharmacy and impacts the ability of the plan network administrator to exclude or terminate underperforming pharmacies or those not equipped to manage complex medications.

Average Manufacturer Price (AMP) – The average price paid to the manufacturer by wholesalers and pharmacies that purchase directly from a manufacturer. AMP, which is defined under federal law, is used to calculate drug rebates under the Medicaid drug rebate program. As of 2024, there no longer is any limit or cap on Medicaid drug rebates, so manufacturers who have large price increases may now be at risk for paying rebates above the total cost of the drug, which may further incentivize manufacturers to launch drugs at higher prices.

Average Sales Price (ASP) – A manufacturer's average sales price to all purchasers, net of discounts, rebates, chargebacks, and credits applied during the sales process for drugs and biologicals covered under Medicare Part B. ASP is calculated by dividing the total revenue earned by the total units sold.

Average Wholesale Price (AWP) – AWP is an average price, or "sticker price" or "list price" for a drug sold by wholesalers to retail pharmacies, physicians, and other retail purchasers before any discounts or concessions. AWP, which is not a government-regulated price, often serves as the basis for payment negotiations between wholesalers and retail pharmacies. AWP, which is reported by commercial publishers of drug pricing data, such as First DataBank and Thomson Medical Economics, is based on information obtained from manufacturers, wholesale distributors, and other suppliers.

B

Beneficiary – Under Medicare, eligible individuals are generally referred to as beneficiaries, but once they enroll in a plan, they are considered enrollees in that plan. (see Enrollee)

Benefits Consultant – Benefits consultants are experts in health care benefits who advise employers and other plan sponsors in developing requests for proposals (RFPs) that set forth detailed requirements for the sponsor's health benefit offerings, including pharmacy benefits. For pharmacy benefit carve-outs, the consultants help select and then negotiate the contract with the PBM to best achieve the plan sponsor's desired pharmacy benefit design.

Best Price – The Medicaid best price policy requires drug manufacturers to give Medicaid programs the best price for drugs among nearly all purchasers, including wholesale distributors, retailers (pharmacies), providers, or government entities. Medicaid in turn must cover all the manufacturer's drugs. Exceptions to best price include prices paid by the Department of Defense, the Veterans Administration, and under 340B, as well as prices negotiated under Medicare Part D.

Biologic License Application (BLA) – The primary goal of a BLA is to demonstrate the safety and effectiveness of a biologic product allowing the FDA to evaluate and ultimately approve the biologic for marketing. A BLA contains specific information on the manufacturing processes, chemistry, pharmacology, clinical pharmacology, and the medical effects of the biologic product (see biological product). If the information provided meets FDA requirements, the application is approved and a license is issued, allowing the firm to market the product. Biological products are approved for marketing under the provisions of the Public Health Service Act (PHSA), which require a firm that manufactures a biologic for sale in interstate commerce to hold a license for the product.

Biological Product – Biological products are a diverse category of products and are generally large, complex molecules. These products may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to characterize than small molecule drugs. Because they are manufactured from living cells, subsequent batches of these products are never exact replicas, but they produce the same predictable results in patients. The biological products are approved under a BLA and listed in the FDA Purple Book (see Purple Book).

Biosimilar – A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference biological product.

Biosimilar Substitution – See Interchangeable Product.

Brand Effective Rate (BER) – BER is the relative rate of the full cost of pharmacy reimbursement (drug ingredient cost and dispensing fee) of all brand drugs over a defined period of time expressed as a discount of the total weighted average AWP for those same brand drugs over the specified time period. Reimbursement in some preferred pharmacy networks may be based at least in part on BER.

Brand-Name Drug – A brand-name drug is a drug marketed under a proprietary, trademark-protected name. Brand-name drugs typically receive multi-year patent protection upon approval by the FDA, which allows the innovator manufacturer to market its product exclusively.

Brown Bagging (also see white bagging) **–** A process that removes the provider from the drug acquisition process by using a specialty pharmacy to dispense provider-administered drugs directly to the patient for delivery to a provider's office, where the provider then administers the drug to that patient. The specialty pharmacy bills the plan sponsor directly for the medication.

C

Carve-Out Pharmacy Benefit – In a carve-out pharmacy benefit, the plan sponsor "carves out" the pharmacy benefit from the medical benefit and hires a PBM separate from the medical benefits administrator to provide and manage these pharmacy benefits.

Catastrophic Coverage – Catastrophic coverage refers to insurance coverage that begins after an individual or an entity has spent or incurred a specified, usually significant sum of money. Under the Medicare Part D prescription drug benefit, starting January 1, 2024, after an enrollee's total drug costs reach $8,000 (i.e., coverage gap limit), the enrollee will not be responsible to pay any OOP cost share for covered Part D drugs for the rest of the year.

Central Fill – An intermediary pharmacy that is permitted by the state to prepare orders for dispensing by a registered retail pharmacy. The central fill pharmacy returns the labeled and filled prescription(s) to the retail pharmacy for delivery to the ultimate user. Such central fill pharmacy is "authorized" to fill prescriptions on behalf of a retail pharmacy only if the retail pharmacy and central fill pharmacy have a contractual relationship providing for such activities or share a common owner. Central fill pharmacies can add efficiency for retail pharmacies and can also provide mail-order pharmacy services.

Certificate of Coverage (COC) – A COC is a contract that sets forth an individual's health insurance coverage as issued by their health plan sponsor. The COC details the health benefits the individual (and their dependents) have under the plan, including exclusions and applicable cost shares.

Chain Pharmacy – A group of pharmacies with four or more pharmacy locations under common ownership. (also see Independent Pharmacy)

Claim – A request from a dispensing entity (e.g., a pharmacy or pharmacist, hospital, or clinician's office) to be reimbursed for the cost of filling or refilling a prescription or for providing a medical service, supply, or device to a patient.

Clawback (also see DIR) **–** A term that may be used to describe the practice of a plan sponsor or PBM retroactively changing the amount reimbursed to a pharmacy for a claim after review, often after finding overpayment or underpayment due to (i) clerical errors submitted by the pharmacy, (ii) the pharmacy not meeting agreed-upon performance metrics; or (iii) the pharmacy's failure to otherwise meet the terms of a network contract. Retractive reconciliations, which may include both increased and decreased payments, are performed to ensure payments align with contract terms.

Coinsurance – Determined by the plan benefit design, coinsurance is a type of OOP patient cost sharing calculated as a predetermined percentage of the billed or allowed costs for a medical service or products, including drugs covered under the plan, where the plan sponsor is responsible for the rest of the costs.

Copayment – Determined by a plan benefit design, copayments are a type of OOP patient cost sharing calculated as a predetermined flat fee a patient pays when visiting a doctor, hospital, or other health care provider or receiving a prescription from the pharmacy.

Copay Accumulator – A health plan program designed to allow a patient to use a drug manufacturer's coupon offerings without a coupon counting toward the patient's deductible and annual out-of-pocket maximum. While the coupon is applied to reduce overall plan expense, once the coupon is exhausted, the patient pays the full amount of the deductible before their plan benefits begin to cover the cost of the drug.

Copay Maximizer – A health plan program designed to allow a patient to use a drug manufacturer's coupon offerings and apply it to the cost sharing. Under this model, the total value of the coupon is applied evenly throughout the benefit year, reducing the patient's out-of-pocket expense as well as the plan's.

Community Pharmacy – (see Retail Pharmacy)

Cost Share – The amount the patient is required to pay OOP that is not covered by the plan sponsor. Coinsurance and copayments are both cost shares.

Coverage Gap/Donut Hole – (see Medicare Part D Redesign) The Medicare Part D coverage gap or donut hole is the phase of coverage after the initial coverage period. Enrollees enter the donut hole when their total covered drug costs, including what they and their plan sponsor have paid, reach a certain limit (the 2024 limit is $5,030); 2024 is the last year for the donut hole.

Catastrophic Coverage – (see Medicare Part D Redesign) Catastrophic coverage under Medicare Part D refers to the phase of coverage where, as of 2024, once reached, the enrollee pays nothing for covered drugs for the rest of the year.

D

Deductible – The amount determined by benefit design that a patient pays for health care services or products before their insurance plan begins to pay. Once this amount has been reached, patients usually pay a copayment or coinsurance for services or products while the insurance company is responsible for the rest.

Delinking – Manufacturers, pharmacies, wholesalers, physicians, PBMs, and other participants in the drug supply chain are often compensated based on the list price of a drug. Delinking is a term used to describe proposals that would prohibit some or all of the participants in the drug supply chain from being compensated based on the list price of a drug or a drug pricing standard.

Digital Therapeutics – Digital therapeutics (DTx) are evidence-based therapeutic interventions that are driven by high-quality software programs to prevent, manage, or treat a medical disorder or disease. They are used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes. Digital therapeutics products incorporate advanced technology best practices relating to design, clinical validation, usability, and data security. They are reviewed and cleared or approved by regulatory bodies as required to support product claims regarding risk, efficacy, and intended use.

Dispensing Fee – A fee paid to a pharmacist for dispensing a medication. The fee is paid in addition to reimbursement for the cost of the drug.

Direct and Indirect Remuneration (DIR) – Under Medicare Part D, DIR includes any price concession received by or paid by a PBM that impacts final prescription drug costs for the Medicare program. In the context of pharmacies, DIR arises when pharmacies participating in the Part D preferred network are assessed against performance standards related to quality of care. When network pharmacies meet or exceed the standards, they are eligible for additional payments, and when they fall short, they are required to reimburse the plan sponsor. The amount owed back to the plan sponsor may be referred to as a "clawback" by the pharmacy. As of 2024, the Centers for Medicare & Medicaid Services (CMS) has eliminated the retroactive application of DIR fees. Such fees must now be reflected in the negotiated price the patient pays when they receive their medication.

Drug Coupon – A marketing tool used by drug manufacturers to reduce patient cost sharing at the pharmacy for certain brand medications. Coupons are often processed after a patient's insurance claim. Removing the cost considerations encourages the use of more expensive drug products instead of lower-cost generics or therapeutically equivalent alternatives. These offerings may come in the form of a coupon, debit card, or some other arrangement that does not clearly indicate the source of payment.

Drug Manufacturer – Manufacturer means an entity that owns or operates an establishment that manufactures a drug. This term includes, but is not limited to, control laboratories, contract laboratories, contract manufacturers, contract packers, contract labelers, and other entities that manufacture a drug.

Drug Patent – Patents, including those for drugs, are a proprietary right granted by the United States Patent and Trademark Office to protect the holder of a unique product, process, or technology against market competition. A patent prevents the invention from being produced, sold, or used by competitors for a limited time. Drug patents typically last for 20 years due to the range of extension schemes utilized by manufacturers.

Drug Patent Thicket – Protecting a product with as many patents as a drug company can attain. Drug patent thickets are made up of duplicate patents linked through terminal disclaimers, secondary patents, and/or patents on each component or feature of a drug or device.

Drug Shortages – The Federal Food, Drug, and Cosmetic Act defines a drug shortage as a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug. FDA tracks shortages at the national level and receives information from manufacturers about their ability to supply the market.

Drug Utilization Review (DUR) – A patient safety check typically required by states and performed by a pharmacist. Pharmacists evaluate prescriptions based on health conditions, allergies, drug interactions, patient demographics, laboratory values, and other values to ensure the medication is safe for the patient. Reviews are concurrently completed by pharmacists dispensing at any pharmacy, and at the PBM or plan sponsor. There are three forms of DUR: prospective (before dispensing), concurrent (at the time of prescription dispensing), and retrospective (after the therapy dispensing).

E

Electronic Prior Authorization (ePA) – Electronic Prior Authorization (ePA) is the electronic transmission of information between the prescriber and health plan sponsor to determine whether the prior authorization on a prescription is granted by the sponsor. The National Council for Prescription Drug Programs (NCPDP) has developed technical standards to support this electronic transmission and improve the timeliness of the exchange of information.

Electronic Prescription (ERx or e-script or e-prescribe) – Using standards created by NCPDP, a prescriber is able to electronically send an accurate, error-free, and understandable prescription directly to a pharmacy from the point of care, which is an important element in improving the quality of patient care. ERx replaces a handwritten, verbal, or faxed prescription.

Electronic Prescriptions for Controlled Substances (EPCS) – EPCS establishes the standards authorizing a prescriber to electronically transmit prescriptions for controlled substances (e.g., opioids or high abuse potential) directly to a pharmacy from the point of care. CMS mandates the use of EPCS, and the Drug Enforcement Agency (DEA) has requirements for provider and pharmacy systems.

Employee Retirement Income Security Act (ERISA) – ERISA is the federal law governing employee health benefit plans, which also applies to employer-provided health insurance. The U.S. Department of Labor (DOL) defines "ERISA" as "a federal law that sets minimum standards for most voluntarily established retirement and health plans in private industry to provide protection for individuals in these plans." First enacted in 1974, federal ERISA law is the result of plan sponsors, including businesses and unions, seeking to have a uniform standard of benefits for their employees across state lines. To achieve this goal, ERISA includes a robust preemption provision that prevents states from imposing a patchwork of conflicting state laws. Many health plans organized under ERISA are self-insured/self-funded, meaning that the plan sponsor, rather than a third party, bears the risk of coverage. This is distinct from fully insured plan sponsors, who purchase third-party health insurance to establish coverage and hold the ultimate risk.

Enrollee – A person enrolled in and covered by a health plan sponsor, also known as a member. Under Medicare, eligible individuals are generally referred to as beneficiaries, but once they enroll in a plan, they are considered enrollees in that plan.

Explanation of Benefits (EOB) – A document provided by the health plan sponsor that helps a person understand the total charges for a health care service or product, such as a prescription drug, the amount negotiated by a plan sponsor or its delegated PBM, how much the health plan sponsor will cover, and how much the patient should expect to pay.

Evergreening – When the original patent applicable to the active compound of a brand-name drug is due to expire, drug manufacturers often claim large numbers of complex and often highly speculative patents. This typically involves filing for new patents on secondary features of the product or on ancillary changes to the product formulation to artificially extend the term of patent protection.

F

Federal Preemption – The doctrine of federal preemption provides that federal law supersedes conflicting state laws pursuant to the Supremacy Clause of the U.S. Constitution. The U.S. Supreme Court has held that federal law can either expressly or impliedly preempt state laws, based on the legislative intent behind the federal law.

Federal Upper Limit (FUL) – The Affordable Care Act (ACA) revised the FUL provisions, which were created to ensure that Medicaid is a prudent purchaser, to require the Secretary of HHS to set a reimbursement limit for some generic drugs, calculated as no less than 175% of the weighted average of the most recently reported AMP (see Average Manufacturer Price).

Fee for Service (FFS) – A traditional payment model for medical and related services where the provider is paid a fixed, separate amount for each service performed, such as office visits, blood work taken, and other tests administered.

Fiduciary – A fiduciary is a person or entity that acts on behalf of another person and has a duty to operate in good faith, trust, and honesty, which typically requires putting that person's interests ahead of the interests of a fiduciary. ERISA defines a fiduciary, in relevant part, as a person who "exercises any discretionary authority or discretionary control respecting management of such plan or exercises any authority or control respecting management or disposition of its assets," or "has any discretionary authority or discretionary responsibility in the administration of such plan." PBMs typically serve in administrative and advisory roles, and do not make decisions about whether the plan sponsor should offer pharmaceutical benefits or the scope or design of those benefits. Accordingly, PBMs are not considered plan fiduciaries.

Flexible Spending Account (FSA) – Set up through an employer, a FSA allows employees to pay for many OOP medical expenses with tax-free payroll-deducted funds. The IRS sets a limit on the amount an employee can put in an FSA each year, and employees can use the funds on expenses like medical care and drug copayments, deductibles, and some non-prescription OTC items. Unlike health savings accounts (HSAs) attached to high-deductible plans (HDHPs), unused funds in FSAs expire at year's end and cannot be rolled into the next year.

Formulary – Formularies are drug lists covered by a health plan sponsor. P&T committees help establish formularies based on clinical standards to encourage the use of safe, effective, and affordable medications. Plans can choose an open formulary, which is where reimbursement is provided for most drugs, or a closed formulary where non-formulary drugs are reimbursed only through an exception process. Formulary categories for drugs are called tiers. Drugs are placed in tiers based on the type of drug. Common tiers include generics, preferred generics, preferred brand, non-preferred brand, and specialty. Formulary tiering often plays a significant role in driving manufacturer price concessions.

Fraud, Waste, and Abuse (FWA) – FWA is a concern in the prescription drug distribution context, as it is in all health care service delivery contexts. While the three terms (fraud, waste, and abuse) are often intertwined, fraud occurs when someone knowingly and willfully uses or tries to use false information, statements, or misrepresentation to improperly obtain prescription drugs or payments. Waste is the overutilization of services caused by misuse of resources. Abuse is an inappropriate action that may directly or indirectly cause financial loss, such as requesting payment or filling prescriptions when there is no legal entitlement. The detection and elimination of FWA is a high priority for stakeholders in the prescription drug supply chain, including PBMs.

Fully Insured – A fully insured policy may be offered directly for purchase to an individual or via an employer or other plan sponsor as a group health plan. Sometimes referred to as a "commercial plan," an individual or group pays an insurer or carrier a monthly premium in order to have claims reimbursed under the terms of the coverage.

G

Generic Drug – A generic drug is the same as the reference brand-name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. Before approving a generic drug product, FDA requires many rigorous tests and procedures to assure that the generic drug can be substituted for the brand-name drug. The FDA evaluates the ANDA for substitutability, or "therapeutic equivalence," of generic drugs on scientific evaluations. By law, a generic drug product must contain 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. Generic drugs often cost 80–90% less than a brand-name drug. Generic drugs are listed in the FDA Orange Book (see Orange Book) with an AB-rating, which means that FDA has determined that the drug is bioequivalent to the brand drug.

Generic Effective Rate (GER) – GER is the relative rate of the full cost of pharmacy reimbursement (drug ingredient cost and dispensing fee) of all generic drugs over a defined period of time expressed as a discount of the total weighted average wholesale price (AWP) for those same generic drugs over the specified time period. Reimbursement in some preferred pharmacy networks may be based at least in part on GER.

Generic Product Identifier (GPI) – A 12- or 14-character number used to identify generic products by therapeutic use. It represents specific information on the drug, including drug group, drug class, drug subclass, drug base name, drug name, dosage form, and dosage strength.

Generic Substitution – The practice of dispensing an FDA equivalent generic drug (see generic drug) for a brand-name drug without needing the approval of the prescriber. Some states have substitution laws for certain drug classes, and prescriptions may need to be written a specific way to either allow or to override substitution.

Gold Carding – A program used by some health plan sponsors that waives, on a limited basis, prior authorization (PA) rules for certain services provided by clinicians who are deemed "high performing." The clinician's "gold card" exemption from PA is effective for a limited service or set of services, for a defined period, and is reviewed regularly by the plan sponsor to ensure the clinician continues providing care meriting the PA exception.

Gross-to-Net-Bubble – The "gross-to-net-bubble" measures the dollar gap between drug manufacturers' gross sales measured by brand drug list prices, and their sales at net prices after rebates, price concessions, and other discounts.

Group Purchasing Organization (GPO) – A group purchasing organization is an entity that helps health care providers and organizations — such as hospitals, nursing homes, PBMs, pharmacies, and home health agencies — realize savings and efficiencies by aggregating purchasing volume and using that leverage to negotiate discounts with manufacturers, distributors, and other vendors. (See also Rebate Aggregator). GPOs have existed in the U.S. since the early 1900s. Congress established the GPO Safe Harbor from the anti-kickback statute in 1987 to facilitate scale purchasing in health care goods and services.

H

Health Equity – Health equity is the state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving health equity requires ongoing societal efforts to: (i) address historical and contemporary injustices; (ii) overcome economic, social, and other obstacles to health and health care; and (iii) eliminate preventable health disparities.

Health Savings Account (HSA) – Available to those enrolled in a high-deductible health insurance plan, an HSA is a savings account used to set aside pre-tax funds to pay for qualified medical expenses, including prescription drugs (as well as certain OTC drugs), such as deductibles and copayments. The IRS sets a limit each year on the tax-deductible dollar amount that may be contributed to an HSA, which is indexed to inflation. The contribution limit for HSAs is higher than the limit for FSAs and, unlike an FSA, the funds in an HSA carry over from year to year. Additionally, HSA dollars can be invested, unlike FSA dollars.

High-Deductible Health Plan (HDHP) – A plan with a higher deductible than a traditional insurance plan. The monthly premium is usually lower, but plan participants pay OOP for more health care costs before their insurance company starts to pay its share. A high-deductible plan, also called an HSA-eligible plan, can be combined with an HSA for patients to pay for certain medical (and related) expenses with pre-tax money. Deductible limits are adjusted annually by the IRS.

HIPAA – The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established rules banning the use of pre-existing condition exclusions for those with continuous health insurance coverage. It also required HHS to issue a regulation governing the use and disclosure of personally identifiable health information, including electronic information. Typically, the phrase HIPAA refers to the privacy and security requirements under the rule promulgated per HIPAA by the HHS Secretary.

HIPAA Standard Transactions – HIPAA standard transactions are exchanges involving the electronic transfer of information between two parties for specific purposes. HIPAA regulations set up the following standard transactions for Electronic Data Interchange (EDI) of health care data: 1) claims and encounter information, 2) claims status, 3) coordination of benefits and premium payment, 4) eligibility, enrollment, and disenrollment, 5) payment and remittance advice, and 6) referrals and authorizations.

Home Delivery (mail order or mail service) – These terms are often used interchangeably for (i) pharmacies that deliver self-administered drugs (such as insulin) directly to a patient's home, typically for the treatment of chronic or longer-term health conditions, and (ii) pharmacies that dispense prescriptions and deliver them to patients' homes (or other designated locations) by mail, common carrier, or other delivery service.

I

Independent Pharmacy – A pharmacy that is either stand-alone or part of a group of two or three pharmacies under common ownership.

In-House Pharmacy – An on-site pharmacy at an employer's facility or at a hospital, which usually is the preferred pharmacy for that employer or organization.

Interchangeable Biosimilar or Product – An interchangeable biological product is a biosimilar that meets additional study requirements and may be substituted for the brand reference product at the pharmacy, depending on state pharmacy laws. Interchangeable biological products (also called interchangeable biosimilars or interchangeable products) may help increase patient access to biologics.

Integrated Pharmacy Benefit – A pharmacy benefit that is developed and administered by the health plan sponsor as part of its overall health care benefits offering.

Investigational New Drug (IND) – The IND is an application that exempts a drug that is in development from current federal law requirements on transportation or distribution across state, thus permitting testing of its diagnostic or therapeutic potential in humans through clinical trials.

Inflation Reduction Act (IRA) – The IRA, enacted in 2022, made several changes to Medicare drug pricing, including the following:

Medicare Drug Price Negotiations: The IRA authorized Medicare Part D to negotiate prices for covered drugs. Negotiations are underway as of 2024 between CMS and manufacturers of the first 10 drugs selected; prices are expected to be finalized so that they can be in effect under Part D in 2026. Negotiated drugs must be covered in Part D, but plans are not prohibited from putting them on non-preferred formulary tiers or imposing prior authorization of step therapy restrictions.

Medicare Part D Redesign: The IRA made several changes to the Part D drug benefit, which generally require Part D plans and manufacturers to pay a greater share of costs for enrollees with high drug costs, including:

- As of 2024, once enrollees hit the catastrophic phase (which is set at $8,000), they no longer have to pay the 5% coinsurance.
- As of 2025, there will be an annual $2,000 cap on enrollee out-of-pocket (OOP) drug spending.
- As of 2025, Part D plan sponsors and manufacturers will pay a larger share of costs for catastrophic coverage, and Medicare will pay a smaller share.
- Other changes include limits on increases to the base beneficiary premium, establishment of insulin copay caps, and a new option for enrollees to spread out their OOP costs over the year rather than face high OOP costs in a given month.

L

Limited Distribution Drug (LDD) – A limited distribution drug is created when a pharmaceutical manufacturer decides to limit the number of specialty pharmacies contracted to dispense a particular specialty medication.

Limited Distribution Network – See pharmacy networks

List Price vs. Net Price – List prices represent manufacturers' price to wholesalers or direct purchasers but do not account for discounts. Net prices represent revenue per unit of the product after all manufacturer concessions are accounted for (including rebates, coupon cards, and any other discount).

M

Mail Order or Mail Service – See home delivery.

Managed Care Organization (MCO), (see also Medicaid MCO) **–** MCO is a general term used to describe entities that manage the cost and utilization of covered services and products to optimize quality patient care through efficient use of limited resources.

Manufacturer Administrative Fee (MAF) – Fees paid by manufacturers to PBMs (or their contracted Rebate Aggregators) for administrative services rendered in connection with aggregating, allocating, collecting, and invoicing claims for rebates.

Manufacturer Discount Program (to replace definition of coverage gap/donut hole) (see also IRA) **–** Beginning in 2025, the IRA eliminates the coverage gap benefit phase and replaces it with manufacturer discounts in the initial and catastrophic coverage phases.

Market Exclusivity – Exclusivity provides a fixed period following drug approval during which the originator can market its drug without direct competition from other manufacturers of duplicate or reformulated products. Exclusivity periods can vary and are dependent on a multitude of factors. Exclusivity is designed to promote a balance between new drug innovation and generic drug competition. Below are each kind of drugs exclusivities and their time frame (not including traditional extensions):

- **Biologics**: 12 years
- **Small Molecule**: 9 years
- **Orphan Drugs**: 7 years (drugs developed to treat certain rare medical conditions)
- **New Drug Application**: 5 years
- **New Indication**: 3 years
- **Pediatrics**: 6 months
- **First Generics**: 6 months

Maximum Allowable Cost (MAC) – A MAC list specifies the maximum amount that a PBM will reimburse a pharmacy for a particular generic drug or brand drug with marketed generic equivalents. PBMs set and regularly update MAC lists at a level that reflects the average acquisition cost of an efficient pharmacy. MAC lists encourage pharmacies to purchase drugs at the lowest possible cost, driving competition among wholesalers and drug manufacturers.

Medicaid – A shared, state-federal health insurance program of public assistance to eligible persons, regardless of age, whose income resources are insufficient to pay for health care. Most recipients are low-income women and children, but 70% of the funds pay for nursing home and other long-term care services for elderly and disabled people. Funded through both state and federal funds, each state administers its own Medicaid program, with some flexibility in benefits provided and according to federal requirements. While pharmacy coverage is an optional state benefit under federal Medicaid law, all states have opted to provide outpatient prescription drug coverage to virtually all their Medicaid covered recipients. Medicaid coverage may be through fee-for-service or through managed care (see Medicaid MCO).

Medicaid MCO – Medicaid MCO is a non-government health care plan sponsor that contracts with a state Medicaid agency to manage the health care of the Medicaid population. The pharmacy benefit may be provided by the MCO through a PBM, or it may be a stand-alone benefit.

Medical Loss Ratio (MLR) – The Affordable Care Act requires health insurance issuers to submit data on the proportion of premium revenues spent on clinical services and quality improvement, also known as the Medical Loss Ratio (MLR). Issuers must incorporate (into this data) information provided by their contracted PBMs regarding the provision of the drug benefits covered under ACA. Incurred claims for drug costs are included in the MLR, net of rebates. It also requires issuers to issue rebates to enrollees if this percentage does not meet minimum standards. The Affordable Care Act requires insurance companies to spend at least 80% or 85% of premium dollars on medical care, with the rate review provisions imposing tighter limits on health insurance rate increases. If an issuer fails to meet the applicable MLR standard in any given year, as of 2012, the issuer must provide a rebate to its customers.

Medicare – A federal program operated by the CMS that provides health insurance benefits primarily to persons over 65 years of age and adults under 65 years of age with permanent disabilities (as well as certain other persons eligible for Social Security benefits). Different "parts" of Medicare cover different health care goods and services:

- **Part A:** Pays for inpatient hospital, skilled nursing facility (SNF), and home health care.
- **Part B:** Pays for physicians' professional services, some outpatient services, preventive services, infusions and durable medical equipment. Part B coverage is optional with no out-of- pocket maximum.
- **Part C (also known as Medicare Advantage or MA):** Pays for Part A and B benefits through private health plan sponsors, certain part D components, and some benefit coverage not provided under traditional Medicare Parts A and B, like vision and dental.
- **Part D:** Pays for outpatient prescription drugs through private plan sponsors. In effect since 2006, Part D benefits are provided through plan sponsors approved by the federal government. These plans receive premiums from both Part D enrollees, as well as the federal government. States are federally preempted from regulating Part D plans, except in specified, narrow instances (e.g. plan solvency).
- **Medicare Advantage with Prescription Drugs (MA-PD):** Enrollees receive all Medicare coverage from one entity.
- **Prescription Drug Plan (PDP):** Medicare FFS beneficiaries may enroll in a stand-alone PDP separately.

Medicare Advantage—Part D Plan (MA-PD) – see Medicare

Medicare Drug Price Negotiations – see IRA

Medicare Part D Redesign – see IRA

Medicare Fee-for-Service (FFS) – The original Medicare Part A and Part B program, sometimes called traditional Medicare, in which the federal government pays physicians, hospitals, and other health care entities for each service provided based on established fees, most of which are updated annually through regulations.

Medicare Star Ratings (Star Ratings) – A system run by CMS that rates the quality of MA-PDs and stand-alone PDPs using a scale of 1 (lowest) to 5 (highest). The quality ratings, which beneficiaries are encouraged to use to compare Part C and Part D options available to them, are based on factors including clinical performance, patient experience, enrollee complaints, and customer services. Star ratings are used by CMS for a range of regulatory and payment incentives and disincentives.

Medication Therapy Management (MTM) – A distinct set of services that a Part D sponsor must establish in a program to ensure optimum therapeutic outcomes for targeted enrollees, typically those with multiple chronic conditions, through improved medication use.

Multisource Brand (MSB) – Multi-source brand drugs are available from multiple brand and generic manufacturers.

N

National Average Drug Acquisition Cost (NADAC) – NADAC pricing benchmark is compiled from a voluntary survey of pharmacies based on wholesale invoices and is intended to indicate the cost at which they purchase drugs for resale. Though voluntary self-reporting has resulted in market distortion, due to the limited number of (mostly independent) pharmacies that participate in the survey, this benchmark is often used as the basis for pharmacy reimbursement (with an added dispensing fee). NADAC does not reflect off-invoice rebates or discounts on drugs.

National Council for Prescription Drug Programs (NCPDP) – A not-for-profit standards development organization that creates and promotes consensus standards for the transfer of data related to medications, supplies, and services within the health care system. Pharmacy systems use NCPDP standards for claims processing, electronic prescribing, ePA, and other technology requirements.

National Drug Code (NDC) – A unique 10-digit, three-segment code assigned by the FDA that identifies the manufacturer, active ingredient with strength, and package size of a drug. The NDC is used to identify the medication in prescription drug claims.

National Provider Identifier (NPI) – A 10-digit unique identification number issued by CMS to providers, pharmacists, and others for HIPAA standard transactions (see HIPAA standard transactions).

Network – See pharmacy networks

Network Adequacy – Established standards that require a specific ratio of pharmacies per population and within a specific geographic radius. CMS pharmacy network adequacy standards build on Tricare (the uniform services health care program for active-duty service members, family members, and others) standards for retail access for Medicare Part D. For more information, go to https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/HPMSMEMORetailHIAccess.pdf.

New Drug Application (NDA) – When the sponsor of a new drug believes that it has obtained enough evidence on the drug's safety and effectiveness to meet FDA's requirements for marketing approval, the sponsor submits an NDA to FDA. The application must contain data from specific technical viewpoints for review, including chemistry, pharmacology, medical, biopharmaceutics, and statistics. If the NDA is approved, the product may be marketed in the United States. For internal tracking purposes, all NDAs are assigned an NDA number.

O

Orange Book – A publication by the FDA that identifies drugs approved on the basis of safety, effectiveness, and therapeutic equivalence under the Federal Food, Drug, and Cosmetic Act. It contains patent and exclusivity information. Biological products are not listed in the Orange Book, but are listed in the Purple Book (see Purple Book).

Orphan Drugs – An orphan drug is a drug for a rare disease or condition. Some rare disease treatments have been "orphaned" or discontinued because there was not enough financial incentive to continue development or production. The Orphan Drug Act incentivizes drug development for rare diseases.

Out-of-Pocket (OOP) Maximum – The OOP maximum is a predetermined amount that an individual must pay before their health plan sponsor will pay 100% of their covered medical treatments and services.

Over- the-Counter (OTC) – OTC drug products are those drugs that are available to consumers without a prescription. There are more than 80 therapeutic categories of OTC drugs, ranging from acne drug products to weight control drug and birth control products. As with prescription drugs, the Center for Drug Evaluation and Research (CDER) within FDA oversees OTC drugs to ensure that they are properly labeled and that their benefits outweigh their risks.

P

Pass-through Payment Model – A pass-through payment model passes through to the plan sponsor the rate paid by the PBM to the pharmacy, which will vary among pharmacies. The PBM typically receives an administrative fee for its services, and the plan experiences fluctuations in its costs among pharmacies. Pass-through models can result in higher and less predictable costs for plan sponsors.

Part D Prescription Drug Plan (PDP) – see Medicare

Patent and Patent Thicket – see Drug Patent and Drug Patent Thicket

Patient Support Programs – An approach to reduce health care costs and improve quality of life for individuals with chronic conditions by preventing or minimizing the effects of the disease through integrated care. Disease management programs are a form of patient support program often used for specialty medications.

Pay-for-Delay Agreement – Typically, these arrangements, which are also known as "reverse payment" settlements, are the result of patent infringement litigation settlements. Brand manufacturers strike deals with potential generic drug competitors (e.g., generic drug manufacturers), paying them to keep their products off the market for a specified period.

Pharmacy and Therapeutics Committee (P&T committee) – A group of typically independent clinicians assembled by or on behalf of PBMs or health plan sponsors to evaluate the available scientific evidence on pharmaceutical treatment options. The basic objectives of a P&T committee are to specify drugs of choice and alternatives for the full range of disease states, based on safety and efficacy; to minimize therapeutic redundancies; and to maximize cost-effectiveness. PBMs use the work of P&T committees to propose drug formularies for adoption by health plan sponsors.

Pharmacy Audit – Health plan sponsors typically delegate authorization to the PBM that manages their drug benefits, to audit pharmacies by reviewing prescription claims made for payment through the PBM under the benefit plan. Pharmacy audits, which are often required by state and federal rules, allow PBMs to facilitate the ability of patients to receive high-quality, proficient services from network pharmacies. Audit protocols also encourage pharmacies to comply with rules set by state Boards of Pharmacy and help identify evidence of FWA.

Pharmacy Benefit Design – Contractually specifies the level of coverage and types of pharmacy services available to health plan sponsor enrollees. A sound pharmacy benefit design balances patient care outcomes, costs, quality, risk management, and provision of services expected by enrollees. The pharmacy benefit options can be integrated, carved out, or purchased by the sponsor on a service-by-service basis.

Pharmacy Benefit Manager (PBM)/Pharmacy Benefit Companies – PBMs are companies that are contracted by health plans, employers, unions, and other plan sponsors to administer prescription drug benefits and negotiate with pharmacies and drug manufacturers to lower costs and improve quality.

Pharmacy Networks – PBMs, working on behalf of health plan sponsors, use selective contracting to create pharmacy networks (which are called preferred pharmacy networks under Medicare Part D). The use of pharmacy networks increases PBMs' bargaining leverage with pharmacies, which helps lower the overall costs of enrollees' prescriptions.

- **Closed Network –** An arrangement made by a plan sponsor that restricts prescription coverage to an exclusive list of pharmacies. This arrangement denies coverage and/or payment of prescriptions provided by a pharmacy not included in the exclusive list, with certain limited exceptions. These types of networks help control costs for a plan sponsor.

- **In-Network –** A licensed pharmacy that is under contract with a plan sponsor to provide negotiated prices and services to patients.

- **Limited Distribution Network –** A pharmaceutical company establishes a select network of specialty pharmacies authorized to distribute a particular specialty medication. When that medication is limited to certain specialty pharmacies by the manufacturer, it becomes a limited distribution drug (LDD).

- **Open Network –** Plan sponsors create a broad network open to virtually all pharmacies. Enrollees can use their prescription drug benefits at all network pharmacies for the same copay or cost share. These network offerings typically result in higher costs to the plan sponsor than a preferred network. Any Willing Pharmacy (AWP) policies protect pharmacies and allow a pharmacy to participate in any network if they agree to the participation terms and conditions. (see Any Willing Pharmacy)

- **Out- of- Network –** A licensed pharmacy that is not under contract with a plan sponsor to provide negotiated prices or services to patients

- **Preferred Network –** Medicare Part D establishes a framework for preferred networks. Plan sponsors create a select group of preferred pharmacies within a broader network of participating drugstores. Preferred pharmacies participate in plan sponsor offerings with better discounts in exchange for higher volume; however, the cost differential for a preferred network pharmacy cannot be so great that it disadvantages pharmacies not participating in a preferred network. Enrollees typically pay lower copays or cost shares at a preferred pharmacy. The use of preferred networks is growing and can lower prescription costs by an estimated 5% compared to open networks while meeting Medicare's pharmacy access standards nationally. Many Medicare Advantage and Medicare Part D Prescription Drug Plans (PDPs) include preferred network pharmacies. These networks incentivize pharmacies to provide a high quality of care and promote improved health outcomes.

Pharmacy Reimbursement – Reimbursement to the pharmacy of the total amount to fill a prescription, which is composed of the drug ingredient cost and professional dispensing fee.

Pharmacy Services Administrative Organizations (PSAO) – An organization that represents independent pharmacies and provides access to pooled purchasing power for these pharmacies. PSAOs negotiate contracts with third-party payers, negotiate reimbursement rates with PBMs, including payment and audit terms, and provide inventory and administrative functions to assist pharmacy business. The largest PSAOs are owned by drug wholesalers.

Physician-Administered Drugs (also see brown bagging and white bagging) **–** Prescription drugs that are administered by a health care provider to a patient through injection or infusion. These drugs, which are typically administered in a hospital outpatient setting or a provider's office, often have high list prices.

Plan Sponsors (or Health Plan Sponsors) – The entity that establishes and subsidizes health coverage and stand-alone drug benefits (if such benefits are carved out of the regular medical benefit), including public and private employers, unions, retiree plans, health insurers, state employees, and government programs such as Medicare and Medicaid and the qualified health plans on the ACA exchanges. Health plan sponsors make active choices about how they design their drug benefits and participant cost sharing.

Point of Sale (POS) Rebate – A POS rebate is when the value of a rebate goes directly to offset an individual patient's cost sharing for that drug (i.e., "at the point of sale") instead of being used by the plan sponsor to offset the cost of health care benefits or to lower premiums for all health plan sponsor enrollees.

Preferred Drug – A drug that is designated as a valuable, cost-effective treatment option under a drug benefit formulary adopted as part of the pharmacy benefit design. Typically, preferred drugs are more affordable to patients than non-preferred drugs.

Preferred Drug List (PDL) – Most state Medicaid programs maintain a PDL of outpatient prescription drugs, which is a list of drugs that the state encourages to be prescribed over other drugs. States use PDLs as a mechanism to negotiate higher supplemental rebates. A drug not on a PDL may require prior authorization or have a higher copayment.

Premiums – The fees paid each month by or on behalf of an enrollee to maintain health insurance coverage from a plan sponsor.

Prescription Drug Supply Chain – The pharmaceutical supply chain is the means through which prescription medicines are delivered to patients. Drugs originate in manufacturing sites; are transferred to wholesale distributors; stocked at retail, mail order, and other types of pharmacies; subject to price negotiations and processed through protocols by plan sponsors, insurers, or PBMs; dispensed by pharmacies; and ultimately delivered to and taken by patients.

Prior Authorization (PA) – Prior authorization is a process where the pharmacy benefit design requires documentation from a prescriber for the prescribed drug before the plan sponsor will agree to cover the drug for a given patient. Plan sponsors use PA to improve clinical safety, decrease inappropriate utilization and waste, and help ensure appropriate use of high-risk and/or high-cost drugs. In the pharmacy benefit, a PA helps ensure the appropriateness of medication prescribed for patients and promotes the most cost-effective therapies. It is also often used to evaluate prescriptions for (i) drugs that are intended for certain age groups or conditions only; (ii) drugs used for both cosmetic or therapeutic reasons, to ensure the drug is being prescribed for therapeutic treatment; (iii) drugs that have potentially harmful side effects, dangerous interactions, or risks for abuse or misuse; (iv) drugs that are not covered under the formulary but are deemed medically necessary by the prescriber; or (v) brand-name drugs that have a more affordable generic or biosimilar equivalent.

Product Hopping – Product hopping occurs when drug manufacturers make incremental changes to a previously approved product (like changing a pill from a capsule to a tablet). They then switch patients onto the new product, which has its own patent and/or exclusivity protections, by discontinuing or discouraging use of the old product. This approach is used to extend a drug's duration of time without competition from generics or biosimilars.

Purple Book – A publication by the FDA that contains licensed biological products regulated by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER). The purple book includes reference products, biosimilar, and interchangeable biologic products licensed and approved by the FDA.

Q

Quantity Limit (QL) – A QL is the maximum amount of a drug that can be dispensed per prescription under a formulary. QLs are used as a measure to ensure appropriate use.

Quality Assurance (QA) – A systemic effort or process to ensure requirements and quality standards are met.

Quality Improvement (QI) – QI is the degree to which health services for individuals increase the likelihood of desired health outcomes and are consistent with current professional knowledge. Quality improvement is the framework used to systematically improve care.

Quality Rating System (QRS) – This is a CMS quality rating system used to calculate a quality rating for each health plan sponsor based on a five-star scale for the Health Insurance Exchanges. In Medicare Part D, the quality rating system is called Medicare Star Ratings.

R

Rebates – Drug rebates are price concessions negotiated by PBMs with drug companies to reduce the net, or true, cost of providing prescription drug coverage. Typically, rebates are paid by brand drug manufacturers to PBMs who then share the negotiated rebates, in whole or in large part, with the plan sponsors. In the Medicare Part D market, 99.6% of rebates are passed back to Part D plan sponsors, and in the commercial market, 91% of rebates are passed on to plan sponsors.

Rebate Aggregator – A rebate aggregator is an entity that provides formulary rebate administrative services for PBMs or otherwise negotiates rebates with manufacturers typically on behalf of PBMs.

Real-Time Benefit Tools (RTBT) – These tools enable the real-time exchange of patient-specific formulary and benefit information between prescribers and PBMs at the time of prescription. RTBTs enable prescribers to know, when prescribing, how much a drug will cost the patient given their coverage, including their status in their deductible or other phase of their benefits. The use of RTBT saves patients up to 40%.

Reference Product – A single biological product, already approved by FDA, against which a proposed biosimilar product is compared.

Request for Proposal (RFP) – The process where businesses solicit proposals for the services they desire. Private industry plan sponsors typically shop for PBMs using benefits consultants that help construct detailed RFPs regarding the sponsor's desired pharmacy benefit design. PBMs compete for this business and tailor their offerings to meet the plan sponsors' needs. In the public space, federal and state programs issue RFPs, and PBMs compete in much the same way either directly or as subcontractors to the plan sponsor.

Retail Pharmacy (also called Community Pharmacy) – These are pharmacies that directly dispense medications to the general public at retail prices. Retail pharmacies can be independent or part of a chain.

Risk Adjustment – A statistical process that accounts for the underlying health status (e.g., age, social determinants) and health spending of enrollees in a plan when assessing their health care outcomes and costs. Risk adjustment provides a methodology to adjust for these factors to better measure the quality of care and the appropriate payment rates.

Risk Evaluation and Mitigation Strategy (REMS) Drug Program – A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. PBMs may support REMS by collecting data and reporting to the FDA as a service to drug manufacturers.

S

Self-Insured/Self-Funded – Health coverage in which an employer, union, or other plan sponsor (rather than an insurance company) bears the financial risk for covered expenses incurred under the plan. Self-insured plans usually contract with a third-party administrator, PBM, or insurance company to administer the health plan (e.g., negotiate provider networks, reduce costs for goods like prescription drugs, pay claims, determine eligibility). Self-insured plans typically operate under ERISA, and, subject to certain exceptions, enjoy broad preemption protection from state insurance laws.

Site of Care – The choice for the physical location of infused drug administration. Sites of care include hospital inpatient, hospital outpatient, physician office, ambulatory infusion suite, or home-based setting.

Small Molecule Drugs – These are compounds with low molecular weight. In contrast to biosimilars, most traditional brand drugs are small molecule.

Spread Pricing Model (or Risk Mitigation Contract) – A risk mitigation (sometimes referred to as spread) pricing model provides employers and other health plan sponsors with cost predictability by giving them a price-certain for prescription drug benefits used by their enrollees, regardless of the how much the pharmacy charges for the prescriptions. Under this model, the PBM has discretion to pay network pharmacies a different rate than the plan sponsor has paid the PBM to arrange the service, often creating a spread. Spread-pricing contracts are offered as an alternative to pass-through contracts.

Specialty Drugs – A "specialty drug" is a prescription drug that typically is high in cost and that:

1. is prescribed for a person with a (a) chronic, complex, or life-threatening condition, and/or (b) rare medical condition; or
2. has limited or exclusive distribution; or
3. requires (a) specialized product handling and/or administration by the dispensing pharmacy, or (b) specialized clinical care, including frequent dosing adjustments, intensive clinical monitoring, or expanded services for patients, including intensive patient counseling, education, or ongoing clinical support beyond traditional dispensing activities, such as individualized disease and therapy management to support improved health outcomes.

Specialty Pharmacy – A pharmacy that has the technology and clinical expertise to enhance the safety, quality, and affordability of care for patients receiving specialty medications. Pharmacists and clinicians at specialty pharmacies offer support to patients with complex medical conditions including blood disorders, cancer, Crohn's, HIV/AIDS, infertility, multiple sclerosis, and rheumatoid arthritis. Specialty pharmacies must meet rigorous requirements for network participation and are licensed by the Boards of Pharmacy.

Specialty Pharmacy Accreditation – The process by which an independent third party (non-plan/PBM) organization reviews the practices of specialty pharmacies against established national quality standards for service and uniformity of care. During the accreditation process, specialty pharmacies are required to demonstrate that they have the infrastructure to provide a full range of personalized clinical and operational services beyond the capabilities of a traditional retail pharmacy, such as handling specialty drugs appropriately and providing the coordinated services required by patients with complex conditions. Pharmacy accreditation is an indicator of a pharmacy's commitment to quality and safety, and goes beyond Board of Pharmacy requirements. The best-known accrediting entities in the specialty pharmacy arena are the Utilization Review Accreditation Commission (URAC) and Accreditation Commission for Health Care (ACHC).

Steering – A practice that plan sponsors use to direct enrollees to network pharmacies that offer drugs at a lower price, or with higher quality, within the pharmacy benefit.

Step Therapy – Step therapy is a process by which plan sponsors (public or private) require patients to take one or more alternative medications before taking certain more expensive, less proven, or more intensive therapies. This process is used by plan sponsors to control health care costs.

T

Terminal Disclaimer – A limit on a term of a patent that is substantially similar to another co-owned patent. It is intended to support a patent continuation, but it can also be used to allow a manufacturer to make slight changes to its drug and file a patent for the same invention.

Therapeutic Interchange – Dispensing a chemically different drug, considered therapeutically equivalent (i.e., will achieve the same outcome, clinical efficacy, and safety profile), in place of a drug originally prescribed. Therapeutic interchange occurs in accordance with procedures and protocols set up and approved by prescribers in advance; as a result, the pharmacist does not have to seek the prescriber's approval for each interchange. The drugs involved are not FDA-rated generic equivalents.

U

Usual and customary (U&C) price – The retail price charged by a pharmacy for a drug without the use of insurance. Also known as the "cash price."

Utilization Management (UM) – Utilization management is a set of programs created by a health plan sponsor to help ensure appropriate use of health care services. In the pharmacy benefit, a PBM administers the plan's UM program. These programs promote safe, appropriate use of medications, and reduce the likelihood of prescription drug waste. Utilization management includes prior authorization (PA), step therapy, drug utilization review (DUR), refill-too-soon edits, and quantity limits.

V

Value-Based Arrangements or Contracts – These are contract agreements that establish reimbursement metrics based on performance standards, including achievement of patient outcome, Medicare Star rating, and QRS measures, opioid dispensing oversight, patient adherence rates, refill rates, offering counseling services, and dispensing volume.

W

White Bagging (also see brown bagging and physician-administered drugs) **–** White bagging is an arrangement between plan sponsors and certain specialty pharmacies to ship a patient's outpatient medication directly to the site of care where the product is then administered to the patient. The specialty pharmacy bills the plan sponsor directly for the medication.

Wholesale Acquisition Cost (WAC) – The manufacturer's list price for a prescription drug for sale to wholesalers or other direct purchasers. WAC is published by pricing services, such as First Data Bank, MediSpan, and Red Book, but does not include discounts, rebates, or other manufacturer incentives.

Wholesale Distributor (or Wholesaler) – An entity in the drug supply chain that purchases drugs directly from a drug manufacturer to sell and distribute to pharmacies. Some wholesalers represent independent pharmacies through their company-owned pharmacy services administrative organizations (PSAOs). About 90% of drugs in the United States are distributed through three wholesalers: AmerisourceBergen, Cardinal Health, and McKesson Corporation.

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