October 27, 2015

Krista Pedley, Director
Office of Pharmacy Affairs (OPA)
Health Resources and Services Administration (HRSA)
5600 Fishers Lane
Mail Stop 08W05A
Rockville, Maryland 20857
(submitted electronically)

Re: 340B Drug Pricing Omnibus Guidance (RIN 0906-AB08)

Dear Captain Pedley:

AIDS United appreciates the opportunity to submit comments regarding the proposed 340B Drug Pricing Program Omnibus Guidance (RIN 0906-AB08) on behalf of our organization and the members of our Public Policy Committee. Born out of the merger of the National AIDS Fund and AIDS Action in late 2010, AIDS United’s mission is to end the AIDS epidemic in the United States through strategic grantmaking, capacity building, formative research and policy. AIDS United works to ensure access to life-saving HIV/AIDS care and prevention services and to advance sound HIV/AIDS related policy for U.S. populations and communities most impacted by the epidemic. To date, our strategic grantmaking initiatives have directly funded more than $85.8 million to local communities, and have leveraged more than $110 million in additional investments for programs that include, but are not limited to, HIV prevention, access to care, capacity building, harm reduction, and advocacy.

The AIDS United Public Policy Committee (PPC) is the oldest continuing federal policy coalition working to end the HIV/AIDS epidemic in the United States since 1984. It is the largest body of community based HIV/AIDS Prevention, Treatment, Research, Education and Service organizations and coalitions in the U.S. The PPC has been instrumental in creating and developing important programs including the Ryan White Program and the National HIV/AIDS Strategy. Its national membership covers jurisdictions that include more than two-thirds of the population of People Living with HIV/AIDS and advocates for the millions of people living with or affected by HIV/AIDS in the U.S. & the organizations that serve them.
Summary of AIDS United Recommendations:

Role of the National HIV/AIDS Strategy

- AIDS United urges HRSA to review of all parts of the guidance and particularly those applying to the Ryan White Program, AIDS Drug Assistance Program (ADAP), and FQHCs, to ensure coordination and maximum impact of the program in meeting the goals of the NHAS. AIDS United urges that such review be made transparent and public with at minimum a public report about the impact of the 340B program on the NHAS, the specific impact of any changes recommended by the guidance, the impact on communities of color and other vulnerable populations specifically designated for review in the NHAS and an explanation of alternatives available under the law.

- AIDS United also urges HRSA to review the impact of the guidance on NHAS specifically for the possibility of a loss of comprehensive health insurance for people living with HIV under state AIDS Drug Assistance Programs (ADAP) or loss of access to services within an FQHC or RWP grantees or subgrantees, elimination of coverage for out-of-pocket medical expenses under ADAP, whether the changes will restrict ADAP client eligibility or cause the removal of drugs from the ADAP formulary. Finally, the guidance should be reviewed for its impact on potentially decreasing the number of people living with HIV receiving care and increased number of HIV infections in FQHCs, RWP grantees or subgrantees or via state ADAPs.

Eligibility and Accountability for the Ryan White Program Providers and Federally Qualified Health Centers

- AIDS United requests that HRSA modify items 1 and 2 to allow common practices such as a referral to an offsite healthcare provider with a defined relationship to the eligible grantee or subgrantee. Such a provider should not have to be a direct employee or contractor but rather should have a formal, transparent relationship with the eligible grantee or subgrantee such as a memorandum of understanding. If the provider is also a covered entity, then the entity providing healthcare services should receive the 340B rebate.

- AIDS United requests HRSA to modify item 3 to allow an individual to receive a drug if the recommended service results in prescription of a drug – e.g. focusing on the service and need for the drug rather than that the entity specifically ordered such a drug.

- AIDS United requests that HRSA create a process to allow participation in the 340B program when a covered entity is acting as a patient’s medical home and maintains responsibility for the overall care for the patient even when the patient is receiving prescriptions from referral physicians.

- AIDS United requests HRSA to modify item 4 to include the term “range of services” and make clear that 340B drugs are available to treat illnesses other than HIV/AIDS including co-morbidities, co-infections, and any other condition which needs treatment.

- AIDS United urges HRSA to limit unneeded regulatory burden by ensuring that audits are reasonably conducted with very clear requirements, and limiting penalties to egregious cases of fraud or loss of institutional control. We additionally urge that HRSA conduct audits in accordance with the government audit standards, provide covered entities with more time to respond to audit findings, provide covered entities with opportunities for oral
hearings and appeals, publish HRSA/OPA’s audit protocol, assist covered entities in knowing how compliance will be evaluated, and increase consistency across auditors.

- A prescription from a 340B covered entity vs. a non-covered entity should not appear different to the payer in order to avoid impacting private negotiations.
- AIDS United supports comments from the National Association of Community Health Centers, which are available at http://www.nachc.com/340Bmega.cfm

### Duplicate Discounts for State Medicaid Programs

- **AIDS United urges HRSA to clearly establish the state Medicaid agency as the entity responsible for avoiding duplicate discounts.**
- **AIDS United recommends that MCOs should not be allowed to retain drug discounts related to the 340B program but rather such discounts must be passed to the eligible entity and used for the purposes of the 340B statute.**

### Issues Related to the AIDS Drug Assistance Program

- **AIDS United calls for the specific review and coordination of the guidance related to ADAP generally and specifically to the qualified payment definition with the National HIV/AIDS Strategy and that HRSA coordinate with the Office of National AIDS Policy.**
- **AIDS United calls upon HRSA to delay implementation of the qualified payment definition and consider reviewing the guidance in the context of reflecting current practice. HRSA should further study the impact of both covered entities and ADAPs under such new regulations.**
- **Should HRSA retain the unacceptable qualified payment definition, AIDS United calls on HRSA to delay implementation until all states are able to pay the portion of the premium attributable to the client**
- **AIDS United calls on HRSA to minimize reporting burdens on rebates and to provide enough time to implement systems for data reporting.**

### Overview

As an organization that advocates for ending the HIV epidemic and on behalf of people with HIV who receive a significant proportion of their care from Ryan White Care programs, AIDS United believes that any changes to the 340B Drug Pricing Program must take into account the federal National HIV/AIDS Strategy and, within parameters of the law, must continue to be a critical tool in ending the HIV epidemic. The 340B program is a vital element in ensuring that Ryan White Care grantees, FQHCs and other HIV service providers have the ability to increase access to antiretroviral medications and provide more care to people living with HIV. This in turn ensures that more people are able to achieve HIV viral suppression, improve their physical health and significantly limit their ability to transmit HIV.

In addition, the 340B program allows safety net providers to treat chronic conditions that can also affect people living with HIV including diabetes, high cholesterol, high blood pressure, and depression. While the Affordable Care Act (ACA) has increased insurance coverage for millions of Americans, there will still be almost 30 million people uninsured in 2025 by Congressional Budget Office estimates. No matter the outcome of ACA implementation, there will still be many patients who remain underinsured or uninsured that will benefit from the 340B program, and many FQHCs and Ryan White Program
(RWP) grantees will rely on 340B discounting to continue serving a safety net population of people living with HIV while coping with strained funding resources. This safety net includes people of color, men who have sex with men, people experiencing poverty and other vulnerable.

While the General Accountability Office (GAO) and Office of the Inspector General (OIG) have cited problems with program oversight, efforts to limit the program’s eligibility to people who are uninsured ignore the fact that patients continue to face challenges accessing medical care or medications despite having insurance and are premature given HRSA’s planned efforts to better define patient eligibility in the near future.

**Role of the National HIV/AIDS Strategy**

We are concerned that changes to the guidance which are responding to the GAO and OIG criticisms similarly ignore both the existence both of the National HIV/AIDS Strategy, now updated to 2020 and the Executive Order Implementing the National HIV/AIDS Strategy (NHAS) for the United States for 2015-2020 (a follow on to the previous executive order implementing the NHAS in the previous period of 2010-2015).

The order clearly requires “coordination and collaboration by, and accountability of, the Federal Government.” It also states that “we must continue to improve our national effort to reduce new HIV infections, increase access to care for people living with HIV, reduce HIV-related disparities and health inequities, and achieve greater coordination across all levels of government.” The order designates HRSA as a lead agency and moreover provides that “All agencies that support HIV/AIDS programs and activities shall ensure that, to the extent permitted by law, they are meeting the goals of the Updated Strategy.” AIDS United is concerned that the guidance does not appear to have taken into account the National HIV/AIDS Strategy as required by the executive order and has therefore unduly and unnecessarily narrowed the provisions as they apply to people with HIV. In particular, AIDS United believes that prior to moving forward, the guidance should specifically review the impact of the possibility of a loss of comprehensive health insurance for people living with HIV under state AIDS Drug Assistance Programs (ADAP) or loss of access to services within an FQHC or RWP grantees or subgrantees, elimination of coverage for out-of-pocket medical expenses under ADAP, whether the changes will restrict ADAP client eligibility or cause the removal of drugs from the ADAP formulary. Finally, the guidance should be reviewed for its impact on potentially decreasing the number of people living with HIV receiving care and increased number of HIV infections in FQHCs, RWP grantees or subgrantees or via state ADAPs.

**Recommendation:**

- **AIDS United urges HRSA to review of all parts of the guidance and particularly those applying to the Ryan White Program, AIDS Drug Assistance Program (ADAP), and FQHCs, to ensure coordination and maximum impact of the program in meeting the goals of the NHAS. AIDS United urges that such review be made transparent and public with at minimum a public report about the impact of the 340B program on the NHAS, the specific impact of any changes recommended by the guidance, the impact on communities of color and other vulnerable populations specifically designated for review in the NHAS and an explanation of alternatives available under the law.**
AIDS United also urges HRSA to review the impact of the guidance on NHAS specifically for the possibility of a loss of comprehensive health insurance for people living with HIV under state AIDS Drug Assistance Programs (ADAP) or loss of access to services within an FQHC or RWP grantees or subgrantees, elimination of coverage for out-of-pocket medical expenses under ADAP, whether the changes will restrict ADAP client eligibility or cause the removal of drugs from the ADAP formula. Finally, the guidance should be reviewed for its impact on potentially decreasing the number of people living with HIV receiving care and increased number of HIV infections in FQHCs, RWP grantees or subgrantees or via state ADAPs.

Eligibility and Accountability for the Ryan White Program Providers and Federally Qualified Health Centers

Many of AIDS United’s Public Policy Committee members have stated that several of the major changes to patient eligibility requirements (pp. 24-26 in the guidance) should be reviewed and clarified. In particular, new guidance states that:

1. The individual receives a health care service at a facility or clinic site which is registered for the 340B Program and listed on the public 340B database.
2. The individual receives a health care service provided by a covered entity provider who is either employed by the covered entity or who is an independent contractor for the covered entity, such that the covered entity may bill for services on behalf of the provider.
3. An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in (2).
4. The individual’s health care is consistent with scope of the Federal grant, project, designation, or contract.
5. The individual’s drug is ordered or prescribed pursuant to a health care service that is classified as outpatient.
6. The individual’s patient records are accessible to the covered entity and demonstrate that the covered entity is responsible for care.

This language, particularly items 1 – 4, alters previous language and may strongly limit the ability of Ryan White Program Grantees and Sub-grantees to engage in the 340b program. For example, it does not allow Ryan White Programs that are medically managing the health care of an individual to arrange care with health care providers who are not direct contractors, or for clients who receive Medicaid or private insurance as a result of coordination or facilitation via the Ryan White Program but do not obtain care on-site. These are common arrangements for Ryan White Program grantees and subgrantees. In fact, it is actually desirable for this type of coordination to take place. Assuming that the health care provider is not themselves eligible, it then makes sense for the entity that is providing the coordination to receive the 340B Program benefit as that may be the reason that the patient is with the provider in the first place. Should the health care provider and the covered entity both be eligible entities, they can easily work out who should receive the benefit for the purposes of deduplication (see recommendation on deduplication below).

We are thus concerned that this guidance potentially delinks the 340B benefit from the program that is directly serving the client from the care and services that help clients adhere to care as called for in the National HIV/AIDS Strategy. Moreover individuals who are receiving such care as a direct result of the Ryan White Program are in fact Ryan White Program clients and the grantee or sub-grantee is a
provider. This potential for fragmentation of the system of care for a vulnerable client is not needed to fulfill the intent of the program.

We do recognize this may not be applicable to all jurisdictions. There are cases in which the converse may also be true and that providers may dispute who is the owner of a medical record which has the potential to create infighting for 340B patients and fractured care in that case as well. However, the solution is to develop best practices regarding the issue of duplication and provide strong guidance on how programs adjudicate 340B patients between them that takes into account all of these possibilities (again, see recommendation on deduplication below). We note that covered entities should also consider maintaining clear ethical standards regarding how to ensure that they allow clients freedom of choice and that they are careful not to steer clients to health care providers or pharmacies with whom they have a financial relationship.

Finally, we note that as the payer of last resort, the Ryan White Program is actually supposed to seek other payers and make alternative arrangements that may not include direct on-site services. Ultimately, one issue is that different regions, states and localities have reasonably pursued different strategies on providing care and the guidance should take into account that there are multiple means of doing so.

**Recommendation:**

- AIDS United requests that HRSA modify items 1 and 2 to allow common practices such as a referral to an offsite healthcare provider with a defined relationship to the eligible grantee or subgrantee. Such a provider should not have to be a direct employee or contractor but rather should have a formal, transparent relationship with the eligible grantee or subgrantee such as a memorandum of understanding. If the provider is also a covered entity, then the entity providing healthcare services should receive the 340B rebate.

An additional issue that may cause problems is the language in item (3) that eligibility occurs if an individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service health care service provided by a covered entity provider. Coordination of services is among the most important functions of the Ryan White Program and this language has the potential to deemphasize such coordination.

Similarly, language in item (4) has the potential to be problematic. An individual’s health care is consistent with the scope of the grant, project, designation, or contract. In this guidance, the term “range of services” was removed from the language regarding the scope of the grant. We believe this probably is an oversight; however, if upheld, it could mean that Ryan White Clinics could only use 340B drugs to treat HIV infection and not use 340B drugs to treat illnesses other than HIV/AIDS. Persons living with HIV/AIDS have numerous co-morbidities, co-infections, and other conditions which need treatment. Without the 340B program to cover these medications, Ryan White prescription drug funds would be buying medications at retail prices. This is clearly not the intent of the program.
Recommendation:

- AIDS United requests HRSA to modify item 3 to allow an individual to receive a drug if the recommended service results in prescription of a drug – e.g., focusing on the service and need for the drug rather than that the entity specifically ordered such a drug.

- AIDS United requests HRSA create a process to allow participation in the 340B program when a covered entity is acting as a patient’s medical home and maintains responsibility for the overall care for the patient even when the patient is receiving prescriptions from referral physicians.

- AIDS United requests HRSA to modify item 4 to include the term “range of services” and make clear that 340B drugs are available to treat illnesses other than HIV/AIDS including co-morbidities, co-infections, and any other condition which needs treatment.

Audit and other paperwork requirements – AIDS United has consistently sought to lower the regulatory paperwork burden of the Ryan White Program and other grant programs including HIV prevention. The proposed guidance sets forth an expectation that covered entities conduct quarterly reviews and annual independent audits of each contract pharmacy location, disclose any 340B program violations to HHS, and subjects the covered entity to the applicable penalties for instances of duplicate discounts and diversion.

AIDS United supports efforts to improve program integrity. However, the proposed additional audit requirements create an undue burden on HRSA grantees participating in the 340B program. These new requirements duplicate existing administrative audits required as a condition of HRSA grants. Having to conduct quarterly reviews and financing an annual independent audit diverts already limited resources from essential patient care. Subjecting the covered entity to penalties for instances of duplicate discounts and diversion found as a result of these reviews and audits further erodes their ability to deliver care to vulnerable patients. Unless there is a specific intent to avoid regulatory control or a reckless lack of controls, yearly audits that are part of routine administration will suffice. Moreover except in intentional cases of fraud, penalties merely divert funding from needed programs and services.

Recommendation:

- AIDS United urges HRSA to limit unneeded regulatory burden by ensuring that audits are reasonably conducted with very clear requirements, and limiting penalties to egregious cases of fraud or loss of institutional control. We additionally urge that HRSA conduct audits in accordance with the government audit standards, provide covered entities with more time to respond to audit findings, provide covered entities with opportunities for oral hearings and appeals, publish HRSA/OPA’s audit protocol, assist covered entities in knowing how compliance will be evaluated, and increase consistency across auditors.

HRSA requested comments regarding how it should be notified of covered entities’ election to carve in or out MCO’s. Some AIDS United PPC Members have expressed concern that if MCO patients are identified, nothing would stop the payer from negotiating rates far below usual and customary rates. This would be discriminatory. A prescription from a 340B covered entity vs. a non-covered entity should appear no different to the payer, and if it did, it could greatly impact the private negotiation between the MCO and covered entity.
**Recommendation:**
- A prescription from a 340B covered entity vs. a non-covered entity should not appear different to the payer in order to avoid impacting private negotiations.

Federally Qualified Health Centers provide substantial care and treatment to people living with HIV. We are strongly concerned about the impact of this guidance upon their operation and strongly agree with their comments, particularly that the one-size-fits-all approach to managing covered entities does not take into account the unique, statutorily-mandated structures and goals, and as a result is often detrimental to HRSA grantees and their clients. Given these concerns, we therefore urge you to pay close attention to their recommendations as well.

**Recommendation:**
- AIDS United supports comments from the National Association of Community Health Centers, which are available at http://www.nachc.com/340Bmega.cfm

**Duplicate Discounts for State Medicaid Programs**

HRSA’s draft guidance dramatically changes the approach to addressing duplicate discounts between the 340B program and state Medicaid programs by shifting the burden of eliminating such duplications from the state Medicaid program to the much smaller 340B entity. This is not appropriate. State Medicaid Programs have access to both the necessary data and coding mechanisms to avoid duplicative payments and in fact many states are already doing so. The guidance additionally would allow Managed Care Organizations to develop systems to avoid duplication. Given that such organizations are often for profit institutions and have often sought to retain funding for themselves (often at the expense of providers) this is not a workable solution.

**Recommendation:**
- AIDS United urges HRSA to clearly establish the state Medicaid agency as the entity responsible for avoiding duplicate discounts.
- AIDS United recommends that MCOs should not be allowed to retain drug discounts related to the 340B program but rather such discounts must be passed to the eligible entity and used for the purposes of the 340B statute.

**Issues Related to the AIDS Drug Assistance Program**

New guidance specifically related to state ADAPs limits rebates to only those copay prescription claims for which the State ADAP has paid the health insurance premium. This is a change to how the ADAPs have previously claimed rebates (on all copay claims) and is estimated to restrict funding from rebates at the state level. This proposal alone would have a major impact on the operability of ADAP programs. Several PPC Members have noted that it seems clear under the new proposal that State ADAPs would not be able to pay copays, etc., in employer programs.

Particularly troubling is the definition of a qualified payment which would stop ADAPs from receiving a rebate on a cost-sharing payment when the ADAP has not paid the portion of the insurance premium attributable to the client. This is contrary to long-established practice and is not contemplated under the
statute. Under current practice, ADAPS are allowed to receive a rebate as long as the ADAP pays a copayment, co-insurance or deductible which simply allows the client to receive insurance. Given that many clients would be forced to go without such insurance without assistance in cost sharing it is both necessary and completely uncontroversial for ADAP to additionally receive the rebate which then allows them to further provide coverage within the purpose of the 340B statute – e.g. to stretch scarce Federal resources … reaching more eligible patients and providing comprehensive services.” In fact given that most clients in this situation are having premiums paid by Medicaid, Medicare and federally subsidized insurance, it could further be argued that these programs are additionally designed to ensure such a goal. Eliminating such subsidies to return funding to pharmaceutical companies cannot be the purpose of this statute. The National Alliance of State and Territorial AIDS Directors (NASTAD) has estimated the cost of such changes to be between $400 - $515 million or an 18-23% reduction in the ADAP budget. This is unsustainable and would result in a loss of care to thousands of individuals destroying progress in reaching the goals of the NHAS.

AIDS United finds this to be completely unacceptable. Going back to our initial comments, had HRSA appropriately coordinated with its very own HIV/AIDS Bureau, it would have taken into account the consequences to the National HIV/AIDS Strategy and in our opinion such a proposal would not have been made.

In addition to our strong opposition to the qualified payment definition, AIDS United notes that the implementation time of one year would likely destabilize many state ADAPS, require a massive changes to state laws to come into conformity, likely result in the loss of insurance to thousands of people with HIV and create a reversion to direct payment for ADAP drugs. Some of these destructive effects may be mitigated with additional time for state legislatures and ADAPs to act. There is also a significant impact on data reporting for rebates which will add additional paperwork and funding burdens to the reporting process for some programs to cull out only those clients who also get premium support. Essentially such reporting which currently relies on automatic uploads will have to be done “by hand.”

Recommendation:

- AIDS United calls for the specific review and coordination of the guidance related to ADAP generally and specifically to the qualified payment definition with the National HIV/AIDS Strategy and that HRSA coordinate with the Office of National AIDS Policy.
- AIDS United calls upon HRSA to delay implementation of the qualified payment definition and consider reviewing the guidance in the context of reflecting current practice. HRSA should further study the impact of both covered entities and ADAPs under such new regulations.
- Should HRSA retain the unacceptable qualified payment definition, AIDS United calls on HRSA to delay implementation until all states are able to pay the portion of the premium attributable to the client.
- AIDS United calls on HRSA to minimize reporting burdens on rebates and to provide enough time to implement systems for data reporting.

AIDS United is concerned about the impact of this new guidance in strongly and unnecessarily narrowing the meaning of the legislative language in such a manner as to undermine the National HIV/AIDS Strategy and against its own purpose to stretch scarce federal resources to reach more
eligible patients and provide more comprehensive services. The unintended consequences of enacting tighter regulations on safety net providers should be reviewed to ensure that the guidance works in the best interest of all the Ryan White 340B Covered entities. The benefit to the 340B Program as it is structured currently is that covered entities have the flexibility in building the capacity to stretch scarce federal resources; this also is part of the primary design of the Ryan White Program.

We appreciate the opportunity to comment on the guidance and strongly urge HRSA to coordinate the guidance with full implementation of the National HIV/AIDS Strategy.

Sincerely,

Ronald Johnson
Vice President of Policy and Advocacy
(On behalf of AIDS United and the AIDS United Public Policy Committee)

AIDS United’s Public Policy Committee membership includes: AIDS Action Committee (Boston); AIDS Alabama (Birmingham); AIDS Arms (Dallas); AIDS Foundation of Chicago; AIDS Project Los Angeles; AIDS Resource Center Ohio/Ohio AIDS Coalition; AIDS Resource Center of Wisconsin; Amida Care (New York City); Association of Nurses in AIDS Care; BOOMHealth! (New York City); Cascade AIDS Project (Portland OR); Christie’s Place (San Diego), Collaborative Solutions (Birmingham), Delaware HIV Consortium; Foundation for a Healthy St. Petersburg, GMHC (New York City), God’s Love We Deliver (New York City); Housing Works, IV-CHARIS (Cincinnati); JRI-Health (Boston); Latino Commission on AIDS, L.A. County Department of Public Health, Legacy Community Health Services, Inc. (Houston); Metro Wellness & Community Centers (Tampa); Minnesota AIDS Project; Nashville CARES; National Alliance for HIV Education & Workforce Development; New Orleans AIDS Task Force; Positive Women’s Network – USA; Project Inform (San Francisco); San Francisco AIDS Foundation; Southern AIDS Coalition; Southern HIV/AIDS Strategy Initiative; Thrive Alabama (Huntsville), Treatment Access Expansion Project (Boston); Urban Coalition for HIV/AIDS Prevention Services; Whitman-Walker Health (Washington, DC); Women With A Vision (New Orleans), The Women’s Collective (Washington, D.C.).