

District of Columbia Department of Health Ryan White Care and Treatment Division - Policy on Program Income		Policies and Procedures Implementing office: HAHSTA Care and Treatment Division Ryan White HIV/AIDS Program Training required: Yes Originally Issued: March 10, 2022 Revised/Reviewed:
Approved by: _____ Name, Interim Bureau Chief	Review by Legal Counsel: _____ N/A _____ Name, Deputy Director of Operations	Effective Date: March 10, 2022 Valid Through Date: February 28, 2023
SUBJECT Program Income and Third-Party Revenue Capture for 340B Eligible Medication		
PURPOSE The primary purpose of this policy and procedure is to delineate the processes required for the successful billing and documentation of income earned through service funds associated with the Ryan White Program and 340B Program. This document articulates the guidance and expectations for generating program income resulting from a program supported, in 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. It defines program income and explains its use and reporting requirements.		
Section 1: 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 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. https://hab.hrsa.gov/sites/default/files/hab/Global/pcn_15-03_program_income.pdf		
Program Income Source Citation 45 CFR 74.24 and 92.25. PHS	Program income is generated by sub-recipient as a result of the Ryan White grant. This includes reimbursement/payments for services provided to self –pay sliding fee patients, Medicaid, Medicare, private insurance, and other third-party sources.	

<p>ACT 2617 (b) (iii) Part A Program Guidance</p>	<p>Typically, sub-recipients charge for services and receive reimbursement for third-party billing. Providers 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 patients with HIV will be returned 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>NOTE</p>	<p>Sub-recipient will bill, track, and report to the recipient all program income billed and obtained (see attached template for reporting).</p> <p>Charges to patients with incomes greater than 100% of the federal poverty level (FPL) are determined by the schedule of charges. Annual limitation on amounts of charge for Ryan White services, including ADAP, are based on percent of patient’s annual income, as follows:</p> <ul style="list-style-type: none"> • 5% for patients with incomes between 100% and 200% of FPL • 7% for patients with incomes between 200% and 300% of FPL • 10% for patients with incomes greater than 300% of FPL • Nominal fee can also be imposed <p><i>DC EMA has a 500% FPL for all services in all the jurisdictions in the EMA</i></p>
<p>Allowable uses of Program Income 92.25 2 CFR and 45 CFR 74.24</p>	<p>The service provider’s retention of program income derived from Ryan White 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%), 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 by reviewing:</p> <ul style="list-style-type: none"> • Provider policy for schedule of charges to ensure that clients with incomes below 100% of the FPL are not charged for services • Customer eligibility determination application to ensure consistency with policies and federal requirements • Sub-recipient’s system of tracking program income • Program income generated by sub-recipient’s Ryan White services on a quarterly basis. (Sub-recipient will generate report using the program income template, see attached). • Expenditures reports from sub-recipient about collection and use of program income or budget to show expected use of program income • Medical practice management systems to obtain reports of total program income derived from Ryan White services

NOTE	<ul style="list-style-type: none"> Sub-recipient's spending of program income on related activities <p><i>HAHSTA will not report sub-recipient aggregate program income in the federal financial report (FFR) and annual data report to HRSA.</i></p>
-------------	--

SECTION 2: Program Income per implementation of 340B Programs

340B Program Income	<p>Definition</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 patient access to 340B drugs.</p> <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 (<i>See 340 B Guidance</i>). 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 Covered entities that utilize contract pharmacies must register each pharmacy Must have a contract in place prior to registration Register during the quarter of open registration Information must be accurate <p><i>See 340 B Program Requirements:</i></p> <p>Registration Periods</p> <ul style="list-style-type: none"> October 1-15, January 1-15, April 1-15, July 1-15
----------------------------	--

<p>340B Contract Pharmacy</p> <p>Third Party Revenue Capture for 340B Eligible Medications from Pharmaceutical Manufacturers</p> <p>45 CFR 74.24 and 92.25.PHS ACT 2617 (b) (iii)</p> <p>DISCLOSURE NOTICE</p>	<p>Contract Pharmacy – means an entity that is licensed and authorized to provide Pharmacy Services to Patients located in the District of Columbia and that has entered into an Agreement with Covered Entity to dispense 340B Covered Drugs to Patients.</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>The Covered Entity is ultimately 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. <i>See 92.25 2 CFR and 45 CFR 74.24</i></p> <p><i>All sub-recipients shall disclose in a letter all 340B contract pharmacy arrangements and their statuses with OPA (office of Pharmacy Affairs) within 15 business days of receipt of the 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 Part A grant number 6. Signature of authorizing official
<p>Documentation and Reporting 340B Program Income</p>	<p>Sub-recipient will bill, track, and report to the recipient all program income billed and obtained (see attached template for reporting).</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 capture 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 • Sub-recipient's system shall provide tracking of program income and pharmacy third-party revenue capture for 340B eligible medication from pharmaceutical manufacturer reimbursements received by the covered entity. • Program 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-recipient will generate report using the program income template, see attached). • Expenditure reports from sub-recipient about collection and use of program income or budget to show expected use of program income and pharmacy third-party reimbursements. • Medical practice management systems to obtain reports of total program income derived from 340B program. • Sub-recipient's spending of program income and third-party revenue capture from pharmacy on related activities <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>NOTE</p>	<p>Once a sub-recipient enrolls and or refers a customer to the DCADAP program they become a client of the DCADAP program and must utilize the ADAP pharmacy provider network.</p>

Application: This policy applies to the Ryan White HIV/AIDS Program staff and sub-recipients unless otherwise noted.

References

Sections 2671(a), (b), and (f) of the PHS Act.

Sections 2691-2693 of the PHS Act.

45 CFR § 75.305(b)(5).

340B Program Requirements

For additional information, see PCN 15-04.