Ryan White HIV/AIDS Program Addressing the Opportunities and Challenges Afforded by Program Income and Pharmaceutical Rebates

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Learning Objectives

At the conclusion of this activity, the participant will be able to:

- 1. Describe RWHAP Policy Clarification Notices (PCN) 15-03 and 15-04 related to RWHAP-related program income and pharmaceutical rebates
- 2. Understand of how to use the program guidance in RWHAP PCNs 15-03 and 15-04 in program implementation.
- 3. Discuss strategies to appropriately use RWHAP-related program income and pharmaceutical rebates in a manner consistent with RWHAP PCNs 15-03 and 15-04



Agenda

- Overview of session
- Highlights of RWHAP PCN 15-03
- Highlights of RWHAP PCN 15-04
- Allowable uses of RWHAP-related program income and rebates
- Questions and Answers



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.



HIV/AIDS Bureau Priorities

- National HIV/AIDS Strategy (NHAR) 2020/President's Emergency Plan For AIDS Relief (PEPFAR) 3.0 - Maximize HRSA HAB expertise and resources to operationalize NHAS 2020 and PEPFAR 3.0
- Leadership Enhance and lead national and international HIV care and treatment through evidence-informed innovations, policy development, health workforce development, and program implementation
- **Partnerships** Enhance and develop strategic domestic and international partnerships internally and externally
- Integration Integrate HIV prevention, care, and treatment in an evolving healthcare environment
- Data Utilization Use data from program reporting systems, surveillance, modeling, and other programs, as well as results from evaluation and special projects efforts to target, prioritize, and improve policies, programs, and service delivery
- Operations Strengthen HAB administrative and programmatic processes through Bureau-wide knowledge management, innovation, and collaboration



Definitions

Both PCNs 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
- Refund amount of money given back to someone who has returned a product or paid too much



Purpose and Timeliness of Policy Clarification Notices 15-03 & 15-04

- With the issuance of the Uniform Guidance, HAB needed to clarify use of program income
- Further, given the increased number of Ryan White HIV/AIDS Program (RWHAP) clients with health insurance, recipients and subrecipients may generate increased program income as access to health care coverage increases
- Amounts of pharmaceutical rebates have increased substantially and states may benefit from additional guidance
- Generation, use, and reporting of program income and pharmaceutical rebates can be complex
- Clarification was needed on how to use program income and pharmaceutical rebates



Policy Clarification Notice 15-03

Clarifications Regarding the Ryan White HIV/AIDS Program and Program Income



PCN 15-03: Expenditure of Program Income

RWHAP recipients and subrecipients must:

 "Disburse all program income <u>before</u> requesting additional cash payments"

Speaks to the order in which resources must be obligated

and

- "Estimate accrued program income and determine RWHAP funds that will be needed during current performance period"
 - Speaks to the importance of estimating program income for planning and budgeting purposes
- There are no exemptions from unobligated balances penalties due to the expenditure of program income



PCN 15-03: Acceptable Uses of Program Income

- Program income must be used for the "purposes for which the award was made"
 - Can only be used for otherwise allowable costs under the <u>award</u> – See PCN 16-02 RWHAP Services: Eligible Individuals & Allowable Uses of Funds
 - Not limited to allowable costs in approved project budget
- RWHAP Parts A, B, C, & D can use program income for the following
 - Core medical services
 - Support services
 - Clinical quality management
 - Administrative expenses, including planning and evaluation
- RWHAP Part F is limited to statutory provisions



PCN 15-03: Flexibility in Using Program Income

Program income is <u>not</u> subject to these statutory provisions

- Minimum 75% distribution of funds for core medical services
- 10% administrative cap
- Cap on clinical quality management
- Not limited to allowable costs in approved project budget



PCN 15-03: Timing for Using Program Income

Recipients cannot control when program income is received

- To extent it is available, program income must be spent first before drawing funds from PMS
- Recipients and subrecipients should strive to estimate the program income accrued during a project period
- Recipients and subrecipients will then be better able to plan for the allocation and utilization of award funds
- Program income obligated for a contract awarded during the project period, the expenditure has been recognized (program income has been spent)



PCN 15-03: Reporting of Program Income

- Recipients are required to track source and use of program income received and expended and report it annually on the federal financial report (FFR)
- Recipients are also required to monitor the program income of their subrecipients – though they do not need to report it on the FFR



Policy Clarification Notice 15-04

Utilization and Reporting of Pharmaceutical Rebates



PCN 15-04: Expenditure of Rebates

- To extent they are available, rebates must be spent first before requesting RWHAP funds
 - Rebate projections should be incorporated into the jurisdiction's planning for services for effective allocation of RWHAP funds during the project period
- Rebates received at the end of a project period are to be expended before requesting and expending RWHAP funds awarded in the subsequent project period



PCN 15-04: Acceptable Use of Rebates

Rebates must be applied to the RWHAP Part B – priority should be given, but is not required, to placing rebates back into ADAP

- Rebates may be used for otherwise allowable costs not included in the RWHAP Part B implementation plan – See PCN 16-02 RWHAP Services: Eligible Individuals & Allowable Uses of Funds
- Rebates can be used to meet a state's match requirement <u>and/or</u> maintenance of effort requirement
- The same rebate dollars may also be used to meet a state's match <u>and</u> maintenance of effort requirements



PCN 15-04: Unacceptable Uses of Rebates

AIDS Drug Assistance Program (ADAP)rebates cannot be used for services and costs that are not allowed by RWHAP Part B (e.g., PrEP) and cannot be shared with other entities, including:

- RWHAP Part A recipients
- Medicaid
- Any other state or Federal program
- Marketplace insurance plans



PCN 15-04: Timing for Using Rebates

Recipients cannot control when rebates are received

- Recipients should strive to estimate the rebates accrued during a project period
- Recipients will then be better able to plan for the allocation and utilization of award funds
- Rebates must be expended in the project period during which they are received
 - If rebates are received at the end of the project period then they can be used in the next project period
- Rebates obligated for a contract awarded during the project period, the expenditure has been recognized (rebates have been spent)

There is an exemption from the Unobligated Balance (UOB) penalties for states that spend rebates first



Side-by-side: Program Income & Rebates

	Program Income	Rebates
Reporting	 Recipients report received and expended program income (not that of subrecipients) in FFR Recipients must monitor subrecipients' program income but do not need to report it in FFR 	States report received and expended rebates in the FFR and ADR
"Additive Alternative" – because it is added to the award	 Must be used for the purposes for which the original award was made May be used for otherwise allowable costs under the award 	 Must be used for the purposes for which the original award was made May be used for otherwise allowable costs under the award
Unobligated Balance Penalty	 Failure to expend award due to spending program income first may impact a future actual award 	 Failure to expend award due to spending rebates first may impact a future actual award



Acceptable Uses for Program Income & Rebates (non-exhaustive list)

	Program Income	Rebates
Services that support a comprehensive system of care	Core medical servicesSupport services	MedicationsCore medical servicesSupport services
Administrative expenses	 Routine grant administration & monitoring activities Development and establishment of reimbursement and accounting systems Compliance with grant conditions and audit requirements Subrecipient monitoring activities EHB infrastructure 	 Routine grant administration & monitoring activities Development and establishment of reimbursement and accounting systems Compliance with grant conditions and audit requirements Subrecipient monitoring activities EHB infrastructure
Clinical Quality Management	 Infrastructure (e.g., staffing) Performance measurement (e.g., analyzing data) Quality Improvement 	 Infrastructure (e.g., staffing) Performance measurement (e.g., analyzing data) Quality Improvement

Conclusions - Major Points

- Program income and rebates must be used before RWHAP funds
 - This is not new guidance
- 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 <u>award</u>
 - Not limited to allowable costs in the budget for the project
- Program income and rebates are <u>not</u> subject to statutory caps
 - Minimum 75% distribution of funds for core medical services
 - Minimum 50% distribution of Part C funds for EIS
 - 10% administrative cap
 - Cap on clinical quality management
- Rebates must be used for RWHAP Part B program, with priority given to ADAP



Relevant PCNs

• 15-03 Clarifications Regarding the RWHAP and Program Income http://hab.hrsa.gov/healthcarelandscape/pcn 15-03 program income.pdf

• 15-04 Utilization and Reporting of Pharmaceutical Rebates

http://hab.hrsa.gov/healthcarelandscape/pcn 15-04 pharmaceutical rebates.pdf

16-02 RWHAP Services: Eligible Individuals & Allowable Uses of Funds

http://hab.hrsa.gov/healthcarelandscape/service category pcn 16-02 final.pdf

• 15-01 Treatment of Costs under the 10% Administrative Cap for Ryan White HIV/AIDS Program Part A, B, C, and D

http://hab.hrsa.gov/healthcarelandscape/pcn1501.pdf



Questions

What questions do YOU have?



For additional questions, please email: AskHAB@hrsa.gov

Thank You to:

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