

## **GLOSSARY**

**340B Drug Pricing Program** - a Federal government program created in 1992 that requires drug manufacturers to provide outpatient drugs at significantly reduced prices to eligible health care organizations and covered entities serving uninsured, low income and indigent patients.

Improve this – add '#s 50% lees, # od f participants

Accountable Care Organization (ACO) - groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high quality care to their Medicare patients to ensure that patients, especially the chronically ill, get the right care at the right time, while avoiding unnecessary duplication of services and preventing medical errors. When an ACO succeeds both in delivering high-quality care and spending health care dollars more wisely, it will share in the savings it achieves for the Medicare program.

**Alternate Payment Models (APMs) -** a payment approach that rewards providers for delivering high quality and cost-efficient care.

Advanced Alternate Payment Models (AAPMs) - a subset of APMs that let practices earn more rewards in exchange for taking on risk related to patient outcomes.

**Average Manufacturers Price (AMP)** - the **average price** paid by wholesalers for drugs distributed to the retail class of trade, net of customary prompt pay discounts. The AMP is statutorily defined and its calculation is based on actual sales transactions.

**Average Sales Price (ASP)** - a manufacturer's average price to all purchasers, net of discounts, rebates, chargebacks, and credits for drugs. ASP is determined using manufacturers' **sales** reports, which include information on total units sold and total revenue for each drug, and is subject to audit by Medicare.

**Average Wholesale Price (AWP)** - the average price at which drugs are purchased at the wholesale level. The term was originally intended to convey real pricing information to third-party payors, including government prescription drug programs.

**Biosimilars** - a type of biological products that are licensed (approved) by FDA because they are highly similar to an already FDA-approved biological product,

known as the biological reference product (reference product), and have been shown to have no clinically meaningful differences from the reference product.

**Cancer Care Delivery System** - the system of the various sources of cancer care available including physician owned practices, commonly referred to as community oncologists, hospital based oncologists and cancer care centers, and academic or teaching institutions.

Centers for Medicare and Medicaid Services (CMS) - a Federal agency within the Department of Health and Human Services (HHS) that administers the Medicare program and works in partnership with state governments to administer Medicaid.

Centers for Medicare and Medicaid Innovation (CMMI) – is an organization of the Federal government under CMS that was created as part of the Affordable Care Act (ACA), the 2010 U.S. health care reform legislation. CMMI's purpose is to test innovative payment and delivery system models that show important promise for maintaining or improving the quality of care in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP), while slowing the rate of growth in program costs. CMMI is mandated to give priority to twenty models specified in the law, including medical homes, all-payer payment reform, and arrangements that transition from fee-for-service reimbursement to global fees and salary-based payment.

**COA Impact Report -** a report issued by the Community Oncology Alliance that tracks closings, hospital acquisitions, and corporate mergers in community oncology practices nationwide.

**COA Patient Advocacy Network (CPAN)** - an organization created to give patients a role in advocating for access to local affordable care for all cancer patients. CPAN, the patient advocacy arm of COA, is a non-cancer type specific national network representing patients, cancer survivors, caregivers, family members, medical and oncology professionals, and members from the general community.

**Co-insurance** - amount that may be required for services after any health insurance plan deductibles are paid. In the Medicare Plan, this is a percentage (usually 20%) of the Medicare approved amount. Co-insurance is often also referred to as the co-pay or co-payment.

**Commercial Insurance** - a type of health insurance that covers medical. Commercial health insurance can be categorized according to its renewal provisions and type of medical benefits provided. Commercial policies can be sold individually or as part of a group plan and are often provided by employers to their employees.

**Community Oncologist** - an oncologist working in private practice, alone or as part of a group, that is privately owned, and not part of hospital-based, corporately owned or academic institution.

**Community Oncology Alliance (COA)** - a non-profit 501 (c)(6) organization dedicated to advocating for community oncology practices, the patients they serve, and the preservation of access to local, affordable care. COA is the only organization dedicated solely to community oncology where close to 55% of Americans with cancer are treated.

**Community Oncology Pharmacy Association (COPA)** - within COA, an association for pharmacists, pharmacy technicians and others working in a community oncology practice.

**Compendia -** a collected body of information on the standards of strength, purity, and quality of drugs. The official compendia in the United States are the United States Pharmacopoeia, the Homeopathic Pharmacopoeia of the United States, and their supplements.

**Co-payment** - in some commercial and Medicare health and prescription drug plans, the amount paid for a medical service, like a doctor's visit, or prescription drug. A co-payment is usually a set amount. For example, this could be \$10 or \$20 for a doctor's visit or prescription. Co-payments are also used for some hospital outpatient services in Medicare Plan Part A and B and are commonplace in most government and private insurance plans. Co-payment is also often referred to as co-pay or co-insurance.

**Cost Sharing** - a system under which patients pay for a portion of health care costs not covered by health insurance. The amount of the payment varies amongst healthcare plans and depends on a number of factors including whether a healthcare provider is contracted with a given healthcare plan's network, also known as in-network, or not contracted, also known as out of network.

Current Procedural Terminology Codes (CPT codes) - the standard for how medical professionals document and report medical, surgical, radiology, laboratory, anesthesiology, and evaluation and management services. All healthcare providers, payers, and facilities use CPT codes. The five-character CPT codes are used by insurers to help determine the amount of reimbursement that a practitioner will receive for services provided.

**Deductible** - amount paid for health care or prescriptions before a prescription drug plan, or other insurance begins to pay. The deductible is a patient out of pocket expense and varies dependent upon the insurance pan or prescription drug plan.

**Dispensing Pharmacy -** a pharmacy that provides prescription drugs and supports patient safety and compliance through counseling when the drugs are dispensed.

**Dispensing Physician -** oncologists whose patient care includes providing direct access to oral cancer drugs through an in-practice dispensary. Practice staff can provide greater continuity of care by managing all aspects of drug therapy - from initial dispensing to completion of therapy. In-practice dispensing allows for improved patient convenience, safety, and compliance. Practice staff in the dispensary area typically work directly with patients to address the insurance coverage limitations and financial toxicity of procuring these drugs.

Direct and Indirect Remuneration Fees (DIR Fees) - In exchange for placing their products on a plan's formulary, pharmaceutical manufacturers give rebates, and similar fees, to PBMs. To arrive at the actual "net" cost of all drugs under Part D, so that it can appropriately and legally base reimbursement on the lowest price, CMS implemented the concept of DIR. Through this concept, plan sponsors and PBMs are required to report all "direct" and "indirect" remuneration (DIR) received from third parties, such as manufacturers. Because manufacturer rebates were not "known or knowable" until a prescription had been dispensed to the patient and claim processed, such remuneration was accounted for and reconciled afterwards, when Medicare did a "true up" of DIR received, or paid out, by a PBM. Over time, Part D plan sponsors and PBMs began to incorporate different payment and network structures for their participating pharmacies. Among those strategies included the introduction pharmacies, and which are distinct from the original and legitimate DIR reported to Medicare. In theory—and as originally contemplated by CMS—these DIR Fees would provide pharmacies with additional reimbursement based on certain quality performance metrics. Over the last year or so, DIR Fees have been become an overly broad "backdoor" vehicle for clawing back additional monies and increasing PBM profits.

**Donut hole** - the coverage gap between a Medicare Part D plan's initial coverage limit (\$3,700 in 2017) and an upper limit (\$4,950 in 2017). Drug costs within the coverage gap, or donut hole, must be paid by the patient. Catastrophic coverage applies to drug costs over \$4950 and the patient pays a small coinsurance amount or a copayment for the rest of the calendar year.

**Diagnosis Related Group Codes (DRG Codes) -** a system to classify hospital cases into one of approximately 500 groups, also referred to as DRGs, expected to have similar hospital resource use. They have been used in the United States since 1983.

**Drug Tier -** within a drug plan's formulary, drugs are divided into three or four tiers. The higher the tier, the higher the drug cost and the higher the patient out of pocket.

**Electronic Health Record (EHR) -** an electronic version of a patient's medical history that is maintained by the provider and includes all of the key administrative clinical data relevant to that patient's care. EHR may also be referred to as EMR or electronic medical record.

**Essential Health Benefits -** ten health benefits that all plans participating in the ACA must provide with no dollar limits. These include: ambulatory patient services, emergency services, hospitalization, maternity and newborn care, mental health and substance use disorder services including behavioral health treatment, prescription drugs, rehabilitative services and devices, laboratory services, preventive and wellness services and chronic disease management, and pediatric services.

**Exempt Cancer Hospitals** - the hospitals excluded from payment under the Inpatient Prospective Payment System. The Centers for Medicare & Medicaid Services (CMS) has designated 11 hospitals as PPS-Exempt Cancer Hospitals, or Medicare PPS-Excluded Cancer Hospitals. These Exempt hospitals get significantly higher payments from Medicare in part because it is assumed they care for sicker populations.

**Fee for Service -** a payment model in which each service is paid for separately. This is in contrast to a bundled payment system that pays one flat fee for all the services normally associated with caring for a single medical condition or a single episode of care.

**Formulary** - a list of drugs covered by an insurance plan.

**FQHC** - is a reimbursement designation from the Bureau of Primary Health Care and the CMS. FQHCs are community-based organizations that provide comprehensive primary and preventive care, including oral, mental health, and substance abuse services to persons of all ages, regardless of their ability to pay or health insurance status. FQHCs are a critical component of the health care safety net.

**Geographic Practice Cost Indices (GPCIs) -** geographic practice cost index established for every Medicare payment locality for each of the three components of a procedure's relative value unit (work, practice expense, and malpractice). This index is intended to take into account geographic cost of living differences.

**Health Insurance Marketplace -** Organizations that facilitate structured and competitive markets for purchasing health coverage. The Health Insurance Marketplace, or "Exchange," offers standardized health insurance plans to individuals, families, and small businesses.

Health Resources and Service Administration (HRSA) - is the primary Federal agency for improving health care to people who are geographically isolated, economically or medically vulnerable. HRSA programs help those in need of high quality primary health care, people living with HIV/AIDS, pregnant women and mothers. The agency also supports the training of health professionals, the distribution of providers to areas where they are needed most and improvements in health care delivery.

**Hospital Outpatient (HOP) -** this term is used most often in relation to the site of care, as in HOP (hospital outpatient) care.

**Hospital Outpatient Physician Fee Schedule -** the reimbursement rates established for outpatient services provided in hospitals. The Hospital Outpatient Physician Fee Sch**edule** is updated annually by the Centers for Medicare and Medicaid Services (CMS).

**ICD-10** - the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD), a medical classification list by the World Health Organization (WHO). The list contains codes for diseases, signs and symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or diseases. The code set allows more than 14,400 different codes and permits the tracking of many new diagnoses.

**In-house dispensing pharmacy -** a pharmacy within a medical practice that provides prescription drugs and supports patient safety and compliance through counseling when the drugs are dispensed. Typically, this type of pharmacy limits its drug dispensing to patients of the practice.

**In-house retail pharmacy -** a pharmacy within a medical practice that provides prescription drugs and supports patient safety and compliance through counseling when the drugs are dispensed. Typically, this type of pharmacy dispenses drugs to patients as well as the general public.

**IPAB (Independent Physician Payment Advisory Board)** - a fifteen-member United States Government agency created in 2010 by sections 3403 and 10320 of the Patient Protection and Affordable Care Act which has the explicit task of achieving specified savings in Medicare without affecting coverage or quality.

**Medicaid** - a health care program that assists low-income families or individuals in paying for long-term medical and custodial care costs. Medicaid is a joint program, funded primarily by the Federal government and run at the state level, where coverage may vary.

**Medicare** - the Federal health insurance program for people who are 65 or older, certain younger people with disabilities, and people with End-Stage Renal Disease (permanent kidney failure requiring dialysis or a transplant). The original

Medicare Plan has two parts: Part A (Hospital Insurance) and Part B (Medical Insurance).

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) - MACRA replaces the previous Medicare reimbursement schedule with a new pay-for-performance program that is focused on quality, value, and accountability. MACRA enacts a new payment framework that rewards health care providers for giving better care instead of more service.

**Medicare Part C** - the part of Medicare that allows private health insurance companies to provide Medicare benefits. These Medicare private health plans, such as HMOs and PPOs, are known as Medicare Advantage Plans.

**Medicare Part D** - the Medicare prescription drug benefit that subsidizes the costs of prescription drugs and prescription drug insurance premiums for Medicare beneficiaries.

**Medicare Physician Fee Schedule -** the reimbursement rates established for services provided by physicians to patients covered by Medicare and Medicaid. The Physician Fee Schedule is updated annually by the Centers for Medicare and Medicaid Services (CMS).

**MedPAC (Medicare Payment Advisory Commission)** - an independent Federal body established by the Balanced Budget Act of 1997. The Commission's 17 members bring diverse expertise in the financing and delivery of health care services.

Merit-Based Incenetive Payment System (MIPS) – a new CMS program that based on a composite performance score, eligible professionals may receive a payment bonus, a payment penalty, or no payment adjustment. The composite performance score is based on four performance categories: quality, resource use, clinical practice improvement activities and eaningful use of certified electronic health records (EHR) technology.

**National Cancer Institute (NCI) Centers -** a group of 69 cancer research institutions in the United States supported by the National Cancer Institute. Three designations are recognized: Comprehensive Cancer Centers, Cancer Centers, and Basic Laboratory Cancer Centers.

Non-Formulary drugs - drugs not on a drug coverage plan's approved drug list.

Oncology Care Model (OCM) - a new payment and care delivery model designed to improve the effectiveness and efficiency of specialty care. Under the Oncology Care Model, physician practices, hospitals, teaching and academic centers and payors enter into payment arrangements that include financial and

performance accountability for episodes of care surrounding chemotherapy administration to cancer patients.

**Oncology Medical Home (OMH)** - a care model based on delivering, ensuring, and measuring quality cancer care; a patient-focused system of delivering coordinated, efficient cancer care designed to meet the needs of patients, payers, and providers.

**Oral Parity -** state and Federal legislation by which oral chemotherapeutic agents are provided under no less favorable financial terms than intravenous (IV) chemotherapy. As of the April 2017, 43 states have oral parity laws. H.R.1409, the Cancer Drug Parity Act of 2017, is before the 115<sup>th</sup> Congress to enact Federal oral parity legislation.

**Part B Demonstration Project -** a proposal to test payment changes for drugs in Medicare Part B. The pilot would have changed the payment rate from 6% of Average Sales Price (ASP) to 2.5% plus a flat fee. A second phase would have tested the use of value-based purchasing tools. The proposal met with criticism from pharmaceutical companies, physician groups, and some patient groups and was dropped before it could be enacted.

**Pathways -** task-oriented care plans that detail essential steps in the care of patients with a specific clinical problem and describes the patients expected clinical course. The goal of clinical pathways is to standardize care, improve outcomes and reduce cost.

**Patient Component** - that portion of the cost of medical care for which the patient is responsible after insurance. This is also known as patient out of pocket.

**Payers/Payors -** persons or organizations who give money for goods or services. In healthcare payers/payors are those commercial or government organizations that pay for healthcare services and/or employers who self-insure.

**Pharmacy Benefit Plan -** prescription drug programs for commercial health plans, self-insured employer plans, Medicare Part D plans, the Federal Employees Health Benefits Program, and state government employee plans.

**Pharmacy Benefit Managers (PBM) -** a third-party administrator of prescription drug programs for commercial health plans, self-insured employer plans, Medicare Part D plans, the Federal Employees Health Benefits Program, and state government employee plans.

**Physician Fee Schedule -** the reimbursement rates established for services provided by physicians to patients covered by Medicare and Medicaid. The Physician Fee Schedule is updated annually by the Centers for Medicare and Medicaid Services (CMS).

**Physician Office Visit (POV) -** This term is used most often in relation to the site of care, as in POV (physician office visit) based care.

**Pre-existing condition** - a health problem in existence prior to the inception of insurance coverage by an insurance policy.

**Prompt Pay -** prompt pay discounts that drug manufacturers give to drug distributors. These discounts are not passed on to the provider but are used in the calculation of ASP thereby reducing the drug reimbursement.

**Qualified Health Plan (QHP) -** a major medical health insurance plan that covers all the mandatory benefits of the Affordable Care Act (ACA). A qualified health plan is also eligible to be purchased with an ACA subsidy, also known as a premium tax credit.

**Relative Value Units (RVUs) -** a measure of value used in the Medicare reimbursement formula for physician services. RVUs are a part of the resource-based relative value scale.

Ryan White Clinics – the Ryan White HIV/AIDS Program provides a comprehensive system of care that includes primary medical care and essential support services for people living with HIV who are uninsured or underinsured. The Program works with cities, states, and local community-based organizations to provide HIV care and treatment services to more than half a million people each year. The Program reaches approximately 52% of all people diagnosed with HIV in the United States. The patient care is delivered in the Ryan White Clinics.

**Sequestration -** the automatic across the board cuts to Federal government spending that were implemented as an austerity fiscal policy as part of the Budget Control Act of 2011. The cuts, which went into effect on March 1, 2012, reduced the reimbursement rate for all cancer drugs purchased on behalf of Medicare patients. Because the 2% cannot be applied to drug cost, it is applied to the 6% added to ASP to calculate drug reimbursement. This reduces actual reimbursement to ASP+4.3%.

**Site of Care** - the location in which healthcare is delivered. The most common locations are hospital inpatient, hospital outpatient and physician office based care. The cost of equivalent care will vary based upon the site of care.

**Site Parity -** the move to make cancer care costs equal regardless of the site of care. The two sites usually considered in site parity are privately owned physician offices and hospital outpatient departments.

**Specialty Pharmacy -** a pharmacy that manages the handling and service requirements of specialty pharmaceuticals, including dispensing, distribution, reimbursement, case management, and other services specific to patients with rare and/or chronic diseases.

**Sunshine Act -** a portion of the Affordable Care Act that requires the manufacturers of drugs, medical devices and biologicals that are participating in U.S. Federal health care programs to report payments and items of value given to physicians and teaching hospitals.

**Sustainable Growth Rate (SGR)** - a method used by the Centers for Medicare and Medicaid Services (CMS) to control spending by Medicare on physician services. If the expenditures for the previous year exceeded the target expenditures, then the conversion factor will decrease payments for the next year. If the expenditures were less than expected, the conversion factor would increase the payments to physicians for the next year. SGR decreases in physician reimbursement have been postponed, and now stand at more than 27%. Legislation to fix this permanently, known as the "doc fix," went into effect in July 2015.

**Under-insured** - not having proper or sufficient health insurance to cover medical expenses related to the diagnosis and treatment of an illness or injury.

**Uninsured** - a person without health insurance coverage.

**USP 797 – Pharmaceutical Compounding – Sterile Preparations -** a set of enforceable sterile compounding standards issued by the United States Pharmacopeia (USP). USP 797 describes the guidelines, procedures, and compliance requirements for compounding sterile preparations and sets the standards that apply to all settings in which sterile preparations are compounded. The mixing of chemotherapy drugs is covered by USP 797.

**USP 800 - Key Changes and Additions to USP 797 –** updates to USP 797 fell short due to a lack of guidance for nonparenteral products. USP 800 is a set of guidelines that addresses that shortfall and deals with hazardous drug handling in health care settings.

**Value Framework** - an assessment of the value of new cancer therapies based on clinical benefit, side effects, and improvements in patient symptoms or quality of life in the context of cost.