Best Practices for Shared ADAP and Other 340B Covered Entity Clients

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Maximizing prescription drug discounts, rebates, and program income allowed under the 340B Drug Pricing Program (340B) and voluntary agreements with manufacturers is essential to the fiscal health of AIDS Drug Assistance Programs (ADAPs), including the cost-effectiveness of ADAP-funded insurance programs. It is also important to the sustainability of Ryan White HIV/AIDS Program (RWHAP) Part B and ADAP service delivery, which is central to statewide efforts to strengthen health equity and support jurisdictional initiatives to end the HIV epidemic.

ADAP rebate and program income practices must adhere to the rules and regulations of 340B and/or federal grant requirements, including: 1) statutory prohibitions on duplicate discounts on prescription drug dispensing for Medicaid beneficiaries also being served by the ADAP, 2) manufacturer prohibitions on duplicate discounts on prescription drug dispensing for ADAP clients receiving care from other 340B covered entities (CEs), and 3) Health Resources & Services Administration (HRSA) HIV/AIDS Bureau's Policy Clarification Notices 15-03 and 15-04 pertaining to RWHAP grantees and subgrantees.

This technical assistance resource focuses primarily on the prevention of duplicate discounts involving prescription drug dispenses for ADAP clients receiving care from other 340B CEs.

NASTAD encourages ADAPs to establish expectations, policies and processes in coordination with other 340B CEs providing care to ADAP clients to ensure that critical program income and/or rebate revenue vital to HIV service delivery in the United States is maximized without the risk of duplication.

BACKGROUND

The 340B Drug Pricing Program was enacted by Section 602 of the Veterans Health Care Act of 1992 and requires drug manufacturers to sell outpatient drugs to eligible health care organizations for eligible patients at discounted prices. It requires manufacturers to apply a statutorily required discounting formula that yields a quarterly ceiling price for covered drugs for 340B CEs. The vast majority of 340B CEs access this ceiling price using a direct purchase system. The program was amended in 1998 to provide ADAPs with access to a statutory rebate when it uses a non-340B pharmacy network.

The benefit of 340B to safety net programs is twofold. First, it results in significant cost savings for programs providing access to prescription drugs to clients who are uninsured or underinsured. Second, it can generate revenue when 340B CEs are able to purchase prescription drugs at a discounted rate but are reimbursed by third-party payers (e.g., commercial insurers) at a higher usual-and-customary rate. This revenue can then be used

to support an array of medical and support services for the 340B CE's clients.

ADAPs are categorically eligible for the 340B Drug Pricing Program. This means that all clients eligible for and enrolled in an individual ADAP meet the 340B patient definition.

ADAPs utilizing a direct purchase mechanism (which are designated in HRSA's 340B OPAIS as "RWIID"), regardless of whether they are purchasing and dispensing drugs through a central pharmacy or through contract pharmacy replenishment, are eligible for statutorily defined 340B pricing plus any voluntary supplemental discounts secured by the Apexus Prime Vendor Program (PVP), negotiated by the ADAP Crisis Task Force (ACTF), or otherwise secured by the ADAP (e.g., wholesaler prompt pay and/or volume discounts). ADAPs utilizing a direct purchase mechanism (or pharmacies on the programs' behalf) can bill the client's insurance company for the medication it purchased at its discounted price, therefore generating program income (the difference between the third-party reimbursement and the 340B price of a medication).

ADAPs utilizing a rebate mechanism (which are designated in HRSA's 340B OPAIS as "RWIIR") are eligible for statutorily defined 340B plus voluntary supplemental rebate payments from manufacturers for formulary medications that are dispensed to their clients.

Additionally, ADAPs are eligible for rebates on partial-pay claims, whereby the ADAP pays either the medication deductible, co-payment, or co-insurance – either with or without ADAP payments toward the client's health insurance premium – in accordance with HRSA HIV/AIDS Bureau program guidance issued in 2005 and voluntary agreement terms executed with manufacturers. This may generate additive revenue for the ADAP, specifically when rebate payments received from manufacturers exceed the program expenditures associated with insurance premium and cost-sharing payments associated with prescription drug coverage.

An individual may receive services from, and thus be considered a patient of, both an ADAP and another CE [1] – an ADAP-funded insurance program client receiving HIV care and support services from a RWHAP Part C clinic, for example – and thus both CEs would be eligible for the 340B discount. However, only one CE is permitted to receive the statutorily defined 340B price, by rebate or discount, for a patient's prescription. The ADAP may receive the 340B price through an up-front discount (direct purchase) or through a manufacturer rebate. Even when the other CE receives the up-front 340B discount, the ADAP is still eligible for any voluntary supplemental rebates negotiated by the ACTF (i.e., the difference between the 340B ceiling price and the ACTF-negotiated sub-340B price), assuming the requirements of the 2005 HRSA HAB program guidance and the voluntary manufacturer agreements are met.

[1] Other entities eligible for the 340B Drug Pricing Program include RWHAP Part A and B subrecipients; Ryan White Part C Early Intervention Services grantees; Federally Qualified Health Centers (FQHCs); FQHC look-alikes; Title X family planning clinics; sexually transmitted disease clinics and other Section 318 grantees and sub-grantees, including HIV prevention and viral hepatitis programs; and a variety of safety-net hospitals. The HRSA Office of Pharmacy Affairs' (OPA) website has a searchable database of all enrolled 340B entities and their contract pharmacies.

NASTAD strongly recommends that ADAPs develop clear expectations, policies, and processes for coordinating 340B discounts, program income, and rebates on prescription drug fills for individuals who are 340B eligible patients of multiple 340B CEs, including the state or territorial ADAP.

Principles of Best Practices for Shared ADAP and Other 340B CE Client Policy and Process Development

Maximizing ADAP 340B rebate or program income revenue is necessary for statewide program operations. As policies, processes, and collaborative opportunities are developed it is equally important to understand the purpose of ADAP and RWHAP Part B overall: to ensure low-income people living with HIV/AIDS (PLWHA) have access to life-saving medications and comprehensive health care services. Revenue generated via rebates and program income effectively allows ADAPs and RWHAP Part B programs to:

- Expand and maintain financial eligibility criteria to maximize program enrollment
- Maximize the number of HIV and other medications available to low-income PLWHA
- Prevent the need to establish ADAP waitlists and other cost-containment measures to balance budgets
- Maximize the cost effectiveness of ADAP services, including insurance purchasing
- Minimize potential disruptions in access to HIV treatment, including streamlining program recertification requirements and minimizing the need for clients to use multiple pharmacies
- Maximize RWHAP Part B core medical and support services available in the jurisdiction to low-income PLWHA
- Ensure parity of, and equitable access to, core medical and support services across the state or territory, including in rural areas
- Provide supplemental fiscal support to other 340B CEs requiring program savings to implement or expand programs for PLWHA
- Fund community-based organizations without 340B CE status serving PLWHA, notably outreach, case management, and housing
- Implement and revitalize clinical quality management (CQM) programs in alignment with federal Ending the HIV Epidemic and National HIV/AIDS Strategy goals
- Optimize client health outcomes for low-income persons with HIV

APPROACHES TO IMPLEMENTING SHARED 340B CLIENT POLICIES AND PROCESSES

Even with the federal RWHAP requirements and 340B regulations, there is flexibility for ADAPs as they ensure best practices and procedures that address the unique needs of their jurisdiction. Each state or territory has its own unique health care landscape and health department governance classifications that might necessitate different policy approaches. ADAPs have different levels of administrative capacity, different populations served, and different statutory and regulatory environments that govern ADAP operations. NASTAD encourages states, territories, and associated jurisdictions to develop a solution that works best for their unique circumstances and to do so in consultation with community stakeholders, including the other 340B CEs providing care to PLWHA within their jurisdictions.

340B Covered Entities and Duplicate Discount Exposure Review

It is an expectation when participating in 340B that CEs prevent duplicate discounts on drugs. This includes statutory prohibitions of 340B discounts being applied to drugs that will be subject to Medicaid rebates, as well as manufacturer policies prohibiting more than one statutorily required 340B discount/rebate being applied to the same drug. As such, it is the responsibility of all CEs to develop, implement, and maintain policies that identify areas of potential duplicate discounting, prevent duplicate discounting, and address any instances in which a duplicate discounting occurs.

ADAPs should assess areas of client overlap and potential exposure that may result in duplicate discounting with another 340B CE. A recommended best practice includes using the HRSA OPA searchable database of covered entities to identify CEs (and their contract pharmacies) known to be providing care to ADAP clients, including RWHAP grant recipients and subrecipients. ADAPs should also work collaboratively with their pharmacy benefit managers (PBMs), 340B pharmacies, and/or their other CE community partners to ensure contractual processes are in place to prevent duplicate discounts.

Models for Establishing 340B Discount, Program Income, and Rebate Policies Across ADAP and Other 340B CEs

ADAPs should develop clear policies and processes that clarify whether, and under what circumstances, the ADAP or the other CE that shares the client is entitled to the 340B discount, program income, or rebate to ensure transparency and compliance with 340B requirements and voluntary agreements with manufacturers. Below are several possible models and processes that may be developed and implemented by ADAPs in consultations with other 340B CE:

- **ADAP Claiming all Discounts or Rebates When Paying 100% of Drug Costs for Full-Pay Program Clients.** For clients for whom ADAP is paying 100% of the client's drug costs (i.e., full-pay clients who have no public or private insurance, or insured clients requiring medications not covered by their public or private insurer), the ADAP should be the entity that receives the 340B rebate/discount.

  In this model the ADAP is claiming all 340B discounting or rebating on medications dispensed or administered to full-pay ADAP clients by other 340B covered entities. The other 340B covered entities should either forego taking the 340B discount or accept reimbursement based on the dispensed (or administered) drug's acquisition costs, in accordance with the ADAP's policy.

- **Other 340B Claiming all Discounts When paying 100% of Drug Costs.** For clients for whom the other 340B CE is paying 100% of the client's drug costs (i.e., uninsured clients requiring medication that is not covered by the ADAP), the other 340B covered entity receives the 340B discount.

  In this model the ADAP should forego claiming or receiving the 340B rebate/discount, as the rebate/discount must not be duplicated by the two entities. The ADAP should also forego claiming or receiving voluntary supplemental rebates/discounts where no expenditures for a client's drugs accrued to the ADAP.

- **ADAP Claiming Rebates Where it is Paying Premium Payments and/or Cost Sharing for Insured Clients.** For clients where the ADAP is using federal funds to cover premium costs associated with insurance plans required for prescription drug coverage and/or deductible, co-payment, or co-insurance expenditures, the ADAP is the entity that receives the 340B rebate/discount. As a reminder, ADAPs may only claim manufacturer rebates on prescription drug fills for which they have made insurance cost-sharing payments and in accordance with manufacturer allowances.

  In this model, the ADAP claims all 340B discount/rebating on 340B-eligible medications prescribed or dispensed by the other 340B CE because it is the primary payer of the insurance policy providing both prescription drug coverage and reimbursement of medical and lab services provided by the other 340B CE, and/or is the payer of cost-sharing requirements associated with the client's prescription drug coverage.

- **ADAPs Claiming Only Supplemental Rebate.** Where the ADAP cannot claim a rebate or program income down to the statutorily defined 340B price but has made cost-sharing deductible, co-payment, and co-insurance payments associated with prescription fills, the ADAP may claim voluntary supplemental rebates in accordance with manufacturer allowances.

  In this model, the ADAP claims the difference between the ACTF sub-ceiling price and the statutory 340B price where it has allowed the other 340B CE to claim the discount down to the statutory 340B price. The number of drugs subject to supplemental rebates in accordance with manufacturer agreements secured by the ACTF is limited.

- **Sharing Insured Clients Meeting Out-of-Pocket Maximum.** If an ADAP-funded insurance client's maximum out-of-pocket (MOOP) for the plan year has been reached and no additional partial-pay claims can be submitted to manufacturers, the other 340B CE is permitted to claim the 340B discount.

  In this model, the ADAPs claims rebates or program income until the client's MOOP has been reached – at which point the ADAP is no longer able to make cost-sharing payments required for partial-pay rebate claims – after which the other 340B CE may claim the discount for the remainder of the year. Close coordination between the ADAP and other 340B CE is required and may be most applicable to shared clients receiving services from a pharmacy contracted with both the ADAP and other 340B CE (as to prevent clients needed to switch or use multiple pharmacies).

- **Other 340B CEs Claim Discounts, Program Income, or Rebates Where Not Claimed by ADAPs.** If an ADAP-funded insurance client requires outpatient prescription drugs for which the ADAP either cannot or does not claim rebates or program income, these dispenses may be subjected to discounted purchasing by the other 340B CE.

  In this model, the ADAP claims rebates or program income on certain drugs, such as antiretrovirals, with other medications subject to 340B discounts accruing to the other 340B CE. This model requires coordination between the ADAP and other 340B CE and may be most applicable to shared clients receiving services from a pharmacy contracted with both CEs.

- **Sharing Discounts/Rebates between ADAPs and other 340B CEs.** ADAPs and other 340B CEs may create an agreement that discounts/rebates earned from dispenses will be shared between both entities. Contractual agreements would need to be created detailing how the discounts/rebates will be shared between the two organizations.

  In this model, the ADAP and other 340B CE would each get a portion (e.g., percentage) of the program income or rebate generated on a prescription fill for a shared client. In the case of RWHAP Part B subrecipients, sharing may be in the form of a subaward increase based on a percentage of 340B discounts not taken by the CE on fills for ADAP-funded insurance program clients.

- **Other 340B CEs Receive Discounts and Program Income for ADAP-Funded Insurance Program Clients.** With this approach, the other 340B CE is the entity that claims the discounts on prescription drug fills for ADAP-funded insurance program clients receiving medical and support services.

  This model may be well suited to states or territories with difficulties redistributing discounts/rebates to organizations providing HIV services or are returning significant funds to HRSA on an ongoing basis. This model may also be limited to select 340B CEs providing care to ADAP-funded insurance program clients, including trusted community partners leveraging 340B program savings to ensure equitable access to HIV care and support services.

Each of these models has benefits and disadvantages and ADAPs must determine which best respond to the needs of PLWHA in their jurisdiction and are required for the ADAP and RWHAP Part B to ensure fiscal sustainability.

IMPLEMENTING 340B DRUG PRICING PROGRAM DISCOUNT/REBATE POLICY

Coordination With Key ADAP and Community Partners

NASTAD strongly encourages ADAPs to coordinate with RWHAP Part A, C, and D programs in developing 340B discount, program income, and rebate policies and processes. RWHAP Part B programs are also encouraged to work with their ADAPs to develop 340B right-of-way policies with Part B subrecipient agencies providing care to ADAP clients.

NASTAD also encourages coordination with Section 318 grantees (e.g., STD, HIV prevention, or viral hepatitis programs) in the state or territorial health department. These programs enable subgrantees receiving federal funds or in-kind contributions to qualify for 340B CE status and are the most likely after RWHAP recipients and subrecipients to potentially overlap with clients served by the ADAP.

ADAPs may be well-suited to introduce or facilitate the establishment of common policies across programs generally housed within the state, territory, or associated jurisdiction health department. This collaboration helps ensure that knowledge, experience, and priorities are shared between the programs. Establishing common policies can also help limit the chance of duplicate 340B discounts when other 340B CEs are providing services to PLWHA that might also be served by ADAP.

ADAPs should also be prepared to educate other 340B CEs, community organizations,

planning bodies, and PLWHA served by the RWHAP and ADAP on the importance of 340B discounts, program income, and rebates on partial-pay claims to the fiscal health of the ADAP, the cost-effectiveness of ADAP-funded insurance programs, and the importance of ADAP-generated 340B revenue allocated to the state or territory RWHAP Part B program. Similarly, other 340B CEs should be encouraged to discuss the importance of 340B revenue to their programs with ADAPs and relevant state health department staff, creating a collaborative dialogue on service provision and client needs within the entire jurisdiction.

Where policy changes will impact clients served by either ADAP, RWHAP Part B, or the other 340B CE, these should be clearly communicated to clients to minimize the disruption in services particularly in cases where a policy change can be expected to require clients to change pharmacies.

USE OF THIS DOCUMENT

ADAPs may wish to developed individualized policies and processes based on the language contained within this technical assistance document in consultation with state health department leadership, legal counsel, and other stakeholders.

Please contact Tim Horn with questions.