Frequently Asked Questions

March 21, 2016 Policy Clarification Notices (PCNs) 15-03 and 15-04

The following are frequently asked questions (FAQs) presented by the Health Resources and Services Administration's (HRSA's) HIV/AIDS Bureau (HAB) for Policy Clarification Notice (PCN) 15-03, *Clarification Regarding the Ryan White HIV/AIDS Program and Program Income*, and PCN 15-04, *Utilization and Reporting of Pharmaceutical Rebates*. PCN 15-03 is applicable to Ryan White HIV/AIDS Program (RWHAP) Parts A, B, C, D, and F where grants and cooperative agreements support HIV care and treatment services, training, special projects, and related activities that generate program income. PCN 15-04 is applicable to RWHAP Part B AIDS Drug Assistance Program (ADAP) grant recipients and their subrecipients. Please also refer to PCN 16-02, *Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds* for additional information.

Questions pertaining to the application of the PCNs to a particular RWHAP award should be addressed to the HAB Project Officer. This document is intended to provide additional context and background for PCNs 15-03 and 15-04 as grant recipients and subrecipients seek to understand and operationalize the policy. These FAQs may be updated as additional questions are received.

GENERAL - Across PCNs

1. Are program income and rebates subject to the same use and reporting requirements?

There are similarities and differences with regard to use and reporting requirements for program income and rebates. Specific requirements are addressed under each PCN heading, below.

2. Can program income or rebates be transferred or shared with other state or Federal programs?

No. Neither program income nor ADAP drug rebates can be transferred or shared with third-party entities including other RWHAP recipients, Marketplace plans, Medicaid, or any other state or Federal program.

3. What rules apply to the expenditure of program income, rebates, and refunds?

The uniform administrative requirements cost principles and audit requirements for Department of Health and Human Services (HHS) awards, 45 CFR § 75.305(b)(5) states: "...to the extent available, recipients and subrecipients must disburse funds available from program income, rebates, refunds, contract settlements, audit recoveries and interest earned

on such funds before requesting additional cash payments." Program income, rebates, and refunds must be used for the purposes and subject to the conditions of the Federal award.

4. Are there specific examples of costs for which program income and rebates cannot be used?

Examples of costs for which program income and rebates cannot be used include:

- Sterile needles or syringes for the hypodermic injection of any illegal drug;
- Pre-exposure Prophylaxis (PrEP) medications;
- Construction and/or major alteration or renovation;
- Cash payments to intended recipients of RWHAP services; and
- Programs or the development of materials designed to promote or encourage, directly, intravenous drug use or sexual activity, whether homosexual or heterosexual.
- 5. Can program income and rebates be considered for maintenance of effort (MOE)?

Recipients are not prohibited from considering program income and rebates with regard to MOE, but HAB urges strongly that recipients use caution if they choose to do so, due to potential fluctuation in program income and rebate funds. Under RWHAP MOE provisions, the recipient is required to maintain its financial contribution to the program at not less than its contribution for a prior time period, usually the fiscal year prior to the application deadline. In addition to prior year non-Federal expenditures, the recipient may choose to include program income or rebates generated under the RWHAP award when calculating the aggregate baseline level of effort to be maintained. Also, elements chosen to be included in an MOE calculation must be consistent year-to-year; thus, it is important to remember that doing so may significantly increase the level of effort to be maintained from year-to-year. Neither program income nor rebates may be used to offset or reduce the recipient's non-Federal contributions to the RWHAP in compliance with an MOE requirement.

6. Do program income and rebates need to have separate accounts?

The source and use of program income and rebates must be tracked and reported separately. Recipients and subrecipients should adhere to their written accounting procedures that must be compliant with 45 CFR§ 75.302(b). Of particular note, recipient and subrecipient financial management systems must provide for the following:

- 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 Catalog of Federal Domestic Assistance title and number, Federal award identification number and year, name of the HHS awarding agency, and name of the pass-through entity, if any.
- records that adequately identify the source and application of funds for federally-funded activities. These records must contain information pertaining to Federal awards, authorizations, obligations, unobligated balances, assets, expenditures, income and interest and must be supported by source documentation.

PROGRAM INCOME

1. What is program income?

Program income is 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 (or grant year) except as provided in 45 CFR §75.307(f). See 45 CFR §75.2.

2. Why does the definition specify "gross" program income?

The costs incidental to the generation of program income may be deducted from gross program income only if those expenses were not charged to the Federal award. By definition, the costs charged to the award (the funded program activities) generate program income. There is typically nothing to deduct.

3. What is the addition or "additive" alternative for the use of program income?

Under the additive alternative, program income is added to the Federal award and must be used for the purposes and under the conditions of the Federal award. Please note that this does not result in a separate or additional notice of grant award. See 45 CFR § 75.307(e)(2).

4. What are some examples of program income?

Examples of program income include:

- The difference between the third party reimbursement and the 340B drug purchase price.
- Funds received by billing public or private health insurance for services provided to eligible RWHAP clients.
- Fees, payments, or reimbursement for the provision of a specific service, such as patient care reimbursements received under Medicare, Medicaid, or Children's Health Insurance Program.
- Charges imposed on clients for services, as required by RWHAP legislation, Parts A, B, and C.
- Tuition or participant fees for training programs developed and/or presented under the award.
- 5. Is all 340B generated revenue considered program income?

Yes, all 340B generated revenue is considered program income. When the RWHAP grant is the sole Federal award that makes an organization eligible as a 340B Drug Pricing Program covered entity, and purchases pharmaceuticals via 340B pricing, all the program income should be attributed to the RWHAP grant. When an entity is 340B eligible and purchases pharmaceuticals via 340B pricing under multiple awards, the recipient must use a reasonable allocation method for the attribution of costs and program income, and be able to document the methodology used.

6. What types of income are not considered program income?

Except as otherwise provided in Federal statutes, regulations, or the terms and conditions of the Federal award, program income <u>does not include</u> rebates, credits, discounts, and interest earned on any of them. Specific examples include:

- Other Federal (including RWHAP) grant awards or subawards.
- Interest earned on advances of Federal funds.
- Refunds for overpayments for goods and services, or the return of a product. (To the extent that refunds relate to allowable costs, they must be credited to the RWHAP award either as a cost reduction or a cash refund, as appropriate.)
- The reduced 340B price a covered entity received on the purchase of a medication; it is, instead, a discount.

Use of Program Income

7. For what purposes can program income be used?

Program income must be used for the purposes and under the conditions of the Federal award.

- For Parts A, B, and C, program income must be used for core medical and support services, clinical quality management (CQM), and administrative expenses (including planning and evaluation) as part of a comprehensive system of care for low-income individuals living with HIV.
- For Part D, program income must be used for family-centered outpatient or ambulatory care, support services, CQM, and administrative expenses for low-income women, infants, children, and youth affected by or living with HIV.
- For Part F, program income must be used for the purpose and under the conditions of the award according to the applicable statutory provisions.
- 8. Can program income be used to supplement staff salaries in excess of the salary rate limitation?

No. The General Provisions in Division H, § 202, of the Consolidated Appropriations Act, 2016 (P.L. 114-113), limits the salary rate that may be awarded and charged to HHS grants and cooperative agreements. Award funds may <u>not</u> be used to pay the salary of an individual at a rate in excess of Executive Level II. (This salary rate limitation also applies to RWHAP subrecipients.)

It is important to note that 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, program income may <u>not</u> be used to pay salaries in excess of the salary rate limitation.

9. Can program income be used to support activities in excess of a cap imposed by the RWHAP legislation?

Yes. In contrast to the answer related to the salary rate limitation, program income may be used to support activities in excess of a cap that is imposed directly by the RWHAP, as such costs are otherwise allowable. For example, indirect costs are allowable, but capped at 10 percent (10%) for RWHAP Parts A through D. Program income may be used for indirect costs in excess of the 10 percent (10%) cap (up to the negotiated rate). This is also true of allocations that exceed the statutory caps imposed on administrative costs and CQM.

10. Can program income be used to pay for services that Medicaid does not cover?

Program income may be used to pay for any medically necessary services which Medicaid does not cover or only partially covers, as well as premiums, co-pays, and any required deductibles otherwise allowable under the RWHAP award. Program income (and RWHAP funds) may be used to cover eligible services (defined in PCN 16-02, *Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds*) if those services are not covered or are only partially covered under Medicaid, even when those services are provided at the same visit as Medicaid-covered service. (See PCN 13-01, *Clarifications Regarding Medicaid-Eligible Clients and Coverage of Services by Ryan White HIV/AIDS Program*).

11. If an ADAP purchases a client's insurance, but the RWHAP Part C program is purchasing medication and billing the insurance, does the program income go to the ADAP or to the Part C program?

In this example, the program income is generated by and would be used by the Part C program.

12. For RWHAP-generated program income, is it permissible to use the income for items listed in PCN 16-02, *Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds*, even if such expenditure is not listed in the current allocation of the grant award?

Yes. If otherwise allowable under the award, it is permissible to use program income generated under Parts A – D (and F where funding supports direct care and treatment activities) for costs incurred for providing allowable services to eligible individuals as outlined in PCN 16-02, even if those costs were not included in the approved project budget and the RWHAP Allocation Report. For example, program income could be used to provide psychosocial support services for affected family members and caregivers, even if such costs were not included in the approved budget, under Part D only. Such costs would be unallowable under Part C, so program income generated under a Part C award may not be used for such costs, as noted in PCN 16-02.

13. In the final year of funding, will program income received at the end of the period of performance need to be expended prior to receiving RWHAP funds awarded in the next competitive cycle (if the RWHAP recipient receives an award)?

Yes. If program income is received at the end of the period of performance, it must be expended by the recipient prior to the expenditure of new grant RWHAP funds awarded in the subsequent period.

14. Under Part A, does the HIV Health Services Planning Council/Body have to identify the priorities for disposition of program income earned by the recipient under the award?

Because program income must be used for the purposes and under the conditions of the award, the planning body allocations should be applied to program income, just as they apply to the rest of the grant funds.

Program Income Tracking and Reporting Requirements

15. How is program income that is earned by subrecipients tracked by recipients?

Recipients are required to monitor and track program income earned by subrecipients and to ensure that subrecipients are using program income earned for the purposes and under the conditions of the award. Recipients should require financial and performance reports necessary to ensure that the subaward, and any income generated by it, is used for authorized purposes, in compliance with Federal statutes, regulations and the terms and conditions of the award. Recipient and subrecipient financial management systems must provide information as described in FAQ Number 6, under "GENERAL – Across PCNs," above.

16. For staff that are not full time equivalents (FTEs) paid solely by the RWHAP grant, but from other sources, does the full amount of program income need to be tracked or just the amount associated with their FTE?

Program income is attributable to a program, not to an individual that may be involved in generating it. If a program receives multiple sources of funding, the recipient must use a reasonable allocation method for the attribution of the program income, and be able to document the methodology used.

17. Where are recipients to report program income?

Recipients report program income on the Federal Financial Report (FFR), but do not report subrecipient income.

REFUNDS

1. Is a refund the same as a credit?

According to 45 CFR § 75.406, refunds are one of many types of applicable credits. A credit offsets or reduces expense items charged to a Federal award. Credits include purchase discounts, rebates or allowances, recoveries or indemnities on losses, insurance refunds or rebates, and adjustments of overpayments or erroneous charges.

2. What would be considered a refund?

The following are examples of refunds:

- The amount a RWHAP recipient recoups, from a client, from a premium tax credit paid on behalf of that client.
- The amount of quarterly insurance premium a RWHAP recipient receives back from an insurer when a client is disenrolled from the insurance prior to the end of the quarter.
- 3. Is the amount an ADAP receives when it back-bills Medicaid for medication costs it paid for a client who later received retroactive Medicaid eligibility considered a refund?
 - No, Medicaid back billing is not a refund. It is program income.
- 4. Are refunds considered to be part of the original grant award, or are refunds considered 'additive' (i.e., additional funding)?

To the extent that refunds relate to allowable costs, they must be credited to the RWHAP award either as a cost reduction or a cash refund, as appropriate. If a refund is received in the grant year it was generated and the recipient had not yet requested RWHAP funds to cover the expense, the recipient would reduce the cost charged to the RWHAP award. If a refund is received in the grant year it was generated and the recipient had used RWHAP funds to cover the expense, the recipient would account for the refund of RWHAP funds in that grant year, and the refund must be immediately disbursed for otherwise allowable costs or returned to HRSA to be drawn down at a later date during the budget period. In both scenarios, the RWHAP award amount remains the same. If a refund is received after the grant year ends, then it must be spent during the budget period in which it is received; no adjustment is needed to the previous year's FFR.

5. How do recipients report refunds?

Recipients are required to track and account for all refunds in accordance with 45 CFR § 75.302(b). Refunds are not reported to HRSA, but HRSA, the HHS Office of Inspector General, or the Government Accountability Office may request documentation related to refunds as part of routine monitoring, an audit, or an examination.

REBATES

1. For what purposes can rebates be used?

The recipient may only use rebates for the purposes and under the conditions of the RWHAP Part B program. These statutorily permitted purposes include core medical services including ADAPs, support services, CQM, and administrative expenses, including planning and evaluation (Section 2612(a) of the Public Health Service (PHS) Act).

In addition, allowable uses of rebates include:

- State match requirement;
- State MOE requirement; and
- Costs for allowable services that exceed the RWHAP Part B implementation work plan.

Rebate Tracking and Reporting Requirements

2. Where are recipients to report rebates?

If rebates are received during the reporting period, recipients are to enter the amount allocated during the reporting period in both the reported expenditures and the funding section of the Grantee Report of the ADAP Data Report (ADR).

Rebates are to be tracked separately and reported on the FFR as follows:

- in the "Ryan White Rebate Funding" section, report both the expended rebate amount and the expended rebate amount to be used to reduce the unobligated balance (UOB) of the grant amount; and
- in the "Remarks" section under line 12, report a Rebate Account Summary, including total rebate revenues, total rebate expenditures and remaining rebates; and if relevant, the following language: "We are requesting that \$_____ of the unobligated balance be reduced by \$_____ of the obligated rebates and that such amount be carried forward to the next budget year."

Because rebates are not part of the recipient's RWHAP Part B award, they should <u>not</u> be included in the HAB RWHAP Part B Program Terms Report, planned RWHAP Allocations Report or final RWHAP Expenditure Report.

3. How should recipients report any UOBs that result from expending rebates?

Recipients must state in the Remarks section of the FFR: "We are requesting that \$____ of the unobligated balance be reduced by \$____ of the obligated Rebates funds and that such amount be carried forward to the next budget year."

4. Will recipients be penalized if they have a UOB greater than five percent (5%) because they spent drug rebates prior to drawing down grant funds?

No. According to section 2622(d) of the PHS Act, there is a specific exemption from the UOB penalties provision. This exemption applies when a RWHAP Part B recipient cannot obligate grant funds because pharmaceutical rebates must be spent first.

5. Must RWHAP Part B recipients formally request that HAB waive the UOB penalty when the UOB is due to the expenditure of rebates?

Yes. The RWHAP Part B recipient must include the statement in line 12, complete the "Ryan White Rebate Funding" section of the FFR in the HRSA Electronic Handbooks

(EHBs), and submit a carryover request through the HRSA EHBs within 30 days of submitting the FFR.

RWHAP Part B recipients who fail to request a carryover and note the need for an adjustment based on the drug rebate amount and have an UOB of five percent (5%) or greater will be subject to the full UOB penalty outlined in PCN 12-02, *Part A and Part B Unobligated Balances and Carryover Provisions*.

6. Are recipients expected to expend rebates prior to drawing funds from the payment management system (PMS) even though pharmaceutical rebate checks are received by RWHAP Part B ADAP recipients on an on-going basis?

Yes. The regulations found at 45 CFR § 75.305(b)(5) require all federally funded recipients, including states with an ADAP that is collecting rebates, to spend their available rebates prior to drawing down grant funds from the PMS. Once available rebates have been expended, recipients should spend grant funds. Recipients should not delay spending grant funds in anticipation of receiving rebates.

7. If a recipient uses rebates to fund a contract for services, does this count as spending the rebates prior to the grant award?

Yes. For additional information on the statutory requirements regarding UOBs see PCN 12-02, *Part A and Part B Unobligated Balances and Carryover Provisions*.