OREGON LEGISLATIVE ASSEMBLY
JOINT TASK FORCE ON FAIR PRICING OF PRESCRIPTION DRUGS

The glossary is to inform the exercises and advance the work of the Task Force. Definitions reflect information provided by members in advance of administering the June survey, as well as key discussions shared at the July 19 meeting. Sources used for definitions include information provided by Task Force members and government resources such as the Office of the Inspector General, Department of Justice, Food and Drug Administration, and the Department of Health and Human Services.

Drug Product Terminology:

Biologic	A therapeutic drug or a vaccine, virus, serum, toxin, antitoxin, blood product, allergenic product, protein, or analogous product made from living cells and applicable to the treatment, prevention, or cure of a disease. Licensed under a Biologic License Application by the FDA. Biologics are also referred to as "large molecule drugs."
Biosimilar	Biologics that are "highly similar" to a previously approved biologic (whose patent or exclusivity period has expired) and which have "no clinically meaningful" differences with the previously approved biologic. Unlike generic drugs, biosimilars are not considered to be the "same" as previously approved biologics
Brand product	Branded products are not generics. A brand can be first-in-class) or not. It is protected by a patent or statutory exclusivity, or has an expired patent or exclusivity. Licensed under a New Drug Application by the FDA. Brand products are also generally referred to as "innovator drugs."
Drug Product	A prescription drug product requires a licensed health professional's authorization to purchase and is usually a finished dosage form that contains a drug substance, generally, but not necessarily in association with other active or inactive ingredients.
Generic Drug	Products considered the "same as" a branded product, e.g., same active ingredient, route of administration) and that compete the with branded product after patent or exclusivity expiry. Licensed under an Abbreviated New Drug Application by the FDA, generic drugs are generally considered to be "therapeutically equivalent" to brand products.
In-Line or Post-Market Drugs	Products that are licensed and in the market.

Large Molecule products	These are known as 'biologics' – and contain live active ingredients. They are infused or injected and are not typically self-administered.
Limited Distribution Drug	Limited distribution drugs (LDD) are medications that have been restricted by the manufacturer to selected pharmacies and wholesalers. Typically, these drugs are used to treat rare conditions affecting small patient populations and have complex dosing requirements, severe side effects and require close monitoring. Through limited distribution, drug manufacturers can confirm those who provide the medication maintain training on appropriate distribution, dispensing and monitoring which will reduce risk to patients and fulfill inventory tracking requirements.
Multisource Drugs	Drugs where both an innovator and one or more generics is available.
Orphan Drug	A drug or biologic for the treatment of diseases and disorders that affect fewer than 200,000 people in the United States or that affect more than 200,000 people but where manufacturers are not expected to recover the costs of developing and marketing a treatment drug.
Physician Administered Drugs	Any kind of drug that cannot typically be self-administered. Usually billed on an office visit claim.
Pipeline Drugs	Drugs (small or large molecule) under development by a manufacturer.
Retail Drugs	Any kind of drug typically available at a pharmacy counter. Usually billed on a pharmacy claim.
Small Molecule products	Non-large molecule drugs, such as chemically synthesized compounds. such as are capsules, tablets, powders, ointments, sprays.
Specialty Drug	A drug that is costly, requires special supply chain features (such as freezing or cold storage), typically indicated for a small group of patients, and where the patients may need special case management services. This is the broadest definition. There is no single agreed-upon definition, so sometimes specialty drug will only mean high-cost. For instance, specialty drugs in the Medicare Part D program are only defined by cost – currently $670/month (2018) and indexed annually.

Distribution System

Specialty Pharmacy	These organizations may or may not take ownership of the drug product. Their clients are drug manufacturers that need limited distribution of specialty drugs. Specialty drugs are typically (but not always) high cost, require special shipping and storage (freezing or cold storage), are indicated for relatively small patient populations treated by physician specialists. Specialty pharmacy can deliver 'just in time' products by working with treating providers to supply the appropriate drug in time for a patient visit at the location where the drug will be used. There is a lack of consistency as to how a drug is determined to be a specialty drug and who make such a determination. There is lack of consistency as to how a drug is determined to be a specialty drug and who determines that. (Erin Moller)
Wholesaler	In a simple distribution system, the wholesaler is the first purchaser of a drug product – direct from the manufacturer. Primary distributors (wholesalers) purchase prescription medicines and other medical products directly from manufacturers for storage in national and regional warehouses and distribution centers across the country. Healthcare providers place orders with distributors for the medicine and products they need, and the distributors process and deliver the orders daily.

Administrative Organizations in the Supply and Payment Chain

Group Purchasing Organization (GPO)	These entities represent groups of drug purchasers, such as hospitals and health systems. A GPO negotiates with manufacturers on behalf of its clients for either up-front, on-invoice discounts or back-end rebates. Importantly, GPOs do not take ownership of a drug; they are not part of the supply chain. GPOs essentially negotiate a purchase-order from which members of the buying group can purchase in whatever quantities needed. Wholesalers supplying to GPO members typically provide the drug at the discounted price on the invoice and then receive a rebate from the manufacturer of the drug after the fact. GPOs may provide additional client administrative services as well.
Pharmacy benefit Manager (PBM)	PBMs handle some or all the pharmacy benefit for health plans (formulary design, cost sharing and tiers, pharmacist networks and contracts, price concession negotiation with manufacturers). PBMs may own mail order pharmacies and/or specialty pharmacies.
Pharmacy Services Administration Organization (PSAO)	Similar to a GPO, but serve independent pharmacies. In addition to price negotiation with PBMs, PSAOs offer a variety of administrative services to pharmacies. PSAOs are often owned by wholesalers or PBMs.

Pricing Terminology

Actual Acquisition Cost (AAC)	The net cost of a drug paid by a pharmacy. It varies with the size of container purchased (e.g., ten bottles of 100 tablets typically costs more than one bottle of 1,000 tablets) and the source of purchase (manufacturer or wholesaler). A drug's AAC includes discounts, rebates, chargebacks and other adjustments to the price of the drug, but excludes dispensing fees.
Average Wholesale Price (AWP)	The price for prescription medicines that is created and published in commercial pricing publications. For brand medicines, this price is almost always higher than the list (WAC) price and represents the starting point for contract negotiations for medicines between payers and pharmacies/providers. AWP serves as an important pricing benchmark for payers because underlying data is continuously current and publicly available, and represents the average cost for a drug purchased at wholesale and published for public knowledge. AWP is a benchmark used for pricing and reimbursement of prescription drugs for both government and private payers. AWP is not a true representation of actual market prices.
List Price	This is also known as the Wholesale Acquisition Cost (WAC). The Average Wholesale Price (AWP) may also be called the 'list price' and is the price for prescription drugs created and published in commercial pricing publications. Refers to the price of drug products that direct purchasers pay the manufacturer, without factoring in any rebates, discounts, or other price reductions.
National Average Drug Acquisition Cost (NADAC)	Designed by Centers for Medicaid and Medicare to create a national benchmark that is reflective of the prices paid by retail community pharmacies to acquire prescription and over-the-counter covered outpatient drugs.
Wholesale Acquisition Cost (WAC)	The price the wholesaler or other direct purchasers pay the manufacturer, without factoring in any rebates or discounts, discounts, or other price reductions. Generally considered the 'list' price, this price is asset by a manufacturer and are publicly reported.

Types of Price Concessions

Charge Back	The amount a distributor bills back to a manufacturer when a product is sold to a customer at a contract price that is less than the distributor's cost. This serves as a pricing mechanism used by wholesalers which allows them to carry products destined for customers paying very different prices to manufacturers. The wholesaler keeps track of sales to various customers under prices negotiated between the manufacturer and the customer. The wholesaler then "charges back" the manufacturer for any difference between the negotiated prices paid by the customer and the wholesaler's cost of goods (WAC).
Cost Minus	Refers to when a wholesaler returns some of their revenue stream to larger customers in the form of a "cost-minus" distribution fee, which results in the customer paying a lower price than the contract cost or WAC for a noncontracted item.
Coupons/Copay Assistance Program	A voucher that is offered to cover all or part of a patient's copayment obligation, which the patient redeems at the point of service (the pharmacy counter). Pharmacies redeem the coupons with the manufacturer or its coupon administration vendor. Coupons are not permitted in Federal health care programs such as Medicare and Medicaid. They are restricted in the commercial markets of California and Massachusetts.
Discounts	These are discounts, charge backs or any other type of consideration provided by a wholesaler, manufacturer, or pharmacy services administrative organization, pharmacy benefit manager, or other entity to a pharmacy that is not included on the invoice and may impact the price paid for a drug. These discounts are provided periodically to the pharmacy based on the fulfillment of contractual terms such as prompt payment or volume purchased.
Rebates	Provided by manufacturers to purchasers (plan sponsors, wholesalers, pharmacy benefit managers, etc.) and are typically based on the ability of a purchaser to move market share for the manufacturer's product. Rebates are confidential and are typically based on the volume of dispensed drug as well as other factors and paid by a manufacturer after a drug has been dispensed or administered. Rebates are billed periodically by the purchaser based on the contractual terms (e.g., drug utilization subject to the rebate).

Medicaid Rebate Terminology

Average Manufacturer Price (AMP)	Used in Medicaid, AMP is calculated by the manufacturer and provided to CMS, which uses it to let state Medicaid programs calculate the unit rebate amount that they receive from manufacturers. It is the average of manufacturer prices to the wholesale and retail class of trade (does not include sales from wholesalers to retailers but only the prices in any direct agreement between manufacturer and a retail seller). AMP is confidential and not publicly available.
Best Price (BP)	BP is the lowest price the manufacturer offers to any purchaser in the commercial market in the U.S.; this could be a clinic, a hospital, a health plan, a PBM, and so on. Generally speaking, if the BP is greater than 23.1% off of the AMP for brand medicines or 13.1% off of AMP for generic medicines, all state Medicaid programs will get the BP rebate. BP is confidential and not publicly available.
CPI Penalty	An additional rebate that holds the state Medicaid program harmless for any price increases taken by the manufacturer that exceed inflation based on the Consumer Price Index (CPI-U). Any price increase in excess of CPI-U has to be rebated back to the Medicaid program by the manufacturer.

Provider Drug Reimbursement Payment Terms

340B Program	A federal program that requires manufacturers to provide outpatient drugs to covered entities, including qualifying hospitals, at significantly reduced prices. The 340B Program enables covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.
Administrative Fee	Administrative and service fees charged by PBMs to manufacturers and to plan sponsors. These fees are typically a percentage of the list (WAC) price of a medicine. PBMs offer a range of administrative (e.g., enrollment, marketing), clinical (e.g., pharmacy and therapeutics committee, appeals support), and other business services to their customers.
Average Sales Price (ASP)	This is a Medicare Part B reimbursement term used to pay for Medicare Part B drugs (which are typically physician-administered drugs). This is the weighted average manufacturer net price for a product in the market. This applies to multi source drugs and patented products. Medicare reimburses physicians ASP+6% for Part B drugs.
Clawback	Practice of charging co-payments to consumers for certain prescription drugs that exceed the cost of medicines, with the difference required to be returned to the PBM by the pharmacy.
Dispensing Fee/Professional Fee	There are two parts to pharmacy payment: ingredient cost and dispensing fee. The ingredient cost reflects the applicable MAC, AWP, AAC etc. The dispensing fee pays for the professional services of the pharmacist.
Fees (general)	Including but not limited to dispensing, administrative, or service fees charged by pharmacy benefit managers or other entities to manufacturers and plan sponsors. Fees are usually based on a range of administrative (e.g., enrollment, marketing), clinical (e.g., pharmacy and therapeutics committee, appeals support), and other business services provided to their customers.

Insurance Benefit Design	Coverage design for health care services in a health insurance plan including prescription drugs covered by the plan, often referred to as formularies, and cost-sharing mechanisms such as co-pays, deductibles, premiums and co-insurance. Formularies often utilize tiers to sort prescription drugs based on type of drug (brand or generic), utilization, and cost-sharing with consumers. Typically, manufacturers and pharmacy benefit managers work to negotiate price and placement on insurance formularies (i.e., formulary placement).
Maximum Allowable Cost (MAC) and Federal Upper Limits (FUL)	Briefly, these payment limit methods apply only to multisource drugs (including off-patent brand drugs). MAC/FUL is the average price of all the multisource drugs in a group. The frequency the MAC/FUL is recalculated is at the discretion of the payer. The multi-source drugs to which a MAC is applied is also at the discretion of the payer.
Pass-through Pricing Model	This alternative contracting approach requires that the PBM pass through the price they pay for medications and earn a negotiated administrative fee.
Pharmacist Gag Clause	Clauses in PBM contracts with pharmacies that prohibit pharmacists from telling customers that they could save money by paying cash for prescription drugs rather than using their health insurance.
Price Protection	PBMs negotiate price protection provisions with manufacturers as a standard feature of contracts. Under these arrangements, manufacturer price increases in excess of predetermined thresholds result in increased rebates to the PBM. These rebates are separate from standard formulary access rebates. Price protection rebates are calculated as a percentage of the list (WAC) price of a medicine.
Reference Price	This is not used in the US for drugs. A reference price limits the amount the insurer will pay for one product to the price of a similar product in the market. There are a number of ways to structure reference pricing, an example would be to tie the amount an insurer will reimburse to the lowest price of any drug in the same therapeutic class, or limit the insurer payment to the average price of drugs in the same class. If the consumer choses a product that exceeds the reference price, the consumer will be responsible for paying the difference between the reference price and the pharmacy's costs/charge for the more expensive drug.

Some percentage of Average Wholesale Price (AWP)	Payers assume that a published AWP is higher than what a pharmacy or provider actually pays for a drug, so payers reimburse pharmacies and other providers some percentage less than AWP, for instance AWP – 17%.
Spread Pricing Model	Under this payment model, plan sponsors (health plan or employer) compensate the PBM by permitting the PBM to retain differences, or spreads, between the amount that a PBM charges to a plan sponsor and the amount that the PBM pays to the pharmacy that dispenses the drug to a consumer. So, the amount paid by the plan sponsor to the PBM for a prescription can be greater than the amount paid by the PBM to the pharmacy, with the difference retained as revenue by the PBM.

Task Force Evaluation Criteria

Ability to Monitor	Enables a regulatory body the oversight of specified entities or cost factors within the pharmaceutical supply chain.
Better Decision Making	Improves the ability for purchasers of pharmaceutical products to make informed decisions based on accurate information regarding payment for pharmaceutical products.
Cost-effective	The ability for a regulatory body or an entity in the pharmaceutical supply chain to implement a strategy or policy with a positive impact for the needed expenditure.
Cost Reduction	Promotes a reduction in cost to purchasers of pharmaceutical products.
Enforceable	The ability for a regulatory body or an entity in the pharmaceutical supply chain to enforce a strategy or policy