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Section IV

ADAP Reporting Responsibilities: Title II Progress Reports and the *Title II Application Guidance*

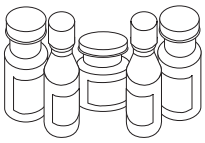


CHAPTER SUMMARY

This chapter outlines the responsibilities of AIDS Drug Assistance Programs (ADAPs) in reporting significant program information in quarterly progress reports. It outlines the ADAP-specific information that can be included in Title II progress reports—especially program accomplishments, challenges, and technical assistance needs.

The chapter also describes ADAP reporting responsibilities for the annual Title II Grant Application, as described each year in the Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau's (HAB) Division of Service Systems' (DSS) Title II Application Guidance.

The chapter includes one Attachment: General Instructions for Completing the ADAP State Profile.



ADAP REPORTING RESPONSIBILITIES: TITLE II PROGRESS REPORTS AND THE *TITLE II APPLICATION GUIDANCE*

Introduction

States must report to the Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau's (HAB) Grants Management Branch (GMB) their progress in implementing Title II-funded program activities and services, including the State's AIDS Drug Assistance Program (ADAP).

ADAPs are an important program component of Title II, and ADAP information is critical to the completeness and accuracy of Title II progress reports. ADAP coordinators should be aware of the scope and purposes of these reports so that they may effectively document information related to the State ADAP.

The primary purposes of these reports are the following:

- to inform Division of Service Systems (DSS) program officials of progress made in the administration of Title II programs;
- to identify accomplishments and challenges in meeting established goals and objectives; and
- to describe the types of technical assistance requested and received.

PREPARING THE CADR

Instructions for preparing and submitting the CADR are available at the following Web address: <http://hab.hrsa.gov/tools.htm>. The AIDS Drug Assistance Program section of the CADR can be found in Section 7 of the CADR.

The required reports include a CARE Act Data Report (CADR), ADAP Monthly Reports (AMR), Title II program progress reports, and the Title II Grant Application.

Preparing the AMR

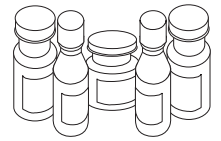
An updated version of the AMR form and information on the Web-based AIDS Monthly Report is provided in Section IV, Chapter 2 of this manual.

Preparing Program Progress Reports

The Title II program progress reports is designed to:

- inform program officials of progress made in the administration of Title II programs;
- identify accomplishments and challenges in meeting established goals and objectives; and
- describe the type of technical assistance received and requested during the grant year.

The Title II grantee is responsible for submitting progress reports to DSS. The State ADAP coordinator should work closely with the Title II director, providing any necessary fiscal and



programmatic information about the State ADAP, as well as any other challenges or successes that would be relevant for a progress report. ADAP coordinators should work with their Title II directors to ensure that information related to the State's ADAP is accurate and complete.

DSS provides specific guidance for preparing program progress reports each year. This chapter provides general descriptions of progress reports and suggestions for their content and format. The sections below outline ADAP-specific information that should be included in a Title II progress report and describe how that information should be organized and presented.

Legislative Background

Title II grantees must submit their CADR and program progress reports on their Title II programs in accordance with 45 CFR Part 92, Sub-part C, "Monitoring and Reporting Program Performance," and provisions of the CARE Act of 2000.

Submission of progress reports is one of the conditions of award for Title II funding recipients. Failure to comply with any of the conditions of award by the specified due date may result in suspension of a grantee's ability to draw down funds or the disallowance of funds.

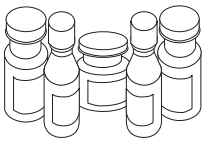
Grantees must submit progress reports each year to DSS. For FY 2002, progress report submissions should follow the schedule below:

| No. | Period Ending | Due Date |
|-----|--------------------|-----------------------|
| 1. | September 30, 2002 | November 1, 2002 |
| 2. | December 31, 2002 | Title II Application* |
| 3. | March 31, 2003 | May 1, 2003 |

*To be determined.

DSS annually determines the components of progress reports and supplies grantees with guidelines for completing them. Grantees must submit an original and a copy of each progress report to:

Grants Management Officer
 HIV/AIDS Bureau, HRSA
 Parklawn Building, Room 7-89
 5600 Fishers Lane
 Rockville, MD 20857



Content and Format of Progress Reports

A program progress report should provide specific, detailed information that answers three basic questions:

1. How much of the grantee's funding has been spent, and where?
2. What, if anything, has changed in the program since submission/approval of the grant application?
3. What, if any, significant accomplishments/barriers have occurred so far, during the grant year?

These questions should be answered and should document progress made by the Title II grantee as it attains the stated goals and objectives as reported in its annual Title II Grant Application.

Information provided in a progress report should flow from related information provided in the grantee's previous report.

Grantees should not repeat basic information from one progress report to the next.

Reporting on "Challenges and Technical Assistance"

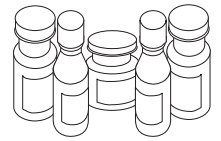
The "Challenges and Technical Assistance" section of a progress report gives grantees the opportunity to identify challenges experienced during implementation of program goals and objectives for the year. ADAPs should include any challenges that have arisen with the administration or implementation of the program.

The ADAP coordinator should summarize plans to address the challenges mentioned and describe any past or current technical assistance provided or arranged by DSS.

Reporting on "Program and Fiscal Accomplishments"

Each progress report should include the progress made in reaching the "Objectives for Program Area" originally submitted in the annual Title II Grant Application. Also, activities supported through the State Matching Fund Requirement should be documented. Finally, submissions should include actual aggregate administrative expenditures, in order to document compliance with the caps on administrative, planning, and evaluation costs. DSS distributes more detailed requirements about these items in its annual guidelines for completing progress reports.

For more information about expenditure limits on administrative, planning, and evaluation activities, please see Section III, Chapter 4 in this manual.



ADAP Portions of the *Title II Application Guidance*

Each year, Title II grantees are required to submit an application for Federal grant funds. To assist grantees in submitting this application and to provide specific directions about format and content, HRSA provides grantees with a *Title II Application Guidance*. This chapter offers a general overview of the principles on which the Guidance is based, and it outlines ADAP reporting requirements for State applications.

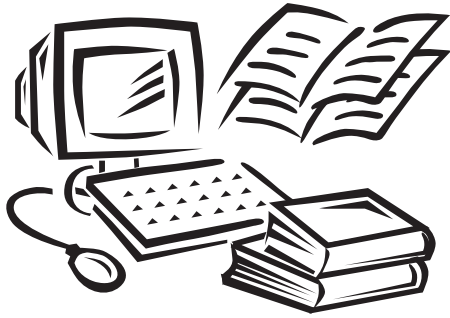
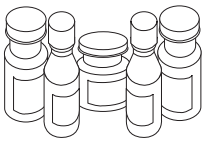
New HIV/AIDS care challenges required changes by States in their future CARE Act planning and implementation plans. The *FY 2002 Title II Application Guidance* was revised to reflect these changes. The *Title II Guidance* asks for information that reflects linkages between services and funding sources to provide a continuum of care that includes access to primary care and quality treatment.

Title II grant applications are reviewed in the HIV/AIDS Bureau by the Grants Management Office and by the Division of Service Systems. DSS project officers and ADAP Branch staff review the ADAP portions of Title II applications for completeness and for program information. The *Title II Guidance* asks grantees to update and verify ADAP information, as displayed in the ADAP State Profile for that individual State. Updated ADAP State Profiles and any important corresponding narratives are entered into the ADAP Branch database. In conjunction with updates received through the ADAP Monthly Report (AMR), this information is used to produce accurate State Profiles, ADAP fact sheets, and other communications material.

In addition to the ADAP section of the *FY 2002 Title II Guidance*, questions about a State's ADAP are interspersed in other sections. For example, ADAP expenditures need to be included in the budget narrative/justification. Also, Section III, Part E asks States to describe major program accomplishments for the previous fiscal year by program area and major activities in the previous fiscal year that impacted HIV/AIDS care. Accomplishments and activities of a State's ADAP should be included in this section. In Part F of Section III, States are asked to identify and describe each planning entity, including ADAP advisory bodies. Finally, Table 5 requests objectives for Title II program areas, which should include ADAPs.

THE TITLE II APPLICATION AND AMR PARTICIPATION

Some questions in the ADAP Section of the *FY 2002 Title II Guidance* were required only of those States that failed to submit at least 7 out of 10 ADAP AMRs during the past fiscal year. On April 1, 1999, however, AMR submission became a condition of grant award and must now be sent in on a monthly basis. Pricing information must be submitted on a quarterly basis. Future *Title II Guidances* will therefore require all ADAPs to report on the status of their Section 340B Drug Discount Program participation or their alternative drug purchasing and dispensing systems and their cost-saving strategies.



R E F E R E N C E S

Sources Used for This Chapter

HRSA, HIV/AIDS Bureau, Division of Service Systems. "Administrative Costs." Issue Paper, January 31, 1997.

HRSA, HIV/AIDS Bureau, Division of Service Systems. *Fiscal Year 2001 Title II Progress Report Guidance*. Rockville, MD: U.S. Department of Health and Human Services.

HRSA, HIV/AIDS Bureau, Division of Service Systems. *Ryan White CARE Act Title II Application Guidance*. Rockville, MD: U.S. Department of Health and Human Services, 2002.

HRSA, HIV/AIDS Bureau, Division of Service Systems. "State Matching Fund Requirements." Issue Paper, January 31, 1997.

HRSA, HIV/AIDS Bureau, Grants Management Branch. *Fiscal Year 2002 Title II Conditions of Award*. Rockville, MD: U.S. Department of Health and Human Services, 2002.

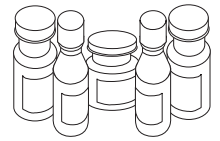
To Obtain More Information on Topics Mentioned

Grants management. See Section II, Chapter 4 in the *Title II Manual*.

Maintenance of effort. See Section II, Chapter 2 in the *Title II Manual*.

Roles of grantees, consortia, and lead agencies. See Section VI, Chapter 1 in the *Title II Manual*.

Title II Program Progress Report examples. See Section III, Chapter 1 in the *Title II Manual*.



Sample
AIDS DRUG ASSISTANCE PROGRAM STATE PROFILE
2002

GRANTEE CODE:

FUNDING SUMMARY

| Year | Total Title II Grant Award | Title II ADAP Funds | | Title I Contribution | State Funds | Other | Cost-Saving Strategies | Total ADAP Resources |
|------|----------------------------|---------------------|-------------|----------------------|-------------|-------|------------------------|----------------------|
| | | Earmark | Base Funds | | | | | |
| 2002 | \$10,132,580 | \$5,822,611 | \$979,591 | \$0 | \$1,500,000 | \$0 | \$0 | \$8,302,202 |
| 2001 | \$9,222,516 | \$5,290,587 | \$1,160,099 | \$0 | \$665,050 | \$0 | \$0 | \$7,115,736 |
| 2000 | \$8,223,550 | \$4,639,040 | \$1,590,261 | \$0 | \$165,050 | \$0 | \$0 | \$6,394,351 |

Notes:

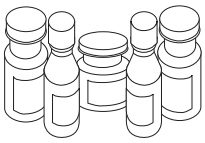
FORMULARY SUMMARY

| Year | Total # of Drugs on Formulary | Number of Protease Inhibitors | Number of Other Anti-Retroviral Drugs | Advisory Body | |
|------|-------------------------------|-------------------------------|---------------------------------------|---------------|-----|
| 2002 | 27 | 7 | 12 | No | Yes |
| 2001 | 24 | 6 | 11 | No | Yes |
| 2000 | 24 | 6 | 11 | No | Yes |

FINANCIAL ELIGIBILITY SUMMARY

| Year | ADAP Eligibility Ceiling as a % of FPL | % of Active Clients Below 200% of FPL | Medicaid Eligibility as a % of FPL | Co-Payment | | Asset Limit (Amount) | Annual Income Cap (Amount) | Frequency of Recertification |
|------|--|---------------------------------------|------------------------------------|------------|---------------|----------------------|----------------------------|------------------------------|
| | | | | Fixed | Sliding Scale | | | |
| 2002 | 250 | 75 | 100 | No | No | | 0 | Annual |
| 2001 | 250 | 75 | 100 | No | No | 0 | 0 | Annual |
| 2000 | 250 | 95 | 100 | No | No | 0 | 0 | Annual |

Notes: Of clients on the waiting list 97% are below 200% of FPL.
For Medicaid Eligibility, 133% FPL for pregnant women and children under 6.



Sample (page 2)

AIDS DRUG ASSISTANCE PROGRAM STATE PROFILE

MEDICAL ELIGIBILITY SUMMARY

| Year | Clinical Criteria to Access ADAP | | | | Clinical Criteria to Access Protease Inhibitors (PIs) | | | |
|--------|----------------------------------|-----------|------------|-------|---|-----------|------------|-------|
| | HIV+ | CD4 Count | Viral Load | Other | Add'l Criteria for PIs | CD4 Count | Viral Load | Other |
| 2002 | Yes | No | No | No | No | No | No | No |
| 2001 | Yes | No | No | No | No | No | No | No |
| 2000 | Yes | No | No | No | No | No | No | No |
| Notes: | | | | | | | | |

CLIENT UTILIZATION SUMMARY

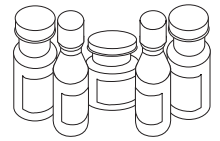
| Year | # Clients Enrolled | # Using ADAP Each Month | % of Clients on PIs | Cap on Expenditures Per Patient: | | ADAP Program Limits | | Limits on PI Access | |
|--|--------------------|-------------------------|---------------------|----------------------------------|-----|---------------------|-----------|---------------------|-----------|
| | | | | All Drugs | PIs | Enrollment Cap | Wait List | Enrollment Cap | Wait List |
| 2002 | 1,240 | 800 | 50 | No | No | 1240 | 182 | No | No |
| 2001 | 950 | 640 | 65 | 4 ARTs | 0 | 750 | 329 | No | No |
| 2000 | 750 | 615 | 75 | 4 ARTs | 0 | 750 | 564 | No | No |
| Notes: There is no limit on OI drugs, 2/01 - 343 on wait list 23 added, 3/01 - 361 on wait list 21 added. May 2001 - 329 on wait list. | | | | | | | | | |

COST-SAVING STRATEGIES SUMMARY

| Year | OPA(1) | Manufacturers' Discount | Manufacturers' Rebate(2) | Pharmacy Discount | Manufacturers' Patient Assistance Program |
|--|--------|-------------------------|--------------------------|-------------------|---|
| 2002 | P | No | N | Yes | Yes |
| 2001 | P | No | N | No | Yes |
| 2000 | P | No | N | No | Yes |
| <p>(1) OPA Codes P = up-front purchase price R = rebate option N = not participating</p> <p>(2) Mfr. Rebate Codes V = voluntary/negotiated M = mandated by State N = no rebates received</p> <p>Notes:</p> | | | | | |

MEDICAID COORDINATION SUMMARY

| Year | Screening for Medicaid Eligibility | | | | | Coordination | | |
|--------|------------------------------------|------------------|----------------------|-----------------|----------------------|-----------------------|----------------------|---------------------|
| | Online Interface | Dual Application | Proof of Application | Proof of Denial | Case Manager Reviews | Common Administration | Coordinated Benefits | Retroactive Billing |
| 2002 | Yes | No | Yes | No | Yes | No | No | Yes |
| 2001 | Yes | No | No | No | Yes | No | No | No |
| 2000 | Yes | No | No | No | Yes | No | No | No |
| Notes: | | | | | | | | |



ATTACHMENT

GENERAL INSTRUCTIONS FOR COMPLETING THE ADAP STATE PROFILE

Please use the attached profile to verify and update the information for your State. **All responses should reflect aggregate or average figures based on the Title II program year, which begins April 1 and ends March 31.** (For example, the program year for 2003 is April 1, 2003 through March 31, 2004.)

When completing the form, please provide legible responses (hand-written responses are acceptable). If information from previous years is correct, then no changes are needed; however, if a correction or update is necessary, simply strike through the incorrect information and legibly enter the correct data. If you have further questions about how to answer specific questions, please call the ADAP Branch Chief, Division of Service Systems (DSS) at (301) 443-2834.

I. Contact Information Box

Please provide the name of the person responsible for the administration of the State's/Territory's AIDS Drug Assistance Program (ADAP). This person should serve as the contact for all inquiries from DSS regarding the ADAP. Also include the name of the ADAP administrative agency, its complete mailing address, telephone number, fax number, **and an E-mail address**, if available. Additionally, please indicate in the respective boxes, whether your State's/Territory's ADAP has submitted a notification of intent to use ADAP funds to purchase insurance, or will request to use, or have been approved to use ADAP funds under the Flexibility Policy.

II. ADAP Funding Summary

For FY 2003, project the amount to be allocated from the sources noted. If you expect no resources to be allocated from a particular source, indicate a zero. For FY 2002 and FY 2001, please verify or correct the figures given based on your most current data. The amount of the total Title II grant-award is listed for reference purposes only. As soon as FY 2003 appropriations are complete, you will be provided the full Title II award amount and ADAP earmark for your State. **For example, please verify or update the amounts listed for Title I, Title II, and State contribution for FY 2001 and 2002.**

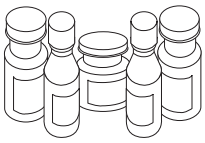
- If the State ADAP received a Supplemental Treatment Drug Grant for FY 2002, enter the amount of the required match for this grant award.

III. Formulary Summary

For FY 2003, indicate the total number of drugs, the number of protease inhibitors and the number of other antiretrovirals you expect to be on your formulary. For FY 2002 and FY 2001, please verify or correct the figures given.

Please note: Saquinavir is available in two forms (Invirase and Fortovase). Both forms are counted as one (1) protease inhibitor (PI). Currently, there are six PI's available.

In the box entitled "Advisory Body," indicate whether or not your ADAP utilizes a formal advisory body for making decisions on drugs to include on the ADAP formulary and/or decisions about limitation on access to certain formulary drugs. If an informal process or mechanism is utilized, write-in "No." In the Notes section, describe the advisory body membership and the frequency of meeting.



IV. Financial Eligibility Summary

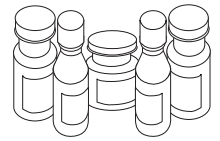
- For FY 2003, indicate the expected financial eligibility criteria as a percent of the Federal Poverty Level (FPL) and verify or correct your ADAP's financial eligibility criteria for previous years.
- Project the percentage of enrolled ADAP clients who have incomes below 200% FPL and verify or correct this information for previous years. If necessary, provide an estimate for previous years' data.
- For FY 2003, indicate the expected Medicaid financial eligibility criteria as a percent of the FPL, and enter the existing Medicaid financial eligibility criteria for FY 2002.
- For the "Co-Payment" boxes, if your program has a fixed amount as a co-pay (e.g., \$2 per prescription), indicate that amount for each fiscal year appropriate or enter "no" if not applicable. If your ADAP uses a sliding fee scale, answer "yes" or "no" for each year applicable and describe the sliding fee scale in the Notes section.
- Please provide specific dollar amounts for the "Asset Limit" and "Annual Income Cap" boxes if these apply to your program during each fiscal year. If your program does not have these characteristics, write "No" for each year applicable.
- In the "Frequency of Re-certification" box, please specify the time period (e.g., annually, semi-annually, or quarterly) to depict how often clients are re-certified as eligible to receive ADAP services.

V. Medical Eligibility Summary

If the only clinical criteria for accessing ADAP and/or protease inhibitors (PIs) is a positive HIV diagnosis, write "yes" in the first box. If there are other specific criteria for accessing ADAP or PIs, complete the remainder of the table projecting for FY 2003 or inserting/verifying the information for FY 2002 and FY 2001. **Please write in the specific criteria where applicable. Use the Notes section to provide an explanation, if necessary.**

VI. Client Utilization Summary

- For FY 2003, project the number of clients who will be enrolled in your ADAP (active clients carried forward from 2002 **plus** new enrollees). *Clients* refer to the total number of individuals who are enrolled in your program whether or not they utilized ADAP services during the program fiscal year. For FY 2002 and FY 2001, please verify the figures given.
- For the box entitled "Number Using ADAP Each Month" project the monthly number of clients who will receive at least one drug through your ADAP.
- For the box entitled "Percentage of Clients on Protease Inhibitors" provide an estimate for the average percentage of clients accessing at least one PI during FY 2002, and complete/verify figures for previous years.
- Indicate any caps or limits on the number of antiretroviral medications a client may receive monthly.



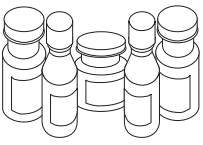
- Information on program caps or waiting lists should reflect your projections for the upcoming program fiscal year recognizing that some may be a continuation of previous years. For FY 2002 and FY 2001, verify the information given. For any answer that is not “No” enter a specific value (i.e., for per patient expenditures, a dollar ceiling; for ADAP program limits, the absolute number of people served/to be served; for PI access limits, the absolute number served/to be served; for wait lists, the projected number on a wait list for services).

VII. Cost-Saving Strategies Summary

- If you anticipate participating in the 340B Drug Discount Program during FY 2003, indicate direct purchase or rebate in the Office of Pharmacy Affairs (OPA) box, utilizing the “OPA Codes.” For FY 2002 and FY 2001, verify or correct the information given.
- If your ADAP anticipates receiving manufacturers’ rebates in FY 2003, please use the “Mfr Rebate Codes” to complete the box entitled “Manufacturers’ Rebate” For FY 2002 and FY 2001, verify or correct the information given.
- For the “Manufacturers’ Discount” box and the “Pharmacy Discount” box, please indicate with a “Yes/No” if your ADAP utilizes or anticipates utilizing either of these cost-savings strategies in FY 2003. The term “Manufacturers’ Discount” applies to situations where the ADAP has directly negotiated a discounted purchase price with a manufacturer. The term “Pharmacy Discount” applies to situations in which the ADAP has negotiated a discount off of the Average Wholesale Price (AWP) with pharmacy providers (e.g., AWP minus 10 per cent, or purchase price equals the Medicaid rate). For FY 2002 and FY 2001, please verify the information given.
- For the box entitled “Manufacturers’ Patient Assistance Program(s)” please indicate with a “Yes/No” if your ADAP utilizes and/or coordinates with these programs to provide ADAP clients with some of their prescribed medications.
- In the Notes section, please describe any additional cost-saving strategies used by the ADAP.

VIII. Medicaid Coordination Summary

- Please provide a “Yes/No” response for the boxes in this table, denoting particular screening and coordination strategies between your ADAP and the State Medicaid program. For FY 2002 and FY 2001, please verify the information given. The following definitions may prove helpful:
- Online Interface*—the ADAP or some entity acting on its behalf has computer access for verifying an individual’s Medicaid eligibility and/or enrollment status.
- Dual Application*—an application for Medicaid is completed at the same time as an application to ADAP.
- Proof of Application*—an individual cannot be enrolled in ADAP without proof that they have previously applied to Medicaid.
- Proof of Denial*—an individual cannot be enrolled in the ADAP without proof that Medicaid has denied them coverage.



- *Case Manager Reviews*—the case manager reviews, enrolls, and/or monitors a client’s Medicaid eligibility status.
- *Common Administration*—the ADAP and Medicaid program are administered by the same entity.
- *Coordinated Benefits*—in States and Territories where individuals may receive medications from Medicaid and ADAP concurrently (e.g., Medicaid is limited to “x” number of prescriptions, per month and other prescriptions must be provided through ADAP), the programs coordinate their services to assure that ADAP covers the less costly medication(s).
- *Retroactive Billing*—the ADAP has a process in place for recouping payments made on behalf of clients whose Medicaid eligibility had not been definitively determined at the time payment was made but is subsequently approved retroactively to the date of application for Medicaid coverage.