ADAP Advocacy Association
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November 12, 2014

Marilyn Tavenner
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Notice of Benefit and Payment Parameters & Essential Health Benefits

Ms. Tavenner:

I am writing to you on behalf of the ADAP Advocacy Association (aaa+®) and its board of directors regarding an issue of particular importance for people living with HIV-infection. Since it has been "rumored" that the Office of Management & Budget (OMB) may delay promulgating regulations on the Essential Health Benefits, we want to express our concerns prior to the Notice of Benefit and Payment Parameters.

aaa+® is a national 501(c)(3) nonprofit organization (EIN #26-0482120) incorporated in the District of Columbia to promote and enhance the AIDS Drug Assistance Programs and improve access to care for persons living with HIV/AIDS. We work with advocates, community, health care, government, patients, pharmaceutical companies and other stakeholders to assure that access to services recognize and afford persons living with HIV/AIDS to enjoy a healthy life.

The Patient Protection and Affordable Care Act (PPACA), or the Affordable Care Act (ACA) - also known as Obamacare – is supposed to see most of the law's major provisions phased in by January 2014, with other provisions phased in by 2020. The ACA will have numerous implications generally on the United State's health care delivery system, but more specifically on the supports and services afforded to people living with HIV-infection, or viral Hepatitis. What's more, ongoing Medicaid expansion and the implementation of insurance exchanges will also impact nearly all healthcare providers, as well as their patients. Unfortunately, people living with HIV-infection have experienced some of the unintended consequences of the law - including discriminatory practices limiting their access to care and treatment.

Over the last year, one of the most frequently asked questions by people living with HIV/AIDS, public policy advocates, representatives from the health care and pharmaceutical industries and others, "*What is the future of the AIDS Drug Assistance Program now that the Affordable Care Act is law?*"

The answer is simple: **It is too early to know for certain!**

At first glance, data trends suggest that the passage of the ACA and its subsequent implementation has not slowed down client enrollment in ADAPs nationwide. According to the "National ADAP Monitoring Project - Annual Report," published by the National Alliance of State & Territorial AIDS Directors (NASTAD), client enrollment increased by over 15,000 between 2012 and 2013, or about an 8% increase. Last year, over 210,000 people living with HIV/AIDS were enrolled in ADAP.

When it comes to patient protections, we are concerned about access, transparency, and discrimination. Access and transparency are critical to individuals and families making important health care decisions. We also hope you will put an end to potentially discriminatory disease-based practices such as establishing formularies that require high cost sharing for all medicines of a specific therapeutic type or "class," which creates access barriers for patients.

More specifically, below are three areas we would like to weigh in on:

Due to the manner in which Essential Health Benefits (EHBs) are defined for plan years 2014 and 2015, select plans do not include all the medications that enrollees may be prescribed to address their health care needs. Plans are further restricting access to care by imposing utilization management policies, such as prior authorization, step therapy and quantity limits. Tying plan formulary requirements to the number of drugs in each class in the state benchmark has resulted in some plans not covering critical medications, including combination therapies. Additionally, there is no requirement for plans to cover new medications and plans can remove medications during the plan year as long as the plan continues to meet the state's benchmark requirements. Narrow provider networks and a lack of access to specialists are also negatively impacting access to quality care for enrollees.

These design elements appear to affect certain patient populations disproportionately – many of the same populations that were subject to pre-existing condition restrictions prior to ACA implementation.

The fact that the plans are allowed to cover more medicines than a state's benchmark does little to protect patients. Under current rules, plans have no requirement or incentive to go beyond the minimums and may fear that they will attract higher-cost patients if they cover more medicines than their competitors. The Notice of Benefit and Payment Parameters should revise this policy and instead limit issuers' ability to make mid-year formulary changes. Medicare Part D offers a good model for potential formulary review guidelines as it only permits mid-year formulary enhancements, the removal of a drug from the formulary for safety reasons, or removal of brand drugs if an approved generic equivalent becomes available and is included on the formulary.

The out-of-pocket maximum is one of the most important patient protections in the Affordable Care Act and gives patients the assurance that no matter what their health care needs are, they will not need to spend more than a set amount out-of-pocket on health care each year. Once patients reach the out-of-pocket maximum, covered expenditures above the maximum are paid 100% by insurance, with no cost sharing for beneficiaries. Despite enrollee out-of-pocket limits that are included in the ACA and reduced cost sharing for people with very low-income levels, some plans place extremely high coinsurance on life-saving medication, and put all or most medications in a given class, including generics, on the highest cost tier. This creates an undue burden on enrollees who rely on these medications. Enrollees in the marketplace are being subject to plans that impose 30%, 40%, and even 50% coinsurance per prescription. Such high coinsurance will lead to

decreased medication adherence and medical complications as people are unable to afford, begin, or stay on their medications. Some plans also impose high deductibles for prescription medications and high cost sharing for accessing specialists. We believe these practices are highly discriminatory against patients with chronic health conditions and, in fact, may violate the ACA non-discrimination provisions.

The Notice of Benefit and Payment Parameters should clarify that cost sharing for medicines covered through the exceptions process should count towards the out-of-pocket maximum. Patients who have gained access to prescription medicines through this process have already demonstrated that they need these medicines and cannot instead take medicines on their plan's formulary. After going through the exceptions process, these medicines should be treated like any other covered medicine and cost sharing should count toward the out-of-pocket maximum. This would help assure that that the out-of-pocket maximum provides a real protection against the problem with excessive cost sharing. While the process of getting a medicine through an exceptions process was strengthened, HHS has not clarified how medicines covered through the exceptions process will count towards the out-of-pocket cap or what cost sharing plans can require for those medicines. Without clarity that cost sharing for these medicines must count towards the out-of-pocket cap, the exceptions process does not provide a meaningful assurance that patients can get the medicines they need.

Regarding combination drugs, HHS must amend the rules to provide incentives for plans to cover these medicines. Currently HIV and diabetes combination medicines are less likely to be covered in exchanges than single-medicine treatments. A stronger EHB rule that reflects the value of combination therapies would help lessen this discrepancy. Cost sharing should be structured to reflect the financial situation of those receiving cost-sharing subsidies. Given the financial challenges patient face, cost sharing should be structured to require more predictable spending and avoid spikes in out-of-pocket costs. The Notice of Benefit and Payment Parameters should prohibit cost sharing reduction plans from using coinsurance. Instead, all cost sharing should be structured as a flat co-payment, with plans determining the dollar amount of the co-payment so as to meet the plan's AV requirement.

Individuals must have access to easy-to-understand, detailed information about plan benefits, formularies, provider network, and the cost of medications and services. Unfortunately, individuals cannot access this information easily through an interactive web tool search the plan find or benefit calculator that matches in individuals prescriptions and provider need with appropriate plans that is the one utilize for the Medicare part D program.

Most troubling is the practice of requiring coinsurance without information for an individual to understand with her actual cost sharing will be. Transparent, easy navigate grievances, and appeals prices are needed, along with special enrollment procedures with patients lose access to a medication do to a formulary changes during the plan year.

The ACA has non-discrimination provisions, but HHS has not provided the tools or oversight to enforce this provisions. Currently primary responsibility rests with the states, but states have never done these reviews before and likely do not have the resources to fully assess whether plans are discriminatory. HHS should provide additional regulations and assessment tools to help states review plans.

In addition, to improve transparency, patients need interactive tools that allow them to estimate their total costs (both premiums and cost-sharing) to find the plan that is best for their individual needs. Something similar to the plan-finding tool of Medicare Part D would go a long way to helping to empower patients to find the plan that works best for them.

aaa+® appreciates the opportunity to provide its public comment on behalf of the approximately 150,000 people living with HIV-infection relying on the AIDS Drug Assistance Programs nationwide. Should you desire any additional information, please do not hesitant to contact me by email at info@adapadvocacyassociation.org. Thank you.

Sincerely,

Brandon M. Macsata
CEO