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HEALTHCARE VALUE HUB

Glossary: Drug Pricing

Rising prescription drug costs are a major concern for consumers and policymakers, but drug pricing is complicated. This glossary contains some of the terms you might encounter. More resources can be found at: w*ww.HealthcareValueHub.org/Drug-Spending*

Term	Acronym	Definition
340B Drug Pricing Program		A federal program that requires drug manufacturers participating in the Medicaid drug rebate program to provide medications at discounted prices to certain designated nonprofit hospitals and other providers.
Abbreviated New Drug Application	ANDA	A form submitted to FDA as part of the generic drug approval process. These applications are called "abbreviated" because a manufacturer is usually not required to include animal and human data to establish safety and effectiveness. Instead, a generic applicant must show that its product is bioequivalent--the same as a brand-name drug in dosage, quality, strength, intended use, and how it performs in the body.
Actual Acquisition Cost	AAC	The net cost of a drug paid by a pharmacy. A drug's AAC includes discounts, rebates, chargebacks and other adjustments to the price of the drug, but excludes the pharmacy's dispensing fees.
Average Manufacturer Price	AMP	The average price paid to a drug manufacturer by wholesalers and retailers who buy direct from manufacturers. AMP is a benchmark created by Congress in 1990 in calculating Medicaid rebates and is not publicly available.
Average Sales Price	ASP	The average sales price is derived from the sales from manufacturers to all purchasers and includes practically all discounts, but is limited in that it is only available for Medicare Part B covered drugs.
Average Wholesale Price	AWP	This is a measurement of the price paid by pharmacies to purchase drug products from wholesalers in the supply chain.
Biosimilar		Drugs that have the same mechanism of action as the original, or reference, biologic treatment. Analogous to generics for small molecule drugs.
"Buy and Build"		Refers to physician management of certain medicines, primarily specialty medicines that require injection or infusion. The physician purchases the drug, manages the inventory, administers the drug, and then submits claims for reimbursement for both the drug and accompanying professional services.

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Bona Fide Service Fees	BFSFs	Payments from drug manufacturers to PBMs, specialty pharmacies and other service vendors in Medicare Part D (and other government drug programs) for an array of patient and product support "services," such as rebate administration, inventory, drug shipping, reimbursement/financial assistance, patient education, phone support and data reports. The only major financial item excluded from Part D “negotiated price” calculations.
Compounding		Compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to an individual patient’s needs.
Exclusivity		Exclusivity is exclusive marketing rights granted by the FDA upon approval of a drug and can run concurrently with a patent or not. It prevents the submission or effective approval of ANDAs or applications. There are three types of exclusivity (5-year, 3- year, and 180-day).
Formulary		List of drugs covered by insurance or PBM in a drug benefit plan. Products listed on a formulary are covered for reimbursement at varying levels.
Generic		Generic drugs are copies of brand-name drugs that have exactly the same dosage, intended use, effects, side effects, route of administration, risks, safety, and strength as the original drug.
Generic Drug User Fee Amendments	GDUFA	Legislation that allows FDA to collect fees to pay for the approval process for generic drugs.
Hatch-Waxman Act		A 1984 federal law that established a process for how generic drugs are approved by the FDA and manufactured by pharmaceutical industry. Also known as the Drug Price Competition and Patent Term Restoration Act.
Investigational New Drug Application	IND	IND’s are a request for authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans.
List Price		The price of a drug that is shown in a pharmacist’s computer.
Maximum Allowable Cost	MAC	The upper limit or maximum amount that a plan will pay for generic and brand-name drugs that have generic versions available (multi-source brands)
Medicaid Best Price	BP	The lowest manufacturer price paid for a Rx drug, regardless of package size, by any purchaser. BP is reported to CMS and states, but is otherwise confidential. Included in BP are cash discounts, free goods that are contingent upon purchase, volume discounts and rebates. Excluded from BP are prices paid by the federal government.
Medicare Part D	Part D	The federal-government program to subsidize the cost of prescription drugs and prescription drug insurance premiums for Medicare beneficiaries. Also called the Medicare prescription drug benefit,

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New Chemical Entity	NCE	A drug that contains an active moiety that has never been approved by the FDA or marketed in the U.S.
New Drug Application	NDA	It is an application in the United States through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing.
New Molecular Entity	NME	Drug that has an active component that has never been approved by the FDA or marketed in the U.S.
Orphan Drug		A pharmaceutical agent that has been developed specifically to treat a rare medical condition, the condition itself being referred to as an orphan disease.
Orphan Drug Exclusivity	ODE	Granted to drugs designated and approved to treat diseases or conditions affecting fewer than 200,000 in the U.S. (or more than 200,000 and no hope of recovering costs).
Patent		A patent is a property right issued by the United States Patent and Trademark Office (USPTO) to an inventor "to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States" for a limited time, in exchange for public disclosure of the invention when the patent is granted.
Patent Thicket		Patent system abuse caused by drug companies using multiple patents to extend their monopolies.
Pay for Delay		Brand-name pharmaceutical companies can delay generic competition that lowers prices by agreeing to pay a generic competitor to hold its competing product off the market for a certain period of time.
Pharmacy Benefit Managers	PBM	Companies that negotiate rebates and manage drug benefits for health plans, businesses and government programs.
Prescription Drug User Fee Act	PDUFA	Enacted in 1992, PDUFA is a law that allows the FDA to collect fees from drug manufacturers in order to fund new and expedited drug approval processes. PDUFA is reauthorized every five years.
Pricing Spreads		Price difference between what a PBM pays a pharmacy for a prescription drug and what it charges the health plan sponsor.
Product Hopping		A strategy drug makers use to keep brand-name drug prices high by reformulating existing brand therapies in order to delay generic entry. Companies discontinue the old formulation of a drug whose patent expiration date has passed or is approaching in an attempt to force consumers to change to the drug's new—and newly patented—formulation.
Rebate		An incentive payment made by a drug manufacturer, to a drug wholesaler or other payer such as a PBM based on how much the entity increases the market share or actual "sales" of a drug.
Retail Pharmaceuticals		Drugs available at retail pharmacies by prescription, instead of ones available in a hospital, physician office, nursing home or home health setting (non-retail drugs).
Risk Evaluation and Mitigation Strategy	REMS	A strategy to manage a known or potential serious risk associated with a drug or biological product.

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Specialty Drugs		Drugs that treat chronic, complex or life-threatening conditions, often manufactured through biologic processes and/or targeting a specific gene. Typically, these drugs are costly and require intensive clinical monitoring, complex patient actions, and/or special handling by the dispensing pharmacy. Although most commonly injected or infused, they may also be taken orally or inhaled.
State Drug Substitution Laws		State substitution laws provide authority to pharmacists to substitute lower-cost generics for higher-cost brand drugs. Some states require pharmacists to substitute generics for the brand, some allow pharmacists to do it, and other states require permission from consumers to substitute.
Single-Source Drug		Brand-name drugs still under patent protection.
Wholesale Acquisition Cost	WAC	The price set by the manufacturer. Pharmacies typically purchase drugs based on the Wholesale Acquisition Cost. The difference between what the pharmacy paid (based on WAC) and what insurers reimburse the pharmacy (based on AWP), is known as the "spread." The larger that difference, the larger the pharmacy's profit.

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