NASTAD

SYSTEMS, PARTNERSHIPS, AND FINANCING STRATEGIES TO

Build and Expand Rapid Start

OCTOBER 2023

I. Introduction

"RAPID START" IS THE RAPID INITIATION OF ANTIRETROVIRAL THERAPY (ART) FOR INDIVIDUALS NEWLY DIAGNOSED WITH HIV OR BEING RE-LINKED TO CARE AFTER A BREAK IN REGULAR ACCESS TO TREATMENT. To facilitate rapid access, HIV systems of testing, linkage, application and enrollment in relevant programs, and treatment initiation all must be tailored to be low barrier. Recognizing the importance of rapid access to treatment, the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) has encouraged Ryan White HIV/AIDS Program (RWHAP) recipients to "develop protocols to facilitate the rapid delivery of RWHAP services, including the provision of antiretrovirals for those newly diagnosed or re-engaged in care." However, RWHAP recipients must balance efforts to quickly engage individuals in care and treatment with federal requirements that RWHAP funds are only used for allowable costs for eligible individuals.

Through funding and additional flexibilities for certain RWHAP Part A and B recipients, the *Ending the HIV Epidemic in the U.S.* (EHE) initiative offers new ways to support streamlined ART access. EHE funds only require an HIV diagnosis for eligibility, allowing programs to simplify and truncate what can be burdensome applications and eligibility verification processes for services. EHE funds also allow recipients flexibility to fund services beyond the traditional RWHAP service categories, allowing for creative responses that tailor service delivery to the needs of clients entering care.

This resource focuses on the financing strategies RWHAP EHE recipients should consider as they develop Rapid Start programs and the systems level partnerships required to make a program successful.

The components of a Rapid Start protocol include the following:

STEP 1	HIV testing
STEP 2	Linkage from testing program to care and treatment
STEP 3	Education/counseling on ART
STEP 4	Accelerated access to medical visit
STEP 5	Early access to ART
STEP 6	Assessment for and linkage to programs and assistance, including public and private insurance, RWHAP services, including AIDS Drug Assistance Program (ADAP), and other supportive services

How rapidly each step can be performed is largely dependent on successful navigation of the various funding streams detailed in Figure 1. The relevant RHWAP allowable services for rapid start programs described in Figure 1 are examples and there may be other relevant service categories described in relevant HRSA/HAB policy clarification notices.[1]

[1]HRSA/HAB, PCN 16-02 Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds, available at https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/service-category-pcn-16-02-final.pdf

Figure 1

FUNDING SOURCE	ALLOWABLE SERVICES	ELIGIBILITY
RWHAP Parts A, B, C, D (non-EHE; non-ADAP)	RWHAP service categories: Early intervention services (EIS), medical and non-medical case management, outpatient/ ambulatory health services (OAHS), adherence counseling, health insurance premium and cost-sharing assistance (HIP-CS)	HIV diagnosis, low-income, residency
RWHAP ADAP (non-EHE)	Full-pay medication for uninsured clients; insurance assistance for insured clients; "ADAP flex" can be used for medication adherence and monitoring services	HIV diagnosis, low-income, residency
RWHAP Part A (EHE)	Initiative Services and RWHAP service categories above	HIV diagnosis
RWHAP Part B/ADAP (EHE)	Initiative Services and RWHAP service categories above	HIV diagnosis
CDC HIV prevention (EHE and non-EHE)	HIV testing and counseling and linkage to care	No eligibility screening beyond service need
340B rebates (ADAP)	Partial pay rebates (i.e., income generated by the ADAP from collecting a full rebate from payment of the copay or coinsurance for a medication) generated by federal RWHAP funds must be invested back into the same program with identical service categories/restrictions.[2]	If ADAP rebates are generated by federal RWHAP funds, RWHAP eligibility requirements apply
340B program income	Allowable services depend on if the program income is generated from federal funds (program income must be invested back into the same program with identical service categories/restrictions). Non-RWHAP 340B entities may have more flexibility to use program income more broadly across programs.[3]	While program income generated from RWHAP funding must be invested back into the program, following the same eligibility rules, program income generated from other funding streams may have more flexibility, including to expand eligibility criteria beyond RWHAP.
State/local funding	Allowable services depend on funder	Eligibility requirements depends on funder
Manufacturer assistance programs	ART approved for Rapid Start	Income criteria
ART samples	Limited number of ART medications	No eligibility for patients, but some providers may prohibit acquiring and/or dispensing samples

[2] When the RWHAP grant is the federal award that makes an organization eligible as a 340B covered entity, and purchases medications via 340B pricing, all the program income should be attributed to the RWHAP grant. When HRSA 330 or CDC 318 grants are the federal award that makes an organization eligible as a 340B covered entity, the program income should be used for the purposes of the federal award.

[3] When the RWHAP grant is the federal award that makes an organization eligible as a 340B covered entity, and purchases medications via 340B pricing, program income must be used for the purposes for which the award was made, and may only be used for allowable costs under the award. When HRSA 330 or CDC 318 grants are the federal award that makes an organization eligible as a 340B covered entity, the program income should be used for the purposes of the federal award.

II. Systems coordination for Rapid Start scale up

The following section will walk through the different system level considerations for RWHAP EHE recipients as they contemplate starting or scaling up a Rapid Start program. Each consideration should be tailored to the specific needs of a jurisdiction, including whether the program is state-wide or regionally focused, whether the program services a primarily urban or rural population, and the availability and accessibility of other programs and services to transition clients from Rapid Start to regular and sustained care and treatment.

Financing Rapid Start

Identifying the financing mechanism for a Rapid Start program is a critical first step to designing a program that will be effective and sustainable. It may be useful to break up the Rapid Start program into component service parts to identify different funding considerations for each service:

MEDICATION ACCESS

A cornerstone to Rapid Start is rapid access to a recommended Rapid Start ART regimen. However, streamlined and, ideally, same-day access to ART is difficult given the expense associated with most ART regimens. Application and eligibility procedures for public and private insurance and other programs that may provide a financing source for the medication are often burdensome and may take anywhere from several days to multiple weeks to process, prompting many programs to rely on other mechanisms to ensure expedited access to an initial supply of medication to eligible clients. The different ART financing strategies are discussed in Figure 2 below.

Figure 2: Rapid Start Medication Procurement for Uninsured

DRUG ACCESS MECHANISM	QUANTITY	MEDICATION AVAILABILITY	ELIGIBILITY CRITERIA	COST CONSIDERATION FOR PROGRAM
ART samples	Sometimes limited to shorter interval than 30 days	Available directly from provider	None, but some providers may have internal policies prohibiting receiving or dispensing samples	Free
Manufacturer patient assistance programs (PAPs)	30-day fill	Pharmacy pick up via PAP pharmacy network (brick and mortar or mail order)	Income eligibility	Free
ADAP	30-day fill	Pharmacy pick up via ADAP pharmacy network (mail order option may be available depending on ADAP)	ADAP income and other eligibility requirements vary by program	340B discount plus possible negotiated supplemental discounts for ADAP eligible clients
RWHAP Part A or B*	30-day fill	Pharmacy pick-up via RWHAP Part A and/or Part B subrecipient pharmacy	RWHAP Part A, Part B, and/or specific EHE eligibility criteria	RWHAP Part A and/or B subrecipients procure and provide the medication via their regular 340B channels and are reimbursed by the RWHAP Part A at acquisition cost.
Non-ADAP 340B entity	30-day fill	Pharmacy pick up (typically at in-house or contract pharmacy)	Income eligibility and must be patient of the 340B clinic	340B discount

*In alignment with RWHAP AIDS Pharmaceutical Assistance (including Local Patient Assistance Program) and/or EHE funding policies and priorities.

ART samples – given to providers from manufacturer drug representatives – are often the most streamlined and cheapest way to provide same-day access to treatment. While the quantity may be less than a 30-day supply, enough medication can be dispensed to give the client and the care team time to transition to a more permanent payer source for long-term care and treatment. ART samples are also available at the clinic and do not require pharmacy pick up, eliminating a second step for clients. Many clinics or hospital systems may have internal policies that limit or prohibit receiving samples from manufacturer representatives and/or dispensing samples to patients. In those instances, providers will have to assess the other medication procurement options discussed below.

Manufacturer patient assistance programs (PAPs) are also available for free from the manufacturer or separate foundations established by manufacturers. While they do require an application, the process is simple and can be expedited for Rapid Start clients. And while many manufacturers do require mail or courier delivery of PAP-covered medications (including next-day delivery), some allow for retail pharmacy pick-up when rapid access is required.

ADAPs may also pay for medication for Rapid Start. ADAPs that receive EHE funding allocations, notably from RWHAP Part B programs in one of the seven state-wide EHE jurisdictions, have additional flexibility to waive income eligibility standards for Rapid Start clients and need only require an HIV diagnosis to be able to provide medications. ADAPs that have not been allocated RWHAP EHE funding, however, may not waive eligibility criteria,

meaning that Rapid Start clients must still go through an application process and eligibility determination. This process may be expedited to reduce administrative burden. The medication is then available via the ADAP's central pharmacy or pharmacy network, which will vary by jurisdiction.

RWHAP Part A recipients may also provide funding for ART medication dispensed by Part A subrecipients. This typically occurs as a reimbursement mechanism to Part A subrecipients who procure Rapid Start ART for eligible clients via their regular 340B drug procurement processes.

And finally, non-ADAP 340B entities may also use their 340B status to purchase medications for Rapid Start at a discounted price. The drug can then be dispensed to individuals who meet the 340B patient definition.

EHE Flexibility Consideration

ADAPs in one of the seven statewide EHE jurisdictions should consider using EHE eligibility flexibility to fund access to Rapid Start, allowing for an expedited approval process and rapid dispense of medication via ADAP.

TESTING AND LINKAGE SERVICES

The next category of services includes HIV testing and linkage services. These services are typically covered across Centers for Disease Control and Prevention (CDC) HIV prevention awards and RWHAP awards. CDC may fund local health departments to engage Disease Intervention Specialists and HIV testing sites to provide HIV testing services with linkage to care and treatment for any individuals who test positive for HIV. Successful Rapid Start programs have cultivated partnerships across CDC-funded HIV testing sites and RWHAP Rapid Start provider sites to ensure that funding streams and provider sites are working collaboratively to connect individuals to care and treatment. RWHAP funding (across RWHAP Part A, B, C, and D) also funds HIV testing and linkage services, usually through the Early Intervention Services (EIS) category. These RWHAP testing and linkage services are provided at both clinical and non-clinical community-based organization sites.

EHE Flexibility Consideration

EHE funding is often a good way to fund additional linkage service and/or full-time linkage-to-care coordinators working exclusively on Rapid Start initiatives. It may also provide flexibility to provide support services to assist individuals to quickly access care. For instance, Rapid Start programs may choose to use EHE funds to provide access to transportation services (including vouchers for ride-sharing apps) to help individuals who receive a positive HIV test at a testing partner get to a clinical site.

CLINICAL VISIT AND ART ASSESSMENT

A key component of Rapid Start is a clinical visit to assess whether immediate initiation of ART is appropriate for the client, including readiness to initiate HIV treatment. This service is typically funded under the RWHAP outpatient/ambulatory health services category. RWHAP recipients may also fund a range of supportive and counseling services through health education/risk reduction and case management services and should think broadly about the suite of services provided for Rapid Start that support a holistic and patient-centered approach to treatment initiation. Jurisdictions may also use EHE funding to expand provider capacity to do same-day clinical visit follow up with eligible clients.

EHE Flexibility Consideration

EHE funding for clinical visit and ART assessment services may help RWHAP recipients to provide these services without first requiring a full RWHAP eligibility determination.

BENEFITS ASSISTANCE

Ensuring that clients are appropriately assessed for eligibility for either the Rapid Start programs and/or other coverage options requires a dedicated workforce assisting clients to navigate application and documentation processes. Benefits assistance is already a core part of ADAP workflows and the infrastructure of many RWHAP clinics and is typically provided by medical or non-medical case managers. Rapid Start programs may need to build staff capacity to provide additional benefits assistance to Rapid Start clients, particularly as they transition from Rapid Start to regular and sustainable coverage options.

For Rapid Start clients that are later found to be eligible for Medicaid, which often has retroactive coverage, providers and programs should back bill Medicaid for services provided to the client after the coverage effective date. This means providers and programs could recoup both Rapid Start clinical service and medication costs from Medicaid.

EHE Flexibility Consideration

RWHAP recipients should consider using EHE funding to bolster benefits assistance staff capacity, particularly to support transitioning clients from the Rapid Start phase of treatment engagement to long-term care and treatment, which will include enrollment into a range of coverage programs and other social services.

Building a Rapid Start provider network

Ensuring there is a robust network of providers who understand the importance of Rapid Start and are adhering to accepted protocols for Rapid Start provisions is critical to a program's success. Many Rapid Start programs start with a subset of RWHAP providers – sometimes RWHAP Part A or Part B subrecipients – to initiate a Rapid Start program. Jurisdictions then work to build the network to include other providers, including RWHAP Part C providers and non-RWHAP funded community health centers. Emergency departments and acute care facilities are also emerging as important partners, particularly those that have already implemented routine HIV screening. (See resources on building provider networks developed by Technical Assistance Provider Innovation Network (TAP-in)).

Engaging new providers and providing them support and capacity building is an important step in sustainably growing a provider network. Jurisdictions have operated training programs and/or learning collaboratives to provide a supportive environment for providers as they initiate Rapid Start.

Eligibility and enrollment systems

At their core, Rapid Start programs necessitate an upending of traditional systems of application and eligibility confirmation before receipt of services. Instead of service delivery after a client has been found eligible for services, Rapid Start programs work best when the opposite occurs and service delivery precedes a full application and documentation of eligibility.

For this reason, many Rapid Start programs opt to focus on service provision first – quickly linking a person to ART and then moving to an assessment of potential eligibility for longer-term services and programs. EHE funding flexibility allows programs to only determine if someone has HIV, while waiving the other eligibility criteria (for instance income documentation). This flexibility allows programs to begin EHE-funded service delivery immediately and then follow up with a more thorough assessment for other coverage options, including full RWHAP eligibility.

Other Rapid Start programs – especially those reliant on a mix of EHE and non-EHE funding, may use a truncated or expedited RWHAP/ADAP application process. This streamlined RWHAP/ADAP application process may allow for less documentation and/or flag certain applications as candidates for expedited eligibility determinations that confirm eligibility either the same day or within 24 hours. The process used largely depends on the extent to which EHE eligibility flexibility is being used as non-EHE RWHAP funds are subject to regular eligibility requirements that require clients to be screened for income eligibility prior to service receipt.

Patient-centered Eligibility Processes

Providing rapid service delivery and access, prior to a full application and eligibility determination may be a more patient-centered way to deliver services. Streamlined and simple application processes that eliminate redundancy and reduce the time someone must remain in a clinic or service provider office applying for services recognize that individuals may have had previously traumatic experiences with the medical system that can cause them to feel more easily triggered in those environments.

Transitioning from Rapid Start to regular care and treatment

Another important component of Rapid Start programs is the process for transitioning clients from a Rapid Start intervention to more comprehensive and sustainable care and treatment. A core part of service delivery is assessing Rapid Start clients for eligibility for other coverage, including Medicaid, private insurance, and full RWHAP services. This type of screening and linkage is not new for RWHAP and is a core part of service delivery. The novelty of this set of services in the context of Rapid Start is that it occurs after service delivery has started. Programs may also build patient-centered approaches into the transition to other coverage and programs by using a client-centered approach that allows clients to set the pace of the transition. This helps the program ensure that the client's goals for care and treatment are met. Programs are also integrating assessment and linkage to other supports and services, including employment services and housing support, to ensure that clients have access to the range of assistance needed to remain adherent to ART long term.

III. Case studies

Las Vegas

SCOPE
RWHAP Part A Transitional Grant Area

FUNDING
RWHAP Part A EHE funding is being used to fund EIS, OAHS, HIP-CS and Medical Transportation for Rapid Start. To fill identified gaps, EHE funding will be allocated this year for Mental Health Services and Psychosocial Support to provide immediate peer support and crisis intervention services to newly diagnosed individuals.

EHE funding is also being used to support a Rapid Start Response Team charged with fielding calls from testing sites, providers, and pharmacies supporting linkage efforts; and linking newly diagnosed individuals from testing sites to clinical care and other supportive services.

Agencies doing Rapid Start typically use a blend of funding that may also include 340B program income.

ELIGIBILITY/APPLICATION PROCESS
The program operates on an assumption that some clients are not ready to go through RWHAP application upon initiating care and treatment, and the EHE Rapid Start program allows those clients to initiate treatment before completing a full application and eligibility determination. The Rapid Start program uses a two-page truncated application.

MEDICATION PROCUREMENT
RWHAP Part A EHE funding is not being used to cover medication costs. Each clinic is procuring Rapid Start medication via samples, PAPs, or 340B discount.

GOAL FOR TIME TO ART
Same day or within 7 calendar days of diagnosis

PROVIDER NETWORK
RWHAP Part A subrecipients and expanding to other providers serving populations with limited access to care in the area. The Rapid Start Response Team is charged with building Rapid Start provider capacity and expanding the Rapid Start provider network.

TRANSITION FROM RAPID START
The program focuses on transitioning clients to sustainable coverage options within 90 days, using a patient-centered approach to client readiness.

Louisiana

SCOPE
Statewide

FUNDING
The ADAP Rapid Start program provides a limited and relatively small safety net payer source for medication and complements other clinic and/or RWHAP Part A supported Rapid Start activities in the state. ADAP uses unrestricted program income dollars generated from the state's PrEP program for individuals discovered to be ineligible after dispensation of medicines, and Medicaid back-billing for the subset that is Medicaid eligible.

ELIGIBILITY/APPLICATION PROCESS
The ADAP uses a streamlined rapid eligibility application with expedited review and approval (the aim is for four hours). The form relies on self-attestation of income and residency.

MEDICATION PROCUREMENT
RWHAP Part B/ADAP is funding medication access and the state's PBM flags all Rapid Start claims so that if manual reassignment is necessary, they may be to be paid with non-federal funding. Clients are then required to use ADAP's pharmacy network for access or mail order or pick-up via the central pharmacy.

GOAL FOR TIME TO ART
Seven days for rural areas, much less for urban centers.

PROVIDER NETWORK
The provider network mirrors the existing RWHAP network. The state hopes to expand the model to rural areas using a network of parish health units with telemedicine capacity.

TRANSITION FROM RAPID START
The Rapid Start expedited application provides 30 days of eligibility as RWHAP providers work to link clients to sustainable coverage options.

Miami Dade County

SCOPE
RWHAP Part A Eligible Metropolitan Area (EMA) (in partnership with the local RWHAP Part B)

FUNDING
RWHAP Part A funding is being used via separate contracts with every RWHAP Part A-funded Outpatient/Ambulatory Health Services subrecipient and all but one Part A-funded Medical Case Management subrecipient in the EMA. Providers are allowed to bill the RWHAP Part A Rapid Start (i.e., Test and Treat / Rapid Access) program for a specific set of services (including the initial medical visit, and limited labs, mental health visit, and substance use disorder counseling visit, if needed) outlined in a detailed provider manual. RWHAP Part B funding is being used via separate contracts with most of the same RWHAP Part A-funded subrecipients to provide a subset of ART medications, access to Emergency Financial Assistance, as well as medical case management and mental health services from non-Part A funded subrecipients for these services.

ELIGIBILITY/APPLICATION PROCESS
The Rapid Start program uses an expedited screening and warm hand-off to a medical provider and medical case manager for individuals who are newly diagnosed with HIV, are entering RWHAP care for the first time, or are returning to care.

MEDICATION PROCUREMENT
Most Rapid Start ARTs may be billed to the RWHAP Part B Rapid Start program. The provider manual referenced above requires providers to use manufacturer assistance programs, or samples if available in the clinic, for some regimens (e.g., Dovato® and Symtuza®).

GOAL FOR TIME TO ART
Same day, but no more than seven days.

PROVIDER NETWORK
RWHAP Part A and Part B subrecipients.

TRANSITION FROM RAPID START
Clients utilizing Rapid Start services are screened for other coverage options, including RWHAP and ADAP, ideally within 14 days of Rapid Start enrollment. However, through the local Rapid Start process, subrecipients have up to 30 days to complete the enrollment process to transition Rapid Start clients into ADAP, Part A, or other payer source for ongoing medical care and support services.

South Carolina

SCOPE
Statewide

FUNDING
The RWHAP Part B program issued competitive subawards to Part B subrecipients using EHE funding. The funding is primarily used to support linkage coordinators, the hiring of peer workers, EIS services, expanded outpatient medical services in newly created clinics and via the use of mobile units. Subrecipients may also use funds to cover "EHE initiative services," defined as services outside of the RWHAP service categories and allowable under the EHE cooperative agreement. Subrecipients have a great deal of flexibility to tailor funding to specific Rapid Start needs. The EHE funds are intended to be used in conjunction with other RHWAP Part B subrecipient funding to expand access to Rapid Start.

ELIGIBILITY/APPLICATION PROCESS
RWHAP Part B subrecipients are able to use a "brief assessment" eligibility screening for Part B services, which may be used as proof of eligibility for Rapid Start services pending a full eligibility determination with documentation.

MEDICATION PROCUREMENT
Some Part B subrecipients are using Part B EHE funds to purchase starter packs, but most are using samples, PAPs, or purchasing discounted medications under the 340B Program . ADAP has not been needed to provide medication access for Rapid Start.

GOAL FOR TIME TO ART
SSame day as diagnosis, but no more than seven days after diagnosis.

PROVIDER NETWORK
RWHAP Part B subrecipients are funded via a subaward with significant flexibility applied to setting up Rapid Start.

TRANSITION FROM RAPID START
Clients utilizing Rapid Start services are screened for other coverage options.

Los Angeles County

SCOPE
RWHAP Part A EMA

FUNDING
Provisions in existing RWHAP Part A subrecipient contracts support using the outpatient/ambulatory health services service category. The program is working to expand the project to also incorporate EHE funding.

ELIGIBILITY/APPLICATION PROCESS
LA County has elected not to use a screening form for Rapid Start as it may pose a barrier to access. Instead, the program is operating on a philosophy of "care first, bureaucracy later." RWHAP Part A subrecipients are expected to initiate benefits screening at the first visit, but have 45 days to complete the process if insurance barriers are encountered. They are asked to use the local data management platform for payment purposes when needed.

MEDICATION PROCUREMENT
Up to RWHAP Part A subrecipient clinic and includes samples, PAP, 340B, or use of expedited California ADAP temporary assistance process

GOAL FOR TIME TO ART
Same day as rapid visit (two days from referral to rapid visit)

PROVIDER NETWORK
RWHAP Part A subrecipients.

TRANSITION FROM RAPID START
Clients utilizing Rapid Start services have 45 days of eligibility as case managers work to link clients to sustainable coverage sources.

IV. Conclusion

Rapid Start presents new opportunities for RWHAP recipients to reach and engage individuals in care and treatment. RWHAP EHE funds offer additional flexibility to design Rapid Start programs that eliminate many documentation and administrative barriers and create patient-centered engagement in care and treatment at the client's pace. As programs consider developing or expanding Rapid Start programs, investing in a strong foundation in financing and systems level policies and procedures will set programs up for sustainability and allow for expansion opportunities.

V. Resources

Rapid Start is a quickly evolving intervention and has been the subject of several demonstration projects and technical assistance cooperative agreements. The following are resources that may be helpful as RWHAP EHE recipients contemplate Rapid Start initiation or scale up existing efforts.

- CDC, Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention
- AETC National Resource Center, Rapid (Immediate) ART Initiation & Restart: Guide for Clinicians
- Technical Assistance Provider Innovation Network (TAP-in), Rapid ART: An Essential Strategy for Ending the HIV Epidemic
- HRSA/HAB, Rapid ART Dissemination Assistance Provider