

ADAP Glossary

April 2016

PURPOSE:

This glossary, developed as a resource for AIDS Drug Assistance Programs (ADAPs), provides definitions and links to relevant resources for terms that are frequently used as part of ADAP administration. The glossary is a "living" document that will be augmented as more information and resources become available.

Included in this glossary are the following topics:

- HIV/AIDS and Hepatitis
- Federal Agencies and Legislation
- <u>AIDS Drug Assistance Program</u> (ADAP)
- Data and Reporting
- Drug Purchasing and Pricing
- Health Systems Integration
- Other Coverage
- Patient Assistance Programs (PAPs)

Also included in this glossary is a list of additional resources.

HIV/AIDS and Hepatitis

Acquired Immunodeficiency Syndrome (AIDS) - A disease of the immune system due to infection with HIV. HIV destroys the CD4 lymphocytes (CD4 cells) of the immune system, leaving the body vulnerable to lifethreatening infections (including opportunistic infections) and cancers. Acquired immunodeficiency syndrome (AIDS) is the most advanced stage of HIV infection.

Antiretroviral (ARV) - A medication that suppresses HIV. In order to be effective against HIV, multiple antiretrovirals must be used in combination to stop the progression of HIV disease.

<u>Antiretroviral therapy</u> (ART) - A medication that suppresses HIV. In order to be effective against HIV, multiple antiretrovirals must be used in combination to stop the progression of HIV disease.

Antiviral therapy - The use of medication to treat viral infections such as HIV and viral hepatitis.

<u>CD4</u> cell - (also known as a T4 cell or T cell) A type of white blood cell called a lymphocyte. Lymphocytes are part of the body's immune system and help to fight viral infections. HIV weakens the immune system by destroying CD4 cells.

CD4 count - A laboratory test that measures the number of CD4 T lymphocytes (CD4 cells) in a sample of blood. The CD4 count is the most important laboratory indicator of immune function and the strongest predictor of HIV progression. The CD4 count is one of the factors used to determine when to start antiretroviral therapy (ART). The CD4 count is also used to monitor response to ART.

Co-infection - When a person has two or more infections at the same time. It is common that individuals are co-infected with HIV and HBV and/or HCV.

Comorbidity - The presence of two or more conditions or diseases at the same time. For example, a person with HIV infection may also have high blood pressure.

Hepatitis – Inflammation of the liver.

<u>Hepatitis B virus</u> (HBV) - A liver-infecting virus that causes the acute (new and typically short-lived) and chronic (long-lasting) forms of hepatitis B infection. The HBV is spread through body fluid exchange. It can be transmitted in several ways including blood transfusion, needle sticks, body piercing and tattooing using unsterile instruments, dialysis, sexual and even less intimate close contact, and childbirth. Although a person may not have any symptoms, infected individuals may experience fatigue, jaundice, nausea, vomiting, dark urine, and light stools. Diagnosis is by blood test(s).

Hepatitis C virus (HCV) - A liver-infecting virus that causes the acute (new and sometimes short-lived) and/or chronic (longlasting) forms of hepatitis C infection. Acute HCV infections are often asymptomatic. Most HCV infections (as many as 80%) lead to chronic hepatitis C, which can lead to liver damage, such as cirrhosis. The virus is spread through body fluid exchange. Individuals for increased risk of infection are current and former injection drug users, recipients of blood clotting factor concentrates before 1987, recipients of blood transfusions or transplants before July 1992, chronic hemodialysis patients, person with HIV infection, and children born to HCV-positive mothers.

Human Immunodeficiency Virus (HIV) -

The virus that causes AIDS. HIV is a type of virus known as a retrovirus. HIV damages a person's body by destroying specific white blood cells, called CD4+ T cells, which are crucial to helping the body fight disease. HIV is spread through body fluid exchange. The most common ways that HIV is transmitted are by:

- Having unprotected sex with a person who has HIV;
- Sharing needles, syringes, rinse water, or other equipment used to prepare drugs for injection;

Being born to an infected mother—HIV can be passed from mother to child during pregnancy, birth, or breast-feeding.

Opportunistic infection (OI) – An infection that occurs more frequently or is more severe in people with weakened immune systems, such as people with HIV or people receiving chemotherapy, than in people with healthy immune systems.

Sustained virological response (SVR) -

When the amount of HCV virus present in an individual's blood is below the level of detectability of the assay used (i.e. "undetectable") six months after completing HCV treatment. People who achieve an SVR are generally considered to be "cured" virologically.

Viral hepatitis – A group of viral infections that are responsible for infecting the liver. The most common types are Hepatitis A, Hepatitis B, and Hepatitis C. Viral hepatitis due to HBV and HCV is the leading cause of liver cancer and the most common reason for liver transplantation. An estimated 4.4 million Americans are living with chronic hepatitis; most do not know they are infected.

Viral load – The amount of virus present in an individual's blood. Tracking viral load is used to monitor therapy during chronic viral infections (i.e., HIV and hepatitis). <u>Viral load suppression</u> – When the amount of HIV virus present in an individual's blood is below the level of detectability of the assay used (i.e. "undetectable"). Individuals whose viral load is detectable and less than or equal to 200 copies/mL are also considered to be "suppressed."

Federal Agencies and Legislation

<u>340B Drug Pricing Program</u> – The 340B Drug Pricing Program (340B Program) resulted from enactment of Public Law 102-585, the Veterans Health Care Act of 1992, which is codified as Section 340B of the PHSA. Section 340B limits the cost of drugs to federal purchasers and to certain grantees of federal agencies. ADAP is a covered 340B Program entity and is entitled to the discounted drug prices available to all 340B entities.

Affordable Care Act (ACA) – The

comprehensive health care reform law enacted in March 2010. The law was enacted in two parts: The Patient Protection and Affordable Care Act (PPACA) signed into law on March 23, 2010 and was amended by the Health Care and Education Reconciliation Act on March 30, 2010. The name "Affordable Care Act" is used to refer to the final, amended version of the law.

Centers for Medicare and Medicaid

<u>Services</u> (CMS) – CMS administers Medicare, Medicaid, and the Children's Health Insurance Program. It provides information for health professionals, regional governments, and consumers. (See Medicaid and Medicare definitions on <u>page 8</u>.)

Consolidated Omnibus Reconciliation Act

(COBRA) – A Federal law that may allow individuals to temporarily keep health coverage after employment ends, loss of coverage as a dependent of the covered employee, or another qualifying event. The individual will pay 100% of the premiums, including the share the employer used to pay, plus a small administrative fee.

<u>Health Resources and Services</u> <u>Administration</u> (HRSA) and the <u>HIV/AIDS</u> <u>Bureau</u> (HAB) – The DHHS, Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB) administers the Ryan White Program. HAB includes:

- The Office of the Associate Administrator: provides leadership and direction for HRSA's HIV/AIDS programs and activities and oversees collaboration with other national health programs.
- The Office of Operations and Management: responsible for administrative and fiscal guidance and support.
- The Division of Metropolitan HIV/AIDS Program (DMHAP): administers the portfolio of grantees and programs funded under Part A of the Ryan White HIV/AIDS Program.
- The Division of State HIV/AIDS Programs (DSHAP): administers the portfolio of grantees and programs funded under Part B of the Ryan White HIV/AIDS Program, including the AIDS Drug Assistance Program (ADAP).
- The Division of Community HIV/AIDS Programs (DCHAP): administers Parts C, D and F, including the HIV/AIDS Dental Reimbursement Program and the community-based Dental Partnership Program.
- The Division of HIV/AIDS Training and Capacity Development (DHTACD): administers planning, training, and technical assistance activities for Part F, Special Programs of National Significance (SPNS), and the AIDS Education and Training Centers (AETC) Program. This office will also administer the Global HIV/AIDS Program as part of the

President's Emergency Plan for AIDS Relief (PEPFAR).

 The Division of Policy and Data (DPD): serves as HAB's principal source of program data collection and evaluation and the focal point for coordination of program performance activities.

Health Resources and Services Administration (HRSA) Project Officers –

Project officers are scientific and/or technical staff members who are experts in their content area. They are responsible for ensuring that grantees and grants comply with legislative mandates and meet programmatic objectives. They write program guidance which define the grant program objectives, monitor grantees' performance and evaluate grantee achievements.

Minority AIDS Initiative (MAI) – Program created in 1998 in response to growing concern about the impact of HIV/AIDS on racial and ethnic minorities in the United States, MAI provides funding across several DHHS agencies/programs, including the Ryan White Program, to strengthen organizational capacity and expand HIV-related services in minority communities. The Ryan White component of the MAI was codified in the 2006 reauthorization. MAI program is administered across all divisions at HAB regardless of Ryan White Program part. In FY 2014, the MAI was funded at \$425.4 million. Under Part B, MAI formula grants fund outreach and education services designed to increase minority access to needed HIV/AIDS medications through state ADAP.

Office of Pharmacy Affairs (OPA) – The

OPA is the office responsible for administering the 340B Program and is part of HRSA.

<u>The Ryan White HIV/AIDS Treatment</u> Modernization Act of 2009 HRSA – The

Ryan White CARE Act, "Title XXVI of the PHS Act as amended by the Ryan White HIV/AIDS Treatment Modernization Act of 2009," or "Ryan White Program" is the single largest federal program designed specifically for people with HIV/AIDS. First enacted in 1990, it provides care and treatment to individuals and families affected by HIV/AIDS. The Ryan White Program has five parts - Part A funds eligible metropolitan areas and transitional grant areas; Part B funds States/Territories and includes ADAP; Part C funds early intervention services; Part D grants support services for women, infants, children and youth; and **Part F** comprises Special Projects of National Significance, AIDS Education & Training Centers (AETCs), Dental Programs and the Minority AIDS Initiative. Seventy-five percent Parts A, B, and C must be spent on a specified list of core services, unless a waiver is approved by HAB. Funds from all Parts may be used to make insurance payments for clients (e.g. premiums, deductibles, and/or co-payments/co-insurance).

- Part A funding: Provided to metropolitan jurisdictions, some of whom make local decisions to allocate funds to ADAPs.
- Part B "base" funding: Formulabased funding to states (other than that earmarked for ADAP); some states choose to allocate some of this funding to ADAPs, but are not required to do so.
- Part B supplemental funding: Funding to states with "unmet need;" some states choose to allocate some of this funding to ADAPs, but are not required to do so.

AIDS Drug Assistance Program (ADAP)

AIDS Drug Assistance Program (ADAP) - A state administered program authorized under Ryan White HIV/AIDS Treatment Modernization Act of 2009 Part B of the Title XXVI of the Public Health Service Act as amended by the Ryan White HIV/AIDS Treatment Modernization Act of 2009 (Ryan White Program) that provides Food and Drug Administration (FDA) approved medications to individuals with HIV who have limited or no coverage from other sources and meet certain income qualifications. ADAPs may also purchase insurance and provide adherence monitoring and outreach under the flexibility policy.

ADAP dollars - Any funds, regardless of source, that comprise the ADAP budget and are expended on the provision of medications and other ADAP allowable services (including administrative costs for the program).

ADAP earmark - The amount of federal Ryan White Program-Part B allocations specifically designated to ADAP for the federal fiscal year by Congress through the annual appropriations process.

ADAP flexibility policy - Provides grantees greater flexibility in the use of ADAP funds and permits expenditures of up to five (5) percent of ADAP funds for services that improve access to medications, increase adherence to medication regimens, and help for clients to monitor their progress in taking HIV-related medications. Grantees must request, in writing from HRSA, to use ADAP dollars for services other than medications.

ADAP Supplemental drug treatment grant award - ADAP Supplemental grants are used for the purchase of medications by states and territories with demonstrated severe need to increase access to HIV/AIDS related medications. These grants must be used to expand ADAP formularies, target resources to reflect the changes in the epidemic and enhance the ADAP's ability to remove eligibility restrictions. States must meet HRSA eligibility criteria in order to apply for ADAP Supplemental funds. The overall supplemental amount is mandated by law to be five percent of the congressionally appropriated ADAP earmark.

Core medical services - Under the Ryan White HIV/AIDS Treatment Modernization Act of 2006, grantees receiving funds under Parts A, B and C must spend at least 75 percent of grant funds on core medical services. These services include: outpatient and ambulatory health services; pharmaceutical assistance (ADAP and other local pharmacy programs); oral health; early intervention services; health insurance premium assistance; home health care; home and community-based services; hospice services; mental health services; medical nutritional therapy; medical case management, including treatment adherence services; and outpatient substance abuse treatment services. Part A and B jurisdictions are able to apply for a waiver to this requirement.

Cost-cutting measures - Any measures taken that restrict/reduce enrollment or that reduce benefits and are instituted out of necessity due to insufficient resources and/or to avoid starting a waiting list. Examples are reductions in ADAP financial eligibility below 300 percent of the <u>Federal Poverty Level (FPL)</u>, capped enrollment, formulary reductions or restrictions with respect to ADAP insurance eligibility criteria (i.e., below 300% of FPL).

Cost-saving measures - Any measures taken to improve the cost-effectiveness of ADAP operations, which are required to achieve, improve and/or maximize HRSA recommended cost-saving strategies that all states should be working to achieve and/or maximize regardless of financial status. Examples are improved systems and back billing procedures for Medicaid; improved client recertification processes; Part B Program structural or operational changes such as expanding insurance assistance; insurance purchasing; collection of 340B Program rebates for insurance co-payments, deductibles. co-insurance, and TrOOP expenditures; and CMS data-sharing agreements.

Cost-sharing - The ADAP client's monetary cost for program participation. Some ADAPs require that participants share in the cost of their medications. The mechanisms for this requirement vary by program, but are usually based on client income and set on a sliding fee scale. Some ADAPs require a monthly cost share payment to the program, while others mandate a nominal cost per prescription. The funds from the cost share component are returned to the ADAP as <u>"program income"</u> to defray costs.

Dis-enroll - The process to remove a client from ADAP. Following dis-enrollment, the individual would have to complete a new application and be enrolled in ADAP, if eligible, to again receive services.

Dispensing fee - The charge for professional services provided by the pharmacist when dispensing a prescription (including overhead expenses and profit). Medicaid and most direct pay insurance prescription programs use dispensing fees to establish pharmacy payment for prescriptions. Dispensing fees do not include any payment for the drugs being dispensed. Dispensing fees will vary based upon the negotiated rates with the pharmacies.

<u>Federal Poverty Level</u> (FPL) - A measure of income level issued annually by DHHS used to

determine eligibility for certain programs and benefits.

Formulary - ADAP drug list that establishes the number of drugs available within a therapeutic class for purposes of drug purchasing, dispensing and/or reimbursement.

- Closed/restricted formulary: Allows only those drug products listed to be dispensed or reimbursed.
- Open formulary: Covers all FDAapproved drugs prescribed by a physician with no restrictions or with restrictions such as higher patient cost-sharing requirements for certain drugs.
- Tiered formulary: Also referred to as "step therapy" and is a cost containment measure that medications categorizes for а particular condition based upon their cost. For example, a tier one medication would be one that is lowest cost and recommended to be used first, unless there are medical restrictions for doing so. Tier two would be a different medication that is prescribed for the same condition as the tier one drug but is more expensive. Step therapy or tiered formularies are most commonly used bv ADAPs with medications prescribed for depression, respiratory problems, opportunistic infections and hepatitis C.

Pay and chase - This occurs when an ADAP pays a prescription bill up front to a retail pharmacy and then requests reimbursement or "bills" a third party payer afterward. For example, John Doe has insurance coverage but ADAP does not have the systems in place to be able to pay only the part of the bill/claim that Mr. Doe would have been responsible for. ADAP pays the whole claim and sends a bill to John Doe's insurance company. The insurance company pays ADAP back minus what the individual would have been responsible for (see back billing page 14).

Payer of last resort - Ryan White Program funds "cannot be used to make payments for any item or service if payment has been made, or can reasonably be expected to be made, with respect to that item or service under any state compensation program, under an insurance policy, or under any federal or state health benefits program; or by an entity that provides prepaid health care." This provision was first introduced in the 1990 authorization of the Ryan White CARE Act with additional instructions regarding implementation of this requirement addressed in all subsequent grant guidance documents. Other payer sources exist that could assume responsibility as payer of last resort for a person applying for, or enrolled in, the ADAP program. Not only should the ADAP consider Medicare, Medicaid and private insurance, but also determine if the client has access to employer, union or retiree group health plans; <u>COBRA</u> continuation coverage; or access to a state Pharmaceutical Assistance Program (SPAP).

State funding - General revenue support from state budgets. States are not required to provide funding to their ADAPs (except in limited cases of matching requirements), although many have historically done so, either over a sustained period of time or at critical junctures to address gaps in funding. Such funding is, for the most part, dependent on individual state decisions and budgets; even where states are required to provide a match of federal Part B Ryan White funds, they are not required to put this funding toward ADAP. The only exception to this is the ADAP supplemental, where states must provide a 1:4 match (or seek a waiver of the requirement, if eligible to do so).

Data and Reporting

<u>ADAP Data Report</u> (ADR) - The reporting system through which ADAP grantees must submit quarterly reports to HRSA as part of the funding requirements. The ADR includes information on patients served, pharmaceuticals purchased, pricing, other sources of support to provide AIDS medications, eligibility requirements, cost data and coordination with Medicaid.

- The Grantee Report: Provides basic information about the organization, program limits, developments and changes. income eligibility requirements, coordination with Medicaid and State Pharmaceutical assistance programs, funding and expenditure amounts and ADAP formulary on a semiannual basis. Annually, grantees will provide information on frequency of recertification, clinical eligibility criteria and cost-saving measures.
- The Client Report (or client-level data): A report online of each client record which contains information on clients enrolled in ADAP during the reporting period, regardless of whether or not they received services.

Information reported includes demographic status, enrollment and certification information, HIV clinical information, type and cost of ADAP services (e.g. medication or insurance coverage). The client-level data is submitted on a semiannual basis.

ADAP Quarterly Report (AQR) - The former reporting system that was in place until the ADR was fully implemented.

<u>CAREWare</u> - A free, scalable software package provided by HRSA to its grantees and their funded providers that enables users to monitor services and report on HIV clinical and supportive care. CAREWare generates, a complete Ryan White HIV/AIDS Services Report (RSR), as well as the ADAP Data Report (ADR). This program is not required to be used by ADAPs.

<u>Electronic Handbook</u> (EHB) - Web-based electronic data and reporting system used by HRSA/HAB for receiving all grant applications, data reports, and financial statements.

Drug Purchasing and Pricing

340B ceiling price - The maximum price that manufacturers can charge covered entities participating in the Public Health Service Act's (PHSA) <u>340B Drug Pricing Program</u>. Covered entities receive a minimum discount of 23.1 percent of <u>Average Manufacturer Price</u> (AMP) for brand name drugs and 11 percent of AMP for generic and over-the-counter drugs and are entitled to an additional discount if the price of the drug has increased faster than the rate of inflation. Covered entities may negotiate lower discounts, i.e., sub-ceiling prices.

<u>340B covered entities and entity</u> <u>enrollment process</u> - Covered entities are those eligible entities or programs authorized by Section 340B of the PHSA to participate in the outpatient discount drug pricing program. The entity enrollment process is the way through which discounted outpatient drugs are available to covered entities under Section 340B of the PHSA.

340B Prime Vendor Program - see definition on page 4.

340B Program - see definition on page 4.

ADAP Crisis Task Force (ACTF) - A group of state ADAP/AIDS directors, convened by NASTAD, that negotiates with the manufacturers of ARVs and other high-cost medications to secure supplemental discounts/rebates for all ADAPs nationally.

Average manufacturer price (AMP) - The average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies. <u>340B Program</u> and Federal Supply Schedule (FSS) prices, as well as prices associated with direct sales to HMOs and hospitals, are excluded from AMP under the rebate. Average wholesale price (AWP) - A national average of list prices charged by wholesalers to pharmacies. AWP is sometimes referred to as the "sticker price" because it is not the actual price that larger purchasers normally pay. AWP information is publicly available.

Best price (BP) - The lowest price available to any wholesaler, retailer, provider, health maintenance organization (HMO), nonprofit entity or the government. BP excludes prices to the 340B Program covered entities as well as the Big 4 (i.e., the Department of Veterans Affairs (VA), Department of Defense (DOD), Public Health Service (PHS) and Coast Guard).

Central state pharmacy - A health department or other state agency's centralized pharmacy that dispenses drugs through mail-order or to a pharmacy or network of pharmacies for dispensing to clients.

Contract pharmacy - An arrangement through which an ADAP contracts with an outside pharmacy to provide comprehensive pharmacy services. Pharmacy services may include dispensing, record keeping, drug utilization review, formulary maintenance, patient profiles and counseling.

Direct purchase state - ADAPs using this model centrally purchase and dispense medications through their own pharmacy or a single contract pharmacy services provider.

Dual purchaser - ADAPs using this model centrally purchase and dispense medications through their own pharmacy or a single contract pharmacy services provider and also bill drug manufacturers for the <u>340B Program</u> and the <u>ACTF</u> discounted prices for the number of units dispensed for people living

with HIV (PLWH) accessing an insurance plan (public or private).

Federal ceiling price (FCP) - The maximum price manufacturers can charge for FSS-listed brand name drugs to the Big 4, even if the FSS price is higher. The FCP must be at least 24 percent below the non-Federal average manufacturer price and are not publicly available.

Hybrid state - A hybrid state is a direct purchase state that utilizes an existing entity (e.g., University Hospital) to purchase and distribute ADAP drugs. The entity maintains a single drug inventory purchased at <u>340B</u> <u>Program</u> prices. To secure the additional supplemental discounts negotiated by the ADAP Crisis Task Force, these ADAPs must submit rebate claims for any supplemental discount amounts.

Insurance benefit manager (IBM)/Third Party Administrator (TPA) - An organization or system that provides administrative and insurance claim adjudication services. An IBM/TPA is neither the insurer nor the insured; it simply handles the administration of the plan.

Medical benefits manager (MBM) - An organization that provides services to monitor and pay medical co-payments and deductibles and processes payments in a timelier manner.

<u>Pharmacy benefits manager</u> (PBM) - An organization that provides administrative services in processing and adjudicating prescription claims for pharmacy benefit programs.

Pharmacy network - A group of pharmacies where an ADAP client may have their prescriptions filled.

Program income - Income earned by a grant recipient from activities which are supported by the direct costs of an award.

Rebate - Amount of money paid by drug manufacturers to ADAPs for drugs dispensed to ADAP clients.

Rebate states - ADAPs who pay retail pharmacies a pre-determined amount at the point of sale for drugs dispensed to ADAP clients. ADAP then bills drug manufacturers for the 340B Program Unit Rebate Amount for the number of units dispensed.

Wholesale acquisition cost (WAC) - The manufacturer's list price of the drug when sold to the wholesaler.

Wholesaler - Firm that buys large quantity of drugs from various producers or vendors, warehouses them, and resells to retailers.

Health Systems Integration

Affordable Care Act (ACA) - see definition on page 4.

Care coordination - The coordination of a patient's treatment across several health care providers. Medical homes and accountable care organizations (ACOs) are two common ways to coordinate care. The coordination of care is through a patient navigator or care coordinator. This is similar to the medical case managers under the Ryan White Program.

Cost-sharing reductions - A discount that lowers the amount you have to pay out-ofpocket for deductibles, co-insurance, and copayments. You can get this reduction if you get health insurance through the Marketplace, your income is below a certain level, and you choose a health plan from the Silver plan category. If you're a member of a federally recognized tribe, you may qualify for additional cost-sharing benefits.

Essential community providers (ECPs) -ACA regulation defines The essential community providers (ECPs) as providers that serve predominantly low-income, medically underserved individuals. It includes 340B provider entities and (1) Ryan White HIV/AIDS program providers; (2) federally qualified health centers (FQHCs) and FQHC "look-alike" clinics; (3) family planning providers; (4) Indian health providers; (5) hospitals; and (6) other ECPs including STD clinics, TB clinics, hemophilia treatment centers, black lung clinics and other entities that serve predominately low-income, medically underserved individuals. Qualified health plans are required to make good faith effort to ensure that 30% of the available ECPs within the plan's service area.

Essential health benefits (EHBs) - A set of health care service categories that must be

covered by certain insurance plans, starting in 2014. The ACA ensures health plans offered in the individual and small group markets offer a comprehensive package of items and services. EHBs must include items and services within at least the following 10 categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder including behavioral services. health treatment; prescription drugs; rehabilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.

Formulary exception - A request made to health insurance plan to receive access to a prescription medication not readily available on an enrollees existing formulary; OR a request to have a prescription drug placed on a lower formulary tier on an individual basis.

Individual mandate - The ACA requirement that the vast majority of individuals who are lawfully present in the United States maintain health insurance coverage, known as minimum essential coverage.

Individual shared responsibility payment -The penalty assessed by the Internal Revenue Service (IRS) for failure to adhere to the individual mandate to maintain minimum essential coverage.

<u>Marketplace</u> - A new transparent and competitive insurance marketplace for affordable and qualified health benefit plans. Affordable Insurance Exchanges will offer you a choice of health plans that meet certain benefits and cost standards. The benchmark plan can be either the largest HMO plan in the state's private market or one of the three largest plans covering small businesses, state employees or federal employees in the state. If a benchmark plan does not cover services of the 10 EHB categories, states will have to come up with supplementary coverage products. If a state does not designate a benchmark plan, the Department of Health and Human Services (DHHS) will select the standard to be the small-business plan with the largest enrollment in the state. The exchanges can be managed by the federal government, state, or partnership (i.e., both federal and state).

Medicaid expansion - Beginning in 2014 state can expand Medicaid eligibility to include persons with income levels at or below 138 percent of the <u>FPL</u>, without a disability determination from the Social Security Administration.

Medical loss ratio (MLR) - A financial measurement used in the ACA to encourage health plans to maximize the value provided to enrollees. For example, if an insurer uses 80 cents out of every premium dollar to pay its customers' medical claims and activities that improve the quality of care, the company has an MLR of 80%. An MLR of 80% indicates that the insurer is using the remaining 20 cents of each premium dollar to pay overhead expenses, such as marketing, profits, salaries, administrative costs, and agent commissions. The ACA sets minimum MLRs for different markets, as do some state laws. Grantees must 'vigorously pursue' MLR payments made to clients on insurance supported with Ryan White funds.

Modified Adjusted Gross Income (MAGI) -

The new formula that will be used to determine income eligibility for most Medicaid and subsidized private insurance and other insurance affordability programs. This new formula will align the Medicaid formula with the IRS practice. The new rules do not require an assets test or take into account income disregards.

Out-of-pocket maximum - The maximum that a consumer (or third party payer such as ADAP) can expect to pay prior to the insurance pay 100% for covered medical and prescription drug expenses. This limit includes deductibles, co-insurance, and co-payments. This limit does not include, balance billing amounts for non-network providers and other out-of-network cost-sharing, or spending for non-essential health benefits. The cap for outof-pocket maximums for any qualified health plans in 2015 is \$6,600 for an individual plan and \$13,200 for a family plan. Plans can choose set maximums which are below these caps.

Premium tax credit - A tax credit that is available to eligible individuals and families whose income fall between 100% and 400% of the <u>federal poverty level</u> to help offset the cost of <u>qualified health plan</u> premiums. Individuals can choose take this tax credit in advance of their tax filing at the time of plan enrollment. If an individual avail themselves of the option to advance the premium tax credit, then they will be directed to engage in a reconciliation to complete their next federal tax filing.

Qualified health plan (QHP) - A private health insurance plan that is certified by a health insurance Marketplace to cover essential health benefits, and follow established limits on cost-sharing (like deductibles, copayments, and out-of-pocket maximum amounts). Eligible individuals must be enrolled in a QHP to receive any applicable premium tax credits or cost-sharing reductions.

Special enrollment period (SEP) - A period in which individuals can obtain QHP coverage outside of open enrollment. In federallyfacilitated Marketplaces special enrollment periods are available 60 days after a qualifying life event such as job loss, marriage, or the birth of child.

Other Coverage

<u>1115 waiver</u> - Application for program flexibility to test new or existing approaches to financing or delivering Medicaid by individual states. 1115 waivers are currently allowed to expand Medicaid coverage to individuals based on income level of at or below 138 percent <u>FPL</u> versus having a disability determination by the social security administration.

Back billing - In some instances, ADAP covers an individual's prescription costs but later determines there is another payer source (e.g., state Medicaid). ADAP can request reimbursement for expenditures previously incurred or "back bill." Another scenario for back billing is when individuals apply and are eligible for Medicaid. Their eligibility coverage back dates three months PRIOR to the application date. ADAP covers the individual while they wait for their Medicaid eligibility determination and then "back-bills" Medicaid for any drugs or services they paid for during the interim wait time (see also <u>pay and chase</u>).

Co-insurance - A percentage of expenses individual must pay upon receiving medical services or prescriptions. For example, if a client incurs a \$100 expense for a prescription drug or medical office visit and their applicable deductibles have been met, if the client's coinsurance is 20% then the amount owed to the medical office or pharmacy is \$20. The health insurance or plan pays the rest of the allowed amount. Some ADAPs pay the coinsurance for ADAP formulary drugs otherwise paid for under an individual's other source of coverage.

Consolidated Omnibus Budget Reconciliation Act (COBRA) - see definition on page 4. Coordination of benefits - Activities that ensure when multiple payers exist for medications and/or services that the appropriate costs are paid by the responsible payer. Ryan White Program funds are the payer of last resort, making it necessary for all other payers (Medicare Part D, Medicaid, private insurance, etc.) to be utilized first before using these federal dollars.

Co-payment - A set amount an individual must pay upon receiving medical services or prescriptions. For example, there may be a \$10 co-payment required each time a prescription is purchased at a retail pharmacy. Some ADAPs pay the co-payments for ADAP formulary drugs otherwise paid for under an individual's other source of coverage.

Cost-recovery - Reimbursement from third party entities such as private insurers and Medicaid.

Deductible - The amount a health insurance beneficiary must pay before a third party payer begins to provide coverage for health services. Amounts can change from year to year. Some ADAPs pay this cost for eligible clients.

Donut Hole, Medicare Prescription Drug -

Most plans with Medicare prescription drug coverage (Part D) have a coverage gap or "donut hole." This means that after an individual and/or their drug plan have spent a certain amount of money for covered drugs; they have to pay all costs out-of-pocket for prescriptions up to a yearly limit. Once the yearly limit is reached, the coverage gap ends and the drug plan pays for covered drugs again. ADAP payments can be used as TrOOP. The ACA will provide seniors with additional savings on their prescription drugs each year until the donut hole is closed altogether by 2020.

Dual-eligible - Individuals who are eligible for both Medicare and Medicaid.

Health Insurance Portability and Accountability Act (HIPAA) Eligible - An individual's status once they have had 18 months of continuous creditable health coverage. To be HIPAA eligible, at least the last day of creditable coverage must have been under a group health plan; also must have used up any COBRA or state continuation coverage; must not be eligible for Medicare or Medicaid; must not have other health insurance; and must apply for individual health insurance within 63 days of losing your prior creditable coverage. When buying individual health insurance, HIPAA eligibility gives greater protections than otherwise have under state law.

Insurance continuation - The payment by ADAP for all or some combination of insurance premiums, co-payments and/or deductibles for clients who have existing insurance policies through their current employment, <u>Consolidated Omnibus Budget Reconciliation</u> <u>Act</u> (COBRA), or other supplemental programs. HRSA allows ADAP funds to be used for insurance continuation with certain restrictions.

Insurance purchasing - The ability to purchase insurance coverage through the insurance industry market or state high risk insurance pools by ADAPs, on behalf of eligible clients.

<u>Medicaid</u> - A state-administered health insurance program provided for low-income families and children, pregnant women, the elderly, people with disabilities, and in some states, other adults. The federal government provides a portion of the funding for Medicaid and sets guidelines for the program. States also have choices in how they design their program, so Medicaid varies state by state and may have a different name in your state.

Medicaid surplus income spend down -Also known as the Medically Needy Program. Some state Medicaid programs require that eligible participants pay a designated amount out of pocket toward their health care costs. The amount is based on the amount by which the person's income exceeds the state's Medicaid income eligibility levels. Once this amount has been paid by the client, Medicaid benefits begin covering 100 percent of these costs. Ryan White Program funds may NOT be used for Medicaid spend down. However, some ADAPs assist clients with spend down requirements using state funds, or use this requirement to reduce the individual's annual income for program eligibility.

<u>Medicare</u> - A federal health insurance program for people who are age 65 or older and certain younger people with disabilities. It also covers people with End-Stage Renal Disease (permanent kidney failure requiring dialysis or a transplant, sometimes called ESRD).

<u>Medicare Part D</u> - A program that helps pay for prescription drugs for people with Medicare plans that includes Medicare prescription drug coverage. There are two ways to get Medicare prescription drug coverage: through a Medicare Prescription Drug Plan or a Medicare Advantage Plan that includes drug coverage. These plans are offered by insurance companies and other private companies approved by Medicare.

Premium - A monthly payment made to the insurer to obtain insurance coverage. Premiums can be paid by employers, unions, employees or individuals or shared among different payers (e.g. ADAP). Third party reimbursement - Payment made by someone other than the receiver of a service or the provider of the service (e.g., a health insurance plan).

True Out of Pocket Expenditures (TrOOP) -

This is the amount of money that a Medicare Part D enrolled client will have to pay to reach the "catastrophic limit" at which point Part D becomes the primary payer for medications. Payments for drugs, co-payments and coinsurance, made by the beneficiary, friends, family members, ADAP, State Pharmacy Assistance Programs, charities and the Medicare low-income subsidy (LIS) portion of Medicare Part D, count towards TrOOP costs. Wrap-around benefits - The mechanism ADAPs use to assist low-income ADAP clients with costs associated with Medicare Part D or other sources of coverage. Paying copayments for medications or monthly premium costs, and covering the beneficiary once they reach the coverage gap (e.g., Medicare Part D donut hole), are all considered "wrap-around" services. ADAPs assist eligible clients with these costs so the clients can maintain their eligibility for Medicare Part D drug benefits or other coverage and because wrapping around is usually less expensive than providing the HIV/AIDS prescription drugs through ADAP.

Patient Assistance Programs (PAPs)

<u>Common Patient Assistance Program</u> <u>Application</u> (CPAPA) - In 2012, seven pharmaceutical companies, HHS and NASTAD worked together to create a single application for HIV patient assistance programs to lessen the burden on the patients and case managers.

Cost-sharing assistance programs (CAPs) -

Programs operated by pharmaceutical companies to offer cost-sharing assistance (including deductibles, co-payments and coinsurance) to people with private health insurance to obtain HIV drugs at the pharmacy. To see information on pharmaceutical company cost-sharing assistance and patient assistance programs, please visit the NASTAD website or the Fair Pricing Coalition's website.

<u>HarborPath</u> - A not for profit organization charged with creating a web-based portal to assist case managers and patient advocates by streamlining the application process for patient assistance programs (PAPs) and will than ship all participating medications to eligible clients directly from its own pharmacy.

Patient assistance programs (PAPs) -

Programs run through pharmaceutical companies to provide free or low-cost medications to people with low-incomes who do not qualify for any other insurance or assistance programs, such as Medicaid, Medicare or AIDS Drug Assistance Programs (ADAPs). То see information on pharmaceutical company cost-sharing assistance and patient assistance programs, please visit the NASTAD website or the Fair Pricing Coalition's website.

Resources

Resources:

- <u>National Alliance of State & Territorial AIDS Directors (NASTAD)</u>
 - <u>National Alliance of State and Territorial AIDS Directors, National ADAP</u> <u>Monitoring Project Annual Report</u>
 - National Alliance of State and Territorial AIDS Directors, National ADAP Monitoring Project Formulary Database
 - <u>NASTAD Factsheet: Pharmaceutical Company Patient Assistance Programs</u> and Cost-sharing Assistance Programs
 - Common Patient Assistance Program <u>Application</u> and <u>Companion</u> <u>Document</u>
- <u>Centers for Disease Control and Prevention</u> (CDC)
- <u>Centers for Medicare and Medicaid Services</u> (CMS)
- <u>Comprehensive information on ARVs and OI medications</u>
- The Fair Pricing Coalition
- Food and Drug Administration
- HarborPath
- HRSA HIV/AIDS Bureau
- HRSA 340B Prime Vendor Program
- <u>HRSA Office of Pharmacy Affairs</u> (OPA)
- <u>HRSA TARGET Center</u> technical assistance for the Ryan White community
- <u>Kaiser Family Foundation</u>
- <u>National Institutes of Health</u> (current treatment guidelines)
- Ryan White HIV/AIDS Treatment Modernization Act (2009)
- <u>U.S. Department of Health and Human Services</u> (Health Care Reform)

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