U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Health Resources and Services Administration

HIV/AIDS Bureau Division of Service Systems

Ryan White HIV/AIDS Program

HIV Care Grant Program Part B
States/Territories Formula and
AIDS Drug Assistance Program Formula and ADAP Supplemental Awards

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FUNDING OPPORTUNITY ANNOUNCEMENT

Fiscal Year 2011

Application Due Date: January 3, 2011

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Legislative Authority: Public Health Service Act as amended, Sections 2620, 42 USC 300ff-29a Title XXVI of the Public Health Service (PHS) Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87)

Executive Summary

The new National HIV/AIDS Strategy (NHAS) has three primary goals: 1) reducing the number of people who become infected with HIV, 2) increasing access to care and optimizing health outcomes for people living with HIV, and 3) reducing HIV-related health disparities.

The NHAS states that more must be done to ensure that new prevention methods are identified and that prevention resources are more strategically deployed. Further, the NHAS recognizes the importance of getting people with HIV into care early after infection to protect their health and reduce their potential of transmitting the virus to others. HIV disproportionately affects people who have less access to prevention and treatment services and, as a result, often have poorer health outcomes. Therefore, the NHAS advocates adopting community-level approaches to reduce HIV infection in high-risk communities and reduce stigma and discrimination against people living with HIV.

To ensure success, the NHAS requires the Federal government and State, tribal and local governments to increase collaboration, efficiency, and innovation. Therefore, to the extent possible, Ryan White program activities should strive to support the three primary goals of the National HIV/AIDS Strategy.

The Ryan White HIV/AIDS Program Part B Application Funding Opportunity Announcement is provided to assist applicants in preparing their fiscal year (FY) 2011 single-grant application for funds under Part B of Title XXVI of the Public Health Service (PHS) Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87) (hereafter referred to as the Ryan White HIV/AIDS Program). The legislation can be obtained at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi? dbmame=111_cong_public_laws&docid=f:publ087.111.pdf.

This funding opportunity announcement contains application instructions for most Part B-related funding, including:

- Part B Formula funding (Part B base),
- ➤ AIDS Drug Assistance Program funding (ADAP),
- ➤ Minority AIDS Initiative (MAI),
- ➤ ADAP Supplemental funding,
- Emerging Communities funding, and
- Pacific Island Jurisdictions Part B funding.

This announcement contains instructions for completing a comprehensive application response and communicates information on current and new program initiatives. It also provides background information on reporting requirements and other forms of documentation that will be required from grantees, once awards have been made.

The HIV/AIDS Bureau (HAB) recognizes that States and Territories have used grant funds to develop and/or expand systems of care to meet the needs of Persons Living with HIV/AIDS (PLWH/A) within their borders. The Centers for Disease Control and Prevention (CDC) has ongoing initiatives that may identify significant new numbers of PLWH/A that will be seeking services. This requires careful reassessment of how States/Territories will assure access to primary care and medications as well as ensure the provision of critical support services

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necessary to maintain individuals in systems of care. In light of the ongoing CDC initiatives, as well as HAB and grantee efforts to estimate and assess Unmet Need and the number of individuals who are unaware of their HIV/AIDS status, States/Territories must ensure that essential core medical services have been adequately addressed when setting priorities and allocating Part B funds. A list of CDC initiatives can be found at http://www.cdc.gov/hiv/topics/prev_prog/index.htm.

As required by the Ryan White HIV/AIDS Program legislation, the Part B grant award for FY 2011 will be computed by using living cases of HIV/AIDS as reported to and confirmed by the Director of CDC and code-based data submitted to the Health Resources and Services Administration (HRSA). This Guidance requires applicants to report on the numbers of HIV and AIDS cases in their jurisdictions.

CDC estimates that of the 1.1 million adults and adolescents at the end of 2006 living with HIV, 21% of infected persons do not know their HIV status. The ultimate United States (US) Public Health goal is to inform all HIV+ persons of their status and bring them into care in order to improve their health status, prolong their lives and slow the spread of the epidemic in the US through enhanced prevention efforts. A new legislative requirement focuses on specific requirements and expectations for identifying the unaware and bringing them into care. This application requires the grantee to provide a description of the strategy, plan and data for reaching this goal within their jurisdiction. As such, specific requirements can be found under – Table of Contents-section IV. Application and Submission Information, A. (FY 2011, Part B Formula Grant Application), (4) Early Identification of Individuals with HIV/AIDS, EIIHA.

As a Condition of Award for Fiscal Year 2011, Ryan White Part B grantees will be required to meet specific requirements regarding the monitoring of both the grantee and their providers/sub-recipients. To help our grantees meet this challenge, HRSA through the Division of Service Systems (DSS) is in the process of developing guidelines outlining the responsibilities of both HRSA staff and grantee staff.

The following information will also assist States/Territories in understanding and completing this year's grant application:

- ➤ Include a description of the Strategy, Plan, and Data associated with the Early Identification of Individuals who are Unaware of their HIV/AIDS Status.
- All Part B funds are subject to Section 2612(b) of the PHS Act, which requires that not less than 75 percent of the service dollars be used to provide core medical services that are needed in the State/Territory for individuals with HIV/AIDS who are identified and eligible under the Ryan White HIV/AIDS Program. Applicants that apply for and receive Minority AIDS Initiative (MAI) grant funds in FY 2011 are reminded that the MAI service dollars must also be considered in determining compliance with this requirement in FY 2011.
- Applicants seeking a waiver to the core medical services requirement must submit a waiver request with this grant application in accordance with the information and criteria published by HRSA in the Federal Register Notice, Vol. 73, No. 113, dated Wednesday, June 11, 2008, and may be found at http://edocket.access.gpo.gov/2008/E8-13102.htm. This waiver request process has been approved by the Office of Management and Budget (OMB) under the paperwork Reduction Act of 1995 (OMB number 0915-0307). In addition, Grantees are

advised that a FY 2011 Part B waiver request must include FY 2011 MAI unless the grantee does NOT apply for MAI formula funds. Otherwise, a waiver request that does not include MAI will not be considered. (A core medical services waiver request should be included as **Attachment 7.)** Consistent with Section 2613(f), all services provided by or through consortia are considered support services.

- The Ryan White Services Report (RSR) captures information necessary to demonstrate program performance and accountability. All Ryan White core service and support service providers are required to submit client-level data for Calendar Year (CY) 2011. Please refer to the HIV/AIDS Program Client Level Data website at http://hab.hrsa.gov/manage/CLD.htm for additional information.
- > States/Territories will be required to sign updated Program Assurances which are included as Appendix A of this funding opportunity announcement.
- ➤ Program Income: HHS Grants Regulations require grantees to collect and report program income. The program income shall be returned to the respective Ryan White HIV/AIDS Program and used to provide eligible services to eligible clients. "Program income is gross income—earned by a recipient, sub-recipient, or a contractor under a grant—directly generated by the grant-supported activity or earned as a result of the award. Program income includes, but is not limited to, income from fees for services performed (e.g., direct payment, or reimbursements received from Medicaid, Medicare and third-party insurance); and income a recipient or sub-recipient earns as the result of a benefit made possible by receipt of a grant or grant funds, e.g., income as a result of drug sales when a recipient is eligible to buy the drugs because it has received a Federal grant."

Direct payments include charges imposed by recipients and sub-recipients for Part B services as required under Section 2617(c) of Program legislation, such as enrollment fees, premiums, deductibles, cost sharing, co-payments, co-insurance, or other charges. As specified on the Part B Notice of Award (NoA), program income must be "Added to funds committed to the project or program and used to further eligible project or program objectives." Grantees are responsible for ensuring that sub-recipients have systems in place to account for program income, and for monitoring to ensure that sub-recipients are tracking and using program income consistent with grant requirements. See the HHS Grants Policy Statement at https://ftp.hrsa.gov/grants/hhsgrantspolicystatement.pdf, the Part B NoA, and 45 CFR 92.25.

For the most up to date policy regarding Unobligated Balances please refer to Policy Notice 10-01 - 2009 Reauthorized Unobligated Balances Provisions, available online at: http://hab.hrsa.gov/law/1001.pdf

According to the statute, drug rebates are not considered part of the grant award and are not subject to the unobligated balances provision. Part B grantees must report Program Income on the SF-425 (Federal Financial Report) long form, however, rebate funds **must not** be included on the SF-425 as part of the reported unobligated balance, and thus, must not be requested at any time for carry over.

➤ The FY 2011 Part B MAI grant application is included in this Part B States/Territories Formula, and AIDS Drug Assistance Program Formula application guidance. The Part B MAI award is formula based and will be awarded along with the Part B formula and ADAP supplemental and formula awards. This section must be completed by Part B grantees

seeking an MAI formula grant award for FY 2011. Eligible Part B Grantees include: the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, the Federated States of Micronesia, the Marshall Islands, the Northern Marianas and the Republic of Palau. States NOT applying for MAI funding should state this in the MAI application section.

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I. Funding Opportunity Description

1. Purpose

The authority for this grant program is the PHS Act as amended, Sections 2611-23, (42 U.S.C. 300ff-21-31b), as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87). The U.S. Department of Health and Human Services (DHHS) administers the Part B program through the Health Resources and Services Administration (HRSA), the HIV AIDS Bureau (HAB), Division of Service Systems (DSS).

Part B funding is used to assist States and Territories in developing and/or enhancing access to a comprehensive continuum of high quality, community-based care for low-income individuals and families living with HIV. A comprehensive HIV/AIDS continuum of care includes the following core medical services: outpatient and ambulatory health services, AIDS Drug Assistance Program (ADAP) treatments, AIDS pharmaceutical assistance (local), oral health care, early intervention services, health insurance premium and cost sharing assistance, home health care, medical nutrition therapy, hospice services, home and community-based health services, mental health services and medical case management, including treatment adherence services and substance abuse outpatient care. These services assist PLWH in accessing treatment of HIV infection that is consistent with HHS Treatment Guidelines. (Current treatment guidelines are available at www.aidsinfo.nih.gov.) The guidelines include ensuring access to antiretroviral and other drug therapies, including prophylaxis and treatment of opportunistic infections as well as combination antiretroviral therapies.

Comprehensive HIV/AIDS care beyond these core medical services also includes access to other support services: case management (non-medical), child care services, emergency financial assistance, food bank/home delivered meals, health education/risk reduction, housing services, legal services, linguistic services, medical transportation services, outreach services, psychosocial support services, referral for health care/supportive services, rehabilitation services, respite care, residential substance abuse services and treatment adherence counseling. This continuum of care may include only those supportive services that enable individuals to access and remain in primary medical care.

Funding for core medical and support services can be provided through the following Part B program components:

HIV Care Consortia: includes any entity that is an association of one or more public, and one or more nonprofit private health care and support service providers and community based organizations operating within service delivery areas determined by the State to be most affected by HIV disease. Funds may be used to provide the core medical and support services described above. However, all services, including core medical services delivered through Consortia will be deemed to be support services. [See: PHS Act Sec. 2613(f).]

Home and Community-Based Care: includes therapeutic, nursing, supportive and/or compensatory health services provided by a licensed/certified home health agency in a home/residential setting, in accordance with a written, individualized plan of care established by a case management team that includes appropriate health care professionals, outreach services and coordination. [See: PHS Act Sec. 2614(a)(1-3).]

Health-Insurance Program: includes health insurance or medical benefits provided under a health insurance program, including risk pools. [See: PHS Act Sec. 2615(a)(1-2).]

Provision of Treatments: includes therapeutics to treat HIV/AIDS disease or to prevent the serious deterioration of health arising from HIV/AIDS in eligible individuals, including measures for the prevention and treatment of opportunistic infections. [See: PHS Act Sec. 2616(a).]

State Direct Services: includes services administered through other State delivery mechanisms or contracted out by the state.

II. Award Information

1. Type of Award

Funding will be provided in the form of a grant to States/Territories as defined by Title XXVI of the PHS Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87).

2. Summary of Funding

This program will provide funding for Federal fiscal year 2011. Approximately 1.2 billion dollars is expected to be available to fund 59 Part B grantees.

Notification of grant awards will be sent to the Chief Elected Official (CEO) or to the delegated administrative agency responsible for dispersing Part B Grant Program funds. Title XXVI of the PHS Act was reauthorized on October 30, 2009 effective retroactively to September 30, 2009.

Part B funding is available through several forms: the formula grant (i.e., Part B base award, MAI and ADAP Earmark award for HIV/AIDS-related medications); the ADAP Supplemental award; and the Emerging Communities award.

Part B "base" and ADAP awards are calculated on the basis of the number of reported living cases of HIV/AIDS cases in the State or Territory in the most recent calendar year as confirmed by CDC and HIV code based data submitted to HRSA. Similarly, for grantees applying for MAI formula funds, awards will be based on the number of reported and confirmed living minority cases of HIV/AIDS for the most recent calendar year and code-based HIV data submitted to HRSA. The most recent calendar year ends December 31, 2009. Supplemental ADAP grants are awarded to states demonstrating severe need for medications. Emerging Communities, located in states, must have between 500-999 cumulative AIDS cases during the most recent 5 years.

To ensure timely notification of the release of the FY 2011 Part B awards and other important documents relating to the Part B grant, States/Territories must forward personnel, address, and email or telephone changes immediately to the appropriate Grants Management Specialist listed on the State's or Territory's most recent Notice of Grant Award.

Please note that the Secretary may reduce the amounts of grants under Part B to a State/Territory or political subdivision of a State/Territory for a fiscal year if, with respect to such grants for the second preceding fiscal year, the State/Territory or subdivision fails to prepare audits in

accordance with the procedures of Section 7502 of Title 31, United States Code. See PHS Act Sec. 2682(a).

III. Eligibility Information

1. Eligible Applicants

The following States and Territories are eligible to apply for program funding: all 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Territories of the Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, the Federated States of Micronesia, and the Republic of the Marshall Islands.

States must designate a lead State/Territory agency that will be responsible for administering all assistance received; conducting a needs assessment and preparing a State/Territory plan; preparing all applications; receiving notices regarding programs; and collecting and submitting to the Secretary every two years all audits from grantees within the State, including an audit regarding funds expended.

2. Cost Sharing/Matching

States meeting the criteria established in Section 2617(d)(1) of the PHS Act for State match, are required to match their FY 2011 Part B Formula (base) and ADAP award as follows. Matching funds are required from States with more than one percent of the total U.S. AIDS cases reported to the CDC during the previous two federal fiscal years (i.e., 2008 and 2009). These matching funds can either be in the form of cash or in-kind resources, and can be provided either directly or through donations to the State from public or private entities, in proportion to their Part B funding. The match begins at \$1 in State funds for every \$5 in Federal funds and increases to \$1 in State funds for every \$2 in Federal funds in later years (Section 2617). Matching funds for ADAP supplemental treatment drug grants are required in an amount equal to \$1 for each \$4 of Federal funds provided in the supplemental grant. [See Section 2618(a)(2)(F)(ii)(III).] The law also provides for a waiver of the ADAP supplemental match pursuant to the language in the statute. Applicants requesting a waiver should include this request in the narrative related to the ADAP Supplemental. Part B MAI and Emerging Community funds are exempt from the matching requirements.

3. Other

a) Maintenance of Effort

Grant funds shall not be used to take the place of current funding for activities described in the application. The grantee must agree to maintain non-Federal funding for HIV-related activities at a level which is not less than expenditures for such activities during the fiscal year prior to receiving the grant [see Section 2617(b)(7)(E)]. Applicants must submit with their FY 2011 Part B application a report detailing the year-to-year HIV-related expenditures by the State/Territory for the previous two complete fiscal years (**Attachment 2**). The report must include:

- 1) Documentation (or worksheet) proving that the overall level of HIV-related expenditures has been maintained year-to-year for the previous two complete fiscal years (i.e., 2008 and 2009), and
- 2) A brief narrative explaining any changes in the data set where HIV-related expenditures have been reduced or where the purpose of an HIV-related expenditure has changed.

IV. Application and Submission Information

1. Address to Request Application Package

Application Materials and Required Electronic Submission Information

HRSA *requires* applicants for this funding opportunity announcement to apply electronically through Grants.gov. All applicants *must* submit in this manner unless they obtain a written exemption from this requirement <u>in advance</u> by the Director of HRSA's Division of Grants Policy. Applicants must request an exemption in writing from <u>DGPWaivers@hrsa.gov</u>, and provide details as to why they are technologically unable to submit electronically through the Grants.gov portal. Your email must include the HRSA announcement number for which you are seeking relief, the name, address, and telephone number of the organization and the name and telephone number of the Project Director as well as the Grants.gov Tracking Number (GRANTXXXX) assigned to your submission along with a copy of the "Rejected with Errors" notification you received from Grants.gov. **HRSA and its Grants Application Center (GAC)** will only accept paper applications from applicants that received prior written approval. However, the application must still be submitted under the deadline.

Refer to HRSA's *Electronic Submission User Guide*, available online at http://www.hrsa.gov/grants/userguide.htm, for detailed application and submission instructions. Pay particular attention to Sections 2 and 5 that provide detailed information on the competitive application and submission process.

Applicants must submit proposals according to the instructions in the Guide and in this funding opportunity announcement in conjunction with Application Form SF-424. The forms contain additional general information and instructions for applications, proposal narratives, and budgets. The forms and instructions may be obtained from the following site by:

- a) Downloading from www.grants.gov or
- **b)** Contacting the HRSA Grants Application Center at:

910 Clopper Road Suite 155 South Gaithersburg, MD 20878 Telephone: 877-477-2123 HRSAGAC@hrsa.gov Specific instructions for preparing portions of the application that must accompany Application Form SF-424 appear in the "Application Format" section below.

2. Content and Form of Application Submission

Application Format Requirements

The total size of all uploaded files may not exceed the equivalent of 90 pages when printed by HRSA, or a total file size of approximately 10 MB. This 90-page limit includes the abstract, project and budget narratives, attachments, and letters of commitment and support. Standard forms are NOT included in the page limit.

Applications that exceed the specified limits (approximately 10 MB, or that exceed 90 pages when printed by HRSA) will be deemed non-compliant. Non-compliant applications will not be considered under the funding announcement.

Application Format

Applications for funding must consist of the following documents in the following order:

SF-424 Non Construction – Table of Contents

- It is mandatory to follow the instructions provided in this section to ensure that your application can be printed efficiently and consistently for review.
 Failure to follow the instructions may make your application non-compliant. Non-compliant applications will not be given any consideration under this
- Failure to follow the instructions may make your application non-compliant. Non-compliant applications will not be given any consideration under this
 funding opportunity announcement.
- For electronic submissions, applicants only have to number the electronic attachment pages sequentially, resetting the numbering for each attachment, i.e., start at page 1 for each attachment. Do not attempt to number standard OMB approved form pages.
- For electronic submissions no table of contents is required for the entire application. HRSA will construct an electronic table of contents in the order specified.
- When providing any electronic attachment with several pages, add Table of Content page specific to the attachment. Such page will not be counted towards the page limit.

Application Section	Form Type	Instruction	HRSA/Program Guidelines	
Application for Federal Assistance (SF-424)	Form	Pages 1, 2 & 3 of the SF-424 face page.	Not counted in the page limit	
Project Summary/Abstract	Attachment	Can be uploaded on page 2 of SF-424 - Box 15.	Required attachment. Counted in the page limit. Refer to the guidance for detailed instructions. Provide table of contents specific to this document only as the first page.	
Additional Congressional District	Attachment	Can be uploaded on page 2 of SF-424 - Box 16.	As applicable to HRSA; not counted in the page limit.	
HHS Checklist Form PHS-5161	Form	Pages 1 & 2 of the HHS checklist.	Not counted in the page limit.	
Project Narrative Attachment Form	Form	Supports the upload of Project Narrative document.	Not counted in the page limit.	
Project Narrative	Attachment	Can be uploaded in Project Narrative Attachment form.	Required attachment. Counted in the page limit. Refer to the guidance for detailed instructions. Provide table of contents specific to this document only as the first page	
SF-424A Budget Information - Non-Construction Programs	Form	Page 1 & 2 to supports structured budget for the request of Non construction related funds.	Not counted in the page limit.	
Budget Narrative Attachment Form	Form	Supports the upload of Project Narrative document.	Not counted in the page limit.	
Budget Narrative	Attachment	Can be uploaded in Budget Narrative Attachment form.	Required attachment. Counted in the page limit. Refer to the funding opportunity announcement for detailed instructions.	

Application Section	Form Type	Instruction	HRSA/Program Guidelines
Project/Performance Site Location(s)	Form	Supports primary and 29 additional sites in structured form.	Not counted in the page limit.
Additional Performance Site Location(s)	Attachment	Can be uploaded in the SF-424 Performance Site Location(s) form. Single document with all additional site location(s)	Not counted in the page limit.
SF-424B Assurances - Non- Construction Programs	Form	Supports assurances for non construction programs	Not counted in the page limit.
Disclosure of Lobbying Activities (SF-LLL)	Form	Supports structured data for lobbying activities.	Not counted in the page limit.
Other Attachments Form	Form	Supports up to 15 numbered attachments. This form only contains the attachment list.	Not counted in the page limit.
Attachment 1-15	Attachment	Can be uploaded in Other Attachments form 1-15.	Refer to the attachment table provided below for specific sequence. Counted in the page limit.

To ensure that attachments are organized and printed in a consistent manner, follow the order provided below. Note that these instructions may vary across programs.

- Evidence of Non Profit status and invention related documents, if applicable, must be provided in the other attachment form.
- Additional supporting documents, if applicable, can be provided using the available rows. Do not use the rows assigned to a specific purpose in the program guidance.
- Merge similar documents into a single document. Where several pages are expected in the attachment, ensure that you place a table of contents cover page specific to the attachment. Table of contents page will not be counted in the page limit.

Attachment Number	Attachment Description (Program Guidelines)
Attachment 1	Organizational Chart (s), brief description of the positions and responsibilities in regards to the Part B grant, FTE equivalent of all key staff and personnel
Attachment 2	MOE Documentation
Attachment 3	The FY 2011 Part B Agreements and Assurances (see Appendix A) & SF-424 Face Page
Attachment 4	HIV/AIDS Epidemiology Tables
Attachment 5	Implementation Plan (includes MAI, if applicable)
Attachment 6	Other Relevant Documents (Unmet Need Framework, ADAP Funding Sources table, Any Others)
Attachment 7	FY 2011 Core Medical Services Waiver Request (if applicable)
Attachment 8	EIIHA Matrix

Application Format

i. Application Face Page

Complete Application Form SF-424 provided with the application package. Prepare according to instructions provided in the form itself. For information pertaining to the Catalog of Federal Domestic Assistance, the CFDA is 93.917.

DUNS Number

All applicant organizations are required to have a Data Universal Numbering System (DUNS) number in order to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a unique nine-character identification number provided by the commercial company, Dun and Bradstreet. There is no charge to obtain a DUNS number. Information about obtaining a DUNS number can be found at http://www.hrsa.gov/grants/dunsccr.htm or call 1-866-705-5711. Please include the DUNS number in item 8c on the application face page. Applications *will not* be reviewed without a DUNS number. Note: A missing or incorrect DUNS number is the number one reason for applications being "Rejected for Errors" by Grants.gov.

Additionally, the applicant organization is required to register annually with the Federal Government's Central Contractor Registry (CCR) in order to do electronic business with the Federal Government. It is extremely important to verify that your CCR registration is active. Information about registering with the CCR can be found at http://www.ccr.gov.

ii. Table of Contents

The application should be presented in the order of the Table of Contents provided earlier. Again, for electronic applications no table of contents is necessary as it will be generated by the system. (Note: the Table of Contents will not be counted in the page limit.)

iii. Application Checklist

Complete the HHS Checklist Form PHS 5161-1 provided with the application package.

iv. Budget

Complete Application Form SF-424A – Budget Information for Non-Construction Programs provided with the application package. Please complete Sections A and B.

In Section B, budget categories are limited to four columns. The four required columns are:

- **i. Administration** this column should include all funds allocated to the following grant activities: grantee administration, planning and evaluation, and quality management;
- **ii. ADAP** this column should include all funds allocated to the following grant activities: the ADAP;
- **iii. Consortia** this column should include all funds allocated to consortia and emerging communities; and

iv. Direct Services- this column should include all funds allocated to the following grant activities: state direct services, home and community-based care, MAI, and health insurance continuation.

Note: MAI funds should be distributed across appropriate object class categories on the SF-424A budget form. All services, including core medical services delivered for or through consortia are deemed to be support services. Fill in all object class categories for these columns.

v. Budget Justification

Provide a narrative that explains the amounts requested for each line in the budget. The budget justification should specifically describe how each item will support the achievement of proposed objectives. The project and budget period is for ONE year. Line item information must be provided to explain the costs entered in the appropriate form, Application Form SF-424. **The budget justification must clearly describe each cost element and explain how each cost contributes to meeting the project's objectives/goals.** Be very careful about showing how each item in the "other" category is justified. The budget justification MUST be concise. Do NOT use the justification to expand the project narrative.

<u>Caps on expenses</u>: Part B grantee administrative costs may not exceed 10% of the total grant award. Planning and Evaluation costs may not exceed 10% of the total grant award. Collectively, Grantee Administration, and Planning and Evaluation may not exceed 15% of the total award. Grantees may allocate up to 5% of the total grant award, or \$3,000,000 (whichever is less) for Clinical Quality Management.

Include the following in the Budget Justification narrative:

Personnel Costs: Personnel costs should be explained by listing each staff member who will be supported from funds. Include the name (if possible) of the staff member, position title, percent full time equivalency (FTE), and annual salary. Additionally, the FTE equivalent of all key staff and personnel should be noted. If there are key personnel and or staff associated with the grant and NOT funded with Ryan White dollars, a brief description of their position and responsibilities in regards to the Part B grant should be included.

Fringe Benefits: List the components that comprise the fringe benefit rate, for example health insurance, taxes, unemployment insurance, life insurance, retirement plan, tuition reimbursement. The fringe benefits should be directly proportional to that portion of personnel costs that are allocated for the project.

Travel: List travel costs according to local and long distance travel. For local travel, the mileage rate, number of miles, reason for travel and staff member/consumers completing the travel should be outlined. The budget should also reflect the travel expenses associated with participating in meetings and other proposed trainings or workshops.

Equipment: List equipment costs and provide justification for the need of the equipment to carry out the program's goals. Extensive justification and a detailed status of current

equipment must be provided when requesting funds for the purchase of computers and furniture items that meet the definition of equipment (i.e., a unit cost of \$5,000 and a useful life of one or more years).

Supplies: List the items that the project will use. In this category, separate office supplies from medical and educational purchases. Office supplies could include paper, pencils, and the like; medical supplies are syringes, blood tubes, plastic gloves, etc., and educational supplies may be pamphlets and educational videotapes. Remember, they must be listed separately.

Contractual: Applicants are responsible for ensuring that their organization and or institution has in place an established and adequate procurement system with fully developed written procedures for awarding and monitoring all contracts. Applicants must provide a clear explanation as to the purpose of each contract, how the costs were estimated, and the specific contract deliverables.

Other: Put all costs that do not fit into any other category into this category and provide an explanation of each cost in this category. In some cases, grantee rent, utilities and insurance fall under this category if they are not included in an approved indirect cost rate.

Indirect Costs: Indirect costs are those costs incurred for common or joint objectives which cannot be readily identified but are necessary to the operations of the organization, e.g., the cost of operating and maintaining facilities, depreciation, and administrative salaries. For institutions subject to OMB Circular A-21, the term "facilities and administration" is used to denote indirect costs. If an organization applying for an assistance award does not have an HHS negotiated indirect cost rate, the applicant may wish to obtain one through HHS's Division of Cost Allocation (DCA). Visit DCA's website at: http://rates.psc.gov/ to learn more about rate agreements, the process for applying for them, and the regional offices which negotiate them.

vi. Staffing Plan and Personnel Requirements

Applicants must present a staffing plan and provide a justification for the plan that includes education and experience qualifications and rationale for the amount of time being requested for each staff position. Position descriptions that include the roles, responsibilities, and qualifications of proposed project staff must be included in **Attachment 1** with the organizational chart. This staffing plan should depict the administrative structure responsible for the administration of the Part B grant. Also submit a staffing plan for the ADAP, if administered separately. Applicants must provide a listing of all key staff and personnel. This listing should include a brief description of the positions and responsibilities in regards to the Part B grant. Biographical sketches and/or resumes are NOT required.

vii. Assurances

Complete Application Form SF-424B – Assurances for Non-Construction Programs provided with the application package. The FY 2011 Ryan White HIV/AIDS Part B Program Agreements and Assurances are included in Appendix A. The Assurances must be signed by the Governor or

Authorized Designated Official of the State/Territory. The HIV/AIDS Part B Program Assurances (Appendix A) should be submitted as **Attachment 3** of the grant application.

viii. Certifications

Use the Certifications and Disclosure of Lobbying Activities Application Form provided with the application package.

ix. Project Abstract

Provide a summary of the application. Because the abstract is often distributed to provide information to the public and Congress, please prepare this so that it is clear, accurate, concise, and without reference to other parts of the application. It must include a brief description of the proposed grant project including the needs to be addressed, the proposed services, and the population group(s) to be served.

Please place the following at the top of the abstract:

- ➤ Project Title;
- ➤ Applicant Name;
- ➤ HRSA Grant Number;
- ➤ Address:
- ➤ Contact Phone Numbers (Voice, Fax);
- ➤ E-Mail Address;
- ➤ Web Site Address, if applicable; and
- List of all grant program funds in this application (e.g. Formula (Base, ADAP), ADAP Supplemental, MAI, Emerging Communities, and Pacific Island Jurisdictions).

The information below should be followed by brief paragraphs that provide, in this order:

- 1) General demographics of the State/Territory;
- 2) Demographics of HIV/AIDS populations in the State/Territory;
- 3) Geography of the State/Territory with regard to communities affected by HIV/AIDS and the location of HIV/AIDS services in relation to those communities;
- 4) Description of the continuum of care offered in the State/Territory, including relevant information about ADAP, primary medical care services, how HIV primary care services are delivered, and how clients are supported in accessing and remaining in care; and
- 5) Description of any ADAP restrictions (such as waiting lists, capitations on medications or expenditures, cost shares, or co-pays, etc.).

The project abstract must be single-spaced and limited to one page in length.

x. Program Narrative

This section provides a comprehensive framework and description of all aspects of the proposed program. It should be succinct, self-explanatory and well organized so that reviewers can understand the proposed project. The narrative should follow the order below:

(A) FY 2011 Part B Formula Grant Application

This Section is to be completed by the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands and Guam

(1) Grantee Administration and Accountability

The purpose of this section is to demonstrate the extent to which the Chief Elected Official in the State/Territory has met the legislative requirements to disburse funds quickly, closely monitor their use and ensure that the Ryan White HIV/AIDS Program is the payer of last resort.

Note: Unobligated formula grant funds up to 5 percent of the award do not incur penalties. There are three penalties if the unobligated formula grant funds exceed the 5 percent threshold.

- Future year award is offset by the amount of UOB less the amount of approved carry over:
- Future year award is reduced by the amount of UOB less the amount of approved carry over; and
- ➤ The grantee will be ineligible to receive competitive supplemental grant funds for a future year.

Note: Grantees may request use of unobligated supplemental funds in a future year, but the same amount of the unobligated supplemental funds will be reduced from that same future year award.

➤ Please refer to HRSA HAB Policy Notice 10-01—The Unobligated Balances Provision at http://hab.hrsa.gov/law/1001.pdf.

(a) Program Organization

Provide a description of how Part B funds are administered in the State/Territory with reference to the positions described in the budget, budget narrative, and the organizational chart included in **Attachment 1**.

(b) Fiscal and Program Monitoring

HRSA/HAB holds grantees accountable for the expenditure of funds awarded under Part B, and expects grantees to monitor fiscal and programmatic compliance with all contracts and other agreements for HIV/AIDS services in the State/Territory. Grantees are also required to have on file a copy of each contractor's procurement documents (contracts), and fiscal and programmatic site visit reports. Provide a narrative that describes the following:

- (1) The process used to separately track formula (base and ADAP), ADAP supplemental (if applicable), MAI, unobligated and carryover funds, including information on the data systems utilized;
- (2) The process used for fiscal and program monitoring, including the frequency of reports;
- (3) The process and timeline for corrective actions when a fiscal or programmatic related concern is identified;
- (4) The process of receiving vouchers or invoices from contractors/subcontractors;
- (5) The process of payment made to contractors/subcontractors, from receipt of voucher/invoice to reimbursement:

- (6) For those states with consortia, describe how consortia monitor their contractors/subcontractors;
- (7) The frequency of fiscal and programmatic monitoring site visits during a program year;
- (8) The total number of contractors funded in FY 2010; and the number and percentage of contractors that received a fiscal and/or programmatic monitoring site visit during FY 2010 grant year;
- (9) Were there improper charges by contractors or other findings in FY 2010 and if there were, summarize of the corrective actions planned or taken to address these findings;
- (10) The number of contractors that received technical assistance (TA) during FY 2010 (and types of TA, scope, and timeline);
- (11) The number and percentage of eligible contractors compliant with audit requirement in OMB Circular A-133; and
- (12) Were there any findings in any subcontractors' A-133 audit reports? Describe what the grantee has done to ensure that subcontractors have taken appropriate corrective action.

(c) Fiscal Staff Accountability

- (1) The role and responsibilities of program and fiscal staff in ensuring adequate reporting, reconciliation, and tracking of program expenditures;
- (2) The process and coordination of program and fiscal staff in ensuring adequate reporting, reconciliation, tracking of program expenditures and program income. For example, the program and fiscal staff's meeting schedule and how fiscal staff share information with program staff regarding contractor expenditures, formula and supplemental unobligated balances, and program income; and
- (3) The applicant should include an organizational chart for fiscal staff, if fiscal staff are not within the program staff personnel. (Include in **Attachment 1**)

(d) Third Party Reimbursement

Summary: Grantees are expected to make effective use of strategies to coordinate between Part B and third party payers who are ultimately responsible to pay the cost of services provided to eligible or covered persons. Third party sources include Medicaid, Children's Health Insurance Programs (CHIP), Medicare (including the Part D prescription benefit) and private insurance. Subcontractors providing Medicaid eligible services must be Medicaid certified. The Ryan White HIV/AIDS Program is the payer of last resort, and grantees must make every effort to ensure that alternate sources of payment are pursued and that program income is used consistent with grant requirements.

Note: The Indian Health Service is exempt from the payer of last resort provision.

- (1) Provide a narrative that describes the following:
 - (a) The process used by grantees to ensure that contractors and consortia contractors and subcontractors are monitoring third party reimbursement. Also describe the contract language or other mechanism to ensure that this takes place;

- (b) How subcontractors document that clients have been screened for and enrolled in eligible programs such as Medicare, Medicaid, private health insurance or other programs to ensure that Ryan White HIV/AIDS Program funds are the payer of last resort;
- (c) How grantee monitors the appropriate tracking and use of any program income; and
- (d) The client eligibility criteria for clients who are supported with Ryan White HIV/AIDS Part B Program services. Also indicate if, in addition to this eligibility determination process, the State/Territory verifies eligibility or conducts certification of clients with other State programs including Medicaid, State Pharmacy Assistance Programs (SPAP), and Children's Health Insurance Programs (CHIP).

(2) HIV/AIDS Epidemiology

<u>Purpose:</u> The purpose of this section is to describe the HIV/AIDS epidemic in the State/Territory. Section 2617 (b) (2) of the PHS Act states that the application for Part B funds shall contain a determination of the size and demographics of the population of people with HIV/AIDS in the State.

(a) Table

Summarize in a table format, the living cases of HIV disease through December 31, 2009 identifying the AIDS and HIV (non-AIDS) prevalence by demographic group and exposure category. Place the table in **Attachment 4** of the application and *clearly label the data sources*.

(b) Narrative

Based on the latest State HIV/AIDS Epidemiologic Profile, provide a narrative description of any trends or changes in the State's/Territory's number of HIV disease prevalence over the past two years (01/01/08-12/31/09). Use the following indicators to provide a comparative description of the HIV disease prevalence by demographic characteristics and exposure category in the State including:

- **(1)** the number of people living with HIV (non-AIDS),
- (2) the number of people living with AIDS, and
- **(3)** the number of new AIDS cases reported within the last two calendar years (2008, 2009).

(3) Unmet Need

<u>Definition:</u> Unmet Need is the need for HIV-related health services by individuals with HIV who are **aware** of their HIV status, but are not receiving HIV primary health care. Unmet Need is further defined as no evidence of any of the following three components of HIV primary medical care during a specified 12 month time frame: viral load (VL) testing, CD4 count, or provision of anti-retroviral therapy (ART).

(a) Provide an updated or refined estimate of unmet need in your jurisdiction, using the HRSA/HAB Unmet Need Framework.

- **(b)** Provide a narrative description of the following:
 - (1) <u>Estimation methods</u>: The methods used to develop the unmet need estimates, reasons for choosing this method, revisions or updates from the FY 2010 estimate, any limitations, and any cross program collaboration that occurred.
 - (2) <u>Assessment of unmet need</u>: Any activities your State/Territory has carried out or is planning to address regarding unmet need. Also, summarize the findings or results of any completed activities. Include the following:
 - i) Determination of the demographics and location of people who know their HIV/AIDS status and are not in care;
 - *ii)* Assessment of service needs, gaps, and barriers to care for people not in care;
 - *iii*) Efforts to find people not in care and get them into primary care;
 - iv) Use of the results of the Unmet Need Framework in planning and decision making about priorities, resource allocations, and adapting the system of care. Examples include: (1) outreach activities, (2) system of care and, (3) collaborations with Ryan White and non Ryan White funded providers.

<u>Note</u>: A copy of the **Unmet Need Framework** must be included showing the: (1) values, (2) all data sources, and (3) calculations. You may wish to use the automated Excel worksheets of the Framework to help calculate your estimates of unmet need, which you can download from the HAB Web site: http://hab.hrsa.gov/tools/unmetneed. Include a copy of the framework in **Attachment 6** of this application.

(4) Early Identification of Individuals with HIV/AIDS (EIIHA)

<u>Purpose</u>: The purpose of this section is to the describe the **strategy**, **plan**, and **data** associated with ensuring that individuals who are unaware of their HIV positive status are identified, informed of their status, referred into care, and linked to care. The purpose of this initiative is to increase the number of individuals who are aware of their HIV status, as well as increase the number of HIV positive individuals who are in care.

EIIHA Definition: Early Identification of Individuals with HIV/AIDS (EIIHA) is the identifying, counseling, testing, informing, and referring of **diagnosed and undiagnosed** individuals to appropriate services, as well as linking newly diagnosed HIV positive individuals to care.

Associated EIIHA Definitions:

➤ **Unaware of HIV Status**: Any individual who has *NOT* been tested for HIV in the past **12-months**, any individual who has *NOT* been informed of their HIV result (HIV positive or HIV negative), and any HIV positive individual who has *NOT* been informed of their *confirmatory* HIV result.

Note: The **12-month** time period is intended to be utilized as a **means to establish a threshold** for the purpose of assisting in the identification of individuals unaware of their HIV status, and is

exclusive to Early Identification of Individuals with HIV/AIDS (EIIHA).

The **12-month** time period is <u>NOT</u> intended to be utilized as a recommended testing frequency, or for the purpose of assessing risk to HIV. For recommended HIV testing frequencies and risk assessments please refer to CDC guidelines. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm

➤ **Identification of Individuals Unaware of Their HIV Status:** The *categorical breakdown* of the overall unaware population into subgroups, which allow for the overall EIIHA strategy to be *customized based on the needs of each subgroup*, for the purposes of identifying, counseling, testing, informing, referring, and linking these individuals into

care. See example EIIHA Matrix 1.1 below:

Example EIIHA Matrix 1.1

All Individuals <u>Unaware</u> of their HIV Status (HIV Positive & HIV Negative)								
ZA. Tested		^{2B.} Untested						
3A.		3B.	3C.				3D.	
Individuals Not Post-Test Counseled (HIV positive & HIV negative) Positive Results Only – No Confirmatory Test		High Risk Individuals			Moderate & Low Risk Individuals			
Tested Confidentially	Tested Anonymously		I V D U	M S M	Infants Of Infected Mothers	Partners of HIV+ Individuals	Not Tested in Past 24 Month	AH. Not Tested in Past 48 Month

- ➤ **Informing individuals of their HIV status:** Informing an HIV negative individual, post-test, of their appropriate HIV screening result. Informing an HIV positive individual, post-test, of their *confirmatory* HIV result.
- ➤ **Referral to care/services:** The provision of timely, appropriate and pre-established guidance to an individual that is designed to refer him/her to a specific care/service provider for the purpose of accessing care/services after the individual has been informed of their HIV status (positive or negative).
- ➤ **Linkage to care:** The post-referral verification that care/services were accessed by an HIV positive individual being referred into care. (i.e. Confirmation first scheduled care appointment occurred.)
- (a) Strategy (Blueprint for implementation)
 - (1) Describe the Strategy to Identify Individuals who are Unaware of their Status
 - *i*) Describe the specific goals this strategy is intended to achieve.
 - a) Describe how each goal is consistent with making individuals who are unaware of their HIV status aware of their status.

- *ii)* Describe how this strategy will coordinate with your RW Part A counterpart with regard to the following:
 - a) Identifying HIV positive unaware individuals.
 - b) Informing HIV positive unaware individuals of their status.
 - c) Referring HIV positive unaware individuals to care.
 - d) Linking HIV positive unaware individuals to care.
 - e) EIIHA Data Collection and Sharing.
- *iii*) Describe how this strategy will coordinate with prevention and disease control/intervention programs-*without supplanting funds*-with regard to the following:
 - a) Identifying HIV positive individuals unaware of their status.
 - b) Informing HIV positive unaware individuals of their status.
 - c) Referring HIV positive unaware individuals to care.
 - d) Linking HIV positive unaware individuals to care.
 - e) EIIHA Data Collection and Sharing.
- *iv*) Describe how this strategy will coordinate with other programs/facilities and community efforts. (i.e., correctional facilities, CBO's, hospitals, etc.)
- *v*) Describe how EIIHA activities and strategies will be incorporated into the program's Requests for Proposals (RFP's).
- *vi*) Describe how ADAP and other medication resources will be considered in order to accommodate the needs of new positives.
- *vii*) Describe the role of Part B Early Intervention Services in implementing this strategy.
- *viii*) Describe how this strategy addresses disparities in access and services among affected subpopulations and historically underserved communities.
- **(b) Plan** (Activities, Methods, and/or Means utilized to implement the strategy)

Note: All Ryan White funded EIIHA activities should be **reported under the EIS service category**. If the activities and/or services needed to implement an EIIHA strategy/plan are funded by a **source other than Ryan White**, then **list the funding source** associated with each activity.

IMPORTANT: Ryan White funds may **NOT** be used to **supplant funds** which support activities to identify, counsel, test, inform, refer, and link to care HIV positive individuals unaware of their status.

(1) Identifying Individuals Unaware of Their HIV Status

i) Within the overall unaware population that encompasses any individual who is unaware of their HIV status, <u>develop a matrix listing the subgroups</u>, which will allow the applicant's strategy to be customized based on the needs of each subgroup. (For an example, please refer to "EIIHA")

- *Matrix 1.1" listed above).* The EIIHA Matrix should include *all sub-groups* that the EIIHA Strategy, Plan, and Data intend to address. Submit the EIIHA Matrix as **Attachment 8**.
- ii) For each subgroup in the EIIHA Matrix, describe how the overall strategy will be customized to address their respective needs specific to identifying HIV positive individuals unaware of their status.
 - a. <u>Example</u>: Reference EIIHA Matrix 1.1 Block 3D. (Moderate & Low Risk Individuals): "...promote universal testing which entails routine HIV testing in everyday medical practice, both public and private..."
- *iii*) For each subgroup in the EIIHA Matrix, describe the respective challenges (*including any local legislation or policies*) associated with *identifying* individuals who are unaware of their HIV status.
- iv) For each subgroup in the EIIHA Matrix, describe the respective activities essential for identifying HIV positive individuals who are unaware of their status.
 - *a.* Describe which essential activities are able to be implemented immediately.
 - *b*. Describe which essential activities are proposed but *NOT* able to be implemented immediately.
 - **1.** Describe the timeline associated with when each essential activity will be implemented.
 - **2.** Describe the parties responsible for ensuring each of these essential activities are implemented according to the timeline described.

(2) Informing Individuals of Their HIV Status

- i) For each subgroup in the EIIHA Matrix, describe how the overall strategy will be customized to address their respective needs in terms of *informing* unaware individuals of their HIV status.
 - a. <u>Example</u>: Reference EIIHA Matrix 1.1 Block 3D. (Moderate & Low Risk Individuals): "...educate providers regarding resources available whenever a client does not return for their HIV results..."
- ii) For each subgroup in the EIIHA Matrix, describe the respective challenges (including any local legislation or policies) associated with informing unaware individuals of their HIV status.
- *iii*) For each subgroup in the EIIHA Matrix, describe the respective activities essential to *informing* unaware individuals of their HIV status.
 - *a.* Describe which essential activities are able to be implemented immediately.

- **b.** Describe which essential activities are proposed but <u>NOT</u> able to be implemented immediately.
 - **1.** Describe the timeline associated with when each essential activity will be implemented.
 - Describe the parties responsible for ensuring each of these essential activities are implemented according to the timeline described.

(3) Referral to Care

- i) For each subgroup in the EIIHA Matrix, describe how the strategy will be customized to address their respective needs specific to *referring* individuals recently informed of their HIV status into care.
 - a. <u>Example</u>: Reference EIIHA Matrix 1.1 Block 3D. (Moderate & Low Risk Individuals): "...educate providers regarding the EMA/TGA's/State's pre-established referral process to ensure..."
- *ii)* For each subgroup in the EIIHA Matrix, describe the respective challenges (*including any local legislation or policies*) associated with *referring* individuals recently informed of their HIV status into care.
- iii) For each subgroup in the EIIHA Matrix, describe the respective activities essential to *referring* individuals recently informed of their HIV status into care.
 - *a.* Describe which essential activities are able to be implemented immediately.
 - **b.** Describe which essential activities are proposed but <u>**NOT**</u> able to be implemented immediately.
 - **1.** Describe the timeline associated with when each essential activity will be implemented.
 - Describe the parties responsible for ensuring each of these essential activities are implemented according to the timeline described.

(4) Linkage to Care

- i) Describe the activities essential to ensuring access to care regardless of where any newly identified HIV positive individual enters into the continuum of care.
- ii) For any newly identified HIV positive individual referred into a *Ryan*White funded program, describe the activities undertaken (post-referral) to verify that care/services were accessed.
 - *a.* Describe which essential activities are able to be implemented immediately.

- **b.** Describe which essential activities are proposed but **NOT** able to be implemented immediately.
 - **1.** Describe the timeline associated with when each essential activity will be implemented.
 - 2. Describe the parties responsible for ensuring each of these essential activities are implemented according to the timeline described.
- *iii*) Describe the activities undertaken to form and maintain relationships with private HIV care providers for the purpose of verifying that individuals referred into private care have accessed care post-referral.
 - *a.* Describe which essential activities are able to be implemented immediately.
 - *b*. Describe which essential activities are proposed but *NOT* able to be implemented immediately.
 - **1.** Describe the timeline associated with when each essential activity will be implemented.
 - 2. Describe the parties responsible for ensuring each of these essential activities are implemented according to the timeline described.
- *iv*) Describe the efforts to address legal barriers, including local and state laws and regulations, to routine testing.

(c) Data

Application of CDC National Estimates (National Proportion Undiagnosed) to Jurisdictional Data: To obtain a local estimate of undiagnosed persons living with HIV for the end of 2008, areas should apply the national percentage using the formula below. The number of persons living with diagnosed HIV infection at the end of 2008 should be obtained from data reported to the local health department as of June 2010 to allow 18 months for cases and deaths to be reported.

- (1) Report the estimated number of living HIV positive individuals who were unaware of their status as of December 31st, 200<u>8</u>.
 - i) Estimated Back Calculation (EBC) Methodology:

(<u>ALL</u> applicants <u>must</u> use the following formula to calculate the local size of the HIV positive unaware population, which is based on CDC's national estimate.)

a. Formula:

National Proportion Undiagnosed HIV (21%) = p

Number of individuals diagnosed with HIV and living as of December 31. 2008 = N

$$Local\ Undiagnosed = \underline{p} \quad x \ N$$

$$(1-p)$$

b. Example:

National Proportion Undiagnosed = 21%

.21
$$x$$
 1,000 (diagnosed living) = **266** (undiagnosed) **(.79)**

Note: The number of **diagnosed living cases** of HIV is used exclusively to calculate the estimated number of undiagnosed HIV positive individuals, and will **NOT** be used to calculate the final award.

- (2) Report the *total number* of HIV tests conducted using *local*, *state* & *federal funds* as of December 31st 2009.
 - *i) Of the total number tested*, report the number of individuals *informed* of their HIV status (*regardless of positive or negative HIV result*), also list as percentage.
 - a. Of the number informed of their HIV status, report the number of HIV positive individuals, also list as percentage.
 - Of the number informed of their HIV positive status, report the number of individuals referred into care, also list as percentage.

Note: Linkage to care numbers will be requested in subsequent years.

- ii) Of the total number tested, report the number of individuals <u>NOT</u> informed of their HIV status (regardless of positive or negative HIV result), also list as percentage.
 - *a. Of the number* <u>**NOT**</u> *informed of their HIV status*, report the number of *HIV positive* individuals, also list as percentage.
- (3) Describe how the data in (c)(2)i-ii will impact your Quality Management Plan.

Note: At this time, the estimated number of living HIV positive individuals who were unaware of their status at the end of **2008** should **NOT** be compared to, or correlated with, any data regarding the number of HIV tests conducted using local, state & federal funds at the end of **2009**.

(5) Clinical Quality Management

<u>Purpose</u>: The purpose of this section is to describe the State's/Territory's overall clinical quality management(CQM) program for Part B (including ADAP) and to describe how the results of the Part B CQM activities are being or have been used to improve service delivery in the State/Territory.

Summary: Clinical Quality Management (CQM) data play a critical role in helping to identify needs and gaps in services as well as in helping to ensure the delivery of quality services to clients. Information gathered through the CQM program as well as client-level health outcomes data should be used as part of the State/Territory planning process and ongoing assessment of progress toward achieving program goals and objectives. It should also be used by the grantee to examine and refine processes for administering the grant at the programmatic and fiscal levels.

- (a) HAB has established the following minimum expectations of Ryan White HIV/AIDS Program grantees regarding CQM. At a minimum, grantees must have:
 - (1) Established and implemented a statewide CQM plan;
 - (2) Established processes for ensuring that services are provided in accordance with Department of Health and Human Services (DHHS) treatment guidelines and standards of care; and
 - (3) Incorporated quality-related expectations into Requests for Proposals (RFPs) and State/Territory contracts, including contractors/subcontractors at the consortia and sub-recipient level.

<u>Note</u>: HRSA's expectations of Ryan White HIV/AIDS Program grantees with respect to improving the quality of care and establishing clinical quality management programs may be found online at: http://hab.hrsa.gov/special/qualitycare.htm. HRSA technical assistance in selecting appropriate service- and client-level outcomes is also available online at: http://hab.hrsa.gov/tools.htm or http://careacttarget.org.

- **(b)** Provide a narrative of the State's/Territory's CQM program including descriptions of the following:
 - (1) CQM Program Structure:
 - *i*) Overall mission, vision, and goals of the clinical quality management program;
 - *ii)* What percentage of FY 2010 Part B funds were allocated to CQM;
 - *iii*) Roles and responsibilities of staff members and/or committees overseeing and managing the CQM activities, including the planning and allocation of resources;
 - *iv*) The process that has been established to monitor and evaluate the CQM program; and
 - *v*) The activities that have been implemented to assess and monitor the quality of services provided by providers/subcontractors;
 - (2) Specific indicators that are being monitored for core medical services, including how these indicators are measured and improve overall clinical health outcomes; and
 - (3) Data collection strategy including how data are collected, what data have been collected to date.

- (c) Describe how the data have been used to improve clinical health outcomes or change service delivery in the State. **Include the following:**
 - (1) Describe grantee preparation for client level data reporting as well as the grantee's plan to use this data to improve quality management;
 - (2) Describe the process that the grantee is using to collect and report to HRSA client level data from all outpatient/ambulatory medical care providers as well as medical and non-medical case management providers;
 - (3) Describe what CQM data have been collected to date, and the results;
 - (4) Discussion of quality improvement activities that have been undertaken to improve service delivery and what improvements have been shown, and;
 - (5) How have clinical quality efforts been used by planning bodies in the priority setting and resource allocation process within the State. Include a description of how these quality efforts reflect collaboration with other Ryan White HIV/AIDS Program Parts A, C, D, and MAI programs.
- (d) Planned Clinical Quality Management Activities:
 - (1) Describe goals and objectives for FY 2011 and any plans for improvements to the State/territory's clinical quality management activities or ADAP quality management program.
- (e) Description of ADAP Clinical Quality Management Program
 - (1) Describe how the data collected has been used to improve or change service delivery in the State/Territory. **Include the following:**
 - *i*) How the ADAP Advisory Committee utilizes the information;
 - *ii)* How does the State/Territory make decisions to add new FDA approved drugs while ensuring that ADAP funds are not depleted before the end of the year. Please describe any tools or methods used to make these decisions.
 - iii) How the ADAP Advisory Committee develops Standard of Care and/or best practice, for the medication distribution component. Identify the decision making process and/or the by-laws governing the Committee and meetings. Include a statement of assurance that this process and/or by-laws are used consistently as a standard practice.
 - iv) How the Grantee works closely with the AETC (AIDS Education Training Center) to develop continuing medical education program(s) for all health care practitioners to ensure that clients receive medication therapies consistent with the current DHHS Public Health Services Treatment Guidelines.
- (6) Consistency with the Statewide Coordinated Statement of Need (SCSN)

<u>**Purpose:**</u> The purpose of this section is to assure that the public health agency administering the grant for the State or Territory periodically convenes a meeting of individuals with HIV/AIDS as required by section 2617(b)(6) of the PHS Act.

(a) SCSN Narrative:

(1) Briefly describe how proposed FY 2011 allocations address significant issues and core service needs identified in the most recent SCSN planning process.

(7) Needs Assessment and Public Advisory Planning Process

Purpose: The purpose of this section is to describe the Needs Assessment process and ensure that public health agencies receiving Part B grants have established a public advisory planning process that includes public hearings, as required by Section 2617(b)(7)(A) of the PHS Act. The public advisory planning process should help the grantee in developing and implementing the comprehensive plan and should include individuals living with HIV, other Ryan White HIV/AIDS Program grantees, other federal and local stakeholders, and community leaders. Federally recognized Indian tribes, as represented in the state, must also be represented in the planning process.

(a) Needs Assessment

- (1) Describe the needs assessment process, including who participated in the process and how participation from PLWHA was obtained.
- (2) Describe the needs of individuals with HIV and affected subpopulations that experience disparities in access to core medical services in historically underserved areas of the State, specifically-urban, suburban, and rural.

(b) Public Advisory Planning Process

- (1) Describe your Public Advisory Planning process and the participating parties.
- (2) Describe the progress towards achieving the goals and objectives in the most recent comprehensive plan.
- (3) Describe the continued involvement of participants in the public advisory planning process (including persons living with HIV, other Ryan White HIV/AIDS Program grantees, other general and local stakeholder and community leaders) in the implementation of the 2009 Comprehensive Plan.

(8) Planned Services and Implementation Plan

Purpose: The purpose of this section is to present the FY 2011 HIV/AIDS service plan, with specific attention to ensuring access to a continuum of HIV/AIDS care. The plan must demonstrate how the State/Territory will reduce or eliminate service and health outcome disparities among populations with specific needs.

Summary: All Part B funds are subject to Section 2612(b) (1) of the PHS Act, requiring that not less than 75 percent of the funds (excluding funds used for grantee administration, planning, evaluation, and clinical quality management) be used to provide core medical services that are needed in the State or Territory for individuals with HIV/AIDS who are identified and eligible under the Ryan White HIV/AIDS Programs. Applicants that receive MAI grant funds are reminded that their FY 2011 MAI award must also be considered in determining compliance with this requirement.

<u>Definitions</u>: Core Medical Services include: Outpatient and ambulatory health services; AIDS Drug Assistance Program treatments in accordance with Section 2616 of the PHS Act; AIDS pharmaceutical assistance (local); Oral health care; Early Intervention Services; Health insurance premium and cost sharing assistance for low-income individuals in accordance with Section 2615; Home health care; Medical nutrition therapy; Hospice services; Home and community-based health services as defined under Section 2614(c) of the PHS Act; Mental health services; Substance abuse outpatient care; and Medical case management, including treatment adherence services.

Support Services include: Case Management (non-medical); Child care; Emergency Financial Assistance; Food bank/home-delivered meals; Health education/risk reduction; Housing; Legal Services; Linguistic Services; Medical Transportation; Outreach; Psychological Support; Referral for health care/supportive services; Rehabilitation; Respite Care; Treatment Adherence Counseling; and Residential substance abuse treatment. **Consistent with Section 2613(f), all services provided by or through consortia are considered support services.**

Note: Applicants seeking a waiver to the core medical services requirement must submit a waiver request with this grant application in accordance with the information and criteria published by HRSA in the Federal Register Notice, Vol. 73, No. 113, dated Wednesday June 11, 2008, and may be found at http://edocket.access.gpo.gov/2008/E8-13102.htm. This waiver request process has been approved by the Office of Management and Budget (OMB) under the paperwork Reduction Act of 1995 (OMB number 0915-0307). A waiver request that does not include MAI will not be considered. A core medical services waiver request should be included as Attachment 7.

(a) Table: FY 2011 Implementation Plan

<u>Summary</u>: The Part B program allows States and Territories to expend grant funds under five eligible program components — HIV Care Consortia, Home and Community-Based Care, Health Insurance Program, Provision of Treatments (including ADAP) and State Direct Services.

- (1) In a table, list each of the five eligible program components that will be funded. Under each program component, list the service categories and amounts of Part B funding that will be allocated for each service category in FY 2011. The table should be placed in **Attachment 5**.
- (2) For each service category listed:
 - i) define the service unit;
 - **ii)** provide the number of persons to be served;
 - **iii)** define the units of service to be delivered:
 - iv) define the time frame of estimated duration of activity, and
 - **v)** provide the estimated cost of meeting the objective.

Note: Program objectives **should not** include administrative processes (i.e., staff attendance at the All Grantee Meeting)

Please refer to the definitions/descriptions below; this will assist you in developing an Implementation Plan:

- ➤ **Objective/s:** List objectives that are required to implement a new or to continue an existing service. Each objective should represent a single, discrete required activity.
- > **Service Unit Definition:** Provide the name and definition of the unit of service to be provided (e.g. one round-trip bus ride, one prescription).
- ➤ **Quantity:** Provide the number of people to be served and service units to be provided during the grant year. Section 3a) List the number of people to be served; 3b) List the total number of service units to be provided to that number of individuals.
- **Time Frame:** Indicate the estimated duration of the activity relating to the objective listed.
- ➤ **Funds:** Provide the approximate amount of Part B funds to be used to provide this service. Where multiple objectives exist beneath one service goal, break out the estimated amount of funding by each individual objective listed.

<u>Note</u>: From the objectives listed under each goal, select a **minimum of two objectives** and **list planned client level outcomes/indicators** to be tracked and include benchmarks for each.

(b) Narrative: FY 2011 Implementation Plan

- (1) Provide a narrative that describes the following:
 - *i)* How the implementation plan reflects the 75/25 core medical services requirement? If not, please explain;
 - *ii)* How the activities described in the plan will provide increased access to the HIV continuum of care for minority communities;
- *iii)* How the activities in the plan address unmet need and reduce the number of persons out of care;
- *iv*) How the activities in the plan address individuals who are unaware of their HIV status with regard to identifying them, making them aware, and referring them into care:
- *v*) How the activities described in the plan will ensure geographic parity in access to HIV/AIDS services throughout the State or Territory;
- *vi*) How the activities described in the plan will address the needs of any emerging populations;
- *vii*) How the activities described in the plan will ensure that PLWH/A remain engaged in HIV/AIDS primary medical care and adhere to HIV treatments;
- viii) How the State/Territory will ensure that resource allocations for services to women, infants, children, and youth (WICY) are in proportion to the percentage of the States/Territories HIV disease cases represented by each population (WICY tables will be provided by HRSA); and
- *ix)* How the services and their goals and objectives relate to the goals of the Healthy People 2010 initiative, as outlined in Chapter 13 of the Healthy People 2010 document (see http://www.health.gov/healthypeople/document).

(c) FY 2011 MAI Planning and Implementation

<u>Note</u>: Some States/Territories that did not apply for funding the last year or that would receive a minimal formula award, may decide that it is not cost-effective to apply for MAI funds this year. **Please state clearly in your Part B application <u>IF YOU ARE NOT applying</u> for an MAI formula award.**

<u>**Purpose:**</u> The purpose of this section is to describe the implementation plan for the State/Territory to increase racial/ethnic minority population participation in Part B ADAP through MAI-funded education and outreach services.

(1) Provide a description of your FY 2011 MAI Planning and Decision making process in terms of:

- i) How program results and data generated from previous MAI-funded outreach/education and/or other Part B funded outreach activities were evaluated and used, and
- *ii)* How persons living with HIV/AIDS, particularly minority individuals, provided input into the MAI planning process.

Note: MAI funds should be distributed across appropriate object class categories on the SF- 424 A budget form.

(1) Coordination of MAI Services and Funding Streams

Summary: Part B MAI planning efforts should be coordinated with all other local funding streams for HIV/AIDS to:

- Ensure that Ryan White HIV/AIDS Program funds are the payer of last resort:
- Maximize education and outreach efforts to link individuals to ADAP; and
- > Reduce any duplication.
- (a) Describe how the following have been taken into consideration and how they will be coordinated with Part B MAI funds:
 - *i)* Education and outreach services provide by other Ryan White programs within the State/Territory that are intended to increase access to ADAP.
 - *ii)* Education and outreach services funded by other Federal, State, and local resources, such as CDC Prevention Services, Medicaid, Medicare Part D, and substance abuse and mental health treatment services.

(2) MAI Plan Narrative and ADAP Capacity

Please describe the following:

- (a) Based on the FY 2011 MAI implementation plan, discuss the following:
 - *i*) How will education and outreach services be provided, in terms of:
 - a. Geographic locations;
 - b. Types of agencies and staff to provide services;
 - c. Coordination with existing services and providers; and
 - d. Involvement of targeted minority populations in plan implementation.
- **(b)** How the grantee is managing the challenges of re-aligning the MAI grant with the Part B program grant year and transitioning to formula funding, including fluctuations in funding due to that transition and/or the overlap in FY 2009 and FY 2010 budget periods.
- (c) Provide an update of current ADAP utilization data and the capacity of the ADAP to absorb additional clients (specify the number) reached through MAI-funded services.
- (*d*) To the extent that ADAP resource constraints may exist, describe the plan to ensure that out-of-care HIV/AIDS clients are linked to other medication/treatment resources in a timely manner.
- (e) Describe the plan for assuring the quality of MAI-funded education and/or outreach services in relation to the FY 2011 Part B/ADAP CQM plan.

(B) FY 2011 AIDS Drug Assistance Program (ADAP) Grant Application

This Section is to be completed by the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam and eligible Pacific Island Jurisdictions

The purpose of this section is to describe the State/Territory's ADAP. In addition, states and territories that had a waiting list in FY 2010 or anticipate instituting an ADAP waiting list for FY 2011 will be required to respond to the questions listed in (3) and (4) of this section.

(1) Program Description

(a) Agency Oversight/Administration

Provide a narrative that identifies any changes in the management/administration of the ADAP in FY 2010, and any proposed changes for FY 2011 include an organizational chart if the ADAP is administered by a different agency. Place this chart in **Attachment 1**.

(b) ADAP Funding Resources

Provide a narrative or table that discusses all sources of funding (including State funds and/or other Ryan White HIV/AIDS Program funds) expected for FY 2011, as well as any anticipated funding shortfalls. If the information is provided in table form, the table should be placed in **Attachment 6**.

(c) Formulary

<u>Summary</u>: The current statute requires that all States/Territories determine the formularies from the list of core classes of antiretroviral medications established by the Secretary. FDA-approved antiretroviral drug classes currently available include: Entry and Fusion Inhibitor, Non-nucleoside Reverse Transcriptase Inhibitor, Nucleoside Reverse Transcriptase Inhibitor, and Protease Inhibitor. Please refer to Section 2616(c)(1) of the PHS Act.

(1) Provide a narrative that discusses any limitations or barriers that affect the inclusion of these drug classes on your ADAP formulary.

(2) Client Utilization of ADAP Services

- (a) For States and Territories that limited access to the ADAP (e.g., waiting lists, enrollment limits, expenditure caps, etc.) at any point during FY 2010 discuss the rationale for these restrictions and the processes used to both establish and remove them.
- **(b)** Provide a narrative that explains how ADAP clients in outlying or rural areas access ADAP services.
- **(c)** In light of rapid testing and CDC's prevention initiative, provide a narrative that discusses any increases in program enrollment and utilization in the ADAP resulting from these initiatives.

(3) For States which have instituted a Waiting list

- (a) What factors (e.g. state general fund cuts, increased enrollment, increased costs of medications or insurance premiums, etc.) contributed to the decision to implement an ADAP waiting list?
- **(b)** Describe how stakeholders (ADAP Advisory Body, PLWH/A, providers) were involved in the decision to begin a waiting list. Describe the process you employed to communicate the implementation of a waiting list to stakeholders, providers, PLWHA, case managers and eligibility specialists.
- **(c)** What preventative measures and cost containment strategies were considered or implemented before beginning the waiting lists (formulary reduction, reducing the income eligibility, cutting support or core medical services funding)?
- (d) Describe the process you employed for training and informing PLWH/A, doctors, providers, eligibility specialist and case managers about the availability of medications through the Pharmaceutical Manufacture's Patient Assistance Programs.
- **(e)** Are all clients on the waiting list screened for ADAP eligibility? How often are they rescreened for ADAP eligibility?
- **(f)** Is your waiting list based on the clinical acuity of PLWH/A's health or based on the model of "first come, first serve"? Please provide a description of your State ADAP waiting list initiation protocol.
- **(g)** Describe the process of how PLWH/A on the current ADAP waiting lists are transitioned into the ADAP when openings arise. How are PLWH/A and providers informed?
- **(h)** Describe how you coordinate with other Ryan White programs in the State to ensure that ADAP eligible PLWH/A have access to medications. How is this communicated and monitored by you, the Grantee?
- (i) Are clients, case managers, doctors, eligibility specialists and providers facing challenges in getting clients on Patient Assistance Programs? What steps have you, the Grantee, taken to assist in meeting these challenges?
- *(j)* What is the average length of time (e.g. 1 month, 3 months) that an ADAP eligible PLWHA stays on the current waiting list?
- **(k)** How many ADAP eligible PLWHA do you estimate will be on the waiting list at the end of the 2010 grant year?
- (*l*) How many ADAP eligible PLWHA do you estimate will be on the waiting list during the 2011 grant year?
- (4) If your program anticipates instituting an ADAP waiting list during the 2011 grant year, please describe the following:

- (a) What factors (e.g. state general fund cuts, increased enrollment, increased costs of medications or insurance premiums, etc.) are contributing to the decision to implement an ADAP waiting list?
- **(b)** Describe how stakeholders (ADAP Advisory Body, PLWH/A, providers) will be involved in the decision to begin a waiting list. Describe the process you will employ to communicate the implementation of a waiting list to stakeholders, providers, PLWHA, case managers and eligibility specialists.
- **(c)** What preventative measures and cost containment strategies are being considered or implemented before you begin the waiting lists (formulary reduction, reducing the income eligibility, cutting support or core medical services funding)?
- (d) What efforts have you undertaken to prevent the waiting list?
- (e) Describe the process that will be used to train and inform consumers, doctors, providers, eligibility specialists and case managers about the availability of medications through the Pharmaceutical Manufacture's Patient Assistance Programs.
- **(f)** How many ADAP eligible PLWHA do you project will be on the waiting list during the 2011 grant year?
- *(g)* Describe your plans to coordinate with other Ryan White programs in the State to ensure that ADAP eligible PLWH/A will have access to medications.

(5) ADAP Cost Saving Strategies

Summary: As recipients of Part B funds, ADAP grantees are required to use every means at their disposal to secure the best price available for all products on their ADAP formularies in order to achieve maximum results with these funds. As covered entities, ADAPs are eligible to participate in the 340B Drug Pricing Program under section 340B of the PHS Act.

(a) All 340B Participating ADAPs

For States/Territories that participated in the 340B Drug Pricing Program during FY 2010, respond to the following questions specific to the cost-saving practices used:

- (1) 340B Direct Purchase
 - i) Describe the State/Territory's cost-saving practices and distribution process for FY 2010.
 - *a.* Provide the name and type of pharmaceutical provider currently used; and
 - **b.** Describe the State/Territory mechanisms for monitoring the contract or subcontract
- (2) Discuss if your program utilizes HRSA's Prime Vendor Program/HealthCare Purchasing Partners International (HPPI), and provide the name of the wholesaler the contractor uses.
- (3) 340B Rebate Option

- i) Describe the pharmacy network used in FY 2010 for distribution (e.g., national drug chain, mail order, state health department pharmacies, local pharmacies, university or disproportionate share hospital pharmacy), including the number of contract pharmacies used.
- *ii)* Discuss any negotiated discounts on the purchase price of drugs, dispensing fees, administrative fees, and additional services for the coming year.
- iii) Discuss how much funding was recouped from rebates in FY 2010.
- *iv*) Discuss how the State/Territory assures that manufacturer's rebates are applied, consistent with Section 2616(g) of the PHS Act. Monies received as a result of participating in the 340B Drug Pricing Program Rebate Option shall be returned to the operating budget of the Part B program, with priority given to activities in ADAP.

(b) For ADAPs Using Either the 340B Direct Purchase or 340B Rebate Options

(1) Describe all other non-340B cost-saving strategy(s) that the State/Territory used in FY 2010, or plan to use in FY 2011 to secure the best price and maximize ADAP resources, such as other supplemental rebates and/or discounts received from pharmaceutical manufacturers in FY 2010.

(c) Non-340B Participating ADAPs:

- (1) For States/Territories that did not participate in the 340B Drug Pricing Program during FY 2010:
 - i) Describe all of the cost-saving strategies used by your ADAP during FY 2010, including any non-340B supplemental rebates and/or discounts received from pharmaceutical manufacturers.
 - *ii)* Explain how these strategies are equal to or more economical than participating in the 340B Drug Pricing Program.

(d) ADAP Linkages

- (1) Discuss how the ADAP coordinates with third-party payers (e.g., State Medicaid program, Department of Veterans Affairs, or private insurance) to assure that ADAP is the payer of last resort.
- (2) Describe any third-party payer limitations that restrict access to HIV pharmaceutical therapies and any ADAP mechanisms to address gaps or limitations in services.
- (3) Discuss how the ADAP coordinates with Part A, Part C, and Part D grantees to provide comprehensive and equitable pharmacy benefits across the state.
- (4) Briefly describe how the ADAP utilizes or coordinates with manufacturer's patient assistance programs and clinical trials.

(e) Medicare (including Medicare Part D Prescription Drug Benefit)

- (1) Describe the policies and procedures established by the State/Territory with respect to the use of Part B ADAP and/or "base" funds (e.g., State Health Insurance Continuation Program (HICP), HIV Care Consortia) to cover Medicare Part D out-of-pocket costs (premiums, deductibles, coinsurance, and/or co-pays) for low-income beneficiaries who meet the State/Territory's ADAP eligibility criteria.
- (2) With regard to each Part B program component that will cover Part D costs, discuss briefly how the State's policies take into account:
 - *i)* Client eligibility in relation to eligibility for the program/service, e.g. ADAP, consortia-funded insurance continuation;
 - *ii)* Costs and resources, including administrative costs;
 - iii) Any limits established with respect to eligible Prescription Drug Plans (PDPs), e.g. PDPs that do not have a 'donut-hole,' do not exceed a certain premium cost, and/or meet certain drug coverage criteria;
 - *iv)* How the program (e.g., ADAP, consortia) will coordinate with eligible PDPs to track and account for these payments;
 - v) Competing access issues such as capped ADAP enrollment and/or waiting lists; and
 - vi) The current or expected impact of the Medicare Part D Prescription Drug Benefit on the specific program component (e.g. ADAP, State Insurance Continuation).
- (3) For each program component that will cover Medicare Part D beneficiary costsharing, identify the number of clients the State/Territory anticipates serving that will be Medicare eligible and the projected amount of FY 2011 funds to be spent on these clients.
- (4) With regard to the Part B ADAP and/or State HICP, identify all sources other than the ADAP Earmark to be used to help cover beneficiary out-of-pocket costs (e.g., Part B base funds allocated for ADAP, contributions from the State, Part A and/or other Ryan White HIV/AIDS Program funded programs to the ADAP or HICP); for each additional funding source, indicate if the funds were allocated specifically for the purpose of covering Part D beneficiary costs and/or to support the ADAP program generally.
- (5) With regard to the use of Part B HIV Care Consortia funds to cover beneficiary Part D costs, discuss how the State/Territory will assure consistency statewide with respect to: client eligibility for coverage of Part D out-of-pocket costs; and coordination with eligible PDP's to track payments.

(f) ADAP Funded Health Insurance

Summary: HAB Policy Notice 07-05 allows States and Territories to use ADAP funds to purchase health insurance. States and Territories must initially provide HAB with a

Notification of Intent to use ADAP funds for the purchase of health insurance. **States** may use this application as the Notification of Intent.

- (1) For States/Territories with existing ADAP-funded health insurance programs, please describe:
 - *i*) The use of ADAP funds to purchase insurance in FY 2010 and any anticipated changes for FY 2011; and
 - *ii)* The anticipated amounts of ADAP funds to be used for health insurance, the types of insurance(s) that will be purchased, and the number of projected clients to be served.
- (2) For those States/Territories establishing new insurance programs during FY 2011, please provide a narrative description of:
 - i) How the State/Territory will ensure that the health insurance to be purchased includes a formulary that is as comprehensive as the current ADAP formulary;
 - *ii)* How the State/Territory will ensure the cost effectiveness of the health insurance to be purchased;
 - iii) The anticipated amounts of ADAP funds to be used for health insurance (i.e. premiums, co-pays and deductibles) and types of insurance(s) that will be purchased using ADAP funds as well as the number of projected clients to be served;
 - iv) How the program will account for, and report on, funds used to purchase and maintain insurance policies for eligible clients, including covering any costs associated with these policies (e.g., premiums, co-payments, or deductibles) to ensure that Ryan White HIV/AIDS Program funds is the payer of last resort;
 - *v*) How the program coordinates with any existing program utilizing Part B funds for the purchase of health insurance; and
 - *vi*) How the implementation of this program will impact the ADAP (e.g., the expansion of formulary or the decrease in waiting list).
- (g) Flexibility Policy as it Relates to Access, Adherence and Monitoring Services

 Summary: HAB Policy Notice 07-03 established guidelines for allowable ADAP-related expenditures under the Ryan White HIV/AIDS Program for services that improve access to medications, increase adherence to medication regimens, and help clients monitor their progress in taking HIV-related medications. The policy provides grantees with greater flexibility in the use of ADAP funds. States may request to redirect up to 5% under this policy, and up to 10% in extraordinary circumstances. The amount that a grantee can request to be redirected is in addition to the aggregate of 15% of ADAP funds allowed for administrative, planning and evaluation costs. This does not include funds under other Parts that may be used to purchase medications. An example of an extraordinary circumstance would be identifying a targeted population with low adherence rates (e.g. substance abusers, homeless persons).

Note: Those States/Territories applying to use ADAP funds under the Flexibility Policy in FY 2011 for access, adherence, and monitoring services should reply to this section. In order to be eligible the States/Territories cannot have any program restrictions (i.e., cost share, waiting list, or co-pays).

(1) Discussion of Proposed Program

- i) If you plan to redirect a portion of ADAP funding to pay for services under the ADAP Flexibility Policy, provide a narrative description that includes the:
 - *a.* Proposed services to be funded (access, adherence, monitoring);
 - **b.** Amount of ADAP funds that will be redirected to pay for the referenced services;
 - Methodology used to determine the cost of the proposed services;
 - d. The total projected expenditures for each service, and the unit cost (e.g. cost for billable hours for adherence and access services, lab services, etc.);
 - *e.* The number of clients who will directly benefit from each of the proposed services;
 - *f.* How the program will monitor the proposed services to ensure that there are no limitations to accessing the State ADAP;
 - g. How the ADAP will ensure that comprehensive coverage of antiretroviral and opportunistic infection medications is maintained;
 - *h*. How the ADAP will report on the use of redirected funds under the Flexibility Policy; and
 - i. How the ADAP will redirect funds back to the ADAP funding stream should it become necessary to maintain the core purpose of ADAP.

(C) Pacific Island Jurisdictions' FY 2011 Part B Grant Application

This Section should be completed only by eligible applicants listed below.

Eligible Jurisdictions:

Republic of the Marshall Islands
Federated States of Micronesia
Republic of Palau
American Samoa
The Commonwealth of the Northern Mariana Islands

Note: For those territories that are eligible to apply for the ADAP Supplement Grant Application, please refer to and complete the FY 2011 ADAP Supplemental Grant Application Section.

(1) The Territory's Organizational Structure

- (a) Describe the Territory's health care delivery system, including the health centers responsible for providing services to low income populations in general.
- **(b)** Describe where HIV/AIDS related services are provided, including relevant laboratory diagnostic facilities. Include organizational charts in **Attachment 1** in order to illustrate the relationships between the Territory-level agencies involved in HIV care. Highlight any changes planned for the next year.
- (c) Within the Territory's structure, identify the proposed entity or entities responsible for managing/administering Part B programs, including ministry or department, unit, staff, fiscal agents, and planning/advisory/evaluation bodies. Highlight any changes for the next year
 - (1) Identify the entity responsible for financial management of the Part B program, including ministry or department.
 - (2) Describe the relationship between the entity responsible for financial administration and the entity responsible for program administration.
 - (3) Identify which entity is responsible for grant-related fiscal reporting and financial monitoring, and how these entities work together to fulfill grant-related reporting and monitoring responsibilities.

(2) Epidemiological Information

Summary: Territories are requested to use AIDS and HIV (not AIDS) prevalence data, as well as available incidence data (i.e., the number of new cases that occur within a given time period), when preparing this application. Place the table in **Attachment 4** of the application and **clearly label the source of the data**.

- (a) Provide a narrative description of the following information. Where applicable, distinguish between cases reported to CDC and those reported locally. Note whether this includes un-confirmed (by Western Blot) cases, and/or cases diagnosed symptomatically.
 - (1) HIV and AIDS incidence within the jurisdiction during the past two calendar years (2008, 2009).
 - (2) Cumulative HIV prevalence (i.e. total HIV cases within the jurisdiction).
 - (3) Cumulative AIDS prevalence (i.e. total AIDS cases within the jurisdiction).
- **(b)** Discuss the demographics and geographic distribution of newly diagnosed HIV and AIDS cases during the past two calendar years (2008, 2009).
- (c) Describe the trends and changes in the HIV/AIDS cases within the Territory.

(3) HIV/AIDS Care System

- (a) Describe the Territory's continuum of care in 2011, including HIV/AIDS services provided in the Territory (i.e., primary medical care, supportive services that enable individuals to access and remain in primary care, and other health and supportive services that promote health and enhance quality of life).
- **(b)** Outline the strategy for identifying individuals with HIV/AIDS who do not know their status, making such individuals aware of their status, and enabling such individuals to access services. The strategy should include discrete goals, a timetable, and be coordinated with other community strategies.
- (c) Describe the current availability and capacity of HIV/AIDS resources and services to provide HIV/AIDS care, planned capacity development activities in the Territory, and/or capacity development needs. Discuss any disparities in access or services among affected subpopulations or communities.
- (d) Describe efforts to inform individuals living with HIV/AIDS about services and to engage individuals in HIV/AIDS care.
- (e) Specifically address how the Medicaid program, if applicable, in the Territory provides services to people living with HIV/AIDS, including eligibility, and what HIV/AIDS services are covered by Medicaid.
- (f) Describe how the Part B program coordinates with Federal- and Territory-funded HIV prevention efforts, including any planned linkages and joint planning mechanisms. Describe how HIV counseling and testing services are designed to facilitate access to care for persons testing positive for HIV. In addition, describe any other linkages with early intervention services.

(4) Clinical Quality Management Program

HAB's Definition of Quality: "Quality is the degree to which a health or social service meets or exceeds established professional standards and user expectations." Evaluations of the quality of care should consider: (1) the quality of the inputs; (2) the quality of the service delivery process; and (3) the quality of outcomes, in order to continuously improve systems of care for individuals and populations.

<u>Note</u>: HRSA's expectations of Ryan White HIV/AIDS Program grantees with respect to improving the quality of care and establishing quality management programs may be found online at: http://hab.hrsa.gov/special/qualitycare.htm. HRSA technical assistance in selecting appropriate service- and client-level outcomes is also available online at: http://hab.hrsa.gov/tools.htm or http://careacttarget.org.

- (a) The HAB has established the following minimum expectations of Ryan White HIV/AIDS Program grantees regarding quality management. At a minimum, grantees are expected to:
 - (1) Establish and implement a quality management plan;
 - (2) Establish processes for ensuring that services are provided in accordance with DHHS treatment guidelines and Standards of Care; and
 - (3) Incorporate quality-related expectations into Requests for Proposals (RFPs) and Part B contracts.
- **(b)** Provide a narrative which describes how the Territory ensures the quality of HIV care provided to Persons Living with HIV/AIDS (PLWH/A). Discuss how Part B funded services, including support services, are improving HIV-related clinical health outcomes of PLWH/A in the Territory.

(5) Planning Mechanisms

- (a) Identify the planning entity/mechanism the Territory uses to make decisions about Part B funds. Discuss the participation of PLWH/A in the planning process, including what the Territory is doing to encourage and support their participation in this process.
- (b) Describe how decisions to allocate dollar amounts to the five program areas HIV Care Consortia, Home and Community-Based Care, Health Insurance Coverage, Provision of Treatments, and Direct Services will be made. Also discuss how allocation decisions are made across/between geographically or politically separate States, and who is involved in making these decisions.

(6) Ryan White HIV/AIDS Program Coordination of Planning and Services

(a) Coordination with other Federal Programs

- (1) Describe how the Part B program coordinates HIV/AIDS funding and service delivery with non-Ryan White HIV/AIDS Program programs.
 - i) Examples include: coordinating with other HRSA funded programs (including Maternal and Child Health, Migrant Health Programs, and Community Health Clinics); CDC (Prevention, Surveillance, STD programs); Medicaid (including Medicaid managed care); Medicare; Veterans Affairs programs; Territory funds; and other programs/initiatives (such as substance abuse prevention and treatment services or Territory social, welfare, and immigration services).
 - *ii)* If applicable, briefly describe any ongoing or planned activities the Territory is participating in through the Global AIDS Fund and how these activities are coordinated with the Part B program.

(7) Implementation Plan for FY 2011

Summary: The Ryan White HIV/AIDS Program requires that grantees funded under Part B use not less than 75 percent of grant funds, after reductions for Program Administration and Quality, for core medical services that are needed in the service area. Core medical services are defined as follows: 1) Outpatient and ambulatory health services; 2) AIDS Drug Assistance Program treatments in accordance with Section 2616 of the PHS Act; 3) AIDS pharmaceutical assistance (local); 4) Oral health care; 5) Early Intervention Services; 6) Health insurance premium and cost sharing assistance for low-income individuals in accordance with Section 2615; 7) Home health care; 8) Medical nutrition therapy; 9) Hospice services; 10) Home and community-based health services as defined under Section 2614(c) of the PHS Act; 11) Mental health services; 12) Substance abuse outpatient care; and 13) Medical case management, including treatment adherence services.

In addition, support services in Section 2612(c) of the PHS Act are described as services, subject to approval of the Secretary, that are needed for individuals with HIV/AIDS to achieve their medical outcomes. Support services include: 1) Case Management (non-medical); 2) Child care services; 3) Emergency Financial Assistance; 4) Food bank/home-delivered meals; 5) Health education/risk reduction; 6) Housing; 7) Legal Services; 8) Linguistic Services; 9) Medical Transportation Services; 10) Outreach Services; 11) Psychological Support Services; 12) Referral for health care/supportive services; 13) Rehabilitation Services; 14) Respite Care and 15) Treatment Adherence Counseling; and 16) Residential substance abuse treatment. All services provided by or through consortia are considered as support services.

- (a) Table: FY 2011 Implementation Plan:
 - (1) Describe how the Territory will expend grant funds.
 - *i*) In a table, list each of the five eligible program components that will be funded. Under each program component, list the service categories and amounts of Part B funding that will be allocated for each service category in FY 2011. For each service category define the:

- a. service unit;
- **b.** number of persons to be served;
- c. units of service to be delivered,
- d. time frame of estimated duration of activity and
- e. estimated cost of meeting the objective.

Note: Program objectives should not include administrative processes. The table should be placed in **Attachment 5** of the application.

(b) Provide a narrative that describes the following:

- (1) How the Territory will allocate funds to the core medical and supportive services as described above. If funds are not allocated to these core medical services, provide a narrative description of how the core medical services are being funded through other sources;
- (2) How the activities described in the plan will assure geographic parity in access to HIV/AIDS services throughout the Territory;
- (3) How the activities described in the plan will ensure that PLWH/A remain engaged in HIV/AIDS primary medical care and adhere to HIV treatments; and
- (4) How the services and their goals and objectives relate to the goals of the Healthy People 2010 initiative, particularly those indicated in Chapter 13 of the document. Copies of the Healthy People 2010 may be obtained from the Superintendent of Documents or downloaded at: http://www.health.gov/healthypeople/document.

(D) ADAP Supplemental Grant Application

This section should be completed only by eligible applicants as listed below.

(1) States/Territories Eligible to Apply for an ADAP Supplemental Treatment Drug Grant

Summary: The process for determining States and Territories with demonstrated severe need was based on a review of existing program limitations, as reported in the ADAP Quarterly Report (AQR). The following States/Territories below are determined to be eligible to apply in FY 2011 for program funding based on program limitations (i.e., enrollment cap, waiting list and capped expenditures) reported in the ADAP 4th Quarterly Report (April 30, 2010). Additional States may become eligible based on requirements for maintaining a core list of drugs and/or identifying an unanticipated increase in clients.

Alabama	Florida	Oregon
Alaska	Indiana	Puerto Rico
American Samoa	Iowa	Rhode Island
Arizona	Kentucky	South Dakota
Arkansas	Louisiana	South Carolina
California	Missouri	Tennessee
Colorado	Montana	Texas
District of Columbia	Nebraska	Utah
Georgia	New Jersey	Virginia
Guam	North Carolina	Virgin Islands
Hawaii	North Dakota	Washington
Idaho	Northern Mariana Islands	West Virginia
Illinois	Oklahoma	Wisconsin
Federated States of	Ohio	Wyoming
Micronesia		

Section 2618(a)(2)(F)(ii) of the PHS Act, states that five percent of the AIDS Drug Assistance Program (ADAP) appropriation will be reserved as supplemental funding to purchase medications for States and Territories with demonstrated severe need. This funding will be available to States and Territories based on one of the following criteria:

- ➤ Financial requirement of Federal Poverty Level (FPL) <200 percent;
- ▶ Limited formulary compositions for all core classes of antiretroviral medications;
- ➤ Waiting list, capped enrollment or expenditures; and
- ➤ An unanticipated increase of eligible individuals with HIV/AIDS.

(a) Eligibility Criteria

(1) To receive this grant States/Territories must satisfy the following criteria:

- i) States/Territories must have obligated 75 percent of their FY 2010 Part B award within 120 days of receipt of grant funds and have reported on the FY 2010 interim Federal Financial Report (FFR), within 150 days after receipt of grant funds. States/Territories that fail to obligate 75 percent of the FY 2010 Part B grant award in this timeframe, or fail to submit the FFR on time, will be ineligible for FY 2011 ADAP supplemental funds.
- ii) States/Territories must use ADAP supplemental funds to provide HIV/AIDS-related medications or the devices needed to administer them, and shall coordinate the use of such funds with the amounts otherwise provided under section 2616 of the PHS Act (ADAP) in order to maximize drug coverage.

(b) Application Requirements

- (1) States and Territories applying for these funds must describe the severity of need for ADAP supplemental funds using the factors below. The narrative should:
 - *i*) Describe any ADAP eligibility restrictions.
 - ii) Identify the barriers in meeting the requirement for maintaining a minimum drug list that includes all currently available Food and Drug Administration (FDA)-approved antiretroviral drug classes. The current statute requires that all States/Territories determine the formularies from the list of core classes of antiretroviral medications established by the Secretary. FDA-approved antiretroviral drug classes currently available include: Entry and Fusion Inhibitor, Non-nucleoside Reverse Transcriptase Inhibitor, Nucleoside Reverse Transcriptase Inhibitor.
 - *iii*) Identify the number of eligible individuals to whom a State or Territory is unable to provide therapeutics to treat HIV/AIDS.
 - iv) Discuss any unanticipated increase in service utilization and program costs, e.g., due to the addition of a new drug or class of drug, or to an unexpected increase in eligible individuals with HIV/AIDS.
 - v) If you are requesting a waiver to the match pursuant to Section 2618(a)(2) (F)(ii)(III) of the PHS Act, please submit this request along with the other application information.

(E) Emerging Communities FY 2011 Grant Application

This section should be completed only by eligible applicants as listed below.

(1) Eligible Jurisdictions:

The following Metropolitan Statistical Areas (MSAs) are eligible:

Albany-Schenectady-Troy, New York Augusta-Richmond County, Georgia/South Carolina Bakersfield, California Birmingham-Hoover, Alabama Buffalo-Niagara Falls, New York Cincinnati-Middletown, Ohio/Kentucky/ Indiana Columbia, South Carolina Columbus, Ohio Jackson, Mississippi Lakeland, Florida Louisville, Kentucky/Indiana Milwaukee-Waukesha-West Allis, Wisconsin Oklahoma City, Oklahoma Philadelphia, Pennsylvania/New Jersey/Delaware/Maryland/ Pittsburgh, Pennsylvania Port St. Lucie-Fort Pierce, Florida Providence-New Bedford-Fall River, Rhodes Island/Massachusetts Raleigh-Cary, North Carolina Richmond, Virginia Rochester, New York Sarasota-Bradenton-Venice, Florida

(2) Program Authority and Eligibility

Summary: The Emerging Communities Supplemental Grant award is authorized under Section 2621 of PHS Act. It is intended to enable eligible States to provide comprehensive services of the type described in section 2612(a)of the PHS Act to supplement the services otherwise provided by the State under a grant under Part B in emerging communities within the State that are not eligible to receive grants under Part A. An eligible State shall agree that the grant will be used to provide funds directly to emerging communities in the State, separately from other funds under this title that are provided by the State to such communities."

Grantees with Jurisdictions that were classified as an Emerging Community are eligible to apply for these funds. Emerging Communities continue their eligibility for these funds so long as they meet the statutory requirements. Areas must meet the statutory incidence requirements (cumulative AIDS cases reported to and confirmed by the Director of the Centers for Disease Control and Prevention during the most recent period of 5 calendar years for which such data are available). An Emerging Community possesses a cumulative total of at least 500, but fewer than 1,000 AIDS cases. In the alternative, areas can retain their eligibility by meeting the savings provisions of the Ryan White Program legislation. That is, they must not have fallen

below, for three consecutive years, the required incidence level already specified AND required prevalence level (cumulative total of living cases of AIDS reported to and confirmed by the Director of the Centers for Disease Control and Prevention as of December 31 of the most recent calendar year for which such data are available). For an Emerging Community, this is 750 living cases of AIDS. Areas are notified by letter when they fall within the savings provisions of the Ryan White Program legislation. According to the past eligibility numbers, all the above ECs will be eligible in FY 2011.

(3) Emerging Community Requirements

- (a) Please describe the following:
 - (1) How the State will disseminate Emerging Community funds;
 - (2) How the State maintains its commitment of local resources, both financial and in-kind;
 - (3) How the State will maintain HIV-related activities at a level that is equal to not less than the level of such activities in the State for the one year period preceding the fiscal year for which the state is applying to receive the grant; and
 - (4) How the State utilizes the funds in a manner that is immediately responsive and cost effective.

(4) Planning and Utilization of Emerging Community Funds

- (a) Please describe how the planning process for the Emerging Community funds meets the following requirements. (A State with multiple Emerging Communities should describe each Emerging Community planning process separately, if the process differs.)
 - (1) The allocation of the funds is based in accordance with the local demographic incidence of AIDS including appropriate allocations for services for infants, children, women and families with HIV/AIDS;
 - **(2)** Affected communities and people living with HIV/AIDS are included in the planning process; and
 - (3) The proposed services are consistent with the local needs assessments and the most recent Statewide Coordinated Statement of Need.
- **(b)** Describe how, as a result of the planning process, the Emerging Community funds will be used. A state with multiple Emerging Communities should describe the use of funds for each Emerging Community separately. Please describe:
 - (1) What services were provided in Fiscal Year 2010 using Emerging Community funds?
 - (2) What services will be provided in Fiscal Year 2011?

Note: The 75% core medical services requirement does not apply to Emerging Community funds.

xi. Attachments:

Please provide the following items to complete the content of the application. Please note that these are supplementary in nature, and are not intended to be a continuation of the project narrative. Be sure each attachment is clearly labeled.

Attachment 1: Organizational Chart(s), brief description of the positions and

responsibilities in regards to the Part B grant, FTE equivalent of all key staff and personnel. (Note: Biographical sketches and or resumes are

NOT required.)

Attachment 2: MOE Documentation

Attachment 3: The FY 2011 Part B Agreements and Assurances (see Appendix A) & SF-

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Attachment 4: HIV/AIDS Epidemiological Tables

Attachment 5: Implementation Table, (including MAI, if applicable)

Attachment 6: Other Relevant Documents (Unmet Need Framework, ADAP Funding

Sources table, Any Others)

Attachment 7: FY 2011 Core Medical Services Waiver (if applicable)

Attachment 8: EIIHA Matrix

3. Submission Dates and Times

Application Due Date

The due date for applications under this funding opportunity announcement is **January 3, 2011 at 8:00 P.M. EST.** Applications completed online are considered formally submitted when the application has been successfully transmitted electronically by your organization's Authorized Organization Representative (AOR) through Grants.gov and has been validated by Grants.gov on or before the deadline date and time

The Chief Grants Management Officer (CGMO) or designee may authorize an extension of published deadlines when justified by circumstances such as natural disasters (e.g., floods or hurricanes) or other disruptions of services, such as a prolonged blackout. The CGMO or designee will determine the affected geographical area(s).

Late applications:

Applications which do not meet the criteria above are considered late applications and will not be considered in the current competition.

4. Intergovernmental Review

HIV Care Grant Program Part B is subject to the provisions of Executive Order 12372, as implemented by 45 CFR 100. Executive Order 12372 allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. Application packages made available under this guidance will contain a listing of States which have chosen to set up such a review system, and will provide a State Single Point of Contact (SPOC) for the review. Information on states affected by this program and State Points of Contact may also be obtained from the Grants Management Officer listed in the AGENCY Contact(s) section, as well as from the following Web site: http://www.whitehouse.gov/omb/grants/spoc.html.

All applicants other than federally recognized Native American Tribal Groups should contact their SPOC as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process used under this Executive Order.

Letters from the State Single Point of Contact (SPOC) in response to Executive Order 12372 are due sixty days after the application due date.

5. Funding Restrictions

The DSS will be strictly enforcing the Ryan White HIV/AIDS Health Care Services Program authorizing statute, which states:

Section 2618(c)(1)(B)--Expedited Distribution,-

- (1) IN GENERAL.- Not less than 75 percent of the amounts received under a grant awarded to a State under this part shall be obligated to specific programs and projects and made available for expenditure not later than
 - (A) In the case of succeeding fiscal years (FY), 120 days after receipt of such amounts by the State.

Section 2618(d)--Reallocation-

(2) Any portion of a grant made to a state under section 2611 for a fiscal year that has not been obligated as described in subsection (c) ceases to be available to the State or Territory and shall be made available by the Secretary for grants under Section 2620, in addition to amounts made available for such grants under section 2623(b)(2).

Part B grant funds cannot be used for:

- International travel.
- Construction; however, minor alterations and renovations to an existing facility, to make
 if more suitable for the purpose of the grant program are allowable with prior HRSA
 approval.
- Entertainment costs. This includes the cost of amusements, social activities and related incidental costs.
- Fundraising expenses.
- Lobbying expenses.

Other non-allowable costs can be found in the OMB circulars, available at http://www.whitehouse.gov/omb/circulars default.

6. Other Submission Requirements

As stated in Section IV.1, except in rare cases HRSA will no longer accept applications for grant opportunities in paper form. Applicants submitting for this funding opportunity are *required* to submit *electronically* through Grants.gov. To submit an application electronically, please use the http://www.Grants.gov apply site. When using Grants.gov you will be able to download a copy of the application package, complete it off-line, and then upload and submit the application via the Grants.gov site.

It is essential that your organization *immediately registers* with Grants.gov and becomes familiar with the Grants.gov site application process. If you do not complete the registration process you will be unable to submit an application. The registration process can take up to one month.

To be able to successfully register in Grants.gov, it is necessary that you complete all of the following required actions:

- Obtain an organizational Data Universal Number System (DUNS) number.
- Register the organization with Central Contractor Registry (CCR).
- Identify the organization's E-Business POC Point of Contact (E-Biz POC).
- Confirm the organization's CCR "Marketing Partner ID Number (M-PIN)" password.
- Register an Authorized Organization Representative (AOR).
- Obtain a username and password from the Grants.gov Credential Provider.

Instructions on how to register, tutorials and FAQs are available on the Grants.gov web site at www.grants.gov. Assistance is also available 24 hours a day, 7 days a week (excluding Federal holidays) from the Grants.gov help desk at support@grants.gov or by phone at 1-800-518-4726.

Formal submission of the electronic application: Applications completed online are considered formally submitted when the application has been successfully transmitted electronically by your organization's AOR through Grants.gov and has been validated by Grants.gov on or before the deadline date and time.

It is incumbent on applicants to ensure that the AOR is available to submit the application to HRSA by the published due date. HRSA will <u>not</u> accept submission or re-submission of incomplete, rejected, or otherwise delayed applications after the deadline. Therefore, you are urged to submit your application in advance of the deadline. If your application is rejected by Grants.gov due to errors, you must correct the application and resubmit it to Grants.gov before the deadline date and time.

If, for any reason, an application is submitted more than once, prior to the application due date, HRSA will only accept the applicant's last electronic submission prior to the

application due date as the final and only acceptable submission of any competing application submitted to Grants.gov.

Tracking your application: It is incumbent on the applicant to track application status by using the Grants.gov tracking number (GRANTXXXXXXXX) provided in the confirmation email from Grants.gov. More information about tracking your application can be found at http://www07.grants.gov/applicants/resources.jsp.

V. Application Review Information

1. Review Criteria

Applications will be reviewed for complete submission of required information as outlined in the 2011 Part B Guidance.

2. Review and Selection Process

Part B formula awards are not subject to the Objective Review Committee process. All applications will be reviewed internally by grants management officials (business and financial review) and Division of Service Systems' program staff (technical review).

3. Anticipated Announcement and Award Dates

HRSA expects to award FY2011 Part B funds by April 1, 2011.

VI. AWARD Administration Information

1. Award Notices

Letters of notification do not provide authorization to begin performance.

The Notice of Award sets forth the amount of funds granted, the terms and conditions of the grant, the effective date of the grant, the budget period for which initial support will be given, the non-Federal share to be provided (if applicable), and the total project period for which support is contemplated. Signed by the Grants Management Officer, it is sent to the applicant agency's Authorized Representative, and reflects the only authorizing document. It will be sent prior to the start date of April 1, 2011.

2. Administrative and National Policy Requirements

Successful applicants must comply with the administrative requirements outlined in 45 CFR Part 74 <u>Uniform Administrative Requirements for Awards and Sub-awards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations</u> or 45 CFR

Part 92 <u>Uniform Administrative Requirements For Grants And Cooperative Agreements to State, Local, and Tribal Governments</u>, as appropriate.

HRSA grant awards are subject to the requirements of the HHS Grants Policy Statement (HHS GPS) that are applicable to the grant based on recipient type and purpose of award. This includes, as applicable, any requirements in Parts I and II of the HHS GPS that apply to the award. The HHS GPS is available at http://www.hrsa.gov/grants/. The general terms and conditions in the HHS GPS will apply as indicated unless there are statutory, regulatory, or award-specific requirements to the contrary (as specified in the Notice of Award).

Cultural and Linguistic Competence

HRSA is committed to ensuring access to quality health care for all. Quality care means access to services, information, materials delivered by competent providers in a manner that factors in the language needs, cultural richness, and diversity of populations served. Quality also means that, where appropriate, data collection instruments used should adhere to culturally competent and linguistically appropriate norms. For additional information and guidance, refer to the National Standards for Culturally and Linguistically Appropriate Services in Health Care published by HHS. This document is available online at http://www.omhrc.gov/CLAS.

Trafficking in Persons

Awards issued under this guidance are subject to the requirements of Section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. 7104). For the full text of the award term, go to http://www.hrsa.gov/grants/trafficking.htm. If you are unable to access this link, please contact the Grants Management Specialist identified in this guidance to obtain a copy of the Term.

Smoke-Free Workplace

The Public Health Service strongly encourages all award recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. Further, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

PUBLIC POLICY ISSUANCE

HEALTHY PEOPLE 2020

Healthy People 2020 is a national initiative led by HHS that set priorities for all HRSA programs. The initiative has two major goals: (1) to increase the quality and years of a healthy life; and (2) eliminate our country's health disparities. The program consists of 28 focus areas and 467 objectives. HRSA has actively participated in the work groups of all the focus areas, and is committed to the achievement of the Healthy People 2020 goals.

Healthy People 2010 and the conceptual framework for the forthcoming Healthy People 2020 process can be found online at http://www.healthypeople.gov/.

3. Reporting

The successful applicant under this guidance must comply with the following reporting and review activities.

a) Audit Requirements

Comply with audit requirements of Office of Management and Budget (OMB) Circular A-133. Information on the scope, frequency, and other aspects of the audits can be found on the Internet at http://www.whitehouse.gov/omb/circulars default.

b) Payment Management Requirements

Submit a quarterly electronic Federal Financial Report (FFR) Cash Transaction Report via the Payment Management System. The report identifies cash expenditures against the authorized funds for the grant or cooperative agreement. The FFR Cash Transaction Reports must be filed within 30 days of the end of each calendar quarter. Failure to submit the report may result in the inability to access award funds. Go to www.dpm.psc.gov for additional information.

c) Status Reports

- 1) Submit a **Federal Financial Report (FFR, SF-425)**. An interim FFR is due within 120 days of the notice of award. A FFR is required within 90 days of the end of the project period. The report is an accounting of expenditures under the project that year. More specific information will be included in the award notice.
- 2) Submit a **Progress Report**(s). Further information will be provided in the award notice. Acceptance of this award indicates that the grantee assures that it will comply with data requirements of the Ryan White Services Report (RSR) and that it will mandate compliance by each of its contractors and subcontractors. The RSR captures information necessary to demonstrate program performance and accountability. All Ryan White core service and support service providers are required to submit client-level data for Calendar Year (CY) 2011. Please refer to the HIV/AIDS Program Client Level Data website at http://hab.hrsa.gov/manage/CLD.htm for additional information.
- 3) Submit **Progress Report(s) and quarterly ADAP Reports**. Further information will be provided in your notice of grant award.

VII. Agency Contacts

Applicants may obtain additional information regarding business, administrative, or fiscal issues related to this funding opportunity announcement by contacting:

Shonda Gosnell Grants Management Specialist Division of Grants Management Operations/HRSA 5600 Fishers Lane, Room 11A-02 Rockville, Maryland 20857 Telephone: (301) 443-4238

Fax: (301) 594-6096

E-mail: sgosnell@hrsa.gov

Additional information related to the overall program issues and/or technical assistance regarding this funding announcement may be obtained by contacting

Douglas Morgan, M.P.A. Director, Division of Service Systems HIV/AIDS Bureau, HRSA 5600 Fishers Lane Room 7A-55 Rockville, Maryland 20857 Telephone: 301-443-6745

Fax: 301-443-8143 Email: DMorgan@hrsa.gov

Applicants may need assistance when working online to submit their application forms electronically. For assistance with submitting the application in Grants.gov, contact Grants.gov 24 hours a day, seven days a week, excluding Federal holidays at:

Grants.gov Contact Center Phone: 1-800-518-4726 E-mail: support@grants.gov

Applicants may need assistance when working online to submit the remainder of their information electronically through HRSA's Electronic Handbooks (EHBs). For assistance with submitting the remaining information in HRSA's EHBs, contact the HRSA Call Center, Monday-Friday, 9:00 a.m. to 5:30 p.m. ET:

HRSA Call Center

Phone: (877) Go4-HRSA or (877) 464-4772

TYY: (877) 897-9910 Fax: (301) 998-7377

Email: Callcenter@HRSA.GOV

VIII. Other Information

1. HIV/AIDS Clinical Performance Measures

The HIV/AIDS Bureau has developed HIV/AIDS Clinical Performance Measures for Adults and Adolescents and a companion guide to assist grantees in the use and implementation of the core clinical performance measures. Information on Performance Measures can be found at: http://hab.hrsa.gov/special/habmeasures.htm

2. ADAP Quality Management

ADAP quality management requirements have been incorporated into the Clinical Quality Management section of this Guidance.

3. Allowable Uses of Funds

For most up to date listings of allowable uses of funds, refer to HAB Policy Notice 10-02: "Eligible Individuals and Allowable Uses of Funds for Discretely Defined Categories of Services" reissued April 8th, 2010. HAB Policy Notice 10-02 is available online at http://hab.hrsa.gov/law/1002.htm.

IX. Tips for Writing a Strong Application

A concise resource offering tips for writing proposals for HHS grants and cooperative agreements can be accessed online at: http://www.hhs.gov/asrt/og/grantinformation/apptips.html.

Appendix A:

FY 2011 AGREEMENTS AND ASSURANCES Ryan White HIV/AIDS Treatment Extension Act of 2009 Part B Grant Program

I, the Governor, or Authorized Designated Official,	, of the State or Territory of
	, hereinafter referred to as "State,"
assure that:	

1. Pursuant to Section 2612¹

a.) Section 2612(a)

Amounts provided will be expended on core medical services, support services, and administrative expenses only.

b.) Section 2612(b)(1)

Unless a waiver is obtained, not less than 75 percent of the portion of the grant remaining after reserving amounts for administration, planning/evaluation and quality management will be used to provide core medical services that are needed in the State for individuals with HIV/AIDS who are identified and eligible under this title (including services regarding the co-occurring conditions of the individuals).

c.) Section 2612(d)(2)

Entities providing Early Intervention Services (EIS) will ensure that the following conditions have been met:

- Federal, State and local funds are otherwise inadequate for the EIS an entity proposes to provide:
- and the entity will supplement, not supplant other funds available to the entity for the provision of providing EIS for the fiscal year involved.

d.) Section 2612(e)

For each of such populations in the eligible area, the State will use not less than the percentage constituted by the ratio of the population involved (infants, children, youth, or women in such area) with HIV/AIDS to the general population in such area of individuals with HIV/AIDS, unless a waiver is obtained from the Secretary.

f.) Section 2612(f)

No amounts received under the grant will be used to purchase or improve land, or to purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or to make cash payments to intended recipients of services.

2. Pursuant to Section 2613

Section 2613(b)

All required assurances will be obtained from applicants who apply to the State for assistance to provide consortia services.

¹ All statutory references are to the Public Health Service Act, unless otherwise specified.

3. Pursuant to Section 2615

Section 2615(b)

Assistance will not be used to pay any costs associated with the creation, capitalization, or administration of a liability risk pool (other than those costs paid on behalf of individuals as part of premium contributions to existing liability risk pools); or to pay any amount expended by a State under title XIX of the Social Security Act.

4. Pursuant to Section 2616

a.) Section 2616(c)(1)

The therapeutics included on the list of classes of core antiretroviral therapeutics established by the Secretary are at a minimum the treatments provided by the State.

b.) Section 2616(g)

Any drug rebates received on drugs purchased from funds provided under the grant are applied to activities supported under Part B, with priority given to AIDS Drug Assistance Program activities.

5. Pursuant to Section 2617

a.) Section 2617(b)(4)

The State shall designate a lead State agency that will:

- administer all assistance received under Part B;
- conduct the needs assessment and prepare the State plan;
- prepare all applications for assistance under Part B;
- receive notices with respect to programs under Title XXVI;
- every two years, collect and submit to the Secretary all audits, consistent with Office of Management and Budget circular A133, from grantees within the State, including audits regarding funds expended in accordance to Part B; and
- carry out any other duties determined appropriate by the Secretary to facilitate the coordination of programs under Title XXVI.

b.) Section 2617(b)(6)

The public health agency that is administering the grant for the State periodically convenes a meeting that includes individuals with HIV/AIDS, members of a Federally recognized Indian tribe as represented in the State, representatives of grantees under each of the Ryan White HIV/AIDS Program, providers, public agency representatives, and if applicable, entities on Part A Planning Councils, in developing the statewide coordinated statement of need (SCSN).

c.) Section 2617(b)(7)(A)

The public health agency that is administering the grant for the State engages in a public advisory planning process, including public hearings, that includes individuals with HIV/AIDS, members of a Federally recognized Indian tribe as represented in the State, representatives of grantees under each Part of Title XXVI of the Public Health Service Act, providers, public agency representatives, Part A Planning Councils (or other planning body), in developing the comprehensive plan and commenting on the implementation of such plan.

d.) *Section 2617(b)(7)(B)(i)*

HIV-related health care and support services delivered pursuant to a program established with assistance provided under Part B will be provided without regard to the ability of the individual to pay for such services and without regard to the current or past health condition of the individual living with HIV/AIDS, to the maximum extent practicable.

e.) Section 2617(b)(7)(B)(ii)

Such services will be provided in a setting that is accessible to low-income individuals living with HIV/AIDS.

f.) Section 2617(b)(7)(B)(iii)

Outreach to low-income individuals living with HIV/AIDS will be provided to inform them of the services available under Part B.

g.) Section 2617(b)(7)(B)(iv)

If using amounts provided under the grant for health insurance coverage, the State will submit a plan that assures that

- such amounts will be targeted to individuals who would not otherwise be able to afford health insurance coverage; and
- income, asset, and medical expense criteria will be established and applied by the State to identify those individuals who qualify for assistance under such a program; and that information concerning such criteria will be made available to the public.

h.) Section 2617(b)(7)(C)

The State will provide for periodic independent peer review to assess the quality and appropriateness of health and support services provided by entities that receive funds from the State under Part B.

i.) *Section 2617(b)(7)(D)*

The State will permit and cooperate with any Federal investigations undertaken regarding programs conducted under Part B.

j.) Section 2617(b)(7)(E)

The State will maintain HIV-related activities at a level that is equal to not less than the level of such expenditures by the State for the one-year period preceding the fiscal year for which the State is applying to receive a grant under Part B.

k.) Section 2617(b)(7)(F)

Grant funds are not utilized to make payments for any item or service to the extent that payment has been made, or reasonably can be expected to be made, with respect to that item or service

- under any State compensation program, insurance policy, Federal or State health benefits program, or
- 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 Services).

l.) Section 2617(b)(7)(G)

Entities receiving funds under this grant will maintain appropriate relationships with entities in the service area that constitute key points of access to the health care system for individuals with HIV/AIDS (including emergency rooms, substance abuse treatment programs, detoxification centers, adult and juvenile detention facilities, STD clinics, HIV counseling and testing sites, mental health programs, and homeless shelters) and other entities eligible to apply for Part B Early Intervention Service Grants for the purposes of facilitating early intervention for individuals newly diagnosed with HIV/AIDS and/or individuals knowledgeable of their HIV status but not in care.

m.) Section 2617(b)(8)

The State will develop a comprehensive plan describing:

- The estimated number of individuals within the State with HIV/AIDS who do not know their status:
- Activities undertaken by the State to find such individuals and to make them aware of the their status;
- The manner in which the State will provide undiagnosed individuals who are made aware of their status with access to medical treatment for their HIV/AIDS;
- Efforts to remove legal barriers, including State laws and regulations, to routine testing;
 and
- A strategy with discrete goals, a timetable, and appropriate funding, for identifying individuals with HIV/AIDS who do not know their HIV status, making such individuals aware of their HIV status, and enabling such individuals to use the health and support services. The strategy should particularly address disparities in access and services among affected subpopulations and historically underserved communities.

n.) Section 2617(c)

The State will comply with the statutory requirements regarding imposition of charges for services, for those providers who charge for services.

o.) Section 2617(d)(1)

If subject to the matching requirement detailed in Section 2617(d), non-Federal contributions will be made available (either directly or through donations from public or private entities).

6. Pursuant to Section 2618

a.) 2618(a)(2)(F)(ii)

States and Territories applying for ADAP Supplemental Treatment Drug Grants will make available non-Federal contributions (directly or through donations from public or private entities) in an amount equal to \$1 for each \$4 of Federal funds awarded, unless a waiver is obtained.

b.) 2618(b)(3)(A-D)

The State will comply with the limitations of grant funds for administration; planning and evaluation; and quality management activities. In the case of contractors (including Consortia), the State will ensure that, of the aggregate amount so allocated, the total of the expenditures by such entities for administrative expenses does not exceed 10% (without regard to whether particular entities expend more than 10% for such expenses).

c.) 2618(b)(3)(E)(i)

The State will provide for the establishment of a clinical quality management program to assess the extent to which HIV health services provided to patients under this grant are consistent with the most recent Public Health Service guidelines for treatment of HIV/AIDS and related opportunistic infections, and as applicable, to develop strategies for ensuring that such services are consistent with the guidelines for improvement in the access to, and quality of HIV health services.

d.) 2618(c)(1)

The State will ensure that 75% of Part B funds will be obligated within 120 days of the start date of the grant award, and that if such funds are not obligated, they will be made available promptly to the Secretary for reallocation.

7. Pursuant to Section 2622

The State will comply with statutory requirements regarding the timeframe for obligation and expenditure of funds, and will comply with any cancellation of unobligated funds.

8. Pursuant to Section 2681(d)

Services funded will be integrated with other such services, programs will be coordinated with other available programs (including Medicaid), and that the continuity of care and prevention services of individuals with HIV is enhanced.

9. Pursuant to Section 2684

No funds shall be used to fund AIDS programs, or to develop materials, designed to promote or encourage, directly, intravenous drug use or sexual activity, whether homosexual or heterosexual.

	Date	
Signature		
Title		
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