



Key Pharmaceutical Terms

340B Ceiling Price: The maximum price that manufacturers can charge covered entities participating in the Public Health Service 340B drug discount program for any covered outpatient drug. The 340B discount is based on the Medicaid rebate formula, but the discount is built into the manufacturer's or wholesaler's selling price rather than paid as a post-purchase rebate. For brand name drugs, the 340B ceiling price is the lower of (a) the manufacturer's "best price" or (b) 15.1 percent off of the drug's average manufacturer price (AMP). For generic and over-the-counter drugs, the 340B ceiling price is 11 percent off of the drug's AMP. Brand name manufacturers must provide an additional discount on a covered outpatient drug if the price of the drug has increased faster than the rate of inflation. Covered entities are free to negotiate prices that are lower than the 340B ceiling price. Although some people may refer to the 340B ceiling price as the "340B price," that term also may refer to a subceiling price that is available to covered entities.

340B Prime Vendor Program: The 340B law required the Department of Health and Human Services (HHS) to create a "prime vendor" program for the entities in the 340B drug discount program. The prime vendor's key responsibilities are to provide distribution services and to negotiate prices below the 340B ceiling price for those entities that choose to join the program. The prime vendor works with a variety of wholesalers in the distribution of pharmaceuticals and provides other value-added services. The Health Resources and Services Administration (HRSA) has a contract with Apexus to serve as the prime vendor.

340B Program: The federal program established by Congress under the Veterans Health Care Act of 1992 as part of Public Law 102-585. The 340B program requires drug manufacturers to enter into pharmaceutical pricing agreements (PPAs) with the Secretary of HHS as a condition of Medicaid covering and paying for the manufacturer's covered outpatient drugs. The PPAs specify, among other things, that manufacturers may not sell covered outpatient drugs above 340B ceiling prices to covered entities.

Actual Acquisition Cost (AAC): The net cost of a drug paid by a pharmacy. AAC varies with the size of the container purchased (e.g., ten bottles of 100 tablets typically cost more than one bottle of 1,000 tablets) and the source of purchase (whether manufacturer or wholesaler). A drug's AAC includes discounts, rebates, chargebacks, and other seller adjustments to the price of the drug, but excludes dispensing fees.

Alternative Method Demonstration Projects: HRSA-approved projects that give 340B covered entities flexibility to operate programs or enter into agreements with other covered entities or pharmacies that would otherwise not be allowed under 340B guidelines. For example, a covered entity is prohibited from dispensing 340B drugs to the patients of a different covered entity, even if the two entities are part of the same system or network, unless the entities have an approved alternative method demonstration project authorizing such practices. These demonstration projects are limited to six years and intended to test new methods of participating in the 340B drug discount program in order to improve access to pharmacy services for vulnerable populations.

Any Willing Pharmacy: By law, Medicare Part D plans must offer network participation contracts to any willing pharmacy that meets the standard terms and conditions of the network contract. Furthermore, Medicare regulations state that Part D plans must have standard contracts with "reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy." 42 C.F.R. § 423.505(b)(18).

Apexus Inc.: The organization under contract with HRSA to administer the 340B prime vendor program. Established in August 2007 as a non-profit corporation, Apexus was first assigned the prime vendor contract in September 2007 by Provista, formerly known as Healthcare Purchasing Partners International. Apexus is responsible for negotiating discounts below the 340B ceiling price for those 340B covered entities that choose to participate in the 340B prime vendor program. Apexus also contracts with wholesalers to distribute 340B pharmaceuticals and with other vendors to provide value-added services. The prime vendor contract was re-bid in 2009 and awarded to Apexus for another five years.

Authorized Generic: An authorized generic is a generic version of a brand name drug produced and/or distributed by either the developer of the brand name drug itself or a generic manufacturer licensed by the developer. Companies that develop

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authorized generics are permitted to sell these drugs under a new drug application during the 180-day exclusivity period awarded to the generic manufacturer that successfully challenges the brand name drug's patent. Manufacturers that release authorized generics are required to include the price of these drugs in the best price calculations for their corresponding brand name drug.

Average Manufacturer Price (AMP): The average price paid to manufacturers by wholesalers for drugs distributed through the retail class of trade. AMP was created by Congress in 1990 to facilitate calculating Medicaid rebates. Federal supply schedule (FSS) prices, 340B prices, prices associated with direct sales to health maintenance organizations (HMOs) and hospitals, and customary prompt pay discounts extended to wholesalers and retailers are excluded from AMP. The Congressional Budget Office (CBO) estimates AMP to be about 21 percent less than the average wholesale price (AWP) for about 130 brand-name drug products frequently purchased by Medicaid recipients. As a result of the Deficit Reduction Act of 2005 (DRA), AMP will be used to determine the federal upper limit on Medicaid pharmacy reimbursement for multiple source drugs and CMS will make AMP data available to states on a monthly basis and to the general public through a website updated at least quarterly. The DRA has also modified the requirements for calculating AMP. In the past, the HHS Office of Inspector General has been critical of the lack of CMS guidance on how to calculate AMP, which results in inconsistency among the methods used by manufacturers. CMS was expected to publish AMP data after the final regulations implementing the DRA took effect on October 1, 2007, but a preliminary injunction issued by the U.S. District Court in D.C. in December 2007 has temporarily blocked CMS' plans. The health care reform measures in the Senate and House contain provisions that would modify the definition of AMP in a manner that would likely increase Medicaid reimbursement to pharmacies for generic drugs.

Average Sales Price (ASP): A measure of a pharmaceutical's price that is equal to a manufacturer's sales to all purchasers divided by units sold. The ASP calculation excludes sales that are excluded from the Medicaid "best price" calculation. ASP was first used by federal and state government prosecutors in settlements with several pharmaceutical manufacturers to ensure more accurate price reporting. Under the Medicare Modernization Act (MMA), Congress adopted the ASP system to replace AWP for reimbursing outpatient drugs in non-hospital settings under Medicare Part B, beginning in 2005. CMS decided several years ago to also use ASP to set reimbursement for drugs administered in hospital outpatient departments under Medicare Part B.

Average Wholesale Price (AWP): A national average of list prices charged by wholesalers to pharmacies. AWP is sometimes referred to as a "sticker price" because it is not the actual price that larger purchasers normally pay. For example, in a study of prices paid by retail pharmacies in eleven states, the average acquisition price was 18.3 percent below AWP. Discounts for HMOs and other large purchasers can be even greater. Although Medicare has historically reimbursed outpatient drugs based on a discount off of AWP, AWP-based reimbursement is being phased out under MMA. In addition, as a result of the Deficit Reduction Act of 2005, AWP will no longer be used in the Medicaid program to determine the federal upper limits (FULs) on pharmacy reimbursement for multiple source drugs. AWP information is available through a number of periodicals published by companies such as First DataBank and Medi-Span. Recent litigation challenging the integrity of reported AWP data resulted in a court settlement under which First Data Bank and Medi-Span agreed, effective September 2009, not to publish AWP values above 120 percent of a drug's wholesale acquisition cost (WAC). The previous AWP ceiling was 125 percent of WAC. First Data Bank and Medi-Span also agreed in the near future to eliminate entirely the use of AWP as a benchmark in their publications.

Best Price: See "Medicaid Best Price."

Big 4: The four largest purchasers of pharmaceuticals within the federal government: Department of Veterans Affairs (VA), Department of Defense (DOD), Public Health Service (PHS), and Coast Guard. These four federal agencies have the right to purchase their pharmaceuticals through federal supply schedule (FSS) contracts like every other federal agency. However, the Big 4 often get pricing below FSS on brand name drugs because these drugs are subject to a maximum statutory price called the federal ceiling price (FCP).

Bundled Sales: The packaging of drugs of different types, where the total price for the package is less than the purchase price of the individual drugs purchased separately.

"Carve Out": A mechanism by which a 340B entity can comply with the 340B program's prohibition against duplicate discounts. A covered entity that chooses the "carve out" option must purchase all the covered outpatient drugs dispensed to Medicaid patients outside the 340B program, while continuing to purchase all other (*i.e.* non-Medicaid) covered outpatient drugs through the 340B program. Because the covered entity does not buy its Medicaid drugs at 340B discounts, state

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Medicaid agencies are free to request manufacturer rebates on such drugs without creating a duplicate discount problem for the manufacturers. In 2009, the California legislature prohibited 340B covered entities from utilizing the Medicaid carve out.

“Catastrophic Limit”: The annual level of out-of-pocket spending that a Medicare Part D enrollee must incur before being eligible for catastrophic coverage. Part D enrollees receive 95% - 100% coverage during the catastrophic coverage phase. The catastrophic limit on out-of-pocket expenses is set at \$4,550 for 2010 (\$6,440 in total drug spending under the standard benefit design).

Centers for Medicare and Medicaid Services (CMS): The federal agency within HHS that administers the Medicare and Medicaid programs, including the Medicaid drug rebate program and the Medicare Part D prescription drug benefit. CMS and the Health Resources and Services Administration (HRSA) are sister agencies within HHS.

CMS-1500: Formerly known as HCFA-1500, the uniform professional claim form used by the non-institutional health care community, including physicians and suppliers (except ambulance suppliers), to transmit claim information to Medicare and Medicaid. The form is developed and maintained by the National Uniform Claim Committee, a consortium of representatives from health care provider and insurer organizations chaired by the American Medical Association. Retail and outpatient pharmacies typically bill Medicaid for covered outpatient drugs using the CMS-1500 form unless the state has developed an alternative electronic billing system.

Comprehensive Pharmacy Services: Services provided by a pharmacy that improve the health status of the patient population through access to affordable medications, medication therapy management, and related pharmaceutical care services that are oriented around improving patient outcomes.

Contract Pharmacy: A pharmacy that enters into a "ship to, bill to" arrangement with a 340B covered entity such that the covered entity purchases the 340B drug and the manufacturer bills the entity for the drug purchased, but ships the drug to the contract pharmacy. The contract pharmacy receives a “dispensing fee” for the services associated with filling each prescription dispensed. The contract pharmacy must also follow certain requirements, such as providing the covered entity with quarterly financial statements and a summary of receiving and dispensing records.

Covered Entity: The statutory name for a facility or program eligible to purchase discounted drugs through the Public Health Service 340B drug discount program. Covered entities include high-Medicaid disproportionate share hospitals owned or operated by or under contract with state or local governments and eleven categories of facilities or programs funded by HRSA, including federally qualified health centers (FQHCs), AIDS drug assistance programs (ADAPs), hemophilia treatment centers (HTCs), and family planning clinics. With passage of the Deficit Reduction Act of 2005, Congress attempted to extend 340B pricing to another category of covered entities, i.e., high-Medicaid children’s hospitals that are exempt from the Medicare prospective payment system. In September 2009, HRSA adopted final guidelines that enable children’s hospitals to enroll in the program.

Covered Outpatient Drug: The category of drugs for which manufacturers must pay rebates to state Medicaid agencies under the Medicaid rebate program. Under 340B program guidance, manufacturers must give 340B discounts on both “covered outpatient drugs” and “covered drugs.”

Corporate Integrity Agreement (CIA): An agreement between the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) and a health care provider or other entity as part of a settlement for alleged civil wrongdoing relating to federal health laws. The government may enter into a CIA with an entity instead of seeking to exclude the entity from federal health care programs such as Medicare and Medicaid. Each CIA is unique to the entity, but a typical CIA will last for five years and will require the entity to implement procedures to comply with federal health care laws, often including developing a compliance plan and hiring a compliance officer. Several pharmaceutical manufacturers have entered into CIAs in connection with, among other issues, their determinations of AWP, reporting of Medicaid best price, and ceasing the promotion of “off-label” uses of drugs not approved by the Food and Drug Administration (FDA).

Deficit Reduction Act of 2005 (DRA): Federal legislation passed by Congress in 2005 and intended to help reduce the federal deficit. Among many other changes, the DRA significantly impacts Medicaid and Medicare spending. Government payments to several health care provider groups, including physicians, hospitals, and pharmacies, were affected by the law, which also contains provisions aimed at reducing Medicare and Medicaid fraud, waste, and abuse. Several of the Medicaid measures within the DRA have had an impact on 340B providers. Among them are provisions requiring the collection of national drug

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codes and manufacturer rebates for physician-administered drugs, changes to the Medicaid drug rebate formula, phasing out AWP-based reimbursement for outpatient drugs and the narrowing of the Medicaid best price exemption for nominal prices.

Dispensing Fee: The charge for the professional services provided by the pharmacist when dispensing a prescription (including overhead expenses and profit). Medicaid and most direct-pay prescription drug insurance plans use dispensing fees to pay pharmacists for their dispensing activities and other professional services. Dispensing fees do not include any payment for the drugs being dispensed.

Disproportionate Share Adjustment: See “Medicare DSH Adjustment Percentage.”

Disproportionate Share Hospital (DSH): A disproportionate share hospital is a hospital with a disproportionately large share of low-income patients. The Medicare and Medicaid programs provide additional payments to DSHs to compensate them for the higher costs attributable to low-income patients. The Medicare DSH adjustment is a percentage add-on to a hospital’s prospective payments and is based on the share of Medicaid patients and supplemental security income (SSI) recipients that the hospital serves. In order for a hospital to qualify for the 340B program, it must have a Medicare DSH adjustment percentage of more than 11.75 percent.

Donut Hole: The range of Medicare Part D annual drug expenditure during which most Medicare Part D enrollees have a 100% co-payment on covered drugs. In 2010, this gap in coverage begins once a beneficiary’s total drug costs exceed \$2,830, and ends once the beneficiary’s total drug costs reach \$6,440.

Drug Repackager: A business that takes drugs out of their original manufacturer stock bottles and puts them into new packaging. Some repackagers specialize in “pre-packed” drugs; these are small quantities of drugs that are ready to dispense, either in bottles or unit-of-use packaging, with pre-printed labels.

DSH Adjustment: See “Medicare DSH Adjustment Percentage.”

DSH Hospital: See “Disproportionate Share Hospital.”

Dual Eligibles: The 8.1 million Medicaid beneficiaries who also qualify as full- or partial-benefit Medicare enrollees. The partial-benefit duals receive Medicaid subsidies for Medicare cost-sharing. Prior to January 1, 2006, full-benefit dual eligibles received their drug coverage through Medicaid, but starting in 2006, all dual eligibles began receiving their drug coverage under the Medicare Part D benefit. Full- and partial-benefit dual eligibles are automatically enrolled into a Medicare prescription drug program. They can switch Part D plans at any time, with their enrollment in the new plan effective the first day of the following month after identification. There are currently 6.3 million full-benefit dual eligibles who were automatically enrolled in Part D and an additional 1.8 million partial-benefit duals automatically enrolled.

“Duplicate Discount”: An instance where a manufacturer gives both an up-front 340B discount to a covered entity at the time of purchase and a post-purchase discount to a state Medicaid agency after Medicaid pays the covered entity for the drug and submits a rebate request to the manufacturer under the Medicaid rebate program. Both the 340B and Medicaid rebate laws protect manufacturers from duplicate discounts. A covered entity must comply with the prohibition against duplicate discounts in one of three ways: (1) bill Medicaid at no more than actual acquisition cost plus a dispensing fee; (2) “carve out” Medicaid drugs from its 340B purchases; or (3) follow state drug reimbursement laws and billing limits that otherwise protect manufacturers from duplicate discounts.

Estimated Acquisition Cost (EAC): A state Medicaid agency’s best estimate of the price generally paid by pharmacies for a particular drug. Federal rules require that states pay for prescription drugs based on the lower of either EAC or “the usual or customary charge to the public.” Traditionally, most states have calculated EAC based on a discount off of AWP. Pursuant to the DRA, however, federal upper limits on state Medicaid drug payments for generics will be based on AMP rather than AWP (although states will still be permitted to use AWP in setting reimbursement rates within those federal upper limits). The DRA required that AMPs be publicly disclosed on the CMS website, but publication has been temporarily enjoined by a federal court. If and when that injunction is lifted, states also will have the option of basing reimbursement for brand name drugs on AMP. The DRA regulation redefined EAC to mean “the state Medicaid agency’s best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.”

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Federal Ceiling Price (FCP): The maximum price manufacturers can charge the Big 4 for federal supply schedule (FSS) listed brand name drugs, even if the FSS price is higher. FCP must be at least 24 percent below the non-federal average manufacturer price (non-FAMP). FCP prices are not publicly available. According to the CBO, FCP prices are on average 49 percent of AWP.

Federal Supply Schedule (FSS): The collection of multiple award contracts used by federal agencies, U.S. territories, Indian tribes and other specified entities to purchase supplies and services from outside vendors. FSS prices for the pharmaceutical schedule are negotiated by the Department of Veterans Affairs (VA) and are based on the prices that manufacturers charge their “most-favored” non-federal customers under comparable terms and conditions. Because terms and conditions can vary by drug and vendor, the most-favored customer price may not be the lowest price in the market. FSS prices are publicly available. CBO reports that FSS prices are on average 53 percent of AWP.

Federal Upper Limit (FUL): The federally-mandated maximum reimbursement that a state Medicaid program is permitted to pay pharmacies for multiple source drugs. As a result of the DRA, more drugs are subject to FULs because the definition of a multiple source drug was expanded to include any drug that has at least one therapeutic equivalent available. FUL has traditionally been calculated as 150 percent of the lowest price published in the national compendia. Pursuant to the DRA, however, FUL now must be calculated at 250 percent of the lowest reported AMP, although health care reform legislation in the Senate and House would further reduce the multiplier. States are permitted to reimburse pharmacies at prices below FUL; for instance, lower rates may be dictated by the state’s Maximum Allowable Cost (MAC) list. States also may reimburse for an FUL drug at a rate higher than the FUL rate as long as total reimbursement for all drugs in the aggregate does not exceed the maximum aggregate reimbursement permitted under the FULs for all drugs.

Formulary: A list of preferred drug products that typically limits the number of drugs available within a therapeutic class for purposes of drug purchasing, dispensing, and/or reimbursement. A government body, third-party insurer, health plan, or provider may establish and use a formulary. Some institutions or health plans develop closed (*i.e.* restricted) formularies where only those drug products listed can be dispensed in that institution or reimbursed by the health plan. Other formularies may have no restrictions (open formularies) or may have certain restrictions such as higher patient cost-sharing requirements or prior authorization procedures for off-formulary drugs. Formularies are used extensively by prescription drug plans (PDPs) and Medicare Advantage plans (MAs) under the Medicare Part D benefit.

Group Purchasing Organization (GPO): An organization through which multiple hospitals, clinics, and other institutions purchase drugs at discounted prices. Outside the 340B program, nonprofit institutions have access to discounted drugs under the Nonprofit Institutions Act, which allows certain nonprofit institutions, including hospitals, to purchase supplies for their “own use” at prices lower than those charged to for-profit and retail purchasers (without running afoul of the Robinson Patman Act’s anti-discrimination standards). This law creates an opportunity for nonprofit hospitals to negotiate significant drug discounts. To maximize these savings, most nonprofit hospitals pool their purchasing power by joining GPOs. Under the 340B law, however, hospitals are required to limit their use of GPOs as a condition of participation. In particular, they are prohibited from purchasing covered outpatient drugs from a GPO or any other group purchasing arrangement. This requirement is often referred to as the GPO exclusion.

GPO Exclusion: A statutory restriction imposed on all DSH hospitals that participate in the 340B drug discount program. According to the GPO exclusion, 340B-participating DSH hospitals may not “obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.” 340B hospitals may use GPOs for inpatient purchases.

HCFA-1500: See “CMS-1500.”

Health Resources and Services Administration (HRSA): The agency within HHS that is charged with improving access to health services for people who are poor and uninsured or live in areas where health care resources are scarce. Working in partnership with many state and community organizations, HRSA also supports programs that help to ensure the health of mothers and children, increase the number and diversity of health care professionals in underserved communities, and provide supportive services for people fighting HIV/AIDS through the Ryan White Care Act. The 340B drug discount program is administered by HRSA through its Office of Pharmacy Affairs.

HHS Office of Inspector General (OIG): The office at HHS charged with improving HHS programs by protecting them against waste, fraud, and abuse. The four offices within OIG—Office of Audit Services, Office of Evaluation and Inspections, Office of Investigations, and Office of Counsel to the Inspector General (OCIG)—carry out their duties by conducting audits, evaluations and investigations and by reporting their findings to HHS agencies, Congress, and the public. The OCIG also

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coordinates with the Department of Justice in resolving health care fraud and abuse cases, develops and monitors Corporate Integrity Agreements (CIAs), conducts administrative litigation, and issues fraud alerts and advisory opinions. The OIG has published reports regarding compliance with the 340B program and assisted in negotiating and implementing settlements with manufacturers that have involved payment of refunds to 340B covered entities.

Independent Charity PAPs: A type of patient assistance program (PAP) in which manufacturers make cash donations to an independent, *bona fide* charitable organization which then provides cash assistance to needy patients. In order for an independent charity PAP to be considered truly independent, donor manufacturers may not exert any direct or indirect control or influence over the assistance program, and the award of assistance must be made without regard to sources of funding. The assistance provided through an independent charity PAP counts towards a Part D enrollee's true out-of-pocket spending (TrOOP). In November 2005, the HHS OIG issued a Special Advisory Bulletin stating that pharmaceutical manufacturers may continue to use independent charity PAPs without violating fraud and abuse laws.

Institutional Patient Assistance Program (IPAP): A type of patient assistance program (PAP) in which a manufacturer donates free drugs to a hospital, clinic, or other health care institution, rather than to a patient. Typically, the drugs are donated to replace stock used by the institution for low-income individuals who meet the eligibility criteria set forth in an IPAP agreement between the manufacturer and institution. IPAP agreements also usually establish inventory control procedures and give manufacturer sponsors audit rights.

Maximum Allowable Cost (MAC): The maximum payment that a state or private payer will make to a pharmacy for certain multiple source drugs. States and private payers with MAC programs typically publish their own lists of drugs containing the maximum price at which the program will reimburse for those drugs. Most state Medicaid agencies currently administer MAC programs for one or more covered outpatient drugs. MAC prices for multiple source drugs in the aggregate may not exceed the FULs in aggregate.

Medicaid Best Price: The lowest price paid to a manufacturer for a brand name drug, taking into account rebates, chargebacks, discounts, or other pricing adjustments, excluding nominal prices. Best price is a variable used in the statutory formula for calculating manufacturer rebates owed to state Medicaid agencies and to determine discounts for 340B covered entities. Prices charged to certain governmental purchasers, including prices charged to the Veteran's Administration (VA), Department of Defense (DOD), Indian tribes, federal supply schedule (FSS), state pharmacy assistance programs, Medicaid, 340B covered entities, and Medicare Part D, are statutorily excluded from best price. Best price data is not publicly available, but the Congressional Budget Office (CBO) estimates that best price is on average 63 percent of AWP.

Medicaid Rebate Net Price: The effective price paid for covered outpatient drugs by state Medicaid programs taking into account the manufacturer rebates received by states. The basic rebate for brand name drugs is the greater of 15.1 percent of the average manufacturer price (AMP), or the difference between AMP and Medicaid best price. Rebates for generic and over-the-counter drugs are 11 percent of the AMP. Manufacturers must pay an additional rebate on brand name drugs for which the AMP increases faster than the rate of inflation based on the consumer price index for urban customers. The Medicaid rebate net price for a drug is the amount that the Medicaid agency reimburses a pharmacy for that drug minus the rebate that the state receives from the drug's manufacturer. The average Medicaid rebate net price is 64 percent of AWP according to the CBO. The Senate and House health care reform bills would increase the minimum brand name rebate to 23.1 percent. The Senate bill would increase the rebate on generics to 13 percent.

Medicare Advantage Local Plans: A category of sponsors that may operate Part D drug benefit plans. Medicare Advantage Local Plans are similar to the original Medicare+Choice plans in so far as they are responsible for providing comprehensive care to Medicare enrollees. They are capitated, closed system managed care plans. Under MMA, Congress increased payment to and decreased the administrative requirements for Medicare Advantage plans with the hope of encouraging their entry/re-entry into the market.

Medicare Advantage Regional Plans: A kind of Medicare managed care plan, similar to a large preferred provider organization, established under MMA to provide comprehensive health care services to Medicare beneficiaries within large service areas. Medicare Advantage Regional Plans are one of three categories of sponsors that may deliver the Medicare Part D drug benefit. The other two kinds of Part D sponsors are prescription drug plans (PDP) and Medicare Advantage Local Plans. The Medicare Advantage program was established by Congress under MMA to update and replace the Medicare+Choice program beginning in 2006.

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Medicare Cost Report Test: The test used by the Office of Pharmacy Affairs to determine whether the 340B eligibility of a DSH hospital extends to outpatient facilities that are affiliated with that hospital. Under the Medicare cost report test, a DSH-affiliated hospital facility is part of the DSH hospital and is therefore 340B-eligible if the facility's costs are reimbursable on the hospital's Medicare cost report.

Medicare DSH Adjustment Percentage: A figure that is used in the calculation of a hospital's Medicare DSH adjustment, which is an add-on to Medicare prospective payment system (PPS) payments, available only to hospitals that serve a disproportionate number of indigent patients. In the context of eligibility for the 340B drug discount program, the Medicare DSH adjustment percentage serves as a proxy of how many indigent or low-income patients are served by the hospital. To be a 340B-eligible "covered entity," a hospital must have a Medicare DSH adjustment percentage that exceeds 11.75 percent.

Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA): Federal legislation passed by Congress in 2003 that introduced the most sweeping amendments to the Medicare program made by Congress since the start of the program. The MMA included the creation of a new outpatient drug benefit, revitalization of the Medicare managed care program, payment methodology changes for virtually every Medicare provider, contracting and appeals reform, and establishment of health savings accounts.

Medication Therapy Management (MTM) Program: A program of professional services aimed at (1) optimizing therapeutic outcomes through improved medication use and (2) decreasing adverse drug interactions. Under the Medicare Part D benefit, each prescription drug plan must include an MTM program that is available to certain targeted beneficiaries with multiple chronic diseases (*e.g.*, diabetes, congestive heart failure, and hypertension). MTM services may include medication consultations and other services traditionally offered by pharmacists, but MMA regulations permit MTM services to be offered by non-pharmacists.

National Drug Code (NDC): The NDC is the identifying drug number maintained by the Food and Drug Administration. The NDC number specifies drug identity, package size, and manufacturer. NDC numbers can be reported in nine-digit format, which represents a weighted average of all package sizes for a particular drug, or 11-digit format, which is package-size-specific. Manufacturers that have executed pharmaceutical pricing agreements report quarterly information to the Office of Pharmacy Affairs by NDC number including labeler code, product code, and package size code.

Nominal Prices: The price of any drug sold by a manufacturer for less than ten percent of the drug's AMP. Traditionally, nominally-priced drugs have been excluded from best price and AMP for purposes of calculating Medicaid rebates and 340B discounts. Nominal prices are also excluded from ASP. However, pursuant to the DRA, *only* sales of nominally-priced drugs to 340B entities and certain other safety net providers specified in the DRA are excluded from best price, AMP, and ASP. The DRA authorized the Secretary of HHS to add other kinds of safety net institutions to the list of entities eligible for nominal price protection, but the Secretary declined to do so. Two additional categories of eligible institutions were added by Congress as part of the 2009 appropriations law, including (1) nonprofit or state-owned or -operated entities that would qualify as 340B covered entities were they to receive federal funds, and (2) public or nonprofit entities that provide a family planning service or university health care entities that provide a family planning service.

Non-Federal Average Manufacturer Price (Non-FAMP): The average price paid to a manufacturer by wholesalers for drugs distributed to non-federal purchasers. The Big 4 are entitled under federal law to discounts on brand name drugs of at least 24 percent off of non-FAMP. Non-FAMP is not publicly available.

Office of Pharmacy Affairs (OPA): The office within HRSA which administers the 340B drug discount program. OPA is located within HRSA's Healthcare Systems Bureau and is located at HRSA headquarters in Rockville, Maryland.

Outside of Part D PAP: A type of patient assistance program (PAP) in which manufacturers provide assistance to Medicare Part D enrollees completely outside of the structure of Part D. Under this type of PAP, the amount of assistance does not count towards an enrollee's true out-of-pocket spending (TrOOP). Furthermore, if an enrollee reaches catastrophic coverage using other prescription costs, the drug provided through the Outside of Part D PAP will not be covered under the Part D catastrophic benefit. Instead, the manufacturer must provide the drug through the PAP until the end of the coverage year. Manufacturers can set limits on the quantity of free drugs available under their PAPs, but those limitations may not coincide with the threshold for catastrophic coverage and must apply equally to all PAP participants, not just those enrolled in Part D. In multiple advisory opinions issued since April 2006, the OIG has viewed this type of PAP favorably, with certain restrictions.

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Part D: The portion of the Medicare statute that Congress added under MMA establishing an outpatient prescription drug benefit for Medicare beneficiaries. Under Part D, Medicare beneficiaries can choose from multiple drug benefit plans sponsored by either Medicare Advantage Local or Regional Plans or by approved prescription drug plans (PDPs). Part D sponsors include insurance companies, health maintenance organizations, and pharmacy benefit managers (PBMs). Although plans must contract with any pharmacy willing to agree to reasonable and relevant standard terms and conditions, they are permitted to set up preferred pharmacies with lower patient co-payments within their pharmacy networks.

Patient Assistance Program (PAP): Programs offered by drug manufacturers to low-income individuals in which free drugs and/or other forms of assistance are donated to individuals who lack prescription drug coverage, fall below designated income levels, and meet other program eligibility requirements. Receipt of free drugs from a PAP typically occurs after a patient submits an application, the PAP approves the application, and the free drugs are delivered to a licensed pharmacy or physician for dispensing or administration to the patient.

Pharmaceutical Pricing Agreement (PPA): An agreement that a drug manufacturer must enter into with the Secretary of HHS as a condition of Medicaid or Medicare Part B covering and reimbursing the manufacturer's covered outpatient drugs. An executed PPA obligates the manufacturer to comply with the terms of the 340B program which include, for example, providing a 340B discount on covered outpatient drugs.

Pharmacy Benefit Manager (PBM): An organization that provides administrative and other services in processing and analyzing prescription drugs claims for insurance plans and other payers that offer pharmacy benefits. PBM services can include: contracting with a network of pharmacies; establishing payment levels for provider pharmacies; negotiating rebate arrangements with drug manufacturers; developing and managing formularies, preferred drug lists, and prior authorization programs; maintaining patient compliance programs; performing drug utilization review; and operating medication therapy management programs. Many PBMs also operate mail order pharmacies or have arrangements to make prescription drugs available through mail order pharmacies. PBMs play a key role in managing drug plans in the Medicare Part D drug program.

Pharmacy Services Support Center (PSSC): A federal contractor funded by HRSA to provide guidance and technical assistance to 340B covered entities and to provide staff support to OPA. The organization's primary mission is to support HRSA grantees and 340B-eligible health care delivery sites in providing comprehensive pharmacy services to low-income and other vulnerable patients. The non-profit organization, which is based at the American Pharmacists Association (APhA), provides information and assistance to make the best use of government resources, to create new programs that promote access to affordable drugs, and to bring the value of pharmacy services to traditionally underserved populations.

Physician-Administered Drugs: Drugs or drug ingredients that must be injected, infused, or otherwise administered by a physician or under the supervision of a physician. Pursuant to the DRA, state Medicaid agencies are required to collect NDC information for physician-administered drugs to facilitate states requesting rebates from manufacturers for those drugs under the Medicaid drug rebate program. In implementing the reporting requirements, the Centers for Medicare and Medicaid Services (CMS) has mandated that NDCs be collected both for drugs administered in physicians' offices and drugs administered in hospital outpatient settings. However, as a result of litigation brought by 340B hospitals and a settlement subsequently reached with CMS, the agency issued an October 2009 transmittal to the state Medicaid programs acknowledging that hospitals billing Medicaid for physician-administered drugs at their "purchasing costs as determined under the state plan" could not be mandated under federal law to submit NDCs.

Preferred Drug List (PDL): The Medicaid program prohibits states from utilizing formularies that would otherwise allow states to exclude listed non-formulary drugs from Medicaid coverage. Instead, the Medicaid law permits states to use PDLs. These are lists of drugs for which prior authorization and step therapy restrictions do not apply. Such procedures do not bar the use of non-preferred drugs, but discourage doctors from writing prescriptions for those drugs because of the administrative burden imposed. The use of non-preferred drugs also is discouraged through the imposition of higher levels of patient cost-sharing.

Prescription Drug Plan (PDP): A state-licensed, risk-bearing insurance plan that offers a stand-alone drug benefit to Medicare beneficiaries under the Medicare Part D program. PDP plan sponsors submit annual bids to contract with the Centers for Medicare and Medicaid Services (CMS) to deliver the Part D drug benefit in defined service areas or nationally. PDP sponsors include insurance companies and pharmacy benefit managers (PBMs).

Prompt Pay Discounts: Discounts off the purchase price of drugs in exchange for payment for the drugs within a specific time period. The DRA redefined the definition of AMP to exclude prompt pay discounts that drug manufacturers extend to

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wholesalers. The CMS rule that implements the DRA defines customary prompt pay discounts as “any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified timeframe and consistent with customary business practices.”

Provider-Based Regulations: Federal regulations that set forth criteria that must be met for a site to be deemed provider-based for Medicare purposes. “Main providers” – such as hospitals, nursing homes and other institutions – may own and operate other departments, facilities, or remote locations and may want to include the cost or revenue of these sites as part of the main provider for Medicare reimbursement purposes. For a site to be considered part of the provider, it must be provider-based. Its relationship with the main provider must meet the following eight criteria: 1) joint licensure; 2) integration of clinical services, including main provider oversight and administration of (and responsibility for) the clinical services rendered at the provider-based site; 3) integration of medical records; 4) integration of financial operations; 5) holding the provider-based site out to the public as part of the main provider; 6) compliance by the provider-based site with rules and regulations applicable to the main provider; 7) billing of services rendered at the provider-based site to Medicare patients as hospital services; and 8) integration of administrative and managerial functions. 42 C.F.R. § 413.65. In changes to the 340B definition of patient proposed in January 2007 and still pending, HRSA suggested that the provider-based regulations be used to determine whether a DSH hospital site is eligible to participate in the program.

Provider Dispensing: The dispensing of drugs by providers rather than by pharmacies. Regulation of provider dispensing varies by state. States may require licensure of providers that dispense, may limit the provider’s dispensing activities to state-licensed “dispensaries,” may license the dispensary, may require a pharmacist consultant to be on record for the provider, or may rely on a combination of these requirements. California has a special law for licensing clinic dispensaries.

Provista: The organization contracted by HRSA to serve as the prime vendor for the Public Health Service 340B program between September 2004 and September 2007. Provista is owned by VHA Inc., a national health care cooperative, and the University HealthSystem Consortium (UHC), an alliance of academic medical centers. Provista is a sister company to Novation, which is also owned by VHA and UHC. Prior to July 2007, Provista was called HealthCare Purchasing Partners International (HPPI). The prime vendor program is currently being administered by Provista subsidiary Apexus Inc.

Reference Pricing: A system of fixed reimbursement for pharmaceuticals under which the government or other third party payers establish a set level at which they are willing to reimburse “interchangeable” products. If manufacturers charge more than the reference price, patients must pay the excess cost.

Safety Net Hospitals for Pharmaceutical Access (SNHPA): A non-profit organization based in Washington, D.C. that represents the interests of hospitals in the 340B program. SNHPA, originally called the Public Hospital Pharmacy Coalition, took the lead role in ensuring that hospitals were included in the program when Congress enacted the 340B law in 1992. It now has approximately 500 member hospitals and provides a range of advocacy and member services. More details about SNHPA can be found at www.snhpa.org or by contacting Karen Hicks at karen.hicks@snhpa.org or 202-552-5854.

Section 402 of MMA: The provision in the MMA that changes the way that rural and small urban hospitals calculate their disproportionate share hospital (DSH) payment adjustments by raising the DSH cap for these hospitals to 12%. As a result of this change, many of these DSH hospitals now meet the 11.75% threshold necessary for participation in the 340B program.

Section 1002 of MMA: The provision in the MMA that extends the best price exemption for 340B purchases to inpatient pharmaceuticals purchased by 340B participating DSH hospitals. As a result, manufacturers are permitted (but not required) to sell their inpatient products to 340B hospitals at prices below Medicaid “best price” (including at 340B prices) without having to increase their rebate payments to the entire Medicaid program.

Section 1927 of the Social Security Act: The federal law that established the Medicaid drug rebate program and governs Medicaid reimbursement of covered outpatient drugs. Among other things, Section 1927 requires a manufacturer to enter into and have in effect both a rebate agreement and a pharmaceutical pricing agreement with the HHS Secretary in order to receive Medicaid payment for certain covered outpatient drugs.

Section 6004 of DRA: The provision in the Deficit Reduction Act under which certain children’s hospitals became eligible to participate in the 340B program.

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Section 602: Section 340B of the Public Health Service Act was established under Section 602 of the Veterans Health Care Act of 1992. As a result, the terms “Section 340B” and “Section 602” are often used interchangeably. The law is codified at 42 U.S.C. § 256b.

State Pharmaceutical Assistance Program (SPAP): A state-administered program that provides assistance with pharmaceutical benefits to disabled, indigent, low-income elderly, or other financially vulnerable persons that wrap around the Part D program. These programs rely on state, local, and private funding rather than federal funding. Since 2007, under the Medicare Part D program, SPAPs may provide payment of premiums or beneficiary cost sharing. Cost sharing by SPAPs that meet certain criteria (such as non-discrimination against particular Part D plans) counts as true out-of-pocket spending (TrOOP), thereby ensuring that the beneficiary is not delayed in reaching the "catastrophic limit." Once the beneficiary reaches the catastrophic limit, most of the beneficiary's drug costs are covered by the Medicare program.

Supplemental Rebates: Rebates paid by manufacturers to state Medicaid agencies in addition to the rebates paid under the Medicaid drug rebate law. These supplemental rebates are typically paid by manufacturers to ensure that the companies' drugs are included on the state Medicaid agency's preferred drug list (PDL).

True Out-of-Pocket Spending (TrOOP): The MMA and accompanying regulations create a distinction between all beneficiary out-of-pocket expenditures and those that count toward the annual Part D out-of-pocket threshold – the latter are known as “true” out-of-pocket (TrOOP) expenditures. TrOOP costs relate to covered Part D drugs that are actually paid by the beneficiary, another person on behalf of the beneficiary, or a qualified state pharmaceutical assistance program, and that are not reimbursed by a third-party (such as a supplemental insurance plan or group health plan sponsored by a former employer) or subsidized through payments made by a governmental program. TrOOP costs count toward the out-of-pocket threshold that a beneficiary must incur before he or she is eligible to receive catastrophic coverage. Most third-party assistance, such as that from employers and unions, does not count as TrOOP. CMS has said that DSH payments do not constitute governmental payments and can therefore be used to subsidize patient Part D cost-sharing waivers or reductions that can then be counted toward TrOOP.

UB-04: Formerly known as UB-92, the electronic version of the CMS-1450 form (formerly HCFA-1450), which is the uniform institutional claim form used by institutional and other selected providers (including 340B hospitals) to transmit claim information to Medicare and most state Medicaid agencies. The form is developed by the National Uniform Billing Committee, which is comprised of key organizations whose members are affected by administrative transactions within the institutional sector of the health care community. Hospitals typically use the UB-04 form to bill physician-administered drugs.

UB-92: See “UB-04.”

VA National Contract Price: The price that the Veterans Administration (VA) has obtained through competitive bids from manufacturers for select drugs in exchange for their inclusion on the VA formulary. Because the VA is entitled to FCP prices under federal statute, VA national contract prices are even lower than FCP prices and are often the lowest prices in the nation. These prices are publicly available.

Wholesale Acquisition Cost (WAC): The price paid by a wholesaler for drugs purchased from the wholesaler's supplier, typically the manufacturer of the drug. On financial statements, the total of these amounts equals the wholesaler's cost of goods sold. Disclosed in published compendia, listed WAC amounts may not reflect all available discounts. A few states use markups of WAC in setting Medicaid reimbursement.

Wholesaler: A wholesaler is a company that purchases drugs from a supplier, usually the manufacturer, for the purpose of distributing the drugs to pharmacies, hospitals, physicians and other purchasers that dispense and/or administer drugs to patients. Wholesalers are regulated under federal and state law and, as a result, are subject to numerous standards designed to protect the integrity of drug products.

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