

THE EFFI BARRY TRAINING INSTITUTE

Compliance Cornerstones of 340B Drug Pricing Programs

Rita Baskett, RPh, CEO
Integrated Pharmacy Services, Inc.

Effi Barry HIV/AIDS Institute

This program is funded wholly, or in part, by the Government of the District of Columbia, DC Health, HIV/AIDS, Hepatitis, STD, and TB Administration (HAHSTA).

Learning Objectives

- Describe the 340B Drug Pricing Program
- Discuss eligibility requirements and compliance of operating a 340B program
- Discuss HRSA/OPA auditing parameters and findings
- Review key steps to maintaining a compliant 340B program

340B Basics

- Created by the Veterans Healthcare Act in 1992: coded section 340B of the Public Health Service Act
- Administered/managed by the Office of Pharmacy Affairs (OPA) within the Health Resources and Services Administration (HRSA)
- The purpose of the 340B program is to enable safety-net entities to stretch scarce federal resources, reaching more eligible patients and providing more comprehensive services
- Requires drug manufacturers participating in Medicaid and/or Medicare Part B to sell “covered *outpatient* drugs” to “covered entities” at discounted prices

Who is eligible to participate in 340B?

- Federally-qualified health centers (FQHC) and FQHC look-alikes
- Family planning project receiving a grant or contract
- **Ryan White and State-operated AIDS Drug Assistance Program (ADAP), TB, STD clinics**
- Black lung clinic
- Hemophilia diagnostic treatment center
- Native Hawaiian health center
- Native American/Indian organization
- Disproportionate share hospital (DSH)*
- Critical access hospital (CAH)*
- Children's hospital*
- Free-Standing cancer hospital*
- Rural referral center*
- Sole community hospital*

Which patients are eligible for 340B?

An individual is a "patient" of a covered entity only if:

- The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; **and**
- The individual receives health care services from a health care professional who is either *employed by the covered entity or provides health care under contractual or other arrangements* (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; **and**
- The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

<https://www.340bpvp.com/resource-center/faqs/patient-definition/>

Program Requirements

To purchase drugs at the 340B price, covered entities must meet the following ongoing requirements:

1. **Keep 340B OPAIS information accurate and up to date.** Register new outpatient facilities and contract pharmacies as they are added.
2. **Recertify eligibility** every year.
3. **Prevent diversion to ineligible patients.** Covered entities must not resell or otherwise transfer 340B drugs to ineligible patients.
4. **Duplicate Discount Prohibition.** Manufacturers are prohibited from providing a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must accurately report how they bill Medicaid fee-for-service drugs on the Medicaid Exclusion File, as mandated by 42 USC 256b(a)(5)(A)(i).
5. **Prepare for program audits.** Maintain auditable records documenting compliance with 340B Program requirements. Covered entities are subject to audit by manufacturers or the federal government. Any covered entity that fails to comply with 340B Program requirements may be liable to manufacturers for refunds of the discounts obtained.

District of Columbia Medicaid Requirements

- Drugs submitted using 340B need to be identified with a NCPDP (National Council for Prescription Drug Programs) claim identifier
- 340B contract pharmacies should exclude Medicaid FFS (fee for service) claims

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Audits

HRSA Audits:

- The Bizzell Group won HRSA government contract Oct 2016
 - Contract for 3 years with 2 years optional renewal
- Audit Focal Points:
 - Diversion (pricing diversion)
 - Duplicate Discount
 - (A) Prohibiting duplicate discounts or rebates (i) In general A covered entity shall not request payment under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] for medical assistance described in section 1905(a)(12) of such Act [42 U.S.C. 1396d(a)(12)] with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act [42 U.S.C. 1396r-8]
 - Registration Information
 - Eligibility Documentation
 - Contract Pharmacy Oversight

Audit Focal Points

- **Diversion (pricing diversion)**
 - Non-eligible patient receiving a 340B priced drug
- **Duplicate Discount**
 - Medicaid state receives rebate or covered entity receives 340B Price
 - Regulated by state laws
 - Carve-in/Carve-out status
 - ***HRSA cannot audit for Medicaid MCO Plans, only Medicaid FFS***
- **Registration Information**
 - Incorrect 340B database record
 - Wrong names of Authorizing Officials
 - Wrong addresses
 - Unregistered child sites
 - Wrong Medicaid or NPI numbers
 - Incorrect shipping address, or shipping address not listed
 - Inactive contract pharmacies

Audit Focal Points Cont.

- **340B Purchasing Diversion**
 - Buying/replenishing without proper dispensations
 - Penny buys
- **Lack of Oversight**
 - No self-auditing of contract pharmacies
 - No independent audits (recommended)
 - Will have you de-register your contract pharmacies
 - Loss of revenue until CAP (Corrective Action Plan) is approved
- **ULTIMATE RESPONSIBILITY LIES WITH THE COVERED ENTITY**

Audit Findings Examples

Diversion:

- 340B drugs dispensed at contract pharmacies for prescriptions originating from ineligible sites
- 340B drugs dispensed at a contract pharmacy for prescription originating from ineligible site, not supported by medical record; Entity did not have adequate controls in place for proper accumulation and prevention of diversion
- 340B drugs dispensed at an ineligible site
- 340B drugs were not properly accumulated

Audit Findings Examples Cont.

Duplicate Discount:

- Inaccurate or incomplete information in the Medicaid Exclusion File
- Entity was billing Medicaid contrary to information included in the Medicaid Exclusion File
- Entity was billing at contract pharmacies without notifying HRSA of an arrangement with contract pharmacy, the entity and the State Medicaid agency
- Entity did not have controls in place to prevent duplicated discounts

Audit Findings Examples Cont.

Incorrect Database Record:

- Offsite outpatient facilities were not listed on the 340B database
- Entity improperly registered a repackager as a contract pharmacy
- Registered contract pharmacy without written contract in place; Utilized contract pharmacies prior to registering on the 340B database
- Incorrect entry for a shipping address

Audit Findings Examples Cont.

Lack of Oversight:

- Entity did not provide contract pharmacy oversight
- **Sanction:**
 - Termination of contract pharmacies from 340B program
 - Repayment to manufacturers

Sanctions and Corrective Action Plan (CAP)

- **Sanction:**

- Termination of contract pharmacy(ies)
- Repayment to manufacturer
 - HRSA leaves repayment issues between covered entity and manufacturer

- **Corrective Action Plan:**

- Written statement on corrective action to prevent error of occurring again
- Has to be approved by HRSA

Audits Cont.

PhRMA Audits:

- Must be approved by HRSA
- Audit Focus:
 - Section 340B(a)(5)(A) of the PHS Act- **PROHIBITING DUPLICATE DISCOUNTS OR REBATES**—A covered entity shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act; and
 - Section 340B(a)(5)(B) of the PHS Act – **PROHIBITING RESALE OF DRUGS**—With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person **who is not a patient of the entity**. Section 340B(a)(5)(C) of the PHS Act requires covered entities to permit a manufacturer to determine if a covered entity is complying with section 340B(a)(5)(A) and (B) of the PHS Act.

<https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/manufacturerauditclarification112111.pdf>

Maintaining a Compliant 340B Program

Policy and Procedures:

- Eligibility
- Prevention of Duplicate Discount
- Oversight
- 340B Committee
- Inventory Management
- Internal Auditing
- External Auditing

QUESTIONS?

Contact

Shayna Linov

HealthHIV

shayna@healthhiv.org

THE EFFI BARRY TRAINING INSTITUTE

340B Contract Pharmacy Relations: Best Practices

Rita Baskett, RPh, CEO
Integrated Pharmacy Services, Inc.

Effi Barry HIV/AIDS Institute

This program is funded wholly, or in part, by the Government of the District of Columbia, DC Health, HIV/AIDS, Hepatitis, STD, and TB Administration (HAHSTA).

Learning Objectives

- Describe 340B basics (eligibility and registration)
- Discuss contracting model with retail pharmacies
- Discuss complexities in compliance
- Review how to maintain a compliant contract pharmacy program

340B Basics

Steps for Enrollment

- Determine eligibility (<http://www.hrsa.gov/opa/eligibilityandregistration/>)
- Complete appropriate forms
- Register during quarterly open enrollment periods

Register

- January 1-15
- April 1-15
- July 1-15
- October 1-15

Start Date

- April 1
- July 1
- October 1
- January 1

- Office of Pharmacy Affairs (OPA) verifies registration data and eligibility
- Await decision from OPA

Contract Pharmacy

- March 2010: Expansion of contract pharmacy by HRSA/OPA
 - From one contract pharmacy to multiple contract pharmacies
- Signed contract in place prior to registration
- Covered entity develops a “ship to-bill to” model for 340B drugs
 - “Ship to” address registered on OPA website

Contract Pharmacy Agreements

Written agreement between covered entity and retail pharmacy:

- Business agreement language
- Eligibility
- Location of contract pharmacy
- Fee schedule
 - Brand-only model vs. generics
- Inventory reconciliation

340B Policies and Procedures

Policy and Procedures:

- Determination of eligibility
- Contract pharmacy locations
- Prevention of duplicate discount
- Inventory management
 - Ordering, reconciliation, “true-ups”
- Internal auditing
- External auditing
- Oversight/340B committee

340B Margin

- Patient is determined to be a patient of the covered entity.
- Prescription determined to have been written by physician of the covered entity.
- Prescription originated at a registered location.

Patient Fills Rx at Contract Pharmacy

Contract Pharmacy Bills Insurance

- Amount of \$200.00 is paid to pharmacy for #30, Drug Y Tablets.
- Contract Pharmacy agrees to accept \$20 dispensing fee from covered entity.

- Contract Pharmacy pays Covered Entity \$180.00.
- Contract Pharmacy places order on Covered Entity's 340B Wholesaler account to Replenish #30, Drug Y 10 mg Tablets.
- Cost at 340B pricing is \$50.00
- Total revenue returned to hospital is \$130.00 for the transaction.

Covered Entity Reimbursed by Contract Pharmacy

Inventory Management

Contract Pharmacy Software (virtual inventory)

Prescription Claim Processed at Contract Pharmacy

Patient demographic data and drug data sent to 3rd party switch.



340B Software

Receives switch data.

Determines patient relationships to covered entity.

Determines eligible provider.

Perpetually tracks opportunity for replenishing stock for the retail pharmacy.

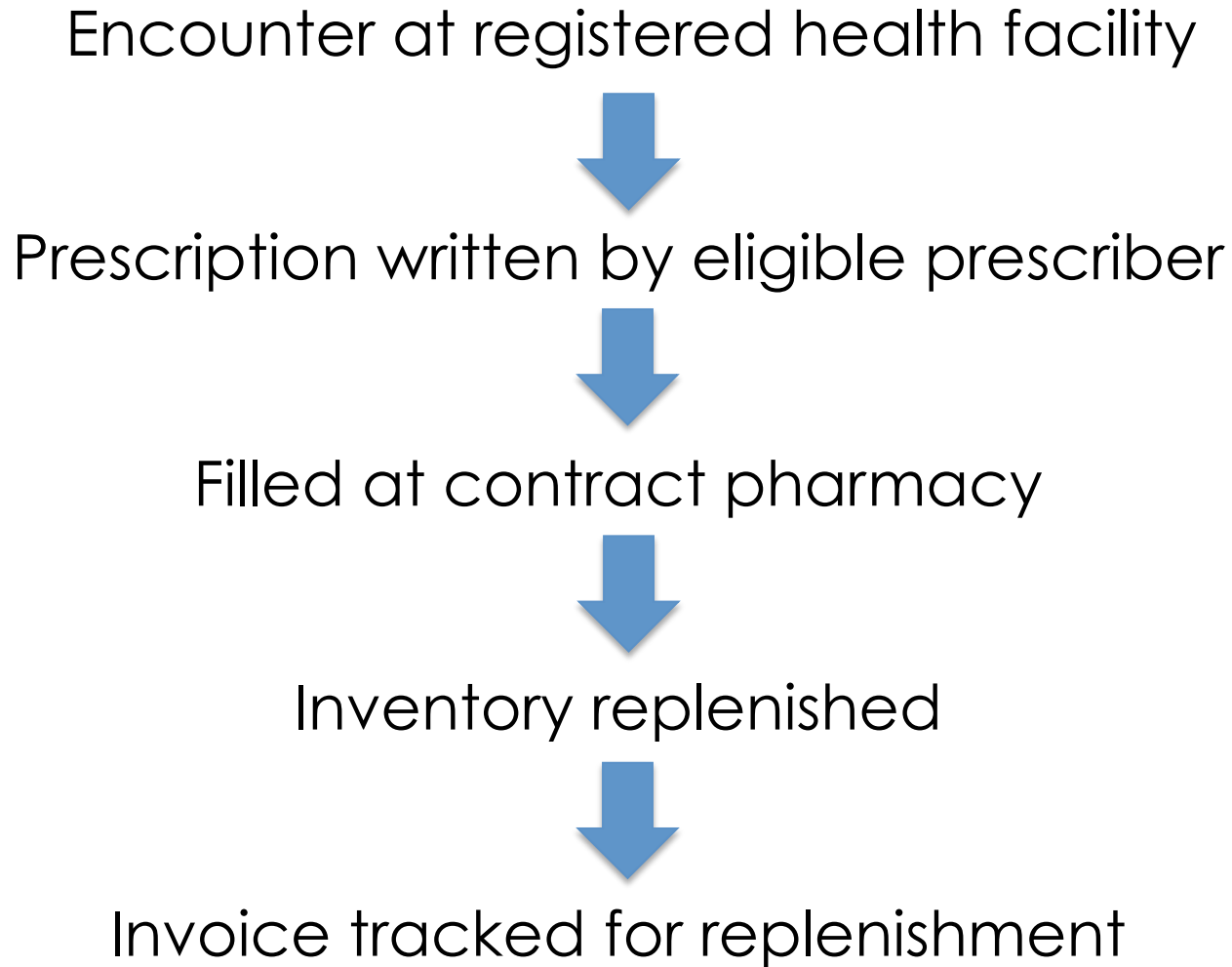
Provides financial transaction framework for reimbursing contract pharmacy and CE.

Inventory Management Cont.

Physical Inventory:

- Physically separate stock/shelves in pharmacy
- National Drug Code (NDC) level spreadsheets to track inventory used
- Monthly inventory reconciliation to invoices

340B Universe



Auditing

- HRSA/OPA expects **quarterly** self-audits
 - Prescription Audit
 - Eligibility test (Encounter, Prescriber)
 - Insurance test (Duplicate Discount)
 - Inventory test (Replenishment)
 - Inventory Audit
 - Pull 20 unique National Drug Codes
 - Verify inventory quantities (ordered vs dispensed)
- HRSA/OPA expects **annual** external audit

HRSA Audit Finding

Lack of Oversight:

- Entity did not provide contract pharmacy oversight
- **Sanction:**
 - Termination of contract pharmacies from 340B Program
 - Repayment to manufacturers

QUESTIONS?

Contact

Shayna Linov

HealthHIV

shayna@healthhiv.org

THE EFFI BARRY TRAINING INSTITUTE

Maximizing 340B Income for Ryan White Program Advancement

Effi Barry HIV/AIDS Institute

This program is funded wholly, or in part, by the Government of the District of Columbia, DC Health, HIV/AIDS, Hepatitis, STD, and TB Administration (HAHSTA).

Learning Objectives

- Describe 340B program intent and define 340B program income
- Identify allowable and unallowable uses of program income for Ryan White recipients and subrecipients
- Determine opportunities to use 340B income to fill gaps in service delivery for Ryan White patients

340B Program Intent

Permits covered entities “to stretch scarce federal resources as far as possible, reaching more patients and providing more comprehensive services.”

<https://www.hrsa.gov/opa/index.html>

340B Opportunity

Provides additional services and/or extends the reach of existing services to improve health outcomes.

Program Income

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

45 CFR 75.2

PCN 15-03

340B Savings as Program Income

- All 340B generated revenue is considered program income
- When the Ryan White grant is the sole federal award that makes an organization eligible as a 340B covered entity, all program income should be attributed to the Ryan White program
- “When an entity is 340B eligible and purchases pharmaceuticals via 340B pricing under multiple awards, the recipient must use reasonable allocation method for the attribution of costs and program income, and be able to document the methodology used.”

Frequently Asked Questions for Policy Clarification Notices 15-03 and 15-04
HRSA/HAB

340B Savings as Program Income: Example # 1

1. Patient receives HIV medical care from the Healthy Clinic which is a Ryan White C & D recipient
2. Patient's provider writes a script for a medication
3. Patient takes the script to the Healthy Clinic's 340B pharmacy (registered based on the clinic's Ryan White funding)
4. The 340B price (discount) for the medication is \$5
5. Patient does not have insurance so s/he (or Healthy Clinic) pays the full 340B price for the medication (\$5)
6. There is no program income generated from this transaction

340B Savings as Program Income: Example #2

1. Patient receives HIV medical care from the Healthy Clinic which is a Ryan White Part C recipient
2. Patient's provider writes a script for a medication
3. Patient takes the script to the Healthy Clinic's 340B pharmacy (registered based on the clinic's Ryan White funding)
4. The pharmacy orders the medication from an approved 340B supplier at \$500 and bills the patient's insurance
5. The insurance company reimburses the pharmacy \$1,100
6. The Healthy Clinic pays the manufacturer/distributor \$500 for the medication
7. The Healthy Clinic keeps \$600 as the 340B revenue, which is tracked as program income and reinvested into the clinic's Ryan White program

Spending Program Income

For Ryan White recipients/subrecipients:

- Program income must be spent within the period of the federal award (varies by Ryan White Part)
- Programs must spend program income within the grant cycle that it is received
- Program income must be spent before additional grant funds are drawn down

Spending Program Income

Support activities in excess of caps imposed by Ryan White:

- Program income may be used to support activities in excess of a cap that is imposed directly by Ryan White
- Examples include: administrative costs (10%), clinical quality management, and indirect costs

Frequently Asked Questions for Policy Clarification Notices 15-03 and 15-04
HRSA/HAB

Methods for Tracking Program Income

- Program income cannot be attributed solely based on the size of the award
- Allocation could be based on:
 - The **client** that received the service (use client level data to track service)
 - The **service** category and associated payer/funding source
 - The **provider** (based on supported time)

Methods for Tracking Program Income

Possible billing system modifiers:

- Patient diagnosis code (HIV)
- Medication type (ART)
- Ryan White-specific provider
- Location code (Ryan White clinic-specific code)
- Payer source
- Secondary or tertiary insurance code to identify Ryan White-eligible/enrolled patients

Tracking Program Income by Provider

- Service assignment and associated program income is based on the funding source of the person providing services and the eligibility criteria of the patient.
- If a provider is funded fully by one Ryan White Part:
 - Then 100% of patients served by that provider should be eligible and enrolled in the sole funding source
 - And all program income would be attributed to the sole funding source

Tracking by Provider: Example

- Physician provides medical care 2 days/week at Healthy Clinic
- 100% of the physician's time at Healthy Clinic is funded by the Ryan White Part A program
- All program income generated by this physician at Healthy Clinic is tracked and attributed to the Ryan White Part A program

(cont'd)

Tracking by Provider: Example

- If the physician is funded by multiple awards, then criteria used to determine where program income is allocated should be applied to the patients served:
 - Physician is funded by Part B and D based on the percentage of PLWH served that meet the WICY (women/infants/children/youth) definition
 - Program income should be calculated similarly

Spending Program Income

- Implication: Program income from 340B reimbursements expands the budget of the program
- Include program income projections when planning for services based on comprehensive HIV care and prevention needs of the service area

Program Income as “Additive”

- Program income is ‘additive’ to grant funds and “used to further eligible project or program objectives” (it expands the program budget)
- Program income is added to the grant award but may only be used:
 - For **allowable costs** under the award to expand the program and to further the objectives of the Ryan White program

Allowable Expenses

- For Ryan White recipients (A, B, and C), allowable expenses are limited to:
 - Core medical services
 - Support services
 - Clinical quality management (CQM)
 - Administrative expenses (including planning & evaluation) as part of a comprehensive system of care for low-income individuals living with HIV

Allowable Expenses

- For **Part D**, allowable costs are limited to services to women, infants, children and youth affected by or living with HIV:
 - Family centered care involving outpatient or ambulatory care
 - Support services
 - CQM
 - Administrative expenses
- **Part F** costs are limited according to appropriate statutory provision:
 - AIDS Education and Training Center
 - Special Projects of National Significance
 - Dental Reimbursement Program
 - Minority AIDS Initiative

Utilizing Program Income

- Program income can support allowable activities in excess of statutory caps that are imposed directly by the Ryan White program, such as:
 - Administrative costs (10%)
 - Indirect Costs
 - CQM
 - Core Medical (75%)
 - EIS (50%)

Unallowable Uses of Program Income

Staff Salaries:

Ryan White recipients and subrecipients may not use award funds or program income to pay the salary of an individual at a rate higher than Executive Level II, currently at \$189,600 as of January 7, 2018

Frequently Asked Questions for Policy Clarification Notices 15-03 and 15-04
HRSA/HAB

Unallowable Uses of Program Income

- Dr. Clayton makes an organizational salary of \$213,000
- She provides medical services to low-income people living with HIV for two clinic sessions a week (0.2 FTE)
- Dr. Clayton's salary on the Ryan White Part A grant is capped at \$189,600, or \$37,920 based on FTE (0.20 FTE)
- The real organizational cost of Dr. Clayton's salary at 0.2 FTE is \$42,600 ($\$213,000 \times 0.20$ FTE)
- Program income can not be used to pay for the \$4,680 difference ($\$42,600 - \$37,920$)

Dr. Clayton	Salary	FTE	Salary Support
Organizational	\$213,000	0.20	\$42,600
Executive Level II	\$189,600	0.20	\$37,920
Difference	\$23,400	0	\$4,680

Unallowable Uses of Program Income

- Construction and/or major alteration or renovation
- Cash payments to recipients of Ryan White services
- HIV “related” but unallowable services under Ryan White:
 - Needle/syringe exchange
 - Post- or pre-exposure prophylaxis (PEP or PrEP) medications or medical services
 - In-patient or emergency related expenses for people living with HIV

Utilizing Program Income

- Program income must be spent within the performance period that it is **received**
- Ryan White Parts A and B have one-year performance periods
- Parts C, D, and F have multi-year performance periods

Budgeting with Program Income

- Program income generated by a Ryan White eligible client must be used on Ryan White allowable costs
- However, program income is not directly federal funds, therefore:
 - Funds can be used for services that are allowable, but are not in the grant budget
 - Can be used expand the scope of services

Spending Program Income

Consider the HIV care continuum in your agency or service area:

- What kind of services would help increase linkage to care?
- What kind of services would help increase retention in care?
- What kind of services would help increase viral suppression rates?

Spending Program Income

Review Policy Clarification Notice 16-02 to consider possible services that can be funded under the Ryan White program

Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds

*Policy Clarification Notice (PCN) #16-02 (Revised 12/05/16)
Replaces Policy #10-02*

Scope of Coverage: Ryan White HIV/AIDS Program (RWHAP) Parts A, B, C, and D, and Part F where funding supports direct care and treatment services.

Spending Program Income

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

Yes. “Program income may be used to pay for any medically-necessary services that Medicaid does not cover, or only partially covers, as well as premiums, copays, and any deductibles otherwise allowable under Ryan White.”

Frequently Asked Questions for Policy Clarification Notices 15-03 and 15-04
HRSA/HAB

Tracking Program Income

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

“Recipients should require financial and performance reports necessary to ensure that the subaward, and any income generated by it, is used for authorized purposes...”

(Include: identification of awards received and expended, and source / application of funds for federally-funded activities)

Budgeting Program Income

- 340B program income should be included in projections and budget tracking
- Budget program income to compliment, not replicate services already funded directly by Ryan White grant funds
- Develop a plan to spend 340B program income to not have unobligated balances

Key Takeaways

- 340B program income expands the budget of the Ryan White program
- All revenue generated from 340B is considered program income
 - And all 340B revenue earned as a result of the Ryan White program is Ryan White program income
- Program income must be tracked by the recipient/subrecipient and used to advance the objectives of the program

QUESTIONS?

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HealthHIV

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