



October 21, 2016

**VIA FEDERAL EXPRESS**

James Macrae  
Acting Administrator  
Health Resources and Services Administration  
5600 Fishers Lane  
Room 13N-192  
Rockville, MD 20857

Re: Recent Notices on Program Income Issued by the Health Resources and Services Administration (HRSA)

Dear Mr. Macrae:

We write to express our concern over HRSA's conclusion that revenue generated by Ryan White grantees<sup>1</sup> furnishing 340B drugs is "program income" as defined by 45 C.F.R. Section 75.2, and subject to restrictions on how that revenue may be spent. We believe that HRSA's conclusion is internally inconsistent and contrary to federal law and regulation. Most importantly, these arbitrary restrictions hamper the ability of Ryan White providers to fully implement effective HIV/AIDS prevention, treatment, and adherence programs, undercutting the the goals of the National HIV/AIDS Strategy and our response to the HIV/AIDS epidemic. We respectfully request that HRSA immediately rescind any conclusion, guidance, or instructions that 340B revenue be considered program income.

RWC-340B is a coalition of HIV/AIDS medical providers receiving support under the Ryan White CARE Act. The 340B program is a lifeline for Ryan White clinics that enables them to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."<sup>2</sup>

**I. REVENUE FROM PHARMACY OPERATIONS IS NOT PROGRAM INCOME**

At the outset, it is helpful to precisely define exactly what "revenue" is at issue. HRSA contends that the difference between third party reimbursement and the 340B price for a drug is

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<sup>1</sup> In this letter, we are excluding state ADAP programs and focusing only on Ryan White grant recipients.

<sup>2</sup> H.R. REP. NO. 102-384(II), at 12 (1992).

program income. Our position is that neither the difference between the market price and the 340B price, nor the difference between the market price and third party reimbursement, is program income.

**a. Standard Pharmacy Revenue, Not Attributable To The 340B Program, Is Not Program Income.**

It should be a given that an entity can operate a pharmacy and/or provide pharmacy services regardless of whether it receives a Ryan White grant or whether such an entity participates in the 340B program. Neither receiving a Ryan White grant nor participating in the 340B program is a condition to operating a pharmacy or providing pharmacy services. Moreover, operating a pharmacy is not a condition of Ryan White funding; in fact, many Ryan White grantees do not provide pharmacy services.

Therefore, revenue generally derived from a standard pharmacy operation or transaction – *i.e.*, third party reimbursement for the drug, and a dispensing fee for filling the prescription – can in no way be attributed to either Ryan White or 340B. In a 340B transaction, the *only* revenue that can *arguably* be attributed to the 340B program is the difference between the 340B price of the drug, and the market price of the drug (the “discounted price”) – third party reimbursement above the market price of the drug is in no way part of or dependent on participation in the 340B program and is paid regardless of whether the transaction involves 340B or not.

As a result, the revenue attributable to the difference between third party reimbursement and the market price does not fit the regulatory definition of “program income,” because it is not revenue that is “directly generated by a supported activity or earned as a result of the Federal award.”<sup>3</sup> Again, an entity need not have a Ryan White or other federal grant, or participate in the 340B program, in order to engage in pharmacy services, nor does a Ryan White grantee have to provide pharmacy services. Therefore, the revenue attributable to the difference between third party reimbursement and the market price of a drug, which is in no way attributable to grant funding, cannot be characterized as program income.

**b. The 340B Price Reduction Is A Discount and Not Program Income.**

It is axiomatic that the difference between the market price for a drug and the 340B price is a discount. First, the practical effect of the 340B statute, which mandates a price lower than the price that regularly would be paid, is to provide a discount on the price of drugs. Moreover, the word “discount” is peppered throughout the statute. *See, e.g.*, 42 U.S.C. §§ 256b(a)(5)(A) and 256b(a)(10). HRSA itself, in its March 21, 2016 Frequently Asked Questions for PCNs 15-03 and 15-04 for Program Income (a copy of which is attached), expressly states in response to

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<sup>3</sup> We also assert that the 340B program itself, as a federal program enacted independently of the Ryan White Act, does not arise as a result of federal award, and is not subject to the rules around program income in the first place.

FAQ 6 that, “[t]he reduced 340B price a covered entity received on the purchase of a medication . . . is . . . a discount.”

Given that the only pharmacy revenue attributable to a 340B transaction is the reduced 340B price, and given that this reduced price is without question a discount, it is manifest that this reduced price does not constitute “program income” pursuant to 45 C.F.R. Section 75.2, as the definition of program income *expressly excludes discounts*. Specifically, that regulation states that “program income does not include rebates, credits, discounts. . . .” This is further confirmed by HRSA’s response to FAQ 6, wherein it states:

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

Program income does not include rebates, credits, discounts and interest earned on any of them. Specific examples include: . . . .

- The reduced price a covered entity received on the purchase of a medication; it is, instead, a discount.

HRSA’s determination that revenue attributable to the 340B discount is considered program income is contrary to HRSA’s own FAQ, and is in error.

As shown above, no part of a 340B pharmacy transaction fits the definition of program income. That 340B transactions are not contemplated by the program income definition is further buttressed by HRSA’s response to FAQ 2, regarding gross program income. HRSA states that the definition anticipates **gross** income because, in a transaction producing program income, the expenses normally would be deducted against the grant and there will be no expenses to net against the 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.* (Emphasis added)

As is apparent, this is completely different than a 340B transaction, as typically *none* of the costs or expenses associated with a pharmacy transaction – cost of drugs, cost of pharmacy, cost of pharmacy staff, pharmacy overhead, etc. – are charged to a Federal award. Virtually no Ryan White grant would allow for these types of direct pharmacy expenses to be charged as a grant cost. The 340B program is a square peg that does not fit into the program income round hole.

Given all this, it makes absolutely no sense that, in response to FAQ 4, HRSA states that program income includes “[t]he difference between the third party reimbursement and the 340B drug purchase price.” As stated above, the difference between third party reimbursement and the drug’s market price is in no way dependent on 340B, and is not revenue generated by a 340B transaction – it is revenue generated by any and every pharmacy transaction. In addition, HRSA concedes in FAQ 6 that the difference between the market price and the 340B price – the “reduced 340b price” – is a discount, and is not program income.

It also makes absolutely no sense that, in response to FAQ 5, HRSA flatly states that, “all 340B generated income is considered program income, and that, “all the [340B] program income should be attributed to the RWHAP grant.” This flies in the face of all that proceeds it, and all that HRSA itself concedes with respect to 340B revenue.

## **II. HRSA’s Conclusion That 340B Revenue Is Program Income Impermissibly Regulates The 340B Program.**

In determining that 340B revenue is program income, and in determining in PCN 15-03 (attached) that “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,” HRSA is purporting to define and restrict the ways in which 340B revenue may be used. However, as the federal courts have made clear, Congress’ delegation to HHS to regulate the 340B program is extremely limited, and extends only to the following areas:

1. The establishment of an administrative dispute resolution process;
2. The “regulatory issuance of precisely defined standards of methodology for calculation of ceiling prices; and
3. The imposition of monetary civil sanctions.

*See Pharmaceutical Research And Manufacturers Of America v. United States Department Of Health And Human Services*, Civil Action No. 13-501 (May 23, 2014 decision).

That extremely narrow delegation of regulatory authority simply does not encompass regulating how 340B entities may spend revenue generated by the 340B program. HRSA is without authority to dictate how 340B revenue may be spent.

Even if HRSA had authority to regulate how covered entities spend program income, it would be required to follow proper procedures to exercise that regulatory authority. Substantive rules must be published in the Federal Register, the public must be given an opportunity to comment upon their content and the agency must take those comments into consideration in issuing the final rule. 5 U.S.C. § 553(b), (c). A substantive rule promulgated without notice-and-comment rulemaking is invalid. 5 U.S.C. § 706(2)(D). The policies announced by HRSA in PCN 15-03 and the FAQs are clearly new policies, as evidenced by the fact that HRSA had to issue multiple FAQs to articulate its policies and that it has never audited

Ryan White clinics to enforce the policies. HRSA did not give Ryan White clinics or other stakeholders an opportunity to comment on these newly announced policies. Because HRSA did not follow proper procedural requirements, the policies are invalid.

### **III. HRSA's Policy Harms People With HIV/AIDS.**

The most frustrating part of HRSA's conclusion is that it arbitrarily restricts the uses to which HIV/AIDS organizations can put 340B revenue to best combat the epidemic. As is widely known, an unacceptably large proportion of people with HIV/AIDS are not linked to, and retained in, care or adherent to a medication regimen, which fuels the epidemic. There are many proven effective steps that can be taken to help these people remain in care, and/or protect themselves and others if they are not in care. HRSA's recent policies, however, would prevent HIV/AIDS organizations from using 340B income to take these steps. This simply is self-defeating, and perpetuates the epidemic for no rational reason.

For all of the foregoing reasons, HRSA's determination regarding the 340B program and program is internally inconsistent, unlawful, and detrimental to ending the HIV/AIDS epidemic. RWC-340B requests that HRSA immediately rescind its prior pronouncements on this matter, and instruct its grantees to treat 340B revenues as outside of program income.

### **IV. Conclusion**

For both the policy and legal reasons stated above, we urge HRSA to rescind all guidance and efforts attempting to classify revenue associated with the 340B program as program income. HRSA has ventured far outside of the regulatory definition of program income and has overstepped its authority to regulate the 340B program. If HRSA continues to press its misguided interpretation, the agency invites certain legal action by those entities adversely affected by its actions. Members of RWC-340B are available to further discuss our concerns at your convenience.

Sincerely,



Sara Dingwall, Pharm.D  
President  
RWC-340B

Cc: Laura W. Cheever, M.D., Sc.M. Associate Administrator, HIV/AIDS Bureau  
Nicholas Burton, Program Examiner, Public Health Branch, OMB  
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# 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 does not include 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 not 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 not 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 not 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*.

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

Policy Clarification Notice (PCN) #15-03

Relates to Policy #15-04

## **Scope of Coverage**

Ryan White HIV/AIDS Program (RWHAP) Parts A, B, C, D, and Part F where grants and cooperative agreements support HIV care and treatment services, training, special projects, and related activities that generate program income.

## **Purpose of PCN**

This notice articulates Health Resources and Services Administration (HRSA)/HIV/AIDS Bureau (HAB) policy regarding program income generated and received as a result of the receipt of a RWHAP award. It provides a definition of program income and guidance regarding its use and reporting requirements.

## **Background**

In the context of the RWHAP, program income is most commonly generated by recipients and subrecipients as a result of charging for services and receiving payment from third-party reimbursement. As the Affordable Care Act implementation continues, recipients and subrecipients may generate higher levels of program income. HAB provides this policy clarification notice regarding the use and reporting of program income as it relates to funds awarded through the RWHAP.

## **Definitions**

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.**<sup>1</sup>

Rebate: a return of a part of a payment.

Refund: an amount of money that is given back to someone who has returned a product, paid too much, etc.

## Instructions

### Use of Program Income

HAB is authorized to consider how program income is to be used and is authorized to make a distinction between income earned by the recipient and income earned by subrecipients.<sup>2</sup> HAB has determined that for RWHAP recipients and subrecipients, the use of program income will be “additive” (as documented in the Notice of Award.<sup>3</sup> RWHAP Part B recipients may also use non-Federal program income to meet matching requirements.<sup>4</sup>

Under the “additive” alternative, 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.

- For Parts A, B, and C, allowable costs are limited to core medical and support services, clinical quality management, and administrative expenses (including planning and evaluation) as part of a comprehensive system of care for low-income individuals living with HIV.<sup>5</sup>

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<sup>1</sup> 45 CFR § 75.2 (emphasis added).

<sup>2</sup> 45 CFR § 75.307(e).

<sup>3</sup> 45 CFR § 75.307(e)(2).

<sup>4</sup> 45 CFR § 75.307(e)(3). See also section 2617(d)(2)(A) of the Public Health Service (PHS) Act.

<sup>5</sup> Sections 2604(a)(2), 2612(a), and 2651(b)(1) of the PHS Act.

- For Part D, allowable costs are limited to family-centered care involving outpatient or ambulatory care, support services, clinical quality management, and administrative expenses for low-income women, infants, children, and youth affected by or living with HIV.<sup>6</sup>
- For Part F, allowable costs are limited according to the appropriate statutory provision.<sup>7</sup>
- Program income may be utilized for elements of the program that are otherwise limited by statutory provisions, such as administrative and clinical quality management activities that might exceed statutory caps, or unique services that are needed to maintain a comprehensive program approach but that would still be considered allowable under the award.

Under the uniform administrative requirements, 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.<sup>8</sup>

- Recipients and subrecipients should strive to proactively secure and estimate the extent to which program income will be accrued. This should be done to effectively determine the need for RWHAP funds and their allocation and utilization during the current period of performance.
- The statutory exemption from Unobligated Balance (UOB) penalties for Part B recipients that expend rebate dollars before requesting additional grant RWHAP funds does not extend to UOBs accrued as a result of expending program income.<sup>9</sup>

## Documentation and Reporting of Program Income

Recipients are required to track and account for all program income in accordance with 45 CFR § 75.302(b)(3). Recipients must report program income on their Federal Financial Report (FFRs).<sup>10</sup>

<sup>6</sup> Sections 2671(a), (b), and (f) of the PHS Act.

<sup>7</sup> Sections 2691-2693 of the PHS Act.

<sup>8</sup> 45 CFR § 75.305(b)(5).

<sup>9</sup> For additional information on Rebates, see PCN 15-04.

<sup>10</sup> See FFR screenshot:

Program Income:	
I. Total Federal share of program income earned	
m. Program income expended in accordance with the deduction alternative	
n. Program income expended in accordance with the addition alternative	
o. Unexpended program income (line I minus line m or line n)	

Additionally, it is the responsibility of the recipient to monitor and track program income earned 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.

Documentation of program income and accounting for its receipt and utilization will be consistent across Parts, to the extent possible.

- a. Parts A and B have a legislatively mandated one-year period of performance and are non-discretionary grants to be awarded each fiscal year.
  - i. For Parts A and B, program income for a service provided within one period of performance may be received in the following period.
  - ii. Such program income should be accounted for and utilized in the year in which it is received by the program,<sup>11</sup> as the services funded are identical and it is burdensome to revise final FFRs, particularly after a new award has already been issued.
  - iii. Program income received at the end of the period of performance will be expended by the recipient prior to the expenditure of new grant RWHAP funds awarded in the subsequent period.
- b. Parts C, D, and F are discretionary awards and have multi-year periods of performance.
  - i. Parts C, D, and F recipients must account for program income and its use within their multi-year period of performance.
  - ii. In the final year of funding, program income received at the end of the period of performance will be expended prior to new grant RWHAP funds awarded in the next competitive cycle, so long as the recipient receives such subsequent award.

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<sup>11</sup> **Insurance refunds** must be credited against insurance costs in the year the refund is received pursuant to 45 CFR § 75.447(e).