October 27, 2015

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

Dear Captain Pedley:

The National Alliance of State and Territorial AIDS Directors (NASTAD) 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). (340B Drug Pricing Omnibus Guidance, 80 Fed. Reg. 52300) While NASTAD strongly supports several of the proposed changes to the program, we are concerned that the proposed guidance would negatively impact AIDS Drug Assistance Programs (ADAPs) by reducing a critical funding stream and by imposing overly burdensome reporting requirements. Further, the proposed guidance would severely limit the ability of Sexually Transmitted Disease (STD) and Tuberculosis (TB) programs to perform essential public health functions, further eroding the infectious disease public health infrastructure. Below, we provide comments on the following aspects of the proposed guidance:

- **Proposed ADAP rebate processes**: The proposed ADAP rebate processes break traditional congruence with Medicaid rebates, are overly burdensome, threaten to disclose ADAP clients’ HIV status to employers, and are inconsistent with the requirements of the 340B program.
- **Impact of proposed restrictions on ADAP rebates**: The proposed qualified payment definition would reduce the national ADAP budget by up to 35%, threatening the entire Ryan White program.
- **Application of the proposed patient definition**: The proposed patient definition would severely burden state STD and TB programs, threatening public health.
- **Contract pharmacy relationships**: The proposed audit standards are unnecessarily burdensome and are inconsistent with the structure of ADAPs.
- **Limited distribution plans**: Limited distribution plans must specifically accommodate access by state covered entities that have limitations on contracting arrangements.
- **Covered entity status of Ryan White, STD, and TB sub-grantees**: The proposed guidance lacks clarity on registration mechanisms for sub-grantees.

The proposed guidance threatens to destabilize the Ryan White Program by cutting an essential source of funding – ADAP rebates. ADAP rebates ensure that low-income persons with HIV are able to access necessary medications to promote viral suppression, furthering broader goals of HIV prevention. Moreover, ADAP rebates allow ADAPs to
purchase insurance for clients, ensuring that Ryan White providers are reimbursed for medical services; ADAP rebates undergird the entire HIV system by allowing states to “stretch scarce Federal resources” in building background infrastructure for HIV prevention and care.

The 340B Drug Pricing Program is critical to ADAPs’ ability to expand care to clients and to support the underlying public health infrastructure that ultimately prevents new HIV infections. ADAPs and the rest of the Ryan White Program have the expertise, services and models of care to successfully enroll people in care and keep them healthy. Underfunding the Ryan White Program system of care will exacerbate existing structural inequities in HIV care, particularly for communities of color and other disproportionately impacted populations. The proposed guidance is at odds with the National HIV/AIDS Strategy (NHAS). NHAS, 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. ADAPs provide access to medications that are 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 for individuals who are virally suppressed. In order to achieve the goals of NHAS, ADAPs must continue to have access to the 340B Drug Pricing Program in order to maintain access to care for their clients.

Building on the successes of the Ryan White Program coordination services and ADAPs is paramount to ending the HIV epidemic, and continued access to ADAP rebates is necessary to provide these services. 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, among ADAP clients, approximately 68 percent of Black men who have sex with men are virally suppressed. This figure far exceeds national viral suppression estimates, demonstrating the unique success of ADAP and the Ryan White Program in accelerating health outcomes for disproportionately impacted populations. These successes, though, are threatened by the proposed guidance. Below, we outline how HRSA can reverse these existential threats to America’s HIV care system.

I. Proposed ADAP Rebate Processes

Qualified payment definition

NASTAD 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 Fed. Reg. 52300) NASTAD outlines the potential impact of this change below (See Impact of Proposed Restrictions on ADAP Rebates, infra), and focuses here on the operational challenges raised 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.”

NASTAD 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 Fed. Reg. 52314) NASTAD instead calls upon HRSA to reject the proposed qualified payment definition and maintain the parity between ADAP and Medicaid rebates.

**Premium payment**

NASTAD 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, NASTAD 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, NASTAD 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 ADAP’s. NASTAD 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

NASTAD maintains that the proposed qualified payment definition only requires the ADAP to pay the portion of the insurance premium attributable to the client, and, absent a contrary indication from HRSA, NASTAD will advise ADAPs to pursue rebates on such qualified payments.

NASTAD 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.

Payment of rebates

NASTAD is concerned that manufacturers sometimes withhold a portion of the rebate due to ADAPs for disputed claims, forcing the ADAP to either accept the lesser amount or engage in a dispute with the manufacturer; under the proposed guidance, this practice is likely to increase. This is inconsistent with the requirement that manufacturers “may not condition the offer of the 340B ceiling price on a covered entity’s assurance of compliance with the 340B program” and with standard HRSA dispute processes. (80 Fed. Reg. 52321) Even in the case of an ongoing audit, “Manufacturers must continue to sell at the statutory price during the audit process. … Not until the entity is found guilty of prohibited activity and a decision is made to remove the entity from the covered entity list, will the manufacturers no longer be required to extend the discount.” (Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65406, 65408) To preserve parity between the direct purchase and rebate option, manufacturers must timely provide rebates invoiced by ADAPs and subsequently dispute any questioned claims; this appropriately places the burden on manufacturers to initiate disputes rather than thinly-staffed ADAPs who may otherwise accept the reduced rebate payment.

NASTAD fully expects that manufacturers will honor all rebate claims submitted to the manufacturer and that manufacturers will adjudicate any disputes over rebate amounts through the processes recommended by HRSA rather than withhold rebates from ADAPs pending dispute resolution. HRSA should clarify this

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expectation of manufacturers in final guidance, as absent this clarity, manufacturers may perceive that they are allowed to withhold rebates to force ADAPs to initiate disputes – something which thinly staffed ADAPs may not be able to do for many manufacturers on a routine basis. Instead, **HRSA should clarify that manufacturers are bound by the same “must offer” provisions when ADAPs use a rebate methodology**, wherein the manufacturer must pay the rebate upon receipt of the invoice from the ADAP and dispute any concerns with the rebate as though it were disputing an initial purchase. This would continue to offer parity between the direct purchase and rebate options available to ADAPs and ensure that manufacturers are not able to negatively impact critical HIV care functions through the withholding of disputed rebates.

**Claims-level data**

NASTAD is deeply concerned that the proposed ADAP rebate processes will be excessively burdensome for ADAPs. The proposed claims-level data requirement for rebate invoices will require substantial effort from ADAPs to prepare, and ADAPs who use Pharmacy Benefit Managers (PBMs) may face additional costs to acquire the data necessary for the proposed claims-level invoicing. NASTAD is particularly concerned that the proposed requirement to submit “the ADAP payment for the medication …, an assurance that the claim is not for a drug subject to a Medicaid rebate, and, when applicable, an assurance that the ADAP paid the patient’s health insurance premium” is unnecessarily burdensome. (80 Fed. Reg. 52313) NASTAD is perplexed as to why the amount the ADAP paid for the medication is relevant, as “the rebate would be paid regardless of how the ADAP expenditure compares to the 340B ceiling price for the drug.” (80 Fed. Reg. 52313) Further, NASTAD believes that the proposed assurance requirements (that the claim is not subject to a Medicaid rebate and that the ADAP paid the portion of the health insurance premium attributable to the patient) violate HRSA’s requirement that “[m]anufacturers may not condition the offer of the 340B ceiling price on a covered entity’s assurance of compliance with 340B Program requirements.” (80 Fed. Reg. 52321)

Instead, NASTAD believes that the appropriate information in a rebate invoice should include the ADAP name and state, invoice period, the medication name/label name, medication national drug code, number of medication units purchased by the ADAP during the invoice period, and the amount to be rebated to the ADAP. This data should be sufficient for the manufacturer to appropriately process the rebate invoices. NASTAD believes that the proposed claims level data requirement is more burdensome than existing requirements for the Medicaid program, and **NASTAD requests that HRSA remove the proposed requirement to ensure parity between the programs**.

**Implementation dates**

NASTAD 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.

NASTAD is deeply concerned that the proposed claims-level data requirements for rebate invoices will be thrust upon states with little or no time to prepare. The current proposed delay only applies to “section b of Part (G);” the claims-level data requirement, however, is in section a of Part (G) and would not be delayed. (80 Fed. Reg. 52313; 80 Fed. Reg. 52322) States will need substantial time to develop the systems necessary to provide claims-level data, aside from the considerable expense required, and HRSA must delay implementation of this requirement to ensure that states are able to comply.

Rebate calculation

NASTAD supports HRSA’s recognition that a percentage rebate would be “so operationally burdensome as to be inoperable.” (80 Fed. Reg. 52314) However, NASTAD 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, NASTAD 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; NASTAD 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.
NASTAD 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.

Multiple 340B discounts and rebates

NASTAD is deeply concerned that the proposed guidance on “Multiple 340B Discounts and Rebates” uniquely burdens ADAPs and will undermine ADAPs’ ability to provide comprehensive insurance for ADAP clients. (80 Fed. Reg. 52313) NASTAD understands and supports the motivating concerns behind the proposed guidance – that an insured ADAP client may receive a drug purchased at the 340B price (by another covered entity) and that the ADAP will receive a rebate on the drug for making a qualified payment. NASTAD agrees that this situation is a duplicate discount under the 340B program; however, the proposed solution is inadequate, and non-ADAP covered entities should be required to carve-out ADAP clients, similar to Medicaid.

The proposed multiple discount guidance must be changed, as it prevents ADAPs from ensuring that the insurance plans purchased for clients meet HRSA’s requirement that ADAPs purchase cost-effective plans. Insured ADAP clients may often use another 340B covered entity as their primary healthcare provider, and that covered entity may understandably wish to fill that client’s prescription with 340B stock, even when the ADAP makes the premium and cost-sharing payments for the client. Under the proposed guidance, the other, non-ADAP, covered entity could choose to fill the patient’s prescription with 340B stock, knowing full well that the patient is also an ADAP client and the ADAP would not be able to pursue a rebate for that prescription. Without these rebates, however, the insurance plan may not be cost-effective, and ADAPs would be forced to place clients on a full-pay, traditional ADAP program. Instead, HRSA should adopt final guidance that requires the ADAP to receive the benefit of the 340B discount when the ADAP makes a qualified payment – a situation that benefits all parties, as shown below.

For example, consider an insurance plan with a $250 monthly premium and a shared $5,000 deductible/out-of-pocket maximum, and a client whose HIV medication costs $1,000 at WAC and $500 at the 340B price. In this example, the ADAP would expect to annually pay $3,000 in premium costs and $5,000 in up-front cost-sharing, receiving a rebate of $2,500, for a total cost of $5,500. On a traditional, full-pay ADAP program, the expected cost would be 12 fills at the 340B price, or $6,000, meaning that this plan is cost-effective. However, if another covered entity fills the insured client’s prescriptions with 340B stock, preventing the ADAP from pursuing a rebate, the insurance plan would cost $8,000 and would not be cost-effective. Knowing in advance that this ADAP client uses another covered entity for primary care, the ADAP would be forced to place that client on the traditional ADAP program – depriving the other covered entity of insurance reimbursement for physician services and the opportunity to take advantage of the insurance payment for 340B stock after the ADAP had exhausted the out-of-pocket maximum and was no longer eligible for a rebate. Manufacturers would also benefit if the ADAP had purchased the insurance policy, as once the out-of-pocket maximum was reached, any prescription fills outside of the 340B program would result in higher earnings for the manufacturer.

Under the proposed guidance, however, higher costs would accrue to ADAPs and other covered entities, the patient would have less stable access to health care, and manufacturers would see lower earnings. When
ADAPs are able to purchase cost-effective insurance, all parties benefit, but ADAPs must be able to earn rebates on all qualified payments to make insurance purchases cost-effective. HRSA should issue clear final guidance that when an ADAP makes a qualified payment for a drug, the pharmacy must fill that prescription with non-340B stock to avoid a duplicate discount, absent a signed written agreement between the ADAP and the other covered entity outlining a different policy. This process would not be overly burdensome to covered entities, as it mirrors existing Medicaid “carve out/carve in” policies to which 340B covered entities are already accustomed.

II. Impact of Proposed Restrictions on ADAP Rebates

NASTAD 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 Fed. Reg. 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 Fed. Reg. 52313)

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. 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 of the ADAP budget; the proposed guidance would cause a 40 to 55 percent drop in ADAP rebate revenue – an 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. Under this extreme scenario, 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, Medicare Part D subsidy, 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 or negotiated sub-ceiling 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 or administrative restrictions 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 Fed. Reg. 52313) The proposed guidance, then, threatens to eviscerate crucial funding from ADAPs that rely on 340B income to “reach[] more eligible patients and provid[e] more comprehensive services.” (80 Fed. Reg. 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 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.,

![NASTAD Logo](image)
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.”


ADAPs are 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 ADAPs’ 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 ADAPs, 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 providers**

Many ADAP clients rely on Ryan White providers for their medical care, and these providers are able to provide higher quality, more comprehensive care when ADAP 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 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 Fed. Reg. 52300) Further, these providers would face a loss of 340B 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. Application of the Proposed Patient Definition

NASTAD appreciates HRSA’s explicit recognition of the unique methods by which ADAPs participate in the 340B program and the categorical inclusion of ADAP clients under the patient definition. (80 Fed. Reg. 52307) Participation in the 340B program is necessary for ADAPs to meet the needs of low-income persons living with HIV/AIDS, as ADAPs would be forced to severely limit client enrollment if required to pay full price for clients’ necessary medications.

We are concerned, however, that the proposed patient definition would eviscerate other core public health functions performed by state health departments. Frequently, state Sexually Transmitted Disease (STD) and Tuberculosis (TB) programs provide necessary public health medications purchased under the 340B program to patients who have not received a prescription from a provider associated with the STD/TB program. Under these arrangements, the STD/TB program administers necessary STD/TB treatment after being contacted by a private provider who diagnosed the patient and prescribed treatment, but the provider did not stock the necessary treatment. Following best public health practice, the STD/TB program immediately provides the necessary treatment before the patient leaves the private provider’s care, limiting the further spread of infectious disease; the STD/TB program continues to provide the necessary medications for the patient under the private provider’s care, as often any barriers to prescription access can reduce medication adherence, threatening the public health. In these instances, the STD/TB program maintains a health care record for the patient after providing services within the scope of the STD/TB program’s grant, meeting the requirements of the current patient definition. Under the proposed patient definition, however, STD/TB patients diagnosed in private practice would need to undergo a second diagnosis by a provider of the STD/TB program and receive a second prescription in a location registered to the STD/TB program on the 340B covered entity database – an administrative barrier that would reduce treatment access and compliance, furthering the spread of infectious disease. Similarly, STD/TB programs often engage in mobile testing and treatment that would not occur in a “facility or clinic site which is registered for the 340B program and listed on the public 340B database.” (80 Fed. Reg. 52306) It would be unnecessarily burdensome and contrary to the public’s health to force individuals who test positive for STDs to travel to a separate clinic to receive treatment rather than have it immediately administered at the testing location.

When STD/TB programs provide necessary treatment to patients diagnosed by a private provider, they act differently than most 340B covered entities, paying for the entire cost of the medication purchased at the 340B price rather than receiving the “spread” between the 340B cost and the payer reimbursement. In these instances, STD/TB programs operate more like ADAPs than other covered entities, as they fulfill core public health functions that facilitate treatment compliance, reducing disease incidence. Without the ability to purchase drugs at the 340B price, STD/TB programs would be unable to provide these drugs at no cost to patients, threatening the public health.

For these reasons, **HRSA should categorically recognize clients of STD/TB programs as 340B eligible patients, similar to the categorical recognition in place for ADAPs.** Absent this extension, STD/TB programs may not be able to purchase necessary public health medications at discounted prices, as manufacturers will be concerned that these sales may not be excludable from Average Manufacturer Price, Average Sales Price, and Non-Federal Average Manufacturer Price calculations.

This recommendation will allow STD/TB programs to continue existing purchasing patterns, and there should be no additional negative impact to manufacturers because STD/TB programs only purchase limited amounts
and types of medications due to federal and state requirements. Therefore, this extension should not be a financial burden to manufacturers and will advance the 340B program’s stated goal of stretching scarce federal resources as far as possible. Without this extension, however, STD/TB programs will be severely crippled in their ability to afford necessary public health medications for patients whose medical care is not directly overseen by the STD/TB program, to the detriment of the public’s health.

IV. Contract Pharmacy Relationships

NASTAD 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 the 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.

Because ADAPs have such unique relationships with contract pharmacies, however, we are concerned that the proposed audit and review guidance is both overly burdensome and unnecessary for ADAPs. In particular, NASTAD is deeply concerned that quarterly reviews and annual independent audits would be uniquely difficult and costly for ADAPs. ADAPs have a limited and defined group of patients eligible to receive medications purchased at 340B prices; therefore, ADAP contract pharmacy arrangements are not subject to the same level of diversion or duplicate discount risks attendant to other covered entities. ADAPs have strict eligibility requirements for clients that clearly determine whether a client is Medicaid-eligible, nearly eliminating the risk of diversion to ineligible patients. Therefore, NASTAD believes that the proposed contract pharmacy audit and review requirements are excessive relative to the risks presented by ADAP contract pharmacy arrangements.

Moreover, it is unclear how an ADAP would perform the proposed quarterly review, as ADAPs do not have “prescribing records” to compare with pharmacies’ dispensing records. (80 Fed. Reg. 52311) Indeed, this proposed requirement demonstrates how inapt generalized audit and review standards are for ADAPs. ADAPs 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, yet they would force ADAPs to expend substantial energy and funds auditing a very low-risk program.

NASTAD therefore requests that HRSA amend the proposed audit and review standards to allow flexibility for ADAPs to perform audits and reviews consistent with the risk of potential diversion and duplicate discounts. We believe that this flexibility is appropriate for ADAPs, as we are not aware of any pattern of manufacturer or other concern regarding ADAP contract pharmacy arrangements. Indeed, the newly proposed requirements for ADAP rebates address the areas of manufacturer concern for ADAP participation in the 340B program; additional contract pharmacy audits and reviews for ADAPs would be superfluous.

V. Limited Distribution Plans

NASTAD commends HRSA for recognizing that manufacturer limited distribution plans need additional scrutiny and protections to ensure that covered entities can continue to access necessary medications at
discounted prices. (80 Fed. Reg. 52312) However, recent experience has demonstrated that limited distribution plans must make special arrangement for ADAPs and STD/TB programs that may not have the contracting flexibility to participate in a manufacturer’s limited distribution plan.

Turing Pharmaceuticals’ recent 5,000 percent price hike of Daraprim (pyrimethamine) was preceded by a limited distribution plan that discriminated against 340B covered entities by requiring covered entities to purchase through a separate distribution channel than entities purchasing at the list price. Because of the extreme price hike and repressive limited distribution arrangement, some ADAPs were unable to purchase Daraprim, leading to its removal from ADAP formularies and ADAP clients being unable to access this necessary medicine. ADAPs were not able to access the 340B price because ADAPs are subject to state purchasing mechanisms that may require extensive approval processes before purchases can be made through a specific vendor. Any limited distribution arrangement, then, could cause ADAP clients to lose access to necessary medications if the distribution arrangement limits purchases to a single wholesaler/distributor with which the ADAP does not have an existing contractual arrangement.

Because of the additional burdens ADAPs and STD/TB programs have in contracting, all limited distribution plans must include specific provisions on how the manufacturer will make the drug available to these state programs that may not be able to quickly establish alternate contracting arrangements. **HRSA should revise the proposed limited distribution plan guidance to require that manufacturers specifically contemplate how state programs will be able to access medication under a limited distribution arrangement, including the provision of free drugs if the ADAP or STD/TB program is unable to develop a purchasing mechanism with the limited distributor(s).**

VI. Covered Entity Status of Ryan White, STD, and TB Sub-Grantees

NASTAD is concerned that the proposed guidance could subject certain state covered entities to liability for the behavior of other, secondary covered entities over which the state covered entity has no control. In the preamble, the proposed guidance discusses the eligibility of “associated sites,” providing the example of off-site locations of STD clinics that would be considered “child sites” of the primary Federal grantee; that discussion continues by noting that sub-recipients of Federal grants seeking their own 340B identification numbers would be approved after providing proof of their Federal grant number. (80 Fed. Reg. 52301) However, in the text of the proposed guidance, the “associated site” definition permits registration as a child site for covered entities authorized to provide “health care services through the scope of a Federal grant…” (80 Fed. Reg. 52316) NASTAD is concerned that sub-recipients eligible for the 340B program could either register as or otherwise be considered “associated sites” of a state Ryan White, STD, or TB program without the approval or oversight of the state covered entity grantee. State Ryan White, STD, and TB programs cannot effectively oversee the day-to-day behavior of sub-recipients, and these covered entities should have independent, not associated site or child site, 340B registrations. **NASTAD encourages HRSA to clarify the registration procedures for sub-recipients to ensure that state covered entities are not responsible for the compliance of sub-recipients absent a formal child site relationship approved by the state covered entity.**
NASTAD sincerely appreciates the opportunity to provide comments on the proposed 340B guidance. Should you have any questions, please do not hesitate to contact me.

Sincerely,

Murray C. Penner
Executive Director
See HIV/AIDS Bureau Policy Clarification Notice 14-01, Revised April 3, 2015 (“[ADAP] clients . . . may be eligible for a premium tax credit to offset the cost of purchasing a qualified health plan through the Marketplace. Per PCN 13-05, grantees and subgrantees may use RWHAP funds to pay for any remaining premium amount owed to the health insurance company that is not already covered by the RWHAP client’s premium tax credits.”) (emphasis added) See also HIV/AIDS Bureau Policy 13-05, Revised June 6, 2014 (“As Affordable Care Act implementation continues, [ADAP] clients will become eligible for and enroll in qualified health plans offered in the Marketplace. … RWHAP grantees and sub-grantees should consider helping individual clients pay for premiums and/or cost-sharing, if cost-effective.”)


