



HIV/AIDS Bureau

NOV 16 2012

Rockville MD 20857

Dear Ryan White Program Grantees:

The purpose of this letter is to clarify the Health Resources and Services Administration (HRSA) guidelines for the utilization and reporting of pharmaceutical rebates and their effect on other program provisions for the Ryan White HIV/AIDS Program - AIDS Drug Assistance Program (ADAP) grantees. This guidance is directed to all states that collect rebates on ADAP drug purchases.

Uses of Rebate Funds

The Ryan White HIV/AIDS Program legislation requires that rebate funds collected on ADAP drug purchases be applied to the Part B Program with a priority, but not a requirement that the rebates be placed back into ADAP (section 2616(g) of the Public Health Service (PHS) Act). These rebates must be used for the statutorily permitted purposes under the Part B Program. These statutorily permitted purposes include core medical services including ADAP, support services, planning and evaluation, and administrative expenses (section 2612(a) of the PHS Act). Furthermore, this provision prohibits budgetary transfer of these rebate funds to other entities, including but not limited to Ryan White Part A grantees, pre-existing condition insurance plans, high risk insurance plans, health exchanges, Medicaid or any other state or federal program.

Rebate funds may be used to meet either maintenance of effort or state match requirements; however, they may not be used for both.

Expenditure of Rebate Funds Regulatory Provision

The regulations that govern federally-funded grants, including the Part B and ADAP awards, require that all grantees (including those states that have a hybrid ADAP) spend their rebate funds prior to drawing down grant funds from the Payment Management System (PMS)(45 CFR § 92.21(f)(2)). **HRSA has determined that it is sufficient for grantees to spend rebate funds in the grant year in which they are received and prior to drawing down grant funds;** the regulations do not require that rebate funds be spent in the year in which they are generated. Grantees are reminded that they are required to track and account for all rebate funds, and must be able to account for the rebate funds in any A-133 audit.

Rebate Fund Reporting

Rebate funds should never be recorded as an unobligated balance on the Final Financial Report (FFR). Rebate funds should be tracked and the total amount should be reported on the FFR under line 12 remarks, but not on line 10b, with attachment(s) as necessary (sample language for inclusion in the remarks section of the FFR is provided in the FAQ document accompanying this letter). Also, rebate funds should not be included in the HRSA HIV/AIDS Bureau (HAB) Part B required planned allocations report as it is not possible to predict the rebate funds amount available for allocation throughout the course of the grant year.

Unobligated Balance Statutory Provision

The Ryan White HIV/AIDS Program statute expects that states obligate all grant funds prior to the end of the grant year. See HAB Policy Notice 12-02 for additional information on unobligated balances, including penalties. However, rebate funds collected on drug purchases are not subject to the unobligated balance penalty provision (section 2622(d) of the PHS Act).

Interplay of Provisions

For any ADAP receiving rebate funds on drug purchases, the Ryan White HIV/AIDS Program legislation has a specific exemption from the unobligated balance penalties provision (section 2622(d) of the PHS Act) that applies when a grantee is unable to expend grant funds because rebate funds must be spent first. If the grantee would otherwise incur a penalty from the unobligated balance, that grantee may request that the amount of the unobligated grant funds balance be reduced by the amount of obligated rebate funds, and that such amount be carried forward to the next budget period without penalty.

A statement indicating that the grantee has an unobligated balance due to rebate funds and a request to reduce the unobligated grant fund balance amount by the amount of the rebate funds should be reported in the FFR under line 12 remarks, not on line 10b. Any grantee that fails to request an adjustment based on rebate funds will be subject to the full unobligated balance penalty as outlined in HAB Policy Notice 12-02.

If you have any questions regarding the content of this letter, please contact your project officer.

Sincerely,



Deborah Parham Hopson, PhD, RN, FAAN
Assistant Surgeon General
Associate Administrator

Financial Report Review - SF-425

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration

Submission Tracking Number: [REDACTED]

Document Number: [REDACTED]

FEDERAL FINANCIAL REPORT

1. Federal Agency and Organizational Element to which Report is Submitted: HRSA

2. Federal Grant or Other Identifying Assigned by Federal Agency

(To report multiple grants, use FFR Attachment) [REDACTED]

3. Recipient Organization (Name and Complete Address Including Zip Code)

Recipient Organization Name:

[REDACTED]

Recipient Name:

[REDACTED]

4a. DUNS Number: [REDACTED]

4b. EIN: [REDACTED]

5. Recipient Account Number or Identifying Number (To report multiple grants, use FFR Attachment) Indx 99121

6. Report Type:

- Quarterly
- Semi-Annual
- Annual
- Final

7. Basis of Accounting:

- Cash
- Accrual

8. Project/Grant Period From (Month,Day,Year): 04/01/2011

To (Month,Day,Year): 03/31/2012

9. Reporting Period End Date (Month,Day,Year): 03/31/2012

10. Transactions	<u>Hide Details</u>		
	Previously Reported	This Period	Cumulative

Federal Cash (To report multiple grants, also use FFR Attachment) (Use lines a-c for single or multiple grant reporting)

a. Cash Receipts			\$0.00
b. Cash Disbursements			\$0.00
c. Cash on Hand (line a minus b)			\$0.00

Federal Expenditure and Unobligated Balance (Use lines d-o for single grant reporting)

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d. Total Federal Funds Authorized			\$15,997,256.00
e. Federal Share of Expenditures	\$0.00	\$15,900,158.23	\$15,900,158.23
f. Federal Share of Unliquidated Obligations			\$0.00
g. Total Federal Share (sum of lines e and f)			\$15,900,158.23
h. Unobligated balance of Federal Funds (line d minus g)			\$97,097.77
Recipient Share			
i. Total recipient share required	\$0.00	\$7,356,261.00	\$7,356,261.00
j. Recipient share of expenditure	\$0.00	\$7,356,261.00	\$7,356,261.00
k. Remaining recipient share to be provided (line i minus j)			\$0.00
Program Income			
l. Total Federal Program Income earned			\$0.00
m. Program income expended in accordance with the deduction alternative			\$0.00
n. Program income expended in accordance with the addition alternative			\$0.00
o. Unexpended program income (line l minus line m or line n)			\$0.00

11. Indirect Expense

a. Type	b. Rate	c. Period From	Period To	d. Base	e. Amount Charged	f. Federal Share
Final	18.10	N/A	N/A	\$87,020.42	\$15,750.70	\$15,750.70
Provisional	18.10	N/A	N/A	\$263,957.56	\$47,776.32	\$47,776.32
g. Totals				\$350,977.98	\$63,527.01	\$63,527.02

12. Remarks: Attach any Explanations deemed necessary or information required by federal sponsoring agency in compliance with governing legislation

Please refer to comments in next page.

13: Certification

By signing this report, I have the authority and certify that this report is true, complete, and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent information may subject me to criminal, civil, or administrative penalties. (U.S Code, Title 18, Section 1001)

a. Typed or Printed Name and Title of Authorized Certifying Official :

[REDACTED]

c. Telephone (Area Code, number and extension):

d. Email Address:

[REDACTED]

b. Signature of Authorized Certifying Official:

[REDACTED]

e. Date Report Submitted: 10/30/2012

14. Agency use only:

Standard Form 425
 OMB Approval Number: 0348-0061
 Expiration Date: 10/31/2011

Paperwork Burden Statement

According to the Paperwork Reduction Act, as amended, no persons are required to respond to a collection of information unless it displays a valid OMB Control Number. The valid OMB control number for this information collection is 0348-0061. Public reporting burden for this collection of information is estimated to average 1.5 hours per response, including time for reviewing instructions searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of the collection of information, including suggestions for reducing the burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0060), Washington, DC 20503

Comments

****Grantees must state in the Remarks section: 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.****

Comments related to Indirect Costs:

Comments related to Remarks:

Note 1: ADAP SUMMARY:

Outlays-ADAP Funds	= \$12,735,894.82
Unliquidated Obl-ADAP	= \$ 0.00
Total Federal Share-ADAP Funds	= \$12,762,599.00
Unobligated Balance-ADAP Funds	= \$ 26,704.18

Note 2: UNOBLIGATED BALANCE SUMMARY:

ADAP UOB	= \$ 26,704.18 (\$12,762,599.00 - \$12,735,894.82)
BASE UOB	= \$ 70,393.59 (\$ 3,234,657.00 - \$ 3,164,263.41)
TOTAL UOB	= \$ 97,097.77 (\$ 15,997,256.00 - \$15,900,158.23)

Note 3: REBATE ACCOUNT SUMMARY

Rebate Revenues:	= \$3,233,505.61
Rebate Expenditures:	= \$3,107,458.69
Remaining Rebate Funds:	= \$ 126,046.92
Unliquidated Obligations:	= \$ 115,566.61
Adj Remaining Balance:	= \$ 10,480.31

The Rebate dollars will be spent on a first in/first out basis during the current grant year ending 03/31/13.

Note 4: Sources of funding on Line 10.d.: Total Funds Authorized - \$15,997,256 is from PMS Account # 11X07HA00080.

Note 5: Line 10.e.: Federal Share of Expenditures will match PMS SF-425 (formally PMS 272) reporting as of 09/30/12 in the amount of \$15,900,158.23 when submitted on the due date of 10/30/12.

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HIV/AIDS Bureau (HAB) Ryan White HIV/AIDS Program
AIDS Drug Assistance Program (ADAP) and Pharmaceutical Rebates Policy Letter
Frequently Asked Questions (FAQs)

GENERAL QUESTIONS

1. Is this policy currently effective?

Yes. The policy is effective on the date signed and issued by the HAB Associate Administrator, Health Resources and Services Administration (HRSA). It reflects current policy and answers several questions grantees have posed to project officers in the recent months regarding the use of rebate funds.

2. Are grantees expected to expend rebate funds prior to drawing funds from the payment management system (PMS) even though pharmaceutical rebate checks are received by Part B ADAP grantees on an on-going basis?

Yes. The regulations found at 45 CFR Section 92.21(f)(2) require all federally funded grantees, including those States with a hybrid ADAP, to spend their rebate funds prior to drawing down grant funds from the PMS. Grantees are required to track and account for all pharmaceutical rebate funds in accordance with the A-133 audit procedures.

3. Do rebate funds have to be spent in the year in which they are generated?

No. The regulations do not require that rebate funds be spent in the year in which they are generated. Rebates are to be spent within the grant year that they are received. Grantees are required to track and account for all pharmaceutical rebate funds in accordance with the A-133 audit procedures.

USES OF REBATE FUNDS

4. Can rebate funds be used to fund Ryan White HIV/AIDS Program Part B support services?

Yes. Rebate funds can be used to support the statutorily permitted purposes under the Part B Program, including core medical and support services, planning and evaluation, clinical quality management and administrative expenses. The priority is that rebate funds be placed back into ADAP.

5. May grantees spend rebate funds collected on ADAP drug purchases to fund HIV services that are not allowed by the Ryan White HIV/AIDS Program for example, syringe services programs?

No. The grantee may use the rebates only for statutorily permitted purposes under the Part B program allowable items and services.

6. Can grantees use drug rebates for the State match requirement and the maintenance of effort (MOE) requirement?

Yes. Grantees may use their rebate funds to meet either the Ryan White HIV/AIDS Program State match requirement or the MOE. However, grantees may not use the same rebate funds for both requirements.

7. Can grantees use the drug rebate funds to add services not on their implementation work plan?

Yes. The funds must be used to support statutorily permitted purposes under the Part B Program. Because it is difficult to estimate the timely receipt of rebate funds, their use may include additional services not on the Part B implementation work plan.

8. Can rebate funds be transferred or shared with other state or federal programs?

No. ADAP drug rebate funds cannot be transferred or shared with other entities including but not limited to Ryan White Part A grantees, pre-existing condition insurance plans, high risk insurance pools, health exchanges, Medicaid, or any other state or federal program.

REPORTING REQUIREMENTS AND PENALTIES

9. Are grantees required to track and report on the use of ADAP drug rebate funds?

Yes. Grantees are required to track and account for all rebate funds and must be able to account for the rebate funds in any A-133 audit. HAB will also consider adding questions regarding the use of drug rebate funds to the final progress report format in FY 2013.

10. Can grantees report the use of rebates on the final expenditure table?

No. Rebate funds must never be recorded on the final expenditure table because it is a report on the expenditure of Ryan White HIV/AIDS Program funds.

11. Are rebates reported on the ADAP Quarterly Report (AQR)?

Yes. Enter the amount of rebates received during each quarter as Item 10.e. Manufacturer Rebates of the AQR.

12. Are grantees required to report their rebate funds on the Final Financial Report (FFR)?

Yes. Drug rebate funds should be tracked separately and the total amount reported on the FFR under **line 12 Remarks**.

13. How should grantees report any unobligated balances that result from expending rebate funds?

Grantees must state in the Remarks section: 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.

- Drug rebate funds should never be recorded as an *unobligated balance* on any FFR.
- Drug rebate funds should *not* be included on **line 10 of the FFR**.
- Drug rebate funds should *not* be included in the HRSA HAB Part B required planned allocations report because it is not possible to predict the drug rebate funds amount available for allocation throughout the course of the grant year.

14. Will grantees be penalized if they comply with the requirement to spend drug rebate funds before drawing down grant funds, resulting in an unobligated balance greater than five percent (5%)?

No. Under the Ryan White HIV/AIDS Program statute, Section 2622(d) of the Public Health Service (PHS) Act, there is a specific exemption from the unobligated balance penalties provision. This exemption applies when a Part B grantee cannot obligate grant funds because pharmaceutical rebate funds must be used first.

15. Must Part B grantees formally notify HAB when an unobligated balance is due to the expenditure of rebate funds and the need for an adjustment to the unobligated balance reported on the FFR?

Yes. Part B grantees may make a request to reduce their unobligated balance by the drug rebate amount by submitting a carryover request to HAB, and including a statement under line 12 of the FFR.

16. Will grantees that fail to request carryover and to include the adjustment statement on the FFR in the remarks section under line 12 be penalized?

Yes. Part B grantees 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 unobligated balance penalty outlined in HAB Policy Notice 12-02 "Part A and Part B Unobligated Balances and Carryover Provisions."