

Legislation Needed to Reverse Designation Of ADAP Rebate Dollars as Program Income

What is the Legislative Fix Needed?

Legislative language is needed to exempt AIDS Drug Assistance Program (ADAP) rebate dollars from 45CFR92.21 so they will no longer be considered “program income.” States would still be required to expend their rebate funds for Part B Base and ADAP services and would certify to that effect. We ask that the following language be included in legislation to extend/reauthorize the Ryan White Program:

“In keeping with Congressional intent and Section 2622 (d) of Public Law 109-415, rebate funds associated with Section 2616 of Public Health Service Act (42 U.S.C. 300ff-26) are exempt from 45CFR92.21. HRSA will consult with state grantees to develop a process that certifies and describes that such funds are in compliance with Section 2616 (g) of Public Law 109-415.”

What is the Issue?

Under the Ryan White Program, ADAPs purchase drugs through two basic models. ADAPs utilizing the rebate model purchase drugs via a pharmacy network and then request rebates from pharmaceutical companies to obtain the 340B program drug prices. Approximately half of the states have rebate model ADAPs. The other half purchase drugs directly from wholesalers at 340B prices and are referred to as “Direct Purchase” ADAPs.

HRSA sent a letter to ADAPs on January 9, 2007 stating that funds generated by rebates must be considered program income, despite the fact that the Ryan White HIV/AIDS Treatment Modernization Act states that rebates may not be considered part of any grant award. Rebate dollars should NOT be counted as program income, per Code of Federal Regulation (CFR) Title 45 Section 92.25 which states “Except as otherwise provided in regulations of the

Which States are Impacted?

California, Connecticut, Idaho, Indiana, Kansas, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, New Hampshire, New York, New Jersey, North Dakota, Oregon, Pennsylvania, Rhode Island, South Dakota, Vermont, Washington, West Virginia, Wisconsin, and Wyoming.

Federal Agency, program income does not include interest on grant funds, rebates, credits, discounts, refunds, etc. and interest earned on any of them.” Despite language to the contrary, HHS Budget Office lawyers have determined that the language included in HRSA’s January 9, 2007 letter triggers CFR Title 45 Section 92.21 and therefore trumps Title 45 Section 92.25. Title 45 Section 92.21 states “Except as provided in paragraph (f)(1) of this section, grantees and subgrantees shall disburse program income, rebates, refunds, contract settlements, audit recoveries and interest earned on such funds before requesting additional cash payments.”

The Ryan White HIV/AIDS Treatment Modernization Act (Public Law 109-415) requires rebate funds be put back in Part B (with preference, but not a requirement, that they be placed in ADAP). Additionally, new carryover rules require states to spend 98 percent of all funds prior to the end of their grant year. Given that this requires states to spend their rebate funds first (no matter when they are received) as well as 98 percent of their direct grant funds, some states have exceeded the unobligated fund limit and thus have lost a portion of their ADAP funds. While the Ryan White Program requires rebates to be put back into the Part B Program with preference given to ADAP, rebate income should not be considered program income and should be able to be accrued after a grant year has ended.

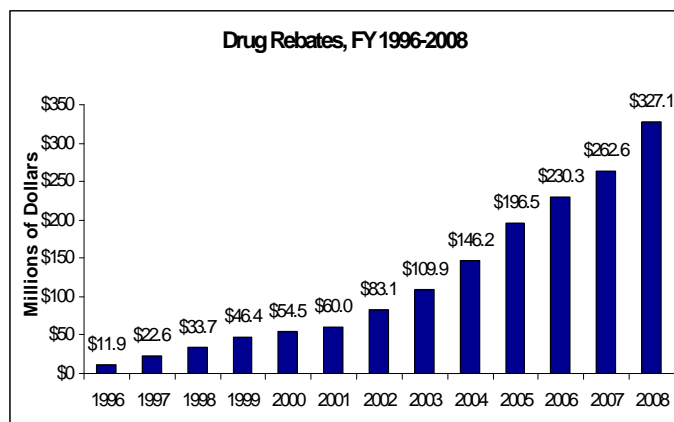
End Unreasonable HRSA Requirement for ADAPs

Further Background

State ADAP programs manage and coordinate funding from all sources to serve as many people as possible each year. Variations in federal and state funding as well as clinical advances in treatment options require ADAP administrators to forecast and project program utilization and expenditures for multiple funding periods. Unlike entitlement programs like Medicaid, ADAP has a limited pool of funds with which to work each year. ADAP programs utilize coordinated funding scenarios to develop systems and processes to assure uninterrupted access to essential medical care and treatments for the people they serve. Planning and forecasting takes place long before the beginning of each fiscal year so that available resources closely match projected expenditures and so that access to life-prolonging medications is not interrupted by a lack of available funds.

With more than 183,000 enrolled ADAP clients in FY2007 rebate recoveries, along with Ryan White ADAP earmark, Part B base, Part A and state funds, were used to provide access to medications for approximately 110,000 people per month. Resources available to each program have varying funding cycles, reporting periods, and accounting rules. Balancing revenues and cash flow with fluctuating utilization and expenditure needs is a complex task, complicated by the unpredictability of rebate payments. Submission of rebate claims are made by ADAPs on a quarterly basis. However, it is not possible to accurately predict the time required by drug manufacturers to process claims, or the amount of rebate due to the confidential pricing data utilized by the manufacturers in calculating the rebates. Due to the variability in federal award amounts and the timing of other funding sources, rebate recoveries must be available as an ongoing resource to assure continued uninterrupted access to medications.

The provision of the Ryan White HIV/AIDS Treatment Modernization Act regarding unobligated funds and the reduction of future awards makes flexibility in the timing of spending rebate recoveries critical. Requiring that rebate recoveries be spent before grant funds, while reducing future awards and eliminating eligibility for supplemental awards based on underspending



Source: National Alliance of State and Territorial AIDS Directors and The Henry J. Kaiser Family Foundation, *National ADAP Monitoring Project: Annual Report*, April 2009.

of grant dollars, sets programs up for failure. In states where partnerships have been formed with Part A regions to jointly support ADAPs, city awards and supplemental funds may also be jeopardized. These circumstances will result in disruptions in care and interruption in the provision of medications to thousands of low-income persons living with HIV disease.

Relevant Ryan White and CFR Language on use of Rebate Recoveries Generated through ADAP

Congress recognized the vast complexities of assuring that sufficient resources are available to provide access to medications and care for the nation's most vulnerable people through the Ryan White Program and require rebates to be returned to Part B, including ADAP:

Section 2616(g)

"A state shall ensure that any drug rebates received on drugs purchased from funds provided pursuant to this section are applied to activities supported under this subpart, with priority given to activities described in this section."

Congress further clarified the intent by specifically excluding rebate recoveries from the grant:

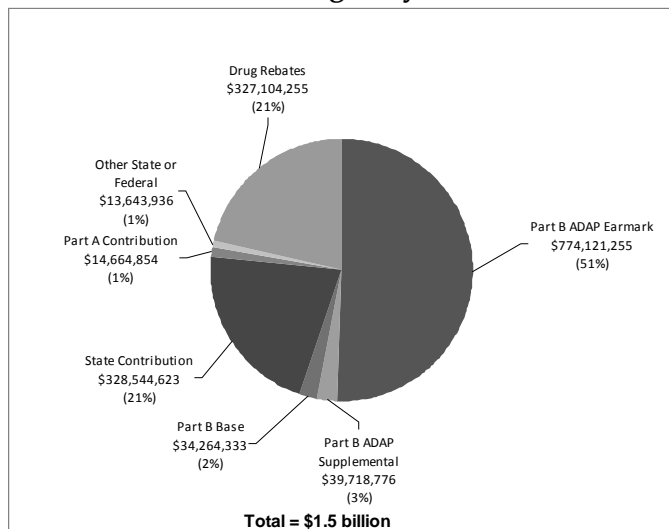
Section 2622(d)

"Treatment of Drug Rebates"

"For purposes of this section, funds that are drug rebates referred to in section 2616(g) may not be considered part of any grant award referred to in subsection (a)."

End Unreasonable HRSA Requirement for ADAPs

National ADAP Budget, by Source, FY 2008



Source: National Alliance of State and Territorial AIDS Directors and The Henry J. Kaiser Family Foundation, *National ADAP Monitoring Project: Annual Report*, April 2009.

Section 2622(d) in particular removes rebate revenue from grants and allows the use of rebate funds for Part B purposes consistent with the intent of the law.

The law's payer of last resort requirement references other potential health care payers and does not specify rebate recoveries as subject to this rule:

Section 2617(b)(7)(F)

"The State will ensure that grant funds are not utilized to make payments for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to that item or service

(i) under any state compensation program, under an insurance policy, or under any federal or state health benefits program; or

(ii) by an entity that provides health services on a prepaid basis (except for a program administered by or providing the services of the Indian Health Service);"

Additional federal guidance and regulation specifically exclude rebate recoveries from consideration as program income. As such, OMB should not impose restrictions with respect to the timing of spending resources to meet program requirements and serve persons with HIV/AIDS:

45 CFR 92.25

"Except as otherwise provided in regulations of the Federal Agency, program income does not include interest on grant funds, rebates, credits, discounts, refunds, etc. and interest earned on any of them."

Despite language to the contrary, HRSA has determined that the language included in its January 9, 2007 letter triggers the following CFR language:

45 CFR 92.21

"Except as provided in paragraph (f)(1) of this section, grantees and subgrantees shall disburse program income, rebates, refunds, contract settlements, audit recoveries and interest earned on such funds before requesting additional cash payments."