Public Comments to Request in Federal Register/ Vol. 84, No 232/ Tuesday, December 3, 2019/ Notices
Submission from the Virginia Department of Health
Submit via email to paperwork@hrsa.gov or by mail to HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville MD 20857

Purpose: To provide feedback regarding proposed modifications in data reporting for AIDS Drug Assistance Programs (ADAPs), administered by the Health Resources and Services Administration (HRSA).

Recipient Report

- Addition of two new "Yes/No" questions

Response:

1. With question, "Has your AIDS Drug Assistance Program (ADAP) experienced an unexpected increase in enrolled clients" additional clarification is requested to help measure and define "unexpected increase".

HRSA HAB response: HAB has not defined what is an 'unexpected increase' in enrolled clients; we leave it up to the recipients to define.

   - The response for question "If yes, how many new clients were enrolled" would also be dependent of clarification provided in previous question.

2. We agree with the addition of the question whether recipients have an open formulary that is inclusive of all Food and Drug Administration (FDA)-approved medications and it will be helpful to collect and share.

HRSA HAB response: Thank you for sharing this information.

- Addition of one new follow-up question that requests the number of new clients enrolled

Response: We have no objections to the proposed request. From review, it is determined that the variable name "enrollment status at the end of the calendar year" is changed but will not affect data collection (18).

HRSA HAB response: Thank you for sharing this information.

- Clarification on two existing questions

Response: After review, clarification for the change in the variable name to "new enrollment" was helpful.

HRSA HAB response: Thank you for sharing this information.

- Revision to one existing question that request program income and manufacturer rebates reinvested in ADAP

  Response: How different would this question be from the reporting completed in the Federal Financial Report (FFR)?

HRSA HAB response: Recipients are required to report any rebates and/or program income they have generated during the grant year on the FFR. They also report on the amount of rebates and/or program income expended during the grant year on the FFR. What is reported on the ADR are only the rebates (and now program income) that have been reinvested in the ADAP during the reporting period.

- Deletion of six obsolete data elements

  Response:

  1. Approve removal of variable "high risk insurance" and agree it should go to "medical insurance" (which is changing to "health care coverage").
  2. Agree to removal of "medication start date".
  3. Agree to removal of "medication day".
  4. Agree to removal of "clinical criteria to get access".
  5. Agree to removal of additional three subset questions "CD4 count requirement and viral load requirement and other clinical criteria".
  6. For questions related to "ADAP funding received during the reporting period"
     - We agree to removal of "Total contributions from Part B Base Funding" and total contribution from part B supplemental funding.
     - We agree with the change of "Total contributions from Part C/D grantees".
     - For manufacturer rebates reinvested in ADAP the proposed change is not a reporting burden for the program, however, HRSA must be consistent in its distinguishing definition of rebates (i.e. it is not considered program income) and program income for both this report and the Ryan White HIV/AIDS Program (RWHAP) Services Report (RSR).

HRSA HAB response: For the ADR, the recipient would only report those rebates and program income that are reinvested by the recipient into ADAP for that reporting period. Likewise, for the RSR, the recipient would report any non-ADAP services that it has funded through either rebates or program income during the reporting period. Please also refer to Policy Clarification Notices 15-03 and 15-04 for additional information around the

definitions and reporting of program income and pharmaceutical rebates.

Client report

- Revision to reporting of RWHAP ADAP funded medications to include all medications rather than a subset of medications

  Response: We have no objection to the proposed revision of reporting all medications as a whole, instead of reporting a subset, in an effort to minimize data reporting. It is recommended medications be presented in alphabetical order and not by drug type or clinical background.

HRSA HAB response: The system can be modified to allow for sorting of the list of medications. We will consider this comment when designing the AIDS Drug Assistance Data Report User Interface in the Electronic Handbooks (EHBs).

- Revision to one existing question that request reporting of all RWHAP ADAP funded medications using the National Drug Code from the Drug Identification Code (d-codes)

  Response: Agree with the change.

- Revision to reporting of clinical data for clients to include all clients rather than a subset of clients

- *Response:* Agree with the change.

- Deletion of three data elements that were combined with other existing data elements

  Response: Please see response to number 5 under "Deletion of six obsolete data elements".

The Virginia Department of Health acknowledges the importance of data collection for program performance reports and its utility in informing programmatic policies, administrative guidance, and potentially resource allocation and appropriations. The estimated time burden for recipients to prepare these reports varies based on the size of the Ryan White team, the time of year the reports are requested vis-à-vis other reporting requirements for HRSA for Ryan White funding, the availability and collaboration of fiscal and program staff to prepare this performance report, and the complexity of having to collect data across more than one grant year to complete the

ADAP Data Report (and the NASTAD annual ADAP surveys). It would be easier for programs if the reporting period were synchronized to the period of performance of the Ryan White Grant Year as opposed to the current reporting requirement of a Calendar Year, which requires data collection across two Ryan White Grant Years. Cross-year data collection creates a greater burden for the team to prepare reports.

Many of the suggested changes reduce duplication of reporting information and there is thoughtful consideration about other sources to extract the data of interest. The burden is eased by deleting obsolete variables. Any dysfunctions in the software to generate or upload performance reports will increase the time burden for completion and submission. HRSA has made significant efforts in the last two years to increase the use and user-friendliness of electronic portals for data and report submission. It could prove beneficial if HRSA were to test the platforms and software each year before activating for recipients and subrecipient use, especially related to Performance Reports such as the ADAP Data Report. Increased used of automated data collection and other forms of information technology can reduce reporting burden if the tools selected actually perform the tasks correctly. Any data pre-population from HRSA, using from the previous year's submission, will be helpful to recipients to minimize data entry each year and the program staff can focus on data entry only for data revisions for the reporting year. If you have any questions related to these comments, please contact Kimberly Scott by email or phone at Kimberly.Scott@vdh.virginia.gov or 804-864-7213. Thank you for the opportunity to submit comments on these issues.

HRSA HAB response: HRSA HAB really appreciates having the opportunity to review your thoughtful comments on the proposed revisions to the AIDS Drug Assistance Data Report (ADR). HAB does consider all comments valuable and will utilize feedback to revise the Information Collection Request proposal and/or the ADR portal in the EHBs. For example, HAB is considering methods to implement beta testing with recipients, reusing existing data to prepopulate reports, and aligning ADR reporting with state budget periods.