

Utilization and Reporting of Pharmaceutical Rebates

Policy Clarification Notice (PCN) #15-04 (Revised 01/11/2019)

Relates to Policy #12-02

Relates to Policy #15-03

Scope of Coverage

Ryan White HIV/AIDS Program (RWHAP) Part B AIDS Drug Assistance Programs (ADAP) that collect rebates on ADAP medication purchases. This policy replaces the "Dear Colleague Letter" dated November 16, 2012.

Purpose of PCN

This policy notice clarifies the Health Resources and Services Administration (HRSA) guidelines for the utilization and reporting of pharmaceutical rebates by RWHAP AIDS Drug Assistance Programs (ADAP) and the effect of other program provisions on these rebates.

Background

The 340B Drug Pricing Program (340B Program) is a Federal drug pricing program administered by HRSA's Office of Pharmacy Affairs that provides eligible entities (including ADAPs and other RWHAP recipients) with access to discounted medications. Under the ADAP 340B rebate option, ADAPs submit claims to pharmaceutical manufacturers for rebates on medications that were not purchased at the 340B prices. Only ADAPs are eligible for 340B rebates.

Definitions

Rebate: a return of a part of a payment.

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.**¹

¹ 45 CFR § 75.2 (emphasis added).

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

General Guidance and Expectations

Uses of Rebates

Acceptable uses:

The RWHAP legislation requires that rebates collected on ADAP medication purchases be applied to the RWHAP Part B Program with a priority, but not a requirement, that the rebates be placed back into ADAP.² These rebates must be used for the statutorily permitted purposes under the RWHAP Part B Program, which are limited to core medical services including ADAP, 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.³

Rebates may be used for allowable RWHAP services that exceed the recipients' RWHAP Part B implementation work plan. Rebates are not part of the recipient's RWHAP Part B award, and so are not subject to the 10% administrative cost cap nor to the RWHAP requirement to spend 75% on core medical services.

Rebates can be used to meet both a recipient's State Match requirement and the Maintenance of Effort (MOE) requirement.

Unacceptable uses:

ADAP medication rebates cannot be shared with other entities including, but not limited to, high risk insurance pools, Marketplace plans, Medicaid, or any other state or federal program.⁴

Expenditure of Rebates

Although ADAP rebates are neither program income nor refunds, they are subject to the same regulatory provision regarding expenditure.⁵ 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. Recipients and subrecipients should proactively project the extent to which rebates will be received. Although projected rebates are not reported as part of the application for RWHAP funding, HRSA's expectation is that the rebate projections will be incorporated into the jurisdiction's planning for service based on the comprehensive HIV care and treatment needs of the recipient's jurisdiction. This should be done to effectively

² Section 2616(g) of the Public Health Service (PHS) Act.

³ Section 2612(a) of the PHS Act. See also PCN # 15-03 (Program Income).

⁴ Section 2615(b) of the PHS Act. The prohibition on "sharing" refers to a direction to the pharmaceutical company to remit a portion of the rebate dollars to any entity other than the ADAP. The prohibition does not extend to appropriate ADAP subawards to other entities for allowable purposes, including subawards to other RWHAP Part recipients.

⁵ 45 CFR § 75.305(b)(5).

determine the allocation and utilization of RWHAP funds during the current period of performance.

Rebates for medications purchased within one period of performance may be received in the following period. Such rebates should be accounted for and utilized in the year in which they are received by the program. Rebates received at the end of the period of performance must be expended by the recipient prior to the expenditure of new RWHAP funds awarded in the subsequent period.

Rebate Reporting

Recipients are required to track and account for all pharmaceutical rebates in accordance with 45 CFR § 75.302(b)(3).

Rebates should never be recorded as an unobligated balance (UOB)(line 10h) or as a cash disbursement (line 10b) on the Federal Financial Report (FFR). Rebates should be tracked and reported on the FFR in the HRSA Electronic Handbooks (EHBs) as follows:

In the “Ryan White Rebate Funding” section, report

- the expended rebate amount; and
- the expended rebate amount to be used to reduce UOB.

In item 12. Record Remarks, report

- a Rebate Account Summary, including: total rebate revenues, total rebate expenditures and remaining rebate funds; 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.”

The amount of rebates received during the reporting period is reported on the annual ADAP Data Report (ADR), in both the ‘Funding’ section of the Grantee Report and in the expenditures reported.

Because rebates are not part of the recipient’s RWHAP Part B award, they should not be included in the HRSA HIV/AIDS Bureau (HAB) RWHAP Part B Program Term Report, planned Allocations Report or final Expenditure Report.

Unobligated Balance Statutory Provision

The RWHAP statute expects that states obligate all award funds prior to the end of the one-year project period.⁶ See [HAB Policy Notice 12-02 Part A and Part B Unobligated Balances and Carryover Provisions](#) for additional information on UOBs, including penalties. For any ADAP receiving rebates on medication purchases, the RWHAP legislation has a specific exemption from the UOB penalties provision that applies when a recipient is unable to expend grant funds because rebates must be

⁶ Section 2622(a) of the PHS Act.

spent first.⁷ If the recipient would otherwise incur a penalty, that recipient may request that the amount of the UOB balance be reduced by the amount of obligated rebates, and that such amount be carried forward to the next budget period without penalty. RWHAP Part B recipients that fail to follow the rebate reporting instructions above and that have an UOB of five percent (5%) or greater will be subject to the full UOB penalty outlined in HAB Policy Notice 12-02.

⁷ Section 2622(d) of the PHS Act.