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| <p>District of Columbia Department of Health Ryan White Care and Treatment Division Policy:</p> <p>Program Income</p> | | <p>Policies and Procedures Implementing office: HAHSTA Care and Treatment Division Ryan White HIV/AIDS Program</p> <p>Training required: Yes</p> <p>Originally Issued: March 10, 2022</p> <p>Revised/Reviewed: 9/14/23</p> |
| <p>Program Approval:</p>  <p>_____ Ebony Fortune Ryan White Program Manager</p> | <p>Recipient Authorization:</p>  <p>_____ Avemaria Smith Ryan White Recipient</p> | <p>Effective Date: March 10, 2022</p> <p>Valid Through Date: September 30, 2024</p> |
| <p>I. SUBJECT Program Income and 340B Program</p> | | |
| <p>II. PURPOSE The purpose of this policy is to delineate the processes required for the successful billing and documentation of income earned through the Ryan White Program and 340B Program. This document articulates the guidance and expectations for generating program income resulting from a program supported, whole or in part, by Ryan White Parts A, B funding and participation in 340B drug pricing programs. This policy is provided in accordance with the requirements of the Ryan White HIV/AIDS Program Title XXVI of the Public Health Service Act enacted in 1990 and amended in 2009 and 340B Drug Pricing Program. This policy defines program income and explains its use and reporting requirements.</p> | | |
| <p>Section A: Program Income per implementation of Ryan White Parts A and B Programs “Program income” means gross income earned by the non-Federal entity that is directly generated by a supported activity or earned because 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. https://hab.hrsa.gov/sites/default/files/hab/Global/pcn_15-03_program_income.pdf</p> | | |
| <p>III. Definitions and Acronyms</p> | <p>Sec. 340B PUBLIC HEALTH SERVICE ACT: LIMITATION ON PRICES OF DRUGS PURCHASED BY COVERED ENTITIES</p> <p>340B Drug Pricing – Is a federal drug pricing program that allows qualifying hospitals and clinics that treat low-income and uninsured patients to buy outpatient prescription drugs at a discount of 25 percent to 50 percent. 340B drug pricing enables covered entities to</p> | |

stretch scarce federal resources as far as possible, reaching more eligible customers and providing more comprehensive services.

AIDS Drugs Assistance Program (ADAP) - The AIDS Drug Assistance Program (ADAP) operates in the District of Columbia and in all 50 states, Guam, Northern Mariana Islands, Puerto Rico, and the Virgin Islands. The program is authorized under Title II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act and provides HIV-related prescription drugs to under-insured and uninsured individuals living with HIV/AIDS.

Contract Pharmacy –an entity that is licensed and authorized to provide Pharmacy Services to customers located in the District of Columbia, that has entered into an Agreement with the Covered Entity to dispense 340B Covered Drugs to Customers.

Customer – A person living with HIV/AIDS who is uninsured or under-insured and meets the eligibility criteria as defined by the EMA in which services are sought. For specifics on eligibility criteria, refer to the Ryan White Enrollment and Eligibility policy.

Eligible health care organizations/covered entities - are defined in statute and include HRSA-supported health centers and look-alikes, Ryan White clinics and State AIDS Drug Assistance programs, Medicare/Medicaid Disproportionate Share Hospitals, children’s hospitals, and other safety net providers.

Federal Financial Report (FFR) - a statement of expenditures associated with a grant. Recipients of federal funds are required to report the status of funds for grants or assistance agreements to the sponsor of the grant using the Federal Financial Report expenditure data. The report must be submitted for each budget period no later than 90 days after the end of the calendar quarter in which the budget period ends.

Federal Poverty Level (FPL) - A measure of income issued every year by the Department of Health and Human Services (HHS). Federal poverty levels are used to determine eligibility for certain programs and benefits, including savings on Marketplace health insurance, and Medicaid and CHIP coverage.

Office of Pharmacy Affairs Information System (OPAIS) - The new 340B Office of Pharmacy Affairs Information System (340B OPAIS) replaced the legacy 340B Database in its entirety and includes security updates and enhancements for covered entity/manufacture registrations, change requests, recertification, and other updates.

Ryan White HIV/AIDS Program - The program funded by the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. A Federal legislation created to address the health care and supportive service needs of people living with HIV/AIDS (PLWHA) and their families in the United States and its territories. The law emphasizes providing lifesaving and life-extending services for people living with HIV/AIDS.

Sub-recipient - A Non-Federal entity that expends Federal awards (from HRSA) received from a pass-through entity (like DC Health) to carry out the Federal (Ryan White) program by providing direct services to customers and their families or to the grantee. Sub-recipients do not include an individual that is a beneficiary of such a program. A

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| | <p>subrecipient may also be a grant recipient of other Federal awards directly from a federal awarding agency.</p> <p>Third Party Revenue Capture- third party revenue capture for prescription medication reimbursement from a pharmaceutical manufacturer(s) for eligible 340B prescription claims submitted on behalf of a covered entity by a contract pharmacy.</p> |
| <p>IV. Policy Requirements Program Income Source Citation 45 CFR 74.24 and 92.25. PHS ACT 2617 (b) (iii) Part A Program Guidance</p> | <p>Program income is revenue generated by sub-recipients because of the Ryan White grant. This includes reimbursement/payments for services provided to self –pay or sliding fee customers, Medicaid, Medicare, private insurance, and other third-party sources. Typically, sub-recipients charge for services and receive reimbursement for third-party billing. Sub-recipients generating program income must keep records documenting the amount and disposition of any income received as a direct result of income/expenditure and the source of funds. All program income generated by customers with HIV must be used to benefit the HIV program.</p> |
| <p>Documentation and Reporting of Program Income (Bill, Track & Report Program Income) 45 CFR Part 74.14</p> | <p>The sub-recipient will bill, track, and report quarterly to the Recipient all program income billed and obtained (see attached template for reporting).</p> <p>Charges to customers with incomes greater than 100% of the federal poverty level (FPL) are determined by the schedule of charges. Annual imposition of charges for Ryan White services, including ADAP, are based on percent of customer’s annual income, as follows:</p> <ul style="list-style-type: none"> • 5% for customers with incomes between 100% and 200% of FPL • 7% for customers with incomes between 200% and 300% of FPL • 10% for customers with incomes greater than 300% of FPL • A nominal fee can also be imposed. <p>Note: DC EMA has a 500% FPL for all services in all the jurisdictions in the EMA</p> |
| <p>Allowable uses of Program Income 92.25 2 CFR and 45 CFR 74.24</p> | <p>The sub-recipient’s retention of program income derived from Ryan White funded services and use of such funds may include the following:</p> <ul style="list-style-type: none"> • Funds added to resources committed to the project or program and used to further eligible project or program objectives. • Funds used to cover program costs. • Program income funds will not be subject to the federal limitations on administration (10%), quality management (5%), or core services (75%). |
| <p>Monitoring Program Income By Recipient PHS ACT 2617 (b) (iii) 45 CFR 74.24 and 92.25</p> | <p>HAHSTA will monitor the sub-recipient's compliance with the program income policy during comprehensive site visits. The monitoring team will review the following:</p> <ul style="list-style-type: none"> • Sub-recipient’s policy for schedule of charges to ensure that clients with incomes below 100% of the FPL are not charged for services. • Sub-recipient’s customer eligibility determination application to ensure consistency with policies and federal requirements. • Sub-recipient’s comprehensive written policies and procedures on: |

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| | <ul style="list-style-type: none"> ○ How the organization tracks program income by the activity that it was generated from. ○ How the program income is being used. ○ Retroactive insurance changes and billing implications ○ Back billing policy ○ Pursuit of retroactive Medicaid/Medicare services if the client is eligible for Medicaid assistance and how they document it. ○ How to reconcile with the Ryan White Parts A/MAI and B once retroactive claims have been paid. <ul style="list-style-type: none"> ● Sub-recipient’s system of tracking program income. ● Sub-recipient’s program income generated by Ryan White program funds on a quarterly basis from: <ul style="list-style-type: none"> ● Self –pay sliding fee customers. ● Medicaid ● Medicare ● Private insurance ● Other third-party sources ● Sub-recipients will generate reports using the program income template (See attached), ● Sub-recipient’s expenditure reports on collection and use of program income. ● Sub-recipient’s program income budget illustrating the use of program income. Note that this budget is due 30 days after the grant start date. ● Sub-recipient’s medical practice management system to obtain reports of total program income derived from Ryan White services. <p>Note: HAHSTA will not report sub-recipient aggregate program income in the federal financial report (FFR) and annual data report to HRSA.</p> |
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SECTION B: 340B Program

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| <p>340B Program Income</p> | <p>340B Contract Pharmacy Agreements and Arrangements</p> <p>Per Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services,’ (61 FR 43549) and any individual correspondence issued by HRSA on the subject. (1) Basic Compliance Issues in Utilization of Pharmacy Services Contracts. A covered entity that wishes to utilize contract pharmacy services to dispense section 340B outpatient drugs must have a written contract in place between itself and a specified pharmacy. A single covered entity that has more than one 340B eligible site at which it provides health care may have individual contracts for each such site or include multiple sites within a single pharmacy services contract. This mechanism is designed to facilitate program participation for those covered entities that do not have access to available or appropriate “in-house” pharmacy services, those covered entities that have access to “in-house” pharmacy services but wish to supplement these services; and covered entities that wish to utilize multiple contract pharmacies to increase customer access to 340B drugs.</p> |
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| | <p>The covered entity has the responsibility to: Ensure against illegal diversion and duplicate discounts; maintain readily auditable records; and meet all other 340B Drug Pricing Program requirements (See 340 B Program Requirements) HRSA has provided essential covered entity compliance elements below as guidance for the type of contractual provisions expected in such agreements.</p> <p>Contract Pharmacy Requirements:</p> <ul style="list-style-type: none"> • Must complete 340B Registration 340 B Contract Pharmacy Registration • Covered entities that utilize contract pharmacies must register with each pharmacy. • Must have a contract in place prior to registration. • Register during the quarter of open registration. • Information must be accurate. <p>Registration Periods</p> <ul style="list-style-type: none"> • October 1-15, January 1-15, April 1-15, July 1-15 |
| <p>45 CFR 74.24 and 92.25.PHS ACT 2617 (b) (iii)</p> | <p>The Covered Entity is responsible for:</p> <ul style="list-style-type: none"> • Ensuring program integrity • Prevention of diversion and duplicate discounts • Ensuring the prescription cannot be Medicaid eligible. • Preparing for program audit <p>All covered entities utilizing a contract pharmacy must comply with the certification requirements. See 92.25 2 CFR and 45 CFR 74.24</p> <p>DISCLOSURE NOTICE <i>All sub-recipients shall disclose to HAHSTA all 340B contract pharmacy arrangements and their statuses with OPA (Office of Pharmacy Affairs) within 15 business days of receipt of the Ryan White grant award.</i></p> <p>The letter is to be addressed to the program officer, must be on the organization’s letterhead and include the following:</p> <ol style="list-style-type: none"> 1. Contract pharmacy participation 2. 340B ID in the OPAIS database 3. The name of their primary contact in the OPAIS database 4. Period for participation (start and end date if applicable) 5. Ryan White grant ID number 6. Signature of authorizing official |
| <p>Documentation and Reporting</p> | <p>The sub-recipient will bill, track, and report to the Recipient all 340B income billed and obtained (see attached template for reporting).</p> |

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| <p>340B Program Income</p> | <p><i>See 45 CFR Part 74.14</i></p> <p>Sub recipients are required to track and account for all pharmaceutical third-party revenue captured from pharmaceutical manufacturers on 340B eligible medications in accordance with 45 CFR § 75.302(b)(3).</p> |
| <p>Monitoring 340B Program Income by Recipient</p> | <p>HAHSTA will monitor the sub-recipient's compliance with the 340B program income policy by reviewing:</p> <ul style="list-style-type: none"> • Customer eligibility determination application to ensure consistency with policies and federal requirements. • The sub-recipient's system shall provide tracking of 340B income and pharmacy third-party revenue capture for 340B eligible medication from pharmaceutical manufacturer reimbursements received by the covered entity. • 340B income and third-party revenue capture of eligible pharmaceutical reimbursements received by the covered entity/sub-recipient's Ryan White services on a quarterly basis. (Sub-recipients will generate reports using the program income/340B template, see attached). • Expenditure reports from sub-recipient about collection and use of 340B income or budget to show expected use of 340B income and pharmacy third-party reimbursements. • Medical practice management systems to obtain reports of total income derived from 340B program. • Sub-recipient's spending of 340B income and third-party revenue capture from pharmacy on related activities • Sub-recipient's chart of accounts and general ledger showing the tracking of 340B income and pharmacy third-party reimbursements and back billing, if appropriate. <p>HAHSTA will not report sub-recipient aggregate program income and pharmacy third-party reimbursements in the federal financial report (FFR) and annual data report to HRSA.</p> <p><i>See PHS ACT 2617 (b) (iii)45 CFR 74.24 and 92.25</i></p> |
| <p>Allowable uses of 340B Program Income</p> | <p>The sub-recipient's retention of program income derived from 340B funded services and use of such funds could be done in one or more of the following ways:</p> <ul style="list-style-type: none"> • Funds added to resources committed to the project or program and used to further eligible project or program objectives. • Funds used to cover program costs. • Program income funds will not be subject to the federal limitations on administration (10%), quality management (5%), and core services (75%). |
| | <p><i>NOTE: Once a sub-recipient enrolls and/or refers a customer to the DC ADAP program, they become a client of the DC ADAP program and must utilize the ADAP pharmacy provider network.</i></p> |

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| V. Key Contacts | Ebony Fortune, Ryan White HIV/AIDS Program Manager, 202.671.4900 or Ebony.Fortune@dc.gov |
| VI. Related Documents, Forms and Tools | <ol style="list-style-type: none">1. HRSA PCN 16-02 https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/service-category-pcn-16-02-final.pdf2. Sections 2671(a), (b), and (f) of the PHS Act.3. Sections 2691-2693 of the PHS Act.4. 45 CFR § 75.305(b)(5).5. 340B Program Requirements.6. For additional information, see PCN 15-03/15-04. |