



Safety Net Hospitals for Pharmaceutical Access

Key Pharmaceutical Terms

340B Ceiling Price: The maximum price that manufacturers can charge covered entities participating in the 340B 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) 23.1 percent off of the drug's average manufacturer price (AMP), except that the rebate for brand name pediatric drugs and clotting factor is the lower of best price or 17.1 percent off of the drug's AMP. For generic and over-the-counter drugs, the 340B ceiling price is 13 percent off of the drug's AMP. For reformulated brand name oral solid drugs, the 340B discount is the higher of the rebate amount applicable to the original formulation or the new formulation rebate amount. Brand name manufacturers must provide an additional discount 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 negotiate prices below the 340B ceiling price and provide distribution services for covered 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 drug discount program authorized under section 340B of the Public Health Service Act and 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 and/or the Medicare Part B program 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.

Accountable Care Organization (ACO): An organization of health care providers that participate in the Medicare fee-for-service program and that agree to be accountable for the quality, cost, and overall care of assigned Medicare beneficiaries, especially with respect to primary care.

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 (AMDP): HRSA-approved projects that give 340B covered entities flexibility to operate programs or enter into agreements with other covered entities 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 are intended to test new methods of participating in the 340B program to improve access to pharmacy services for vulnerable populations. Until HRSA's multiple contract pharmacy guidelines went into effect on April 5, 2010, covered entities were prohibited from having more than one contract pharmacy arrangement per site in the absence of an approved AMDP.

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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.”

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 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 covered entities that choose to participate. 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: 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 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 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. Health reform broadened the AMP exclusions by also excluding those payments received from, and rebates or discounts provided to, pharmacy benefit managers (PBMs), managed care organizations (MCOs), HMOs, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy. After health care reform, Congress amended the definition of AMP to expressly permit the use of non-retail transactions in calculating AMP for inhalation, infusion, instilled, implanted and injectable drugs that are not generally dispensed through a retail community pharmacy. Before health care reform, the Congressional Budget Office (CBO) estimated AMP to be about 21 percent less than the average wholesale price (AWP) for about 130 frequently purchased brand-name drugs.

The Deficit Reduction Act of 2005 (DRA) required CMS to make AMP data available to states on a monthly basis and to the general public through a website updated at least quarterly, but a preliminary injunction issued in December 2007 blocked CMS’ plans. That injunction was lifted in December 2010, but CMS has not yet made AMP data available. The new health reform law modified DRA’s mandate to instead require posting of the weighted average of the most recently reported monthly AMPs and the average retail survey price determined for each multiple source drug. Pursuant to health reform, CMS withdrew the old definition of AMP and will be releasing a new proposed definition for public comment. Also as a result of the DRA, AMP is used to determine the federal upper limit (FUL) on Medicaid pharmacy reimbursement for multiple source 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 Part B.

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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. Although Medicare has historically reimbursed outpatient drugs based on a discount off of AWP, AWP-based reimbursement for Medicare 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 has traditionally been available through a number of periodicals. 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). 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. Thompson Publishing has said it will continue to publish its Red Book compilations of AWP values after the other publications discontinue theirs. A study group of Medicaid directors and pharmacy directors recommended in October 2009 that states switch to using WAC to set reimbursement until a different standard can be developed after the elimination of AWP.

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 covered outpatient drugs through the 340B program. Because the covered entity does not buy its Medicaid drugs at 340B discounts, state 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 and 2011 (\$6,440 in total drug spending under the standard benefit design in 2010, \$6447.50 in 2011).

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 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. 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.

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 serves as the covered entity’s dispensing

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agent and is paid a dispensing fee for the services associated with filling each prescription dispensed. Contract pharmacies may provide other services for covered entities and typically serve as the entity's billing agent. On March 5, 2010, HRSA published revised contract pharmacy guidelines allowing covered entities to contract with multiple contract pharmacies or to have both an in-house outpatient pharmacy and one or more contract pharmacies. Covered entities were previously prohibited from having a contract pharmacy if they operated their own outpatient pharmacy and, even in the absence of an in-house pharmacy, they were limited to one contract pharmacy arrangement per site. Under the new guidelines, contract pharmacies must agree to provide the covered entity with reports consistent with customary business practices such as quarterly billing statements, status reports of collections, and receiving and dispensing records. Auditable records must be maintained for a period of time that complies with all applicable federal, state, and local laws. Both contracting parties must acknowledge that they may be audited by manufacturers or the government with respect to records directly pertaining to compliance with drug diversion and duplicate discount prohibitions. The agreement also must specify the respective parties' responsibilities to provide comprehensive pharmacy services including dispensing, recordkeeping, drug utilization review (DUR), formulary maintenance, patient profile, patient counseling, and medication therapy management (MTM) and other clinical services.

Covered Entity: The statutory name for a facility or program eligible to purchase discounted drugs through the 340B program. Covered entities include six categories of hospitals and eleven categories of non-hospitals.

With respect to the hospitals, each hospital must be owned or operated by or be under contract with state or local government to qualify for 340B, regardless of the category to which it belongs. One of the categories of hospitals – disproportionate share (DSH) hospitals – must have received DSH adjustment payment percentages greater than 11.75 percent for their most recent cost reporting year. Two other categories – freestanding children's and cancer hospitals – are exempt from the Medicare prospective payment system (PPS) and therefore do not receive DSH payments. Their eligibility is conditional upon demonstrating that they would have received DSH payments above 11.75 percent if they were DSH hospitals. DSH hospitals, children's hospitals and cancer hospitals are each subject to another 340B eligibility requirement – they must certify that they will not purchase covered outpatient drugs through a group purchasing organization (GPO). The remaining three categories of hospitals are all rural hospitals. They include rural referral centers and sole community hospitals with DSH adjustment percentages of 8 percent or greater and critical access hospitals. The children's hospitals were added as covered entities pursuant to the DRA under guidelines adopted in September 2009, while free-standing cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals were added in 2010 under the Patient Protection and Affordable Care Act (PPACA).

With respect to the non-hospital facilities and programs, eleven categories of covered entities must be a federal grantee or sub-grantee. They include federally qualified health centers (FQHCs), FQHC "look-alikes", state-operated AIDS drug assistance programs, the Ryan White CARE Act Title I, Title II, and Title III programs, tuberculosis, black lung, family planning and sexually transmitted disease clinics, hemophilia treatment centers, public housing primary care clinics, homeless clinics, Urban Indian clinics, and Native Hawaiian health centers. The only group that is not federally funded is FQHC "look-alikes"

Covered Outpatient Drug: The category of drugs for which manufacturers must pay rebates to state Medicaid agencies under the Medicaid rebate program and give 340B discounts to covered entities under the 340B program.

Corporate Integrity Agreement (CIA): An agreement between the 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,

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reporting of Medicaid best price, and ceasing the promotion of “off-label” uses of drugs not approved by the Food and Drug Administration (FDA).

Critical Access Hospital (CAH): A rural hospital with 25 or fewer inpatient acute care beds that furnishes 24-hour emergency services, either with its own staff or on-call staff, and has an average annual length of stay of 96 hours or less. The CAH may have up to 10 additional rehabilitation or psychiatric beds. A CAH must be located either more than 35 miles from the nearest hospital or CAH or more than 15 miles in areas with mountainous terrain or only secondary roads, or be state-certified as a “necessary provider” of health care services to area residents. The CAH must be located in one of the 46 states with a “FLEX” program (Connecticut, Delaware, Maryland, New Jersey and Rhode Island do not have such programs). CAHs are eligible for the 340B program if they are either publicly owned or a private nonprofit institution with a contract with state or local government to serve non-Medicare and non-Medicaid low-income patients.

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 codes (NDCs) 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 a 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 actual drugs being dispensed.

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

Disproportionate Share Hospital (DSH): A category of hospitals that may participate in the 340B drug discount program if they meet certain 340B eligibility criteria. A DSH hospital serves a disproportionately large share of low-income patients. The Medicare and Medicaid programs provide additional payments to DSH hospitals 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 payment and is based on the share of Medicaid patients and supplemental security income (SSI) recipients that the hospital serves on an inpatient basis. In order for a DSH 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 percent co-payment on covered drugs. In 2010 and 2011, this gap in coverage begins once a beneficiary’s total drug costs exceed \$2,830. It ends once the beneficiary’s total drug costs reach \$6,440 in 2010 and \$6,447.50 in 2011. Provisions of the PPACA provide for the elimination of the donut hole by 2020, when Part D beneficiaries who do not receive the Part D low-income subsidy (LIS) will only be responsible for the same 25 percent co-payment they currently pay during the initial coverage period. Beginning in 2011, manufacturers will have to provide a 50 percent discount on brand name drugs dispensed when a beneficiary is in the donut hole. The government will phase in a subsidy for generic drugs as well, starting with a 7 percent subsidy in 2011.

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.

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DSH Adjustment: See “Medicare DSH Adjustment Percentage.”

DSH Hospital: See “Disproportionate Share Hospital.”

Dual Eligibles: The 8.9 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 2006, full-benefit dual eligibles received their drug coverage through Medicaid but now receive 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 6.9 million full-benefit and 2 million partial-benefit dual eligibles who are automatically enrolled in Part D.

“Duplicate Discount”: An instance where a manufacturer gives both an upfront 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. Language was added under PPACA requiring, for the first time, that manufacturers pay rebates on drugs provided to Medicaid managed care (MCO) enrollees. However, to avoid the risk of duplicate discounts, Congress exempted manufacturers from having to pay MCO rebates on drugs purchased through the 340B program.

Estimated Acquisition Cost (EAC): A Medicaid agency’s best estimate of the price generally paid by pharmacies for a particular drug. Federal rules require that states pay for 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).

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 a 2005 CBO report, 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. Federal law requires the setting of an FUL for any multiple source drug that has at least three or more equivalent generic products. FULs are calculated at not less than 175 percent of the weighted average of the most recently reported monthly AMPs for equivalent generic products that are available for purchase by retail community pharmacies on a nationwide basis. 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

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rate as long as total reimbursement for all drugs in the aggregate does not exceed the maximum aggregate reimbursement permitted under the aggregate FULs.

Free-Standing Cancer Hospitals: Independent, nonprofit hospitals that are not parts of larger institutions and that are designated by federal statute as exempt from Medicare’s prospective payment system. A hospital not currently designated by the Medicare program as a cancer hospital can become so only through legislative action. Eleven hospitals are currently recognized as cancer hospitals nationwide. To qualify for 340B, a free-standing cancer hospital must (1) be owned or operated by or be under contract with state or local government, (2) certify that it will not purchase covered outpatient drugs through a GPO and (3) have a payer mix that would entitle the hospital to a Medicare DSH adjustment percentage greater than 11.75 percent if it were a DSH hospital.

Free-Standing Children’s Hospitals: Hospitals whose patients are mostly under age 18 and that are exempt from the Medicare prospective payment system. To qualify for 340B, a free-standing children’s hospital must (1) be owned or operated by or be under contract with state or local government, (2) certify that it will not purchase covered outpatient drugs through a GPO and (3) have a payer mix that would entitle the hospital to a Medicare DSH adjustment percentage greater than 11.75 percent if it were a DSH hospital.

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 MCOs, PBMs, hospitals and Part D prescription drug plans (PDPs). Almost all Medicaid programs have preferred drug lists (PDLs) that operate like formularies except that a state may not prohibit use of drugs excluded from its PDL. Rather, the state may set prior authorization procedures that must be exhausted before non-PDL drugs can be prescribed.

Government Accountability Office (GAO): An independent, nonpartisan federal agency – often called the "Congressional watchdog" – that works for Congress and investigates how the federal government spends taxpayer dollars. The head of GAO is the Comptroller General of the United States. The GAO supports Congressional oversight by (1) auditing agency operations to determine whether federal funds are being spent efficiently and effectively; (2) investigating allegations of illegal and improper activities; (3) reporting on how well government programs and policies are meeting their objectives; (4) performing policy analyses and outlining options for Congressional consideration; and (5) issuing legal decisions and opinions, such as bid protest rulings and reports on agency rules. PPACA directs the GAO to undertake a study of the 340B program within 18 months of enactment of the legislation in order to examine whether individuals served by covered entities under the program “are receiving optimal health care services.” The report is required to include recommendations on: (1) whether the 340B program should be expanded given the expansion of health insurance coverage under PPACA; (2) whether mandatory sales of certain products by the 340B program could hinder patients access to those therapies; and (3) whether income from the 340B program is being used by covered entities to further program objectives.

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, DSH hospitals, free-standing children’s hospitals, and free-standing cancer hospitals are required to limit their use of GPOs as a

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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. Sole community hospitals, rural referral centers, and critical access hospitals are not subject to the GPO exclusion.

GPO Exclusion: A statutory restriction imposed on all DSH hospitals, free-standing children's hospitals, and free-standing cancer hospitals that participate in the 340B drug discount program. Under the GPO exclusion, these hospitals may not "obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement." 340B hospitals may use GPOs for purchasing inpatient drugs and non-drug items like medical and surgical supplies. The GPO exclusion does not apply to rural referral centers, sole community hospitals, or critical access hospitals.

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 program is administered by HRSA through its Office of Pharmacy Affairs (OPA).

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 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. A provision in the proposed 340B-1 legislation would subject all hospitals participating in 340B-1 to mandatory OIG audits.

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 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. State Medicaid programs 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.

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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 the Veteran's Administration, Department of Defense, Indian tribes, federal supply schedule, 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 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. With the passage of PPACA, the basic rebate for most brand name drugs is the greater of 23.1 percent of the average manufacturer price or the difference between AMP and Medicaid best price. The basic rebate for brand name pediatric drugs and blood clotting factor is 17.1 percent or the difference between AMP and best price. Rebates for generic and over-the-counter drugs are 13 percent of the AMP, with no consideration of best price. 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 consumers. The average Medicaid rebate net price is 64 percent of AWP.

Medicare Advantage Local Plans: Medicare Advantage Local Plans are one of three categories of sponsors that may operate Medicare Part D drug benefit plans. The other two types of Part D sponsors are prescription drug plans (PDPs) and Medicare Advantage Regional Plans. Medicare Advantage Local Plans are capitated, closed system managed care plans that provide comprehensive health services to Medicare enrollees in one or more counties. Medicare pays Local Plans based on their enrollees' counties of residence. Local Plans can be health maintenance organizations (HMOs), preferred provider organizations (PPOs), private fee-for-service (PFFS) plans, and special needs plans (SNPs). Local Plans must establish a mandatory out-of-pocket amount for all Medicare Part A and B services to mirror the same out-of-pocket costs an average beneficiary would have under Medicare's fee-for-service program. The Medicare Advantage program was established by Congress under the Medicare Modernization Act of 2003 to update and replace the Medicare+Choice program beginning in 2006.

Medicare Advantage Regional Plans: Medicare Advantage Regional Plans are one of three categories of sponsors that may operate Medicare Part D drug benefit plans. The other two types of Part D sponsors are prescription drug plans (PDPs) and Medicare Advantage Local Plans. Medicare Advantage Regional Plans are capitated, managed care plans that provide comprehensive health care services to Medicare beneficiaries in one or more of 26 regions established by CMS. Each region comprises one or more entire states. Unlike the Medicare Advantage Local Plans which can be HMOs, PPOs, PFFS plans, or SNPs, Regional Plans must be PPOs. Like the Local Plans, Regional Plans must limit a beneficiary's liability for costs not covered by the plan. They have the option of using the out-of-pocket limits applicable to Local Plans. The Medicare Advantage program was established by Congress under the Medicare Modernization Act of 2003 to update and replace the Medicare+Choice program beginning in 2006.

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 payments, available only to hospitals that serve a disproportionate number of indigent patients. In the context of eligibility for the 340B program, the Medicare DSH adjustment percentage serves as a proxy of how many indigent or low-income patients are served by the hospital. DSH hospitals must have a Medicare DSH adjustment percentage that exceeds 11.75 percent to qualify for 340B. Although free-standing children's and cancer hospitals do not receive DSH payments because

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they are PPS-exempt, they must have a patient mix that would result in the payment of DSH adjustments greater than 11.75 percent if they were DSH hospitals participating in the PPS program. Critical access hospitals are also PPS-exempt and do not receive DSH payments. However, in contrast to children's and cancer hospitals, CAHs are not subject to minimum DSH adjustment percentages to qualify for 340B. Rural referral centers and sole community hospitals must have DSH adjustment percentages of 8 percent or greater to participate in 340B.

Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA): Legislation passed by Congress in 2003 that introduced the most sweeping amendments to the Medicare program since the start of the program. The MMA included the creation of a new outpatient drug benefit called Medicare Part D, 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 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 FDA. 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. NDCs are utilized by Medicaid programs to identify specific drugs on which rebates and supplemental rebates are due.

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 that administers the 340B drug discount program. OPA is located within HRSA's Healthcare Systems Bureau and is located at HRSA headquarters in Rockville, Maryland.

Orphan Drugs: Drugs which the FDA determines (1) are designed to treat rare diseases and conditions that affect fewer than 200,000 patients in the U.S., or (2) if the disease or condition affects more than 200,000 patients in the U.S., will produce sales that fail to cover the costs of the drug's development and production. Orphan drug designation by the FDA is for a particular "indication" – a condition or illness which the FDA determines the drug can be used to treat. Manufacturers of orphan drugs are granted seven years of market exclusivity. Under health

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care reform legislation, manufacturers are not required to give 340B discounts on orphan drugs purchased by free-standing cancer hospitals, sole community hospitals, rural referral centers, and critical access hospitals. The orphan drug exemption does not apply to any other category of 340B covered entities. On May 20, 2011, HRSA published a proposed regulation stating that the exemption applies only when an orphan drug is used to treat rare conditions or diseases, but not when that orphan drug is used to treat other indications. The proposed regulation is subject to a 60-day public comment period. HRSA will develop a final regulation after the comment period ends, but there is no deadline by which the agency must promulgate a final regulation.

Patient Protection and Affordable Care Act (PPACA): Legislation enacted in 2010 that made the most extensive changes to the 340B program since its enactment in 1992. PPACA added free-standing cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals as covered entities, while also conferring formal 340B status to free-standing children's hospitals. PPACA also added a number of program integrity provisions designed to ensure that 340B program requirements are appropriately enforced, both for and against covered entities and manufacturers. Among the integrity provisions established under PPACA are: giving covered entities access to 340B ceiling prices, authorizing HRSA to impose fines, and making HRSA's informal dispute resolution process formal and mandatory for all parties. In addition, PPACA increased the minimum rebate percentages for both the Medicaid rebate and 340B programs, and modified the way that AMP is to be calculated in determining FULs, Medicaid rebates, and 340B discounts.

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 (MA) plans or by approved prescription drug plans (PDPs). Part D sponsors include insurance companies, HMOs and 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 drug coverage, fall below designated income levels, and meet other 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 HHS Secretary 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 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 PSSC is a non-profit organization based at the American Pharmacists Association (APhA).

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Physician-Administered Drugs: Drugs or drug ingredients that must be injected, infused, or otherwise administered by a physician or a non-physician professional 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, 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 reached with CMS, the agency issued an October 2009 transmittal to state Medicaid programs acknowledging that hospitals billing Medicaid for physician-administered drugs at their "purchasing costs as determined under the state plan" cannot be mandated under federal law to submit NDCs. Besides facilitating payment of Medicaid rebates for physician-administered drugs, states mandate NDC reporting for other purposes such as tracking drug utilization and to assist with the collection of state supplemental rebates.

Preferred Drug List (PDL): Medicaid 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 CMS to deliver the Part D drug benefit in defined service areas or nationally. PDP sponsors include insurance companies and PBMs.

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

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.

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. Under HRSA's 2009 guidelines authorizing children's hospitals to enroll in the 340B program, 340B children's hospitals that do not file Medicare cost reports may only enroll new hospital sites into the program if those sites are provider-based within the meaning of Medicare regulations.

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

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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 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.

Rural Referral Center (RRC): A rural, high-volume hospital that meets one of three sets of conditions: (1) it has 275 or more beds available for use; (2) (i) at least 50 percent of its Medicare patients are referred from other hospitals or from physicians not on the hospital's staff; (ii) at least 60 percent of its Medicare patients live more than 25 miles away; and (iii) at least 60 percent of all services it furnishes to Medicare beneficiaries go to those living more than 25 miles away; or (3) (i) either more than 50 percent of its active medical staff are specialists or at least 60 percent of its discharges are inpatients who live more than 25 miles away and (ii) it meets certain case mix standards set by CMS and discharge standards set by statute and CMS. To be 340B eligible, an RRC must have a Medicare DSH adjustment percentage of 8 percent or greater and either be publicly owned or be a private nonprofit institution with a contract with state or local government to serve non-Medicare and non-Medicaid indigent patients.

Safety Net Hospitals for Pharmaceutical Access (SNHPA): A non-profit advocacy organization based in Washington, D.C. that represents the interests of hospitals in the 340B program. SNHPA, originally called the Public Hospital Pharmacy Coalition (PHPC), took the lead role in ensuring that hospitals were included in the program when Congress enacted the 340B law in 1992 and led the effort to expand the program to rural hospitals. It now has over 700 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 Anna Mangum at anna.mangum@snhpa.org or 202-552-5863.

Section 602 of the Veterans Health Care Act: 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.

Sole Community Hospital (SCH): A hospital that is: (1) located 35 miles from other like hospitals; (2) a rural hospital 45 minutes or more in travel time distant from a like hospital; (3) a rural hospital that is between 15 and 25 miles from other like hospitals but, because of local topography or prolonged severe weather conditions, inaccessible from other hospitals at least 30 days in each of two out of three years; or (4) a rural hospital that is between 25 and 35 miles from other hospitals and (i) is inaccessible from other hospitals for at least 30 days in each of two out of three years due to local topography or prolonged severe weather conditions, (ii) for which no more than 25 percent of residents who become hospital inpatients or no more than 25 percent of Medicare beneficiaries who become hospital inpatients in the hospital's service area are admitted to other like hospitals within a 35-mile radius of the hospital or, if larger, within its service area, or (iii) has fewer than 50 beds and would meet the 25 percent criterion in item (ii) but for the fact that some residents or beneficiaries had to seek specialized care outside of the service area due to the hospital's lack of specialty services. To be admitted to the 340B program, an SCH must receive a Medicare DSH adjustment percentage of 8 percent or higher. In addition, it must either be publicly owned or be a private nonprofit institution with a contract with state or local government to serve non-Medicare and non-Medicaid indigent patients.

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

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funding. Since 2007, under the 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, thereby ensuring that the beneficiary is not delayed in reaching the "catastrophic limit." Once the beneficiary reaches the limit, most of the beneficiary's drug costs are covered by Medicare. There are currently 35 qualified SPAPs operating in 25 states or territories.

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.

True Out-of-Pocket Spending (TrOOP): The MMA and accompanying regulations created 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 expenditures. TrOOP costs relate to 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, 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 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. A study group of Medicaid directors and pharmacy directors recommended in October 2009 that states switch to using WAC to set reimbursement until a different standard can be developed after AWP is abandoned.

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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