Dear Captain Pedley:

The Ryan White Working Group (RWWG) appreciates the opportunity to submit comments on the Health Resources and Services Administration’s (HRSA) proposed 340B Drug Pricing Program Omnibus Guidance (the proposed guidance). The undersigned organizations are concerned that the proposed guidance would negatively impact the Ryan White Program. Below, we provide comments on the following aspects of the proposed guidance:

- Proposed ADAP rebate processes
- Impact of proposed restrictions on ADAP rebates
- Proposed audit standards and contract pharmacy relationships

The 340B Drug Pricing Program is critical to the Ryan White Program’s ability to expand care to clients and to support the underlying public health infrastructure that prevents new HIV infections. The Ryan White Program has the expertise, services and models of care that successfully enroll people in care and keep them healthy. Underfunding the Ryan White Program system of care will only serve to exacerbate existing structural challenges such as the disproportionate impact of HIV on communities of color, greater poverty, lack of employment and educational opportunities, and lack of access to vital prevention, care, and treatment services.

Building on the success of the Ryan White Program coordination services is paramount to ending the HIV epidemic. For example, data from HRSA’s 2012 Ryan White HIV/AIDS Program Services Report of a subset of jurisdictions in the South (Atlanta, GA; Memphis TN; Miami, FL; North Carolina; South Carolina) indicate that approximately 68% of Black men who have sex with men are virally suppressed. This figure far exceeds national PLWH viral suppression estimates. This demonstrates the unique success of the Ryan White Program in accelerating health outcomes for disproportionately impacted populations. Among the services necessary to improve health outcomes are linkage to, and retention in care, and access to medications that suppress viral loads and thereby reducing transmission which leads to fewer new HIV infections.

The National HIV AIDS Strategy, released in 2010 and updated in 2015, sets the goals of reducing new HIV infections, increasing access to care and improving health outcomes for people living with HIV, reducing HIV-related disparities and health inequities and achieving a more coordinated national response to the HIV epidemic. The Ryan White Program provides
access to comprehensive care that is critical to viral suppression and that improve health outcomes for people living with HIV. Access to treatment is vital to preventing new infections, as antiretroviral treatment can reduce the risk of transmission by 96 percent when virally suppressed. The 340B Drug Pricing Program’s support of the Ryan White Program’s system of care is critical to achieving the goals of the National HIV/AIDS Strategy.

I. Proposed ADAP Rebate Processes

Qualified payment definition

The RWWG is deeply troubled by the proposed “qualified payment” definition, which would strip ADAPs of a critical funding source that truly allows ADAPs “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” (80 FR 52300) the RWWG outlines the potential impact of this change below (See Impact of proposed restrictions on ADAP rebates, infra), and focuses here on the operational challenges posed by the proposed definition as well as its conflict with long-established Medicaid policies.

ADAP rebates have long followed procedures established for Medicaid rebates. Since the establishment of the ADAP rebate program in 1998, ADAPs have been “encouraged to use Medicaid claims form[s],” and Medicaid rebates are the “model to be emulated” by ADAPs. (Notice Regarding Section 602 of the Veterans Health Care Act of 1992—Rebate Option, 63 Fed. Reg. 35240) Without explanation, the qualified payment definition in the proposed guidance aims to sever this relationship by specifically prohibiting 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 – a practice that has been long-defended in the Medicaid program. In three policy releases and one final rule, the Department of Health and Human Services reiterated that the law requires manufacturers to pay Medicaid rebates when a Medicaid program pays a prescription co-payment as a secondary payer. Specifically:

- **MDRP Manufacturer Program Release #6**: “There are many instances where the costs of Medicaid prescriptions are partially offset … by submitting claims to third party insurers. This situation has no bearing on Medicaid rebates…”
- **MDRP Program State Release #64**: “Once again, we are reiterating that the level or amount of Medicaid reimbursement is irrelevant to rebate liability … Manufacturers that persist in withholding rebates based solely on the level of Medicaid reimbursement may be found in violation of the rebate agreement and risk termination from the program.”
- **MDRP Program State Release #113**: “As discussed in previous releases, if a state Medicaid agency paid any portion of a drug claim to the provider … the manufacturer is liable for the payment of rebates …”
- **2007 Medicaid Final Rule, 72 Fed. Reg. 39218**: “We disagree that the rebate should be proportional to the amount of the claim paid by Medicaid. Neither the law nor the national rebate agreement makes provision to reduce the rebate liability … This has been the consistent policy position of the Agency since the start of the Medicaid Drug Rebate Program.”
The RWWG cannot fathom why HRSA has proposed to decouple the long-standing relationship between Medicaid and ADAP rebates, as the rebate serves the same purpose in both programs – to ensure the fiscal stability necessary to provide core services. Indeed, it is strange that HRSA proposes to more closely align the programs in terms of rebate calculation while insisting that ADAP secondary payer rebates are categorically different than their Medicaid counterparts. (80 FR 52314) The RWWG instead calls upon HRSA to reject the proposed qualified payment definition and maintain the parity between ADAP and Medicaid rebates.

**Premium payment**

The RWWG understands the proposed qualified payment definition to be met when the ADAP pays the portion of the insurance premium attributable to the client. Nearly all ADAP clients with insurance have their premiums subsidized by another party; the majority of these subsidies are Federal (Advance Premium Tax credits for Affordable Care Act marketplace plans, partial or full subsidies for lower-income Medicare Part D enrollees), though most ADAP clients with employer-sponsored insurance also receive a premium subsidy from their employer. If the ADAP pays the portion of the insurance premium attributable to the client for one of these clients and makes a cost-sharing payment for a prescription, the RWWG believes this is a qualified payment, as the ADAP has made “payment of the health insurance premium, and pays the copayment, coinsurance, or deductible that covers the drug purchase[].” (80 Fed. Reg. 52313) For these qualified payments, the RWWG fully expects that manufacturers will provide the appropriate ADAP rebate.

Any other interpretation of the premium component of the proposed qualified payment definition would be both illogical and disastrous for ADAPs. The RWWG understands that certain manufacturers are asserting the aggressive position that, under the proposed qualified payment definition, only ADAP-paid premiums with no additional subsidy would meet the proposed definition. This would eliminate over 80 percent of insured ADAP clients from the qualified payment definition, as only those clients with Standard Benefit Medicare Part D plans and clients with incomes greater than 400 percent of the Federal Poverty Level (FPL) enrolled in marketplace plans would qualify. This runs contrary to long-standing HRSA policy encouraging ADAPs to enroll clients in marketplace plans, undermining the success of ADAPs in maintaining viral suppression and broadening access to care.¹

The RWWG further requests that HRSA establish an exception for employer-sponsored insurance from the premium payment requirement of the proposed qualified payment definition. For ADAP clients with employer-sponsored insurance, the ADAP can only pay the premium by submitting a check to the client’s employer or insurer and asking the employer to stop deducting the portion of the premium attributable to the client from the client’s paycheck. Many ADAP clients are unwilling to allow the ADAP to do this, as it risks disclosing the ADAP client’s HIV status or sexual orientation to the employer, subjecting the ADAP client to possible dismissal or discrimination. Depending on the client’s insurance structure, however, it may not be cost-effective for the ADAP to pay the client’s cost-sharing obligations without rebates (e.g.,
for grandfathered high-deductible plans). Requiring the ADAP to enroll the client in marketplace insurance or to place the client on traditional, full-pay ADAP would be overly burdensome and inconsistent with ADAP’s role as a payer of last resort. Absent the ability to receive rebates on cost-sharing payments for clients with employer-sponsored insurance, however, ADAPs may be forced to engage in these ridiculous work-arounds. It would be far simpler for HRSA to provide an exemption from the premium payment requirement of the qualified payment definition for ADAP clients with employer-sponsored insurance. This exception recognizes the ongoing stigma faced by people living with HIV and allows ADAPs to provide continuity to existing employer-sponsored insurance enrollments.

**Implementation dates**

The RWWG does not support the proposed qualified payment definition, given its staggering blow to ADAP financial health (discussed infra). If implemented as written, however, a one-year delay is far too little time for states to adopt the necessary procedures to comply with the uniquely burdensome requirements of the proposed definition. As HRSA notes, existing state laws prohibit some state ADAPs from being eligible to pay the portion of the insurance premium attributable to the client; in other states, the Executive has limited ADAP participation in insurance marketplaces or other premium payments under the Affordable Care Act. (80 Fed. Reg. 52313) Some states have either short annual legislative sessions or may only meet biennially, making it nearly impossible to change state law to allow states to make “qualified payments” within a one-year delay.

Further, any discussion of ADAP payment of the portion of the insurance premium attributable to the client will be uniquely contentious during a presidential election year when the Affordable Care Act will dominate public discourse, meaning that many states may not be able to adapt state laws before the implementation period begins. In these states, without rebates to off-set premium costs, it will no longer be cost-effective to purchase marketplace or other private insurance coverage for clients, forcing the entire ADAP to revert to a full-pay traditional ADAP program. This will be enormously destabilizing to currently-insured ADAP clients, as they may lose access to their existing primary care and HIV care providers; simultaneously, many medical providers are restricting the amount of regular indigent care they provide following changes in payment methodologies under the Affordable Care Act. Simply put, the proposed qualified payment definition threatens the existence of comprehensive ADAP services in the places that need them most. If HRSA chooses, against all wisdom, to adopt the qualified payment definition, then it must delay implementation until all states are able to pay the portion of the premium attributable to the client.

**Rebate calculation**

The RWWG supports HRSA’s recognition that a percentage rebate would be “so operationally burdensome as to be inoperable.” (80 Fed. Reg. 52314) However, the RWWG believes that the proposal to use “the Medicaid drug rebate amount described in section 1927(c) of the Social Security Act” violates the requirements of the 340B program, as often the rebate amount would not bring the ADAP purchase price to the 340B ceiling price. (80 Fed. Reg. 52314) The proposed guidance recognizes that the rebate option must result in a price “equivalent to the direct
purchase option,” but the proposal to use the 1927(c) rebate would not result in an equivalent price unless the ADAP purchased the drug at the Average Manufacturer Price (AMP). (80 Fed. Reg. 52314) For ADAPs with a direct purchase program, it is highly unlikely that an ADAP would be purchasing at AMP, as AMP is a confidential price and ADAPs would typically be purchasing at market rates, often the Wholesale Acquisition Cost (WAC). Indeed, the proposed guidance recognizes that ADAPs often purchase at a range of prices; the first portion of the proposed qualified payment definition addresses “ADAP purchase[s] of a covered outpatient drug at a price greater than the 340B ceiling price.” (80 Fed. Reg. 52313) When making these purchases, if an ADAP purchases a drug at WAC, then the proposed rebate amount would not result in a price “equivalent to the direct purchase option.” A 2005 report from the HHS Office of the Inspector General found that AMP is, at median, 25% lower than WAC (for generic drugs, the AMP was, at median, 40% below WAC; for single-source and multi-source brand drugs, the AMP was 4% and 8% below WAC, respectively).2

Because the 1927(c) rebate calculation would violate the direct purchase equivalence requirement, the RWWG requests that HRSA continue to allow ADAPs to calculate rebates under their existing methods. Because each ADAP has different purchase mechanisms, ADAPs tailor rebate calculations to their purchasing models. Further, requiring ADAPs to use the 1927(c) rebate process prevents ADAPs from being able to accurately estimate projected rebates, as AMP is a confidential figure and not known to ADAPs. This could prevent ADAPs from accurately assessing, ex-ante, the cost-effectiveness of various insurance plans. If a manufacturer has concerns about an ADAP’s rebate calculation methodology, the manufacturer has existing mechanisms to dispute the rebate amount; the RWWG believes that ADAPs and manufacturers are typically able to work through any rebate disputes with few challenges. HRSA should clarify that manufacturers are required to pay the invoiced rebate amount upon receipt, consistent with long-standing “must offer” provisions of the 340B program, and subsequently dispute any issues rather than withhold invoices.

The RWWG commends HRSA’s statement that “nothing in this proposed guidance prohibits a manufacturer from voluntarily extending additional discounts or rebates on 340B drugs.” (80 Fed. Reg. 52314) ADAPs have historically negotiated sub-ceiling discounts with manufacturers, and NASTAD expects that manufacturers will continue to provide sub-ceiling prices to ADAPs on rebate claims, particularly in light of the drastic effect the proposed qualified payment definition would have on ADAPs.

II. Impact of Proposed Restrictions on ADAP Rebates

The RWWG is gravely worried that the proposed restrictions on ADAP rebates will severely undermine ADAPs’ ability to serve vulnerable clients, contrary to the 340B program’s stated intent of “stretch[ing] scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” (80 F.R. 52300) Indeed, not only does the proposed “qualified payment” definition “present unique challenges” for ADAPs, it will raise costs for manufacturers and may cause ADAPs to restrict client eligibility. (80 F.R. 52313) This will have an impact on the Ryan White Program’s ability to provide comprehensive care and will destabilize the underlying public health infrastructure.

Impact on ADAP budget
The proposed qualified payment definition, wherein a qualified payment is made if the ADAP pays the portion of the insurance premium attributable to the client and the associated cost-sharing for an individual prescription, would affect more than half of ADAPs’ insured clients. According to the National Alliance of State & Territorial AIDS Directors (NASTAD)’s 2014 National ADAP Monitoring Project Annual Report, in June 2014, ADAPs served 61,456 clients with insurance assistance; assistance for 35,150 of these clients would not meet the proposed qualified payment definition (8,264 clients with premium assistance only, 26,886 clients with cost-sharing assistance only). Further, based on annual enrollment figures from 2013, NASTAD estimates that almost 20,000 additional clients received insurance assistance outside of the qualified payment definition in 2014 – these clients would have received cost-sharing assistance between January and June and would have reached out-of-pocket maximums prior to NASTAD’s annual June census. Based on these enrollment figures, NASTAD estimates that the proposed qualified payment definition would result in a $400,000,000 to $515,000,000 loss in rebate revenue to ADAPs. In 2014, ADAPs estimated that rebates accounted for $960,335,569; the proposed guidance would cause a 40 to 55 percent drop in ADAP rebate revenue – a 18 to 23 percent reduction in the entire national ADAP budget ($2.21B).

Under the aggressive qualified payment definition advanced by certain manufacturers, which eliminates over 80 percent of existing insured ADAP clients from the qualified payment definition, the impact would be catastrophic. NASTAD estimates that ADAPs would lose $585,000,000 to $750,000,000 (60 to 80 percent of expected ADAP rebate revenue, 28 to 35 percent of the national ADAP budget), with no possibility of recouping any of those losses. While, if given additional time to implement program changes, ADAPs may be able to pay the portion of the insurance premium attributable to the client and thus make a qualified payment, under this aggressive interpretation, ADAPs would never be able to receive rebate payments for these clients because the client receives a marketplace Advance Premium Tax Credit or an employer subsidy. This aggressive interpretation goes too far – not only does it permanently eviscerate the ADAP model, but it transfers $750,000,000 from Federally-funded safety net programs directly to drug manufacturers.

This loss would be crippling for ADAPs and would likely force ADAPs to transition many currently insured clients to other forms of ADAP coverage, hurting both patients and pharmaceutical manufacturers. ADAP clients with employer-sponsored insurance would be particularly vulnerable, as ADAP payment of the portion of the insurance premium attributable to the client could reveal the client’s HIV status or sexuality to an employer. For these clients, high deductibles or other cost-sharing would require the ADAP to make substantial payments without any ability to pursue rebates; if those cost-sharing payments exceed the cost of purchasing the client’s HIV medications at the 340B price, the insurance may no longer be cost-effective and the ADAP may need to transition the client to a traditional, full-pay ADAP model. This would be detrimental to the client, as the ADAP would not be assisting the client in meeting cost-sharing burdens, raising the cost of non-HIV care to the client; further, it would severely burden manufacturers, as they would be forced to provide an entire year’s worth of HIV medication at the 340B price, rather than only providing rebates for the portion of the year before the client’s out-of-pocket maximum was met, after which the insurance payer would purchase medication at the full commercial price.
While the impact of the proposed qualified payment definition would be felt nationwide, it will disproportionately affect some states with exceptionally high HIV incidence – the states in most need of “stretch[ing] scarce Federal resources.” Based on June 2014 ADAP data, five of the ten jurisdictions with the highest HIV incidence would lose all or nearly all of their rebate income from insured patients under the proposed qualified payment definition. Further, as noted in the proposed guidance, some states have laws prohibiting ADAPs from making premium payments; these states are unlikely to be willing to rescind such prohibitions in the face of political concerns about supporting the Affordable Care Act, particularly in the polarized climate of a presidential election year. (80 FR 52313) The proposed guidance, then, threatens to eviscerate crucial funding for ADAPs and the Ryan White Program that rely on 340B income to “reach more eligible patients and provid[e] more comprehensive services.” (80 FR 52300)

Impact on Public Health

ADAPs’ primary function is to support the public’s health by ensuring that eligible clients living with HIV remain in care, adherent to medication, and, ultimately, virally suppressed. The proposed qualified payment definition threatens this critical mission, as any reduction in rebate funds will reduce the number of persons living with HIV that ADAPs can serve. ADAPs are extremely effective at bringing clients to viral suppression. Nationally, only 75 percent of persons living with HIV retained in medical care are virally suppressed – however, 84% of ADAP clients are virally suppressed, rising to 90% of ADAP clients with ADAP-funded insurance. With the loss of rebate funds, ADAPs may have to reduce the number of clients eligible for ADAP services, particularly clients with employer-sponsored or other private insurance where the ADAP cannot pay the premium. This could be disastrous for maintaining these clients’ viral suppression, as it is well-established that even nominal cost-sharing burdens can reduce medication adherence, much less the exorbitant deductible and specialty cost-sharing to which many HIV drugs are subject.

Increasing patients’ cost-sharing runs counter to Federal HIV treatment guidelines. Indeed, the National Institutes of Health (NIH) addresses the dangers of increased cost-sharing for patients with HIV, specifically noting the role of ADAPs in protecting medication adherence through reduced cost-sharing:

“In one comprehensive review, increased patient cost sharing resulted in decreased medical adherence and more frequent drug discontinuation; for patients with chronic diseases, increased cost sharing was also associated with increased use of the medical system. Conversely, co-payment reductions, such as those that might be used to incentivize prescribing of generic drugs, have been associated with improved adherence in patients with chronic diseases. Whereas cost-sharing disproportionately affects low income patients, resources (e.g., the Ryan White AIDS Drug Assistance Program [ADAP]) are available to assist eligible patients with co-pays and deductibles. Given the clear association between out-of-pocket costs for patients with chronic diseases and the ability of those patients to pay for and adhere to medications, clinicians should minimize patients’ out-of-pocket drug-related expenses whenever possible.”
The Ryan White Program is an established and effective model to promote and ensure medication adherence, protecting the health of individuals living with HIV and reducing community HIV incidence. By eliminating ADAPs’ ability to pursue rebates for clients for whom the ADAP makes substantial cost-sharing payments but does not pay premiums, the proposed guidance threatens the Ryan White Program’s ability to vigorously protect the public health by expanding ADAP services to clients with private insurance.

Manufacturers have repeatedly asserted that manufacturer co-pay assistance programs provide insured patients with the same access to medication as the Ryan White Program, but patients living with HIV cannot rely on manufacturers as a safety net for medication affordability. Income limits for manufacturer assistance programs are not fixed and have a history of volatility, meaning that patients who may currently be eligible for assistance could soon be left behind. Patients with employer-sponsored insurance would be most affected, as these plans may not be cost-effective under the proposed guidance yet still maintain burdensome cost-sharing that would be vulnerable to changes in manufacturer assistance programs, threatening continued medication adherence. Some programs, such as Gilead Sciences’, have a cap on monthly co-pay assistance that is of little use to clients facing high deductible costs (e.g., $300/month for Emtriva, Truvada, and Viread; $50/month for Tybost). By not providing fixed income limits or adequate assistance for deductible payments, companies are incapable of filling gaps in ADAP coverage under the proposed qualified payment definition. Under the proposed guidance, patients established on stable, long-term HIV medications with limited or no cost-sharing will face sudden cost-shocks that could lead them to interrupt medication adherence, threatening both their own and the public’s health.

**Impact on Ryan White Program providers**

Ryan White Program providers are able to provide higher quality, more comprehensive care when those clients are insured. However, under the proposed guidance, many ADAP clients may be moved from insurance plans to traditional, full pay ADAP because the insurance plans are not cost-effective without rebate off-sets. This would severely reduce Ryan White Program providers’ ability to “stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services,” as these providers would be faced with a sudden increase in the amount of uncompensated care provided. (80 FR 52300) Further, these providers would face a loss of 340B Program revenue from prescriptions filled by patients after the patient has reached the out-of-pocket maximum and the ADAP is no longer making a cost-sharing payment. Based on an informal survey of 35 Ryan White providers by the American Academy of HIV Medicine, providers estimate that, on average, approximately 40% of their patients have ADAP-funded insurance – some providers estimated that over 80% of their patients have ADAP-funded insurance. If providers lose the reimbursement from these patients, this loss of insurance income will destabilize the entire Ryan White care system, particularly in high-incidence states that will lose all or nearly all of their rebate income.
III. Proposed Audit Standards and Contract Pharmacy Relationship

Contract pharmacy relationships

The RWWG commends HRSA’s attempt to balance competing interests in the proposed contract pharmacy guidance. In particular, we applaud HRSA’s decision not to limit the number of contract pharmacies that may be associated with a covered entity. Because ADAPs must serve an entire state as a single covered entity, it is often necessary for ADAPs to have multiple contract pharmacies spread across an entire state. Therefore, any restrictions on the number of contract pharmacies a covered entity may have or how far those contract pharmacies may be from a covered entity would unduly and uniquely harm ADAPs and the Ryan White Program overall.

Because the Ryan White Program has such unique relationships with contract pharmacies, however, we are concerned that the proposed audit and review guidance is both overly burdensome and unnecessary for Ryan White Program entities. In particular, the RWWG is deeply concerned that quarterly reviews and annual independent audits would be uniquely difficult and costly for Ryan White Program covered entities. Ryan White Program covered entities are already subject to extensive reporting requirements and oversight as federal grantees, and the proposed audit and review standards would be unlikely to flag any additional potential areas of 340B program concern while forcing Ryan White Program covered entities to expend substantial energy and funds auditing a very low-risk program.

We appreciate the opportunity to comment on the proposed guidelines. We hope HRSA will appreciate the depth and breadth of the long experience of the signers in providing quality care for people with HIV. Our comments draw on that experience as well as our deep commitment to the patients we serve. We value their lives and health as our own; indeed, in many cases they are our own or that of those close to us.

We believe that implementation of the guidelines in their current form will likely create dangerous, immediate disruptions of essential patient care along with long term reductions of care quality and access to care. Should you have any questions, please do not hesitate to contact the co-chairs, Ann Lefert (alefert@NASTAD.org) or Bill McColl (wmccoll@aidsunited.org).

Sincerely,

Access Support Network
ADAP Advocacy Association (aaa+)
AIDS Foundation of Chicago
AIDS Healthcare Foundation
AIDS Project Los Angeles
AIDS Resource Alliance
AIDS United
APLA Health & Wellness
Cascade AIDS Project
Community Access National Network (CANN)
Foothill AIDS Project

http://hab.hrsa.gov/stateprofiles/HHS-Indicators.aspx

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