

**Minimum Standards of Care  
AIDS Pharmaceutical Assistance (local)**

AIDS Pharmaceutical Assistance (local) includes local pharmacy assistance programs implemented by Part A or Part B Grantees to provide HIV/AIDS medications to clients. This assistance can be funded with Part A grant funds and/or Part B base award funds. Local pharmacy assistance programs are **not** funded with ADAP earmark funding.

These minimum standards as developed by the Planning & Evaluation Committee have been adopted by the Care Council. Minimum standards of care are intended to establish measurable guidelines for providing convenient, accessible and non-discriminatory services. No standard will be applied retroactively. The Grantee is responsible for assuring that in addition to these standards, all contracts with providers have provisions requiring the protection of clients' confidentiality and their eligibility for services without regard to gender identity, age, religion, ethnicity, and sexual orientation. The Grantee shall also require providers to have clear policies and procedures for client grievances and for the assessment of client satisfaction with services. The Grantee verifies that providers meet the minimum standards established by the Care Council. The Grantee will report significant and/or consistent challenges with particular Care Council approved minimum standards to the Planning & Evaluation Committee.

STANDARD	MEASURE
1. Providers shall maintain records of quarterly quality improvement meetings including pharmacy staff as required by FAC 64B16-27.300, Standards of Pharmacy Practice. These records are considered peer review documents and are not subject to discovery in civil litigation or administrative actions.	1. Records of meetings on file as examined by Grantee
2. Patient counseling will be provided by qualified staff as needed. Counseling shall include but not be limited to, administration, drug-drug interaction, side effects, dosage, adherence education and food-drug interactions.	2. Policy on file as examined by Grantee.

Adopted: 11/06/02

Revised: 12/03/03, 11/1/06, 11/7/07, 6/3/09

**Minimum Standards of Care for  
Food Bank/Home Delivered Meals/Nutritional Supplements**

Such services include the provision of food, meals, or nutritional supplements.

**Food Bank:**

Food bank/home-delivered meals include the provision of actual food or meals. It does not include finances to purchase food or meals. The provision of essential household supplies such as hygiene items and household cleaning supplies should be included in this item. Includes vouchers to purchase food.

Such service may include the provision of actual foodstuffs and basic hygiene and toiletry items, delivered through the food pantry or by use of vouchers. The food pantry is generally used as a supplementary supplier to other sources of foodstuffs and basic hygiene and toiletry items.

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STANDARD	MEASURE
1. If a food voucher/card system is used, reimbursement procedures must be followed.	1. Fiscal Monitoring.

**Home Delivered Meals:** Not a funded service.

**Nutritional Supplements:**

On-going service/program to pay for approved nutritional supplements for persons with no other payment source. These standards are for the local nutritional supplement program which is established, operated, and funded locally by a Part A EMA to make nutritional supplements available to eligible low-income clients.

Nutritional supplements are defined as a liquid dietary supplement taken by mouth to improve nourishment, specifically by adding calories, carbohydrates, protein, fat and/or fiber in specific amounts. Providers of this service must comply with established client eligibility guidelines as adopted by the Council.

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<b>STANDARD</b>	<b>MEASURE</b>
1. Patient must meet clinical eligibility criteria. (See attached document.)	1. Documentation of inspection by provider on file. Onsite inspection by Grantee.

Adopted 09/01/99  
Revised: 6/04, 7/07, 11/7/07, 6/3/09

## Nutritional Supplements: Client Eligibility Criteria for Standard, High Calorie, Diabetic, and Renal Formulas

### Introduction:

The West Central Florida Ryan White Care Council adopted a formulary related to nutritional supplements during the March 3, 2004 meeting. Effective March 15, 2004 nutritional supplements are limited to the least expensive product for which the provider can negotiate. Product brands may fluctuate, and clients will need to be informed and educated on the formulary and the following eligibility guidelines, which have been revised as of January 19, 2006.

<b>Clinical Eligibility Criteria</b>	<b>Supportive Documentation</b>
(At least <u>one</u> of the following criteria must be met to be eligible to receive nutritional supplements)	(Supportive documentation must be submitted to pharmacy at the time the prescription is filled)
Body Mass Index (BMI) < 20	BMI calculation documented on prescription form
>/= 5% weight loss in 1 month	Percentage of weight loss over one month documented on prescription form
>/= 10% weight loss in 3 months	Percentage of weight loss over three months documented on prescription form
Phase angle of < 5.0 (male) or <4.5 (female) as measured by bioelectrical impedance testing (BIA)	BIA calculation documented on prescription form
Current evidence of illness preventing adequate food intake (especially when nutritional demands are increased)	Documentation of appropriate illness on prescription form: hypoalbuminemia, thrush (oral Candidiasis), esophageal Candidiasis, CVA, surgery, chemotherapy and/or radiation associated with cancer treatment, severe dental problems, other acute illness and/or opportunistic infection

### Unacceptable Use of Nutritional Supplements

1. Client convenience
2. Lack of finances (food banks, food stamps, financial assistance should be pursued first)

### Miscellaneous Information:

1. Exceptions to the above guidelines will be considered on a case-by-case basis and are at the discretion of the Grantee.
2. Questions and/or concerns should be addressed to the Grantee's Office (813-272-6935 or [arnolda@hillsboroughcounty.org](mailto:arnolda@hillsboroughcounty.org)).
3. Patients who have active substance abuse should be referred for additional assessment and intervention to address those issues.

Revised: 9/5/07, 6/1/11

**Minimum Standards of Care  
Health Insurance**

The provision of financial assistance for eligible individuals living with HIV to maintain a continuity of health insurance or to receive medical benefits under a health insurance program. This includes premium payments, risk pools, co-payments, and deductibles.

Since the eligible PLWH (Person Living with HIV) does not access services directly from the health insurance services provider but through a case manager, these minimum standards have been developed to reflect this unique fiscal relationship. The case management relationship ensures PLWH confidentiality and grievance procedures. These minimum standards as developed by the Planning & Evaluation Committee have been adopted by the Care Council. Minimum standards of care are intended to establish measurable guidelines for providing convenient, accessible and non-discriminatory services. No standard will be applied retroactively. The Grantee is responsible for assuring that in addition to these standards, all contracts with providers have provisions requiring the protection of clients' confidentiality and their eligibility for services without regard to gender identity, age, religion, ethnicity, and sexual orientation. The Grantee shall also require providers to have clear policies and procedures for client grievances and for the assessment of client satisfaction with services. The Grantee verifies that providers meet the minimum standards established by the Care Council. The Grantee will report significant and/or consistent challenges with particular Care Council approved minimum standards to the Planning & Evaluation Committee.

STANDARD	MEASURE
1. Upon receipt of the request for payment, the service provider will notify the case manager within three working days of the outcome of the request.	1. Written procedure and documentation on file as examined by the Grantee.
2. The provider will issue payments for approved requests within 30 working days of receipt of an invoice for payment.	2. Written procedure and documentation on file as examined by the Grantee.
3. The provider will identify error-prone case management agencies and offer individualized on-site training to up to two (2) agencies annually. The provider will also provide written updates on changes in eligibility or service benefits, procedural changes and other related information to case management agencies on a timely and regular basis.	3. Written procedure and documentation on file as examined by the Grantee.
4. The provider will establish and maintain a mechanism to assure that upon the PLWH's disenrollment, any unused portion of issued premium payments is reimbursed to the program.	4. Written procedure and documentation on file as examined by the Grantee.

Adopted: 03/05/03

Revised: 8/4/04, 3/7/07, 11/7/07, 6/3/09, 6/1/11

provided by supervisory staff.	
7. Case managers must maintain up to date documentation on all activities with, or on behalf of clients.	7. Documentation on file as examined by the Grantee.
8. Case managers must provide the client a choice of service providers if available.	8. Documentation on file as examined by the Grantee.
9. Case managers must ensure that a copy of a client's record in its entirety is sent to the receiving agency within 10 business days from receipt of original signed release.	9. Documentation on file as examined by the Grantee.

Adopted: 04/03/02

Revised: 12/03/03, 12/6/06, 11/7/07, 6/3/09

**Minimum Standards of Care  
Medical Case Management Services**

Medical Case management services (including treatment adherence) are a range of client-centered services that link clients with health care, psychosocial, and other services. The coordination and follow-up of medical treatments is a component of medical case management. These services ensure timely and coordinated access to medically appropriate levels of health and support services and continuity of care, through ongoing assessment of the client's and other key family members' needs and personal support systems. Medical case management includes the provision of treatment adherence counseling to ensure readiness for, and adherence to, complex HIV/AIDS treatments. Key activities include (1) initial assessment of service needs; (2) development of a comprehensive, individualized service plan; (3) coordination of services required to implement the plan; (4) client monitoring to assess the efficacy of the plan; and (5) periodic re-evaluation and adaptation of the plan as necessary over the life of the client. It includes client-specific advocacy and/or review of utilization of services. This includes all types of case management including face-to-face, phone contact, and any other forms of communication.

Services can take place at the client's home, clinic and/or provider office.

Case Managers should reflect competence and experience in assessing client needs and be familiar with community as well as city, county and state resources available for clients. Case management agencies are encouraged to consider the Florida Department of Health Case Management Standards and Guidelines for items not addressed in these minimum standards.

These minimum standards, as developed by the Planning & Evaluation Committee have been adopted by the Care Council. Minimum standards of care are intended to establish measurable guidelines for providing convenient, accessible and non-discriminatory services. No standard will be applied retroactively. The Grantee is responsible for assuring that in addition to these standards, all contracts with providers have provisions requiring the protection of clients' confidentiality and their eligibility for services without regard to gender identity, age, religion, ethnicity, and sexual orientation. The Grantee shall also require providers to have clear policies and procedures for client grievances and for the assessment of client satisfaction with services. The Grantee verifies that providers meet the minimum standards established by the Care Council. The Grantee will report significant and/or consistent challenges with particular Care Council approved minimum standards to the Planning & Evaluation Committee.

STANDARD	MEASURE
1. Case managers must attempt to contact clients at least once every 60 days. Contact is defined as phone, face-to-face, leaving a message or a mailing.	1. Documentation on file as examined by the Grantee.
2. Active files must have individualized service plan reviewed by client and case manager semi-annually.	2. Documentation on file as examined by the Grantee.
3. Active files must reflect a face-to-face visit conducted on a semi-annual basis.	3. Documentation on file as examined by the Grantee.
4. Clients will have access to a case manager during normal business hours for the agency.	4. Written policy exists as examined by the Grantee.
5. Case managers will work collaboratively with client and medical/psychosocial providers to promote adherence to treatment.	5. Written policy exists as examined by the Grantee.
6. Case managers and direct supervisors must attend training sessions as offered by the Grantee. Additional training must be coordinated and/or	6. Documentation on file as examined by the Grantee.

**Minimum Standards of Care  
Medical Transportation Services**

Medical transportation services include conveyance services provided, directly or through voucher, to a client so that he or she may access health care services.

Such services may include taxi, tokens, bus passes, vouchers or agency vehicle transportation.

Transportation services include:

1. Supporting and expanding transportation services that enhance the ability of people with HIV infection to obtain health services.
2. Agencies that coordinate transportation services.
3. Emergency transportation to assure timely access to needed services for low income and/or physically disabled residents of the service area who have HIV-related illnesses or AIDS.
4. Consideration for HIV-disabled clients needing assistance in navigating stairs and in getting in and out of vehicles and folding wheelchairs.

These minimum standards of care are intended to describe transportation services; to establish measurable guidelines for providing the most convenient, accessible and non-discriminatory transportation; and to ensure that there is ongoing and consistent programmatic oversight of such services.

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STANDARD	MEASURE
1. Providers must have appropriate licensure and insurance coverage.	1. Written procedures and/or documentation on file as examined by the Grantee.

Adopted: 09/01/99

Revised: 12/03/03, 9/5/07, 6/3/09

**Minimum Standards of Care  
Mental Health Services**

Such services may include psychological and psychiatric treatment and counseling services, offered to individuals with a diagnosed mental illness, conducted in a group or individual setting, and provided by a mental health professional licensed or authorized within the State to render such services. This typically includes psychiatrists, psychologists, and licensed clinical social workers.

Mental health care for persons with HIV disease should reflect competence and experience in evaluation, formulation, and diagnosis as well as in evidence-based therapeutics, using contemporary practice guidelines where available.

These minimum standards as developed by the Planning & Evaluation Committee have been adopted by the Care Council. Minimum standards of care are intended to establish measurable guidelines for providing convenient, accessible and non-discriminatory services. No standard will be applied retroactively. The Grantee is responsible for assuring that in addition to these standards, all contracts with providers have provisions requiring the protection of clients' confidentiality and their eligibility for services without regard to gender identity, age, religion, ethnicity, and sexual orientation. The Grantee shall also require providers to have clear policies and procedures for client grievances and for the assessment of client satisfaction with services. The Grantee verifies that providers meet the minimum standards established by the Care Council. The Grantee will report significant and/or consistent challenges with particular Care Council approved minimum standards to the Planning & Evaluation Committee.

<b>STANDARD</b>	<b>MEASURE</b>
1. License-eligible staff delivering mental health services will receive direct, professional supervision by a licensed mental health provider of the type of care they are providing to individual patients/clients.	1. Written procedures and/or documentation on file as examined by Grantee.
2. The provider must provide mechanisms for urgent care evaluation and triage.	2. Written statement of policy and procedures on file as examined by the Grantee.
3. The provider will establish procedures for continuity of mental health/psychiatric care to their patients/clients in all settings in which they may need care.	3. Written statement of procedures on file as examined by the Grantee.
4. The provider will provide referrals for continuity of substance abuse care to their patients/clients as needed.	4. Documentation of referrals on file as reviewed by the Grantee.
5. The provider will develop and maintain client specific collaboration with primary medical care service providers.	5. Written statement of procedures on file as examined by the Grantee.
6. The provider will maintain an initial mental health assessment of each participating client that consists of: presenting problem(s), psychosocial history, mental status examination, differential diagnoses, treatment recommendations and signature of the licensed or license-eligible professional conducting the assessment.	6. Written documentation on file as examined by the Grantee.

Adopted: 06/07/00

Revised: 12/03/03, 3/7/07, 11/7/07, 6/3/09

**Minimum Standards of Care  
Oral Health**

Oral health care includes diagnostic, preventive, and therapeutic services provided by general dental practitioners, dental specialists, dental hygienists and auxiliaries, and other trained primary care providers.

The following minimum standards are in place to describe and establish measurable guidelines in order to offer clients the most convenient, accessible and non-discriminatory oral services.

These minimum standards as developed by the Planning & Evaluation Committee have been adopted by the Care Council. The Grantee is responsible for assuring that in addition to these standards, all contracts with providers have provisions requiring the protection of clients' confidentiality and their eligibility for services without regard to gender identity, age, religion, ethnicity, and sexual orientation. The Grantee shall also require providers to have clear policies and procedures for client grievances and for the assessment of client satisfaction with services. The Grantee verifies that providers meet the minimum standards established by the Care Council. The Grantee will report significant and/or consistent challenges with particular minimum standards to the Planning & Evaluation Committee.

<b>STANDARD</b>	<b>MEASURE</b>
1. Provider shall follow nationally accepted treatment guidelines.	1. Written documentation on file as examined by the Grantee.
2. Dental care shall have the primary focus of alleviating discomfort, keeping teeth and gums healthy, preventing infection and maintaining the ability to eat nutritional foods with the goal of optimizing overall health. Procedures that are for cosmetic purposes only will not be covered.  Treatment must be completed within a reasonable and customary time frame.	2. Written documentation on file as examined by the Grantee.
3. Normal treatment plan shall, at a minimum, include a thorough dental examination, x-rays and cleaning. Follow-up services shall include education, preventative home care instructions, and any additional services necessary to maintain dental health.	3. Written documentation on file as examined by the Grantee.
4. Provider shall have a policy in place to address dental emergencies.	4. Written documentation on file as examined by the Grantee.

Adopted: 05/01/02

Revised: 12/03/03, 12/6/06, 11/7/07, 6/3/09

**Minimum Standards of Care  
Outpatient/Ambulatory Medical Care**

Such services may include provision of professional diagnostic and therapeutic services rendered by a physician, physician's assistant, clinical nurse specialist or nurse practitioner in an outpatient setting. Settings include clinics, medical offices, and mobile vans where clients generally do not stay overnight. Emergency room services are not outpatient settings. This includes diagnostic testing, early intervention and risk assessment, preventive care and screening, practitioner examination, medical history taking, diagnosis and treatment of common physical and mental conditions, prescribing and managing medication therapy, care of minor injuries, education and counseling on health and nutritional issues, minor surgery and assisting at surgery, well-baby care, continuing care and management of chronic conditions, and referral to and provision of specialty care (includes all medical subspecialties). Primary medical care for the treatment of HIV infection included the provision of specialty care that is consistent with Public Health Service guidelines. Such care must include access to antiretrovirals and other drug therapies, including prophylaxis and treatment of opportunistic infections and combination antiretroviral therapies.

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<b>STANDARD</b>	<b>MEASURE</b>
1. Providers shall follow nationally accepted treatment guidelines, i.e., Centers for Disease Control (CDC), Infectious Disease Society of America (IDSA), or Department of Health and Human Services (DHHS).	1. Written procedures and/or documentation on file as examined by the Grantee.

Adopted: 07/11/01

Revised: 12/03/03, 3/7/07, 11/7/07, 6/3/09

**Minimum Standards of Care  
Peer Support Services**

Peer Support services are provided by and for individuals who are living with HIV/AIDS and help clients empower themselves and develop effective strategies for living healthy lives. Through one-on-one interactions and in small groups, these services support clients' engagement in health care and provide opportunities for education, skill-building, and emotional support in a respectful environment. With harm reduction as a foundation, peer support helps clients access health and benefit information, develop coping skills, reduce feelings of social isolation, and increase self determination and self-advocacy, helping improve quality of life for both participants and peer leaders.

The overall objectives of the Peer Support standards of care are to provide opportunities for sharing information and resources, with the goal of promoting self-advocacy; and facilitate the development of social and emotional support networks by and for people living with HIV/AIDS.

The objectives of the competencies standards for Peer Support are to:

- provide clients with the highest quality services through experienced and trained staff;
- ensure that peer support providers are able to provide culturally and linguistically appropriate services; and
- ensure that the provision of peer support service is documented appropriately.

A peer support client may disclose information within support groups or in one-on-one sessions that the individual has chosen not to share with a case manager and/or with another provider in the agency. When documenting peer support service provision, peer support staff should be aware of this and be sensitive to how and what information is recorded in the client's file. Documentation should identify general topic areas discussed during the session (e.g., disclosure, adherence, or risk reduction), but not an individual participant's comments, feedback, or thoughts.

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STANDARD	MEASURE
1. One-on-one peer support services are provided by people living with HIV/AIDS.	1. Peer support staff self-identify as people living with HIV/AIDS.
2. Peer support groups are facilitated or co-facilitated by people living with HIV/AIDS.	2. Peer support staff self-identify as people living with HIV/AIDS.
3. Provision of one-on-one peer support services is documented in client file, including date, duration, and general topics covered.	3. Documentation in client file.
4. Provisions of support group services is documented, including date, name of group, number of participants, and general topics covered; client participation in support groups is documented in client file.	4. Documentation of support groups on file at agency; documentation of support group attendance in client file.

<p>5. Peer support staff (paid, stipend and volunteer) will receive at least one hour of administrative supervision per month and one hour of clinical supervision per month. Administrative and clinical supervision should be conducted by separate individuals.</p>	<p>5. Signed documentation on file indicating dates of one-on-one and/or group supervision, types of supervision (clinical or administrative), and name of supervisor.</p>
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Adopted: 9/2/09

**Minimum Standards of Care  
Substance Abuse Services Outpatient**

Substance abuse services outpatient is the provision of medical or other treatment and/or counseling to address substance abuse problems (i.e., alcohol and/or legal and illegal drugs) in an outpatient setting, rendered by a physician or under the supervision of a physician, or by other qualified personnel.

The following minimum standards are in place to describe and establish measurable guidelines in order to offer clients the most convenient, accessible and non-discriminatory substance abuse treatment and counseling services.

These minimum standards as developed by the Planning & Evaluation Committee have been adopted by the Care Council. Minimum standards of care are intended to establish measurable guidelines for providing convenient, accessible and non-discriminatory services. No standard will be applied retroactively. The Grantee is responsible for assuring that in addition to these standards, all contracts with providers have provisions requiring the protection of clients' confidentiality and their eligibility for services without regard to gender identity, age, religion, ethnicity, and sexual orientation. The Grantee shall also require providers to have clear policies and procedures for client grievances and for the assessment of client satisfaction with services. The Grantee verifies that providers meet the minimum standards established by the Care Council. The Grantee will report significant and/or consistent challenges with particular Care Council approved minimum standards to the Planning & Evaluation Committee.

<b>STANDARD</b>	<b>MEASURE</b>
1. The provider will provide referrals for continuity of mental health, and/or psychiatric care to their patients/clients as needed.	1. Documentation of referrals on file as reviewed by the Grantee.
2. Treatment incorporates an initial assessment of client that consists of medical history and a psychosocial history with treatment recommendations.	2. Written procedures and/or documentation on file as examined by the Grantee.
3. Outpatient treatment incorporates continuum of care strategies to provide a safe environment for a client to return to after detox or other initial intervention.	3. Written statement of policy and procedures on file as examined by the Grantee.
4. The need for mental health treatment can not preclude a client from receiving substance abuse counseling/treatment.	4. Written statement of this policy and procedures on file as examined by the Grantee.
5. Qualified professionals who possess current professional licensure or who are authorized by the state will participate in the care and treatment of clients as required by law.	5. Written documentation on file as examined by the Grantee.

Adopted: 06/07/00

Revised: 12/03/03, 3/7/07, 11/7/07, 6/3/09

**Minimum Standards of Care  
Treatment Adherence Counseling**

The provision of counseling or special programs to ensure readiness for and adherence to complex HIV/AIDS treatments by non-medical personnel outside of the medical case management and clinical setting.

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STANDARD	MEASURE
1. Providers of this service have specific experience in caring for HIV infected clients or receive appropriate training including AIDS 101 level training within first 90 days of hire or as soon as training is available but not to exceed six months.	1. Written procedures and/or documentation on file as examined by the Grantee.
2. Providers of this service will receive a minimum of four hours of HIV/AIDS updates annually.	2. Documentation on file as examined by the Grantee.
3. Providers of this service will receive a minimum of four hours of training on treatment adherence issues annually.	3. Documentation on file as examined by the Grantee.
4. Providers of this service will receive a minimum of four hours of training on psychosocial issues annually.	4. Documentation on file as examined by the Grantee.

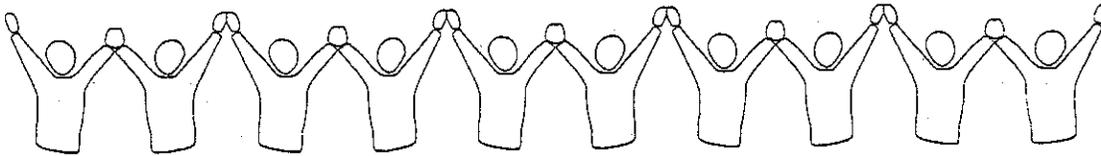
Adopted: 05/07/03

Revised: 12/03/03, 3/7/07, 11/7/07, 6/3/09, 6/1/11

# 1

## Section IV

# Title I and II Policies



(Note: All these policies were reviewed and reissued on June 1, 2000.)

**DSS Program Policy Guidance No. 1**  
**Eligible Individuals and Services for Individuals Not Infected with HIV**

Formerly Policy No. 97-01, First Issued: February 1, 1997

**DSS Program Policy Guidance No. 2**  
**Allowable Uses of Funds for Discretely Defined Categories of Services**

Formerly Policy No. 97-02, First Issued: February 1, 1997

See the HRSA/HAB Web Site at  
<http://www.hab.hrsa.gov>  
for the latest policies.

**DSS Program Policy Guidance No. 4**  
**Clarification of Legislative Language Regarding Contracting with For Profit Entities**

Formerly a "Dear Colleague Letter" First Issued March 6, 1997 to  
All Title I and II CARE Act Grantees

**DSS Program Policy Guidance No. 5**  
**AIDS Drug Assistance Program: Eligibility and Formulary Parity and Uses of Funds**

Formerly Policy No. 97-04, First Issued: April 2, 1997

**DSS Program Policy Guidance No. 6**  
**Clarification of DSS/HAB Guidance Regarding AIDS Drug Assistance Program: Administration, Eligibility and Cost-Savings**

Formerly a "Dear Colleague Letter" First Issued October 17, 1997 to  
All Title I and II CARE Act Grantees and Reissued in July, 1999

**DSS Program Policy Guidance No. 7**  
**Residence of Planning Council Members and Consortia Members**

Formerly Policy No. 98-01, First Issued: February 1, 1998

**DSS Program Policy Guidance No. 8**  
**Staff Training**

Formerly Policy No. 98-02, First Issued: February 1, 1998

**DSS Program Policy Guidance No. 9**  
**Guidelines for Reimbursement of Individuals Serving on a Ryan White Title I Planning Council and/or Title II Consortium**

Formerly a Program Guidelines Memorandum. Issued in January of 1997 and 2000



## ***DSS Program Policy Guidance No. 1***

### ***Eligible Individuals and Services for Individuals Not Infected with HIV***

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June 1, 2000 (Formerly Policy No. 97-01, First Issued: February 1, 1997)

The principal intent of Titles I and II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act is the provision of services to persons infected with the Human Immunodeficiency Virus (HIV), including those whose illness has progressed to the point of clinically defined Acquired Immune Deficiency Syndrome (AIDS). Grantees, planning councils, or consortia when setting and implementing priorities for allocation of funds may optionally define eligibility for certain services more precisely, but they may not broaden the definition of who is eligible for services. Grantees are expected to establish and monitor procedures to ensure that all providers verify and document client eligibility. This policy clarifies eligibility for services provided to individuals. It does not define eligibility for services such as outreach, which are directed to groups of people or which seek to identify those who may become eligible for individual services.

Non-infected individuals may be appropriate candidates for CARE Act services in limited situations, but these services must always have at least indirect benefit to a person with HIV infection. Funds awarded under Title I or Title II of the Ryan White CARE Act may be used for services to individuals not infected with HIV only in the circumstances described below.

- a. The service has as its primary purpose enabling the non-infected individual to participate in the care of someone with HIV disease or AIDS. Examples include caregiver training for in-home medical or support service; and support groups, counseling, and practical support that assist with the stresses of caring for someone with HIV.
- b. The service directly enables an infected individual to receive needed medical or support services by removing an identified barrier to care. Examples include payment of premiums for a family health insurance policy to ensure continuity of insurance coverage for a low-income HIV+ family member, or child care for non-infected children while an infected parent secures medical care or support services.
- c. The service promotes family stability for coping with the unique challenges posed by HIV/AIDS. Examples include permanency planning for infected and uninfected children of HIV parents, mental health services which focus on equipping uninfected family members and caregivers to manage the stress and loss associated with HIV, and short-term post-death bereavement counseling. Services to non-infected clients that meet this criterion may not continue subsequent to the death of the HIV-infected family member beyond the period of short-term bereavement counseling and/or permanency planning for uninfected children.



## ***DSS Program Policy Guidance No. 2*** ***Allowable Uses of Funds for Discretely Defined Categories of Services***

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June 1, 2000 (Formerly Policy No. 97-02, First Issued: February 1, 1997)

This policy statement concerns the use of funds awarded under Title I or Title II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act for the provision of services to eligible individuals. Guidance regarding allowable uses of funds awarded under other Titles of the CARE Act must be obtained from the Federal program offices responsible for their administration.

### ***Existing Federal Policy on Allowable Uses of Funds***

The Office of Management and Budget (OMB) has developed cost principles and uniform administrative requirements for all organization types (State and Local governments, nonprofit and educational institutions, and hospitals) in all Federally funded programs. These are known as OMB Circulars, and are management directives to Federal agencies, which apply to all recipients. Fiscal officers for all grantees should be thoroughly familiar with all relevant Circulars. The grantee may be more strict in the administration of grant funds, but may not be more lenient. Grantees must further apply the requirements to sub-recipients, as noted in each OMB Circular.

The cost principles permit an organization to establish and use its own accounting system to determine costs, provided it is based on sound accounting principles, consistently applied to all organization activities regardless of the source of funds supporting those activities. Recipients of Federal grant funds are expected to exercise the same degree of prudence in the expenditure of Federal funds as they use in expending their own funds.

### ***Division of Service Systems Policies***

DSS has developed program guidance policies, which incorporate both OMB directives and program-specific requirements. Grantees, planning groups, and others are advised that independent auditors and auditors from the Office of the Inspector General of the Department of Health and Human Services may assess and publicly report the extent to which a grant is being administered in a manner consistent with program policies such as these. Grantees can expect oversight through DSS monitoring and review of budgets and contractors. DSS is able to provide technical assistance to grantees, planning councils, and consortia where assistance with policy compliance is needed.

Grantees are reminded that it is their responsibility to be fully cognizant of limitations on uses of funds as outlined in the Public Health Service (PHS) Grants Policy Statement (copies of which have been previously provided to every grantee; additional copies are available from the Grants Management Branch at 301-443-2280). In the case of services being supported in violation of an existing Federal policy (e.g., payment of home mortgages), the use of CARE Act funds must be terminated immediately and grantees may be required to return already spent funds to the Federal government.



### ***Further Guidance on Allowable Uses of CARE Act Funds***

The CARE Act stipulates that "funds received...will not be utilized to make payments for any item or service to the extent that payment has been made, or can reasonably be expected to be made..." by sources other than Ryan White funds. At the individual client level, this means that grantees and/or their subcontractors are expected to make reasonable efforts to secure other funding instead of CARE Act funds whenever possible. In support of this intent, it is an appropriate use of CARE Act funds to provide case management or other services which have as a central function ensuring that eligibility for other funding sources (*e.g.*, Medicaid or Medicare, other local or State-funded HIV/AIDS programs, or private-sector funding) is aggressively and consistently pursued.

In every instance, DSS expects that no service will be supported with CARE Act Title I funds unless it (1) falls within the legislatively defined range of services, and (2) has been selected as a local priority by the HIV Health Services Planning Council. In the case of Title II funds, services must fall within the legislatively defined range of services and, in the case of allocations decisions made by a State or by a local or regional consortia, services must meet documented needs and contribute to the establishment of a continuum of care.

CARE Act funds are intended to support only the HIV-related needs of eligible individuals. Grantees, planning councils, and consortia should be able to make an explicit connection between any service supported with CARE Act funds and the intended recipient's HIV status, or care-giving relationship to a person with HIV/AIDS.

In no case may CARE Act funds be used to make direct payments of cash to recipients of services. Where direct provision of the service is not possible or effective, vouchers or similar programs, which may only be exchanged for a specific service or commodity (*e.g.*, food or transportation), must be used to meet the need for such services. Grantees are advised to administer voucher programs in a manner, which assures that vouchers cannot be readily converted to cash.

This general policy statement has been effective since February 1, 1997 and applies to all services provided to individuals, including those for which separate clarifying statements have been developed (see following pages). Any subsequent statements on other services will be individually dated, but will also be subject to all provisions on these pages. For clarification, or a copy of the most recent list of services governed by this policy, contact the Office of the Director, Division of Service Systems, at 301-443-6745.

#### **2.1 Benefits and Entitlement Counseling for Eligible Individuals**

Funds awarded under Title I or II of the Ryan White CARE Act may be used for programs which assist CARE Act-eligible clients to secure access to other public and private programs for which they may be eligible.

#### **2.2 Child Care for Eligible Individuals**

Funds awarded under Title I or II of the CARE Act may be used for child care in these instances:

- a. To support a licensed or registered child care provider for intermittent or continuing care of HIV+ children



- b. To enable an infected adult or child to secure needed medical or support services through:
- (1) support to a licensed or registered provider of child care to infected or non-infected children, and/or
  - (2) support for informal child care provided by a neighbor, family member, or other person (with the understanding that existing Federal restrictions prohibit giving cash to individuals to pay for these services).

In those cases where funds are allocated for child care of the type described under b(2) above, such allocations should be limited and carefully monitored to assure compliance with the prohibition on direct payments to eligible individuals. Such arrangements may also raise liability issues for the funding source, which should be carefully weighed in the decision-making process.

### 2.3 Clinical Trials for Eligible Individuals

#### *Definitions:*

Clinical trials are Food and Drug Administration (FDA)-approved controlled experiments of investigational agents or treatments, with costs typically shared by pharmaceutical manufacturers and government. The FDA initiated expanded access programs in 1989 as a mechanism for making promising new treatments available for those with life-threatening diseases and no other treatment options. Compassionate use programs are a product of pharmaceutical companies which make investigational new pharmaceuticals available for the same group. Pharmaceutical companies sponsor both expanded access and compassionate use programs.

Funds awarded under Title I or II of the CARE Act may not be used to support the costs of operating clinical trials of investigational agents or treatments (to include administrative management or medical monitoring of patients).

Funds may be used to support clinical costs (exclusive of pharmaceuticals) of expanded access or compassionate use programs where efficacy data exist and where the FDA has authorized such expanded use. Funds may also be used to support participation in clinical trials and in expanded access and compassionate use programs.

### 2.4 Complementary Therapies for Eligible Individuals

Funds awarded under Title I or II of the CARE Act may be used to support specific services that are generally referred to as complementary therapies upon written referral by the client's primary health care provider (or substance abuse counselor in the case of referrals for acupuncture associated with substance abuse treatment). All complementary therapies are to be provided by certified or licensed practitioners and/or programs wherever State certification or licensure exists.

### 2.5 Developmental Services for HIV+ Children

Funds awarded under Title I or II of the CARE Act may be used to provide clinician-prescribed developmental services for HIV+ infants/children when such services are not covered by specific State and Federal legislation that mandates health care coverage for all children with developmental disabilities.



## 2.6 Emergency Assistance for Eligible Individuals

Funds awarded under Title I or II of the CARE Act may be used to support emergency assistance in one of two ways. Planning councils, Title II grantees, or consortia – in making allocations to the service categories of transportation, food, housing, or medication assistance – may specify that some portion of those allocations is to be used for emergency assistance. Alternatively, planning councils or consortia may establish a separate category of emergency assistance in their priority-setting processes. In such cases, however, the decision makers must deliberately and clearly delineate and/or monitor what part of the overall allocation to emergency assistance is obligated to transportation, food, housing (to include essential utilities), or medication assistance. Careful monitoring of expenditures within a category of “emergency assistance” is necessary to assure that planned amounts for specific services are being implemented, and to indicate when reallocations may be necessary.

Grantees and planning councils/consortia are to develop standard limitations on the provision of CARE Act-funded emergency assistance to eligible individuals/households and mandate their consistent application by all contractors. It is expected that all other sources of funding in the community for emergency assistance will be effectively utilized and that any allocation of CARE Act funds to these purposes will be for limited amounts, limited use, and limited periods of time.

## 2.7 Funeral and Burial Expenses

Funds awarded under Title I or II of the CARE Act may not be used for funeral, burial, cremation, or related expenses.

## – 2.8 Maintenance of Privately Owned Vehicles for Eligible Individuals

Funds awarded under Title I or II of the CARE Act may not be used for direct maintenance expense (e.g., tires, repairs) of a privately owned vehicle or any other costs associated with a vehicle, such as lease or loan payments, insurance, or license and registration fees. This restriction does not apply to vehicles operated by organizations for program purposes. Mileage reimbursement that enables individuals to travel to needed medical or other support services may be supported with Title I or II funds, but should not in any case exceed the established rates for Federal programs. Federal Joint Travel Regulations provide further guidance on this subject.

### *Additional Allowable Uses of Funds for Discretely Defined Categories of Services*

The following policy guidance additions (No. 2.9 through No. 2.23) were issued on February 1, 1998 as a supplement to this policy notice, as they also concern the use of funds awarded under Title I or II of the CARE Act for the provision of services to eligible individuals. Program policy guidance regarding allowable uses of funds awarded under other Titles of the CARE Act must be secured from the respective Federal program offices responsible for their administration.

## 2.9 Legal Services for Eligible Individuals

Funds awarded under Title I or II of the Ryan White CARE Act should not be used for any criminal defense, or for class action suits unrelated to access to services eligible for funding under the CARE Act. CARE Act funds may be used for certain legal services directly necessitated by an individual's HIV/AIDS serostatus. These include:



- a. Preparation of Powers of Attorney, Do Not Resuscitate Orders, wills, trusts, etc.
- b. Bankruptcy proceedings, and
- c. Interventions necessary to ensure access to benefits for which an individual may be eligible, including discrimination or breach of confidentiality litigation as it relates to services eligible for funding under the CARE Act.

### **2.10 Pastoral Counseling for Eligible Individuals**

Funds awarded under Title I or II of the Ryan White CARE Act may be used for pastoral counseling services only if they are provided by institutional pastoral care programs (*e.g.*, components of AIDS interfaith networks; separately incorporated pastoral care and counseling centers; or components of a larger service, such as home care or hospice). Programs are to be licensed or accredited wherever such licensure or accreditation is either required or available. Pastoral counseling services funded under Title I or II of the CARE Act are to be available to all individuals eligible for CARE Act services regardless of their religious or denominational affiliation.

### **2.11 Permanency Planning for Eligible Individuals**

Funds awarded under Title I or II of the Ryan White CARE Act may be used for permanency planning for an individual or family where the responsible adult is expected to pre-decease a dependent (usually a minor child) due to HIV/AIDS. Permanency planning includes the provision of social service counseling or legal counsel regarding (a) the drafting of wills or delegating powers of attorney, and (b) preparation for custody options for legal dependents including standby guardianship, joint custody, or adoption.

### **2.12 Property Taxes**

Funds awarded under Title I or II of the CARE Act may not be used to pay local or State personal property taxes (for residential property, private automobiles, or any other personal property against which taxes may be levied).

### **2.13 Purchase of Non-Food Products for Use by Eligible Individuals**

Funds awarded under Title I or II of the Ryan White CARE Act may be used to purchase non-food products, such as personal hygiene products, to be provided to eligible individuals through food and commodity distribution programs. CARE Act funds may not be used for household appliances, pet foods or products.

### **2.14 Recreational and Social Activities for Eligible Individuals**

Funds awarded under Title I or II of the CARE Act may be used to support program expenses of adult and child day or respite care centers, and drop-in centers in primary or satellite facilities.

Funds may not be used for off-premise social/recreational activities.

### **2.15 Substance Abuse Treatment for Eligible Individuals**

**Outpatient Substance Abuse Treatment Services:** Funds awarded under Title I or II of the Ryan White CARE Act may be used for outpatient drug or alcohol substance abuse treatment, including



expanded HIV-specific capacity of programs if timely access to treatment and counseling is not available. Such services should be limited to:

- (1) The pre-treatment program of recovery readiness
  - (2) Harm reduction
  - (3) Mental health counseling to reduce depression, anxiety, and other disorders associated with substance abuse
  - (4) Outpatient drug-free treatment and counseling
  - (5) Methadone treatment
  - (6) Neuro-psychiatric pharmaceuticals, and
  - (7) Relapse prevention.
- a. **Syringe Exchange:** In accordance with Sec. 2678 and Sec. 422 of the CARE Act, as amended, funds may not be used for syringe exchange programs.
  - b. **Residential Substance Abuse Treatment Services:** CARE Act funds may be used for residential substance abuse treatment programs, including expanded HIV-specific capacity of programs if timely access to treatment is not available. The following limitations apply to use of CARE Act funds for residential services:
    - (1) Because of the CARE Act limitations on inpatient hospital care [see Sec. 2604(b)(1)(B) and Sec. 2613(a)(2)(A)(B)], CARE Act funds may not be used for inpatient detoxification in a hospital setting.
    - (2) However, if detoxification is offered in a separate licensed residential setting (including a separately-licensed detoxification facility within the walls of a hospital), CARE Act funds may be used for this activity.
    - (3) If the residential treatment service is in a facility that primarily provides inpatient medical or psychiatric care, the component providing the drug and/or alcohol treatment must be separately licensed for that purpose.

### **2.16 Vision Care for Eligible Individuals**

Funds awarded under Title I or II of the Ryan White CARE Act may be used for optometric or ophthalmic services and purchase of corrective prescription eye wear that is necessitated by HIV infection.

### **2.17 Vocational, Employment, and Employment-Readiness Services**

Funds awarded under Title I or II of the CARE Act may not be used to support employment, vocational rehabilitation, or employment-readiness services.

### **2.18 Clothing**

Funds awarded under Title I or II of the CARE Act may not be used for purchase of clothing.



### **2.19 Day or Respite Care for Eligible Individuals**

Funds awarded under Title I or II of the CARE Act may be used for day care or respite care in the following instances:

- a. To support a licensed or registered provider of continuing day care for HIV+ adults or children
- b. To enable an infected adult or child to secure needed medical or support services through: (1) support to a licensed or registered provider for day care for an infected adult; or (2) support for informal adult day care provided by a neighbor, family member, or other person (with the understanding that existing Federal restrictions prohibit giving cash to an eligible individual to pay the neighbor or family member for this service), and/or
- c. To provide periodic and time-limited respite for the caregiver(s) of infected adults or children which is necessary to support the caregiver in continuing those responsibilities.

In those cases where funds are allocated for care of the type described under b(2) above, such allocations should be limited and carefully monitored to assure compliance with the prohibition on direct payments to eligible individuals. Such arrangements may also raise liability issues for the funding source, which should be carefully weighed in the decision-making process.

### **2.20 Health Insurance Co-payments and Deductibles for Eligible Individuals**

Funds awarded under Title I or II of the CARE Act may be used to pay for public or private health insurance co-payments and deductibles for low-income individuals only. Consistent with the CARE Act, "low income" is to be locally defined.

### **2.21 Hospice Care for Eligible Individuals**

Funds awarded under Titles I or II of the CARE Act may be used to pay for hospice care by providers licensed in the State in which services are delivered. Hospice services may be provided in a home or other residential setting, including a non-acute care section of a hospital that has been designated and staffed to provide hospice care to terminal patients. A physician must certify that a patient is terminal, defined under Medicaid hospice regulations as having a life expectancy of 6 months or less. Counseling services provided in the context of hospice care must be consistent with the definition of mental health counseling in the DSS Glossary of HIV Related Services. Palliative therapies must be consistent with those covered under the State Medicaid program.

### **2.22 Transportation for Eligible Individuals**

Funds awarded under Titles I or II of the CARE Act may be used to provide transportation services for an eligible individual to access HIV-related medical or support services.

Transportation should be provided through:

- a. A contract(s) with a provider(s) of such services
- b. Voucher or token systems
- c. Use of volunteer drivers (through programs with insurance and other liability issues specifically addressed), or



- d. Purchase or lease of organizational vehicles for client transportation programs. (See also Policy No. 2.8 above, Maintenance of Privately Owned Vehicles, for further information.)

### **2.23 Water Filters for Eligible Individuals**

Funds awarded under Title I or II of the CARE Act may be used to purchase water filtration/purification devices (either portable filter/pitcher combinations or filters attached to a single water tap) in communities/areas where recurrent problems with water purity exist. Such devices (including their replacement filter cartridges) purchased with CARE Act funds must meet National Sanitation Foundation standards for absolute cyst removal of particles less than one micron. This policy does not permit installation of permanent systems for filtration of all water entering a private residence.



## ***DSS Program Policy Guidance No. 4 Clarification of Legislative Language Regarding Contracting with For Profit Entities***

June 1, 2000 (Formerly a "Dear Colleague Letter" First Issued March 6, 1997 to All Title I and II CARE Act Grantees)

The CARE Act Amendments of 1996 provide for contracting with for-profit entities under certain limited circumstances. Specifically, the Amendments allow Title I and Title II funds to be used to "provide direct financial assistance" through contracts with "private for-profit entities if such entities are the only available provider of quality HIV care in the area." [SEC 2604(b)(2)(A); Section 2631(a)(1)]

This constitutes a formal clarification of legislative language by the Division of Service Systems, HIV/AIDS Bureau in consultation with the Grants Management Officer within the Bureau and with the Office of General Counsel of the Department of Health and Human Services, and is effective immediately.

Based on limitations contained in the CARE Act Amendments, grantees and other contracting agents must observe the following conditions in developing and implementing Requests for Proposals (RFPs) and other local procurement procedures.

- a. "Only available provider" means that there are no nonprofit organizations able and willing to provide quality HIV service and that the grantee or other contracting agent is able to document this fact.
- b. "Quality HIV care" must be defined in a reasonable manner. Quality care may not be defined exclusively as a numerical score in an RFP process (i.e., all funds go to the highest scored proposal regardless of corporate status). An entity should only be deemed incapable of providing quality HIV care if written documentation of substantive quality of care deficiencies exists.
- c. Cost of service may not be the sole determinant in vendor selection processes whether internal or external (i.e., all funds go to the lowest bidder regardless of corporate status). However, grantees should not overlook cost considerations in developing and implementing RFP processes and are in fact expected to seek maximum productivity for each CARE Act dollar within the contracting limits of the legislation.
- d. Grantees must prohibit nonprofit contractors from serving as conduits who pass on their awards to for-profit corporations and may find it necessary to monitor membership of corporate boards in enforcing this prohibition. Federal Grants Management Policy is clear that the eligibility requirements that apply to first-level entities cannot be evaded by passing awards through to second- or subsequent-level entities that could not have received awards in the original competition.
- e. Proof of nonprofit status (local and/or State registration and approved articles of incorporation) should be required of all applicants claiming such status. Grantees are also strongly advised to require copies of letters of determination from the Internal Revenue Service.



- f. A grantee or other contracting agent may not contract with both nonprofit and for-profit entities for the same service in the same geographic area unless qualified nonprofit providers do not have the capacity to meet identified need. Any nonprofit provider able to provide quality HIV care is given legislative preference over for-profit entities seeking to serve the same area.

No new contracts may be executed after the date of issuing this notice (3/7/97) that violate these conditions on contracts with private for-profit organizations. Any contracts in place using funds awarded in fiscal year 1997 or later are in violation of this program policy guidance notice. Failure to comply with this requirement may result in required return of funds to the Federal government, suspension of grant awards, or other remedies deemed necessary.

Grantees and other contracting agents are encouraged to include in all RFP materials disclaimers which advise private for-profit organizations of the significant legislative barriers to their receiving contracts. Alternatively, and if local/State regulations and laws allow it, grantees may seek to define "qualified applicants" at the beginning of the process in a way which would save private for-profit organizations the time and effort needed to develop applications which could not be considered for funding.

Any questions about this program policy should be directed to the grantee's Project Officer.



## ***DSS Program Policy Guidance No. 5 AIDS Drug Assistance Program: Eligibility and Formulary Parity and Uses of Funds***

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June 1, 2000 (Formerly Policy No. 97-04, First Issued: April 2, 1997)

Eligibility criteria for enrollment of persons living with HIV disease in a CARE Act-funded State AIDS Drug Assistance Program (ADAP), and treatments available on the approved ADAP formulary to enrolled individuals, must be equally and consistently applied across the State. If a State chooses to operate its ADAP through contracts to consortia or other entities, it must develop and implement procedures to monitor compliance with the requirement of consistent application of eligibility standards and formulary access.

### ***Use of Federal Funds in State AIDS Drug Assistance Programs***

Funds awarded under Title I or Title II of the CARE Act that are allocated for use by State AIDS Drug Assistance Programs (ADAPs) for therapeutics that treat Human Immunodeficiency Virus (HIV) disease or prevent the serious deterioration of health arising from HIV disease, and the ancillary devices (e.g., IV tubing, nebulizers) needed to administer these therapeutics, may only be used to purchase FDA-approved medications and the devices needed to administer them.

CARE Act funds that are allocated to ADAPs may not be used for laboratory or other diagnostic and monitoring tests and procedures such as radiographs, blood counts, or viral load testing. These services may, however, be paid for with CARE Act funds allocated by States, consortia, or planning councils to primary care or related categories of service.

Neither of the preceding limitations precludes use of CARE Act funds for ADAP administration costs within the legislative limits on such expenditures.



## ***DSS Program Policy Guidance No. 6 Clarification of DSS/HAB Guidance Regarding AIDS Drug Assistance Program: Administration, Eligibility, and Cost-Savings***

June 1, 2000 (Formerly a "Dear Colleague Letter" First Issued October 17, 1997 to All Title I and II CARE Act Grantees and Reissued in July, 1999)

### ***Background***

A formal letter was sent to all grantees funded under Title I and Title II of the CARE Act in October 1996, concerning the administration of State AIDS Drug Assistance Programs (ADAPs). That letter contained recommendations for ADAPs regarding issues related to administration, eligibility, formularies, and cost-savings. Several recommendations became formal program policy in April 1997 (please refer to DSS/HAB Program Policy No.5, "ADAPs: Eligibility and Formulary Parity and Uses of Funds").

Subsequently, a second formal letter was issued to Title I and Title II grantees on July 7, 1999 which reiterated some of the remaining program guidance and recommendations from the October 1996 letter that are critical to the successful management and administration of State ADAPs. They also help to insure that ADAPs are the payers of last resort, as mandated by the CARE Act. Therefore, DSS/HAB is re-issuing the contents of that letter as a formal clarification of program guidance and recommendations as they relate to ADAP administration, eligibility, and cost-savings.

### ***6.1 ADAP Administration***

- a. States should consider establishing a centrally administered ADAP. It is the observation of the DSS/HAB that centrally administered ADAPs are better able to achieve accountability, parity, consistency, and cost-savings than decentralized ADAPs.
- b. States subject to the matching requirement for Title II must match ADAP supplemental funds as well as Title II base funds. The CARE Act as amended in 1996 requires Title II grantees (i.e., each of the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands and Guam) to maintain State expenditures for HIV-related activities at a level equal to the one-year period preceding the fiscal year (FY) for which the grantee is applying to receive a Title II grant. Grantees are accountable to ensure that Federal funds do not displace State spending but instead expand HIV-related activities. For additional information on matching requirements, please see Maintenance of Effort: DSS Issue Paper released on October 17, 1997.
- c. The Department of Health and Human Services (HHS), in requesting the supplemental funds for ADAP, and the Congress, in appropriating them, clearly expect Title II grantees to use these funds to expand current efforts to improve access to pharmaceuticals for low-income individuals with HIV disease. Compelling reasons may exist or occur where ADAP supplemental funds supplant other funding sources (e.g., Title II base funds, Title I funds); however, the grantee should be prepared to document the rationale for making these changes in ADAP funding.



## **6.2 Eligibility**

The CARE Act indicates that ADAPs are to serve “low-income individuals,” as defined by the States. The State’s poverty criterion for ADAP eligibility should be based on Federal poverty guidelines.

All States should devise, implement, and rigorously monitor the use of consistent eligibility standards across all entities involved in certifying and re-certifying ADAP eligibility. Such certification is expected to include review and documentation of an applicant’s income from all sources and any pharmaceutical benefits derived from private health insurance or other sources.

Every State should establish and implement procedures for ADAP client re-certification on a periodic basis, and for de-certifying individuals who qualify but have not utilized the program for a specific period of time (*e.g.*, one year or longer). Re-certification procedures should include mechanisms to assure that individuals who have become eligible for Medicaid are transferred to the Medicaid program at the earliest possible date.

## **6.3 Cost-savings**

Both HHS and the Congress expect that States 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.

Every ADAP should adopt cost-saving strategies that will be equal to or greater than the cost savings realized with the Office of Drug Pricing’s Section 340B Drug Discount Program which can be accessed by ADAPs through either the direct purchase discount or rebate option.

Any questions regarding this program policy guidance should be directed to the Chief, AIDS Drug Assistance Branch, Division of Service Systems, at 301-443-6745.



## ***DSS Program Policy Guidance No. 7*** ***Residence of Planning Council Members and Consortia Members***

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June 1, 2000 (Formerly Policy No. 98-01, First Issued: February 1, 1998)

The principal residence of Title I planning council members who represent affected communities, people with HIV, non-elected community leaders, or historically underserved groups and sub-populations must be within the geographic boundaries of the EMA for the length of the term in which they are serving on the council. In cases where a Title I planning council also serves as a Title II regional consortium and the consortium boundaries are larger than those of the EMA, residency requirements shall apply to the larger boundaries.

The principal residence of individuals filling legislatively mandated organizational seats on Title I planning councils (health care providers, including federally qualified health centers; community-based organizations serving affected populations and AIDS service organizations; social service providers; mental health and substance abuse providers; local public health agencies; hospital or health care planning agencies; State government, including the Medicaid agency and Title II administering agency; other CARE Act grantees; and other Federal HIV programs) should be within the geographic boundaries of the EMA, but this is not required. It is recognized that this may not be possible for individuals representing the Title II administering agency and/or the State Medicaid agency. To qualify for organizational representation on a planning council, entities of the types named above must provide services within the boundaries of the EMA.

States are strongly encouraged to develop and monitor similar residency requirements for membership of Title II consortia.



## ***DSS Program Policy Guidance No. 8 Staff Training***

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June 1, 2000 (Formerly Policy No. 98-02, First Issued: February 1, 1998)

Funds awarded under Title I or II of the Ryan White CARE Act may not be used to pay for professional licensure or to meet program licensure requirements. Title I or Title II funds may be used to support specific HIV staff training which enhances an individual's or an organization's ability to improve the quality of services to affected clients.



## ***DSS Program Policy Guidance No. 9 Guidelines for Reimbursement of Individuals Serving on a Ryan White Title I Planning Council and/or Title II Consortium***

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June 1, 2000 (Formerly a Program Guidelines Memorandum. Issued in January of 1997 and 2000)

The Public Health Service (PHS) Grants Policy Statement provides guidance on reimbursable costs to members of consumer/provider boards for participation in planning council, consortium, and/or associated grantee meetings. The PHS policy allows for the reimbursement of reasonable and actual out-of-pocket expenses incurred by an individual solely as a result of attending a scheduled meeting.

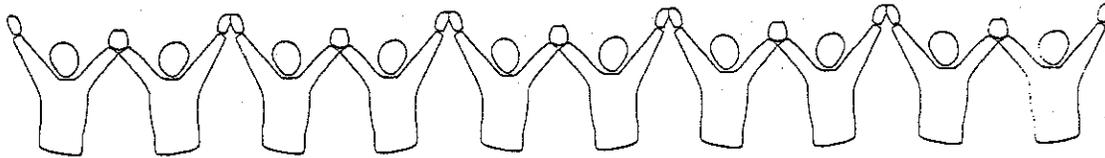
The PHS Grants Policy Statement is the basis for these policies. Only planning council and consortium members are eligible for reimbursement of actual out-of-pocket expenses incurred as a result of attending scheduled meetings. Vouchers, flat rates, or other reimbursement structures that are not reimbursing for actual expenses are not allowable. Reasonable and out-of-pocket expenses include transportation, meals, babysitting fees, and lost wages. Funds for supplies, telephone, and facsimile charges must be included in the appropriate line item of the planning council or consortium budget.

When issuing statements, press releases, requests for proposals, bid solicitations, and other documents describing projects or programs funded in whole or in part with Federal money, all grantees receiving Federal funds, including but not limited to State and local governments and recipients of Federal research grants, shall clearly state: 1) the percentage of the total costs of the program or project which will be financed with Federal money, 2) the dollar amount of Federal funds for the project or program, and 3) percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

# 2

## Section IV

# HIV/AIDS Bureau Policies for the CARE Act



*The following policies apply all CARE Act titles as noted.*

**HAB Policy Notice 99-02**

The use of Ryan White CARE Act funds for Housing Referral Services and Short-term or Emergency Housing Needs

See the HRSA/HAB Web Site at  
<http://www.hab.hrsa.gov>  
for the latest policies.

**HAB Policy Notice 99-03**

The Use of the Ryan White CARE Act Funds for HIV Diagnostics and Laboratory Tests Policy

**HAB Policy Notice 00-01**

The Use of Ryan White CARE Act Funds for American Indians and Alaska Natives and Indian Health Service Programs

**HAB Policy Notice 00-02**

The Use of Ryan White CARE Act, Title II, AIDS Drug Assistance Program (ADAP) Funds for Access, Adherence, and Monitoring Services

**HAB Policy Notice - 00-02, Amendment # 1**

The Use of Ryan White CARE Act, Title II, AIDS Drug Assistance Program (ADAP) Funds for Access, Adherence, and Monitoring Services

**HAB Policy Notice - 01-01**

Use of Ryan White CARE Act Funds for Transitional Social Support and Primary Care Services for Incarcerated Persons

**HAB Policy Notice - 02-01**

Use of Ryan White CARE Act Funds for Outreach Services

***Q & A on the Use of Ryan White CARE Act Funds for Outreach Services***



## **HAB Policy Notice 99-02: The Use of Ryan White CARE Act Funds for Housing Referral Services and Short-term or Emergency Housing Needs**

*Below is the HIV/AIDS Bureau (HAB) policy describing the use of Ryan White CARE Act funds for housing referral services and short-term or emergency housing needs. Funds designated to carry out the provisions of Section 2616 of the Public Health Service Act may be used to fund housing and related services under certain conditions, as described.*

### **HAB Policy Notice 99-02**

The following policy establishes guidelines for allowable housing-related expenditures under the Ryan White CARE Act. The purpose of all Ryan White Care Act funds is to ensure that eligible HIV-infected persons and families gain or maintain access to medical care.

- A. Funds received under the Ryan White CARE Act (Title XXVI of the Public Health Service Act) may be used for the following housing expenditures:
  - I. Housing referral services defined as assessment, search, placement, and advocacy services must be provided by case managers or other professionals who possess a comprehensive knowledge of local, State, and Federal housing programs and how they can be accessed; or short-term or emergency housing defined as necessary to gain or maintain access to medical care and must be related to either:
    - a. Housing services that include some type of medical or supportive service including, but not limited to, residential substance abuse or mental health services (not including facilities classified as an Institute of Mental Diseases under Medicaid), residential foster care, and assisted-living residential services, or
    - b. Housing services that do not provide direct medical or supportive services but are essential for an individual or family to gain or maintain access and compliance with HIV-related medical care and treatment. The necessity of housing service for purposes of medical care must be certified or documented.
  - II Short-term or emergency assistance is understood as transitional in nature and for the purpose of moving or maintaining an individual or family in a long-term, stable living situation. Thus, such assistance cannot be permanent and must be accompanied by a strategy to identify, relocate, and/or ensure the individual or family is moved to, or capable of maintaining, a long-term, stable living situation.
  - III. Housing funds cannot be in the form of direct cash payments to recipients or services and cannot be used for mortgage payments.
  - IV. The Ryan White CARE Act must be the payer of last resort. In addition, funds received under the Ryan White CARE Act must be used to supplement but not supplant funds currently being used from local, State, and Federal agency programs. Grantees must be capable of providing the HIV/AIDS Bureau with documentation related to the use of funds as payer of last resort and the coordination of such funds with other local, State, and Federal funds.
  - V. Ryan White CARE Act housing-related expenses are limited to Titles I, II, and IV and are not an allowable expense for Title III.



## **HAB Policy Notice 99-03: The Use of the Ryan White CARE Act Funds for HIV Diagnostics and Laboratory Tests**

*Below is the HIV/AIDS Bureau policy describing the use of the Ryan White CARE Act Funds for HIV diagnostics and laboratory tests. This policy is consistent with the Public Health Service "Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents." The enclosed policy supports the importance of diagnostics and laboratory tests as clinical tools in medical assessment and treatment decision making related to HIV/AIDS antiretroviral agents and other medications that treat HIV/AIDS or opportunistic infections related to HIV disease.*

### **HAB Policy Notice 99-03**

The purpose of all Ryan White CARE Act funds is to ensure that eligible HIV-infected persons and families gain and/or maintain access to medical care. In accordance with the provisions of Title XXVI of the Public Health Service Act, the following policy establishes guidelines for the use of Federal Ryan White CARE Act funds for HIV diagnostics and laboratory tests.

- I. Federal Ryan White CARE Act funds for Title I, II (excluding Federal ADAP funds), III, and IV may be used by grantees for support of diagnostic and laboratory tests integral to the treatment of HIV infection and related complications (for example, but not limited to, CD4 counts, viral load tests, genotype assays) under the following conditions:
  - A. The tests are consistent with medical and laboratory standards as established by scientific evidence and supported by professional panels, associations, or organizations. Types of standards include, but are not limited to: U.S. Public Health Service Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents, U.S. Public Health Service Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection, and standards supported by professional associations, such as the Infectious Diseases Society of America, American Medical Association, American Pediatric Association, and American College of Obstetricians and Gynecologists.
  - B. Such diagnostics and laboratory tests (1) are approved by the FDA, when required under the FDA Medical Devices Act and/or (2) are performed in an approved Clinical Laboratory Improvement Amendments of 1988 (CLIA) certified laboratory or State-exempt laboratory.
  - C. Such diagnostics and laboratory tests (1) are ordered by a registered, certified, or licensed medical provider and (2) are necessary and appropriate based on established clinical practice standards (refer to Section 1) and professional clinical judgement.
  - D. Ryan White CARE Act funds are the payer of last resort by statute. Therefore, grantees must demonstrate a procedural mechanism for purposes of identification and billing of liable payers. Funds for diagnostics and laboratory tests cannot be expended without such a procedure in place.



## **HAB Policy Notice 00-01: The Use of Ryan White CARE Act Funds for American Indians and Alaska Natives and Indian Health Service Programs**

*Below is the HIV/AIDS Bureau policy establishing guidelines for allowable expenditures under the Ryan White CARE Act to provide services to American Indians and Alaska Natives (AIs/ANs), and for health care services provided by the Indian Health Service (IHS) programs directly or under contract or compact.*

### **HAB Policy Notice 00-01**

The following policy establishes guidelines for allowable expenditures under the Ryan White CARE Act: (1) to provide services to American Indians and Alaska Natives (AIs/ANs) and (2) for health care services provided by the Indian Health Service (IHS) programs directly or under contract or compact. The purpose of all Ryan White CARE Act funds is to ensure that eligible HIV-infected persons and families gain or maintain access to medical care.

The AIs/ANs hold triple citizenship. Federally recognized AIs/ANs are documented members of tribal entities officially recognized by the U.S. Bureau of Indian Affairs, as well as citizens of the United States. In addition, they are citizens of an individual State. It is this multi-citizenship that enables them to receive services under the Ryan White CARE Act. Thus, AIs/ANs can claim CARE Act services for which they are eligible where they choose, regardless of the availability of services that may also be available to them (e.g., through Indian Health Service, tribal, or urban Indian health programs and services). This policy ensures that AIs/ANs have direct and unfettered access to CARE Act programs. In addition, this policy clarifies the circumstances under which the IHS may and may not receive funds under the Ryan White CARE Act.

- I. Coverage of American Indians and Alaska Natives under the Ryan White CARE Act Who are Eligible for Services Provided by or Supported by the Indian Health Service
  - A. Any AI or AN who is otherwise eligible to receive CARE Act-funded services from any Title may request and must receive those services regardless of whether or not s/he is also eligible to receive the same services from the IHS, and regardless of whether or not those IHS services are available and accessible to the AI or AN. A CARE Act grantee or provider cannot deny services based on American Indian or Alaska Native status. However, individuals must meet the same established eligibility criteria as all other individuals receiving care through a Ryan White CARE Act funded grantee or provider.
  - B. AIs/ANs may seek care at a Ryan White CARE Act funded facility without referral or a purchase order from the "IHS operated" or "638 contract" or compact facility. The Ryan White CARE Act-funded facility or provider should follow established procedures to determine health care coverage as it usually does as the payer of last resort program. Even though the CARE Act program is the payer of last resort, the IHS is not obligated to reimburse a CARE Act grantee or provider for services provided to an AI or AN who requests services without a purchase order referral from the IHS. However, the grantee or provider must seek payment from other payers as indicated (e.g., Medicaid, if the individual is Medicaid-eligible).



## II. Eligibility of Indian Health Service or Tribally Operated Facilities to Receive Ryan White CARE Act Funds

### A. "IHS-operated" facilities:

1. Are not eligible to receive direct funds under Title I, Title II, Title III, and Title IV of the Ryan White CARE Act since it would be considered an augmentation of the Indian Health Service Congressional Appropriations.
2. Are eligible to receive funds as subcontracts under Title I, Title II, Title III and Title IV funds, as long as the IHS-operated facility can demonstrate that the provision of CARE Act services to CARE Act-eligible individuals supplements and does not supplant IHS-funded programs, and the IHS-operated facility adheres to the requirements of the grantee or provider from which the subcontract is awarded.

### B. "638 contract" facilities:

1. Titles I and II: "638 contract" facilities are not eligible to receive grant funds as direct grantees under Title I and Title II of the Ryan White CARE Act. However, "638 contract" facilities are eligible to receive funds as subcontractors under Titles I and II of the Ryan White CARE Act if they meet the statutory criteria as appropriate entities. Financial assistance (as a subcontractor) may be made "to public or nonprofit private entities, or private for-profit entities if such entities are the only available provider of quality HIV care in the area...." (Section 2604(b)(2)(A) of the Public Health Service Act).
2. Title III: "638 contract" facilities are eligible to receive direct grant funds under Title III of the Ryan White CARE Act under the criteria set forth in Section 2652(a) of the Public Health Service Act as "public and nonprofit private entities" and Section 2652(b) status as Medicaid providers -- "the applicant for the grant must have entered into a participation agreement with the approved Title XIX (Medicaid) State plan and qualified to receive Medicaid payments."

In addition, if the tribe has (or receives) nonprofit status, it is eligible as a nonprofit private entity. A Tribe is required to produce a copy of its "638 contract" with the IHS/ DHHS to establish its status as owner and operator of the facility. In addition, a tribe claiming nonprofit status is required to produce a letter from the appropriate Federal, State, or local entity as proof of such status.

3. Title IV: "638 contract" facilities are eligible to receive direct and subcontractor grant funds under Title IV of the Ryan White CARE Act if they meet the criteria in Section 2671(a) of the Public Health Service Act "as public and nonprofit private entities that provide primary care (directly or through contracts)" and demonstrate nonprofit status as described in Section III B 2 above.
4. The "638 contract" facilities and services must meet established eligibility criteria of the Ryan White CARE Act. Thus, for CARE Act services provided to eligible individuals who present for services, a "638 contract" facility must serve those individuals without regard to their status as non-AI or non-AN.



C. Urban Indian Health Programs Designated by the IHS:

1. Urban Indian health programs designated by the IHS are not eligible to receive direct funds under Titles I and II.
2. Urban Indian health programs designated by the IHS are eligible to receive direct funds under Titles III and IV. However, the Urban Indian health programs must meet established eligibility criteria of the Ryan White CARE Act. Thus, for CARE Act services provided to eligible individuals who present for services, an urban Indian health program must serve those individuals without regard to their status as non-AI or non-AN.
3. Urban Indian health programs designated by the IHS are eligible to receive subcontract funds under Titles I, II, III, and IV as long as they met the established Ryan White CARE Act criteria for those titles, and if they meet the statutory criteria as appropriate entities. Financial assistance (as a subcontractor) may be made "to public or nonprofit private entities, or private for-profit entities if such entities are the only available provider of quality HIV care in the area..." (Section 2604(b)(2)(A) of the Ryan White CARE Act).
4. The urban Indian health programs must meet established eligibility criteria of the Ryan White CARE Act. Thus, for CARE Act services provided to eligible individuals who present for services, an urban Indian health program must serve those individuals without regard to their status as non-AI or non-AN.

The Ryan White CARE Act must be the payer of last resort. Grantees must be capable of providing the HAB with documentation related to the use of funds as payer of last resort and the coordination of such funds with the tribes and with the IHS, and other sources of payment (*e.g.*, Medicaid, Medicare, Department of Veterans Affairs, State-funded programs).



## **HAB Policy Notice 00-02: The Use of Ryan White CARE Act, Title II, AIDS Drug Assistance Program (ADAP) Funds for Access, Adherence, and Monitoring Services**

*Below is the HIV/AIDS Bureau (HAB) policy describing the use of Ryan White CARE Act, Title II, AIDS Drug Assistance Program (ADAP) funds for access, adherence, and monitoring services. The Congress, in its Appropriations Committee reports for HRSA's FY 2000 budget, requested that HRSA consider allowing States to redirect a reasonable portion of ADAP funds, as determined in collaboration with the States, to such services that enhance the ability of eligible people with HIV/AIDS to gain access to, adhere to, and monitor their progress in taking HIV-related medications. The policy states that ADAP funds (including the 10 percent administrative funds) designated to carry out the provisions of Section 2612(a)(5), in accordance with Section 2616, may be used to provide access, adherence, and monitoring services under certain conditions, as described.*

### **HAB Policy Notice 00-02**

The following policy establishes guidelines for allowable ADAP related expenditures under the Ryan White CARE Act. The purpose of all Ryan White CARE Act ADAP funds is to ensure that eligible HIV-infected persons gain or maintain access to HIV-related medications. This policy provides grantees greater flexibility in the use of ADAP funds, including the 10 percent of ADAP funds allowed for administrative costs (but not other funds under other titles that may be used to purchase medications) and permits expenditures of ADAP funds for services that improve access to medications, increase adherence to medication regimens, and help clients monitor their progress in taking HIV-related medications.

- I. Federal funds received under the Ryan White CARE Act, ADAP, as established by Section 2612(a)(5), in accordance with Section 2616 of the Public Health Service Act, may be used for access, adherence, and monitoring services under the following conditions:
  - A. Funded services are related to: (1) enabling eligible individuals to gain access to drugs; (2) supporting adherence to the drug regimen necessary to experience the full health benefits afforded by the medications; and (3) services to monitor the client's progress in taking HIV-related medications (refer to HAB Policy Notice 99-03, "The Use of Ryan White CARE Act Funds for HIV Diagnostics and Laboratory Tests Policy").
  - B. There are no current limitations to accessing ADAP in the State, including: (1) no client waiting list or limits on client enrollment; (2) no restrictions or limitations on HIV medications, such as caps on the number of prescriptions or cost to the client (such as co-pays), except for purposes of clinical quality assurance or the prevention of fraud and abuse; and (3) administrative support is maintained (e.g., administrative support and eligibility staff).



- C. There is current, comprehensive coverage of antiretroviral and opportunistic infection (OI)/preventive therapies including: (1) an ADAP formulary that includes a full complement of Public Health Service-recommended anti-retroviral medications; and (2) medication necessary for the prophylaxis and treatment of opportunistic infections. Compliance with formulary coverage may be adjusted or modified based on the State's alternative methods of providing comprehensive pharmacy coverage (*e.g.*, health insurance, or State-funded pharmacy assistance program).
- II. It is expected that no more than 10 percent of ADAP funds (including carryover funds), will be used to purchase services referenced in I. A. (1)-(3) above, unless otherwise determined in agreement with HAB staff.
- III. In addition:
- A. The grantee will work with HAB staff to ensure the grantee's plan to redirect ADAP funds still meets the core purposes of ADAP.
- B. The Ryan White CARE Act must be the payer of last resort. Grantees must be capable of providing the HAB with documentation related to the use of funds as payer of last resort and the coordination of such funds with other local, State, and Federal funds. For example, the grantee should back bill Medicaid for CARE Act services provided to Medicaid-eligible individuals. In addition, funds received under the Ryan White CARE Act, including ADAP, must be used to supplement, but not supplant, funds currently being used from local, State, and Federal agency programs.
- C. The grantee must have a mechanism to report on the use of redirected funds—for example, an estimation of unspent funds, including carryover, the impact of such services in improving access and use of ADAP-funded medications, and any procedural plans to shift funds back to purchasing medications.
- D. The request to provide additional services with ADAP funds must be submitted on an annual basis either through the grant application process or by requesting prior approval from the Grants Management Branch during the grant year.



## **HAB Policy Notice - 00-02, Amendment # 1: The Use of Ryan White CARE Act, Title II, AIDS Drug Assistance Program (ADAP) Funds for Access, Adherence, and Monitoring Services**

*Below is the amendment to the existing HIV/AIDS Bureau (HAB) policy that addresses changes to the policy necessitated by the reauthorized Ryan White CARE Act affecting the Title II AIDS Drug Assistance Program (ADAP).*

### **HAB Policy Notice - 00-02, Amendment # 1**

On July 26, 2000, the HIV/AIDS Bureau issued a policy clarifying how CARE Act funds from the ADAP appropriation could be used to provide services to increase access to medications, adherence to medication regimens, and monitoring of progress to therapy. The reauthorized CARE Act (P.L. 106-345), signed by the President on October 20, 2000, contained a provision which affected the July 26, 2000, policy.

Specifically, Section 204 of the reauthorized CARE Act revised Section 2616(c) of the Public Health Service Act by inserting language that permits ADAP funds to be used to "encourage, support, and enhance adherence to and compliance with treatment regimens, including related medical monitoring." However, the law places some limits on the use of ADAP funds for these purposes. It states, "Of the amount reserved by a State for a fiscal year for use under this section, the State may not use more than 5 percent to carry out services under [the] paragraph [quoted in the previous sentence], except that the percentage applicable with respect to such paragraph is 10 percent if the State demonstrates to the Secretary that such additional services are essential and in no way diminish access to the therapeutics described in [Section 2616(a) of the 1996 revisions to the CARE Act]."

In the "Managers' Statement" accompanying the final bill, they noted that "the Managers recognize that existing Federal policy provides adequate guidelines to States for carrying out provisions under this section."

We interpret the bill, and the Managers' intent, to say that the criteria for using ADAP funds for services related to access, adherence, and monitoring are still appropriate and in force, and that no more than 5 percent of a State's ADAP funding in a given year may be used for these services unless there are extraordinary circumstances that would warrant up to 10 percent of a State's ADAP funding being used. We have included some examples of extraordinary circumstances.

The HAB Policy Notice (00-02) is amended as follows: No more than 5 percent of ADAP funds may be used for these services, except that under extraordinary circumstances, no more than 10 percent of ADAP funds (including carryover funds), may be used to purchase services referenced in I. A. (1)-(3) in Policy Notice 00-02. The State can use ADAP funds to purchase these services referenced only if the State demonstrates to the Secretary that such additional services are essential and in no way diminish access to the therapeutics describes in Section 2616(a).



Extraordinary circumstances may include such factors as demonstrated exceptionally low compliance and adherence rates among targeted segments of the clients receiving ADAP medications (*e.g.*, active substance users, persons with serious mental illnesses), or significant new numbers of clients entering ADAP who are new recipients of drug therapies (as a result of other outreach activities) that necessitate devoting added resources to these activities. The State must work with HAB to ensure that any requested use of ADAP funds for these services above 5 percent is necessary and appropriate and that existing ADAP services to clients will not be diminished or disrupted.



## **HAB Policy Notice – 01-01: Use of Ryan White CARE Act Funds for Transitional Social Support and Primary Care Services for Incarcerated Persons**

*Below is the HIV/AIDS Bureau policy describing the use of the Ryan White CARE Act funds for transitional social support and primary care services for incarcerated persons. The enclosed policy supports the use of CARE Act funds for incarcerated persons as they prepare to exit the correctional system as part of effective discharge planning or when they are in the correctional system for a brief period, which would not include any discharge planning.*

### **Overview**

The following policy establishes guidelines for allowable expenditures under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act for incarcerated persons (a) as they prepare to exit the correctional system as part of effective discharge planning, or (b) when they are in the correctional system for a brief period, which would not include any type of discharge planning. "Incarcerated person" refers to an individual involuntarily confined in association with an allegation or finding of behavior that is subject to criminal prosecution. Thus, the policy applies to individuals who are involuntarily living in the secure custody of law enforcement, judicial, or penal authorities. Furthermore, this includes individuals who reside in a community setting (which is not part of the institutional setting of the prison system, such as a pre-release residential halfway house) if the individual is still involuntarily confined to those settings.

The intent of all Ryan White CARE Act funds is to ensure that eligible HIV-infected persons gain or maintain access to HIV-related care and treatment. This policy recognizes that many incarcerated persons will ultimately be the responsibility of CARE Act programs, so early detection, entry into care, and access to and continuity of care are important reasons to use CARE Act funds for incarcerated persons. The purpose of the policy is to provide grantees flexibility in providing necessary, and otherwise unavailable, transitional primary care and social support services to incarcerated persons in the custody of a local, State, or Federal correctional system who are either nearing release or whose incarceration is of short duration. Grantees who want to develop these linkages should become familiar with local prisons or jails and the State and Federal correctional facilities and the procedures established to prepare inmates for release into the community. These systems could vary greatly across localities and regions. Grantees should work with the appropriate corrections administrators to determine what health services are legally expected to be provided within the correctional system and how, and whether, the correctional system addresses the discharge planning needs, continuity of treatment, and community linkages for inmates.

We envision grantees who establish transitional social services will link the inmate to HIV care and treatment and transitional primary care services. These services could be provided in the correctional facility prior to release as part of discharge planning (or if it is a short-term facility, like a local jail, which does not provide discharge planning, it would be outside of the jail or prison). In either situation, these services are not covered by the correctional system. Transitional primary care services can also be provided on a short-term basis in an outpatient setting. Grantees must determine, working with the correctional system, the release status of the inmate, that is, when they will be released, sort out what health care services are covered and provided by the correctional system, and what services the Ryan White CARE Act can provide.



There are several important provisions within the CARE Act and statutory points of reference that define the ability of CARE Act to provide services for incarcerated persons. Specifically, it is important to recognize that the purpose of the policy is not to supplant resources that are otherwise available, or can reasonably be expected to be available, for social service or health-related benefits for incarcerated persons under any State program, an insurance policy or under any Federal or State health benefits program, or an entity that provides services on a prepaid basis as stated in the statute and usually referred to as payer of last resort language found in Sections 2605(a)(4)(A) and (B), 2617(b)(4)(F)(i) and (ii), and 2664(f)(1)(A) and (B) of the Public Health Service Act. For instance, in 1996, the Office of the Inspector General's (OIG) audit of a State's CARE Act Title II program found CARE Act funds were used to provide transitional services to inmates within 90 days of release, even though under that State's law inmates "have a right to medical care and prison officials have a corresponding duty to provide such care." The OIG did not disagree with the use of CARE Act funds to support transitional services for inmates, but rather, in this audit, said that the State used CARE Act funds to support such services when the State was already paying for transitional services for other inmates. Additionally, within the newly reauthorized CARE Act, Congress highlighted the critical nature of coordinating and increasing access to social services and health-related services for incarcerated persons and directed that the Secretary develop and submit to the Congress, within 2 years, a comprehensive plan to address the provision of such services (Section 2675(e)).

Under the context as described above, the policy provides for the use of funds for transitional social services (*e.g.*, medical case management and social support services) to help achieve immediate linkages to community-based care and treatment services upon release from custody, where no other services exist, or where these services are NOT the responsibility of the correctional system. Second, the policy also provides for the use of funds for transitional primary care services prior to release or during a period of short-term incarceration where no other services exist, or where these services are NOT the responsibility of the correctional system.

### **HAB Policy Notice – 01-01**

Federal funds received under the Ryan White CARE Act, as established in Title XXVI of the Public Health Service Act, may be used for short-term, transitional social support, and primary care services for incarcerated persons as they prepare to exit the correctional system as part of effective discharge planning (or who are incarcerated for a brief period with no formal discharge planning) and are otherwise eligible for CARE Act services under the following conditions:

#### **I. Incarcerated Person**

"Incarcerated person" refers to an individual involuntarily confined in association with an allegation or finding of behavior that is subject to criminal prosecution. Thus, the policy applies to individuals who are involuntarily living in the secure custody of law enforcement, judicial, or penal authorities. Furthermore, this includes individuals who reside in a community setting (which is not part of the institutional setting of the prison system, such as a pre-release residential halfway house) if the individual is still involuntarily confined to those settings.



## II. Transitional Social Services

- A. Funded transitional social support services must be related to establishing or re-establishing linkages to HIV care and treatment services in community-based systems of care for incarcerated persons prior to release from custody during the time period as indicated in this policy. A service, such as medical case management, that links the individual with established primary care is an example of a transitional service that would be appropriate.
- B. Recognizing that the determination of non-covered services is unique to each local, State, and Federal facility, and the grantee is responsible for assessing the extent to which such services are or should be covered by the correctional institution, the grantee must delineate precisely what services will be provided by the grantee and by the correctional system that are otherwise not available.
- C. The grantee must ensure that these services supplement, but do not supplant, existing programs or responsibilities administered by the correctional system, or other local, State, or Federal agencies.

## III. Transitional Primary Care Services

- 0.1 Transitional primary care services are services delivered in an outpatient basis or an outpatient setting for a brief period of time until a more permanent health care provider can be arranged, which includes a comprehensive continuum of care, such as primary medical care and prescription drugs. These services may also include HIV counseling and testing and referral services to obtain health care. CARE Act funds may only be used for these services when other sources of funds are not available.
- 0.2 This policy does NOT generally permit the use of Ryan White CARE Act funds in State and Federal prison facilities, since the State and Federal prison systems are responsible for providing health care services to all individuals remanded to their facility. Such care is the responsibility of law enforcement, judicial, and penal authorities in whose secure custody the individual is held. This limitation, however, does not apply to State or Federal inmates about to be released to the community and who are receiving health-related services using community resources, when not actually living in the correctional facility, such as home detention and halfway house programs, based on III. E.
- 0.3 Grantees wishing to institute a program of transitional primary care services in a local, State, or Federal correctional setting must either deliver these services directly or through subcontracts with qualified HIV community-based providers to deliver HIV primary care services directly to eligible incarcerated persons to ensure that CARE Act funds are properly expended and only for services not otherwise available to any incarcerated persons.
- 0.4 Grantees can use CARE Act funds to support local (*e.g.*, county, city) jails if these institutions are not legally responsible for meeting the HIV health care and treatment needs of persons in their custody.
- 0.5 Grantees can use CARE Act funds to support primary care services for incarcerated persons who reside in the community (*e.g.*, an individual who is not part of the prison or jail system but resides in a pre-release facility) ONLY to the extent to which services are not available or should not be reasonably expected to be available to the incarcerated person involuntarily confined. Furthermore, funding is available only to support incarcerated persons who are expected to be eligible for and the responsibility of CARE Act programs.



#### IV. Timeframe

Flexibility in the timeframe available is essential to the effectiveness of our programs. The determination of the exact amount of time that is required should be determined by a collaborative effort between the Ryan White CARE Act project staff who will be involved in care during and after release, the correctional institution's medical staff who are providing the care while the inmate is in custody, and based on inmate needs. While recognizing that the timeframe must be flexible and determined collaboratively, it is recommended not to exceed 180 days. The time delineation must be done in collaboration with Ryan White CARE Act HAB project officers.

- V. Recognizing that the determination of non-covered support or primary care services is unique to each locality, the grantee is responsible for assessing the extent to which such services are or should be covered. The grantee must delineate precisely what services will be provided by the grantee and by the correctional system that are otherwise not available.
- VI. The grantee must assess the availability of other public resources for social support and health-related services and benefits programs in order to ensure the CARE Act funds remain the payer of last resort.
- VII. The HAB expects that grantees will coordinate the use of funds for prison health services among publicly funded HIV-related community-based organizations across the other local, State, Federal, and public programs, in order to assure an efficient, seamless, and comprehensive continuum of HIV care for the transition of incarcerated persons into the community.
- VIII. Grantees must develop methods to ensure that communication between the correctional system and the grantee and/or qualified provider preserve and protect patient privacy and confidentiality, including the patient's right not to disclose or to have disclosed her or his HIV status. Grantees and/or qualified providers must ensure that only those incarcerated persons who wish to receive primary care and/or transitional services are referred for participation.
- IX. The grantee must have a mechanism to report to the HAB on the use of funds to provide transitional services and social services in correctional systems, and to include the individuals served in the same reporting process as other CARE Act service recipients for primary care services.



## **HAB Policy Notice - 02-01: Use of Ryan White CARE Act Funds for Outreach Services**

*Below is the HIV/AIDS Bureau policy describing the use of the Ryan White CARE Act funds for outreach services. This policy reflects the changes in the Ryan White CARE Act Amendments of 2000 and establishes new guidelines for allowable expenditures for outreach services for all of the Titles, except for the Special Projects of National Significance (SPNS) Program.*

*A separate question and answer (Q & A) document on the Use of CARE Act Funds for Outreach Services is also included to assist CARE Act grantees, and their planning bodies and contractors, in developing effective implementation strategies in compliance with the policy.*

### **Introduction**

This policy reflects the provisions in the Ryan White Comprehensive AIDS Resources Emergency Act (CARE) Amendments of 2000, replaces "Division of Service Systems (DSS) Program Policy Guidance No. 3: Outreach, June 1, 2000" (formerly Policy No. 97-03, March 31, 1997), and establishes new guidelines for allowable expenditures for outreach services. The purpose of all Ryan White CARE Act funds is to ensure that eligible HIV-infected persons gain or maintain access to HIV-related care and treatment. The new requirements give grantees increased flexibility in providing outreach services that are designed to identify persons at high risk for HIV, to bring HIV-infected persons into care, and for the purpose of early treatment in order to provide an array of early intervention and prevention services. Outreach services include services to both HIV-infected persons who know their status and are not in care and HIV-infected persons who do not know their status and are not in care. The policy applies to all Titles and programs of the CARE Act, except for the Special Projects of National Significance (SPNS) Program, due to its innovative nature and search for better models of care.

### **Outreach Services Prior to the Ryan White CARE Act Amendments of 2000**

Prior to the reauthorization of the CARE Act, Titles I to IV grantees were allowed to use funds to pay for outreach services with certain restrictions. As outlined in former DSS Program Policy Guidance, Title I and Title II grantees could use CARE Act funds for "outreach programs which have as their principal purpose identifying people with HIV disease so that they become aware of and may be enrolled in care and treatment services and receive related support services that enable them to remain in care." Titles I and II funds could not be used for outreach programs "which exclusively promote[d] HIV counseling and testing and/or which [had] as their purpose HIV prevention education." The policy also stated that grantees could not use funds for "broad-scope awareness activities about HIV services which target the general public (poster campaigns for display on public transit, TV or radio public service announcements, etc.)."

Title III and Title IV had similar allowances and restrictions on the use of CARE Act funds for outreach services. According to their respective program guidances, Title III and Title IV grantees could use funds for outreach services to target high-risk individuals, who knew their HIV status, or if they did not know their HIV status, for counseling and testing and ultimately to link these individuals into care (that is, case finding). Grantees could not use funds for mass media

campaigns or HIV prevention education efforts that did not include linking people into care, as described above. However, unlike Title I and Title II grantees, Titles III and IV grantees could use CARE Act funds to pay for counseling and testing services.

### ***Outreach Services After the Ryan White CARE Act Amendments of 2000***

On October 20, 2000, the Ryan White CARE Act Amendments of 2000 (Public Law 106-345) were enacted. These amendments reauthorized the CARE Act (Title XXVI of the Public Health Service Act) through 2005. The goal of the Amendments was to ensure that individuals living with HIV and AIDS receive health care and related support services. During the reauthorization process, the Congress paid close attention to significant changes in the HIV/AIDS epidemic and treatments that occurred between 1995 and 2000. In 2000, the CDC estimated that there were between 800,000 and 900,000 persons living with HIV disease in the United States, with 40,000 new infections annually. CDC found that only approximately one-third of those individuals are in medical care, one-third know their HIV status but are not in medical care, and one-third do not know their HIV status. Early access to highly active antiretroviral therapy (HAART) and other care modalities reduces morbidity and mortality among persons living with HIV disease.

In 2002, CDC updated these estimates and found 850,000 to 950,000 persons are living with HIV/AIDS. The proportion of infected persons who know their status is increasing. CDC found that about 75 percent (670,000) have been diagnosed but a large proportion, approximately one-third, may not be receiving ongoing care. CDC indicates these two groups, persons diagnosed and undiagnosed, about 400,000 to 500,000 HIV-infected persons, may not have been tested, not receiving treatment or both.

In response to these and other trends, Congress placed a new emphasis on identifying and referring people with HIV disease into regular care and treatment, especially under Title I and II. The primary goal of this new emphasis was to improve early diagnosis of HIV and to enhance access to HIV care and treatment for persons infected or at high risk for HIV infection. The managers' statement that accompanied the CARE Act Amendments stated that, "[the] intent is to ensure that EMAs and States understand that outreach activities which are consistent with early intervention services and necessary to implement the linkage into care strategies, are appropriate uses of Titles I and II funds." (The Managers' Statement of Explanation, Congressional Record, October 5, 2000, pages H-8841 to 8844). It was not the Managers' intent that such activities supplant or duplicate activities such as case finding, surveillance and social marketing campaigns currently funded and administered by the CDC. Instead, the Managers' wanted to relay the urgency of increasing the coordination between HIV prevention and HIV care and treatment services.

### ***New Outreach Service Guidance for Grantees***

All CARE Act grantees, including Titles I and II grantees can now use funds to pay for HIV counseling and testing, outreach, and referral services. This policy clarifies what constitutes eligible outreach services for all Titles. In the provision of these services, grantees should target individuals who already know their HIV status, but are not receiving treatment. Vulnerable, high-risk HIV individuals who may or may not know they are HIV positive are often hesitant to seek care for various reasons (e.g., stigma, distrust of the health care system, lack of insurance, providers



who lack cultural competence). Congress acknowledged the difficulties associated with outreach and recruitment among these individuals. In support of these efforts, the fiscal year 2001 appropriations to the Title II AIDS Drug Assistance Program (ADAP) provided \$7 million to support targeted education and outreach to vulnerable communities, including racial/ethnic minorities who are disproportionately impacted by the HIV/AIDS epidemic.

The goal of outreach services is to link individuals into care that would ultimately result in ongoing primary care and increased adherence to medication regimens. Outcome measures need to be defined by grantees that reflect the goal to evaluate the success of outreach activities. Even with the changes in the CARE Act Amendments, it appears that broad activities such as providing "leaflets at a subway stop" or "a poster at a bus shelter" would not meet the intent of the law. This policy would give CARE Act grantees flexibility to target and identify individuals who may or may not know their HIV status and are not in care, have not returned for treatment services or do not adhere with treatment requirements.

### ***Policy for Use of Ryan White CARE Act Funds for Outreach Services***

Federal funds received under the Ryan White CARE Act, as established by Title XXVI of the Public Health Service Act, may be used for outreach activities which have as their principal purpose targeting activities, under specific needs assessment-based service categories, that can identify individuals with HIV disease. This includes those who know their HIV status and are not in care as well as those individuals whose HIV status is unknown, so that they become aware of the availability of HIV-related services and enroll in primary care, AIDS Drug Assistance Programs, and support services that enable them to remain in care.

### ***Outreach activities supported with CARE Act funds must be:***

- a. Planned and delivered in coordination with State and local HIV prevention outreach activities to avoid duplication of effort and to address a specific service need category identified through State and local needs assessment processes;
- b. Directed to populations known, through local epidemiological data or through review of service data, to be at disproportionate risk for HIV infection;
- c. Conducted in such a manner, (i.e., time of day, month, events, sites, method, cultural appropriateness) among those known to have delayed seeking care relative to other populations, etc., and continually reviewed and evaluated in order to maximize the probability of reaching individuals infected with HIV who do not know their serostatus or know their status but are not actively in treatment;
- d. Designed to:
  - Establish and maintain an association with entities that have effective contact with persons found to be disproportionately impacted by HIV or disproportionately differ in local access to care (e.g., prisons, homeless shelters, substance abuse treatment centers).
  - Direct individuals to early intervention services (EIS) or primary care (HIV counseling and testing, diagnostic, and clinical ongoing prevention counseling services with appropriate providers of health and support services).
  - Include appropriately trained and experienced workers to deliver the message when applicable.



- e. Designed to provide quantifiable outcome measures such as the number of individuals reached of previously unknown HIV status who now know they are positive, and/or the number of HIV positive individuals not in care who are now in care; and
- f. Determined to be a priority service by Title I planning bodies and Title II consortia or State planning bodies, and be necessary to implement the EMA or State wide comprehensive plan and associated strategies.

Funds awarded under the CARE Act may not be used for outreach activities that exclusively promote HIV prevention education. Broad scope awareness activities that address the general public (poster campaigns for display on public transit, billboards, TV or radio announcements, etc.) may be funded provided that they are targeted and contain HIV information with explicit and clear links to health care services.

Outreach activities should supplement, and not supplant, such activities that are carried out with amounts appropriated under Section 317 of the Public Health Service Act, "Project Grants for Preventive Health Services" administered by the CDC or with other Federal, State or local funds.

The grantee must ensure that Ryan White CARE Act funds remain the payer of last resort.



## **Q & A on the Use of Ryan White CARE Act Funds for Outreach Services**

### **1. What is an example of a targeted outreach service?**

The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act funds are intended for targeted outreach services to link persons with HIV who may or may not know their HIV status into care. Each grantee must determine who these persons are, where it is most likely these targeted services will reach intended individuals and result in them gaining access to, or maintaining in, HIV-related medical care or treatment. For example, a grantee could fund outreach workers to locate persons who tested positive and were informed of their test results but never returned for treatment. The grantee could use local epidemiological data to target HIV infected women with an appropriate media campaign that reaches this targeted audience and also informs them of the location and hours of a clinic in their area.

### **2. Can CARE Act funds be used in place of funds currently being used from local, State, and Federal agency for similar outreach program efforts?**

CARE Act funds must be the payer of last resort. Funds used for outreach service must be used to supplement but not supplant funds currently used from local, State, and Federal agency programs. Similar outreach program efforts are defined as those efforts targeting persons with HIV who may or may not know their HIV status and are not in care.

### **3. If a grantee (or subgrantee) wants to begin an outreach effort targeting persons with HIV who may or may not know their status and are not in care, what must grantees have in place in order to proceed?**

While HRSA/HAB policy does not specify all of the types of outreach services that can be funded with CARE Act funds, grantees and providers are responsible for utilizing Ryan White CARE Act funds for outreach activities and plans that have been approved in their grant award. Such plans, when submitted by grantees to HRSA must include in their budget and narrative:

- Funding amount for outreach services
- A description of outreach activities to be conducted along with a rationale for why these activities will identify persons with HIV not in care, and
- Supporting data describing the need for such targeted outreach efforts.

In addition, grantees must develop outcome measures that include what their expected results are from such efforts.

### **3a. What are some examples?**

These outcome measures are to be determined by the grantee. Here are examples of these types of output or performance measures. Grantees may also want to review the HRSA/HAB "Outcomes Evaluation Technical Assistance Guides" located on the Bureau's web site <http://hab.hrsa.gov/tools/outcomeguides.htm>. An outcome indicator or measure are observable, measurable data sets, that are used to track a program's success in reaching desired outcomes such as changes in CD4 counts over time that are used to track a program's success in reaching desired outcomes. Client-level outcomes are results or benefits for an individual client, including biological measures such as improved CD4 count or viral load.



System level outcomes are results for all clients receiving services, such as reduced morbidity or mortality rates. Outputs are measures of the direct products or volume of program operations, such as the number of service units that a program delivers. A primary care example includes the number of clients served, CD4 and viral load tests completed, or specialty care consultation provided. For outreach, this measure may be tracking persons who get into care as a result of outreach and monitoring their clinical progress. Grantees must document achievements made in identifying and bringing persons into care through such outreach services.

**4. Can grantees combine HIV prevention outreach activities with Ryan White CARE Act outreach activities?**

HIV prevention outreach services funded through CDC, states, localities, and community based organizations are broader in scope, than RWCA funded outreach activities. The difference is in the scope, intent, and content of the message. CARE Act outreach is targeted to reach persons with HIV who may or may not know their HIV status and are not in care. CARE Act outreach services should be planned and delivered in a manner that: 1) targets outreach based on local needs assessment or epidemiologic data, to specific populations that are known to be at high risk or knowledgeable of their status, but not in care; and 2) establishes a "relationship or association" between the person targeted for the outreach and a program able to provide the service. While HIV broad based prevention outreach services can be co-located or coordinated with Ryan White CARE Act outreach programs, grantees' Ryan White CARE Act outreach activities must establish separate outreach planning, outcome measures, and financial accounting for their specific outreach activity.

**5. The Ryan White CARE Act Amendments contained certain changes. Explain how to coordinate with points of entry, and early intervention services within my outreach activities under RWCA?**

***Points of Entry:***

The Ryan White CARE Act Amendments of 2000 allow Title I and Title II to fund outreach services to link persons with HIV disease into care. This law also introduces language such as "key points of entry" (such as emergency rooms, substance abuse treatment programs, detoxification centers, adult and juvenile detention facilities, sexually transmitted disease clinics, HIV counseling and testing sites, mental health program and homeless shelters) and "early intervention services" (HIV counseling and testing, diagnostic, and clinical ongoing prevention counseling services with appropriate providers of health and support services) where persons with HIV disease can be identified, referred, and maintained in health care and related supportive services. Grantees should coordinate outreach services such that they include key points of entry as sites where targeted outreach activities are conducted.

***Early Intervention Services (EIS):***

The grantee can use outreach to identify and refer individuals to new and existing early intervention services. Early intervention services stress the importance of bringing persons into care earlier in HIV disease progression. Outreach services are aimed at 1) identifying persons



with HIV who may or may not know their status and are not in care; and 2) providing HIV counseling and testing, diagnostic, and clinical ongoing prevention counseling services with appropriate providers of health and support services. These early intervention services are now eligible for all Titles under the Ryan White CARE Act.

**6. Can grantees receive Technical Assistance (T/A) to implement this policy?**

Grantees should discuss any outreach services T/A needs with their Project Officer who can provide technical T/A directly or determine if additional T/A is needed from other HRSA/HAB sources. The outreach plan must meet CARE Act legislative requirements and HRSA/HAB policy and guidance.

**7. If I wanted to launch an outreach activity targeting persons with HIV who may or may not know their status and are not in care, what should I take into account in my program and other area providers?**

CARE Act funds should be used for outreach services that are carefully planned by grantees to bring persons with HIV into care. The implementation of this policy is intended to ensure grantees carefully consider their outreach strategy before implementing any outreach services. In planning a potential outreach activity, the grantee should take into consideration the capacity of their programs to handle the estimated or increase in new clients. Grantees and providers are responsible for developing plans in coordination with other programs such that these programs know of the grantees effort to launch an outreach activity.



**SERVICE CAPS/LIMITS\* AND ELIGIBILITY**

Currently Funded Service Category	Cap/limit	Eligibility Criteria
	All limits are established per client per contract year beginning with the '07 program year unless otherwise indicated	
Food Bank Supplements      Nutritional	No cap/limit established	HIV+, proof of residency, proof of income, income <150% Federal Poverty level (FPL) which includes a provision for waiver when required.
Transportation	No cap/limit established	HIV+, proof of residency, proof of income, income <400% Federal Poverty level (FPL)
Substance Abuse	No cap/limit established	HIV+, proof of residency, proof of income, income <400% Federal Poverty level (FPL)
Mental Health	No cap/limit established	HIV+, proof of residency, proof of income, income <400% Federal Poverty level (FPL)
Drug Reimbursement	No cap/limit established No coverage is provided for over-the-counter medications except diabetic supplies	HIV+, proof of residency, proof of income, income <400% Federal Poverty level (FPL)
Health Insurance	Enrolled clients receive up to \$175 per month for co-pays and up to \$400 per month for COBRA, group and individual insurance premium payments	HIV+, proof of residency, proof of income, income <400% Federal Poverty level (FPL)
Oral Health	\$2000 Covered services are limited to: exams, x-rays, fillings, extractions, cleanings (prophylaxis, scaling and root planing, gross debridement), dentures (partial or full) and oral health instruction.	HIV+, proof of residency, proof of income, income <400% Federal Poverty level (FPL) Grantee considers exceptions on a case by case basis only if medically necessary
Primary Care  Patient Education/ Treatment Adherence*	No limit on office visits or labs No more than 25% of total primary care contract may be used for patient education	HIV+, proof of residency, proof of income, income <400% Federal Poverty level (FPL) Babies born to HIV+ mothers (Pediatric indeterminate) may be served until 2 years of age. Must be receiving primary care from a Ryan White funded provider.
Treatment Adherence	No cap/limit established	Available only to Minority AIDS Initiative (MAI) clients HIV+, proof of residency, proof of income, income <400% Federal Poverty level (FPL)
Case Management	\$2400	HIV+, proof of residency, proof of income, income <400% Federal Poverty level (FPL) Grantee considers exceptions on a case by case basis
Case Management (non-medical)	No cap/limit established	HIV+, proof of residency, proof of income, income <400% Federal Poverty level (FPL) State Eligibility Rule 64D allows a one-time exception.

\*The Care Council designated pregnant women, infants, children and adolescents as special populations and does not include them in the service cap for primary care patient education (revision 3/7/07)

It is the Provider's responsibility to respond flexibly to a changing environment as long as they do not exceed the cap established for a particular service. (revision 9/2/09)

Approved 9/6/06  
Revised 6/1/11



MAY 13 2003

Reauthorization - Unmet Need

Dear Title I and II Colleagues:

The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, Public Law 106-345, re-authorized amendments of 2000 contains multiple provisions focused on enhancing access to primary care for persons living with HIV disease *who are not in care*. These new provisions also include enhancements to your needs assessment requirements.

The amendment also directs the Secretary to develop epidemiologic measures "for establishing the number of individuals living with HIV disease who are not receiving HIV-related health services." This is particularly important to the Centers for Disease Controls (CDC) new initiative regarding prevention of new infections from, people living with HIV (PLWH).

The following outlines the Health Resources and Services Administrations (HRSA), HIV/AIDS Bureau (HAB) expectations of Title I and Title II Grantees reporting the estimated number of individuals in your jurisdictions for Fiscal Years (FY) 2004 and 2005 Grant applications.

Assessing unmet needs of individuals who know their HIV status but who are not in care is part of your overall comprehensive needs assessment conducted in each of your service areas. It will require you and your Planning Councils to engage in the challenging and time-consuming process of *finding and determining the needs and service gaps* of PLWH who are not receiving primary health care.

To assist you in fulfilling your reporting requirements we have developed the following guidelines:

- HAB contracted the University of California San Francisco (UCSF) to create an Unmet Need Framework to determine unmet need for persons who know their HIV status but are not receiving primary medical care.
- A joint HRSA, CDC project titled: *Integrated Guidelines for Developing Epidemiologic Profiles*, has been completed and will be available this summer. The purpose of the collaborative is to streamline the epidemiologic-profile process for both prevention and care.

- The HAB Needs Assessment Guide has been revised and includes an Unmet Need section that can be found at <http://hab.hrsa.gov/tools/needs/>
- The HAB All Titles Meeting held in August 2002 featured an Unmet Need Institute, provided updated information on unmet need, the Unmet Need Framework, and examples from Grantees using the model.

The FY05 Title I and Title II Grant Application Guidances instructs all Grantees to implement the Unmet Need Framework method to determine unmet need for primary health care *with their reporting results*. Attached is your *Practical Guide* outlining the steps in the framework method. In FY04 no points will be applied to this section because you are asked to give your best efforts in reporting your implementation measures. During FY04 each Grantee has an opportunity to report challenges and technical assistance needs in completing the methodology to prepare you to be in full compliance in FY05 when all Title I and Title II Grantees will be required to report their estimate on unmet need *for primary health care* by State and EMA using the Unmet Need Framework methodology.

To assist you in implementing these requirements we are providing the following technical assistance:

- HAB has a new contract with UCSF to conduct a survey of all Title I and Title II Grantees to determine their level of readiness to implement the Unmet Need Framework. Completion date: July 2003
- A National Technical Assistance Conference Call on Unmet Need Determination. is scheduled for June 24, 2003
- A Title I, Title II Joint Conference call on Unmet Need is scheduled for July 8, 2003
- Grantee Meetings. HAB will conduct two Grantee meetings to provide technical assistance to Grantees on the Unmet Need Framework scheduled for July-August 2003
- On site technical assistance. On site technical assistance will be available on unmet need determination for those Grantees requiring additional assistance. Completion date: Fall 2003
- Revision of the "unmet need" chapter in the Needs Assessment Guide. This will outline a process for quantifying unmet need using the Unmet Need Framework methodology. Completion date: June 2003
- HAB Project Officer Training. Project Officer Training will occur internally on unmet need determination is scheduled for May 2003

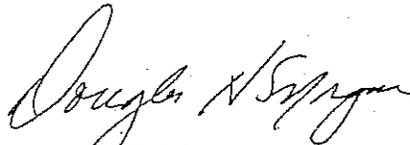
Page 3 - Title I & Title II, UnMet Need re-authorization

Finally, please find attached the UCSF Final Report: "Measuring Unmet Need, A Practical Guide for HIV Primary Medical Care for Ryan White Title I and II CARE Act Grantees, Planning Councils, and Consortia." This guide describes in detail how to use the framework to estimate how many HIV+ aware individuals in a jurisdiction are "in" or "out" of HIV primary medical care.

I want to continue to express my appreciation for the hard work and commitment that has been demonstrated over the years in our States and EMAs to improving the lives of persons living with HIV/AIDS.

If you have any questions regarding unmet need determination requirements, please contact your Project Officer.

Sincerely,



Douglas H. Morgan, M.P.A.  
Director,  
Division of Service Systems

Enclosure: UCSF Final Report: *Measuring Unmet Need: A Practical Guide for HIV Primary Medical Care for Ryan White Title I and Title II CARE Act Grantees, Planning Councils, and Consortia.*

cc: Title I Planning Council Chairs

**A Practical Guide to Measuring Unmet Need for HIV-  
Related Primary Medical Care:  
Using the Unmet Need Framework**

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May 2003

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# I. Introduction

## A. Purpose of the Guide

This Guide was prepared to help CARE Act grantees and planning bodies, particularly Title I and Title II jurisdictions, estimate the number of individuals in your jurisdiction who know they are HIV-positive but are not receiving regular HIV-related primary medical care. The University of California at San Francisco (UCSF) has developed a practical framework you can use to develop a quantitative estimate of unmet need. This Guide explains the reasons you need to estimate unmet need, describes the Unmet Need Framework, and provides practical steps and examples to help you use it in your State or eligible metropolitan area (EMA). The first two sections will help you understand the Unmet Need Framework and why it is important. The other sections will guide you through using it to estimate unmet need in your jurisdiction.

## B. Background

The first of the four fundamental principles guiding the HIV/AIDS Bureau (HAB) of the Health Resources and Services Administration (HRSA) is: “to better serve the underserved in response to the HIV/AIDS epidemic’s growing impact among underserved minority and hard-to-reach populations.”

In keeping with this principle, jurisdictions need to assess the shifting demographics of new HIV/AIDS cases throughout the State, territory, or EMA. This helps in adapting care systems to respond to needs of emerging communities and populations. Jurisdictions also need to pay particular attention to identifying people living with HIV (PLWH) who know their status but are not receiving regular HIV-related primary health care (people who are “not in care”). This is the first step towards ensuring that they obtain primary medical care and supportive services, through CARE Act programs or other sources.

This focus on people living with HIV (PLWH) who know their status but are not in care has a legislative basis. The 2000 Amendments to the CARE Act require each Title I and Title II program to:

- “determine the size and demographics of the population of individuals with HIV disease,” and to
- “determine the needs of such populations, with particular attention to both individuals with HIV disease who know their HIV status and are not receiving HIV-related services” and “disparities in access and services among affected subpopulations and historically underserved communities.”

The Amendments also require HRSA/HAB to prepare State and national estimates of unmet need—the number of individuals who know their status but are not in care—as input to Congress about the need for continued appropriations for HIV/AIDS treatment. More specific information about unmet need (*e.g.*, geographic areas and populations most affected) also guides national planning and resource allocations, including discretionary grant funds for capacity development.

The legislation requires estimation of the number of individuals who know their HIV status, not the total number of individuals who are HIV-positive (true prevalence). While the CARE Act supports outreach and counseling and testing to encourage people who are at risk to get tested, its focus is on ensuring care for those who know they are HIV-positive.

### C. Definitions

HRSA/HAB has developed the following definitions related to unmet need. The most important definitions are summarized in the box. These definitions are used throughout the Guide.

#### Definitions Related to Unmet Need

Following are HRSA/HAB definitions:

- **Unmet Need for Health Services** (also referred to as **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 regular primary health care.
- **Primary medical care** is medical evaluation and clinical care that is consistent with U.S. Public Health Service guidelines for the treatment of HIV/AIDS. Such care must include access to anti-retrovirals and other drug therapies, including prophylaxis and treatment of opportunistic infections and combination antiretroviral therapies
- **Other primary health care** includes HIV-related health services other than primary medical care – oral health care, outpatient mental health care, outpatient substance abuse treatment, nutritional services; and specialty medical care referrals.
- **Non-medical supportive services** are other services that contribute to PLWH accessing and remaining in primary medical care.
- **In care:** A person is considered to be **in care** when s/he is receiving regular primary HIV-related medical care (clinical evaluation and clinical care). This medical care should meet U.S. Public Health Service guidelines for the treatment of HIV/AIDS
- **Service gaps** are *all* service needs for *all* PLWH except primary health services for those who know their status and are not in care. The term **unmet need** is used only to describe the unmet need for HIV-related primary health care.

The Unmet Need Framework has operational definitions for **unmet and met need for HIV primary medical care**. These definitions are used in estimating met and unmet need in your jurisdiction.

- An individual with HIV or AIDS is considered to have an **unmet need for care** (or to be **out of care**) when there is no evidence that s/he received any of the following three components of HIV primary medical care during a defined 12-month time frame: (1) viral load (VL) testing, (2) CD4 count, or (3) provision of anti-retroviral therapy (ART).
- A person is considered to have **met need** (or to be **in care**) when there is evidence of any one or more of these three measures during the specified 12-month time frame.

## D. The Framework

HRSA/HAB supports ongoing efforts to develop methods to assist States and EMAs in assessing unmet need. This framework is the result of one of those initiatives. CARE Act grantees and planning bodies can use the framework to estimate how many PLWH who know their status (HIV+/aware individuals) in a jurisdiction are “in” and “out” of HIV primary medical care. Those who are “out of care” constitute your jurisdiction’s estimate of unmet need.

The framework is logical and straightforward. It requires you to obtain data on (1) the total number of people in your jurisdiction who are HIV+/aware (those diagnosed with HIV or AIDS), and (2) the number of people who are “in care,” using the framework’s operational definitions of “in” and “out” of care. By subtracting those in care from the total number of people who are HIV+/aware, you will obtain an estimate of the number of people who know they are HIV-positive and are not in care – those with an unmet need for primary medical care. In other words, you assume that those individuals you cannot identify as “in care” are “out of care.”

The Unmet Need Framework uses data on the number of people in your jurisdiction who are HIV+/aware and not the total number of people with HIV or AIDS (true HIV prevalence). This is consistent with CARE Act Amendments. In addition, an individual must have an HIV diagnosis before receiving HIV primary medical care,

Because care needs and patterns are generally quite different depending on disease progression, the framework distinguishes between individuals who have been diagnosed with AIDS (PLWA) and those who have not been diagnosed with AIDS (PLWH non-AIDS/aware). You will notice that the PLWA term does not require an additional “aware” or “unaware” designation, since all people diagnosed with AIDS are presumed to be aware of their HIV and AIDS status.

The framework will be useful in creating estimates of unmet need unless a jurisdiction has neither existing data sources nor the resources to collect new data. Review the remainder of this Guide. *If, after reviewing it, you decide that your jurisdiction does not have the expertise needed to evaluate the ability to use and/or collect data (e.g., using locally available epidemiologists or health planners), please request technical assistance through your HRSA/HAB Project Officer.*

## II. Understanding the Unmet Need Framework

### A. Operational Definitions

The Unmet Need Framework starts with basic operational definitions of “unmet” and “met” need for HIV primary medical care. These basic definitions meet minimum HRSA/HAB requirements and provide your jurisdiction with a set of measures you can use in estimating unmet need. These are the definitions:

- **Unmet Need for HIV Primary Medical Care** is defined as no evidence of any of the following three components of HIV primary medical care during a specified 12-month

time frame: (1) viral load (VL) testing, (2) CD4 count, or (3) provision of anti-retroviral therapy (ART).

- **Met Need for HIV Primary Medical Care** is defined as evidence of any one or more of these three measures during a specified 12-month time frame.

If desired, jurisdictions can expand the definition of “met” and “unmet” need. For example, you might want to include additional HIV-related services in your definition. However, the basic definition meets minimum HRSA/HAB requirements for an operational definition of the unmet need for HIV primary medical care. As explained in the definitions box, unmet need is different from “service gaps,” which encompass the supportive services that PLWH may also need.

In order to help HRSA/HAB compare or aggregate data across jurisdictions, you should use the basic definition in addition to any expanded definitions when you estimate unmet need using the framework.

## **B. Data Inputs and Sources**

The Unmet Need Framework uses two types of inputs:

1. **Population Size**
2. **Care Patterns**

In order to measure unmet need for HIV primary medical care using the basic operational definition, you must first determine the Population Size inputs and Care Patterns inputs for a particular geographic area—whether a State, an EMA, or another area such as a county, region, or Public Health Service Area. Jurisdictions usually have a number of potential sources of data for both Population Size and Care Patterns.

### **1. Population Size**

Population Size is the number of people diagnosed with HIV disease (HIV+/aware) living in the jurisdiction during a particular time period. This includes two separate data inputs:

- a. **Number of people Living with AIDS (PLWA)**
- b. **Number of People Living with HIV non-AIDS who are aware of their status (PLWH non-AIDS/aware)**

Note that combining (a) and (b) results in the total number of HIV+/aware individuals. You may choose to use totals for the numbers of people living during a particular *year* or numbers of people diagnosed and living as of a particular *date*.

These data come mainly from AIDS and HIV reporting, primarily from the HIV/AIDS Reporting System (HARS) managed by the CDC.

- a. **Number of People Living with AIDS (PLWA):** This information is available in all jurisdictions. Since AIDS cases are reported in all States, jurisdiction-specific AIDS data from HARS are available through local or State surveillance departments.
- b. **Number of People Diagnosed and Living with HIV/non-AIDS (PLWH non-AIDS/aware):** In jurisdictions with name- and/or code-based HIV reporting, this input will also come from local or State HARS data. In jurisdictions without HIV reporting, or where HIV data are not yet usable because of recent implementation of HIV reporting, you have two other data options:
  - **Midpoint of CDC estimate:** The Centers for Disease Control and Prevention (CDC) and HRSA/HAB periodically work together to provide an estimate of the number of people who have been diagnosed with HIV in each EMA and State without fully implemented HIV reporting. The midpoint of that estimate is a convenient source for this input. The benefit of this data source is that it is available for all States and EMAs. The limitation is that the estimates are not updated every year.
  - **Alternative estimates:** Jurisdictions with the capacity to create methodologically sound models for calculating the number of HIV+/aware individuals may choose to use their own estimates.

## 2. Care Patterns

Care Patterns are measures of how many HIV+/aware persons are receiving HIV primary medical care from any provider (not just Ryan White care providers). Like Population Size, this requires two separate inputs

- a. **Percent (or number) of PLWA in care** – individuals with AIDS who meet the operational definition of met need for primary medical care
- b. **Percent (or number) of PLWH non-AIDS/aware in care** – individuals with HIV disease who know their status and meet the operational definition of met need for primary medical care

Total count methods will provide data in numbers, while methods based on sampling will typically provide data in a percentage format.

Whenever possible, you should separate care pattern data or estimates for those with advanced HIV disease (AIDS) from estimates for PLWH non-AIDS/aware. This is because care patterns differ substantially by severity of illness. Data can be separated by whether the individual has ever been diagnosed with AIDS or by lowest CD4 count.

Data providing the percent or number of HIV+/aware (AIDS and non-AIDS) meeting primary medical care definition generally come from three major data sources:

- **HIV/AIDS related surveillance data** (CD4 and viral load reporting)

- **Linked utilization databases** (from CARE Act client-based data systems and claims databases such as Medicaid and the AIDS Drug Assistance Program or ADAP)
- **Special studies** (e.g., Adult Spectrum of Disease or ASD, or studies done within a specific jurisdiction)

**a. HIV/AIDS-Related Surveillance Data**

In jurisdictions with mandatory viral load and CD4 reporting, you can use surveillance data for the care inputs. The advantage in using this data source is that reporting applies to all sources of care. This is a simple method for ensuring the inclusion of information that is sometimes difficult to obtain from other sources, such as number of people receiving privately provided care (e.g., care obtained from private physicians or health maintenance organizations, typically funded by private health insurance).

The value of surveillance reporting data depends on both what is mandated in a given jurisdiction and how those mandates are implemented. For example, laboratory reporting provides better estimates for fulfilling the definition of HIV primary medical care than does provider-based reporting. Laboratory reporting is more comprehensive. This is true because typically a limited number of laboratories are used by all HIV-testing and monitoring providers and the laboratories overall tend to be timelier and more complete in their reporting practices than individual health care providers.

Jurisdictions where HIV surveillance requires that all CD4 and viral load tests be reported will find their data more useful than jurisdictions that use an initial CD4 and/or viral load report only to confirm an HIV diagnosis, but require no further reporting. Some States require reporting of CD4 counts at 500 or below, while others require reporting at 200 or below.

Because surveillance is generally based on where an individual was diagnosed (as opposed to where they live or actually receive their care), jurisdictions that are concerned with migration issues may choose to make adjustments to the surveillance data based on estimates of in- and out-migration. Currently, the rules and implementation vary widely by State. Thus, each jurisdiction must evaluate the usefulness of surveillance data in the context of local and State factors.

**b. Linked Utilization Data**

You can also obtain measures of patterns of HIV primary medical care by linking billing or service information included in various client-level databases, using adequate measures to protect confidentiality (a non-identifying unique identifier or soundex code,<sup>1</sup> for example). In many jurisdictions, combining data from CARE Act (ideally Titles I-IV providers), Medicaid, and the Department of Veterans Affairs will cover the largest sources of HIV primary medical care in the jurisdiction.

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<sup>1</sup> A soundex code is a coded last name index based on the way a surname sounds rather than the way it is spelled. It is a census coding system developed so you can find a surname even if it may have been recorded under various spellings. A soundex code consists of a letter and three numbers.

The text in this section provides a more detailed description of some of the issues presented in abbreviated format in Table 1. In addition, sources marked with an asterisk (\*) have an expanded description in the CDC/HRSA *Integrated Guidelines for Developing Epidemiologic Profiles*. Please contact your HRSA/HAB Project Officer for more information.

### C. Setting Up the Framework

The table below (Table 1) shows you how the data described above are put into the table and used to calculate unmet need. Later sections of the Guide provide examples and specific guidance in using the framework.

**Table 1: Setting Up the Framework**

Input	Value	Data Source
<b>Population Sizes</b>		
A. Number of persons living with AIDS (PLWA), recent time period		
B. Number of persons living with HIV (PLWH non-AIDS/aware), recent time period		
<b>Care Patterns</b>		
C. Number/percent of PLWA who received the specified primary medical care services in 12-month period		
D. Number/percent of PLWH (aware, non-AIDS) who received the specified primary medical care services in 12-month period		
<b>Calculated Results</b>		
E. Number of PLWA who did not receive primary medical services		
F. Number of PLWH (non-AIDS, aware) who did not receive primary medical services.		
G. Total HIV+/aware not receiving specified primary medical care services (quantified estimate of unmet need)		

**Table 2 – Potential Data Sources and Utility within Framework**  
 Sources with an asterisk (\*) have expanded descriptions in CDC/HRSA Integrated Guidelines for Epidemiologic Profiles

Data Source	Content	Timing	# Sites	Utility for Unmet Need Framework
AIDS Surveillance*	All persons who have met the 1993 CDC AIDS surveillance case definition	AIDS Diagnosis	All	<b>Population Input: PLWA.</b> Very good as is. Jurisdiction may choose to adjust for migration if data are available.
HIV Surveillance*	All persons who test HIV-positive and are reported to the surveillance system	HIV Diagnosis	All except GA	<b>Population Input: PLWH non-AIDS/aware.</b> Very good if surveillance system long-established. Some testing (e.g. anonymous) not reported, and some surveillance too recently implemented to reflect all HIV+/aware.
HARS - CD4 reporting	Mostly CD4 < 200	HIV and/or AIDS	>27	<b>Care Input:</b> Useful for PLWA where reporting is required for all CD4 counts <200, and for PLWA and PLWH non-AIDS/aware where reporting is required for all tests or all counts < 500. Underestimate if omits CD4 counts above certain level. Completeness of reporting also an issue, especially if non-lab based.
HARS - Viral load reporting	Where reported, may be all, last, or confirmatory for HIV only	HIV/AIDS	Unknown	<b>Care Input: PLWA and PLWH/non-AIDS/aware,</b> where reporting is required for all viral load counts or where last count is tracked. Where HIV confirmatory only, information already should be captured in population inputs from surveillance, but will not be useful as a Care Input.
NEDSS (designed to replace HARS) National Electronic Disease Surveillance System	HARS, SHAS, ASD, more; will allow tracking of multiple CD4 & viral load counts	HIV/AIDS	n/a	<b>Care Input: PLWA and PLWH non-AIDS/aware.</b> Once implemented, will be an excellent data source in locations tracking multiple CD4 and viral load counts.

**Table 2 – Potential Data Sources and Utility within Framework**

Sources with an asterisk (\*) have expanded descriptions in CDC/HRSA Integrated Guidelines for Epidemiologic Profiles

Data Source	Content	Timing	# Sites	Utility for Unmet Need Framework
SHAS* Supplement to HIV/AIDS Surveillance	12-month lookback from HARS entry	HIV and/or AIDS	21	Care Input: Depending on site, representative data for either PLWA or both PLWA and PLWH non-AIDS/aware, (or) non-representative data with a potential for linking or statistical manipulation. Completeness and interview assessment time frame can be issues.
APS* AIDS Progression Study	12-month medical records lookback from AIDS diagnosis	HIV	6	Care Input: Representative data for PLWH non-AIDS/aware, assuming completeness of medical records.
ASD* Adult/adolescent Spectrum of Disease Study	Longitudinal medical record reviews of a cohort of HIV+/aware	HIV/AIDS	11	Care Input: Depending on site, representative data or non-representative data (with potential for linking or statistical manipulation) for both PLWA and PLWH/non-AIDS. Completeness of medical records can be an issue.
PSD* Pediatric Spectrum of Disease Study	Longitudinal medical record reviews of a cohort of HIV+ and HIV-exposed children	HIV/AIDS	8	Care Input: Depending on site, representative data or non-representative data (with potential for linking or statistical manipulation) for both PLWA and PLWH non-AIDS/aware. Completeness of medical records can be an issue.
HERS* HIV Epidemiology Research Study	Longitudinal interviews/med exams and abstractions of a cohort of HIV+ women aged 16-55	HIV/AIDS	4	Care Input: Non-representative data (with potential for linking or statistical manipulation) for both PLWA and PLWH/non-AIDS.
SHDC* Survey of HIV Disease & Care	Medical chart abstraction from representative sample of HARS reports	HIV and /or AIDS	12	Care Input: Representative data for either PLWA or both PLWA and PLWH non-AIDS/aware. Completeness of medical records can be an issue.

**Table 2 – Potential Data Sources and Utility within Framework**  
 Sources with an asterisk (\*) have expanded descriptions in CDC/HRSA Integrated Guidelines for Epidemiologic Profiles

Data Source	Content	Timing	# Sites	Utility for Unmet Need Framework
<p>HCUP Healthcare Cost &amp; Utilization Project</p>	<p>State-specific hospital- discharge databases and a national sample of discharges from community hospitals</p>	<p>HIV/AIDS</p>	<p>29</p>	<p><b>Care Input:</b> Insurance data from hospitalizations. Depending on site, representative data or non- representative data (with potential for linking or statistical manipulation) for both <b>PLWA</b> and <b>PLWH non-AIDS/aware</b>. Completeness of medical records can be an issue.</p>
<p>Medicaid</p>	<p>Data systems vary by state and within some states, there is variation by managed care vs. fee-for- service</p>	<p>HIV and/or AIDS</p>	<p>All</p>	<p><b>Care Input:</b> Non-representative data (with potential for linking or statistical manipulation) for both <b>PLWA</b> and <b>PLWH non-AIDS/aware</b>.</p>
<p>Medicare</p>	<p>Data systems vary by state and within some states, there is variation by managed care vs. fee-for- service</p>	<p>HIV and/or AIDS</p>	<p>All</p>	<p><b>Care Input:</b> Non-representative data (with potential for linking or statistical manipulation) for both <b>PLWA</b> and <b>PLWH non-AIDS/aware</b>.</p>
<p>ADAP AIDS Drug Assistance Program</p>	<p>Data systems vary by state</p>	<p>HIV/AIDS</p>	<p>All</p>	<p><b>Care Input:</b> Non-representative data (with potential for linking or statistical manipulation) for both <b>PLWA</b> and <b>PLWH non-AIDS/aware</b>.</p>
<p>VA Veterans Affairs</p>	<p>Database (Immunology Case Registry) automatically abstracts demographic and clinical data</p>	<p>HIV/AIDS</p>	<p>All</p>	<p><b>Care Input:</b> Non-representative data (with potential for linking or statistical manipulation) for both <b>PLWA</b> and <b>PLWH non-AIDS/aware</b>.</p>

### III. The Unmet Need Estimation Process: Six Steps

The following six steps will help your Title I or Title II jurisdiction develop a quantitative estimate of the unmet need for HIV primary medical care among HIV+/aware individuals in your service area. The process assumes you will use the Unmet Need Framework described in this Guide as a way to organize and interpret State and local data. However, a similar process could be used to implement other models for estimating unmet need.

#### Step 1: Review your objectives for estimating unmet need.

Before you begin to estimate unmet need, be sure you agree on the purpose and specific objectives of your effort. A principal objective should be the creation of a quantitative estimate of unmet need for HIV primary medical care in your jurisdiction. Other objectives might include the following:

- To generate data that will inform planning and decision making to respond to unmet need
- To obtain data that let us track our progress in reducing unmet need over time
- To be able to link these data to other indicators of unmet need to obtain a more complete understanding of unmet need
- To meet CARE Act legislative requirements and HRSA/HAB expectations related to estimating unmet need

Be sure to review CARE Act guidelines and data requirements within applicable sections of the Title I and II applications as you develop your objectives. This will help you understand HRSA/HAB expectations regarding estimating unmet need. It will also help you identify possible uses of the data in planning and decision making.

#### Step 2: Review and select among options for estimating unmet need.

To decide how you will go about estimating unmet need, read HRSA technical assistance materials, such as the rest of this *Guide* and the following:

- The Ryan White CARE Act *Needs Assessment Guide* (the 2003 version can be downloaded from the HRSA website at [www.hrsa.gov](http://www.hrsa.gov)).
- The CDC/HRSA *Integrated Guidelines for Developing Epidemiological Profiles* (available on the HRSA website in 2003).

If you decide to use the Unmet Need Framework described in this Guide, you will need to investigate potential data sources for the Population Size and Care Patterns inputs. Data on Care Patterns are likely to be especially important and perhaps challenging to identify. Invite collaborators, such as data managers from State HIV/AIDS surveillance and Medicaid departments, to help you assess currently and potentially available data sources. Assess technical, personnel, and financial resources, outline options, and choose the best option—keeping in mind that the best short- and long-term strategies for estimating unmet need may differ. Since you are

likely to need to estimate unmet need regularly, it makes sense to identify a framework and a set of data sources that you can continue to use in future years. This enables you to improve your estimates with experience and to be able to compare levels of unmet need over time.

When you meet with potential collaborators in the unmet need estimation process, discuss not only data availability but also capacity – including both technical skills and time and other resources – to do data handling or special studies. For example, suppose you decide to use linked databases including your CARE Act client-level database, Medicaid data, and Veterans Affairs data. You will need a team with the skills and resources to link and “unduplicate” the data using a soundex code or other unique identifier, to ensure that individuals are not double-counted. If you decide to conduct a special study such as records review of a sample of PLWH, you will need to arrange for the necessary resources.

During this period, you need to decide whether your focus will be a single-number estimate of unmet need, or whether you want to go beyond this basic analysis and look at other services, population subgroups, or specific geographic areas. This requires consideration of data availability, technical expertise, and resources.

Your intent during this step is to understand different approaches and data sources available in your jurisdiction for estimating unmet need, and to choose those most appropriate for your situation. You will also want to decide on a planned level and scope of analysis using these data.

### **Step 3: Develop your work plan.**

Once you have agreed on objectives and decided what approaches and data sources to use, you are ready to develop a work plan to guide the entire process. The work plan typically includes the following tasks:

- Select and refine the team who will participate in your process. The team should generally be both internal and external, including data specialists and planners from within the CARE Act system as well as individuals with access to other major data sources and/or researchers who can assist with analyses and special studies.
- Agree on your technical strategy.
- Agree on the responsibilities the grantee and all team members in helping to implement that strategy.
- Estimate the effort required of each team member for all planned tasks and be sure all team members are prepared to provide that level of effort.
- Develop a timeline with benchmarks to guide your work. Give yourselves enough time to complete the work, but not so much that the process drags on and loses momentum.
- Seek technical assistance as needed through local expertise and your HRSA/HAB Project Officer.

#### Step 4: Implement the work plan.

Now bring your team together to implement your work plan. As you work, regularly reassess and refine your technical strategy as logistic challenges and opportunities become clearer. Be sure team members meet regularly to review progress and challenges. Periodically report back to the planning body(ies) in your jurisdiction. As you insert data into the Unmet Need Framework, review, document, and refine your data inputs. Again, seek technical assistance through local expertise and your HRSA/HAB Project Officer as needed.

#### Step 5: Prepare a report on estimating unmet need for HIV primary medical care.

Once your estimates are complete, prepare a report that presents those estimates, how you obtained them, and any constraints or limitations. Include background information on the options discussed and the reasons for choosing the particular strategy and data sources used. Explain methods. If you did special studies, be explicit about data sources, definitions, and methodology, including sample size and recruitment activities as applicable, data collected, analyses, and results. If you were able to go beyond the minimum analysis and look at other services, population subgroups, or specific geographic areas, present both overall unmet need (i.e., single estimate) and the additional results. Discuss the implications of the estimate for your jurisdiction's efforts to meet unmet need. Present lessons for future unmet need estimates as well as needs assessments.

#### Step 6: Disseminate the information.

Distribute your report broadly. Begin with team members and your own planning body(ies). Also disseminate the report to HIV care providers including non-Ryan White providers, the HIV prevention community planning group, community members, and elected officials. Make the report available electronically. Present results and implications in venues that allow community members and providers to ask questions and better understand the results. Present findings in your CARE Act applications, incorporate results into your decision making about service priorities and resource allocations, your needs assessment, and your comprehensive plan – and continue working to reduce unmet need.

### **IV. Setting Up and Using the Unmet Need Framework in Different Jurisdictions: Some Examples of Data Sources**

This section provides examples to help you see how other jurisdictions have set up and used the Unmet Need Framework, using data sources available in their jurisdictions.

Table 3 provides some examples of how four jurisdictions set up an Unmet Need Framework, based on the data sources available for the Population Size and Care Patterns inputs. This table is based on actual field-testing of the framework in States and EMAs, although the numbers provided in the table are for illustration only.

## A. Population Size Data Input Examples

All four jurisdictions in the chart are using surveillance data from their HARS to calculate the number of PLWA. Jurisdictions 3 and 4 are HIV-reporting States and are also using their HARS data to calculate PLWH non-AIDS/aware. Jurisdictions 1 and 2 do not yet have HIV reporting. To calculate PLWH non-AIDS/aware, Jurisdiction 1 is using CDC's midpoint estimate for its geographic location, while Jurisdiction 2 is using modeled estimates created within its own HIV/AIDS surveillance and epidemiology department.

**Table 3: Setting Up and Using the Framework in Different Jurisdictions**

	Jurisdiction 1	Jurisdiction 2	Jurisdiction 3	Jurisdiction 4
<b>Population Size:</b>				
A. Number of persons living with AIDS (PLWA), recent time period	HARS	HARS	HARS	HARS
B. Number of persons living with HIV (PLWH non-AIDS/aware), recent time period	CDC midpoint estimate	Estimates based on local modeling	HARS (HIV-reporting State)	HARS (HIV-reporting State)
<b>Care Patterns:</b>				
C. Percent of PLWA who received the specified primary medical care services in a 12-month period	Chart review of all PLWA (or representative sample)	Linked claims databases + private care	Demonstration of viral load, CD4, or ART in ASD	CD4/viral load reporting in HARS
D. Percent of PLWH non-AIDS/aware who received the specified primary medical care services in a 12-month period	AIDS progression study	Linked claims databases + private care	Demonstration of viral load, CD4, or ART in ASD	CD4/viral load reporting in HARS

## B. Care Patterns Data Input Examples

Each jurisdiction is using different data sources for Care Patterns inputs, as explained below.

**Jurisdiction 1:** This jurisdiction already conducts extensive chart reviews of all PLWA, including viral load, CD4, and ART information. Since the same information does not exist for individuals who are PLWH non-AIDS/aware, the jurisdiction uses data from its AIDS progression study, which is an interview conducted with people upon AIDS diagnosis. This information is not a care input for people living with AIDS, because the interview includes questions on whether or not the individual received different types of primary care services in the 12 months prior to her/his AIDS diagnosis (i.e., while s/he was still HIV+/non-AIDS).

**Jurisdiction 2:** In this example, the jurisdiction is using its client-level database of CARE Act services, since this particular jurisdiction pays for viral load testing, CD4 counts, and the provision of ART through its ADAP program. Through agreement among State agencies, the jurisdiction is able to link Ryan White CARE Act and Medicaid data using a unique identifier to protect the confidentiality of client-level data. Through a formal agreement with the Department of Veterans Affairs, and by using the same unique identifier, the jurisdiction is also able to link Veterans Affairs HIV primary medical care data. The estimate for how many HIV+/aware individuals are receiving their HIV primary medical care through private sources alone will come from an existing study of local hospital discharge data.

**Jurisdiction 3:** In this example, the jurisdiction uses its CDC-funded Adult Spectrum of Disease (ASD) study to calculate numbers of people who meet the basic definition for HIV primary medical care and are in care at an ASD facility. It is also using a match between ASD and HARS data to estimate how many individuals are at an ASD or non-ASD care site.

**Jurisdiction 4:** Since this jurisdiction has mandatory reporting of viral load and CD4 counts, it uses surveillance data for both population and care inputs. The strength of this data source is that it will include these particular primary care measures for all HIV primary medical care sources. In some jurisdictions, it may include the actual lab counts. It may or may not include up-to-date information on anti-retroviral therapy, but if a jurisdiction is reasonably confident that anyone being prescribed ART would also be receiving viral load testing and/or CD4 counts within the time frame of interest, then this may not be a problem.

## V. Calculating Unmet Need Estimates

Once you have identified and where necessary linked or combined data sources, you are ready to begin calculating unmet need estimates for your jurisdiction. Tables 4 and 5 demonstrate how unmet need estimates can be calculated, depending on the population and care inputs used. The tables provide examples from two different sample jurisdictions. Both these examples demonstrate a single-number unmet need estimate.

These examples assume some familiarity with databases, methods of linking multiple databases, and HIV/AIDS surveillance data sets. Review them with data specialists from your health department or planning body. If you have no one available who is familiar with these databases or methods, contact your HRSA/HAB Project Officer for technical assistance.

These examples show how you can generate an overall estimate of the number of HIV+/aware individuals in your jurisdiction who are not in care. This meets the minimum requirement of a quantitative estimate. However, in order to make the information as useful as possible for planning and decision making, you will want additional information about the characteristics of individuals who are not in care. Where you have the necessary data, you should do further analysis of sociodemographic variables, including gender, age, and race/ethnicity for both Population Size and Care Patterns data in order to compare levels of met and unmet need

among different subpopulations. You may also want to look at data by geographic area, since outreach to identify such individuals will need to be geographically focused.

Table 4: Unmet Need Calculations: Jurisdiction 1, Example Data Sources

Input	Value	Data Source
<b>Population Sizes</b>		
A. Number of persons living with AIDS (PLWA), recent time period (as of 12/01)	7,812	Local AIDS Reporting System. Counts for the 20 County EMA in year 2001.
B. Number of persons living with HIV (PLWH, non-AIDS) and aware, recent time period (as of 12/01)	7,550	CDC Estimates, midpoint, for 20- county EMA in year 2001.
<b>Care Patterns</b>		
C. Number of PLWA who received the specified primary medical care services in 12-month period	5,032	Linked client data (based on date of birth, race and gender) from Medicaid, VA, and CARE Act databases for year 2001.
D. Number of PLWH (aware, non-AIDS) who received the specified primary medical care services in 12-month period	3,019	Same as above.
E. Percent of PLWH/A who use private care only	15.4%	State inpatient/discharge data from National HCUP project (1998).
<b>Calculated Results</b>	<b>Value</b>	<b>Calculation</b>
F. Number of PLWA who did not receive specified primary medical care services	2,352	$= (A - C) \times (1 - E)$ or $(7812 - 5032) \times (1 - .154)$
G. Number of PLWH (aware, non-AIDS) who did not receive specified primary medical care services	3,833	$= (B - D) \times (1 - E)$ or $(7550 - 3019) \times (1 - .154)$
H. Total HIV+/aware not receiving specified primary medical care services (quantified estimate of unmet need)	6,185	$= F + G$

Table 5: Unmet Need Calculations: Jurisdiction 2, Example Data Sources

Input	Value	Data Source
<b>Population Sizes</b>		
A. Number of persons living with AIDS (PLWA); recent time period	6,682	Jurisdiction-specific surveillance data
B. Number of persons living with HIV (PLWH, non-AIDS) and aware, recent time period	7,000	Midpoint of estimates provided by CDC
<b>Care Patterns</b>		
C. Percent of PLWA who received the specified primary medical care services in 12-month period	72%	CD4 +/-or viral load +/-or ART from HARS-linked chart reviews
D. Percent of PLWH (aware, non-AIDS) who received the specified primary medical care services in 12-month period	47%	CD4 +/-or viral load +/-or ART, retrospective from AIDS progression study, adjusted for sampling bias due to ART effects
<b>Calculated Results</b>	<b>Value</b>	<b>Calculation</b>
E. Number of PLWA who did not receive primary medical services	1,871	= A x (1 - C) or 6,682 x (.28) = 1,871
F. Number of PLWH (non-AIDS, aware) who did not receive primary medical services.	3,710	= B x (1 - D) or 7,000 x (.53) = 3,710
G. Total HIV+/aware not receiving specified primary medical care services (quantified estimate of unmet need)	5,581	= E + F

## VI. Cost of Implementing the Unmet Need Framework

The cost of implementing this framework is mainly a function of the data sources and approach you use in obtaining input data for Population Sizes and Care Patterns. In general, the following ranges apply:

- **Analysis of Existing Data Set:** Field testing suggests that this process requires about two weeks of time for a programmer familiar with the data set, or about \$2,500 - \$3,000. This cost is likely to drop substantially in subsequent years, assuming the same methods are used. The required time will be less since details of data extraction and analysis will not need to be worked out again.
- **Analysis of Utilization Databases:** Analysis of Medicaid and other utilization databases is likely to require 1-2 months of programmer time. Costs can vary widely (e.g., from \$8,000 to \$25,000 or more) depending on the number of databases and whether existing staff can perform this work or outside consultants are required. Costs should be less in subsequent years.
- **Collecting New Data:** Fielding a survey or conducting chart reviews is likely to cost \$25,000 to \$75,000 or more, depending on whether survey instruments already exist, the size of the sample, and whether staff or consultants perform the work. Cost may not drop much in subsequent years.
- **Client-level Databases:** These databases are likely to be used for many purposes (e.g., billing). Establishing such databases may cost hundreds of thousands of dollars or more. The added cost for use in estimating unmet need is likely to be low, similar to that for analysis of an existing data set.

## VII. Enhancing the Basic Definition of Unmet Need

One way to enhance the basic definition of unmet need is by using 6-month in addition to 12-month increments to test whether HIV+/aware individuals received primary medical care. This is consistent with knowledge that PLWH/A receiving appropriate care will be accessing care more than one time a year.

Another way to strengthen the definition is to require at least two separate occurrences of the primary care measures in a particular time period (such as 12 months) for an individual to be counted as "in care." One benefit of using multiple occurrences is that you are then less likely to misinterpret a single event as "in care." For example, this refinement will avoid counting an individual as "in care" because s/he received a CD4 count used to diagnose AIDS but never previously accessed care and did not continue in care after diagnosis.

The basic definition can also be expanded to include other primary care measures and support services, as indicated in the examples below.

- **Definition 1: Unmet Need for HIV Primary Medical Care:** No demonstration of a viral load count (or) a CD4 count (or) ART for 6-month and 12-month periods for years 2000 and 2001.
- **Definition 2: Unmet Need for Core Health Care Services:** No demonstration of utilization in 6-month and 12-month periods for years 2000 and 2001 of any of the

following services: primary care, mental health, oral health, substance abuse, and all meds on ADAP formulary. Hospitalization/emergency room and ambulance services are excluded, since these can be indicative of no care or inappropriate outpatient care access (e.g., someone's hospitalization at AIDS diagnosis should not be counted as "in care").

- **Definition 3: Unconnected to Any Care:** No demonstration of any utilization of any billable service, excluding hospitalization/emergency room and ambulance.

## VIII. Analyzing Unmet Needs of Subpopulations: Adding to the Picture of Who Needs HIV Care

### A. Importance of Subpopulation Analysis

For planning and decision making, it is not enough to determine the total number of people who are HIV+/aware and are not receiving HIV primary medical care. Jurisdictions must also be able to describe who and where these people are. This detail helps the planning body consider what the State or EMA should do to improve primary care access overall and for specific populations and locations.

Further, Ryan White CARE Act Title I grantees are required to provide an "Assessment of Populations with Special Needs" (Table 6 in the FY 2003 Title I grant applications) for six populations: youth (13-24 years old), injecting drug users (IDUs), other substance users, men of color who have sex with men, white/Caucasian men who have sex with men, and women of child-bearing age (13 years old and older). Additional categories, which may or may not be mutually exclusive, are to be determined by each EMA. Examples of these subpopulations may include homeless, immigrants (e.g., undocumented, documented, newly arrived), residents of a specific geographic area who are particularly affected by the epidemic, or any other identified subpopulation that an EMA feels needs more discussion.

The Instructions for Title I Grant Application Table 6 are to: "Describe the extent to which members of this population are not in a system of HIV/AIDS primary care and the barriers to care for those individuals." The data needed to quantify the number of HIV+/aware persons who are out of care also generally allow the jurisdictions to look at who those people are in terms of gender, race/ethnicity, and age, and potentially other important demographic and behavioral characteristics. Some population and care pattern data can also be analyzed for smaller geographic areas, such as Public Health Service Areas or Counties, allowing for even better targeting of resources and activities. Unfortunately, risk behavior (or route of HIV acquisition) is often not coded in medical care data.

## B. Factors Affecting Analysis of Subpopulations

The ability to analyze subpopulations depends on two factors: the availability of data to define the subpopulations and adequate sample size. These two requirements for subpopulation analysis are described below.

### 1. Subpopulation analysis requires the availability of person-level descriptive variables for both Population Size and Care Patterns.

Subpopulation requires both that you have access to person-level descriptive data for both Population Size and Care Patterns, and that these variables be similarly defined. If you have access to client-level data bases, it is likely that they will provide data on race/ethnicity, gender, and age. Often, you are able to describe the total HIV+/aware population and those individuals who are in care. As with the basic estimation of unmet need, you will subtract the "in care" population from the total HIV+/aware population and assume that the characteristics of the remaining individuals reflect those who are not in care.

It is important that these variables are similarly defined by all data sources. For example, a jurisdiction may want to use the framework to look at differences in numbers or proportions of individuals out of care by race/ethnicity. If so, the jurisdiction will first need to answer such questions as:

- Are race/ethnicity markers present, and defined similarly, in both the numerator (Care Patterns) and the denominator (Population Size)?
- If "white/Caucasian" includes Latinos in the population estimates, but Latinos are broken out separately within Care Pattern data, can Latinos also be broken out separately in the population estimates?
- If race/ethnicity is defined in one place by self report and in the other by the eligibility worker, are the definitions sufficiently similar?

It is important to identify problems or inconsistencies between data sets before attempting to interpret any results. This allows for corrections—and the opportunity to make changes in the future collection of data.

### 2. The number of individuals in the subpopulation sample must be large enough to offer precision.

In doing subpopulation analyses, be sure the numbers are large enough to provide information you can trust. With small numbers (e.g., only 25 female IDUs in the data used for care estimates), the uncertainty of calculations based on the data is substantial. Such estimates should be characterized as very approximate, or not made. On the other hand, you can feel comfortable with analyses of 1,120 women with HIV or 692 African American men. You may find that categories remain large enough for analysis when your groupings involve only two of the following three variables: broad age categories, race/ethnicity, and/or gender. Numbers may become smaller when you look at groups

described by all three variables – such as Latina women under 25 or African American men over 45.

## IX. Complementary Data within the Needs Assessment Process

A comprehensive needs assessment comprises multiple components, rather than the results of a single data source. The different components together create a picture of need. The framework presented in this Guide is one of many components needed to estimate and assess unmet need for HIV care and to determine service gaps other than primary care, overall and for specific populations and particular geographic areas within your jurisdiction.

The Ryan White CARE Act *Needs Assessment Guide* describes needs assessment as a “process of collecting information about the needs of persons living with HIV (both those receiving care and those not in care), identifying current resources (CARE Act and other) available to meet those needs, and determining what gaps in care exist.”

Thus, your estimates of numbers (and, where possible, characteristics) of HIV+/aware individuals who are “out of care” are most useful if they are linked to your investigations into reasons for unmet need for care. These investigations may focus on structural and individual barriers that keep people from care. Your findings may describe services or systems that need to change in order to reduce the gap between what people need and what your care system provides them.

The research methods may be quantitative, using the framework for measuring unmet need for HIV primary medical care and surveys of PLWH, or qualitative, employing client or patient interviews and focus groups. Ideally, your estimates for numbers of HIV+/aware individuals who are “in care” should be linked to your quality management program and your evaluation of quality of care, patient satisfaction, and improvements in health outcomes within the community.

Below is one example of a subpopulation analysis that links unmet need data to clinical outcomes data. Earlier in this document, you saw the presentation of unmet need estimates in terms of numbers. The following map is an example using preliminary San Francisco data and demonstrates geo-mapping techniques. It demonstrates an example of unmet need broken out by neighborhood of residence. This map was used to relate to an important clinical outcome. Unmet need was shown to be highest in the same neighborhoods where five-year survival rates after AIDS diagnosis were lowest.

For more information on the needs assessment process, refer to your *Needs Assessment Guide* and use other technical assistance resources available from HRSA/HAB.



# **The West Central Florida Ryan White Program Quality Management Plan**

**2011-2014**

**Revised 9/1/11**

Prepared by the Health Council of East Central

Under contract by The Health Councils, Inc.



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## Executive Summary

The purpose of the West Central Florida Ryan White Quality Management (QM) Program is to improve the quality of care and services and ultimately the quality of life for people living with HIV/AIDS(PLWHA). The QM Program is a collaborative initiative between the Grantee Office, the Care Council and its committees, providers within the eight county total service area (TSA) and the subcontracted QM provider.

The vision of the QM Program is “to create a strong and varied system of care that mirrors the diverse consumer base, promotes diverse community partnerships, maximizes resources, and ensures continuous quality in the delivery of care.” The QM Program is guided by the Public Health Service (PHS) Guidelines, prioritization and allocation by the Care Council, local Standards of Care and input from the Ryan White Quality Management Technical Workgroup. These guiding factors support the QM Program’s mission “to advance the health and well-being of all PLWHA within the total service area by creating and delivering innovative and quality HIV care.”

The following Quality Management Plan outlines the various components of the West Central Florida Ryan White QM Program and the process by which data is shared and disseminated to improve quality throughout the TSA.

The overarching goals of the Quality Management Program are to:

1. Monitor the extent to which HIV health services are consistent with Public Health Service (PHS) guidelines, local and national standards of care.
2. Develop strategies to ensure that services are consistent with the guidelines for improvement in the access to and quality of HIV services.
3. Focus on cost efficiency and quality of care through monitoring and evaluation of the core services, support services, administrative mechanisms and planning processes.
4. Align quality management findings with the Care Council’s priority setting and resource allocation activities.
5. Align quality management findings to grant management functions, specifically procurement and contract negotiations, billing and reimbursement and program management functions.

## **Acknowledgements**

The West Central Florida Ryan White Quality Management (QM) Plan was developed by the Health Council of East Central Florida with input and feedback from the Ryan White Technical Workgroup and providers. The QM Plan has been adapted from the Health Resources Services Administration (HRSA), HIV/AIDS Bureau *Quality Management Technical Assistance Manual* and quality management documents from the Orlando Eligible Metropolitan Area (EMA) and the State of New York AIDS Institute.

## **Description of Quality Management**

The West Central Florida Ryan White Program is committed to promoting, monitoring, and supporting the quality of HIV/AIDS clinical services for people living with HIV/AIDS in Hernando, Hillsborough, Pasco, and Pinellas counties (Part A funded) and Hardee, Highlands, Manatee, and Polk counties (Part B funded). The Ryan White Program, within the Hillsborough County Family and Aging Services Department, oversees the Quality Management activities for the eight county total service area (TSA).

The vision of the West Central Florida Ryan White Quality Management (QM) Program is “to create a strong and varied system of care that mirrors the diverse consumer base, promotes diverse community partnerships, maximizes resources, and ensures continuous quality in the delivery of care.” A Quality Management Technical Workgroup has been established and charged with developing clinical performance measures, monitoring and reporting outcomes, and identifying performance improvement opportunities to support the QM Program’s mission “to advance the health and well-being of all PLWHA within the total service area by creating and delivering innovative and quality HIV care.”

The QM Program is designed to ensure that “services adhere to PHS guidelines and established clinical practice; program improvement includes supportive services linked to access and adherence to medical care; and demographic, clinical and utilization data are used to evaluate and address characteristics of the local epidemic.”

The Quality Management Program includes consumers in planning, implementing and evaluating quality of care program activities. Additional input is also received from the various Care Council committees, including, but not limited to:

- Client Services
- Health Services Advisory
- Planning & Evaluation
- Resource Prioritization and Allocation Recommendations
- Standards, Issues and Operations

## **Quality Statement**

The West Central Florida Ryan White Quality Management Program strives to improve the quality of care delivered to all consumers seeking health care services through planning, assessing, measuring and implementing a continuous quality improvement program. A multi-disciplinary approach is used to identify and select areas for improvement such as process improvement teams, focus groups, and provider and consumer education.

The purpose of the QM Program is to ensure that all consumers of the TSA are receiving access to basic health care services as recommended by the Department of Health and Human Services, Health Resources Services Administration (HRSA).

HRSA's HIV/AIDS Bureau (HAB) working definition of quality is "the degree to which a health or social service meets or exceeds established professional standards and user expectations."

## **Quality Management Infrastructure**

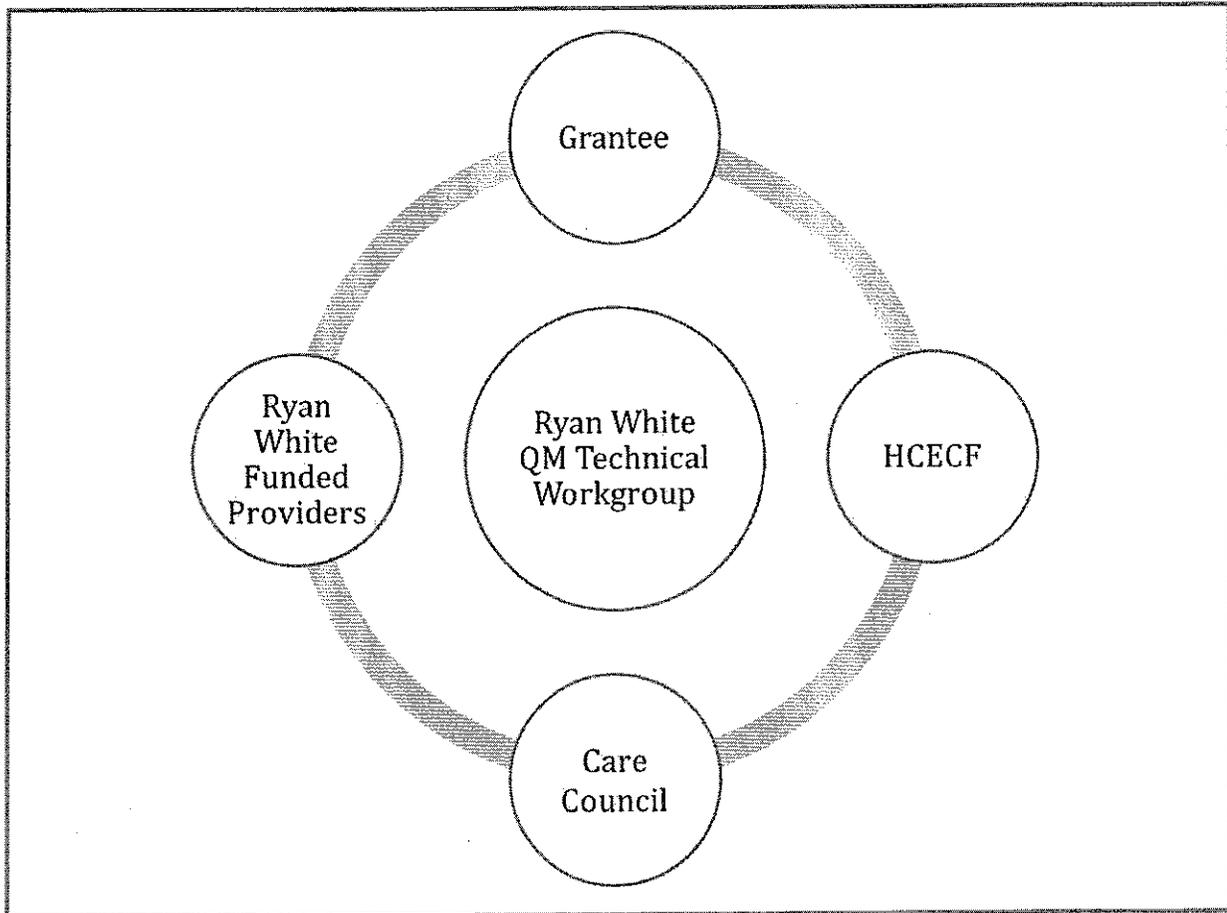
### **Accountability**

The QM Program is supported through multiple entities, including the Ryan White Program Grantee Office, the West Central Florida Care Council, the Ryan White Program funded providers, the Ryan White Quality Management (QM) Technical Workgroup and the Health Council of East Central Florida (HCECF). The Grantee provides the administrative oversight to the QM Program and contracts for a provider to coordinate the QM activities for the Ryan White Program. The Care Council will work in conjunction with the QM Program to align quality management findings with the priority setting and resource allocation process. Primary data for the QM Program will be collected and reported by the Ryan White Program funded providers who will also work collaboratively with the QM Technical Workgroup to implement quality improvement initiatives.

### **Ryan White Technical Work Group**

The Ryan White QM Technical Workgroup is a multi-disciplinary team that provides leadership and direction for the QM Programs activities and reporting. The Health Council of East Central Florida (HCECF) is a subcontracted provider that facilitates and leads the Ryan White QM Technical Workgroup, coordinates QM activities and reports to the various planning bodies. The following diagram illustrates the collaborative relationship between the various entities that support the QM Program.

## Ryan White Quality Management Structure



In Spring 2010, HCECF was awarded the subcontract to coordinate QM activities for the Ryan White Program. As a key approach to QM, HCECF worked with the Grantee to establish a quality management workgroup. The Ryan White QM Technical Workgroup is comprised of eight provider agency staff, two Care Council members, a Ryan White program manager, the Ryan White Information System (RWIS) coordinator and a former QM manager from the private healthcare sector. The composition of the workgroup is designed to facilitate input by consumers, providers, the Care Council and the Grantee Office. The workgroup is supported by HCECF staff and meets monthly to allow for ongoing communication and feedback into the quality management process.

## Quality Management Goals and Objectives

The overarching goals and objectives of the Quality Management Program are to:

**Goal #1:** Monitor the extent to which HIV health services are consistent with Public Health Service (PHS) guidelines, local and national standards of care.

**Objective #1:** Develop key indicators for core clinical and support services.

**Objective #2:** Conduct quarterly reporting of quality indicators to stakeholders, including the Care Council, Care Council committees, providers and QM Technical Workgroup members.

**Goals #2:** Develop strategies to ensure that services are consistent with the guidelines for improvement in the access to and quality of HIV services.

**Objective #1:** Review performance measure and outcome data quarterly to determine progress toward relevant, evidenced-based benchmarks.

**Objective #2:** Utilize key stakeholder input to develop quality improvement initiatives that focus on linkages, efficiencies, and provider and client expectations.

**Goal #3:** Focus on cost efficiency and quality of care through monitoring and evaluation of the core services, support services, administrative mechanisms and planning processes.

**Objective #1:** Conduct an annual review of the provision of services while aligning the quality management framework with other internal and external quality assurance and improvement activities.

**Goal #4:** Align quality management findings with the Care Council's priority setting and resource allocation activities.

**Objective #1:** Ensure that quality management findings are communicated to the Planning and Evaluation and RPARC Committees on a quarterly basis.

**Objective #2:** Maintain representation of Care Council membership on the QM Technical Workgroup.

**Goal #5:** Align quality management findings to grant management functions, specifically procurement and contract negotiations, billing and reimbursement and program management functions.

**Objective #1:** Ensure that quality management findings are communicated to the Grantee Office on a quarterly basis.

**Objective #2:** Maintain representation of Grantee Office membership on the QM Technical Workgroup.

## Data Collection and Reporting

In Summer 2010, utilizing the HRSA Quality Management Technical Assistance Manual as a guiding document, the QM Technical Workgroup conducted an assessment of the current QM Program. Upon review of the data collection methods and indicators, the QM Technical Workgroup determined to streamline data collection to more accurately report quality

measures and outcomes. In alignment with the Grantee’s Strategic Automation Plan, the QM Technical Workgroup began the planning and development process to collect performance measure data directly from the Grantee’s Ryan White Information System (RWIS).

**Performance Measures**

The QM Technical Workgroup identified the following categories for performance measure (PM) data collection: 1) core clinical services, 2) medical case management and 3) oral health. Selection of the indicators was determined with input from providers and review from the QM Technical Workgroup.

Providers reviewed the HRSA HIV/AIDS Bureau (HAB) performance measures while considering the impact of the measure on PLWHA, presence of available data fields in RWIS and the capacity of providers to input new data points to capture the HRSA/HAB performance measure. Through the provider driven and data informed process, the following performance measures were identified for data collection. See Appendix B for performance measure definitions.

<b>CORE CLINICAL PERFORMANCE MEASURES</b>
<b>HAB Group 1</b>
ARV Therapy for Pregnant Women
CD4 T-Cell Count
HAART
Medical Visits
PCP Prophylaxis
<b>HAB Group 2</b>
Cervical Cancer Screening
Hepatitis B Vaccination
Hepatitis C Screening
HIV Risk Counseling
Lipid Screening
Syphilis Screening
TB Screening
<b>HAB Group 3</b>
Substance Use Screening
<b>MEDICAL CASE MANAGEMENT PERFORMANCE MEASURES</b>
Care Plan
Medical Visits
<b>ORAL HEALTH PERFORMANCE MEASURE</b>
Dental Visits

Automated RWIS performance measure reports were developed with input from providers, Grantee staff and Hillsborough County Government Information Technology System (ITS) staff. Annual targets for each performance measure will be developed by the QM Technical Workgroup based on established national benchmarks or localized standards of care. Performance measure reports will be reviewed by the QM Technical Workgroup on a quarterly basis.

**Client Outcomes**

In addition to monitoring performance measures for all consumers, the following outcomes will be monitored by the CQM Program to assess the overall impact of outpatient and ambulatory health services and medical case management on client outcomes.

**Client Outcomes**

Outcome	Indicator
CD4 T-Cell Count (Baseline <200 mm <sup>3</sup> )	Percentage of clients engaged in outpatient and ambulatory health services, who are on antiretroviral therapy, whose baseline CD4 count is <200mm <sup>3</sup> .
CD4 T-Cell Count (Baseline <200 mm <sup>3</sup> and Increased)	Percentage of clients whose baseline CD4 count was <200mm <sup>3</sup> and were engaged in outpatient and ambulatory health services and are on antiretroviral therapy, whose CD4 count increased.
CD4 T-Cell Count (Baseline <200 mm <sup>3</sup> and Increased >200 mm <sup>3</sup> )	Percentage of clients whose baseline CD4 count was <200mm <sup>3</sup> and were engaged in outpatient and ambulatory health services and are on antiretroviral therapy, whose CD4 count increased >200 mm <sup>3</sup> .
Viral Load (Undetectable)	Percentage of clients engaged in outpatient and ambulatory health services, who are on antiretroviral therapy, who have an undetectable viral load.
Viral Load (Stabilized or Decreased)	Percentage of clients engaged in outpatient and ambulatory health services who stabilize or decrease their viral loads.

Outcomes for consumers receiving services through the Minority AIDS Initiative (MAI) will also be tracked. MAI consumer outcomes will be compared to overall consumer outcomes to examine possible disparities and to examine trends over time for the target populations. The following are the MAI specific client outcomes that will be monitored.

### Minority AIDS Initiative (MAI) Client Outcomes

Outcome	Indicator
CD4 T-Cell Count (Baseline <200 mm <sup>3</sup> )	Percentage of MAI clients engaged in outpatient and ambulatory health services, who are on antiretroviral therapy, whose baseline CD4 count is <200mm <sup>3</sup> .
CD4 T-Cell Count (Baseline <200 mm <sup>3</sup> and Increased)	Percentage of MAI clients whose baseline CD4 count was <200mm <sup>3</sup> and were engaged in outpatient and ambulatory health services and are on antiretroviral therapy, whose CD4 count increased.
CD4 T-Cell Count (Baseline <200 mm <sup>3</sup> and Increased >200 mm <sup>3</sup> )	Percentage of MAI clients whose baseline CD4 count was <200mm <sup>3</sup> and were engaged in outpatient and ambulatory health services and are on antiretroviral therapy, whose CD4 count increased >200 mm <sup>3</sup> .
Medical Visits	Percentage of MAI clients with HIV infection who had two or more medical visits in an HIV care setting in the measurement year.

Client outcome data complements performance measure data and further support the QM Program's goal to align quality management findings with the Care Council's priority setting and resource allocation activities. Automated client outcome data reports were also developed for reporting through RWIS. Client outcomes reports will be reviewed by the QM Technical Workgroup on a quarterly basis in conjunction with the PM reports.

### Client Satisfaction

A critical aspect of the QM Program is to ensure that input is solicited and received from clients directly. The QM Technical Workgroup conducted a review of existing tools and indicators and generated a self-administered survey that will be mailed back to the Ryan White Program Office (see Appendix B).

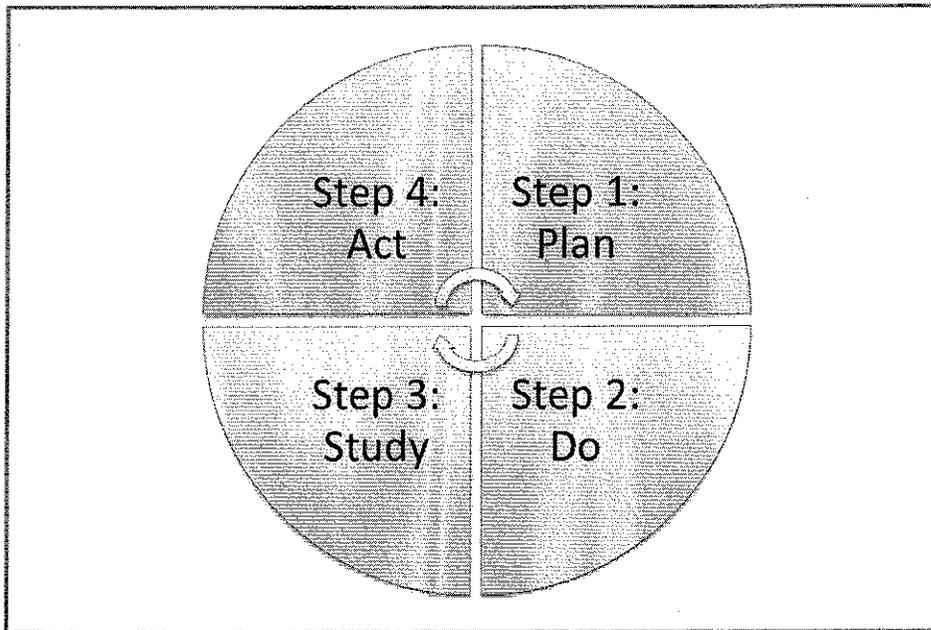
In order to facilitate an ongoing data collection process, clients will be asked to complete a satisfaction survey after each visit to a Ryan White provider. Survey results will be tabulated by the Grantee's office and disseminated back to the individual provider agencies on a quarterly basis.

Client satisfaction survey results will also be reviewed by the QM Technical Workgroup on a quarterly basis and utilized with performance measure and outcome data to support continuous quality improvement initiatives.

## Continuous Quality Improvement

Continuous quality improvement efforts will be implemented utilizing the Plan-Do-Study-Act (PDSA) cycle as a framework. The PDSA cycle is widely used for quality improvement initiatives throughout the health services sector, including Ryan White programs. The following diagram illustrates the steps of the PDSA cycle.

**Plan-Do-Study-Act Cycle**



### **Step 1: Plan**

- Meet with QM Technical Workgroup members.
- Solicit input from providers, Care Council committee members, consumers and Grantee staff.
- Review data and prioritize processes or procedures that require improvements.
- Identify multi-disciplinary teams to implement quality improvement activities.

### **Step 2: Do**

- Assign tasks to specific team members.
- Create a realistic timeline for implementation.
- Test improvement activities on a small scale.

### **Step 3: Study**

- Collect data and observe changes resulting from implementation of activities.
- Identify challenges or unintended consequences from implementation.
- Discuss results among team members.

#### **Step 4: Act**

- Adapt processes as determined by team members and consumers.
- Take the activities “to scale” within the agencies.

Once a quality improvement activity has been implemented, the PDSA cycle will once again be initiated to reassess its impact. This continuous quality improvement process ensures that the QM Program is responsive to fluid changes that may result from both internal and external factors.

#### **Information Dissemination**

The QM Technical Workgroup will review performance measures, client outcomes and client satisfaction data on a quarterly basis. Each provider agency will receive its own quarterly data and system wide Ryan White program data for comparison. System wide data will also be shared with the Planning and Evaluation Committee, the Resource Prioritization and Allocation Recommendations Committee and the Client Services Committee on a quarterly basis for their review, and subsequently reported to the Care Council.

The QM Technical Workgroup will work with additional Care Council committees to review data reports as it relates to developing quality improvement projects. As noted through the PDSA cycle, data will be utilized during the planning phase to determine what types of quality improvement activities will be initiated.

Annual reporting to the Care Council will be conducted to articulate trends and progress towards quality management goals and benchmarks. A summary of quality management initiatives and program successes will also be shared with the Care Council and key stakeholders.

As the QM Program continues to grow and develop, provider agencies will have the opportunity to share best practices and lessons learned from the own quality improvement initiatives. The multi-disciplinary design of the QM Program is meant to foster ongoing communication and information sharing in order to promote improved quality of care throughout the system of care.

## Appendix A – Performance Measures

<b>CORE CLINICAL PERFORMANCE MEASURES</b>	
<b>HAB Group 1</b>	
ARV Therapy for Pregnant Women	Percentage of pregnant women with HIV infection who are prescribed antiretroviral therapy
CD4 T-Cell Count	Percentage of clients with HIV infection who had two or more CD4 T-cell counts performed in the measurement year
HAART	Percentage of clients with AIDS who are prescribed HAART
Medical Visits	Percentage of clients with HIV infection who had two or more medical visits in an HIV care setting in the measurement year
PCP Prophylaxis	Percentage of clients with HIV infection and a CD4 T-cell count below 200 cells/mm <sup>3</sup> who were prescribed PCP prophylaxis
<b>HAB Group 2</b>	
Cervical Cancer Screening	Percentage of women with HIV infection who have a Pap screening in the measurement year
Hepatitis B Vaccination	Percentage of clients with HIV infection who completed the vaccination series for Hepatitis B
Hepatitis C Screening	Percentage of clients for whom Hepatitis C (HCV) screening was performed at least once since the diagnosis of HIV infection
HIV Risk Counseling	Percentage of clients with HIV infection who received HIV risk counseling within the measurement year
Lipid Screening	Percentage of clients with HIV infection on HAART who had a fasting lipid panel during the measurement year
Syphilis Screening	Percentage of adult clients with HIV infection who had a test for syphilis performed within the measurement year
TB Screening	Percentage of clients with HIV infection who received testing with results documented for latent tuberculosis infection (LTBI) since HIV diagnosis
<b>HAB Group 3</b>	
Substance Use Screening	Percentage of new clients with HIV infection who have been screened for substance use (alcohol & drugs) in the measurement year
<b>MEDICAL CASE MANAGEMENT PERFORMANCE MEASURES</b>	
Care Plan	Percentage of HIV-infected medical case management clients who had a medical case management care plan developed and/or updated two or more times in the measurement year
Medical Visits	Percentage of HIV-infected medical case management clients who had two or more medical visits in an HIV care setting in the measurement year
<b>ORAL HEALTH PERFORMANCE MEASURES</b>	
Dental Visits	Percentage of clients with HIV infection who had one or more dental visits in the measurement year

\* HIV/AIDS Bureau (HAB)

# Appendix B - Client Satisfaction Survey Tool



www.hillsboroughcounty.org

## Ryan White Client Satisfaction Survey

The Ryan White Program would like feedback about the quality of services you have received today. Please read each statement below and indicate with an (x) which rating most closely fits your opinion about the quality of service you received from the agency. Thank you!

	Strongly agree	Agree	Neutral	Disagree*	Strongly disagree*	N/A
1. Staff was friendly and courteous.						
2. I was served in a timely manner.						
3. I received the information/ service I needed.						
4. The information or service I received was clear and understandable.						
5. The staff was knowledgeable about resources and/or referrals.						
6. I would recommend this service to other people.						

\*For those responses that you indicated a "disagree" or "strongly disagree," please indicate your reasons why in the "Additional Comments" section below.

Please indicate (x) your demographic information below and report all Ryan White services that you received today.

Race	Age	Ryan White Services Received*	
<input type="checkbox"/> Black	<input type="checkbox"/> <13	<b>CORE SERVICES</b>	<b>SUPPORT SERVICES</b>
<input type="checkbox"/> White	<input type="checkbox"/> 13-19	<input type="checkbox"/> Outpatient Medical Care	<input type="checkbox"/> Food Bank/ Nutritional Supplements
<input type="checkbox"/> American Indian	<input type="checkbox"/> 20-24	<input type="checkbox"/> Case Management	<input type="checkbox"/> Transportation
<input type="checkbox"/> Asian	<input type="checkbox"/> 25-34	<input type="checkbox"/> Medications	<input type="checkbox"/> Treatment Adherence
<input type="checkbox"/> Native Hawaiian/ Pacific Islander	<input type="checkbox"/> 35-44	<input type="checkbox"/> Dental/Oral Health	
<input type="checkbox"/> More than one race	<input type="checkbox"/> 45-54	<input type="checkbox"/> Mental Health Services	
	<input type="checkbox"/> 55-65	<input type="checkbox"/> Substance Abuse Treatment	
	<input type="checkbox"/> Over 65		

\*See definitions for Ryan White Services on the back of the survey.

**Additional Comments:** Please specifically explain the reason why you indicated "disagree" or "strongly disagree" to any of the questions above, or share any additional comments or feedback about the Ryan White services you received today.

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For Office Use Only				
Date			Provider Name	

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