

Welcome to Day 2 of the 2017 Administrative Reverse Site Visit

Ryan White HIV/AIDS Program (RWHAP) Part B Working Together to Ensure Optimal HIV Care and Treatment for People Living with HIV

Presented by:

Division of State HIV/AIDS Programs (DSHAP)

HIV/AIDS Bureau (HAB)

Health Resources and Services Administration (HRSA)



Pharmaceutical Rebates and Program Income August 30, 2017

Glenn Clark

ADAP Advisor

Division of State HIV/AIDS Programs

Jan Joyce

Sr. Advisor for Grants Policy

Office of the Associate Administrator

HIV/AIDS Bureau (HAB)

Health Resources and Services Administration (HRSA)



HIV/AIDS Bureau Vision and Mission

Vision

Optimal HIV/AIDS care and treatment for all

Mission

Provide leadership and resources to assure access to and retention in high quality, integrated care, and treatment services for vulnerable people living with HIV/AIDS and their families



Learning Objectives

At the conclusion of this session, you will:

1. Have a better understanding of

- what program income and rebates are
- how they are generated under your Ryan White HIV/AIDS Program (RWHAP) award(s)
- the allowable use of program income and rebates
- when to spend program income and rebates
- how to track and report program income and rebates earned and expended

2. Understand available HIV/AIDS Bureau (HAB) resources and how to use them

- Policy Clarification Notices (PCN) 15-03 and 15-04 and related frequently asked questions (FAQs)
- RWHAP Part B and AIDS Drug Assistance Program (ADAP) Manuals
- Technical Assistance

3. Be able to comply with requirements set forth in statute and regulation related to program income and rebates



Agenda

- **Overview of session**
- **Definition of key terms**
- **Generation of program income and rebates**
- **Allowable uses of RWHAP-related program income and rebates**
- **Spending, tracking and reporting program income and rebates**
- **Questions and answers**



Introduction

As the healthcare landscape has changed, HAB has provided the following resources related to pharmaceutical rebates and program income:

- PCN 15-03 and 15-04 and accompanying FAQs
- A renewed monitoring and technical assistance (TA) effort regarding the long standing requirements about tracking, spending, and reporting program income and rebates generated by RWHAP grants and cooperative agreements



Definitions (PCN)

Both PCN 15-03 and 15-04 define key terms

- **Rebate** – a return of a part of a payment
- **Program income** – gross income earned that is generated by activity(ies) supported by a Federal award or earned as a result of the Federal award
- **Refund** – amount of money given back to someone who has returned a product or paid too much



Pharmaceutical Rebate Source

340B Rebates

The 340B Drug Discount Program is a U.S Federal government program created in 1992 that requires drug manufacturers to provide outpatient drugs to eligible health care organizations/covered entities at significantly reduced prices

ADAPs access the 340B pricing in the following ways:

- For “Direct Purchase,” the ADAP purchases the medications from a drug wholesaler at the 340B price
- For “Rebate Model,” the ADAP reimburses the pharmacy at a negotiated rate, then invoices the manufacturer for the difference between the rate paid and the 340B price
- For “Dual/Hybrid,” the ADAPs do a combination of the above

Supplemental Rebates

In addition to the 340B price reduction, ADAPs have negotiated deeper discounts on antiretroviral therapies (ARV) through the ADAP Crisis Task Force (ACTF). ACTF discounts received as rebates may be referred to as “supplemental rebates” or “voluntary rebates”



Program Income Definition (CFR)

Per 45 CFR §75.2, Program Income: Program income means gross income earned by the non-Federal entity that is directly generated by a supported activity or earned as a result of the Federal award during the period of performance except as provided on 45 CFR §75.307(f). Program income includes, but is not limited to, income from fees for services performed, the use or rental of [sic.] real or personal property acquired under Federal awards, the sale of commodities or items fabricated under a Federal award, license fees and royalties on patents and copyrights, and principal and interest on loans made with Federal award funds. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in Federal statutes, regulation, or the terms and conditions of the Federal award, **program income does not include rebates, credits, discounts, and interest earned on any of them.**



Program Income Sources

- Fees, payments, or reimbursement for the provision of a specific service, such as patient care reimbursements received by billing public (Medicare, Medicaid, or Children's Health Insurance Program) or private health insurance
- Charges imposed on clients for services, as required by RWHAP Parts A, B, and C legislation
- The difference between the third party reimbursement and the 340B drug purchase price



Program Income and 340B: FAQ #1

How does the 340B drug pricing program generate program income?



340B Drug Pricing Program

The difference between the purchase price and the third party reimbursement is considered program income [also known as the “savings benefit”]

$$\begin{aligned} & \text{Third party reimbursement} \\ - & \text{the 340B purchase price} \\ \hline = & \text{Program income} \end{aligned}$$

340B Drug Pricing Program (Cont.)

The discount itself is not program income

Third party reimbursement for drugs sold at the discounted purchase price

— the 340B purchase price

— **\$0 Program income**

Program Income—Use Alternatives

Alternatives for use (45 CFR §75.307(e))

Alternative	Use of program income
Additive	Added to funds committed to the project or program and used to further eligible project or program objectives
Deductive	Deducted from total allowable costs of the project or program to determine the net allowable costs on which the Federal share of costs will be based
Combination	Uses all program income up to (and including) \$25,000 as specified under the additive alternative and any amount of program income exceeding \$25,000 under the deductive alternative
Matching	Used to satisfy all or part of the non-Federal share of a project or program

HRSA/HAB must specify the alternative and allowable use of program income on the Notice of Award – ADDITION ALTERNATIVE

You must notify your subrecipients in the subaward agreement/contract that the additive alternative is used for the disposition of program income



Program Income—Notice of Award

- **Program Term**

Recipients are required to track and report all sources of service reimbursement as program income on the annual Federal Financial Report and in annual data reports. All program income earned must be used to further the objectives of the RWHAP program. For additional information, see PCN #15-03 available online at [Policy Notices and Program Letters](#)

You must include a term regarding the allowable use of program income in the subaward agreement/contract



Rebates—Notice of Award

- **Program Term**

In accordance with Guidelines for the Utilization and Reporting of Pharmaceutical Rebates (Rebate Policy), recipients that collect rebates on ADAP medication purchases must adhere to the provisions outlined in this policy. [Utilization and Reporting of Pharmaceutical Rebates](#)



Allowable Uses

- **Program income and rebates must be used for the “purposes for which the award was made”**
 - Can only be used for otherwise allowable costs under the award – See PCN 16-02 *RWHAP Services: Eligible Individuals & Allowable Uses of Funds*
 - Not limited to costs in the project budget submitted as part of the Program Terms Report and approved by HAB
- **RWHAP Part B can use program income and rebates for the following:**
 - Core medical services
 - Support services
 - Clinical quality management
 - Administrative expenses, including planning and evaluation



Allowable Uses, continued

Program income and rebates “cannot be shared with other entities including, but not limited to, RWHAP Part A recipients, high risk insurance pools, Marketplace plans, Medicaid, or any other state or federal program”

- RWHAP Part B can use program income and rebates to pay for health insurance related costs for a client (i.e. health insurance premium costs), but cannot be transferred to an insurance plan to cover their administrative costs
- RWHAP Part B can be used to fund services, but cannot be given to other providers for administration



Flexibility in Using Program Income and Rebate

Program income and rebates are not subject to these statutory provisions:

- Minimum 75% distribution of funds for core medical services
- 10% administrative cap
- Cap on clinical quality management

Program Income and rebates may be used for **otherwise allowable costs** not included in the RWHAP Part B implementation plan

- Priority should be given to placing rebates back into ADAP, but is not required

Rebates and program income may be used to meet a state's match requirement and/or maintenance of effort requirement. The same rebate dollars may also be used to meet a state's match and maintenance of effort requirements



Allowable Uses: FAQ #1

**Can program income or rebates be used
for construction?**



Allowable Uses: FAQ #1

No, neither program income nor rebates may be used for construction. Construction is an unallowable cost under the RWHAP.

Program income and rebates *may* be used for minor alterations & renovations (A&R)

- Changes the interior arrangements or other physical characteristics of an existing facility
- Does not add square footage by building up or out
- Threshold = \$150,000 or 25% of the award or subaward (whichever is less)



Allowable Uses: FAQ #2

Can program income or rebates be used for pre-exposure prophylaxis (PrEP)?



Allowable Uses: FAQ #2 Continued

No, RWHAP funds cannot pay for PrEP medications or the related medical services as the person using PrEP is not diagnosed with HIV prior to the exposure and, therefore, not eligible for RWHAP-funded medication. Consequently, neither program income nor rebates can be used to pay for PrEP.

Also see the [June 22, 2016 RWHAP and PrEP program letter](#)



Allowable Uses: FAQ #3

Can program income or rebates be used to pay salaries in excess of the salary rate limitation?



Allowable Uses of Program Income: FAQ #3

No. The General Provisions in Division H, § 202, of the Consolidated Appropriations Act, 2017 (P.L. 115-31), limits the salary rate that may be awarded and charged to HHS grants. RWHAP funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II.

This is a salary rate limitation imposed by appropriations law, not a salary cap. Salary expenses in excess of the Executive Level II are unallowable costs. Consequently, neither rebates nor program income may be used to pay salaries in excess of the salary rate limitation.

This salary rate limitation also applies to RWHAP subrecipients – include this information in each subaward agreement/contract



Allowable Uses – Salary Rate Limitation Example

- Individual's full time salary: **\$255,000**

50% of time will be devoted to the project

Direct salary	\$127,500
Fringe (25% of salary)	\$31,875
Total amount	\$159,375

- Amount that may be claimed on the Federal grant due to the legislative salary limitation:

- Individual's base full time salary *adjusted* to Executive Level II: \$187,000

50% of time will be devoted to the project

Direct salary	\$93,500
Fringe (25% of salary)	\$23,375
Total amount	\$116,875



Allowable Uses: FAQ #4

Can program income or rebates be used to hire more case managers and to provide outpatient substance abuse care if such activities were not in the approved application and budget?



Allowable Uses: FAQ #4 Continued

Yes, program income and rebates may be used to provide services to eligible clients in accordance with PCN 16-02 even if such costs were not included in the approved project scope and budget

In order to maximize the impact of limited grant funds, recipients must include program income and rebate projections when planning for services based on the comprehensive HIV care and treatment needs of the recipient's service area



Spending Program Income and Rebates

RWHAP recipients and subrecipients must:

- To the extent they are available, spend program income and rebates prior to drawing grant funds
 - Rebates received at the end of a project period must be spent before requesting and expending RWHAP funds awarded (including any carry over of unobligated balances) in the subsequent budget period

And:

- As part of your overall planning and budgeting, estimate anticipated program income and rebates and determine when RWHAP funds will be needed during the upcoming budget period

Important to estimate and include program income and rebate revenue as part of the planning and budgeting process



Tracking and Reporting

- Recipients are required to track and account for all program income and rebates in accordance with 45 CFR § 75.302(b)(3). Recipients must report on their Federal Financial Report (FFR) program income and rebates earned and spent by the recipient
- Additionally, it is the responsibility of the recipient to monitor and track program income earned and spent by subrecipients. Subrecipients should retain program income for “additive” use within their own programs. Consequently, program income earned by subrecipients should not be reported on the recipient’s FFR



Spending, Tracking and Reporting: FAQ #1

How can we spend program income and/or rebates first and still spend our grant funds within the budget period?



Spending, Tracking and Reporting: FAQ #1 (Cont.)

It is all about **BUDGETING**. Recipients should develop a reasonable and transparent process for budgeting and expending federal funds and related program income that balances both the program requirements for programmatic reporting and fiscal requirements for expending the funds. Recipients must proactively project the extent to which program income and/or rebates will be received, and budget accordingly.



Spending, Tracking and Reporting: FAQ #2

How does HRSA define 'spend'?



Spending, Tracking and Reporting: FAQ #2 (Cont.)

Per 45 CFR Part § 75.2, “expenditures” means charges made by the recipient to the RWHAP award.

Cash vs **Accrual** basis of accounting

Cash: the sum of cash disbursements, cash advance payments, and payments made to subrecipients

Accrual: the sum of amounts owed for goods and property received; services performed by employees, contractors, recipients, etc.

Are your subrecipients on a cash or accrual basis of accounting?



Spending, Tracking and Reporting: FAQ #2

For recipients/subrecipients on an accrual basis of accounting, the expenditure is recognized at the time the cost is incurred (when the subaward or contract is awarded). If program income or rebates is obligated for a contract awarded during the project period, the expenditure has been recognized (program income has been spent). Neither the contract's period of performance nor when the funds are actually paid (liquidated) is a factor.



Spending, Tracking and Reporting: FAQ #3

If a recipient has a Part C grant, a Part D grant, and a Part B subaward—may they distribute the aggregate total program income to each based on the relative size of each award?



Spending, Tracking and Reporting: FAQ #3 (Cont.)

No. Per 45 CFR § 75.302(b), **source and use of program income must be tracked and reported separately**

- Identification, in its accounts, of all Federal awards received and expended and the Federal programs under which they were received. Federal program and Federal award identification must include, as applicable, the CFDA title and number, Federal award identification number and year, name of the Federal awarding agency, and name of the pass-through entity, if any
- Records must contain information pertaining to Federal awards, authorizations, obligations, unobligated balances, assets, expenditures, income and interest and be supported by source documentation



Spending, Tracking and Reporting: FAQ #4

In an effort to spend 340B rebates, we're considering funding RWHAP provider subawards/contracts solely with rebate funds.

- Are 340B rebate considered Federal funds?**
- If not, would the subrecipients still be considered RWHAP Part B participants?**
- How would this impact RSR reporting?**



Spending, Tracking and Reporting: FAQ #4 (Cont.)

- 340B rebates (and program income) are NOT considered federal funds
 - However, subrecipients would still be considered RWHAP Part B participants subject to programmatic requirements
- Subrecipient providers funded solely through RWHAP generated rebates or program income currently do not submit RSR reports
- **IMPORTANT NOTE:** The loss of federal funds may impact the subrecipient's 340B eligibility
 - If subrecipients do not receive other qualifying federal awards, they would immediately lose their 340B eligibility

Consider including RWHAP Part B funds in each subaward



Spending Tracking and Reporting: FAQ #5

What sort of documentation should be retained related to rebates or program income earned and expended, and what is the retention period?



Spending Tracking and Reporting: FAQ #5 (Cont.)

- Recipients/subrecipients should maintain the same documentation they would for other income and expenditures under the award (e.g., invoices, receipts, time and effort reports, reimbursement statements, etc.)
- Retain for 3 years after the date the final FFR was submitted to HRSA per Federal requirements
 - Document retention periods beyond the required 3 years may apply based on state regulations
- Records related to program income received after the project period must be retained for 3 years after the last day of the recipient's fiscal year

This information should be conveyed to subrecipients in the subaward agreement/contract



Resources

Policy Clarification Notices:

- **15-03** *Clarifications Regarding the Ryan White HIV/AIDS Program and Program Income and Accompanying FAQs*
[Clarifications Regarding the Ryan White HIV/AIDS Program and Program Income](#)
- **15-04** *Utilization and Reporting of Pharmaceutical Rebates*
[Utilization and Reporting of Pharmaceutical Rebates](#)
- **16-02** *RWHAP Services: Eligible Individuals & Allowable Uses of Funds*
[Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds](#)
- **15-01** *Treatment of Costs under the 10% Administrative Cap for Ryan White HIV/AIDS Program Part A, B, C, and D*
[Treatment of Costs under the 10% Administrative Cap for Ryan White HIV/AIDS Program Parts A, B, C, and D](#)

45 CFR Part 75 - Uniform Administrative Requirements, Cost Principles, And Audit Requirements for HHS Awards
[Electronic Code of Federal Regulations](#)



Questions and Answers

Questions?



Evaluation Survey

- Please use the following link to complete a short evaluation of this session
- The link may also be found on your agenda

https://www.surveymonkey.com/r/ARSV2017_Rebates



Contact Information

Glenn Clark

AIDS Drug Assistance Program Advisor, Division of State HIV/AIDS Programs

Email: glclark@hrsa.gov

Phone: 301-443-3692

Jan Joyce

Senior Grants Policy Advisor, Office of the Associate Administrator

Email: jjoyce@hrsa.gov

Phone: 301-443-5468

HIV/AIDS Bureau (HAB)

Health Resources and Services Administration (HRSA)

Web: hab.hrsa.gov

Twitter: twitter.com/HRSAgov

Facebook: facebook.com/HHS.HRSA

