



HHS Operational Plan:

ACHIEVING THE VISION OF THE NATIONAL HIV/AIDS STRATEGY

February 2011





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Executive Summary

Inspired and informed by the President's National HIV/AIDS Strategy (NHAS), the U.S. Department of Health and Human Services' (HHS) National HIV/AIDS Strategy Operational Plan is the result of a 4-month, cross-departmental, collaborative effort on the part of all HHS agencies and offices to build on, better coordinate, and refocus our existing HIV/AIDS efforts. Prepared at the request of the President, the HHS Operational Plan reflects ongoing efforts to align existing activities with the NHAS and initiate new activities in support of Strategy goals: reducing new HIV infections; increasing access to care and improving health outcomes for people living with HIV; and reducing HIV-related disparities and health inequities. The Department-wide planning process that produced this Operational Plan will continue in the months ahead, requiring, as we move forward, heightened coordination within and beyond HHS. We will continue to assess progress and, in consultation with the Office of National AIDS Policy (ONAP) and other partners and stakeholders, work together to develop a refreshed plan for 2012.

To develop the Operational Plan, HHS undertook a planning process that solicited input from within and outside the Department via a number of channels. A cross-agency working group, facilitated by the Assistant Secretary for Health (ASH) and the Deputy Assistant Secretary for Health, Infectious Diseases, convened multiple times and was responsible for developing the plan. Members of the working group were informed by significant external input received in writing, online, and through meetings with the community and the Presidential Advisory Council on HIV/AIDS.

The HHS Operational Plan provides a detailed summary of the Department's current level of domestic HIV/AIDS spending. This summary provides important baseline data against which to gauge unmet need and to assess any future resource realignment.

A significant component of the HHS Operational Plan is the "HHS 12 Cities Project," an effort to accelerate comprehensive HIV/AIDS planning and cross-agency response in the 12 U.S. jurisdictions hit hard by HIV/AIDS. The demonstration project embodies many of the overarching principles of the NHAS: **innovate, concentrate resources where the epidemic is most severe, coordinate federal resources and actions across categorical program lines, and scale up effective HIV prevention, care, and treatment strategies.** The project, under the direction of the Office of the ASH (OASH), actively engages HHS agencies, including the Centers for Disease Control and Prevention, the Centers for Medicare and Medicaid Services, the Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, the Substance Abuse and Mental Health Services Administration, and other HHS components in a collective effort to leverage departmental resources and assets.

The remainder of the plan outlines key HHS actions that are underway—or planned for the near term (subject to the availability of resources)—to work towards achieving the goals of the NHAS. This outline does not detail every HIV/AIDS activity taking place within HHS, or even provide exhaustive detail on the priority activities highlighted. Rather, the Operational Plan emphasizes key action steps

that are integral to achieving the goals of the NHAS. These actions are organized by the three fundamental goals of the NHAS and indicate which agency or office has been designated the lead for this activity. In most instances, other partners from all sectors of society will be involved in carrying out these actions. The activities detailed are consistent with those tasked to HHS by the NHAS Federal Implementation Plan.

Recognizing several cross-cutting critical change issues, the HHS Operational Plan identifies actions to help facilitate successful implementation of the Plan and realization of the Strategy's goals. The Plan also explores some unmet needs and knowledge gaps that HHS will work to address as planning, implementation, and evaluation of activities continue in tandem.

The U.S. Department of Health and Human Services is committed to working with federal, state, local and tribal governmental partners, nongovernmental organizations, communities, people living with HIV/AIDS, the private sector, and all sectors of society to realize the vision of the National HIV/AIDS Strategy:

The United States will become a place where new HIV infections are rare and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual orientation, gender identity or socio-economic circumstance will have unfettered access to high-quality, life extending care, free from stigma and discrimination.



Section 1: Background

On July 13, 2010, the White House released the National HIV/AIDS Strategy (NHAS) for the United States, with an accompanying Federal Implementation Plan. The vision of the NHAS calls for the United States to “become a place where new HIV infections are rare and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual orientation, gender identity or socio-economic circumstance will have unfettered access to high-quality, life extending care, free from stigma and discrimination.”

The U.S. Department of Health and Human Services (HHS), along with five other “lead federal agencies” (i.e., the Departments of Justice, Labor, Housing and Urban Development, and Veterans Affairs, and the Social Security Administration), were called upon to develop and submit operational plans to the Office of National AIDS Policy (ONAP) and the Office of Management and Budget (OMB) “within 150 days” of the Strategy’s release date and the issuance of a Presidential Memorandum for the heads of Executive departments and agencies. The Memorandum directed that the operational plans include “appropriate actions to advance the Strategy,” as well as “steps to strengthen coordination in planning, budgeting for, and evaluating domestic HIV/AIDS programs within and across agencies.”



Section 2: HHS Planning Process

Input into the HHS Operational Plan came from three major sources: a formally constituted, HHS cross-department working group (see Appendix 1, attached); detailed budget and program information provided online by each of the HHS agency and staff offices; and extensive community input received in writing, online (via AIDS.gov), and at various conferences and other venues in 2011 including the International AIDS Conference in Vienna, Austria (July 18-23); a meeting of women leaders hosted by the HHS Office on Women's Health (September 10); the U.S. Conference on AIDS (September 13-16); two national Web conferences hosted by the Coalition for a National HIV/AIDS Strategy (September 2 & 7); a meeting of the Presidential Advisory Council on HIV/AIDS (PACHA, September 30-October 1); and a community check-in meeting hosted by the Office of the Assistant Secretary for Health (October 13).

On July 20, 2010, Secretary Sebelius sent an email to the heads of HHS Operating Divisions and Staff Divisions asking each to name a representative to a working group to be responsible for overseeing the development of the HHS Operational Plan. This NHAS Implementation Group met initially on August 18, 2010, at which time participants reviewed the requirements for the Plan, explored various format options, reviewed the timetable for completing the Plan, and discussed options for an innovative cross-HHS project. To further refine the template and reporting structures for the HHS Operational Plan, a smaller subset of the HHS NHAS Implementation Group held several teleconferences prior to the second meeting of the entire group, on September 27, 2010. During that meeting, group members were briefed on a revised format for collecting information online from HHS agencies and staff offices and were given an overview of the proposed cross-agency project. The final meeting of the HHS NHAS Implementation Group, a planning retreat, was held on October 21-22, 2010. This meeting enabled HHS agencies and staff offices to highlight their priorities for achieving the goals of the NHAS, identify constraints, and obtain direct feedback from colleagues in other agencies and offices.

The HHS Operational Plan is organized in sections. Background and a description of the planning process are found in Sections 1 and 2. Section 3 contains a detailed description of the current level of domestic HIV/AIDS funding within HHS. An innovative demonstration project ("HHS 12 Cities Project") that embodies the principles of the NHAS is outlined in Section 4. Section 5 reports on key HHS actions that are underway or planned for the near term; these are organized by the three major goals of the NHAS. The HHS Operational Plan concludes with a listing of planned actions to support cross-governmental change (Section 6) and recognition of unmet needs and knowledge gaps (Section 7).

EXECUTIVE SUMMARY



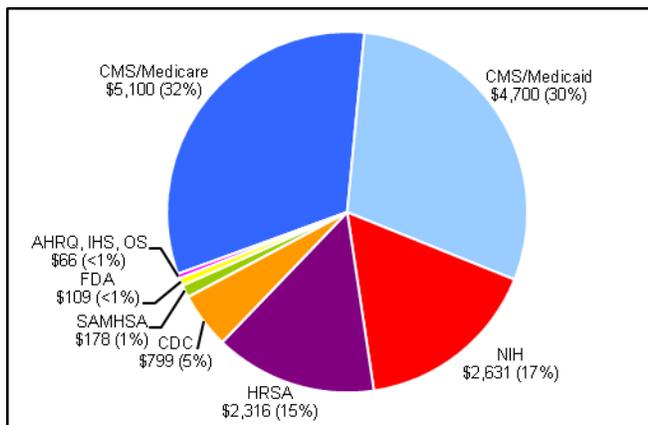
Section 3: HHS HIV/AIDS Funding

3.1: Overview

An important element of the HHS Operational Plan is a detailed understanding of the current level of domestic HIV/AIDS funding within HHS. This section will summarize HHS' HIV/AIDS funding *estimates* for fiscal year (FY) 2010 (actual expenditures are not available at the time of this report), as reported by HHS Operating and Staff Divisions. The details provided in Sections 3.2, 3.3, and 3.4 are based on estimates provided by those Operating and Staff Divisions. Although the precision of these estimates

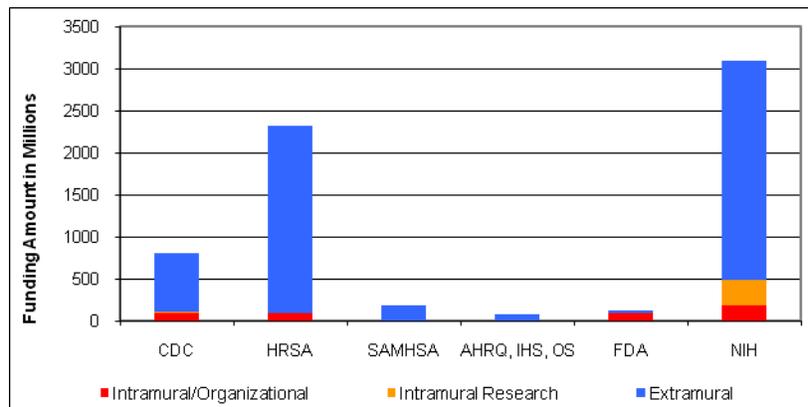
may vary, arraying funding resources in this manner provides important baseline data against which to gauge unmet need and to assess any future resource realignment. Please note that all numbers have been reported to the nearest million. Also note the NIH funding depicted in Figure 1a does not include approximately \$454,000,000 in international HIV/AIDS research.

Figure 1a. HHS FY 2010 HIV/AIDS Funding by Agency/Office: Discretionary and Entitlement, \$15,900,000,000 (in millions)



The HHS FY 2010 HIV/AIDS funding estimates, including discretionary and entitlement funding, total approximately \$15,900,000,000 (Figure 1a). Most of this funding (77%) is associated with HIV/AIDS care and treatment services as follows: 62% through the Centers for Medicare and Medicaid Services (CMS, 32% to Medicare and 30% to Medicaid) and 15% through the Health

Figure 1b. HHS FY 2010 HIV/AIDS Funding: Discretionary Type within Agency/ Office, \$6,553,000,000



Resources and Services Administration's (HRSA) Ryan White HIV/AIDS Program. The National Institutes of Health (NIH) received 17% of the budget for HIV/AIDS-related research activities (described later). The remaining ~6% of the HHS FY 2010 HIV/AIDS budget went to: the Centers for Disease Control and Prevention (CDC, 5%); the Substance Abuse and Mental Health Services Administration (SAMHSA, 1%); the Food and Drug Administration (FDA, <1%); and others (<1% combined for the Indian Health Service (IHS), the Agency for Healthcare Research and Quality (AHRQ), the Office of the Secretary (OS) offices including the Offices of Civil Rights (OCR), HIV/AIDS Policy (OHAP), Minority Health (OMH), Population Affairs (OPA),

Women’s Health (OWH), and the Regional Health Administrators (RHA)). Included in the OS funding is the \$53,900,000 Secretary’s Minority AIDS Initiative (MAI) funding, which is competitively distributed to OS offices (60%) and HHS agencies (40%). Approximately one-third (\$62,000,000) of the SAMHSA HIV/AIDS budget comes from the Substance Abuse Block Grant set-aside.

HHS FY 2010 HIV/AIDS discretionary spending (\$6,553,000,000) is shown in Figure 1b. Please note this amount includes an additional \$454,000,000 in NIH funding (not shown in Figure 1a) to support international HIV/AIDS research, which directly benefits domestic efforts. The recently released iPrEX study (pre-exposure prophylaxis for high-risk men who have sex with men) is an excellent example of this point. Figure 1b presents discretionary funding by three categories: intramural/organizational (i.e., administrative), intramural/research, and extramural; the vast majority of discretionary funding supports extramural efforts. Except for FDA, which reports that 78% of its HIV/AIDS budget supports intramural/administrative activities, the reported percentage of intramural/administrative spending ranged from 0-11%.

3.2: HIV/AIDS Activities

Looking at HHS discretionary funding (i.e., excluding intramural/organizational funding, hereafter referred to as “discretionary extramural funding”) for HIV/AIDS (\$6,332,000,000) by activity (Figures 2a-f), we note that overall activities tend to parallel the mission of the agencies (Figure 2a): 47% to research and dissemination (largely NIH), 27% for HIV medical/health care services (largely HRSA), and 7% for prevention and education (largely CDC). Six percent (6%) of extramural discretionary funding supports capacity building and technical assistance, and 1% each for surveillance and HIV testing. Figures 2b, 2c, and 2d depict, respectively, CDC, HRSA, and SAMHSA’s discretionary funding by activity type. Over half (58%) of CDC’s funding supports prevention and education, three-quarters (76%) of HRSA’s funding supports HIV medical and health care services and over one third (35%) of SAMHSA’s budget derives from the Block Grant Set-Aside.

Figure 2a. HHS FY 2010 HIV/AIDS Funding: Discretionary Extramural by Activity Type, \$6,332,000,000

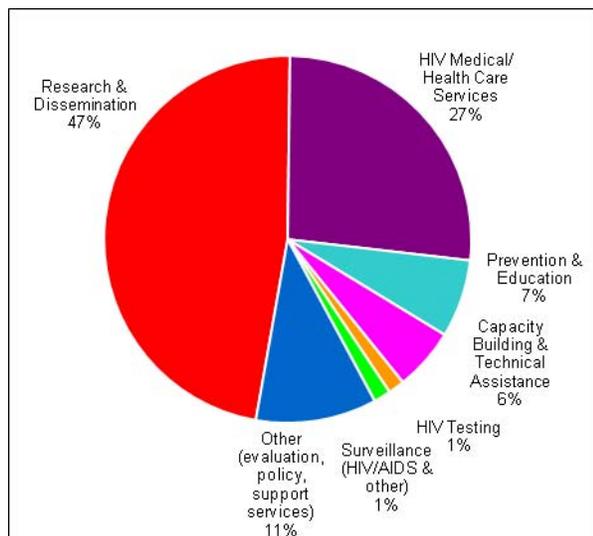


Figure 2b. CDC FY 2010 HIV/AIDS Discretionary Funding (Extramural and Intramural Research) by Activity Type, \$705,000,000

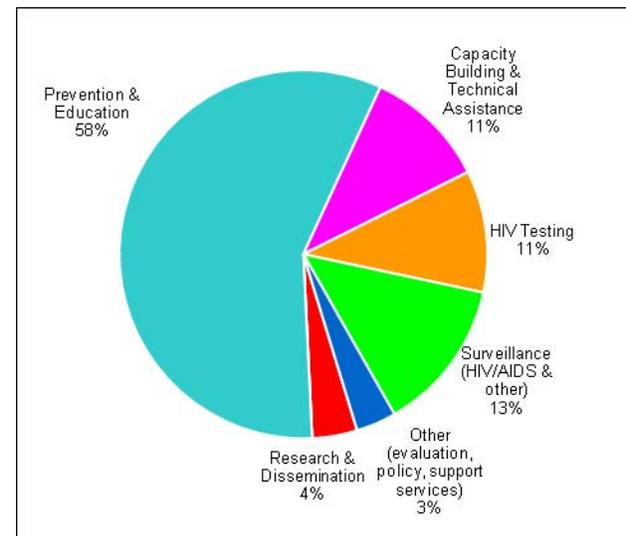


Figure 2c. HRSA FY 2010 HIV/AIDS Discretionary Funding (Extramural and Intramural Research) by Activity Type, \$2,220,000,000

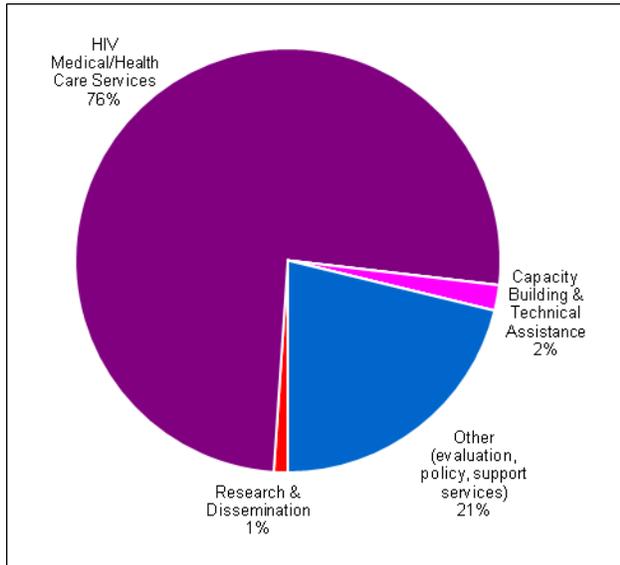


Figure 2d. SAMHSA FY 2010 HIV/AIDS Discretionary Funding (Extramural) by Activity Type, \$177,800,000

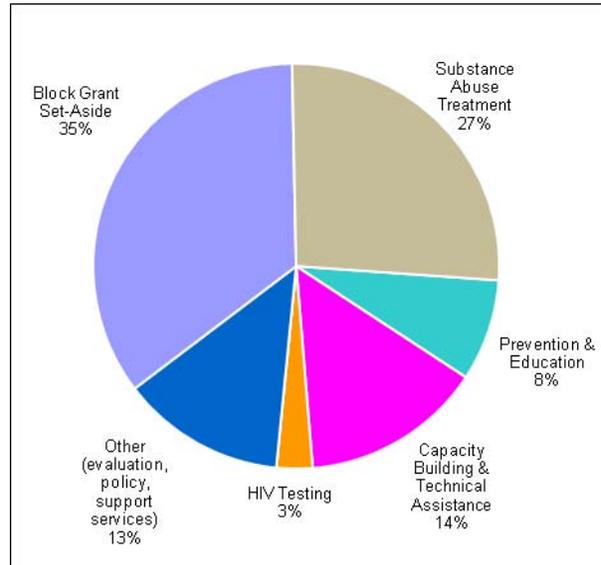


Figure 2e. NIH FY 2010 HIV/AIDS Funding (Intramural & Extramural) by Research Type, \$3,086,000,000

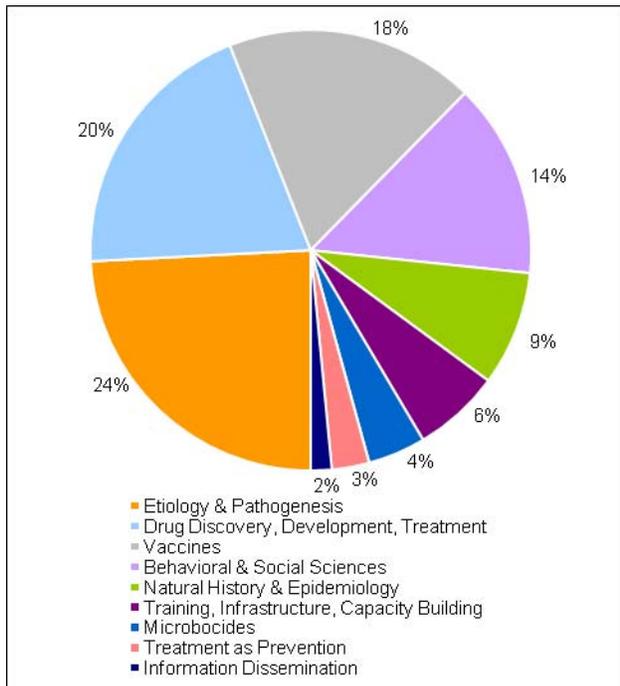
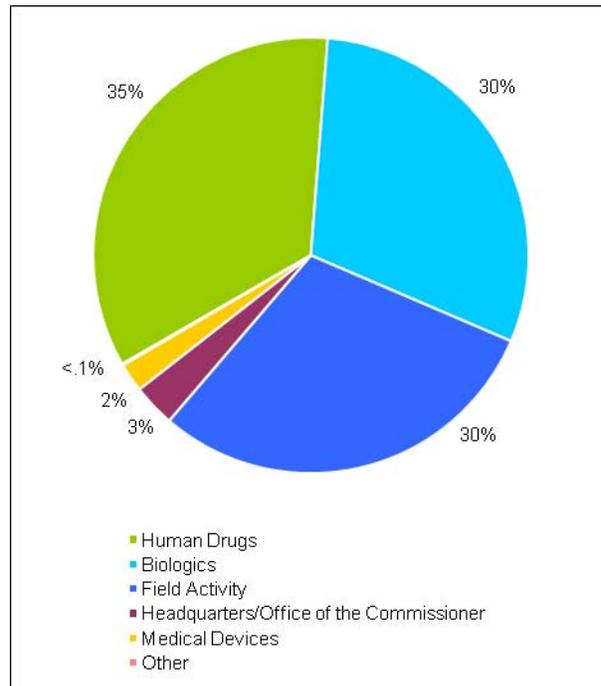


Figure 2f. FDA FY 2010 HHS HIV/AIDS Funding by Activity Type, \$109,000,000



Further breakdown of the NIH domestic and international intramural and extramural research funding (\$2,631,000,000 domestic and \$454,000,000 international; see Figure 2e) shows that prevention research, including microbicides (4%), vaccine development (18%) behavioral and social science (14%) and treatment as prevention (3%) account for 39% of NIH research funding. Twenty percent supports drug discovery, development, and treatment. HIV/AIDS etiology and pathogenesis, the basic science that supports all HIV research, receives 24%; 9% supports studies for natural history and epidemiology, and 6% goes for training, infrastructure, and capacity building. Over 90% of the FDA HIV/AIDS budget (\$109,000,000; see Figure 2f) goes to support human drugs (35%), biologics (30%) and HIV/AIDS-related field activities (30%).

3.3: Demographic Factors

The HHS FY 2010 HIV/AIDS discretionary extramural budget was further analyzed by key demographic factors of the intended recipients/target audiences. It is not possible to describe fully how HHS resources are specifically utilized at the client level for a number of reasons, including: there is no common system of reporting on the specific uses of HIV funding across HHS agencies and offices; HHS resources may be directed to state and local governments which, in turn, distribute resources based on state- or local-level planning processes; and resources may fund research and other enterprises that will broadly benefit the general population (e.g., funding to support microbicide development), as well as activities serving those from multiple risk groups. Nevertheless, this initial description provides an important baseline from which to build future efforts. It should be noted that we use the term “multi-targeted” to describe funding that supports services for more than a single, defined subgroup or population. Please note the following distinctions for demographic funding descriptions for HRSA, CMS, and NIH. HRSA demographic funding information is presented in terms of number of Ryan White HIV/AIDS service visits. CMS information in this section is presented in terms of number of HIV/AIDS beneficiaries, based on actual expenditures in calendar year (CY) 2008 for Medicare and in CY 2007 for Medicaid, thus differing from the CMS data presented in Figure 1a. NIH demographic funding information is presented only for HIV/AIDS-related behavioral and social science research, both domestic and international.

3.3a: Risk Groups

Approximately \$910,000,000 was spent on HHS discretionary extramural activities in FY 2010 for HIV/AIDS activities funded by CDC/SAMHSA/IHS/OS offices. This figure does not include HRSA and NIH funding, which will be presented separately. Figures 3a-c illustrate this funding by risk group. Most (90%) of the CDC/SAMHSA/IHS/OS Office funding was multi-targeted (Figure 3a). Of the remaining funds, 43% went to programs for substance users, 33% for men who have sex with men (MSM), 20% for high-risk heterosexuals, and 4% to reduce perinatal transmission.

As mentioned, HRSA data are presented in terms of number of Ryan White HIV/AIDS service visits in FY 2010 (Figure 3b). Thirty-six percent (36%) of Ryan White-funded visits were for high-risk heterosexuals, and 34% were for MSM; 9% of visits served substance users and 13% of HRSA-funded visits served persons whose behaviors and circumstances placed them in multiple risk groups. For NIH-funded intramural and extramural behavioral and social science research (Figure 3c; \$441,000,000), well over half (61%) of the research was multi-targeted; of the remaining funds, 50% was targeted specifically for substance users, 34% for high-risk heterosexuals, and 16% for MSM.

Figure 3a. HHS FY 2010 HIV/AIDS Funding: Discretionary Extramural by Risk Group (CDC, SAMHSA, IHS, OS)

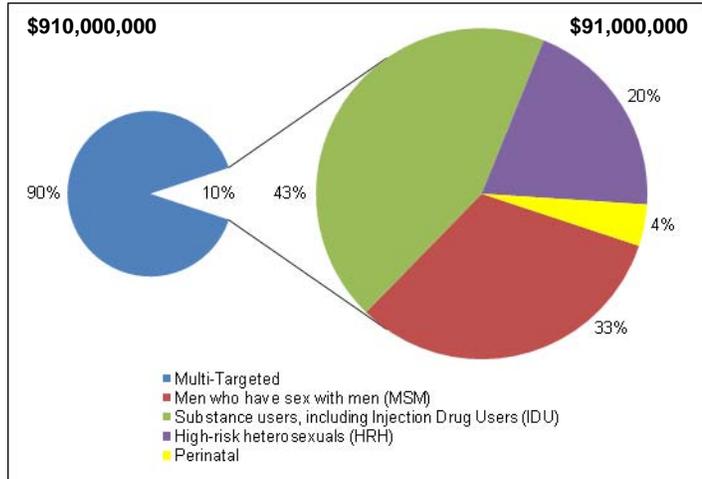


Figure 3b. HRSA FY 2010 HIV/AIDS Service Visits by Risk Group, n=388,835 visits

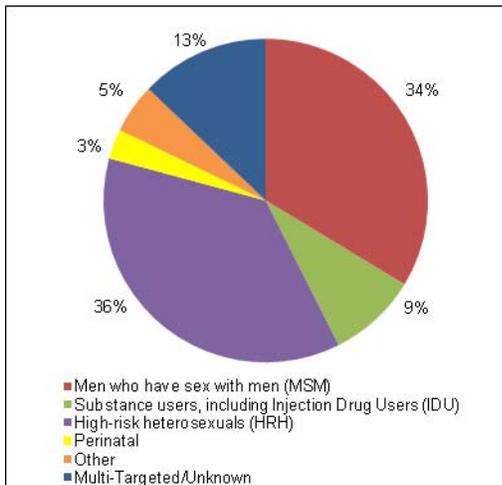
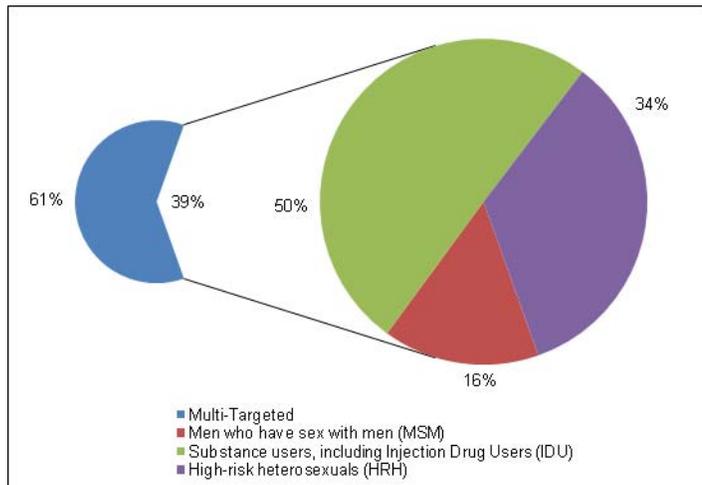


Figure 3c. NIH FY 2010 HIV/AIDS Funding: Behavioral and Social Science Research (Intramural and Extramural) by Risk Group, \$441,000,000



3.3b: Race/Ethnicity

Most of the HHS FY2010 discretionary extramural funding for CDC/SAMHSA/IHS/OS (\$910,000,000) was categorized as multi-targeted in terms of race and ethnicity (Figures 4a and 4b). For those programs that were not multi-targeted, 70% served African Americans, 22% served Whites, 6% served American Indian/Alaska Natives, 2% served Asian/Pacific Islanders (Figure 4a), and 17% served Hispanic or Latino populations (Figure 4b). HRSA Ryan White service visits by race/ethnicity (Figure 4c) were distributed as follows: 47% Blacks, 27% Whites, 23% Latinos, 2% Asian/Pacific Islanders, and 1% American Indian/Native Alaskans.

Figure 4a. HHS FY 2010 HIV/AIDS Funding: Discretionary Extramural by Race (CDC, SAMHSA, IHS, OS)

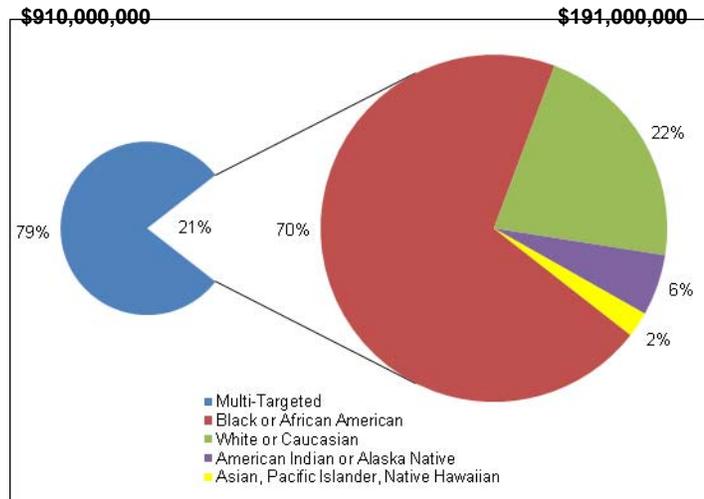


Figure 4b. HHS FY 2010 HIV/AIDS Funding: Discretionary Extramural by Ethnicity (CDC, SAMHSA, IHS, OS)

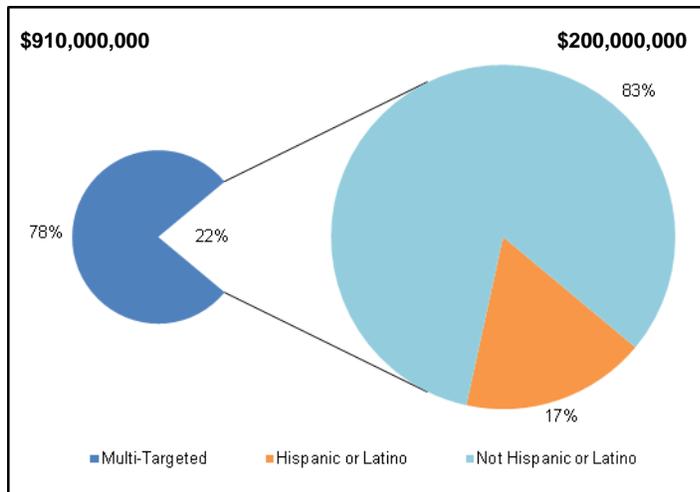
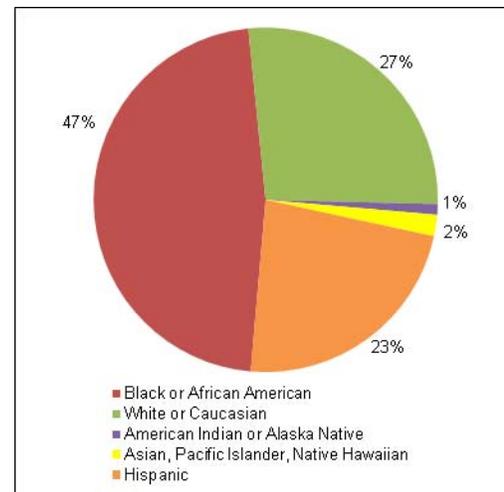


Figure 4c. HRSA FY 2010 HIV/AIDS Service Visits by Race/Ethnicity, n=855,230 visits



CMS data are presented in terms of the number of HIV/AIDS beneficiaries (including approximately 76,000 dual beneficiaries in 2007) separately for Medicare (114,041 in CY 2008, the most recent data available) and Medicaid (172,541 in CY 2007, the most recent data available). For Medicare (Figure 4d), 45% of HIV/AIDS beneficiaries were White, 39% were Black, and 14% were Hispanic; 2% “other” includes Asian/Pacific Islander and American Indian/Alaska Native. For Medicaid (Figure 4e), 47% of

HIV/AIDS beneficiaries were Black, 29% were White, and 17% were Hispanic; 3% “other” includes Asian/Pacific Islander and American Indian/Alaska Native.

Figure 4d. CMS/Medicare CY 2008 Number of HIV/AIDS Beneficiaries by Race/Ethnicity within Program, n=114,041

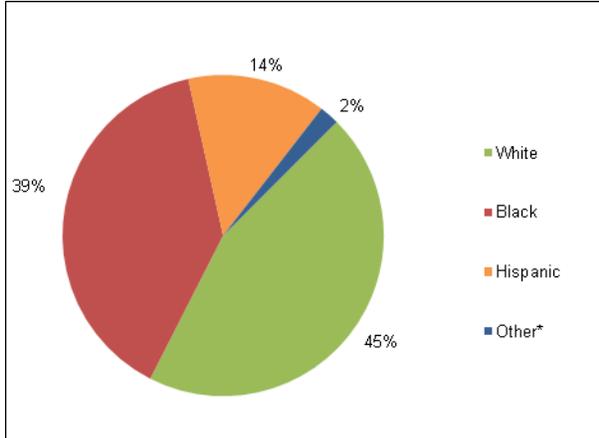
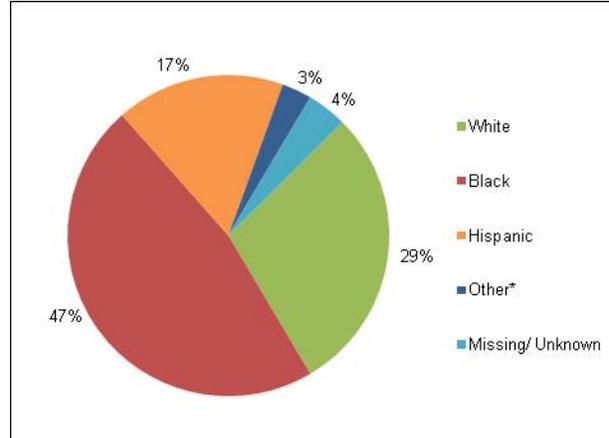


Figure 4e. CMS/Medicaid CY 2007 Number of HIV/AIDS Beneficiaries by Race/Ethnicity within Program, n=172,541



3.3c: Gender

Figure 5a presents gender information on discretionary extramural activities for CDC/SAMHSA/IHS/OS offices. The majority of activities were multi-targeted for gender. Among the remaining 17% of extramural funding, 61% was for males, 38% for females, and 1% for transgender individuals. Two-thirds of HRSA's Ryan White service visits were for males (67%), nearly one-third (32%) for females, and 1% for transgender persons (Figure 5b).

Figure 5a. HHS FY 2010 HIV/AIDS Funding: Discretionary Extramural by Gender (CDC, SAMHSA, IHS, OS)

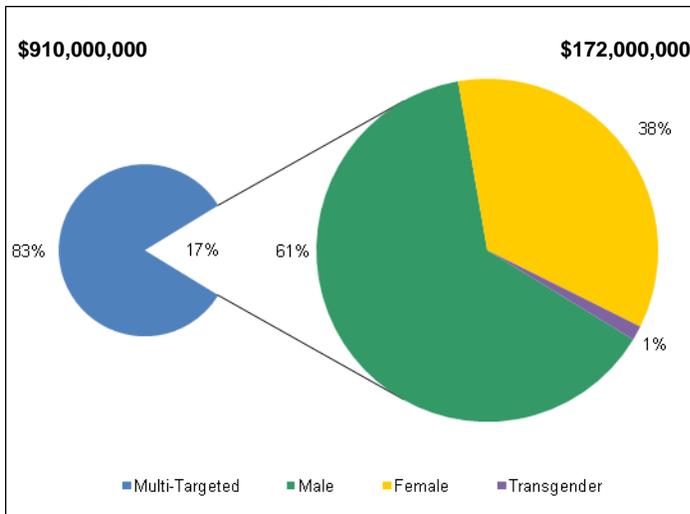
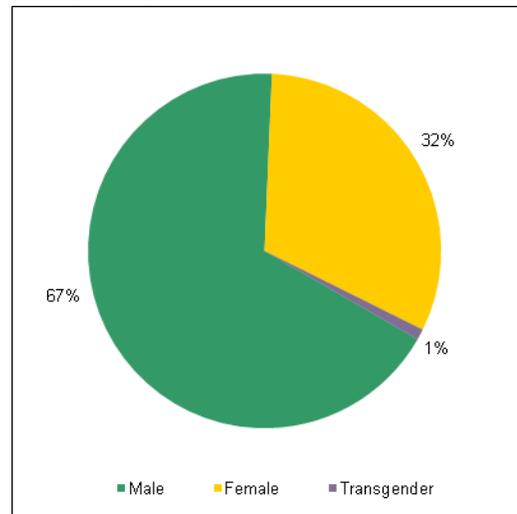


Figure 5b. HRSA FY 2010 HIV/AIDS Service Visits by Gender, n=876,987 visits



CMS HIV/AIDS Medicare beneficiaries (CY 2008) were 77% male and 23% female (Figure 5c). CMS HIV/AIDS Medicaid beneficiaries (CY 2007) were 63% male, 37% female, and <1% unknown persons (Figure 5d).

Figure 5c. CMS/Medicare CY 2008 Number of HIV/AIDS Beneficiaries Gender within Program, n=114,041

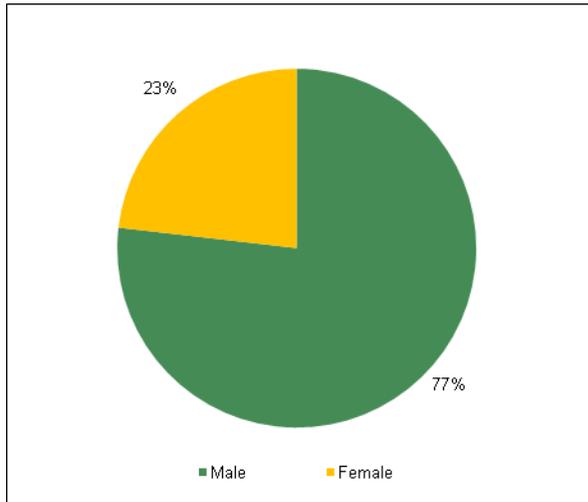
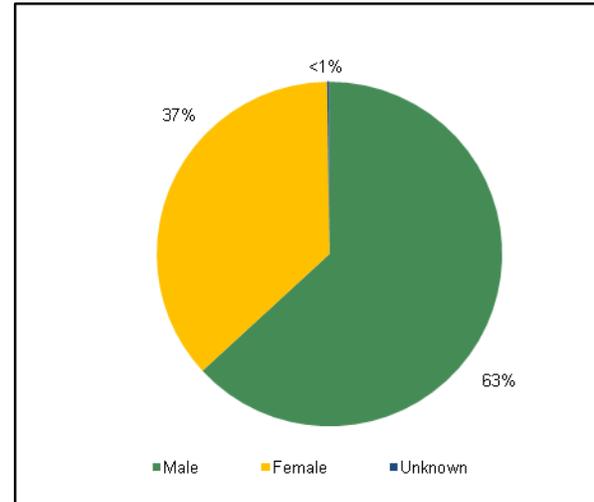


Figure 5d. CMS/Medicaid CY 2007 Number of HIV/AIDS Beneficiaries by Gender within Program, n=172,541



3.3d: Age Groups

Figure 6a illustrates CDC/SAMHSA/IHS/OS offices discretionary extramural funding (\$910,000,000) for which the specific age group of intended recipients was known (16%). Over a third each were for ages 18-29 (35%) or for ages 30-49 (35%). Seventeen percent (17%) was for ages 50-64, and 12% was for individuals under age 18. For HRSA (Figure 6b), 45% of Ryan White service visits were for adults aged 45–64; 42% of visits were for adults aged 25-44; 7% of visits were for youth and young adults aged 13-24.

Figure 6a. HHS FY 2010 HIV/AIDS Funding: Discretionary Extramural by Age Group (CDC, SAMHSA, IHS, OS)

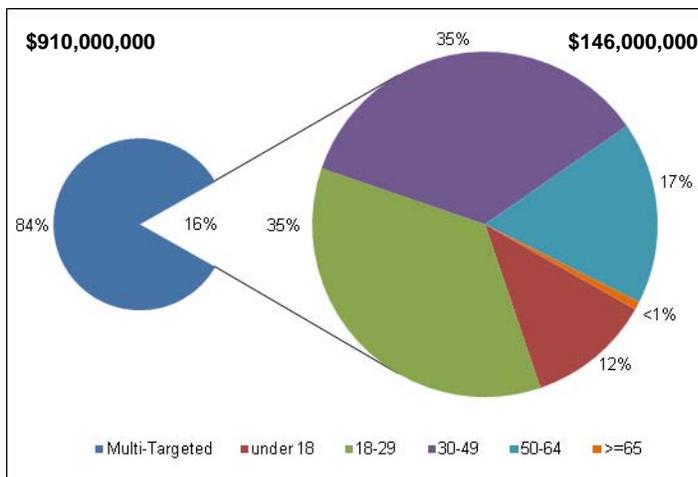
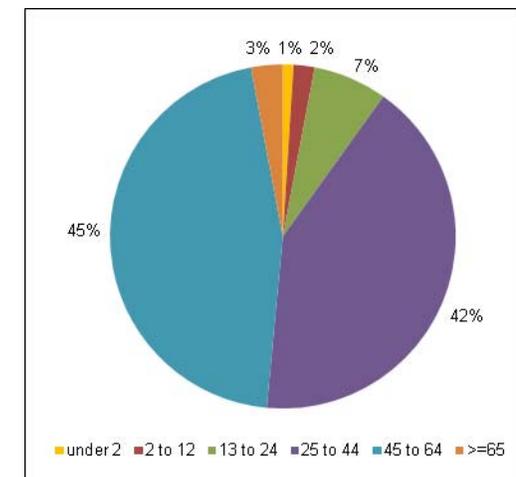


Figure 6b. HRSA FY 2010 HIV/AIDS Service Visits by Age Group, n=876,552



Over half (59%) of CMS HIV/AIDS Medicare (CY 2008) beneficiaries were aged 45-64, 26% were aged 21-44, 11% were aged 65-74, and 4% were 75 years or older (Figure 6c). The age breakdown of CMS HIV/AIDS Medicaid (CY 2007) beneficiaries (Figure 6d) was distributed as follows: 51% were aged 45-64, 39% were 21-44, 5% were under 21, 4% were 65-74, and 1% were 75 years or older.

Figure 6c. CMS/Medicare CY 2008 Number of HIV/AIDS Beneficiaries Gender within Program, n=114,041

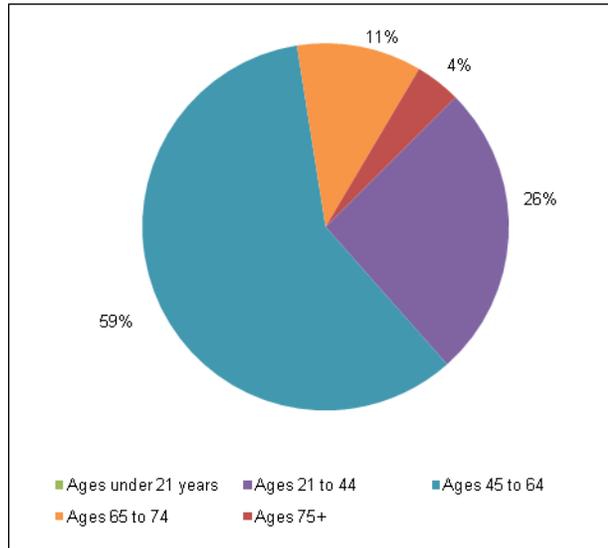
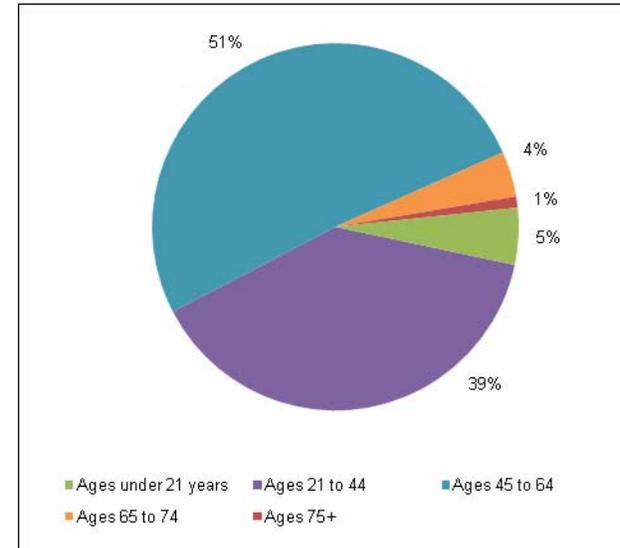


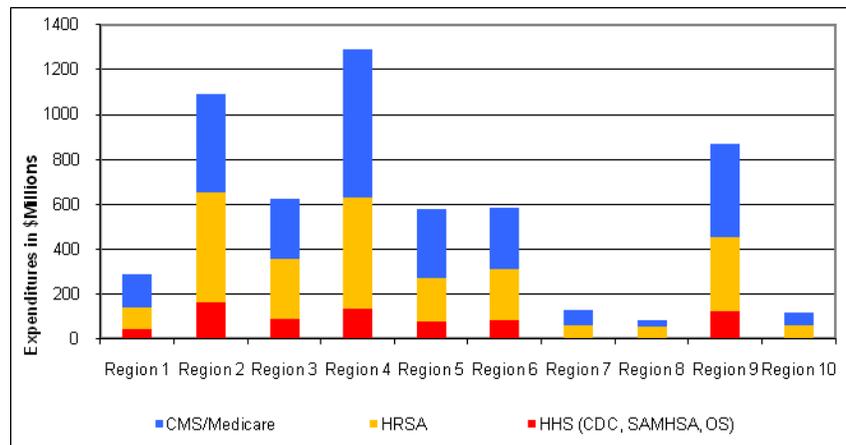
Figure 6d. CMS/Medicaid CY 2007 Number of HIV/AIDS Beneficiaries by Gender within Program, n=172,541



3.4: Geographical Area

The geographical area of funding distribution (Figure 7) was among the most complete data available for HIV/AIDS-related funding estimates across HHS agencies and offices. For simplification, we present aggregate information from CMS/Medicare, HRSA, and CDC/SAMHSA/OS offices at the HHS regional level¹. Listed below (Table 1) are the cumulative AIDS cases by area of

Figure 7. HHS FY 2010 Funding by US Region: CMS/Medicare, HRSA and Other HHS (CDC, SAMHSA, OS), \$5,700,000,000



¹ Region 1 (CT, ME, MA, NH, RI, VT); Region 2 (NJ, NY, PR, VI); Region 3 (DE, DC, MD, PA, VA, WV); Region 4 (AL, FL, GA, KY, MS, NC, SC, TN); Region 5 (IL, IN, MI, MN, OH, WI); Region 6 (AR, LA, NM, OK, TX); Region 7 (IA, KS, MO, NE); Region 8 (CO, MT, ND, SD, UT, WY); Region 9 (AZ, CA, HI, NV, American Samoa, Northern Mariana Islands, Micronesia, Guam, Marshall Islands, Palau); Region 10 (AK, ID, OR, WA).

residence through 2008, as reported by CDC².

Table 1. Cumulative AIDS cases through CY 2008, by area of residence

Region 1	Region 2	Region 3	Region 4	Region 5	Region 6	Region 7	Region 8	Region 9	Region 10
43,229	280,483	118,581	227,287	91,482	110,165	19,183	13,335	181,865	20,786

Figure 7 shows HIV/AIDS FY 2010 funding estimates for HRSA, CMS/Medicare (CY 2008), and CDC/SAMHSA/OS offices combined for the 10 regions. Comparing Figure 7 to Table 1, regions with the largest cumulative number (through 2008) of AIDS cases (i.e., Regions 2, 4, and 9) also had the most HHS HIV/AIDS funding. Conversely, regions with the least number of cumulative AIDS cases had less HHS funding. Additional information about HIV/AIDS resource distribution, including resources to tribal nations, was reported by HHS agencies and offices, but is not described here.

3.5: Funding Summary

The vast majority of HHS’s nearly \$16 billion HIV/AIDS funding supports extramural prevention, care, treatment, and research activities for people at risk for, or living with, HIV/AIDS. Over three-quarters (77%) of HHS’ HIV/AIDS funding goes to care and treatment, nearly two-thirds of which supports Medicare and Medicaid funding for HIV/AIDS beneficiaries. Less than one-fifth (17%) of HHS funding supports HIV/AIDS-related research at NIH and 5% supports prevention activities administered by the CDC. SAMHSA, FDA, AHRQ, IHS, and OS staff offices each receive 1% or less of the HHS HIV/AIDS budget to support their HIV/AIDS activities. Because of differences in reporting practices at the program level, and given the broad array of diverse activities supported, it is not possible to provide comprehensive, client-level data across HHS for all of the intended recipients/beneficiaries of these programs. Nevertheless, this summary provides important baseline data and identifies areas where enhanced reporting practices will provide a more detailed picture of how these funds are serving their intended target populations.

Based on this experience, prior to the development of the next HHS Operational Plan in FY 2012, the HHS OS will work with budget and program leads from each agency and staff office to develop standardized definitions and processes to report on specific uses of HIV funding. Future reports will also include information about funding formulas and policies used to allocate prevention, treatment and care resources as a means of demonstrating that resources are allocated to the highest prevalence populations and communities.

² CDC HIV/AIDS Surveillance Report – through 2008 (<http://www.cdc.gov/hiv/surveillance/resources/reports/2008report/table20.htm>)



Section 4: Bringing Programs to Scale in 12 High-Burden MSAs

A significant component of the HHS Operational Plan is the “HHS 12 Cities Project,” an effort to support comprehensive HIV/AIDS planning and cross-agency response in 12 communities hit hard by HIV/AIDS. In many ways, the 12 Cities Project is a microcosm of the NHAS itself. Namely, this demonstration project embodies many of the overarching principles of the NHAS: concentrate resources where the epidemic is most severe, coordinate federal resources and actions across categorical program lines, and scale up effective HIV prevention and treatment strategies.

The project builds on a funding opportunity announcement (FOA) released by the CDC on August 13, 2010 (“Enhanced Comprehensive HIV Prevention Planning and Implementation for Metropolitan Statistical Areas Most Affected by HIV/AIDS” (ECHPP)). ECHPP identifies the 12 U.S. jurisdictions with the highest estimated AIDS prevalence (Atlanta, Baltimore, Chicago, Dallas, Houston, Los Angeles, Miami, New York City, Philadelphia, San Francisco, San Juan, and Washington, DC) and requires the relevant grantees in those jurisdictions (Georgia, Maryland, Chicago, Texas, Houston, Los Angeles, Florida, New York City, Philadelphia, San Francisco, Puerto Rico, and Washington, DC) to undertake “enhanced” HIV prevention planning so as to identify and address gaps in scope and reach of HIV prevention interventions and strategies among high-risk populations, especially “gay and bisexual men and transgender persons, Black Americans, Latino Americans, and substance users.” These 12 MSAs account for a large proportion (44%) of the total estimated persons living with AIDS in the United States.

Although this cross-agency initiative purposely builds upon the platform established by the CDC funding announcement, its goals, scope, oversight, and, potentially, funding, are broader than those outlined in the original CDC FOA. Specifically, by actively engaging HRSA, SAMHSA, NIH, IHS, CMS, and other federal partners, we intend to leverage departmental resources and assets so as to:

- support coordinated planning for HIV prevention, care, and treatment in each of the 12 jurisdictions, including a complete mapping of federally funded HIV/AIDS resources in each jurisdiction;
- assess the current distribution of HIV prevention, care, and treatment resources in each of the 12 jurisdictions with special emphasis on program coverage, scale, and efficacy;
- identify and address local barriers to coordination across HHS grantees;
- develop cross-agency strategies for addressing gaps in coverage and scale of necessary HIV prevention, care, and treatment services;
- coordinate the implementation of and develop the capacity to deliver strategies and interventions addressing HIV prevention, care and treatment;

- develop common measures and evaluation strategies to assess process and outcomes as they relate to the goals of the NHAS;
- actively promote opportunities to blend services and, where appropriate, funding streams across federal programs; and
- develop and apply lessons learned in these 12 jurisdictions to federally funded activities in other jurisdictions, including creating technical guidance on the development of statewide plans, as called for in the NHAS.

Phase I of this project (October 2010 through April 2011) will focus on data collection and planning, with an explicit focus on identifying gaps in coverage in terms of populations, interventions, and services. The second phase of this project (May 2011 through September 2011 and beyond) will focus on responding to the results of the enhanced planning process, including making recommendations about redirecting resources so as to optimize outcomes.

This project will be managed through a collaborative governance structure. The overarching governance will be provided by a Steering Committee chaired by the Deputy Assistant Secretary for Health, Infectious Diseases (DASH, ID) and composed of principals from CDC, HRSA, SAMHSA, NIH, IHS, CMS, and other staff offices as appropriate. CDC will chair a working group composed of staff-level personnel from each of the agencies and offices cited above to address day-to-day operational issues.

4.1: Phase One: Planning (October 2010 through April 2011)

- OASH: The DASH, ID will convene the Steering Committee on a regular basis to identify and address emerging policy issues and provide ongoing oversight.
- CDC actions during the planning phase: a detailed description is provided in the FOA “Enhanced Comprehensive HIV Prevention Planning and Implementation for Metropolitan Statistical Areas Most Affected by HIV/AIDS.”
- HRSA actions during the planning phase:
 - identify all Ryan White-funded HIV/AIDS programs in the 12 cities and all sub-grantees that provide medical care and support services;
 - provide information on unmet HIV/AIDS need calculations, needs assessments, etc., in the 12 cities;
 - identify staff contacts in the HHS Regional Offices for each of the 12 cities;
 - educate Part A Ryan White HIV/AIDS Program grantees in each of the 12 cities about the project and ask them to actively participate;
 - educate the leadership of community health centers in each of the 12 cities and actively enlist their support and engagement;

- describe and share HRSA-funded data collection (HIV/AIDS Bureau, Bureau of Primary Health Care, other programs) taking place in the 12 jurisdictions;
- collaborate with CDC and other partners to help define denominator size for populations of interest in each of the 12 cities; and
- participate with CDC and other partners in efforts to identify common, cross-agency performance metrics.
- SAMHSA actions during the planning phase:
 - identify all SAMHSA-funded grantees in each of the 12 jurisdictions and request that they provide information about their target populations, service areas, and service capacity;
 - describe SAMHSA-funded data collection taking place in the 12 jurisdictions and share data relevant to planning efforts;
 - actively engage Single State Authorities (the state agency responsible for distributing the Block Grant funds) and SAMHSA grantees and technical assistance providers to support this project in each of the 10 states where the 12 cities are located;
 - engage the 14 Addiction Technology Transfer Centers (ATTCs) in these 12 jurisdictions to support this project; and
 - participate with CDC, HRSA, and other partners to determine common, cross-agency performance metrics.
- IHS actions during the planning phase:
 - map current resources in terms of location and budget;
 - share any relevant data/information relevant to American Indian/Alaska Native populations with the planning group; and
 - participate in the development of common performance metrics.
- CMS actions during the planning phase: provide demographic data for each of the 12 jurisdictions. on Medicare and Medicaid clients who are receiving HIV/AIDS services
- NIH actions during the planning phase: notify the Directors of the Centers for AIDS Research (CFARs), located in 9 of the 12 MSAs, and ask that they work with the health department leadership to define evaluation strategies for the 12 city program. Where applicable CFARS can also build and expand the bridge between public health programs for testing, linkage to care, treatment, and the local research community.
- HHS staff offices supporting HIV/AIDS-related activities in some or all of these 12 MSAs (e.g., ACF, OAH, OHAP, OMH, OPA, OWH) will provide information to each of the planning groups.

4.2: Phase Two: Implementation (May 2011 through September 2011 and beyond)

- OASH/OHAP will set aside \$15 million in FY 2011 Secretary's MAI funds to support services/programs for racial/ethnic minority populations found to be in need of scale-up during Phase I.
- OASH will work with CDC, HRSA, SAMHSA, CMS, IHS, and other agencies and offices to develop specific recommendations encompassing the following domains:
 - harmonizing and, where feasible, streamlining reporting requirements for federally funded HIV/AIDS prevention, treatment, and care programs;
 - blending and/or braiding federal HIV/AIDS funding streams;
 - assuring that federal HIV/AIDS resources go to the states and localities with the greatest need; and
 - developing guidance for statewide HIV/AIDS planning processes that cuts across categorical, programmatic, and jurisdictional lines.
- CDC actions: as outlined in the FOA. Please note that a subset of the 12 cities will be selected by CDC to receive CDC funding in Phase II. Selection will be competitive, based on performance in Phase I.
- HRSA actions during the implementation phase:
 - direct the AIDS Education and Training Centers (AETCs) to provide care-related training in subject areas found to be lacking or inadequate as a result of the assessment in Phase I;
 - develop and deliver targeted technical assistance packages to community health centers in each of the 12 jurisdictions to expand HIV/AIDS care and treatment capacity through the AETC Capacity-Building Assistance to Community Health Centers Cooperative Agreement;
 - develop and provide training for Project Officers monitoring community health center grantees in each of the 12 jurisdictions regarding HIV/AIDS Performance Improvement Activities (PIA) for grantees, including: enhancing local needs-assessment activities for hard-to-reach and high-risk populations; addressing HIV/AIDS care in ongoing quality assurance activities; supporting the involvement of people living with HIV/AIDS on health center boards of directors; and establishing, as necessary, formal referral agreements for HIV/AIDS care and treatment; and
 - identify lessons learned and leading practices from the implementation phase of this activity and integrate these elements into HIV/AIDS PIAs for community health centers outside of these 12 jurisdictions.
- SAMHSA actions during the implementation phase:

- explore the feasibility of developing a treatment-on-demand referral network of treatment providers who can collaborate with local HRSA and CDC grantees in some or all of the 12 jurisdictions;
- direct SAMHSA grantees and technical assistance providers to identify training, educational activities, and technical assistance activities in the 12 jurisdictions and proactively share information with local partners engaged in this project; and
- explore the feasibility of Single State Authorities allowing states to use block grant funds to fill service gaps for injection drug users (IDUs) and other drug users identified during Phase I.



Section 5: Key HHS Actions to Achieve the Goals of the NHAS

Reducing the occurrence of infectious diseases and supporting the NHAS are two explicit objectives of the HHS FY 2010-2015 Strategic Plan. The following section of the HHS Operational Plan will highlight key actions that are underway—or planned for the near term—in order to achieve the NHAS goals. They are organized by the three fundamental goals of the Strategy: reduce HIV incidence, improve access to care and health outcomes for people living with HIV, and reduce HIV-related disparities and health inequities. Given that “achieving a more coordinated national response” to the U.S. epidemic is expressly stated as integral to achieving the goals of NHAS, each section will highlight specific actions to improve coordination within HHS. Many of these actions will also require improved coordination with other federal departments, such as working with the Department of Justice to better address the prevention and care needs of incarcerated populations and working with the Department of Housing and Urban Development (HUD) to improve access to housing for homeless, HIV-infected persons. Specific actions to enhance these interdepartmental collaborations will be detailed in subsequent updates of the HHS Operational Plan. Although this section does not describe every HHS activity addressing HIV/AIDS, it does, nevertheless, represent a substantial portfolio.

Given the significance of this first operational plan, we have erred on the side of transparency and inclusion. Future operational plans will place greater emphasis on those highest-priority activities and efforts that will be most critical in achieving the goals of the NHAS. The current summary does not provide exhaustive detail on any of the highlighted activities. Greater detail, including timelines, is available from the lead HHS organizational unit identified in each item. In addition, the actions described in the plan are subject to the availability of resources. Finally, it should be noted that while a “lead HHS entity” is highlighted in each of the key actions below, many other partners will be involved in carrying out these actions, both governmental and nongovernmental—and in many instances partners from the private sector. For reference, Appendix 2 (attached) provides a brief agency/office-level status report on each of the action steps outlined in the NHAS Federal Implementation Plan.

5.1: Reduce New HIV Infections

In order to reduce new HIV infections in the U.S., we must: intensify HIV prevention efforts in communities where HIV is most heavily concentrated; expand targeted efforts to prevent HIV infection using a combination of effective, evidence-based approaches; and educate all Americans about the threat of HIV and how to prevent it. Achieving this goal will require active steps to diagnose the nearly 220,000 Americans who are infected with HIV yet unaware of their health condition. Our efforts to reduce HIV incidence must also include structural approaches to preventing HIV infection that recognize the broader social determinants of health and risk.

Intensify HIV prevention in communities where HIV is most heavily concentrated.

- In FY 2011, CDC will continue to fund FOA PS10-10138 “Expanded Human Immunodeficiency Virus (HIV) Testing for Disproportionately Affected Populations.” This funding serves to increase HIV testing opportunities for African American and Hispanic men and women, MSM of all races/ethnicities, and IDUs of all races/ethnicities. Eligibility for funding (awarded September 2010) was based on combined AIDS diagnoses among African Americans and Hispanics.
- In FY 2011, IHS will continue to work with health providers and tribal leaders to support streamlined HIV testing in IHS health care facilities.
- In FY 2011, the HHS Office of Population Affairs (OPA) will continue to support routine HIV testing in Title X Family Planning Clinics, especially in those MSAs with the highest burden of HIV/AIDS.
- In FY 2011, AIDS.gov will work across HHS and other federal Departments and agencies with HIV/AIDS programs to use new and social media to develop, deliver, and evaluate targeted HIV prevention and testing messages to the most at-risk populations, including MSM, IDUs, and African American and Latino men, women, and youth.
- In FY 2011, CDC will undertake an extensive evaluation of the community planning process to determine whether, and to what degree, prevention resources are following the epidemic. HIV prevention planning processes should be streamlined and, where feasible, combined with HRSA’s Ryan White HIV/AIDS Program planning efforts. Policy changes will be incorporated into the upcoming revision of guidance to state and local health departments receiving HIV prevention funds.
- In FY 2011, CDC will develop a prevention fact sheet recommending HIV prevention approaches for transgender persons. This fact sheet will be made available online and will be disseminated through a variety of channels to community partners and prevention stakeholders.
- In FY 2011, HRSA will continue to work with Ryan White Program grantees to provide education/risk reduction messages aimed at reducing HIV high-risk behaviors, while, at the same time, delivering HIV care and treatment services to people living with HIV/AIDS who receive services through the Ryan White HIV/AIDS program.
- In FY 2011, NIH will continue to support behavioral research exploring the factors associated with HIV risk among transgender youth and the cultural context of HIV-related risk and protective factors among transgender women.
- In FY 2011, OASH will hold a series of public, technical consultations, involving multi-sectoral experts, to elucidate current funding policies for HIV resource allocation and, where appropriate, suggest policy and legislative changes to ensure better targeting of resources.

- SAMHSA will work with the HHS OS, the Assistant Secretary for Legislation (ASL), and Office of the General Counsel (OGC) to develop a strategy for updating the criteria that allow states to use Substance Abuse Prevention and Treatment Block Grant funds for HIV/AIDS Services.
- In FY 2011, OASH/OHAP will revise the criteria for the Secretary's Minority AIDS Initiative (MAI) Fund internal guidance to the Operational Divisions so as to more specifically support activities, projects, and interventions that align with the goals of the NHAS.
- In FY 2011, CDC, IHS, and NIH will convene one or more multi-disciplinary technical consultations to identify surveillance strategies and a research agenda to better characterize the extent and burden of HIV/AIDS among populations that represent a small share, nationally, of the U.S. epidemic, including: American Indians, Alaska Natives, Asian Americans, and Pacific Islanders.
- In FY 2011, CDC will convene several stakeholder consultations (by teleconference, webinar, and in-person) to discuss a new formula for the "flagship" cooperative agreement with states to ensure that all funds are directed to the communities and populations at highest risk for the most effective interventions.

Expand targeted efforts to prevent HIV using a combination of effective approaches.

- After the planning phase is completed, lessons learned from CDC's "Enhanced Comprehensive HIV Prevention Planning and Implementation" effort in the 12 MSAs most affected by HIV/AIDS will be documented and work will begin on translating these lessons into technical guidance for the remaining U.S. jurisdictions, so that other areas can adjust their prevention portfolios to obtain maximal reductions in HIV incidence. (See below: "Bringing Programs to Scale in 12 High-Burden MSAs") CDC will continue to fund the Enhanced Comprehensive HIV Prevention Planning and Implementation grant in FY 2011.
- In FY 2011, CDC will prioritize those Diffusion of Effective Behavioral Interventions (DEBI) in the existing compendium that have biologic outcomes (e.g. reduced rates of sexually transmitted disease (STD) acquisition), are scalable to produce a community-level impact, and have documented "long-term" (i.e., 6 months or longer) success in reducing risk behaviors.
- In FY 2011, SAMHSA will conduct a needs assessment of HIV testing capacity and frequency in SAMHSA-funded drug-treatment and appropriate mental health centers and will use the results from the assessment to determine areas for expanding HIV testing capacity in SAMHSA funded drug-treatment and appropriate mental health centers.
- In FY 2011 HRSA will support an assessment of HIV testing capacity and frequency in community health centers across the United States. Results from this assessment will be presented to the OASH, along with specific, time-phased recommendations for expanding HIV testing capacity in federally funded community health centers.

- In FY 2011, the HHS OS will work with its respective Operating and Staff Divisions to harmonize federal recommendations on routine HIV screening in support of achieving the goals of the NHAS.
 - AHRQ will request that the U.S. Preventive Services Task Force (USPSTF) undertake a new review of data/studies related to routine screening for HIV among adults and adolescents receiving services in U.S. health care settings.
- In FY 2011, CDC, SAMHSA, NIH, and AHRQ will collaborate to review the existing knowledge base and develop technical guidance outlining best public health practices related to syringe services programs for IDUs who are at risk for, or infected with, HIV. Knowledge/research gaps, including operational research, should be explicitly identified as part of this effort.
- Based on new and emerging findings, NIH and CDC will collaborate in FY 2011 to develop research opportunities to investigate the social and behavioral factors that are likely to influence the roll-out, uptake, effectiveness, and long-term impact of biomedical interventions like pre-exposure prophylaxis (PrEP), microbicides, and Test, Linkage to Care and promotion of adherence (“Test and Treat”).
- In FY 2011, NIH and CDC will support a study to pilot the evaluation of combinations of effective strategies for preventing HIV acquisition, encouraging testing for HIV, and ensuring access to treatment and appropriate care—especially for vulnerable populations.
- In FY 2011, CDC will continue to support the evaluation of new and innovative HIV prevention approaches, including:
 - four sites that are evaluating prevention outcomes (including behavioral and biomedical outcomes) of previously evaluated HIV prevention interventions that have been adapted to address the local needs and circumstances of high-risk populations. Target populations include African American adolescents, incarcerated female populations, and HIV-positive MSM who report episodic substance use.
 - the evaluation of locally-developed (“homegrown”) HIV prevention interventions for African American and Hispanic/Latino MSM. Three interventions under evaluation were developed by community-based organizations (CBOs) with substantial input from the served communities. Organizations with research capacity are partnering with the respective CBOs to evaluate these interventions.
 - share methods and best practices derived from locally developed (“homegrown”) HIV prevention interventions for unique, at-risk populations, including: transgender persons; American Indian/Alaska Native MSM; recent immigrants (both legal and non-) exposed to high-risk circumstances and/or engaging in high-risk behaviors; incarcerated, sexually active populations; disabled Americans at high risk for HIV; at-risk populations with limited English proficiency, especially Asian Americans and Latino Americans; and homeless persons, including homeless youth.

- In FY 2011 and beyond, NIH will continue to invest in AIDS vaccine research by supporting a broad AIDS vaccine research portfolio encompassing basic, preclinical, and clinical research, including studies to identify and better understand potentially protective immune responses in HIV-infected individuals.
- In FY 2011 and beyond, NIH will continue to support a comprehensive microbicide research program that includes the screening, discovery, development, preclinical testing, and clinical evaluation of microbicide candidates for both vaginal and rectal use, as well as behavioral and social science research on acceptability and use of microbicides in different populations.
- In FY 2011 and beyond, NIH will continue to support studies evaluating the use of antiretroviral therapy to prevent HIV acquisition (“treatment as prevention”), including pre- and post-exposure prophylaxis, prevention of mother-to-child transmission, and community-wide HIV testing and treatment programs.
- In FY 2011 and beyond, CDC, HRSA, SAMHSA, IHS, and HHS staff offices will actively develop opportunities and approaches to create and evaluate more holistic and “wellness-centered” approaches to HIV prevention that address the individual in the context of his/her emotional, mental, and physical health needs.
- In FY 2011 and beyond, CDC, HRSA, SAMHSA, IHS, and HHS staff offices will make public existing results of evaluated activities and programs. HHS will also develop a comprehensive list of planned evaluations in FY 2011 and beyond.

Educate all Americans about the threat of HIV and how to prevent it.

- In FY 2011 and beyond, HHS Operating and Staff Divisions will actively engage social, civic, and business organizations that represent the broader interests of racial/ethnic minority populations and not just those organizations which have a specific HIV/AIDS focus—emphasizing that HIV prevention is everyone’s responsibility.
- In FY 2011 and beyond, OASH will engaged federal partners within and outside of HHS in a process to review and develop strategies to more effectively share, repurpose, cross-promote, and disseminate each other’s consumer-focused HIV/AIDS educational content, materials, and messages.
- In FY 2011 CDC will continue to implement the *Act Against AIDS* campaign to provide all Americans with information about the threat of HIV and how to prevent it, and to improve the ability of health care providers to provide appropriate HIV screening and prevention services. Emphasis will be placed on efforts that reach communities that have been most heavily affected by HIV (i.e., Blacks, Latinos, and MSM).
- CDC (including the Division of Adolescent and School Health, Division of STD Prevention, and Division of HIV/AIDS Prevention) will continue to work with state and local departments of health and education and other partners to ensure that school- and community-based health

educators have access to scientifically sound, age-appropriate HIV, STD, and pregnancy prevention information.

- In FY 2011, OASH/OWH will launch a national STD awareness social marketing campaign to empower teen girls to make informed decisions about sexual activity so as to reduce STDs and minimize their serious health consequences, including cancer and infertility.
- In FY 2011, OASH/OWH will publish and disseminate an “HIV Prevention Gender Toolkit” that will train providers to develop and implement gender-responsive programming at the community, state, and local level. Gender-responsive programming will serve to identify and proactively address the influence of gender in the mediation of risk for HIV among U.S. women and girls and men and boys.
- In FY 2011, the HHS OS will continue to work with the Department of Education (ED) to identify opportunities to actively engage and partner with ED constituents (e.g., grantees, teacher organizations, parent-teacher organizations, student organizations) in efforts to educate all Americans about the threat of HIV/AIDS and how to prevent it.
- In FY 2011, the HHS Office of Adolescent Health (OAH) will work with the grantees receiving teen pregnancy-prevention program funds to replicate evidence-based approaches and to identify new strategies and approaches to reduce teen pregnancies and improve health outcomes for adolescents. Many projects support comprehensive sex education.
- In FY 2011, the Administration for Children and Families (ACF) will continue to support “personal responsibility” education programs for youth that include information on reducing high-risk sexual behavior, contraception, and information on HIV and other STDs.
- In FY 2011, OPA will continue to support family planning and STD and HIV-related services and counseling, with the majority of services provided to low-income and uninsured or underinsured individuals.

5.2: Increase access to care and improve health outcomes

In order to improve access to care and health outcomes for all persons living with HIV/AIDS in the U.S. we must: ensure that persons who are newly diagnosed are immediately linked to high-quality and continuous care; increase the number and diversity of providers who are able to deliver high-quality HIV care; and support people living with HIV who have other health conditions and/or require basic support, such as housing. HHS must continue to actively support its operating divisions and engage with a broad variety of partners in implementing the Affordable Care Act (ACA) so that people living with HIV/AIDS can benefit from expansion of Medicaid, increased funding for prevention, and the creation of state-based health insurance exchanges. Equally critical is the need to develop new and better therapies and improved drug regimens. While the focus of this operational plan is on efforts within HHS, it is important to note that other federal departments (e.g., HUD, DOJ, VA) are critical to

achieving this goal, especially when considering the special needs of unique populations such as the incarcerated and the homeless.

Create a seamless system to immediately link people to continuous and coordinated quality care when they learn they are infected with HIV.

- In FY 2011, the HHS OS, including ASL, will work with HRSA and senior Department leadership to develop a detailed strategy—including legislative options, policy guidance, and programmatic steps—to support states and jurisdictions in better managing AIDS Drug Assistance Program (ADAP) and pharmacy access programs. Components of this strategy will include:
 - The Office of Health Reform (OHR) will issue guidance and work with other HHS staff offices and agencies to develop and provide technical assistance for states regarding provisions in the Affordable Care Act (ACA) that are of immediate benefit and could potentially reduce demand for ADAP (and other Ryan White HIV/AIDS Program) services.
 - HRSA will develop, issue, and provide technical assistance for guidance to maximize state ADAP support of Medicare Part D beneficiaries when the new Affordable Care Act ADAP contribution rule goes into effect on January 1, 2011.
 - CMS will develop and deliver technical assistance on the mechanics of the TrOOP (“true out-of-pocket expenses”) facilitation and coordination of benefits processes as per the ACA.
- In FY 2011, HRSA and CDC will identify community health centers that provide “co-located” HIV testing and care and treatment services. Information about these “co-located” services will be actively disseminated to state and local health departments and other partners providing HIV/AIDS care, and strategies will be jointly developed to incentivize the co-location of services in communities with high HIV prevalence.
- In FY 2011, CMS will publish a toolkit letter that will remind states and stakeholders about various Medicaid options (e.g., 1115 waiver option, 1915c options, health home option) they can use to increase access and improve care coordination for people with HIV/AIDS. The toolkit letter will be developed in conjunction with states to determine what would be most helpful to them in increasing access for this population.
- In FY 2011, CMS will actively assist states in efforts to cover pre-disabled people living with HIV (State Medicaid 1115 waivers) through actions such as: providing waiver guidance simplifying the submission of waivers to cover people with HIV/AIDS; expediting the application review process; and providing technical assistance opportunities for state Medicaid directors and their staffs.
- In FY 2011, in consultation with HHS OS, CMS will collaborate with HRSA and other key partners in the federal government and the private sector to explore options for evaluating

the key components of comprehensive, coordinated Ryan White HIV/AIDS program-funded care to determine if these elements can be identified and replicated within Medicare and Medicaid programs

- In FY 2011 HRSA will translate and disseminate the findings of a 4-year Special Projects of National Significance (SPNS) project (“Enhancing Linkages to HIV Primary Care and Services in Jail Settings”) to develop technical guidance and training materials detailing “best practices” for promptly linking persons living with HIV/AIDS in jail settings, or those who have been recently released, into HIV care.
- In FY 2011, HRSA and CDC will continue to support a six-clinic, multi-year evaluation of interventions designed to increase HIV-positive client appointment attendance among patients at risk for missing scheduled appointments. The current phase of this project is a randomized controlled trial that compares two interventions designed to increase retention in HIV care to standard HIV clinical care.
- In FY 2011, OASH/OPA will facilitate linkages to HIV care for clients who test positive in Title X Family Planning Clinics (FPCs) by:
 - increasing the number of personnel who are trained to ensure linkage between FPC testing sites and HIV/AIDS care sites;
 - increasing the number of formal referral agreements in FPCs; and
 - improving systems and processes for documenting referral episodes.
- In FY 2011, OASH/OMH will administer projects under the “Collaborative Technical Assistance and Capacity Development Program.” This effort is designed to improve the coordination and continuum of HIV prevention, treatment, and support services provided by organizations that serve minority communities heavily burdened by HIV/AIDS.
- In FY 2011, FDA will continue to monitor antiretroviral clinical trials to ensure scientific integrity and ethical conduct. FDA will also collaborate closely with NIH and AHRQ in areas of research regarding optimal and safe combination therapies for HIV/AIDS.

Take deliberate steps to increase the number and diversity of providers of clinical care and related services for people living with HIV.

- The OASH, in consultation with HRSA, other federal partners, and relevant professional organizations will develop specific strategies to increase the number and diversity of clinical care providers serving persons living with HIV/AIDS. Special emphasis will be placed on underserved populations, including rural populations. Strategies will include a careful consideration of how HHS can work proactively with the National Health Care Workforce Commission to highlight and address the special needs of people living with HIV/AIDS.

- In FY 2011, the HHS OS will convene CDC, HRSA, AHRQ, CMS, IHS, VA and other technical experts, including professional organizations, to begin the development of a scientifically sound and practical set of clinical performance measures to monitor quality of HIV care.
 - The HHS Office of the National Coordinator for Health Information Technology (ONC) will work to ensure that evolving electronic-health-record (EHR) standards are consistent with clinical performance measures to monitor quality of HIV/AIDS care and are supportive of monitoring relevant NHAS goals, especially as they relate to improving health outcomes for people living with HIV/AIDS.
- In FY 2011, HRSA will work with the AETCs to expand training for HIV clinicians and provider organizations to address cultural competency, provider continuity, and other provider-associated factors that affect HIV treatment adherence.
- In FY 2011, HRSA will explore the feasibility of designating Ryan White HIV/AIDS Program-funded clinical settings as eligible sites for National Health Service Corps programs.
- In FY 2011, HRSA will fund eight regional AETCs to provide specific training, technical assistance, and ongoing consultation to providers who are caring for American Indian/Alaska Native populations. AETCs will collaborate with the IHS to achieve the following goals: improve/enhance HIV diagnostic opportunities; establish and maintain robust linkages to care and treatment; and help ensure high-quality, culturally competent treatment.
- In FY 2011, HRSA's Bureau of Health Care Professions will provide training on the NHAS and the Federal Implementation Strategy to all project officers and subsequently develop an action plan to work with schools of medicine, dentistry, nursing, pharmacy, and other allied health professions to implement changes that will improve the quality and content of HIV-related curricula, with special emphasis on health disparities and evolving co-morbidities of various U.S. populations living with HIV/AIDS.
- In FY 2011, SAMHSA will release an online curriculum for substance-use treatment providers serving minority MSM.
- In FY 2011, NIH will continue to support research training opportunities designed to recruit individuals from under-represented populations into research careers and to build research infrastructure in minority-serving institutions in the United States. This effort will include the first HIV/AIDS-focused initiative for American Indian/Alaska Native health researchers.

Support people living with HIV and co-occurring health conditions and those who have challenges meeting basic needs, such as housing.

- In FY 2011, the OASH, on behalf of the HHS OS, should proactively consult with a broad array of public- and private-sector providers serving diverse populations of people living with HIV/AIDS, including those with co-morbid conditions, in order to better inform the subsequent definition of an essential health benefits package for persons living with HIV/AIDS.

- In FY 2011 and beyond, NIH will initiate new programs to support a comprehensive therapeutics research program to design, develop, and test drugs and drug regimens to: maintain long-term, undetectable viral load; overcome drug resistance and treatment failure; and eradicate persistent viral reservoirs that may lead to a potential or functional cure for HIV disease.
- In FY 2011, and beyond, HRSA will increase the capacity of providers to prevent, diagnose, and treat viral hepatitis among persons living with HIV/AIDS. This will involve working with CDC, other federal partners, and professional organizations to develop and disseminate technical assistance tools and documents to assist HIV and other primary care providers in the diagnosis, treatment, and prevention of viral hepatitis.
- In FY 2011, HRSA will develop and disseminate technical guidance on how to integrate buprenorphine treatment (for opioid abuse) into HIV primary care settings.
- In FY 2011 and beyond, SAMHSA will work with state and local substance use agencies to develop policies and technical assistance materials for implementing “treatment on demand” for HIV-infected drug users in those jurisdictions (identified by CDC surveillance data) with a substantial percentage of HIV-infected drug users.
- In FY 2011, SAMHSA will issue best-practice guidelines (“treatment improvement protocol” or TIP) for the diagnosis and treatment of hepatitis C among substance users, with particular focus on those who are co-infected with HIV.
- In FY 2011, CDC will work with governmental and nongovernmental partners to identify and disseminate culturally competent and scientifically sound patient-education materials to improve health literacy about viral hepatitis among IDUs, including those who are infected with HIV.
- In FY 2011, NIH will continue to support the National Institute on Drug Abuse’s (NIDA) Clinical Trials Network (CTN). The CTN provides an enterprise in which NIH, treatment researchers, and community-based service providers cooperatively develop, validate, refine, and deliver new treatment options to substance users (including those who are HIV-infected) in community-level clinical practice. These efforts include multi-site clinical trials to determine effectiveness across a broad range of community-based treatment settings.
- In FY 2011 and beyond, NIH will initiate new programs of basic, preclinical, and clinical research on prevention and treatment of AIDS-related co-infections and co-morbidities, including malignancies, cardiovascular, neurological, metabolic, and other complications and side effects, including AIDS and aging issues.
- In FY 2011 and beyond, NIH will continue to lead the process to develop, update, and disseminate federal treatment guidelines for the medical management of HIV. This process will include other federal partners (CDC, HRSA, FDA, VA), as well as a variety of HIV experts from across the U.S.

- In FY 2011, the OASH/OMH will continue to support the “Linkage to Life” (L2L) and HIV/AIDS Health Improvement for Re-Entering Ex-Offenders (HIRE) programs. L2L funds community-based organizations to identify and address gaps in available healthcare and social and supportive services for high-risk minority families living with HIV/AIDS (or at high risk for HIV) who are in transition from incarceration, domestic violence, and/or substance abuse treatment. HIRE funds community networks designed to bridge health care gaps and improve HIV/AIDS health outcomes for ex-offenders re-entering the mainstream population.

5.3: Reduce HIV-Related Disparities and Health Inequities

To support a concerted national effort to reduce health-related disparities and inequities in HIV care, the following steps must be taken: reduce HIV-related mortality in communities at high risk for HIV infection; adopt community-level approaches to reduce HIV infection in high-risk communities; and reduce stigma and discrimination against people living with HIV.

Reduce HIV-related mortality in communities at high risk for HIV infection.

- In FY 2011, the HHS OASH will work with CDC, HRSA, SAMHSA, NIH, IHS, and other agencies and offices to ensure that current HIV/AIDS social-marketing materials are accessible to target populations with limited English proficiency.
- In FY 2011, HRSA will develop a guide with lessons learned on model practices for engaging and retaining underserved, hard-to-reach, HIV-positive persons in medical care. The content of this guidance will derive from the “Targeted Outreach and Intervention Model Development Initiative,” a 6-year, multi-site evaluation conducted in community and clinical settings. Training curricula will be developed and disseminated as a component of the guidance document.
- In FY 2011, HRSA will identify and disseminate “best practices” in caring for male and female Hispanic/Latino clients obtained from a qualitative assessment of “exemplary” HIV service providers serving substantial populations of Hispanics/Latinos in six states. These best practices will encompass clinical strategies, administrative actions, and organizational practices.
- In FY 2011, CDC will review and assess the quality of data measuring community viral load (CVL); following this consultation, technical guidance on the collection and use of CVL data will be developed and disseminated to health departments. Working with health-department and other public-health leadership, collaborative strategies will be developed to leverage resources so as to increase capacity to measure CVL. These strategies will include targeted training and technical assistance to health department grantees supporting the implementation and adoption of high-quality CVL monitoring.
- In FY 2011, the IHS will continue to support partnerships between American Indian/Alaska Native (AI/AN) Tribes and institutions that conduct academic-level biomedical, behavioral, and

health-services research. The goal of this effort is to develop and evaluate effective AI/AN-focused interventions to prevent HIV and/or encourage early diagnosis and entry into treatment.

- In FY 2011, NIH will continue to support a series of projects to study behavioral interventions to prevent HIV transmission in MSM populations, especially among adolescents and minorities. Ongoing efforts include: behavioral interventions; studies related to scale-up; and studies related to adherence to, and acceptability of, biomedical interventions such as circumcision, pre-exposure prophylaxis, and rectal microbicides.
- In FY 2011, NIH will continue to support a research initiative designed to evaluate strategies to enroll IDUs and other drug users in frequent testing for HIV and link them into early care if they are found to be HIV-positive. This effort entails innovative strategies to engage, retain, and support IDUs and other drug users into HIV/AIDS care, including adherence strategies.
- OASH/OMH will continue to support the “CHAT” (Curbing HIV/AIDS Transmission Among High-Risk Youth and Adolescents) program. Utilizing a peer-to-peer outreach model, this intervention supports community-based grantees in their efforts to increase HIV prevention/education, HIV testing, counseling, and referral into care for high-risk minority youth and adolescents.

Adopt community-level approaches to reduce HIV infection in high-risk communities.

- In FY 2011, CDC, HRSA, SAMHSA, IHS, NIH, and other HHS agencies and offices will continue to invest in strategies to enhance the capacity of high-risk and high-burden communities to implement and sustain effective HIV prevention, treatment, and care programs. These strategies should include: replication studies; intervention packaging and dissemination; training and capacity-building; and evaluation.
- In FY 2011, CDC will continue to work with large, historically African American and Hispanic/Latino national organizations that have proven reach and credibility in their respective communities in order to integrate HIV prevention into ongoing communication, mobilization, and outreach activities (e.g., public service announcements, new media tools, community forums).
- In FY 2011, OASH will host one or more technical consultations with leaders from national lesbian, gay, bisexual, and transgender (LGBT) organizations to develop strategies that re-envision HIV prevention in a broader, social context of health promotion/health equity.
- In FY 2011, the OASH RHAs will continue, through the HIV/AIDS Regional Resource Network Program (RRNP) and other means, to provide technical assistance for communities to promote HIV prevention, opportunities for early diagnosis of HIV infection, and stigma reduction.
- In FY 2011, HHS and CDC will publicize opportunities for communities that are at disproportionate risk for HIV/AIDS disease, on the basis of race, ethnicity, behavioral characteristics, or socioeconomic circumstances, to compete for appropriate public health and

wellness resources. For example, Community Transformation Grants (CTG) should be considered.

- In FY 2011 and beyond, NIH will collaborate with other federal partners to support studies defining social processes (e.g., mobility, migration, resilience) and structural factors (e.g., housing, employment, access to substance-use treatment, access to health care) that mediate risk of HIV infection.

Reduce stigma and discrimination against people living with HIV.

- In FY 2011, CDC, HRSA, SAMHSA, IHS, and OS staff offices will actively explore opportunities for partnering with nongovernmental and private-sector partners to develop new approaches for addressing stigma related to HIV/AIDS, including HIV stigma, racism, sexism, and homophobia.
- In FY 2011, the HHS OCR will continue to provide information to the public (via Web, brochures, national meetings, and other outreach events) on the civil rights and the health-information privacy rights of people living with HIV/AIDS. OCR will continue to investigate and take action on complaints alleging discrimination against people living with HIV/AIDS by health care providers and human service agencies and on complaints alleging violations of the health-information privacy rights of people living with HIV/AIDS by health care providers and health plans.
- In FY 2011, the HHS Office of Disability will continue to advocate and educate on behalf of Americans with disabilities and HIV/AIDS. These efforts will include policy development, dissemination of research findings, and identification of knowledge gaps.
- In FY 2011, NIH will continue to support a series of ongoing studies investigating how stigma and discrimination may prevent at-risk populations, including minorities, MSM, prisoners, formerly incarcerated individuals, and high-risk heterosexual men and women (including minority men and women who use drugs and women whose partners are in prison) from accessing HIV testing and treatment. The goal of these efforts is to develop culturally appropriate HIV prevention and treatment interventions to overcome these barriers.
 - One NIH-funded study is investigating longitudinal relationships between medication adherence and discrimination due to HIV serostatus, race, and sexual orientation among African American men living with HIV/AIDS.
 - Another NIH-funded effort is studying HIV stigma among medical students in Puerto Rico. This intervention utilizes the medical training model, combined with Social Cognitive theory to reduce HIV stigma among future medical providers. The study will follow the students as they enter medical residency and measure stigmatizing behaviors using standardized patient methodology.
- In FY 2011, the HHS Center for Faith-Based and Neighborhood Partnerships and OASH, in partnership with counterparts from the Departments of Labor, Justice, Housing and Urban Development, Veterans Affairs, and Education, will develop a national outreach effort to

engage faith- and community-based leaders, organizations, and members in promoting routine screening for HIV, with the primary goal of encouraging early diagnosis of HIV and a secondary goal of de-stigmatizing HIV and people living with HIV/AIDS, in order to promote early entry into care and support ongoing prevention efforts.



Section 6: Critical Change Issues

To achieve the goals of the NHAS, it will be necessary for HHS to align its policies, activities, and operations with the specific goals and objectives of the Strategy. Given the assumption that achieving the goals of the Strategy will, in some instances, eventually require the redirection of resources (both in terms of activities supported, as well as locales/entities funded), close, proactive communication with a variety of stakeholders, such as congressional offices, professional organizations, and community advocates—including persons living with HIV/AIDS—will be necessary at every stage of this process.

Finally, given the reality of constrained resources and competing demands, evaluation becomes more important than ever. We must be able to demonstrate that the hard decisions we make and the tough actions we take are making a difference in the lives of Americans at risk for, and living with, HIV/AIDS. Listed below are several key actions that are planned to support this cross-governmental change.

- Continue to use AIDS.gov as a credible source to provide, leverage, and syndicate information about the HHS Operational Plan and ongoing implementation of the NHAS. Also, continue to incorporate new/social media tools in HHS programs supporting NHAS to sustain implementation of the Strategy.
- Following the submission of the HHS Operational Plan to ONAP on December 9, 2010, each HHS agency and staff office will identify a senior-level administrator to serve as a “champion” for the NHAS and to coordinate all implementation activities for that agency/staff office.
- After the HHS plan has been reviewed by ONAP, and any required clarifications have been made, the contents of the plan will be shared publicly on AIDS.gov and with a wide variety of governmental and nongovernmental partners and stakeholders. (February 2011, exact date to be determined).
- The 2011-2012 performance plans for all HHS senior staff should contain specific elements directly related to one or more of the goals of the NHAS.
- In FY 2011 and beyond, the HHS OS must continue to identify existing and new mechanisms, including funding opportunities, which can be used to incentivize the organizational behaviors necessary to achieve the NHAS goals.
- In FY 2011, any HHS Operating and Staff Divisions using discretionary HIV/AIDS funds to support intramural costs, including FTEs, will undertake an assessment and review of its current capacity to support the goals of the NHAS and realign personnel resources as necessary to best meet those goals.
- All HHS Operating and Staff Divisions will review their strategic plans and emerging communications to ensure that the goals of the NHAS are included.

- In FY 2011 and beyond, the OASH will serve as the central focus for coordination and monitoring of HHS activities outlined in this Operational Plan. Strategies for monitoring and gauging progress toward achieving NHAS goals will include:
 - development of metrics to measure progress at various levels (i.e., federal, state, local);
 - development of standardized tools that can help agencies/staff offices conduct rigorous program evaluation;
 - development of processes that will provide accurate information about how federal HIV/AIDS resources are being used at state and local levels; and
 - convening of a Department-wide retreat, in the third quarter of CY 2011, to assess and critically review progress made and gaps remaining.
- In FY 2011 and beyond, OASH will actively explore policy, budgetary, and programmatic strategies to better align HHS domestic HIV/AIDS efforts with those being conducted in other federal departments. Programmatic and budget strategies will include joint funding announcements and other opportunities to blend or braid funding across programs.
- In FY 2011 and beyond, the HHS Assistant Secretary for Planning and Evaluation (ASPE) will coordinate with HHS agencies to conduct program-evaluation activities and assist with refining strategies for monitoring the progress of HHS' implementation of the NHAS.
- In FY 2011, working closely with the OASH, the Office of Intergovernmental Affairs (IGA) will proactively engage key stakeholders in discussions related to HIV/AIDS funding realignment.



Section 7: Unmet Needs and Knowledge Gaps

Given the current economic situation, with shrinking state-level resources for HIV prevention and care, we recognize that many may characterize the goals of the NHAS as ambitious and that there may be some resistance to undertaking new approaches.

While not shying away from the reality that new resources may be necessary to achieve the ultimate goals of the Strategy, it is also imperative that, as a Department, we work across agency, office, and program lines to ensure that we are targeting and coordinating resources to support the most cost-effective interventions and strategies so as to serve the most severely impacted populations. The American public and the populations we serve deserve nothing less! Furthermore, HHS will use ongoing experience with implementation of the NHAS to identify priorities and incorporate them into the Department's annual budget planning and legislation development process. This is an essential step in order to maintain momentum and institutionalize the changes we are putting in place.

Without question, there are gaps in the knowledge we require in order to finally achieve the vision of the NHAS. Most often cited, perhaps, is the lack of an effective vaccine against HIV. But this is by no means the only obstacle we face in our efforts to achieve the NHAS vision. Different domains engender equally complex questions. What is the correct combination and scale of biomedical and behavioral interventions to result in optimal reduction of HIV incidence? How do we allocate resources equitably and effectively so that the major focus is on populations who bear a disproportionate burden of disease and poor health—while not ignoring the needs of communities and groups who represent small numbers, nationally, but suffer, nonetheless, from HIV disease? How do we combine client-level approaches to HIV prevention with those that embrace a broader social context and recognize the importance of structural and community-level interventions? How do we reconcile our need for improved client-level budget information with the absolute necessity of streamlining reporting and reducing administrative burden across state, local, tribal, and community grantees?

None of these questions will be easily—or quickly—answered. But we can answer them. As we move forward with our implementation of this ambitious, albeit necessary, Strategy, let's keep in mind the following. Change is necessary. Change is expected. And change is possible.



Appendix



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